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, 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 8.01 Other Events.

Genentech, Inc. ("Genentech"), a member of the Roche Group, today announced the voluntary withdrawal of the U.S. indication of GAVRETO® (pralsetinib) for the treatment of adult and pediatric patients 12 years of age and older with advanced or metastatic rearranged during transfection (RET)-mutant medullary thyroid cancer ("MTC") who require systemic therapy. Genentech stated that its decision to withdraw the indication is not due to any new safety or efficacy data for GAVRETO or a product safety or quality issue, and other approved indications for GAVRETO in the United States are unaffected. Under Blueprint Medicines Corporation's (the "Company," "our" or "we") collaboration, Genentech remains the New Drug Application sponsor in the United States.

This decision was made in consultation with the U.S. Food and Drug Administration ("FDA"), in accordance with the requirements of the FDA's Accelerated Approval Program. Specifically, AcceleRET-MTC, a Phase III clinical trial required by the FDA to convert the accelerated approval of GAVRETO for MTC to a full approval, will no longer be pursued due to feasibility. The confirmatory studies to meet the commitments required to convert the remaining indications for GAVRETO, also approved under accelerated approval, to full approval, are ongoing.

Genentech has previously disclosed that the MTC indication contributes a small fraction of its annual GAVRETO revenues in the United States. The Company anticipates that this decision will have no impact to its 2023 collaboration revenue guidance of $40 to $50 million. In February 2023, Roche provided written notification of their decision to terminate the collaboration agreement, which will become effective in February 2024.

The Company, in partnership with Genentech, remains committed to supporting appropriate treatment continuity for MTC patients in the United States who are currently treated with GAVRETO, and to supporting patients and healthcare practitioners navigate the near-term impacts of this update.

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: June 30, 2023

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