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): **February 22, 2023**

Blueprint Medicines Corporation

(Exact name of registrant as specified in its charter)

Delaware	**001-37359**	**26-3632015**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

45 Sidney Street **Cambridge, Massachusetts**	**02139**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(617) 374-7580**

(Former name or former address, if changed since last report)

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.

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	BPMC	Nasdaq Global Select Market

Item 1.02 Termination of a Material Definitive Agreement

On February 22, 2023, Blueprint Medicines Corporation (the "Company") received written notice from F. Hoffmann-La Roche Ltd and Genentech, Inc., a member of the Roche Group (collectively, "Roche"), of Roche's election to terminate for convenience the Collaboration Agreement dated July 13, 2020 between Roche and the Company (the "Collaboration Agreement") pursuant to which the Company granted Roche exclusive rights to develop and commercialize GAVRETO® (pralsetinib) worldwide, excluding Mainland China, Hong Kong, Macau and Taiwan ("Greater China") and a co-exclusive license in the U.S. to develop and commercialize GAVRETO. In accordance with the Collaboration Agreement, the termination will become effective on February 22, 2024, which is 12 months following the date of receipt of the notice by the Company.

Until the termination of the Collaboration Agreement is effective, the parties will continue to perform their respective obligations under the Collaboration Agreement, including with respect to the development and commercialization of GAVRETO. In accordance with the Collaboration Agreement, the Company and Roche will negotiate and enter into a transition plan to facilitate the reversion of the product, including reasonable terms and conditions and allocation of costs and expenses. Upon the termination becoming effective, the Company's exclusivity obligations under the Collaboration Agreement will terminate. In addition, the licenses granted to Roche will terminate except to the extent necessary for Roche to perform its obligations under the agreement, and certain licenses granted by Roche to the Company will survive and become exclusive, fully-paid, perpetual, irrevocable, royalty-free (in the case of pralsetinib) and sub-licensable.

Effective on the effective date of termination, Roche will assign to the Company all regulatory approvals and materials, pricing and reimbursement approvals, non-clinical and clinical data and reports, and other materials related to GAVRETO that are owned by Roche or its affiliates. Roche will also provide reasonable consultation and assistance for the purpose of disclosing and providing the Company with certain know-how. At the Company's request, Roche will also assign commercial arrangements to the extent relating solely and specifically to GAVRETO. To the extent allowable under such agreements, Roche will assign to the Company or its affiliates the portion of Roche's agreement(s) with its third party manufacturing providers related to the GAVRETO or, alternatively, use commercially reasonable efforts to facilitate the Company's entering into a direct supply agreement with such third party manufacturing providers on comparable terms to those between Roche and such providers. The Company will additionally have the right to immediately have Roche commence the transfer of the manufacturing process for GAVRETO to the Company or its designee. At the Company's election, on a country-by-country basis until such time as all regulatory approvals for GAVRETO in such country have been assigned and transferred to the Company, Roche will appoint the Company or its designee as its exclusive distributor of GAVRETO and grant the Company or its designee the right to appoint sub-distributors, to the extent not prohibited by any written agreement between Roche or any of its affiliates and a third party. Upon written request of Roche, any existing sublicense granted by Roche to a third party in the Roche Territory will remain in full force and effect (subject to certain conditions) and the Company will enter into a direct license with such sublicensee on terms consistent with the Collaboration Agreement. At the Company's election, Roche and its affiliates will fully cooperate the Company to transfer the conduct of clinical trials of GAVRETO to the Company or its designees. Subject to certain limitations, the Company will assume any and all liability for the conduct of such transferred clinical trials after the effective date of such transfer. If the Company does not elect to assume control of any such clinical trials, then Roche will wind-down the conduct of any such Clinical Trial in an orderly manner and be responsible for any costs and expenses associated with such wind-down. In addition, Roche will be entitled, for a period of time following termination of the Collaboration Agreement, to finish any work-in-progress and to sell, any GAVRETO product that remains on hand as of the effective date of the termination and will pay the Company the amounts applicable to such sales in accordance with the terms and conditions of the Collaboration Agreement.

The Company will not be entitled to receive payment for milestones, if any, achieved after the receipt of the notice of termination but before the effective date of termination. Other material terms of the Collaboration Agreement not related to termination are set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

The foregoing description of the material terms of the Collaboration Agreement is qualified in its entirety by reference to the complete text of the Collaboration Agreement, which the Company filed with the Securities and Exchange Commission ("SEC") as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020.

Item 7.01 Regulation FD Disclosure.

On February 23, 2023, the Company issued a press release announcing Roche's decision to terminate the Collaboration Agreement for convenience. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K (this "Form 8-K"). The information in this Item 7.01, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed "filed" for 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 in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Cautionary Note Regarding Forward-Looking Statements

This Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding: expectations concerning the transition process with Roche and Genentech and continued patient access to GAVRETO, and the anticipated impact of the termination of the collaboration on Blueprint Medicines' 2023 financial guidance; Blueprint Medicines' plans to explore options for the path forward for GAVRETO; the anticipated U.S. launch of AYVAKIT for indolent systemic mastocytosis; expectations regarding Blueprint Medicines' pipeline; and Blueprint Medicines' strategy, goals and anticipated financial performance, milestones, business plans and focus. The words "aim," "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this Form 8-K are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this Form 8-K, including, without limitation, the actual timing of the transition of responsibilities and activities related to GAVRETO from Roche and Genentech, and the parties' ability to successfully execute the transition in an orderly fashion and without interruptions or changes to patient access to GAVRETO; risks and uncertainties related to the impact of the COVID-19 pandemic to Blueprint Medicines' business, operations, strategy, goals and anticipated milestones, including Blueprint Medicines' ongoing and planned research and discovery activities, ability to conduct ongoing and planned clinical trials, clinical supply of current or future drug candidates, commercial supply of current or future approved products, and launching, marketing and selling current or future approved products; Blueprint Medicines' ability to continue to establish and expand its commercial infrastructure, and successfully launch, market and sell current or future approved products; Blueprint Medicines' ability to successfully expand the approved indications for AYVAKIT/AYVAKYT or obtain marketing approval for AYVAKIT/AYVAKYT in additional geographies in the future; the delay of any current or planned clinical trials or the development of Blueprint Medicines' current or future drug candidates; Blueprint Medicines' advancement of multiple early-stage efforts; Blueprint Medicines' ability to successfully demonstrate the safety and efficacy of its drug candidates and gain approval of its drug candidates on a timely basis, if at all; the timing and results of preclinical and clinical studies for Blueprint Medicines' drug candidates, which may not support further development of such drug candidates or may impact the anticipated timing of data, publications or regulatory submissions; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; the risk that the partial clinical hold on the VELA trial may or may not be resolved in a timely manner or that additional adverse events observed could impact the extent of the partial clinical hold or Blueprint Medicines' resolution of the partial clinical hold; Blueprint Medicines' ability to obtain, maintain and enforce patent and other intellectual property protection for AYVAKIT/AYVAKYT or any drug candidates it is developing; Blueprint Medicines' ability to develop and commercialize companion diagnostic tests for AYVAKIT/AYVAKYT or any of its current and future drug candidates; Blueprint Medicines' ability to successfully expand its operations and scientific platform and the costs thereof; and the ability to establish, and the success of, Blueprint Medicines' current and future collaborations, partnerships, financing or licensing arrangements. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Blueprint Medicines' filings with the Securities and Exchange Commission, including Blueprint Medicines' most recent Annual Report on Form 10-K, as supplemented by its most recent Quarterly Report on Form 10-Q and any other filings that Blueprint Medicines has made or may make with the SEC in the future. Any forward-looking statements contained in this Form 8-K represent Blueprint Medicines' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Except as required by law, Blueprint Medicines explicitly disclaims any obligation to update any forward-looking statements..

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued by Blueprint Medicines Corporation on February 23, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and incorporated as Exhibit 101)

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.

BLUEPRINT MEDICINES CORPORATION

Date: February 23, 2023

By: /s/ Kathryn Haviland
Kathryn Haviland
Chief Executive Officer

Exhibit 99.1

Blueprint Medicines to Regain Global Rights to GAVRETO® (pralsetinib) from Roche

CAMBRIDGE, Mass., February 23, 2023 – Blueprint Medicines Corporation (NASDAQ: BPMC) today announced it will regain global commercialization and development rights to GAVRETO® (pralsetinib), excluding Greater China, following a decision by Roche to discontinue the collaboration agreement between the companies for GAVRETO for strategic reasons.

Under the terms of the agreement, the termination will be effective 12 months from the notification date of February 22, 2023. During the transition period, Blueprint Medicines and Roche are mutually committed to ensuring a smooth transition process with no anticipated interruptions or changes to patient access. In addition, the company will explore options to advance and simplify the continued global commercialization and development of GAVRETO.

"At Blueprint Medicines, we are dedicated to driving innovation and changing outcomes for patients with lung cancer. GAVRETO is an important treatment option for patients with RET fusion-positive lung cancer and other RET-altered cancers, and we are committed to ensuring that patients being treated with GAVRETO in the commercial and clinical trial settings continue to have access," said Kate Haviland, Chief Executive Officer of Blueprint Medicines. "Over the next year, we will work alongside Roche to transition the GAVRETO program. In parallel, Blueprint will determine the optimal path forward to bring GAVRETO to patients in a way that maximizes its impact and value. As we do this, we will remain focused on our 2023 goals, with our highest priorities being the anticipated U.S. launch of AYVAKIT® (avapritinib) in indolent systemic mastocytosis and the ongoing advancement of our pipeline of investigational medicines."

Since the initiation of the collaboration with Roche in July 2020, Blueprint Medicines has benefited from approximately $1 billion between upfront and milestone payments and from cost-sharing the commercialization and development of GAVRETO. The company anticipates no impact to its 2023 revenue guidance, which includes $40 million to $50 million in collaboration revenues from existing collaborations, or its anticipated operating expenses in 2023. In addition, the company continues to expect that its existing cash, cash equivalents and investments, together with anticipated future product revenues, will provide sufficient capital to enable the company to achieve a self-sustainable financial profile.

About GAVRETO (pralsetinib)

GAVRETO (pralsetinib) is a once-daily oral targeted therapy approved by the U.S. Food and Drug Administration (FDA) for the treatment of three indications: adult patients with metastatic RET fusion-positive NSCLC as detected by an FDA approved test, adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy, and adults and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate). In addition, GAVRETO has conditional marketing authorization from the European Commission as a monotherapy for the treatment of adults with RET fusion-positive advanced NSCLC not previously treated with a RET inhibitor. GAVRETO is also approved by the National Medical Products Administration (NMPA) of China for the treatment of adult patients with locally advanced or metastatic RET fusion-positive NSCLC after platinum-based chemotherapy, adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant MTC who require systemic therapy, and adult and pediatric patients 12 years of age and older with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and are radioactive iodine-refractory (if radioactive iodine treatment is appropriate).

Blueprint Medicines has an exclusive collaboration and license agreement with CStone Pharmaceuticals for the development and commercialization of GAVRETO in Greater China, which encompasses Mainland China, Hong Kong, Macau and Taiwan.

GAVRETO is designed to selectively and potently target oncogenic RET alterations, including secondary RET mutations predicted to drive resistance to treatment. For more information, visit GAVRETO.com.

About Blueprint Medicines

Blueprint Medicines is a global precision therapy company that invents life-changing therapies for people with cancer and blood disorders. Applying an approach that is both precise and agile, we create medicines that selectively target genetic drivers, with the goal of staying one step ahead across stages of disease. Since 2011, we have leveraged our research platform, including expertise in molecular targeting and world-class drug design capabilities, to rapidly and reproducibly translate science into a broad pipeline of precision therapies. Today, we are delivering our approved medicines to patients in the United States and Europe, and we are globally advancing multiple programs for systemic mastocytosis, lung cancer, breast cancer and other genomically defined cancers, and cancer immunotherapy. For more information, visit www.BlueprintMedicines.com and follow us on Twitter (@BlueprintMeds) and LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding: expectations concerning the transition process with Roche and Genentech and continued patient access to GAVRETO, and the anticipated impact of the termination of the collaboration on Blueprint Medicines' 2023 financial guidance; Blueprint Medicines' plans to explore options for the path forward for GAVRETO; the anticipated U.S. launch of AYVAKIT® for indolent systemic mastocytosis; expectations regarding Blueprint Medicines' pipeline; and Blueprint Medicines' strategy, goals and anticipated financial performance, milestones, business plans and focus. The words "aim," "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, the actual timing of the transition of responsibilities and activities related to GAVRETO from Roche and Genentech, and the parties' ability to successfully execute the transition in an orderly fashion and without interruptions or changes to patient access to GAVRETO; risks and uncertainties related to the impact of the COVID-19 pandemic to Blueprint Medicines' business, operations, strategy, goals and anticipated milestones, including Blueprint Medicines' ongoing and planned research and discovery activities, ability to conduct ongoing and planned clinical trials, clinical supply of current or future drug candidates, commercial supply of current or future approved products, and launching, marketing and selling current or future approved products; Blueprint Medicines' ability to continue to establish and expand its commercial infrastructure, and successfully launch, market and sell current or future approved products; Blueprint Medicines' ability to successfully expand the approved indications for AYVAKIT/AYVAKYT or obtain marketing approval for AYVAKIT/AYVAKYT in additional geographies in the future; the delay of any current or planned clinical trials or the development of Blueprint Medicines' current or future drug candidates; Blueprint Medicines' advancement of multiple early-stage efforts; Blueprint Medicines' ability to successfully demonstrate the safety and efficacy of its drug candidates and gain approval of its drug candidates on a timely basis, if at all; the timing and results of preclinical and clinical studies for Blueprint Medicines' drug candidates, which may not support further development of such drug candidates or may impact the anticipated timing of data, publications or regulatory submissions; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; the risk that the partial clinical hold on the VELA trial may or may not be resolved in a timely manner or that additional adverse events observed could impact the extent of the partial clinical hold or Blueprint Medicines' resolution of the partial clinical hold; Blueprint Medicines' ability to obtain, maintain and enforce patent and other intellectual property protection for AYVAKIT/AYVAKYT or any drug candidates it is developing; Blueprint Medicines' ability to develop and commercialize companion diagnostic tests for AYVAKIT/AYVAKYT or any of its current and future drug candidates; Blueprint Medicines' ability to successfully expand its operations and scientific platform and the costs thereof; and the ability to establish, and the success of, Blueprint Medicines' current and future collaborations, partnerships, financing or licensing arrangements. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Blueprint Medicines' filings with the Securities and Exchange Commission (SEC), including Blueprint Medicines' most recent Annual Report on Form 10-K, as supplemented by its most recent Quarterly Report on Form 10-Q and any other filings that Blueprint Medicines has made or may make with the SEC in the future. Any forward-looking statements contained in this press release represent Blueprint Medicines' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. Except as required by law, Blueprint Medicines explicitly disclaims any obligation to update any forward-looking statements.

Trademarks

Blueprint Medicines, AYVAKIT, GAVRETO and associated logos are trademarks of Blueprint Medicines Corporation.

Media Relations Contact

Jim Baker
+1 (617) 844-8236
media@blueprintmedicines.com

Investor Relations Contact

Jenna Cohen
+1 (857) 209-3147
ir@blueprintmedicines.com