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): **October 28, 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 October 28, 2021, Blueprint Medicines Corporation announced its financial results for the quarter ended September 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 October 28, 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: October 28, 2021

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

Exhibit 99.1

Blueprint Medicines Reports Third Quarter 2021 Financial Results

-- Strong AYVAKIT launch in advanced SM with $17.3 million in net product revenues in the first full quarter following U.S. approval --

-- Raising guidance for 2021 total revenue to $170-$180 million, based on portfolio progress including anticipated achievement of multiple collaboration milestones in the fourth quarter --

-- Broad clinical pipeline advancing toward multiple key data readouts in 2022 --

CAMBRIDGE, Mass., October 28, 2021 -- Blueprint Medicines Corporation (NASDAQ:BPMC) today reported financial results and provided a business update for the third quarter ended September 30, 2021.

“We successfully executed across our entire portfolio in the third quarter, expanding the commercial adoption of AYVAKIT and GAVRETO and further advancing our next wave of therapeutic candidates toward potentially transformative proof-of-concept datasets,” said Jeff Albers, Chief Executive Officer of Blueprint Medicines. “We are particularly encouraged by the launch momentum for AYVAKIT in advanced systemic mastocytosis, where we see broad prescriber demand across both academic and community centers and in patients regardless of prior therapy. In addition, we are pleased by the progress across our clinical portfolio, with topline data from the PIONEER trial of AYVAKIT in non-advanced systemic mastocytosis expected in mid-2022, strong patient interest fueling enrollment in the ongoing SYMPHONY trial of our EGFR inhibitor BLU-945, and multiple trial initiations on-track for the months ahead. Overall, this commercial and clinical progress across our portfolio, combined with the strength of our financial position and diversity of revenue, provides a robust foundation for growth and continuous innovation.”

Third Quarter 2021 Highlights and Recent Progress

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

- Recorded $17.3 million in net product revenue during the third quarter of 2021, an increase of 104 percent over the second quarter, for AYVAKIT/AYVAKYT.

GAVRETO® (pralsetinib): RET-altered cancers

- Transferred responsibilities associated with the booking of U.S. product sales of GAVRETO to our collaboration partner Roche on July 1, 2021 and began to recognize the company’s share of U.S. revenue in the GAVRETO profit and loss. As previously reported by Roche, net end user product revenues for GAVRETO were $5.5 million.
- Received, via our collaboration with Roche, a positive opinion from the European Medicines Agency’s (EMA) Committee for Medicinal Products for Human Use (CHMP) for GAVRETO for the treatment of adults with RET fusion-positive advanced non-small cell lung cancer (NSCLC). If approved, GAVRETO will be the first and only targeted treatment approved by the EMA that includes first-line treatment of people with RET fusion-positive advanced NSCLC.

Key Upcoming Milestones

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

- Initiate a Phase 1 trial of BLU-701 in patients with EGFR-driven NSCLC in the fourth quarter of 2021.
- Present preclinical data supporting combination of BLU-945 and BLU-701 in EGFR-driven NSCLC at a medical conference in early 2022.
- Initiate a Phase 1 trial of BLU-222, a CDK2 inhibitor targeting cyclin-E aberrant cancers, in the first quarter 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.

- Initiate a Phase 1 trial of BLU-852, a MAP4K1 inhibitor for the treatment of advanced cancers, in 2022. BLU-852 is the first development candidate nominated under Blueprint Medicines' cancer immunotherapy collaboration with Roche.

Third Quarter 2021 Financial Results

- **Revenues:** Revenues were $24.2 million for the third quarter of 2021, including $17.3 million of net product revenues from sales of AYVAKIT/AYVAKYT and $6.9 million in collaboration revenues. Blueprint recorded revenues of $745.1 million in the third quarter of 2020, including $6.1 million of net product revenues from sales of AYVAKIT, $0.2 million of net product revenues from sales of GAVRETO and $738.8 million in collaboration revenues.
- **Cost of Sales:** Cost of sales was $3.8 million for the third quarter of 2021, as compared to $0.1 million for the third quarter of 2020. Cost of sales included manufacturing costs associated with our product sales as well as costs associated with the sale of drug product to our collaboration partners. The increase in cost of product sales was primarily driven by lower margin product sales to our collaboration partners during the third quarter of 2021.
- **Collaboration Loss Sharing:** Collaboration loss sharing was $3.3 million for the third quarter of 2021 under our collaboration with Roche for GAVRETO.
- **R&D Expenses:** Research and development expenses were $84.4 million for the third quarter of 2021, as compared to $74.2 million for the third quarter of 2020. This increase was primarily due to a decrease in reimbursement from the global development cost sharing arrangement under our collaboration with Roche for GAVRETO and increased costs related to early discovery efforts. Research and development expenses included $10.3 million in stock-based compensation expenses for the third quarter of 2021.
- **SG&A Expenses:** Selling, general and administrative expenses were $49.8 million for the third quarter of 2021, as compared to $37.4 million for the third quarter of 2020. This increase was primarily due to increased costs associated with expanding our commercial infrastructure for commercialization of AYVAKIT/AYVAKYT and GAVRETO, partially offset by reimbursement under our collaboration with Roche for GAVRETO. General and administrative expenses included $13.7 million in stock-based compensation expenses for the third quarter of 2021.
- **Net Income (Loss):** Net loss was $117.2 million for the third quarter of 2021, or a net loss per share of $2.00, as compared to a net income of $634.0 million for the third quarter of 2020, or a diluted net income per share of $11.16.
- **Cash Position:** As of September 30, 2021, cash, cash equivalents and investments were $1,293.8 million, as compared to $1,549.7 million as of December 31, 2020.

Financial Guidance

Based on product revenue growth and strong collaboration execution with multiple milestone payments anticipated during the fourth quarter of 2021, the company expects to report full year 2021 total revenues in the range of $170-$180 million.

Conference Call Information

Blueprint Medicines will host a live conference call and webcast at 8:30 a.m. ET today to discuss third quarter 2021 financial results and recent business activities. The conference call may be accessed by dialing 844-200-6205 (domestic) or 929-526-1599 (international) and referring to conference ID 963004. 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 global precision therapy company that invents life-changing therapies for people with cancer and hematologic disorders. Applying an approach that is both precise and agile, we create medicines 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 approved medicines directly 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 financial performance, 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, AYVAKIT, AYVAKYT, GAVRETO and associated logos are trademarks of Blueprint Medicines Corporation.

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

	September 30, 2021	December 31, 2020
Cash, cash equivalents and investments	$ 1,293,798	$ 1,549,722
Working capital (1)	652,157	796,957
Total assets	1,477,322	1,718,393
Deferred revenue	35,397	41,158
Total liabilities	230,235	248,305
Total stockholders' equity	1,247,087	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 September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenues:				
Product revenue, net	$ 17,270	$ 6,308	$ 37,658	$ 15,446
Collaboration revenue	6,918	738,810	35,401	744,183
Total revenues	24,188	745,118	73,059	759,629
Cost and operating expenses:				
Cost of sales	3,790	146	10,385	297
Collaboration loss sharing	3,269	—	3,269	—
Research and development	84,419	74,230	244,157	249,456
Selling, general and administrative	49,806	37,375	141,093	115,203
Total cost and operating expenses	141,284	111,751	398,904	364,956
Other income (expense):				
Interest income, net	552	1,173	1,923	5,663
Other expense, net	(522)	(192)	(1,109)	(416)
Total other income	30	981	814	5,247
Income (loss) before income taxes	(117,066)	634,348	(325,031)	399,920
Income tax expense	175	370	368	370
Net income (loss)	$ (117,241)	$ 633,978	$ (325,399)	$ 399,550
Net income (loss) per share — basic	$ (2.00)	$ 11.49	$ (5.58)	$ 7.40
Net income (loss) per share – diluted	$ (2.00)	11.16	$ (5.58)	$ 7.20
Weighted-average number of common shares used in net loss per share — basic	58,647	55,169	58,361	54,018
Weighted-average number of common shares used in net loss per share — diluted	58,647	56,786	58,361	55,492

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