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): **July 30, 2020**

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 2.02 Results of Operations and Financial Condition.

On July 30, 2020, Blueprint Medicines Corporation (the "Company") announced its financial results for the quarter ended June 30, 2020 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 Form 8-K shall be deemed to be furnished and not filed:

Exhibit No.	Description
99.1	Press release issued by Blueprint Medicines Corporation on July 30, 2020
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: July 30, 2020

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

Blueprint Medicines Reports Second Quarter 2020 Financial Results

-- Recorded $5.7M Second Quarter Net Revenue for AYVAKIT™ (avapritinib) --
-- Initiated registration-enabling Part 2 of PIONEER trial of avapritinib in indolent SM --
-- Received positive CHMP opinion for avapritinib for PDGFRA D842V mutant GIST in EU --
-- Entered into global collaboration with Roche for pralsetinib, including $775 million in upfront payments --
-- On track to report top-line EXPLORER and PATHFINDER trial data for avapritinib in advanced SM in Q3 2020,
and submit supplemental NDA to FDA in Q4 2020 --

CAMBRIDGE, Mass., July 30, 2020 – 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 second quarter ended June 30, 2020.

“In recent months, we made substantial progress toward cementing Blueprint Medicines as the leading precision medicine company, presenting compelling clinical data for avapritinib and pralsetinib across multiple patient populations, entering into a global collaboration with Roche for pralsetinib and bolstering our financial position to create a path to self-sustainability,” said Jeff Albers, Chief Executive Officer of Blueprint Medicines. “We are poised to build on these pillars of growth in the second half of 2020 as we continue to execute on our focused strategy. We look forward to delivering multiple precision therapies to patients in the near-term, while continuing to support the commercialization of AYVAKIT™ (avapritinib) and investing in our broad portfolio of new innovative research programs.”

Second Quarter 2020 Highlights and Recent Updates

Avapritinib: systemic mastocytosis (SM)

- Reported updated data from Part 1 of the PIONEER trial of avapritinib in patients with indolent SM at the European Academy of Allergy and Clinical Immunology (EAACI) Digital Congress in June 2020, showing a 60 percent response rate in patients treated with avapritinib 25 mg once daily (QD), compared to a zero percent response rate in patients treated with placebo at 24 weeks, with response defined as a 30 percent or greater reduction as measured by the Indolent SM Symptom Assessment Form (ISM-SAF) total symptom score (TSS). Avapritinib 25 mg QD was well-tolerated, and safety results were consistent with previously reported data, with no Grade ≥3 adverse events (AEs) or discontinuations due to AEs. Read the press release here.
- Initiated patient screening in the registration-enabling Part 2 of the PIONEER trial. Based on feedback from the U.S. Food and Drug Administration (FDA), Blueprint Medicines has selected response rate at 24 weeks as the primary endpoint for Part 2 and plans to enroll approximately 200 patients.

Avapritinib: gastrointestinal stromal tumor (GIST)

- Recorded $5.7 million in net product revenue during the second quarter for AYVAKIT, which was approved by the FDA in January 2020 for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutations.
- Received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP), recommending the conditional marketing authorization of avapritinib for the treatment of adult patients with unresectable or metastatic GIST harboring the PDGFRA D842V mutation. The CHMP recommendation will now be reviewed by the European Commission, which has the authority to grant marketing authorization for medicinal products in the European Union (EU). A final decision on the marketing authorization application for avapritinib is anticipated by the end of September 2020.
- Published data from the NAVIGATOR clinical trial in *The Lancet Oncology*, showing an unprecedented overall survival rate and well-tolerated safety profile for AYVAKIT in patients with advanced PDGFRA D842V mutant GIST. Read the press release here.

Pralsetinib: RET-altered cancers

- Announced a global collaboration with Roche and Genentech, a member of the Roche Group, to develop and commercialize pralsetinib. Under the collaboration, Blueprint Medicines and Genentech will co-commercialize pralsetinib in the U.S., and Roche will obtain exclusive commercialization rights for pralsetinib outside the U.S., excluding Greater China. In addition, Blueprint Medicines and Roche will co-develop pralsetinib globally in RET-altered solid tumors, including NSCLC, MTC and other thyroid cancers, and other solid tumors. Read the press release here.
- Reported updated data from the ongoing ARROW clinical trial of pralsetinib in RET fusion-positive non-small cell lung cancer (NSCLC), thyroid cancer and other solid tumors treated with pralsetinib at 400 mg QD at the American Society of Clinical Oncology 2020 Virtual Scientific Program. The data showed deep, durable clinical activity and a well-tolerated safety profile for pralsetinib across a broad range of RET fusion-positive tumors. Read the press release here.
- Announced acceptance and validation of U.S. and EU marketing applications for pralsetinib for the treatment of locally advanced or metastatic RET fusion-positive NSCLC, respectively. The FDA granted priority review and set an action date of November 23, 2020 under the Prescription Drug User Fee Act.
- Submitted new drug application (NDA) to the FDA for pralsetinib for the treatment of advanced RET mutant and RET fusion-positive thyroid cancer under the FDA's Oncology Center of Excellence Real-Time Oncology Review (RTOR) pilot program. The RTOR program aims to explore a more efficient review progress to ensure that safe and effective treatments are available to patients as early as possible, while maintaining and improving review quality by the FDA.

BLU-263: systemic mastocytosis

- Initiated a Phase 1 clinical trial in healthy volunteers with BLU-263, our next-generation KIT inhibitor, in June 2020.

Key Upcoming Milestones

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

- Report top-line data from the EXPLORER and PATHFINDER trials of avapritinib in advanced SM in the third quarter of 2020.
- Gain marketing authorization from the European Commission for avapritinib by the end of September 2020.
- Gain FDA approval and, if approved, launch pralsetinib in RET fusion-positive NSCLC in the fourth quarter of 2020.
- Submit a supplemental NDA to the FDA for avapritinib for the treatment of patients with advanced SM in the fourth quarter of 2020.
- Present preclinical data for BLU-945 in resistant EGFR-positive NSCLC at the ESMO Virtual Congress in September 2020.

Second Quarter 2020 Financial Results

- **Revenues:** Revenues were $8.3 million for the second quarter of 2020, including $5.7 million of net product revenues from sales of AYVAKIT and $2.6 million in collaboration revenues under the collaboration agreements with CStone, Roche and Clementia. Blueprint Medicines recorded $5.1 million in collaboration revenues for the second quarter of 2019.
- **Cost of Sales:** Cost of sales was $0.1 million for the second quarter of 2020. Blueprint Medicines did not incur cost of sales in the second quarter of 2019 as no product sales were generated during that period.
- **R&D Expenses:** Research and development expenses were $91.1 million for the second quarter of 2020, as compared to $87.1 million for the second quarter of 2019. This increase was primarily due to increased personnel expenses. Research and development expenses included $8.7 million in stock-based compensation expenses for the second quarter of 2020.

- **SG&A Expenses:** Selling, general and administrative expenses were $42.2 million for the second quarter of 2020, as compared to $21.9 million for the second quarter of 2019. This increase was primarily due to increased costs and personnel expenses associated with building Blueprint Medicines' commercial infrastructure for commercialization of AYVAKIT and for the potential commercialization of pralsetinib. General and administrative expenses included $10.8 million in stock-based compensation expenses for the second quarter of 2020.
- **Net Loss:** Net loss was $123.5 million for the second quarter of 2020, or a net loss per share of $2.28, as compared to a net loss of $99.7 million for the second quarter of 2019, or a net loss per share of $2.04.
- **Cash Position:** As of June 30, 2020, cash, cash equivalents and investments were $650.3 million, as compared to $548.0 million as of December 31, 2019. This increase was primarily related to $308.4 million in net proceeds received from the company's January 2020 follow-on underwritten public offering, partially offset by cash used in operating activities. Cash, cash equivalents and investments as of June 30, 2020 do not include upfront payments of approximately $769.0 million received in July 2020 under Blueprint Medicines' collaboration with Roche for pralsetinib.

Financial Guidance

Based on its current operating plans, Blueprint Medicines expects that its existing cash, cash equivalents and investments, together with the upfront payments under its collaboration with Roche and anticipated future product revenues, will provide sufficient capital to enable the company to achieve a self-sustainable financial profile.

Conference Call Information

Blueprint Medicines will host a live conference call and webcast at 8:30 a.m. ET today to discuss second quarter 2020 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 2769677. A webcast of the call will be available under "Events and Presentations" in the Investors & Media 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 have one precision therapy approved by the U.S. Food and Drug Administration and are currently advancing multiple investigational medicines in clinical development, along with a number of 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 AYVAKIT™ (avapritinib), pralsetinib, fisogatinib and BLU-263, including the timing, designs, implementation, enrollment, plans and announcement of results regarding Blueprint Medicines' ongoing and planned clinical trials; plans and timelines for submitting additional marketing applications for avapritinib and pralsetinib and, if approved, commercializing avapritinib for additional indications or in additional geographies or commercializing pralsetinib; the potential benefits of the FDA's RTOR program; the potential benefits of Blueprint Medicines' current and future approved drugs or drug candidates in treating patients; expectations regarding

Blueprint Medicines' existing cash, cash equivalents and investments and the ability to achieve a self-sustainable financial profile; and Blueprint Medicines' strategy, goals and anticipated milestones, business plans and focus. 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, risks and uncertainties related to the impact of the COVID-19 pandemic to Blueprint Medicines’ business, operations, strategy, goals and anticipated milestones, including Blueprint Medicines’ ongoing and planned research and discovery activities, ability to conduct ongoing and planned clinical trials, clinical supply of current or future drug candidates, commercial supply of current or future approved products, and launching, marketing and selling current or future approved products; Blueprint Medicines’ ability and plans in establishing a commercial infrastructure, and successfully launching, marketing and selling current or future approved products; Blueprint Medicines’ ability to successfully expand the approved indications for AYVAKIT or obtain marketing approval for AYVAKIT in additional geographies in the future; the delay of any current or planned clinical trials or the development of Blueprint Medicines’ current or future drug candidates; 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, 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.

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

	June 30, 2020	December 31, 2019
Cash, cash equivalents and investments	$ 650,273	$ 547,960
Working capital (1)	463,226	410,304
Total assets	817,457	707,694
Deferred revenue	44,705	46,073
Total liabilities	236,090	243,335
Total stockholders' equity	581,367	464,359

(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)

	Three Months Ended June 30,	
	2020	2019
Revenues:		
Product revenue, net	$ 5,680	$ -
Collaboration revenue	2,663	5,110
Total revenues	8,343	5,110
Cost and operating expenses:		
Cost of sales	127	-
Research and development	91,079	87,101
Selling, general and administrative	42,174	21,923
Total cost and operating expenses	133,380	109,024
Other income (expense):		
Interest income, net	1,586	4,275
Other income, net	(23)	(42)
Total other income	1,563	4,233
Net loss	$ (123,474)	$ (99,681)
Net loss per share — basic and diluted	$ (2.28)	$ (2.04)
Weighted-average number of common shares used in net loss per share — basic and diluted	54,217	48,843

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