
**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 7, 2018

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.)

79 T.W. Alexander Drive
4501 Research Commons, Suite 100
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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 7, 2018, G1 Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the third-quarter ended September 30, 2018. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated November 7, 2018

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 hereunto duly authorized.

Date: November 7, 2018

G1 THERAPEUTICS, INC.

/s/ Barclay A. Phillips

Barclay A. Phillips
Chief Financial Officer and Senior Vice President of
Corporate Development



G1 Therapeutics Reports Third Quarter 2018 Financial Results and Corporate Update

- *Positive data from randomized Phase 2 trilaciclib/chemotherapy trial in first-line small cell lung cancer presented at ESMO 2018 highlight myelopreservation and immune system benefits of trilaciclib*
- *Preliminary data from three additional randomized Phase 2 clinical trials of trilaciclib expected by end of 2018*
- *Management to host webcast and conference call today at 4:30 p.m. ET*

RESEARCH TRIANGLE PARK, NC, November 7, 2018 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today reported financial results and provided an update on its corporate activities and product pipeline for the third quarter ended September 30, 2018.

“Data from our randomized Phase 2 clinical trial of trilaciclib and chemotherapy in first-line small cell lung cancer showed robust myelopreservation benefits. By the end of the year, we will report data from three additional randomized Phase 2 trials in a variety of indications. Collectively these trials will provide preliminary data on the potential anti-tumor efficacy and myelopreservation benefits of trilaciclib across different indications, lines of therapy, and chemotherapy regimens,” said Raj Malik, M.D., Chief Medical Officer and Senior Vice President, R&D. “We plan to request meetings with U.S. and European regulatory authorities in early 2019 to discuss data from more than three hundred participants who received trilaciclib across multiple clinical trials.”

“Enrollment remains on track for lerociclib clinical trials in ER+, HER2- breast cancer and EGFRm non-small cell lung cancer, as well as our G1T48 trial in ER+, HER2- breast cancer, and we plan to report data on each of these programs in 2019,” said Mark Velleca, M.D., Ph.D., Chief Executive Officer. “Our strong balance sheet enables us to advance our three product candidates and begin investment in pre-commercialization activities for trilaciclib.”

Corporate Highlights

- **Presented additional data from randomized Phase 2 trial of trilaciclib in combination with etoposide/carboplatin for treatment of first-line small cell lung cancer (SCLC):** In October, new data analyses presented at the European Society for Medical Oncology (ESMO) 2018 Congress demonstrated improvements in neutrophil, red blood cell and lymphocyte measures in patients treated with trilaciclib compared to placebo. With regard to lymphocytes, trilaciclib preserved or improved B cell and T cell subset counts, including activated CD8+ cells, and increased CD8+/regulatory T cell and activated CD8+/regulatory T cell ratios in peripheral blood compared to placebo. The poster titled “Trilaciclib preserves and enhances immune system function in extensive-stage small cell lung cancer (SCLC) patients receiving first-line chemotherapy” was recognized as a “Best Poster” at ESMO.
- **Expediting analyses of myelopreservation data from the randomized Phase 2 trial of trilaciclib/chemotherapy/Tecentriq® (atezolizumab) in SCLC; data to be reported by year end 2018:** As disclosed on September 17, the company elected to make myelopreservation the primary outcome measure and overall survival a secondary outcome measure of the trilaciclib/chemotherapy/Tecentriq trial in first-line SCLC. This protocol amendment was made to provide earlier access to myelopreservation data that has the potential to confirm the myelopreservation results observed in the company’s randomized Phase 2 trial of trilaciclib in combination with chemotherapy. Both trials evaluated trilaciclib in first-line SCLC using the same chemotherapy backbone of etoposide and carboplatin.



- **Appointed Garry Nicholson to the board of directors:** Mr. Nicholson previously led the global oncology franchise at Pfizer in the role of President, Pfizer Oncology. During his tenure, he oversaw the development and commercialization of the CDK4/6 inhibitor Ibrance® (palbociclib). Mr. Nicholson currently serves on the boards of directors of Five Prime Therapeutics, Inc., TESARO, Inc., and SQZ Biotechnologies.

Anticipated Milestones for Fourth Quarter 2018

- Report preliminary data from the randomized Phase 2 clinical trial of trilaciclib/chemotherapy/Tecentriq in first-line SCLC.
- Report preliminary data from the randomized Phase 2 clinical trial of trilaciclib/chemotherapy in second-/third-line SCLC.
- Present preliminary data from the randomized Phase 2 clinical trial of trilaciclib/chemotherapy in metastatic triple negative breast cancer (mTNBC) in a poster discussion Spotlight Session at the San Antonio Breast Cancer Symposium on December 5, 2018.
- Present preclinical data on trilaciclib/chemotherapy combinations in CDK4/6-dependent tumor models at the 30th EORTC-NCI-AACR Symposium on November 13, 2018.
- Complete enrollment of the Phase 2a trial of lerociclib/Faslodex® (fulvestrant) in ER+, HER2- breast cancer.

Third Quarter 2018 Financial Highlights

- **Completed offering of common stock:** The company completed an underwritten public offering of 3,450,000 shares of its common stock at a public offering price of \$60.00 per share, including 450,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, in September. G1 received approximately \$194.9 million in proceeds from the offering, net of underwriting discounts and commissions and other offering expenses payable by G1.
- **Cash Position:** Cash, cash equivalents and short-term investments totaled \$390.5 million as of September 30, 2018, compared to \$103.8 million as of December 31, 2017. This increase results from the receipt of \$107.9 million in net proceeds from a secondary offering in March, \$36.1 million in net proceeds from "at the market offerings" between June 18 and August 2, 2018, and \$194.9 million in net proceeds from a follow-on offering in September, partially offset by \$53.1 million of cash used for operating activities.
- **Operating Expenses:** Operating expenses were \$20.8 million for the third quarter of 2018, compared to \$15.9 million for the third quarter of 2017. GAAP operating expenses include stock-based compensation expense of \$3.3 million for the third quarter of 2018, compared to \$1.0 million for the third quarter of 2017.
- **Research and Development Expenses:** Research and development (R&D) expenses for the third quarter of 2018 were \$15.9 million, compared to \$14.1 million for the third quarter of 2017. The increase in expense was due to an increase of \$3.6 million in clinical program costs, offset by a decrease of \$1.0 million in drug manufacturing costs and a decrease of \$0.8 million in preclinical expenses.



- **General and Administrative Expenses:** General and administrative (G&A) expenses for the third quarter of 2018 were \$4.9 million, compared to \$1.9 million for the third quarter of 2017. The increase in expense was largely driven by personnel-related costs due to an increase in headcount and non-cash stock compensation expense charges.
- **Net Loss:** G1 reported a net loss of \$19.9 million for the third quarter of 2018, compared to \$15.6 million for the third quarter of 2017.

Webcast and Conference Call

The management team will host a webcast and conference call at 4:30 p.m. ET today to provide a corporate and financial update for the third quarter of 2018. The live call may be accessed by dialing 866-763-6020 (domestic) or 210-874-7713 (international) and entering the conference code: 6188644. A live and archived webcast will be available on the Events & Presentations page of the company's website: www.g1therapeutics.com.

About G1 Therapeutics

G1 Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the discovery, development and delivery of innovative therapies that improve the lives of those affected by cancer. The company is advancing three clinical-stage programs, trilaciclib, lerociclib and GIT48, that are designed to enable more effective combination treatment strategies and improve patient outcomes across multiple oncology indications.

G1 is based in Research Triangle Park, NC. For additional information, please visit www.g1therapeutics.com and follow us on Twitter @G1Therapeutics.

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 news release include, but are not limited to, the therapeutic potential of trilaciclib, lerociclib and GIT48, and 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 clinical trials for, obtain approvals for and commercialize any of its product candidates; 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 development-stage company; the Company's development of a CDK4/6 inhibitor to reduce chemotherapy-induced myelosuppression is novel, unproven and rapidly evolving and may never lead to a marketable product; 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)

	September 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 390,524	\$ 103,812
Working capital	\$ 378,339	\$ 92,957
Total assets	\$ 393,019	\$ 105,171
Accumulated deficit	\$ (190,315)	\$ (129,118)
Total stockholders' equity	\$ 379,255	\$ 93,388

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses				
Research and development	15,873	14,054	51,605	38,806
General and administrative	4,949	1,875	11,595	4,881
Total operating expenses	20,822	15,929	63,200	43,687
Operating loss	(20,822)	(15,929)	(63,200)	(43,687)
Other income (expense)				
Other income	904	328	2,003	588
Change in fair value in warrant liability and other liabilities	—	—	-	(41)
Total other income, net	904	328	2,003	547
Net loss	\$ (19,918)	\$ (15,601)	\$ (61,197)	\$ (43,140)
Accretion of redeemable convertible preferred stock	—	—	-	(4,757)
Net loss attributable to common stockholders	\$ (19,918)	\$ (15,601)	\$ (61,197)	\$ (47,897)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.59)	\$ (0.55)	\$ (1.91)	\$ (3.24)
Weighted average common shares outstanding, basic and diluted	33,829,437	28,318,656	32,006,978	14,772,621