
**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 8, 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 August 8, 2018, G1 Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the second-quarter ended June 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 August 8, 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: August 8, 2018

G1 THERAPEUTICS, INC.

/s/ Barclay A. Phillips

Barclay A. Phillips

Chief Financial Officer and Senior Vice President of Corporate
Development



G1 Therapeutics Provides Second Quarter 2018 Corporate and Financial Update

- *Presenting additional data from randomized Phase 2 trilaciclib/chemotherapy trial in first-line small cell lung cancer at ESMO 2018 in October*
- *Initiated Phase 2a enrollment of lerociclib (G1T38) in ER+, HER2- breast cancer; positive Phase 1b data presented at ASCO 2018*
- *Management to host webcast and conference call today at 4:30 p.m. ET*

RESEARCH TRIANGLE PARK, NC, August 8, 2018 – G1 Therapeutics, Inc. (Nasdaq: GTHX), a clinical-stage oncology company, today provided an update on its corporate activities, product pipeline and financials for the second quarter ended June 30, 2018.

“We have made impressive clinical progress on trilaciclib in the first half of 2018 and are approaching several important clinical milestones later this year. Additional data from the randomized Phase 2 trilaciclib/chemotherapy trial in first-line small cell lung cancer have been accepted for presentation at the European Society for Medical Oncology Congress in October. We will also be reporting preliminary data from our randomized Phase 2 trials of trilaciclib in second-/third-line SCLC and triple-negative breast cancer in the fourth quarter,” said Mark Velleca, M.D., Ph.D., Chief Executive Officer. “We have been engaged in productive discussions with U.S. and European regulatory authorities regarding the trilaciclib development program and expect that dialogue to continue.”

Dr. Velleca added: “We presented the first clinical data on lerociclib in patients with ER+, HER2- breast cancer in June at the 2018 American Society of Clinical Oncology Annual Meeting, which showed promising safety, tolerability and anti-tumor activity. We are currently enrolling the Phase 2a dose-expansion portion of that trial, with patients receiving 500 mg once daily without a dosing holiday. In addition, we have initiated the first clinical trial for G1T48, our oral SERD, in ER+, HER2- breast cancer and expect preliminary data next year.”

Corporate Highlights

- **Completed enrollment of Phase 2 trials of trilaciclib in second-/third-line small cell lung cancer (SCLC) and triple negative breast cancer (TNBC):** G1 expects to report preliminary data from both randomized trials in the fourth quarter of 2018.
- **USAN name lerociclib adopted for G1T38:** G1 has received approval from the United States Adopted Names Council that lerociclib has been adopted to refer to G1T38. All future communications from G1 will refer to G1T38 as lerociclib.
- **Reported positive lerociclib data in breast cancer patients at ASCO 2018:** in June, G1 announced preliminary Phase 1b data on lerociclib in combination with Faslodex® (fulvestrant) that showed promising safety, tolerability and anti-tumor activity when lerociclib was dosed continuously as a treatment for people with estrogen receptor-positive, HER2-negative (ER+, HER2-) breast cancer.

- **Initiated enrollment of Phase 2a expansion of lerociclib in combination with Faslodex in ER+, HER2- breast cancer:** based on Phase 1b data, the Phase 2a dose expansion portion of the trial is enrolling. Approximately 30 patients will receive lerociclib 500 mg once daily without a dosing holiday.
- **Initiated Phase 1/2a clinical trial of G1T48, an oral SERD, as monotherapy for treatment of ER+, HER2- breast cancer:** in June, G1 initiated the first clinical trial of G1T48, an oral selective estrogen receptor degrader (SERD). This open-label study is expected to enroll up to 96 patients in two parts: a safety, pharmacokinetic and dose escalation portion (Phase 1); and an expansion portion at the recommended Phase 2 dose (Phase 2a). G1 plans to study a G1T48/lerociclib combination regimen for breast cancer in 2019, contingent on the Phase 1 findings.
- **Expanded leadership team, appointing Chief Commercial Officer and General Counsel:** in July, the company named John Demaree as Chief Commercial Officer and Stillman Hanson as General Counsel. Mr. Demaree has more than 20 years of oncology experience, building commercial capabilities and leading multiple successful product launches. Mr. Hanson most recently served as Associate General Counsel and Vice President at IQVIA, and has extensive life sciences corporate legal experience.
- **Appointed Cynthia Schwalm and Willie Deese to G1 Board of Directors:** in June, the company announced the election of two new Board members. Ms. Schwalm most recently served as President and Chief Executive Officer of Ipsen North America. Mr. Deese previously served as President of the Merck Manufacturing Division and as a member of the Merck Executive Committee before retiring in 2016.

Anticipated Upcoming Milestones

- Present additional data from the randomized Phase 2 trilaciclib/chemotherapy trial in first-line SCLC at ESMO 2018, being held October 19-23 in Munich, Germany.
- Report preliminary data from the randomized Phase 2 trilaciclib/chemotherapy trials in second-/third-line SCLC and first-/second-/third-line TNBC in the fourth quarter of 2018.
- Complete enrollment of the Phase 2a trial of lerociclib/Faslodex in ER+, HER2- breast cancer by the end of 2018.

Second Quarter 2018 Financial Highlights

- **Cash Position:** Cash, cash equivalents and short-term investments totaled \$188.2 million as of June 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 the secondary offering in March of this year and \$12.1 million in net-proceeds from “at the market offerings” in June, partially offset by cash used in operating activities.
- **Operating Expenses:** Operating expenses were \$21.7 million for the second quarter of 2018, compared to \$15.4 million for the second quarter of 2017. GAAP operating expenses include stock-based compensation expense of \$2.1 million for the second quarter of 2018, compared to \$0.8 million for the second quarter of 2017.
- **Research and Development Expenses:** Research and development (R&D) expenses for the second quarter of 2018 were \$18.4 million, compared to \$13.7 million for the second quarter of 2017. The increase in expense was due to an increase in clinical program costs, drug

manufacturing costs to support clinical programs and personnel costs due to additional headcount.

- **General and Administrative Expenses:** General and administrative (G&A) expenses for the second quarter of 2018 were \$3.3 million, compared to \$1.7 million for the second quarter of 2017. The increase in expense was largely due to an increase in personnel-related costs.
- **Net Loss:** G1 reported a net loss of \$20.9 million for the second quarter of 2018, compared to \$15.2 million for the second quarter of 2017.

Webcast and Conference Call

The G1 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 second 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: 3088562. 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. (G1) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for the treatment of cancer. Two of the company's pipeline assets, trilaciclib and lerociclib, are CDK4/6 inhibitors, a validated and promising class of oncology therapeutics. Trilaciclib and lerociclib have broad therapeutic potential in many forms of cancer and may serve as backbone therapy of multiple combination regimens. Trilaciclib is a short-acting IV CDK4/6 inhibitor designed to preserve hematopoietic stem cell and immune system function (myelopreservation) during chemotherapy. Lerociclib is a potential best-in-class oral CDK4/6 inhibitor for use in combination with other targeted therapies. G1 is also advancing G1T48, a potential best-in-class oral selective estrogen receptor degrader, or SERD, which is targeted for the treatment of ER+ breast cancer.

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 press release include, but are not limited to the following: the therapeutic potential of trilaciclib, lerociclib and G1T48; the inherent uncertainties associated with developing new products or technologies and operating as a development-stage company; our ability to complete clinical trials for, obtain approvals for and commercialize any of its product candidates; our ability to recruit and enroll patients in its studies; competition in the industry in which we operate; and market conditions. Each of these forward-looking statements involves risks and uncertainties and are based on our expectations and assumptions as of the date of this press release. Factors that may cause our actual results to differ from those expressed or implied in the forward-looking statements in this press release are further discussed in our filings with the U.S. Securities and Exchange Commission (SEC), including the "Risk Factors" section in our annual report on Form 10-K for the fiscal year ended December 31, 2017 filed with the

SEC. Such factors may be amended or updated from time to time in our subsequent periodic and other filings with the SEC, which are accessible on the SEC's website at www.sec.gov. We assume no obligation to update any forward-looking statement after the date of this press release to reflect any change in expectations or future developments, even as new information becomes available.

###

Contact:

Jeff Macdonald
Head of Investor and Public Relations
919-213-9835
jmacdonald@g1therapeutics.com



G1 Therapeutics, Inc.
Balance Sheet Data
(in thousands)

	June 30, 2018	December 31, 2017
Cash and cash equivalents	\$ 188,227	\$ 103,812
Working capital	\$ 175,892	\$ 92,957
Total assets	\$ 190,600	\$ 105,171
Accumulated deficit	\$(170,397)	\$ (129,118)
Total stockholders' equity	\$ 176,524	\$ 93,388

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses				
Research and development	18,385	13,667	35,732	24,752
General and administrative	3,268	1,712	6,646	3,006
Total operating expenses	21,653	15,379	42,378	27,758
Operating loss	(21,653)	(15,379)	(42,378)	(27,758)
Other income (expense)				
Other income	785	185	1,099	260
Change in fair value in warrant liability and other liabilities	—	—	—	(41)
Total other income, net	785	185	1,099	219
Net loss	\$ (20,868)	\$ (15,194)	\$ (41,279)	\$ (27,539)
Accretion of redeemable convertible preferred stock	—	(289)	—	(4,757)
Net loss attributable to common stockholders	\$ (20,868)	\$ (15,483)	\$ (41,279)	\$ (32,296)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.64)	\$ (1.09)	\$ (1.33)	\$ (4.09)
Weighted average common shares outstanding, basic and diluted	32,781,921	14,208,115	31,080,650	7,887,341