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 29, 2021**

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 29, 2021, Blueprint Medicines Corporation announced its financial results for the quarter ended June 30, 2021 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 29, 2021
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 29, 2021

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

Blueprint Medicines Reports Second Quarter 2021 Financial Results

-- Obtained FDA approval and launched AYVAKIT™ (avapritinib) for advanced systemic mastocytosis --
-- Expect topline data from Part 2 of registration-enabling Phase 2 PIONEER trial of AYVAKIT in non-advanced SM in mid-2022 --
-- Initiated Phase 1/2 trial of BLU-945 in EGFR-driven NSCLC and Phase 2/3 HARBOR trial of BLU-263 in non-advanced SM --
-- Announced strategic research collaboration with MD Anderson to accelerate development of BLU-222 --

CAMBRIDGE, Mass., July 29, 2021 -- Blueprint Medicines Corporation (NASDAQ:BPMC) today reported financial results and provided a business update for the second quarter ended June 30, 2021.

“In the second quarter, we achieved one of our foundational corporate goals, securing U.S. approval of AYVAKIT for advanced systemic mastocytosis, and the launch of this therapy is off to a great start with broad prescriber demand,” said Jeff Albers, Chief Executive Officer of Blueprint Medicines. “In addition, we continued to progress our expanding clinical portfolio with the initiation of the Phase 1/2 trial of BLU-945, the initiation of the Phase 2/3 HARBOR trial of BLU-263 and the announcement of a strategic research collaboration with MD Anderson to accelerate the development of BLU-222, all of which exemplify the potential impact of our next wave of therapeutic candidates. This commercial and clinical progress, combined with our financial strength, provides a robust foundation for future growth as we look to address the needs of many more patients with cancer and hematologic disorders.”

Second Quarter 2021 Highlights and Recent Progress

AYVAKIT™/AYVAKYT® (avapritinib): systemic mastocytosis (SM) and gastrointestinal stromal tumor (GIST)

- Recorded $8.5 million in net product revenue during the second quarter of 2021 for AYVAKIT/AYVAKYT, which was approved by the U.S. Food and Drug Administration (FDA) in June 2021 for the treatment of adult patients with advanced systemic mastocytosis (Advanced SM), including aggressive SM (ASM), SM with an associated hematologic neoplasm (SM-AHN) and mast cell leukemia (MCL). Read the press release announcing the expansion of the FDA label for AYVAKIT into advanced SM here. AYVAKIT received its initial approval from the FDA in 2020 for the treatment of adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. Please click here to see the full Prescribing Information for AYVAKIT and visit www.AYVAKIT.com for more information on AYVAKIT.

GAVRETO® (pralsetinib): RET-altered cancers

- Recorded $2.9 million in net product revenue during the second quarter of 2021 for GAVRETO, which was approved by the FDA in September 2020 for the treatment of adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test and in December 2020 for the treatment of patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) and RET fusion-positive thyroid cancer. Blueprint Medicines is commercializing GAVRETO in the U.S. together with Genentech, Inc., a member of the Roche Group. Please click here to see the full Prescribing Information for GAVRETO and visit www.GAVRETO.com for more information on GAVRETO.
- Reported updated data from the Phase 1/2 ARROW clinical trial of GAVRETO in metastatic RET fusion-positive NSCLC and other advanced solid tumors at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting. The data showed high response rates to GAVRETO in treatment-naïve patients with RET fusion-positive NSCLC, clinical activity across a number of RET fusion-positive tumor types and a safety profile consistent with previously reported results. Read the press release here.

BLU-263: SM

- Initiated the HARBOR trial, a randomized, double-blind, placebo-controlled Phase 2/3 trial in non-advanced SM.

BLU-945: treatment-resistant EGFR-driven NSCLC

- Initiated the global Phase 1/2 trial of BLU-945 in patients with treatment-resistant EGFR-driven NSCLC.

BLU-222: Cyclin E-aberrant cancers

- Announced a strategic research collaboration with The University of Texas MD Anderson Cancer Center focused on accelerating development of BLU-222, an investigational precision therapy designed to target cyclin-dependent kinase 2 (CDK2). Read the press release here.

Corporate:

- Announced the appointment of Percy Carter, MBA, Ph.D., as Chief Scientific Officer. In this role, Dr. Carter oversees all research and preclinical development. Read the press release here.

Key Upcoming Milestones

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

- Present preclinical data supporting combination of BLU-945 and BLU-701 in treatment-naïve EGFR-driven NSCLC in the second half of 2021.
- Initiate a Phase 1 trial of BLU-701 in patients with treatment-resistant EGFR-driven NSCLC in the second half of 2021.
- Initiate a Phase 1 trial of BLU-222, a CDK2 inhibitor targeting cyclin-E aberrant cancers, in the first half of 2022.
- Disclose topline data for the registration-enabling Part 2 of the PIONEER trial of AYVAKIT in non-advanced systemic mastocytosis in mid-2022.

Second Quarter 2021 Financial Results

- **Revenues:** Revenues were $27.3 million for the second quarter of 2021, including $8.5 million of net product revenues from sales of AYVAKIT/AYVAKYT, $2.9 million of net product sales from GAVRETO and $15.9 million in collaboration revenues. Blueprint recorded revenues of $8.3 million in the second quarter of 2020, including $5.7 million of net product revenues from sales of AYVAKIT and $2.7 million in collaboration revenues. The increase in net product revenues was driven by increased sales quantity and the increase in collaboration revenues was primarily driven by the sales of drug substance and drug product to our collaboration partners.
- **Cost of Sales:** Cost of sales was $6.5 million for the second quarter of 2021, as compared to $0.1 million for the second quarter of 2020. Cost of sales includes manufacturing costs associated with our products sales as well as costs associated with the sale of drug product to our collaboration partners. The increase in costs of product sales was primarily driven by the lower margin product sales to our collaboration partners during the second quarter of 2021.
- **R&D Expenses:** Research and development expenses were $80.0 million for the second quarter of 2021, as compared to $91.1 million for the second quarter of 2020. This decrease was primarily due to decreased expenses associated with clinical supply manufacturing activities and reimbursement from the global development cost sharing arrangement under our collaboration with Roche for pralsetinib, partially offset by increased costs related to early discovery activities. Research and development expenses included $10.5 million in stock-based compensation expenses for the second quarter of 2021.
- **SG&A Expenses:** Selling, general and administrative expenses were $49.3 million for the second quarter of 2021, as compared to $42.2 million for the second quarter of 2020. This increase was primarily due to increased costs associated with building our commercial infrastructure for commercialization of AYVAKIT/AYVAKYT and GAVRETO, partially offset by reimbursement under our collaboration with Roche for pralsetinib. General and administrative expenses included $13.8 million in stock-based compensation expenses for the second quarter of 2021.

- **Net Loss:** Net loss was $108.4 million for the second quarter of 2021, or a net loss per share of $1.86, as compared to a net loss of $123.5 million for the second quarter of 2020, or a net loss per share of $2.28.
- **Cash Position:** As of June 30, 2021, cash, cash equivalents and investments were $1,380.1 million, as compared to $1,549.7 million as of December 31, 2020.

Conference Call Information

Blueprint Medicines will host a live conference call and webcast at 8:30 a.m. ET today to discuss second quarter 2021 financial results and recent business activities. The conference call may be accessed by dialing 844-200-6205 (domestic) or +44-208-0682-558 (international) and referring to conference ID 619159. 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.

Upcoming Investor Conference

Blueprint Medicines will participate in the 2021 Wedbush Pacgrow Healthcare Virtual Conference on Tuesday, August 10, 2021. Christina Rossi, Chief Commercial Officer, will participate in a panel discussion, “Building Back a Better Commercial Infrastructure – Selling in COVID Times,” beginning at 8:35 a.m. ET. A live webcast of the panel discussion will be available by visiting the Investors & Media section of Blueprint Medicines' website at http://ir.blueprintmedicines.com. A replay of the webcast will be archived on Blueprint Medicines' website for 30 days following the presentation.

About Blueprint Medicines

Blueprint Medicines is a global precision therapy company that invents life-changing medicines for people with cancer and hematologic disorders. Applying an approach that is both precise and agile, we create therapies 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 genomically defined cancers, systemic mastocytosis, 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 plans, strategies, timelines and expectations for Blueprint Medicines' current or future approved drugs and drug candidates, including timelines for marketing applications and approvals, the initiation of clinical trials or the results of ongoing and planned clinical trials; Blueprint Medicines' plans, strategies and timelines to nominate development candidates; plans and timelines for additional marketing applications for avapritinib and pralsetinib and, if approved, commercializing avapritinib and pralsetinib in additional geographies or for additional indications; the potential benefits of any of Blueprint Medicines' current or future approved drugs or drug candidates in treating patients; the potential benefits of Blueprint Medicines' collaborations; 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 continuing to establish and expand 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/AYVAKYT and GAVRETO or obtain marketing approval for AYVAKIT/AYVAKYT 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 obtain, maintain and enforce patent and other intellectual property protection for AYVAKIT/AYVAKYT, GAVRETO or any drug candidates it is developing; Blueprint Medicines' ability to develop and commercialize companion diagnostic tests for AYVAKIT/AYVAKYT, GAVRETO or any of 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.

Trademarks

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

	June 30, 2021	December 31, 2020
Cash, cash equivalents and investments	$ 1,380,051	$ 1,549,722
Working capital (1)	578,673	796,957
Total assets	1,568,795	1,718,393
Deferred revenue	38,277	41,158
Total liabilities	239,991	248,305
Total stockholders' equity	1,328,804	1,470,088

(1) Blueprint 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,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues:				
Product revenue, net	$ 11,433	$ 5,680	$ 20,388	$ 9,138
Collaboration revenue	15,862	2,663	28,483	5,372
Total revenues	27,295	8,343	48,871	14,510
Cost and operating expenses:				
Cost of sales	6,493	127	6,595	150
Research and development	80,027	91,079	159,738	175,225
Selling, general and administrative	49,286	42,174	91,288	77,829
Total cost and operating expenses	135,806	133,380	257,621	253,204
Other income (expense):				
Interest income, net	633	1,586	1,371	4,490
Other expense, net	(373)	(23)	(587)	(224)
Total other income	260	1,563	784	4,266
Loss before income taxes	(108,251)	(123,474)	(207,966)	(234,428)
Income tax expense	(193)	—	(193)	—
Net loss	$ (108,444)	$ (123,474)	$ (208,159)	$ (234,428)
Net loss per share — basic and diluted	$ (1.86)	$ (2.28)	$ (3.58)	$ (4.39)
Weighted-average number of common shares used in net loss per share — basic and diluted	58,406	54,217	58,216	53,436

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