

**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): **August 1, 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 August 1, 2019, Blueprint Medicines Corporation announced its financial results for the quarter ended June 30, 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 August 1, 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: August 1, 2019

By: /s/ Jeffrey W.

Albers

Jeffrey W. Albers

Chief Executive Officer



Blueprint Medicines Reports Second Quarter 2019 Financial Results

- NDA and MAA submitted for avapritinib for defined GIST patient populations --
- Updated data presented for avapritinib and pralsetinib (formerly BLU-667) to support planned NDA submissions in 2020 --
- Company plans to highlight research vision, platform capabilities and portfolio strategy at R&D Day on November 5, 2019 --

CAMBRIDGE, Mass., Aug. 1, 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 June 30, 2019.

“The first half of 2019 was a defining period for Blueprint Medicines marked by the submission of our first marketing applications for avapritinib in the United States and Europe, just four years after we initiated clinical development,” said Jeff Albers, Chief Executive Officer of Blueprint Medicines. “As we prepare for the potential launch of avapritinib, we continue to advance our broader portfolio toward critical program milestones, including multiple planned marketing applications for avapritinib and pralsetinib in 2020. In addition, we plan to present initial clinical data from our ongoing Phase 2 PIONEER trial of avapritinib in patients with indolent systemic mastocytosis in the fourth quarter of 2019 and share an update on our research vision and portfolio strategy at our first R&D Day in November 2019.”

Second Quarter 2019 Highlights and Recent Progress:

Avapritinib: Gastrointestinal stromal tumors (GIST)

- Submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for avapritinib for the treatment of adult patients with PDGFRA exon 18 mutant GIST, regardless of prior therapy, and fourth-line GIST.
- Submitted a marketing authorization application (MAA) to the European Medicines Agency (EMA) for avapritinib for the treatment of adult patients with PDGFRα D842V mutant GIST, regardless of prior therapy, and fourth-line GIST and received EMA validation of the submission. Validation of the MAA confirms that the application is sufficiently complete to begin the formal review process.
- Presented updated clinical data from the ongoing registration-enabling NAVIGATOR trial of avapritinib in patients with PDGFRA Exon 18 mutant GIST and fourth-line GIST at the American Society of Clinical Oncology (ASCO) 2019 Annual Meeting. Read the full data here.
- Dosed the first patient in China in the ongoing Phase 3 VOYAGER trial of avapritinib in patients with third-line GIST, under Blueprint Medicines’ collaboration with CStone Pharmaceuticals.

Avapritinib: Systemic mastocytosis (SM)

- Presented updated clinical data from the ongoing EXPLORER trial of avapritinib in patients with advanced systemic mastocytosis (SM) at the 24th Congress of the European Hematology Association (EHA). Read the full data here.

Pralsetinib (formerly BLU-667): RET-altered solid tumors

- Presented updated clinical data from the ongoing registration-enabling Phase 1/2 ARROW trial of pralsetinib in patients with RET-altered non-small cell lung cancer (NSCLC), medullary thyroid cancer (MTC) and other cancers at ASCO. Read the full data here.
- Based on encouraging clinical data for pralsetinib in patients with treatment-naïve RET fusion-positive NSCLC and preliminary FDA feedback, expanded the enrollment target for the ARROW trial cohort for treatment naïve patients with RET-fusion NSCLC to enable potential expedited development in first-line NSCLC.

Fisogatinib (formerly BLU-554): Advanced hepatocellular carcinoma (HCC)

- Under Blueprint Medicines’ collaboration with CStone Pharmaceuticals, the China National Medical Products Administration granted approval to conduct a Phase 1b/2 clinical trial evaluating fisogatinib in combination with CS1001, CStone Pharmaceuticals’ anti-PD-L1 inhibitor, in patients with HCC.

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

Key Upcoming Milestones:

The company expects to achieve the following milestones by the end of 2019:

- Complete enrollment in the Phase 3 VOYAGER trial of avapritinib in third-line GIST.
- Initiate the Phase 3 COMPASS-2L precision medicine trial evaluating avapritinib in second-line GIST.
- Present initial data from the Phase 2 PIONEER trial of avapritinib in indolent and smoldering SM.
- Complete enrollment of the Phase 2 PATHFINDER trial of avapritinib in advanced SM.
- Initiate a Phase 3 trial evaluating pralsetinib in first-line RET-fusion NSCLC.
- Initiate a Phase 2 trial evaluating pralsetinib in combination with osimertinib in EGFR-mutant NSCLC harboring an acquired RET alteration.
- Initiate a Phase 1b/2 trial in China evaluating fisogatinib in combination with CS1001, CStone Pharmaceuticals' anti-PD-L1 inhibitor, in patients with HCC.
- Initiate a Phase 2 trial of BLU-782 in fibrodysplasia ossificans progressiva.
- Share research vision and provide portfolio strategy update at an R&D Day on November 5, 2019, including disclosure of up to two new targets.
- Nominate at least one new wholly-owned discovery program.

Second Quarter 2019 Financial Results:

- **Cash Position:** As of June 30, 2019, cash, cash equivalents and investments were \$667.3 million, as compared to \$494.0 million as of December 31, 2018. This increase reflects net proceeds of approximately \$327.4 million from the company's follow-on underwritten public offering of common stock, which closed in April 2019, partially offset by cash used in operations.
- **Collaboration Revenues:** Collaboration revenues were \$5.1 million for the second quarter of 2019, as compared to \$41.4 million for the second quarter of 2018. This decrease was primarily due to \$40.0 million in revenue recognized under the CStone collaboration in the second quarter of 2018 upon execution of the collaboration agreement. During the second quarter of 2019, the company achieved and recognized a \$4.0 million development and regulatory milestone payment under the CStone collaboration.
- **R&D Expenses:** Research and development expenses were \$87.1 million for the second quarter of 2019, as compared to \$58.6 million for the second quarter of 2018. This increase was primarily due to increased clinical and manufacturing expenses driven by the company's lead programs and increased personnel expenses. Research and development expenses included \$7.5 million in stock-based compensation expenses for the second quarter of 2019.
- **G&A Expenses:** General and administrative expenses were \$21.9 million for the second quarter of 2019, as compared to \$12.3 million for the second quarter of 2018. This increase was primarily due to increased personnel expenses and increased professional fees for commercial-readiness and other activities. General and administrative expenses included \$6.2 million in stock-based compensation expenses for the second quarter of 2019.
- **Net Loss:** Net loss was \$99.7 million for the second quarter of 2019, or a net loss per share of \$2.04, as compared to a net loss of \$27.0 million for the second quarter of 2018, or a net loss per share of \$0.62.

Financial Guidance:

Based on its current plans, Blueprint Medicines expects that its existing cash, cash equivalents and investments, 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 second 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 1096287. 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, pralsetinib, fisogatinib and BLU-782, including the timing, designs, implementation, enrollment, plans and announcement of results regarding Blueprint Medicines' ongoing and planned clinical trials for avapritinib, pralsetinib, fisogatinib and BLU-782, plans and timelines for submitting marketing applications for avapritinib and pralsetinib, 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, pralsetinib, fisogatinib 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' filings with the Securities and Exchange Commission (SEC), including Blueprint Medicines' 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.

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

	<u>June 30,</u>	<u>December 31,</u>
	<u>2019</u>	<u>2018</u>
Cash, cash equivalents and investments	\$ 667,259	\$ 494,012
Working capital ⁽¹⁾	531,446	439,464
Total assets	807,178	540,124
Deferred revenue	44,470	46,167
Total liabilities	214,351	121,115
Total stockholders' equity	592,827	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>June 30,</u>	
	<u>2019</u>	<u>2018</u>
Collaboration revenue	\$ 5,110	\$ 41,439
Operating expenses:		
Research and development	87,101	58,573
General and administrative	21,923	12,333
Total operating expenses	109,024	70,906
Other income (expense):		
Other income (expense), net	4,235	2,442
Interest expense	(2)	(23)
Total other income	4,233	2,419
Net loss	\$ (99,681)	\$ (27,048)
Net loss per share — basic and diluted	\$ (2.04)	\$ (0.62)
Weighted-average number of common shares used in net loss per share — basic and diluted	48,843	43,856

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