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 4, 2021

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 August 4, 2021, G1 Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the second-quarter ended June 30, 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 August 4, 2021
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 4, 2021

G1 Therapeutics Provides Second Quarter 2021 Financial Results and Operational Highlights

- Achieved $6.6 Million in Total Revenue, including $2.5 Million in Net Revenue from Sales of COSELA™ (trilaciclib) -

- Initiated Pivotal Phase 3 Trial in Metastatic Triple-Negative Breast Cancer (TNBC) Evaluating the Survival Benefit of COSELA Compared with Placebo -

- Initiated Randomized Phase 2 Studies of COSELA in Non-Small Cell Lung Cancer (NSCLC) and Bladder Cancer -

- Received Fast Track Designation from U.S. Food and Drug Administration (FDA) for COSELA in Combination with Chemotherapy for the Treatment of Locally Advanced or Metastatic TNBC -

- Management to Host Webcast and Conference Call today at 4:30 PM ET -

RESEARCH TRIANGLE PARK, NC, August 4, 2021 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today provided a corporate and financial update for the second quarter ended June 30, 2021.

“The second quarter of 2021 was a period of solid progress across G1, as we seek to develop COSELA for patients suffering from a variety of cancers,” said Jack Bailey, Chief Executive Officer of G1 Therapeutics. “In our first full quarter of sales of COSELA, the commercial team continued to build the commercial foundation for this important myeloprotection drug for patients with ES-SCLC undergoing chemotherapy. We believe that COSELA is a paradigm-changing product, allowing cancer patients to be treated proactively to reduce the impact of the multilineage myelosuppression side effects of chemotherapy. So far, the enthusiasm for COSELA is encouraging. We also initiated three new COSELA clinical trials during the second quarter, including a registrational trial in metastatic TNBC and two Phase 2 trials, one in NSCLC and the other in bladder cancer. With the ongoing commercial launch, the expansion of our innovative tumor-agnostic pipeline, and a strong financial position, we are excited about the opportunities ahead for COSELA.”

Second Quarter 2021 and Recent Highlights

Financial

- **Achieved Net COSELA (trilaciclib) Revenue of $2.5 Million.**
- **Ended the Second Quarter with Cash and Cash Equivalents of $244.0 million:** The current financial position expected to be sufficient to fund G1’s operations and capital expenditures into 2023.

Medical

- **Presented New Data Describing the Estimated Economic Impact of Treating Myelosuppression in Patients with ES-SCLC at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR):** The first poster used a cost-benefit model to predict an estimated economic value from a general U.S. commercial payer perspective of using COSELA prior to chemotherapy in ES-SCLC to project a significant payer cost savings based on assumptions that myelosuppressive adverse events and their associated treatment costs would be reduced. The second poster quantified the significant health burden, economic toll, and health-related quality-of-life effects of chemotherapy-induced myelosuppression among Medicare patients diagnosed with SCLC. (Press release here)

- **Presented Results of Analyses Evaluating the Immune Effects of COSELA in Patients with ES-SCLC at the American Society of Clinical Oncology (ASCO) annual meeting:** Patients receiving COSELA prior to chemotherapy had greater peripheral T-cell clonal expansion than patients receiving placebo. The data suggest that, among patients treated with COSELA plus either etoposide and carboplatin (E/C) or E/C plus atezolizumab, increased clonal expansion is associated with clinical response, indicating that COSELA may enhance antitumor immunity in patients with ES-SCLC treated with chemotherapy. (Press release here)
- **Presented Positive Data Suggesting Strong Safety Profile and Evidence of Antitumor Activity of Rintodestrant Combined with Palbociclib in ER+/HER- Advanced Breast Cancer at ASCO:** In the 40-patient combination arm of the Phase 1 trial, rintodestrant was very well tolerated and did not result in additional or more severe toxicities when added to Palbociclib. The clinical benefit rate (CBR; percentage of patients with either confirmed complete or partial response or stable disease lasting ^{3} 24 weeks) doubled from 30 percent with rintodestrant monotherapy to 60 percent with the combination of rintodestrant and Palbociclib; among patients with early relapse, the CBR was 73%. (Press release here)

Clinical

- **Initiated Pivotal Trial of COSELA in Locally Advanced Unresectable or Metastatic TNBC:** Patient enrollment is underway in PRESERVE 2, a randomized, double-blind, placebo-controlled Phase 3 registrational trial of COSELA in patients receiving first- or second-line gemcitabine/carboplatin chemotherapy for locally advanced unresectable or metastatic TNBC. (Press release here)
- **Received Fast Track Designation for COSELA in TNBC:** The FDA granted Fast Track designation to COSELA investigation for use in combination with chemotherapy for the treatment of locally advanced or metastatic TNBC. Fast track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill unmet medical needs. (Press release here)
- **Initiated Phase 2 Trial of COSELA in Metastatic NSCLC:** Patent enrollment is underway in PRESERVE 4, a randomized double-blind placebo-controlled Phase 2 trial of COSELA administered prior to docetaxel in patients with NSCLC in the 2nd and 3rd line setting who have previously been treated with a checkpoint inhibitor and chemotherapy. The primary endpoint of the trial is to evaluate the anti-tumor effect of COSELA on overall survival (OS) compared to placebo. (Press release here)
- **Initiated Phase 2 Trial of COSELA in Bladder Cancer:** Patent enrollment is underway in PRESERVE 3, a randomized double-blind placebo-controlled Phase 2 trial of COSELA administered with first-line platinum-based chemotherapy and the immune checkpoint inhibitor avelumab maintenance therapy in patients with untreated, locally advanced or metastatic urothelial carcinoma. (Press release here)

Corporate

- **Announced Andrew Perry as Chief Commercial Officer:** Mr. Perry, formerly the Vice President of US Marketing for ViiV Healthcare NA, brings nearly 25 years of leadership experience in commercial launch strategy, digital marketing, and co-promotion management to G1, with extensive capabilities in launching and growing brands in multiple areas including oncology. (Press release here)

Second Quarter 2021 Financial Results

As of June 30, 2021, cash and cash equivalents totaled $244.0 million, compared to $207.3 million as of December 31, 2020.

Total revenues for the second quarter of 2021 were $6.6 million, including $2.5 million in net product sales of COSELA and license revenue of $4.1 million, primarily related to a development milestone payment from the Company's license agreement with Simcere, clinical trial reimbursements from EQRx, and delivery of clinical drug supply and manufacturing services to Simcere, EQRx and Genor. Total revenues for the six months ended June 30, 2021 were $20.8 million.

Operating expenses for the second quarter of 2021 were $44.8 million, compared to $33.0 million for the second quarter of 2020. GAAP operating expenses include stock-based compensation expense of $5.7 million for the second quarter of 2021, compared to $4.4 million for the second quarter of 2020. Total operating expenses for the six months ended June 30 was $84.5 million.

Cost of goods sold expense for the second quarter of 2021 were $0.8 million, compared to $0 for second quarter of 2020. The increase related to the Company's period costs for the sales of COSELA. Cost of goods sold for the six months ended June 30 was $1.1 million.

Research and development (R&D) expenses for the second quarter of 2021 were $18.8 million, compared to $18.5 million for the second quarter of 2020. The increase in R&D expenses was primarily due to an increase in clinical trial spend, which is offset by a decrease in costs associated with the manufacturing of active pharmaceutical ingredients and drug product to support clinical trials, as well as external costs related to discovery and pre-clinical development. R&D expenses for the six months ended June 30 were $35.3 million.

Selling, general and administrative (SG&A) expenses for the second quarter of 2021 were $25.2 million, compared to $14.4 million for the second quarter of 2020. The increase in SG&A expenses was largely due to an increase in commercialization activities, an increase in compensation due to increases in headcount, and increased spend on information technology, professional services, and other administrative costs. SG&A expenses for the six months ended June 30 were $48.2 million.

The net loss for the second quarter of 2021 was $39.4 million, compared to $31.2 million for the second quarter of 2020. The basic and diluted net loss per share for the second quarter of 2021 was $(0.94) compared to $(0.83) for the second quarter of 2020. The net loss for the six months ended June 30 was $65.9 million. The basic and diluted net loss per share for the six months ended June 30 was $(1.59).

Financial Guidance

The Company expects its current financial position to be sufficient to fund its operations and capital expenditures into 2023.

Webcast and Conference Call

G1 will host a webcast and conference call at 4:30 p.m. ET today to provide a corporate and financial update for the second quarter 2021 ended June 30, 2021. The live call may be accessed by dialing (866) 763-6020 (domestic) or (210) 874-7713 (international) and entering the conference code: 3553037. 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 COSELA 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), COSELA's (trilaciclib) possibility to improve patient outcomes across multiple indications, and our reliance on partners to develop and commercial 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)

	June 30, 2021	December 31, 2020
Cash and cash equivalents	$ 244,023	$ 207,306
Working Capital	$ 240,059	$ 192,949
Total Assets	$ 276,755	$ 228,552
Accumulated deficit	$(501,971)	$ (436,107)
Total stockholders' equity	$ 213,196	$ 177,351

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

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Revenues:				
Product sales, net	$ 2,532	$ —	$ 3,141	$ —
License revenue	4,072	2,140	17,681	2,140
Total revenues	6,604	2,140	20,822	2,140
Operating expenses:				
Cost of goods sold	808	—	1,051	—
Research and development	18,752	18,531	35,292	38,965
Selling, general and administrative	25,236	14,431	48,206	25,818
Total operating expenses	44,796	32,962	84,549	64,783
Loss from operations	(38,192)	(30,822)	(63,727)	(62,643)
Other income (expense):				
Interest Income	9	91	28	872
Interest Expense	(927)	(265)	(1,675)	(265)
Other income (expense)	(92)	(214)	(132)	(197)
Total other income (expense), net	(1,010)	(388)	(1,779)	410
Loss before income taxes	(39,202)	(31,210)	(65,506)	(62,233)
Income tax expense	220	—	358	—
Net loss	$ (39,422)	$ (31,210)	$ (65,864)	$ (62,233)
Net loss per share, basic and diluted	$ (0.94)	$ (0.83)	$ (1.59)	$ (1.65)
Weighted average common shares outstanding, basic and diluted	42,119,850	37,786,208	41,414,254	37,722,965