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): June 30, 2020 (June 29, 2020)

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 June 29, 2020, G1 Therapeutics, Inc. (the "Company") entered into a Co-Promotion Agreement (the "Agreement") with Boehringer Ingelheim Pharmaceuticals, Inc. ("BI"). Under the Agreement, the Company and BI will collaborate within the territories of the United States and Puerto Rico (the "Territory") on the commercialization and promotion of the trilaciclib product, a first-in-class investigational therapy designed to improve outcomes for people with cancer treated with chemotherapy (the "Product").

Under the Agreement, the Company granted to BI a co-exclusive right (with the Company) to co-promote the Product in the Territory for the prevention of chemotherapy-induced myelosuppression in small cell lung cancer.

The Company will make certain payments to BI in exchange for BI's performance of the promotion services described in the Agreement. Specifically, the Company will make initial payments to BI to cover start-up expenses and pre-approval initiatives to support a successful commercial launch. Further, BI will receive additional monthly payments commencing six months after the effective date of the Agreement until the First Commercial Sale (as defined in the Agreement) of the Product to conduct pre-launch activities.

The Company will also pay to BI certain payments based on a percentage of the Company's "Net Sales" (as defined in the Agreement) of the Product within the Territory for each of the three years following the First Commercial Sale of the Product within the Territory (the "Sales Payments"). The Sales Payments will be in the mid-twenties percentage of Net Sales in the first year of commercialization, which decreases to a low double-digit/high single-digit percentage in the second and third years of commercialization, respectively (subject to certain adjustments for Net Sales above pre-specified levels to reward out-performance). The Sales Payments vary based on the level of Net Sales in an applicable contract year.

The Agreement specifies that BI will have the co-exclusive right (with the Company) to use certain Company trademarks and copyrights in connection with the promotion of the Product in the Territory. The Agreement also contains provisions regarding payment terms, confidentiality and indemnification, as well as other customary provisions.

The co-promotion of the Product in the Territory pursuant to the terms of the Agreement will be supervised by a joint promotion committee composed of an equal number of representatives from the Company and BI.

Under the terms of the Agreement, BI will provide salesforce engagements for the Product within the Territory utilizing BI's own sales and marketing personnel. BI will hire and maintain, and be solely responsible for, its own personnel conducting the promotion services described in the Agreement, including ensuring that such personnel adhere to certain guidelines and practices with respect to the promotion of the Product. The Company will lead marketing, market access, and medical engagement initiatives under the Agreement. The Company will also be responsible for the costs of maintaining regulatory approval of, manufacturing, supplying and distributing the Product, and will prepare and control the content of Product marketing and training materials, subject to review and feedback by BI.

Subject to early termination, the Agreement will expire on the third anniversary of the First Commercial Sale. Subject to specified notice periods and specified limitations, either Party may terminate the Agreement in the event of (i) uncured material breach by the other Party, (ii) the Product not having obtained regulatory approval from the FDA by September 30, 2021, (iii) withdrawal of the Product from the market by the Company as a result of a decision by the FDA or a material safety concern; (iv) the bankruptcy, insolvency, dissolution or winding up of the other Party, or (v) for convenience (which termination right, in the case of BI, may only be exercised six months after First Commercial Sale). In addition, the Company may terminate the Agreement if the Company receives feedback from a regulatory authority that the Company reasonably believes indicates that the Product is unlikely to receive regulatory approval. BI may also terminate the Agreement if the First Commercial Sale has not occurred by September 30, 2021 or upon a change of control of the Company.

If the Agreement is terminated early by the Company for convenience, or by BI for a change of control of the Company to a successor that is materially adverse to BI and such change of control occurs after the First Commercial Sale, then the Company's annual minimum Sales Payments obligations will end on the date of such termination, but the Company will pay to BI a percentage of the Sales Payments actually achieved for the remainder of the term of the Agreement, which percentage will vary depending on the contract year in which such termination occurs. If the Agreement is terminated for any other reason, the Company's annual minimum Sales Payments will immediately cease and the Company will not accrue any further payment obligations following such termination.

The Company intends to file a copy of the Agreement with the Securities and Exchange Commission as an exhibit to its Quarterly Report on Form 10-Q for the quarter ended June 30, 2020.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release dated June 30, 2020
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: June 30, 2020

G1 Therapeutics and Boehringer Ingelheim Announce Co-Promotion Agreement for Trilaciclib in Small Cell Lung Cancer in the United States and Puerto Rico

- Partnership leverages Boehringer Ingelheim's oncology expertise to lead trilaciclib SCLC launch sales engagements
- G1 to retain full development and commercialization rights and book revenue for trilaciclib
- New Drug Application (NDA) for trilaciclib submitted in June 2020

RESEARCH TRIANGLE PARK, N.C., and RIDGEFIELD, C.T., June 30, 2020 – G1 Therapeutics, Inc. (Nasdaq: GTHX) and Boehringer Ingelheim today announced that the companies have entered into a co-promotion agreement for trilaciclib in the United States and Puerto Rico. Under the terms of the three-year agreement, G1 and Boehringer Ingelheim will collaborate on the commercialization of trilaciclib for its first potential indication in small cell lung cancer (SCLC), with the Boehringer Ingelheim oncology commercial team, well-established in lung cancer, leading sales force engagement initiatives. Discovered and developed by G1, trilaciclib is a first-in-class investigational therapy designed to improve outcomes for people with cancer treated with chemotherapy.

"We believe that trilaciclib has the potential to benefit patients with cancer being treated with chemotherapy across a broad range of solid tumors," said Mark Velleca, M.D., Ph.D., Chief Executive Officer of G1. "Our clinical trials of trilaciclib in small cell lung cancer have demonstrated significant myelopreservation benefits, and we are excited to collaborate with Boehringer Ingelheim's experienced commercial oncology team to bring this innovative therapy to patients with SCLC. In addition, this capital efficient launch structure provides us with the ability to make investments in a robust development program to assess trilaciclib in other solid tumors, including colorectal cancer and breast cancer."

Under the terms of the agreement, G1 will book revenue in the United States and Puerto Rico and retain global development and commercialization rights to trilaciclib. In the U.S. and Puerto Rico, G1 will lead marketing, market access and medical engagement initiatives; Boehringer Ingelheim will lead sales force engagements. G1 will make initial payments to Boehringer Ingelheim to cover start-up expenses and pre-approval initiatives to support a successful commercial launch. G1 will pay a promotion fee of a mid-twenties percentage of net sales in the first year of commercialization, which decreases to a low double-digit/high single-digit percentage in the second and third years of commercialization, respectively (subject to certain adjustments for sales above pre-specified levels to reward out-performance). There are no payments due by either party beyond the expiration of the three-year term of the agreement. The agreement does not extend to additional indications that G1 may pursue for trilaciclib.

“Boehringer Ingelheim’s commitment to transform treatment expectations for the oncology community extends beyond research and drives us to explore innovative solutions for patients. We are pleased to be collaborating with G1 Therapeutics and applying our commercial strengths focused on lung cancer to support a new therapy for patients with clear synergies across customer audiences,” said Kelli Moran, Senior Vice President, Specialty Care, Boehringer Ingelheim. “This strategic agreement builds on Boehringer Ingelheim’s achievements in oncology and contributes to our long-term vision to give patients new hope by taking cancer on.”

G1 received Breakthrough Therapy Designation for trilaciclib from the U.S. Food and Drug Administration (FDA) in 2019 and submitted a New Drug Application (NDA) in June 2020. More than 25,000 people in the U.S. and Puerto Rico are diagnosed with SCLC each year. Approximately 90% of SCLC patients receive first-line chemotherapy treatment, and approximately 60% of those patients receive subsequent second-line chemotherapy treatment. Chemotherapy is an effective and important weapon against cancer. However, chemotherapy does not differentiate between healthy cells and cancer cells and kills both. One of the most common side effects of chemotherapy is myelosuppression – the result of damage to stem cells in the bone marrow that produce white blood cells, red blood cells and platelets. Myelosuppression often requires the administration of rescue interventions such as growth factors and blood or platelet transfusions, and may also result in chemotherapy dose delays and reductions. Immune cell damage may decrease the ability of the immune system to fight the cancer, as well as infection. Trilaciclib has the potential to be the first proactively administered myelopreservation therapy that can make chemotherapy safer and improve the patient experience.

Additional information regarding this agreement is disclosed in a Current Report on Form 8-K filed by G1 with the U.S. Securities and Exchange Commission (available here).

About Trilaciclib

Trilaciclib is a first-in-class investigational therapy designed to improve outcomes for people with cancer treated with chemotherapy. Trilaciclib has received Breakthrough Therapy Designation based on positive myelopreservation data from three randomized, double-blind, placebo-controlled clinical trials in which trilaciclib was administered prior to chemotherapy treatment in patients with small cell lung cancer (SCLC). In a randomized trial of women with metastatic triple-negative breast cancer, trilaciclib improved overall survival when administered prior to chemotherapy. In June 2020, G1 submitted a New Drug Application (NDA) for trilaciclib for myelopreservation in SCLC and began a study in neoadjuvant breast cancer as part of the I-SPY 2 TRIAL. The company expects to initiate a Phase 3 trial in colorectal cancer in the fourth quarter of 2020.

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 is a first-in-class FDA-designated Breakthrough Therapy designed to improve outcomes for patients being treated with chemotherapy. Rintodestrant is a potential best-in-class oral selective estrogen receptor degrader (SERD) for the treatment of ER+ breast cancer. Lerociclib is a differentiated oral CDK4/6 inhibitor designed to enable more effective combination treatment strategies.

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

About Boehringer Ingelheim in Oncology

Cancer takes. Takes away time. Takes away loved ones. At Boehringer Ingelheim Oncology, we are giving patients new hope by taking cancer on. We are dedicated to collaborating with the oncology community on a shared journey to deliver leading science. Our primary focus is in lung and gastrointestinal cancers, with the goal of delivering breakthrough, first-in-class treatments that can help win the fight against cancer. Our commitment to innovation has resulted in pioneering treatments for lung cancer and we are advancing a unique pipeline of cancer cell directed agents, immune oncology therapies and intelligent combination approaches to help combat many cancers.

About Boehringer Ingelheim

Making new and better medicines for humans and animals is at the heart of what we do. Our mission is to create breakthrough therapies that change lives. Since its founding in 1885, Boehringer Ingelheim is independent and family-owned. We have the freedom to pursue our long-term vision, looking ahead to identify the health challenges of the future and targeting those areas of need where we can do the most good.

As a world-leading, research-driven pharmaceutical company, more than 51,000 employees create value through innovation daily for our three business areas: Human Pharma, Animal Health, and Biopharmaceutical Contract Manufacturing. In 2019, Boehringer Ingelheim achieved net sales of around $21.3 billion (19 billion euros). Our significant investment of over $3.9 billion (3.5 billion euros) in R&D drives innovation, enabling the next generation of medicines that save lives and improve quality of life.

We realize more scientific opportunities by embracing the power of partnership and diversity of experts across the life-science community. By working together, we accelerate the delivery of the next medical breakthrough that will transform the lives of patients now, and in generations to come. Boehringer Ingelheim Pharmaceuticals, Inc., based in Ridgefield, CT, is the largest U.S. subsidiary of Boehringer Ingelheim Corporation and is part of the Boehringer Ingelheim group of companies. In addition, there are Boehringer Ingelheim Animal Health in Duluth, GA and Boehringer Ingelheim Fremont, Inc. in Fremont, CA.

Boehringer Ingelheim is committed to improving lives and strengthening our communities. Please visit www.boehringer-ingelheim.us/csr to learn more about Corporate Social Responsibility initiatives. For more information, please visit www.boehringer-ingelheim.us, or follow us on Twitter @BoehringerUS.

G1 Therapeutics 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 the therapeutic potential of trilaciclib, rintodestrant and lerociclib, the timing of marketing applications in the U.S. for trilaciclib in SCLC, trilaciclib's possibility to improve patient outcomes across multiple indications, rintodestrant's potential to be best-in-class oral SERD, lerociclib's differentiated safety and tolerability profile over other marketed CDK4/6 inhibitors and the impact of pandemics such as COVID-19 (coronavirus), 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; 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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