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 3, 2021 (November 1, 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 1.01 Entry into a Material Definitive Agreement.

On November 1, 2021 (the "Closing Date"), G1 Therapeutics, Inc. (the "Company"), as borrower, and Hercules Capital, Inc. and certain of its affiliates (collectively, the "Lender") entered into a second amendment (the "Second Amendment") to amend that certain loan and security agreement, dated as of May 29, 2020, as amended by that certain First Amendment to Loan and Security Agreement, dated as of March 31, 2021 (the "First Amendment"; and the loan and security agreement, as amended by the First Amendment and the Second Amendment, the "Loan and Security Agreement"), under which the Lender has agreed to lend the Company up to $150.0 million, to be made available in a series of tranches, subject to specified conditions. The Company borrowed an additional $45.0 million on the Closing Date, which brings the total loan amount outstanding to $75.0 million.

Under the terms of the Loan and Security Agreement, the Company has an option to borrow up to an additional $25.0 million through September 15, 2022. A second tranche (the "Second Tranche"), consisting of $20.0 million, will become available to the Company for drawdown upon the Company's achievement of $50,000,000 trailing six-month net product revenue of COSELA™ no later than June 30, 2023. The Second Tranche will be available, if specified conditions are met, during the period beginning on the Closing Date through December 15, 2023. A third tranche (the "Third Tranche") of $15.0 million will become available upon achievement of certain development performance milestones. The Third Tranche will be available to the Company through December 15, 2023. A fourth tranche of $15.0 million will be available, at the Lender's option, in minimum increments of $5 million through June 30, 2024.

The loan will mature on November 1, 2026. The Company may make payments of interest only through December 1, 2024. Thereafter, the interest only period may be extended through December 1, 2025, in quarterly increments, subject to continued compliance with the covenants of the Loan and Security Agreement. Amounts borrowed under the Loan and Security Agreement accrue interest at a rate equal to the greater of either (A) (i) the prime rate as reported in The Wall Street Journal, plus (ii) 5.90%, or (B) 9.15%.

The Company paid the Lender an upfront fee on the Closing Date in the amount of $675,000. The Company may prepay all or a portion of the outstanding principal amount under the Loan and Security Agreement subject to a prepayment fee equaling a percentage of the amount to be prepaid, as follows: (A)(i) 3.0% of the prepayment amount in the first year from the Closing Date; (ii) 2.0% of the prepayment amount in the second year from the Closing Date; or (iii) 1.0% of the prepayment amount thereafter, plus (B) a charge of 6.75% of the amount of the loan being prepaid. The Company will be required to make a final payment to the Lender in the amount of 6.75% of the aggregate amount of all loan advances, less any amount previously paid. In addition, the Company will be required to make a final payment to the Lender in the amount of $2,085,000 on the earliest occurrence of (i) June 1, 2025, (ii) the date that the Company prepays the outstanding principal amount under the Loan and Security Agreement in full, or (iii) the date that the principal amount becomes due and payable in full.

As security for obligations arising under the Loan and Security Agreement, the Company has granted the Lender a blanket lien on substantially all of the Company's assets, including intellectual property, subject to certain exemptions.

Under the Loan and Security Agreement, the Lender has the right to participate in any equity offerings by the Company that are marketed to multiple investors during the term of the loan under the Loan and Security Agreement in an amount up to $5.0 million.

The Loan and Security Agreement contains a minimum revenue covenant. Beginning August 15, 2022, with the reporting of the financial results for the second fiscal quarter ended June 30, 2022, and tested monthly, the Company must have achieved net product revenue of COSELA of at least 65% of the amounts projected in the Company's forecast.

The foregoing description is only a summary of certain provisions of the Second Amendment and is qualified in its entirety by reference to the Second Amendment, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending September 30, 2021 and will be incorporated by reference herein.

Item 2.02 Results of Operations and Financial Condition.

On November 3, 2021, the Company issued a press release announcing its financial results for the third-quarter ended September 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 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

The information in Item 1.01 of this Current Report on Form 8-K is incorporated by reference into this Item 2.03.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release dated November 3, 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: November 3, 2021

G1 Therapeutics Provides Third Quarter 2021 Financial Results and Operational Highlights

- Achieved $4.9 Million in Total Revenue, Including $3.6 Million in Net Revenue from Sales of COSELA™ (trilaciclib) -

- Announced Supplemental COSELA Sales Force to Target Top Tier Accounts and Publication of Permanent J-Code for COSELA—

- Initiation of Two New Phase 2 Trials Expected in the Fourth Quarter of 2021 to Further Investigate Trilaciclib's Immune-Based Mechanism of Action (MOA) and Potential Benefits in Combination with an Antibody-Drug Conjugate (ADC) -

- Amended Debt Facility Extends Cash Runway into 2024 -

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

RESEARCH TRIANGLE PARK, NC, November 3, 2021 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today provided a corporate and financial update for the third quarter ended September 30, 2021.

"The third quarter of 2021 was a period of rapid execution on initiatives designed to maximize the current and future opportunity of COSELA for patients, physicians, and investors," said Jack Bailey, Chief Executive Officer of G1 Therapeutics. "We believe COSELA is a paradigm-changing drug. In just a matter of months, we have a number of important drivers such as exceptional reimbursement, high awareness and intention to treat, and excellent physician experience. However, our recent sales were impacted by less-than-optimal execution and access challenges at key accounts that treat up to 50 percent of patients diagnosed with small cell lung cancer. We are moving aggressively to address this, including by the deployment of a supplemental sales force to target these largest accounts. Longer term, our clinical programs are strategically designed to maximize the potential of trilaciclib and meaningfully improve the lives of people living with cancer, including our plans to initiate two new Phase 2 trials this quarter. We expect these studies to add to our broader development effort to demonstrate the potential of trilaciclib with therapies likely to be relevant in future treatment paradigms."

Third Quarter 2021 and Recent Highlights

Financial

- **Achieved Net COSELA™ (trilaciclib) Revenue of $3.6 Million.**
- **Ended the Third Quarter of 2021 with Cash and Cash Equivalents of $212.1 million.**
- **Upsized Debt Facility with Hercules Capital:** The Hercules loan terms were amended to provide total commitments of $150 million, with $100 million fully available as November 1, 2021. The Company's current financial position is expected to be sufficient to fund G1's operations and capital expenditures into 2024.

Commercial

- **Announced New Supplemental COSELA Sales Force:** G1 is in the process of hiring and training up to 15 people for the Company's supplemental oncology sales force. The expansion will allow G1 to target top tier accounts to accelerate sales activities and help maximize the adoption of COSELA. The new G1 sales representatives will supplement the existing Boehringer Ingelheim oncology commercial team. (Press release here)

- **Permanent J-code for COSELA Effective for Provider Billing as of October 1, 2021:** The permanent J-code that was issued in July 2021 by the Centers for Medicare & Medicaid Services (CMS) is now effective for provider billing for all sites of care. All hospital outpatient departments, ambulatory surgery centers and physician offices in the United States now have one consistent Healthcare Common Procedure Coding System (HCPCS) code to standardize the submission and payment of COSELA insurance claims across Medicare, Medicare Advantage, Medicaid and commercial plans. The New Technology Add-on Payment (NTAP) for COSELA when administered to Medicare beneficiaries in the hospital inpatient setting is also effective. (Press release here)

Clinical

- **Initiation of New Phase 2 Study of Trilaciclib to Support its Immune-based Mechanism of Action Expected in 4Q21:** The Company confirmed its expectation to initiate a Phase 2 study of trilaciclib and chemotherapy in patients with early-stage triple negative breast cancer (TNBC) in the fourth quarter of 2021 to further investigate the role of trilaciclib in modulating the anti-tumor immune response.
- **Initiation of New Phase 2 Study of Trilaciclib in Combination with an Antibody-Drug Conjugate (ADC) in Triple-Negative Breast Cancer Expected in 4Q21:** G1 intends to initiate a Phase 2 single arm study of trilaciclib administered prior to an ADC in patients with unresectable locally advanced or metastatic TNBC in the fourth quarter of 2021.
- **Received Fast Track designation for Trilaciclib for Use in in Triple-Negative Breast Cancer (TNBC):** The U.S. Food and Drug Administration (FDA) granted Fast Track designation to trilaciclib for use in combination with chemotherapy for the treatment of locally advanced or metastatic triple negative breast cancer. Trilaciclib is currently being evaluated in PRESERVE 2, a pivotal Phase 3, randomized, double-blind, placebo-controlled study in patients receiving first- or second-line gemcitabine and carboplatin chemotherapy for TNBC. (Press release here)
- **NSCLC Market Changes Drive Strategic Decision to Discontinue Phase 2 Trial of Trilaciclib in 2L/3L NSCLC and Shift Resources to New Phase 2 MOA and ADC Trials:** The future treatment paradigm in 2L/3L NSCLC is expected to shift further away from docetaxel, the chemotherapy backbone in PRESERVE 4, suggesting minimal future market opportunity in this setting. As such G1 is discontinuing this trial and shifting those resources to support the new Phase 2 MOA and ADC trials
- **Initiation of Investigator Initiated Study (IIS) of Trilaciclib in 1L Non-Small Cell Lung Cancer (NSCLC) Expected in 1Q22:** As part of its broad investigator-initiated study program, G1 expects to support an IIS assessing the anti-tumor efficacy of trilaciclib in first-line NSCLC in combination with chemo and a checkpoint inhibitor.

Third Quarter 2021 Financial Results

As of September 30, 2021, cash and cash equivalents totaled $212.1 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 million, of which $100 million was fully available as of amendment closing. The Company has drawn down $75 million in total from the Hercules debt facility; $30 million had been drawn as of the end of the quarter and an additional $45 million was drawn on November 1, 2021.

Total revenues for the third quarter of 2021 were $4.9 million, including $3.6 million in net product sales of COSELA and license revenue of $1.3 million. This license revenue is primarily related to clinical trial reimbursements from EQRx and Simcere, and delivery of clinical drug supply and manufacturing services to Simcere, EQRx and Genor.

Operating expenses for the third quarter of 2021 were $46.0 million, compared to $36.3 million for the third quarter of 2020. GAAP operating expenses include stock-based compensation expense of $5.5 million for the third quarter of 2021, compared to $4.9 million for the third quarter of 2020.

Cost of goods sold expense for the third quarter of 2021 were $0.6 million, compared to $0 for third quarter of 2020. The increase 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.

Research and development (R&D) expenses for the third quarter of 2021 were $21.1 million, compared to $17.9 million for the third 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.

Selling, general and administrative (SG&A) expenses for the third quarter of 2021 were $24.3 million, compared to $18.4 million for the third 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, increased spend on medical affairs costs related to trilaciclib and information technology, professional services, and other administrative costs.

The net loss for the third quarter of 2021 was $42.5 million, compared to $11.7 million for the third quarter of 2020. The basic and diluted net loss per share for the third quarter of 2021 was $(1.00) compared to $(0.31) for the third quarter of 2020.

Financial Guidance

Including the contribution from the amended Hercules agreement, the Company 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 third quarter 2021 ended September 30, 2021. The live call may be accessed by dialing (866) 763-6020 (domestic) or (210) 874-7713 (international) and entering the conference code: 4404009. 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), our ability to address less-than-optimal execution and access to top tier accounts, our ability to generate data to maximize trilaciclib's applicability to future treatment paradigms, 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.

###

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)

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 212,089	$ 207,306
Working Capital	$ 206,144	$ 192,949
Total Assets	$ 243,497	$ 228,552
Accumulated deficit	$ (544,439)	$ (436,107)
Total stockholders' equity	$ 178,339	$ 177,351

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

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
Revenues:				
Product sales, net	$ 3,576	$ —	$ 6,717	$ —
License revenue	1,282	26,599	18,963	28,739
Total revenues	4,858	26,599	25,680	28,739
Operating expenses:				
Cost of goods sold	591	—	1,642	—
Research and development	21,143	17,932	56,435	56,897
Selling, general and administrative	24,268	18,412	72,474	44,230
Total operating expenses	46,002	36,344	130,551	101,127
Loss from operations	(41,144)	(9,745)	(104,871)	(72,388)
Other income (expense):				
Interest Income	7	50	35	922
Interest Expense	(934)	(757)	(2,609)	(1,022)
Other income (expense)	(76)	(291)	(208)	(488)
Total other income (expense), net	(1,003)	(998)	(2,782)	(588)
Loss before income taxes	(42,147)	(10,743)	(107,653)	(72,976)
Income tax expense	321	931	679	931
Net loss	$ (42,468)	$ (11,674)	$ (108,332)	$ (73,907)
Net loss per share, basic and diluted	$ (1.00)	$ (0.31)	$ (2.60)	$ (1.95)
Weighted average common shares outstanding, basic and diluted	42,383,573	38,009,204	41,740,911	37,819,071