
**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): **March 27, 2019**

Blueprint Medicines Corporation
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37359
(Commission File Number)

26-3632015
(I.R.S. Employer
Identification No.)

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

02139
(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.

Item 8.01 Other Events

On March 27, 2019, Blueprint Medicines Corporation issued a press release providing an update on recent developments and a press release announcing the commencement of an underwritten public offering of shares of its common stock. Copies of these press releases are attached to this Current Report on Form 8-K as Exhibits 99.1 and 99.2, respectively, and are each incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Blueprint Medicines Corporation on March 27, 2019
99.2	Press release issued by Blueprint Medicines Corporation on March 27, 2019

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: March 27, 2019

By: /s/ Jeffrey W. Albers
Jeffrey W. Albers
Chief Executive Officer

Blueprint Medicines Announces Accelerated Regulatory Submission Plans and Recent Clinical Progress

- *Avapritinib: plan to submit MAA for PDGFR α D842V mutant GIST and fourth-line GIST in Q3 2019 and NDA for advanced systemic mastocytosis in Q1 2020* —
- *BLU-667: plan to submit NDA for previously treated RET-fusion non-small cell lung cancer in Q1 2020 based on early achievement of enrollment target; top-line interim data show 62 percent ORR* —
- *BLU-782: plan to initiate Phase 2a trial in patients with fibrodysplasia ossificans progressiva in Q4 2019* —

CAMBRIDGE, Mass., March 27, 2019 /PRNewswire/ — Blueprint Medicines Corporation (NASDAQ: BPMC), a precision therapy company focused on genomically defined cancers, rare diseases and cancer immunotherapy, today announced plans to expedite development of avapritinib, BLU-667 and BLU-782 based on recent clinical progress and interactions with regulatory authorities.

“The updates we are announcing today for avapritinib, BLU-667 and BLU-782 represent the acceleration of multiple clinical-stage programs, including planned marketing applications for avapritinib and BLU-667, and highlight our commitment to executing a portfolio-based strategy,” said Jeff Albers, Chief Executive Officer of Blueprint Medicines. “In addition, as we prepare to submit marketing applications for avapritinib for the treatment of PDGFRA-driven and fourth-line GIST in the United States in the second quarter and Europe in the third quarter, we are rapidly building global commercial capabilities to enable us to deliver this important new medicine, if approved, to patients in need.”

Summary of Accelerated Regulatory Submission Plans and Recent Clinical Progress

Avapritinib: Gastrointestinal Stromal Tumors (GIST)

- Blueprint Medicines now plans to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for avapritinib for the treatment of both PDGFR α D842V mutant GIST and fourth-line GIST in the third quarter of 2019.

Avapritinib: Advanced Systemic Mastocytosis (SM)

- Blueprint Medicines now plans to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for avapritinib for the treatment of advanced SM in the first quarter of 2020, subject to continuing discussions with the FDA under its breakthrough therapy program to determine the required clinical data for an NDA submission.

BLU-667: RET-Altered Cancers

- Top-line interim data from the Phase 1 ARROW clinical trial of BLU-667 for patients with RET-fusion non-small cell lung cancer (NSCLC) and RET-mutant medullary thyroid cancer (MTC) who were response evaluable and treated at the recommended Phase 2 dose of 400 mg once daily, as of November 14, 2018 with follow-up through a data cutoff date of March 1, 2019, showed the following:
 - In 34 patients with RET-fusion NSCLC previously treated with platinum-based chemotherapy, the overall response rate (ORR) was 62 percent. (1)
 - In 16 patients with RET-mutant MTC previously treated with the approved multi-kinase inhibitors cabozantinib and/or vandetanib, the ORR was 63 percent. (2)
 - BLU-667 was generally well-tolerated, and most adverse events (AEs) reported by investigators were mild or moderate (Grade 1 or 2). Across all doses and treatment cohorts (n=217), only eight patients
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discontinued treatment with BLU-667 due to treatment-related AEs, with one Grade 5 AE (pneumonia/lung infection) determined by the investigator to be possibly related to BLU-667.

- Detailed clinical safety and efficacy data from the ARROW trial in RET-fusion NSCLC patients and RET-mutant MTC patients have been submitted for presentation at the American Society of Clinical Oncology Annual Meeting in June 2019.
- The enrollment target has been reached and patient screening is now closed for the registration-enabling ARROW trial cohort for patients with previously treated RET-fusion NSCLC. Blueprint Medicines anticipates reaching the enrollment target for the registration-enabling ARROW trial cohort for patients with previously treated MTC in the second quarter of 2019.
- Based on the early achievement of the enrollment target for the RET-fusion NSCLC cohort, Blueprint Medicines now plans to submit an NDA to the FDA for BLU-667 for the treatment of patients with NSCLC previously treated with platinum-based chemotherapy in the first quarter of 2020. Blueprint Medicines continues to expect to submit an NDA to the FDA for BLU-667 for the treatment of patients with RET-mutant MTC previously treated with an approved multi-kinase inhibitor in the first half of 2020.

BLU-782: Fibrodysplasia Ossificans Progressiva (FOP)

- Based on the progress of the ongoing Phase 1 clinical trial in healthy volunteers and input from clinical experts, Blueprint Medicines now plans to initiate a Phase 2a clinical trial of BLU-782 in patients with FOP in the fourth quarter of 2019.

Footnotes:

(1) 95 percent confidence interval (CI): 44-78 percent; five responses pending confirmation.

(2) 95 percent CI: 35-85 percent; three responses pending confirmation.

About Blueprint Medicines

Blueprint Medicines is a precision therapy company striving to improve human health. With a focus on genomically defined cancers, rare diseases and cancer immunotherapy, we are developing transformational medicines rooted in our leading expertise in protein kinases, which are proven drivers of disease. Our uniquely targeted, scalable approach empowers the rapid design and development of new treatments and increases the likelihood of clinical success. We are currently advancing four investigational medicines in clinical development, along with multiple research programs.

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 plans and timelines for the development of avapritinib, BLU-667 and BLU-782; plans and timelines for submitting an MAA to the EMA for avapritinib for the treatment of PDGFR α D842V mutant GIST and fourth-line GIST; plans and timelines for submitting an NDA to the FDA for BLU-667 for the treatment of patients with NSCLC previously treated with platinum-based chemotherapy; plans and timelines for submitting an NDA to the FDA for BLU-667 for the treatment of patients with RET-mutant MTC previously treated with an approved multi-kinase inhibitor; plans and timelines for presenting additional data from the ongoing ARROW trial for BLU-667; plans and timelines for initiating a Phase 2a clinical trial of BLU-782 in patients with FOP; and Blueprint Medicines' strategy, business plans and focus. The words "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, risks and uncertainties related to the delay of any current or planned clinical trials or the development of Blueprint Medicines' drug candidates, including avapritinib, BLU-667, BLU-554 and BLU-782; Blueprint Medicines' advancement of multiple early-stage efforts; Blueprint Medicines' ability to successfully demonstrate the safety and efficacy of its drug candidates; the preclinical and clinical results for Blueprint Medicines' drug candidates, which may not support further development of such drug candidates; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; Blueprint Medicines' ability to develop and commercialize companion diagnostic tests for its current and future drug candidates, including companion diagnostic tests for avapritinib for PDGFR α D842V-driven GIST, BLU-667 for RET-driven NSCLC and BLU-554 for FGFR4-driven hepatocellular carcinoma; the success of Blueprint Medicines' current and future collaborations, including its cancer immunotherapy collaboration with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. and its collaboration with CStone Pharmaceuticals. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Blueprint Medicines' Annual Report on Form 10-K for the quarter ended December 31, 2018, as filed with the Securities and Exchange Commission (SEC) on February 26, 2019, 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.

Investor and Media Relations Contact

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Blueprint Medicines Announces Proposed Public Offering of Shares of Common Stock

CAMBRIDGE, Mass., March 27, 2019 — Blueprint Medicines Corporation (NASDAQ: BPMC), a precision therapy company focused on genomically defined cancers, rare diseases and cancer immunotherapy, today announced that it has commenced an underwritten public offering of \$300,000,000 in shares of its common stock. In addition, Blueprint Medicines expects to grant the underwriters a 30-day option to purchase up to an additional \$45,000,000 in shares of its common stock in connection with the public offering. All shares of common stock will be offered by Blueprint Medicines.

Blueprint Medicines expects to use the net proceeds of the offering to further build its commercial infrastructure and operations in support of one or more anticipated commercial launches of its drug candidates, including potential commercial launches of avapritinib in the United States and Europe, subject to regulatory approval; to fund clinical trials for avapritinib in gastrointestinal stromal tumors (GIST) and systemic mastocytosis (SM), including its planned registration-enabling Phase 3 COMPASS-2L clinical trial for second-line GIST and its ongoing registration-enabling Phase 2 PIONEER clinical trial for indolent and smoldering SM, as well as future indication expansion clinical trials; to fund clinical trials for BLU-667 in RET-driven cancers, including its planned Phase 3 clinical trial for BLU-667 in first-line RET-altered non-small cell lung cancer (NSCLC) and its planned Phase 2 clinical trial for BLU-667 in combination with osimertinib in treatment-resistant, EGFR-mutant NSCLC harboring an acquired RET alteration; to fund a planned Phase 2a clinical trial for BLU-782 in patients with fibrodysplasia ossificans progressiva; to fund manufacturing costs for ongoing and anticipated drug development efforts for its most advanced drug candidates, including a potential commercial launch of avapritinib; and the balance, if any, to fund additional discovery research efforts, its other ongoing and planned clinical trials, working capital requirements and other general corporate purposes.

Goldman Sachs & Co. LLC and Cowen and Company, LLC are acting as joint book-running managers for the offering. Guggenheim Securities, LLC and Wedbush Securities Inc. are acting as co-lead managers for the offering. The offering is subject to market and other conditions, and there can be no assurance as to whether or when the offering may be completed or as to the actual size or terms of the offering.

A registration statement on Form S-3 (File No. 333-216573) relating to these securities has been previously filed with the Securities and Exchange Commission (SEC) and has become effective. This press release shall not constitute an offer to sell or a solicitation of an offer to buy, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

The offering will be made only by means of a prospectus. A copy of the prospectus supplement relating to the offering will be filed with the SEC and may be obtained, when available, from Goldman Sachs & Co. LLC by mail at Prospectus Department, 200 West Street, New York, NY 10282, by telephone at (866) 471-2526, by fax at (212) 902-9316, or by email at prospectus-ny@ny.email.gs.com, or from Cowen and Company, LLC, c/o Broadridge Financial Services, 1155 Long Island Avenue, Edgewood, NY 11717, Attention: Prospectus Department, by telephone at (631) 274-2806, or by fax at (631) 254-7140.

About Blueprint Medicines

Blueprint Medicines is a precision therapy company striving to improve human health. With a focus on genomically defined cancers, rare diseases and cancer immunotherapy, we are developing transformational medicines rooted in our leading expertise in protein kinases, which are proven drivers of disease. Our uniquely targeted, scalable approach empowers the rapid design and development of new treatments and increases the likelihood of clinical success. Blueprint Medicines is currently advancing four investigational medicines in clinical development, along with multiple research programs.

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' anticipated public offering; future expectations, plans and prospects for Blueprint Medicines and the timing of these

events; and Blueprint Medicines' strategy, business plans and focus. The words "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, uncertainties related to market conditions and the completion of the public offering on the anticipated terms or at all. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Blueprint Medicines' Annual Report on Form 10-K for the fiscal year ended December 31, 2018, as filed with the SEC on February 26, 2019, the prospectus supplement related to the public offering and 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. Blueprint Medicines explicitly disclaims any obligation to update any forward-looking statements.

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