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 8, 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.

On February 10, 2023, Blueprint Medicines Corporation (the "Company") issued a press release disclosing that the U.S. Food and Drug Administration verbally informed the Company on February 8, 2023, that it has placed a partial clinical hold on the Company's VELA trial, a Phase 1/2 trial of BLU-222 in CDK2-vulnerable cancers. A copy of the press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press release issued by Blueprint Medicines Corporation on February 10, 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 10, 2023

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

Exhibit 99.1

Blueprint Medicines Announces Partial Clinical Hold for Phase 1/2 VELA Trial of BLU-222

CAMBRIDGE, Mass., February 10, 2023 – Blueprint Medicines Corporation (NASDAQ: BPMC) today announced that the U.S. Food and Drug Administration (FDA) verbally informed the company on February 8, 2023 that it has placed a partial clinical hold on the Phase 1/2 VELA trial of BLU-222 due to visual adverse events (AEs) observed in a limited number of patients. Patients currently enrolled in the trial are continuing on study drug at this time, and additional patients will not be enrolled until the partial clinical hold is resolved.

BLU-222 is currently being evaluated in the Phase 1 dose escalation portion of the VELA trial. Patients have been treated with BLU-222 at doses ranging from 50 mg BID to 800 mg BID to date, with evidence of clinical benefit observed and no discontinuations due to AEs.

The reported visual AEs consisted of transient, reversible episodes of light sensitivity and blurred vision. All events were Grade 1, except one Grade 3 event involving light sensitivity and blurred vision in a patient treated at 600 mg BID. All events resolved with dose interruption or reduction. No treatment-emergent abnormal findings, including uveitis, have been observed in patients who have received detailed ophthalmologic examinations.

“Patient safety is our first priority, and we are working closely with the FDA to investigate the reported visual adverse events as well as amend the VELA trial protocol to provide specific guidance to investigators on how to monitor for and manage these events should they occur,” said Becker Hewes, M.D., Chief Medical Officer at Blueprint Medicines. “We have confidence in the benefit-risk profile of BLU-222 based on the activity and safety data we have seen to date in the dose escalation study. In addition, we recognize the urgency to treat patients with CDK2-vulnerable cancers, many of whom have seen their disease progress after exhausting all other options, and we aim to resume enrollment as expeditiously and responsibly as possible.”

Consistent with prior guidance, Blueprint Medicines plans to present initial dose escalation data from the VELA trial of BLU-222 in the first half of 2023.

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 Blueprint Medicines' expectations for its interactions with the FDA, the continuation of participants in Blueprint Medicines' VELA trial, Blueprint Medicines' ongoing investigation into the underlying cause of the reported visual adverse events, Blueprint Medicines' ability to resolve the partial clinical hold and resume enrollment in and complete the VELA trial, Blueprint Medicines' expectations regarding the benefit-risk profile of BLU-222, potential of the Blueprint Medicines' current or future drug candidates in treating patients with CDK2-vulnerable cancers, and the anticipated timing of initial clinical data from the VELA trial. 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 risk that the partial clinical hold may or may not be resolved in a timely manner; the partial clinical hold may or may not impact the timing of presentation of initial dose escalation data; there may be additional adverse events observed that could impact the extent of the partial clinical hold or Blueprint Medicines' resolution of the partial clinical hold; there may be amendments to the trial protocol that impact the timing of the trial or evaluation of the data; the FDA may not agree with Blueprint Medicines' proposed approach or may not do so in a timely manner; preliminary activity and safety data may not be representative of more mature data; the ongoing COVID-19 pandemic may impact Blueprint Medicines' business, operations, strategy, goals and anticipated milestones, including ongoing and planned research and discovery activities, Blueprint Medicines' ability to conduct ongoing and planned clinical trials, or the supply of its current or future drug candidates; the risk of delay of any current or planned clinical trials or the development of our current or future drug candidates; risks related to Blueprint Medicines' ability to successfully demonstrate the safety and efficacy of Blueprint Medicines' drug candidates and gain approval of its drug candidates on a timely basis, if at all; preclinical and clinical results for Blueprint Medicines' drug candidates may not support further development of such drug candidates either as monotherapies or in combination with other agents or may impact the anticipated timing of data or regulatory submissions; the timing of the initiation of clinical trials and trial cohorts at clinical trial sites and patient enrollment rates may be delayed or slower than anticipated; actions of regulatory agencies may affect the initiation, timing and progress of clinical trials; risks related to Blueprint Medicines' ability to obtain, maintain and enforce patent and other intellectual property protection for its products and current or future drug candidates; and the success of Blueprint Medicines' current and future collaborations, financing arrangements, partnerships 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.

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