

**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): **May 9, 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
(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.

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 2.02 Results of Operations and Financial Condition.

On May 9, 2019, Blueprint Medicines Corporation announced its financial results for the quarter ended March 31, 2019 and other business highlights. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

The information in this Current Report on Form 8-K, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit relating to Item 2.02 of this Current Report on Form 8-K shall be deemed to be furnished and not filed:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Blueprint Medicines Corporation on May 9, 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: May 9, 2019

By: /s/ Jeffrey W.

Albers

Jeffrey W. Albers

Chief Executive Officer



Blueprint Medicines Reports First Quarter 2019 Financial Results

- Avapritinib NDA for PDGFRA Exon 18 mutant GIST and fourth-line GIST on track for submission to FDA in second quarter --
- BLU-667 granted Breakthrough Therapy Designation for the treatment of RET fusion-positive NSCLC --
- Avapritinib data in GIST and BLU-667 data in RET-altered NSCLC and MTC accepted for presentation at ASCO --
- Avapritinib data in advanced systemic mastocytosis accepted for presentation at EHA --
- Completed follow-on offering and raised approximately \$327.2 million in net proceeds --

CAMBRIDGE, Mass., May 9, 2019 – Blueprint Medicines Corporation (NASDAQ:BPMC), a precision therapy company focused on genomically defined cancers, rare diseases and cancer immunotherapy, today reported financial results and provided a business update for the quarter ended March 31, 2019.

“Based on significant clinical and regulatory progress in the first quarter, we accelerated multiple programs and advanced our ‘2020 Blueprint’ strategy to transform Blueprint Medicines into a fully-integrated precision therapy company,” said Jeff Albers, Chief Executive Officer of Blueprint Medicines. “We are especially encouraged that the FDA granted Breakthrough Therapy Designation to BLU-667 for RET-fusion-positive NSCLC, and we look forward to presenting updated data from our Phase 1 ARROW trial at the ASCO Annual Meeting next month. In addition, our follow-on public offering in April further strengthened our financial position, enabling us to continue to build the company ahead of multiple planned marketing applications for avapritinib and BLU-667 in the United States and Europe over the next 18 months.”

First Quarter 2019 Highlights and Recent Progress:

Avapritinib: Gastrointestinal stromal tumors (GIST):

- Announced plans to submit a marketing authorization application (MAA) to the European Medicines Agency (EMA) for avapritinib for the treatment of PDGFR α D842V mutant GIST and fourth-line GIST in the third quarter of 2019.

Avapritinib: Systemic mastocytosis (SM):

- Announced plans to accelerate the submission of 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 to determine the required clinical data for an NDA submission.

BLU-667: RET-altered solid tumors:

- Received FDA Breakthrough Therapy Designation for BLU-667 for the treatment of patients with RET fusion-positive non-small cell lung cancer (NSCLC) that has progressed following platinum-based chemotherapy.
 - Announced top-line interim data from the Phase 1 ARROW trial of BLU-667 in patients with previously treated RET-fusion NSCLC and previously treated RET-mutant medullary thyroid cancer (MTC). Read the full data here.
 - Achieved enrollment targets for registration-enabling ARROW trial cohorts for patients with previously treated RET-fusion NSCLC and previously treated RET-mutant MTC. Based on the early achievement of the enrollment target for the RET-fusion NSCLC cohort, Blueprint Medicines 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.
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BLU-554: Advanced hepatocellular carcinoma (HCC)

- Dosed the first patient in China in the ongoing Phase 1 clinical trial of BLU-554 in patients with advanced HCC, under Blueprint Medicines' collaboration with CStone Pharmaceuticals.

BLU-782: Fibrodysplasia ossificans progressiva (FOP):

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

Corporate:

- Closed an underwritten public offering of 4,662,162 shares of common stock at a public offering price of \$74.00 per share, including the exercise in full by the underwriters of their option to purchase additional shares of common stock. Blueprint Medicines received estimated net proceeds of approximately \$327.2 million, after deducting underwriting discounts and commissions and estimated offering expenses.

Key Upcoming Milestones:

The company expects to achieve the following near-term milestones:

- Submit an NDA to the FDA and an MAA to the EMA for avapritinib for the treatment of patients with PDGFRA Exon 18 mutant GIST and fourth-line GIST in the second quarter and third quarter of 2019, respectively.
- Present the registration dataset for avapritinib in PDGFRA Exon 18 mutant GIST and fourth-line GIST at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting.
- Present updated data from the Phase 1 EXPLORER trial of avapritinib in advanced SM at the 24th Annual Congress of the European Hematology Society.
- Present updated data from the Phase 1 ARROW trial of BLU-667 in RET-altered cancers at the 2019 ASCO Annual Meeting.

First Quarter 2019 Financial Results:

- **Cash Position:** As of March 31, 2019, cash, cash equivalents and investments were \$415.9 million, as compared to \$494.0 million as of December 31, 2018. This decrease was primarily related to cash used in operating activities. Cash, cash equivalents and investments as of March 31, 2019 do not include the estimated net proceeds of approximately \$327.2 million from the company's follow-on underwritten public offering of common stock, which closed in April 2019.
 - **Collaboration Revenues:** Collaboration revenues were \$0.7 million for the first quarter of 2019, as compared to \$1.0 million for the first quarter of 2018. This decrease was primarily due to revenue recorded under the Roche collaboration.
 - **R&D Expenses:** Research and development expenses were \$74.3 million for the first quarter of 2019, as compared to \$50.0 million for the first quarter of 2018. This increase was primarily due to increased clinical and manufacturing expenses driven by our lead development candidates and increased personnel-related expenses. Research and development expenses included \$5.8 million in stock-based compensation expenses for the first quarter of 2019.
 - **G&A Expenses:** General and administrative expenses were \$16.6 million for the first quarter of 2019, as compared to \$9.9 million for the first quarter of 2018. This increase was primarily due to increased personnel-related expenses, commercial-readiness activities and increased other professional fees. General and administrative expenses included \$4.5 million in stock-based compensation expenses for the first quarter of 2019.
 - **Net Loss:** Net loss was \$87.4 million for the first quarter of 2019, or a net loss per share of \$1.98, as compared to a net loss of \$56.5 million for the first quarter of 2018, or a net loss per share of \$1.29.
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Financial Guidance:

Based on its current plans, Blueprint Medicines expects that its existing cash, cash equivalents and investments, including the estimated net proceeds of approximately \$327.2 million from its April 2019 follow-on public offering but excluding any potential option fees and milestone payments under its existing collaborations with Roche and CStone Pharmaceuticals, will be sufficient to enable it to fund its operating expenses and capital expenditure requirements into the middle of 2021.

Conference Call Information:

Blueprint Medicines will host a live conference call and webcast at 8:30 a.m. ET today to discuss first quarter 2019 financial results and recent business activities. The conference call may be accessed by dialing (855) 728-4793 (domestic) or (503) 343-6666 (international) and referring to conference ID 9671728. A webcast of the conference call will be available in the Investors section of the Blueprint Medicines' website at <http://ir.blueprintmedicines.com>. The archived webcast will be available on Blueprint Medicines' website approximately two hours after the conference call and will be available for 30 days following the call.

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. 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 plans and timelines for the development of avapritinib, BLU-667, BLU-554 and BLU-782; plans and timelines for submitting an NDA to the FDA and an MAA to the EMA for avapritinib for the treatment of GIST; plans and timelines for presenting the registration dataset for avapritinib in PDGFRA Exon 18 mutant GIST and fourth-line GIST; plans and timelines for submitting an NDA to the FDA for avapritinib for the treatment of advanced SM; plans and timelines for presenting updated data from the Phase 1 EXPLORER trial of avapritinib in advanced SM; plans and timelines for submitting NDAs to the FDA for BLU-667 for the treatment of RET-fusion NSCLC and RET-fusion MTC; plans and timelines for presenting updated data from the Phase 1 ARROW trial of BLU-667 in RET-altered cancers; expectations regarding the results from the Phase 1 clinical trial of BLU-782 in patients with FOP; plans and timelines for initiating a Phase 2 clinical trial of BLU-782 in patients with FOP; plans and timelines for patient enrollment in China in the ongoing global Phase 1 trial of BLU-554 in patients with advanced HCC; the potential benefits of Blueprint Medicines' current and future drug candidates in treating patients; expectations regarding Blueprint Medicines' existing cash, cash equivalents and investments; and Blueprint Medicines' strategy, goals and anticipated milestones, 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 and gain approval of its drug candidates on a timely basis, if at all; 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; and 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 year 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.

Blueprint Medicines Corporation
Selected Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	<u>March 31,</u>	<u>December 31,</u>
	2019	2018
Cash, cash equivalents and investments	\$ 415,856	\$ 494,012
Working capital ⁽¹⁾	361,753	439,464
Total assets	544,663	540,124
Deferred revenue	45,436	46,167
Total liabilities	200,450	121,115
Total stockholders' equity	344,213	419,009

⁽¹⁾ Blueprint Medicines defines working capital as current assets less current liabilities.

Blueprint Medicines Corporation
Condensed Consolidated Statements of Operations Data
(in thousands, except per share data)
(unaudited)

	<u>Three Months Ended</u>	
	<u>March 31,</u>	
	2019	2018
Collaboration revenue	\$ 730	\$ 954
Operating expenses:		
Research and development	74,250	49,954
General and administrative	16,553	9,911
Total operating expenses	90,803	59,865
Other income (expense):		
Other income, net	2,669	2,394
Interest expense	(3)	(32)
Total other income	2,666	2,362
Net loss	\$ (87,407)	\$ (59,549)
Net loss per share — basic and diluted	\$ (1.98)	\$ (1.29)
Weighted-average number of common shares used in net loss per share — basic and diluted	44,097	43,700

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