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): **February 16, 2022**

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 February 16, 2022, Blueprint Medicines Corporation (the "Company") announced its financial results for the quarter and year ended December 31, 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.

Exhibit No.	Description
99.1	Press release issued by Blueprint Medicines Corporation on February 16, 2022
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: February 16, 2022

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

Exhibit 99.1

Blueprint Medicines Reports Fourth Quarter and Full Year 2021 Results

-- Achieved $53.0 million in AYVAKIT net product revenues and $180.1 million in total revenues in 2021 --

-- Anticipate approximately $115 million to $130 million in AYVAKIT net product revenues and $180 million to $200 million in total revenues in 2022 --

-- Multiple abstracts accepted for presentation at the AACR annual meeting including initial Phase 1/2 SYMPHONY trial dose escalation data for BLU-945 in EGFR-driven NSCLC --

-- IND applications cleared by FDA for BLU-451 in EGFR exon 20-positive NSCLC and BLU-222 in cyclin E-CDK2 aberrant cancers; on track to initiate Phase 1/2 studies for both programs in Q1 2022 --

CAMBRIDGE, Mass., February 16, 2022 – Blueprint Medicines Corporation (NASDAQ: BPMC) today reported financial results and provided a business update for the fourth quarter and full year ended December 31, 2021.

“Following a year of outstanding execution across our portfolio, we are well positioned in 2022 to drive significant year-over-year product revenue growth, achieve multiple anticipated clinical data milestones for our precision therapies in systemic mastocytosis and lung cancer, and expand our portfolio with new therapeutic candidates, all supported by a strong cash position,” said Jeff Albers, Chief Executive Officer of Blueprint Medicines. “In addition, as we execute on this near-term vision, we will put in place drivers of future growth, including the expansion of our research platform to incorporate targeted protein degradation, as well as plans for targeted sourcing of external innovation. Together, these efforts have the potential to significantly strengthen and broaden our impact as a leading global precision therapy company.”

Fourth Quarter 2021 Highlights and Recent Progress

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

- Recorded global net product revenues of $53.0 million and $20.0 million for the full year and the fourth quarter of 2021, respectively, representing approximately 150 percent year-over-year growth based on strong initial U.S. demand in advanced SM.
- Received a positive opinion from the European Medicines Agency’s Committee for Medicinal Products for Human Use for AYVAKYT for the treatment of adult patients with advanced SM, including aggressive SM, SM with an associated hematological neoplasm, or mast cell leukemia, after at least one systemic therapy. Read the press release here.
- Announced two publications in *Nature Medicine* on the registration-enabling EXPLORER and PATHFINDER trials highlighting AYVAKIT’s robust efficacy and safety data in advanced SM. Read the press release here.

GAVRETO® (pralsetinib): RET-altered cancers

- Following the transition of certain responsibilities from Blueprint Medicines to Roche in the third quarter of 2021, Roche recorded and reported $9.8 million in U.S. net end user product revenues for the second half of 2021. Full year 2021 U.S. net end user product revenues for GAVRETO were $14.5 million, including sales booked by Blueprint Medicines in the first half of 2021.
- Received, via the collaboration with Roche, conditional marketing authorization by the European Commission for GAVRETO for the treatment of adults with RET fusion-positive non-small cell lung cancer (NSCLC) not previously treated with a RET inhibitor.

BLU-945, BLU-701 and BLU-451 (formerly LNG-451): EGFR-driven NSCLC

- Treated the first patient in the Phase 1/2 HARMONY trial of BLU-701 in EGFR-driven NSCLC.
- Presented new preclinical data supporting the development of BLU-945 and BLU-701 combination therapy in EGFR-driven NSCLC at the British Thoracic Oncology Group annual conference. Read the poster presentation here.
- Multiple abstracts accepted for presentation at the American Association for Cancer Research (AACR) annual meeting, including initial Phase 1/2 SYMPHONY trial dose escalation data for BLU-945 in EGFR-driven NSCLC.
- Announced a strategic collaboration and license agreement with Zai Lab Limited for the development and commercialization of BLU-945 and BLU-701 for the treatment of EGFR-driven NSCLC in Greater China. Read the press release here.
- Completed the acquisition of Lengo Therapeutics and its lead compound BLU-451, a potential best-in-class precision therapy for EGFR exon 20 insertion-positive NSCLC. Read the press release here.
- Received clearance from the U.S. Food and Drug Administration (FDA) for an investigational new drug (IND) application for BLU-451 in EGFR exon 20 insertion-positive NSCLC.

BLU-222: ovarian, breast and other cyclin E-CDK2 aberrant cancers

- Received FDA clearance for an IND application for BLU-222 for cyclin E-CDK2 aberrant cancers.

Corporate

- Announced Kate Haviland, who has served as Chief Operating Officer and previously Chief Business Officer since 2016, has been appointed by the company's Board of Directors to succeed Jeff Albers as President and Chief Executive Officer, effective April 4, 2022. At that time, Mr. Albers will transition from his current role as Chairman, President and Chief Executive Officer to Executive Chairman of the Board of Directors. In addition, Ms. Haviland will join the Board of Directors. Read the press release here.
- Announced promotions for Christina Rossi to Chief Operating Officer and Philina Lee, Ph.D., to Chief Commercial Officer. In addition, announced a role expansion for Helen Ho, Ph.D., to Chief Business Officer. Read the press releases here and here.
- Announced the appointment of Daniella Beckman, Chief Financial Officer of Tango Therapeutics, to the company's Board of Directors. Read the press release here.

Key Upcoming Milestones

The company plans to achieve the following milestones by mid-2022:

- Initiate a Phase 1/2 trial of BLU-222 in cyclin E-CDK2 aberrant cancers in the first quarter of 2022.
- Initiate a Phase 1/2 trial of BLU-451 in EGFR exon 20 insertion-positive NSCLC in the first quarter of 2022.
- Present initial clinical data from the Phase 1/2 SYMPHONY trial of BLU-945 in the second quarter of 2022.
- Present preclinical data supporting the development of BLU-451 in EGFR exon 20 insertion-positive NSCLC in the second quarter of 2022.
- Present preclinical data supporting the development of BLU-222 in cyclin E-CDK2 aberrant cancers in the second quarter of 2022.
- Launch AYVAKYT in advanced SM in Europe in the second quarter of 2022.
- Report topline data from the registration-enabling Part 2 of the PIONEER trial of AYVAKIT in non-advanced SM in mid-2022.

Fourth Quarter and Year End 2021 Results

- **Revenues:** Revenues were $107.0 million for the fourth quarter of 2021, including $20.0 million of net product revenues from sales of AYVAKIT and $87.0 million in collaboration revenues. Revenues for the year ended December 31, 2021 were $180.1 million, including $53.0 million of net product revenues from sales of AYVAKIT, $4.7 million of net product revenues from sales of GAVRETO and $122.4 million in collaboration revenues. Blueprint Medicines recorded $34.1 million and $793.7 million in revenues in the fourth quarter and year ended December 31, 2020, respectively.
- **Cost of Sales:** Cost of sales was $7.5 million for the fourth quarter of 2021 and $17.9 million for the year ended December 31, 2021, as compared to $0.1 million for the fourth quarter of 2020 and $0.4 million for the full year ended December 31, 2020. This increase was primarily driven by lower margin drug product sold to our collaboration partners during the fourth quarter of 2021.
- **R&D Expenses:** Research and development expenses were $356.9 million for the fourth quarter of 2021 and $601.0 million for the year ended December 31, 2021, as compared to $77.4 million for the fourth quarter of 2020 and $326.9 million for the year ended December 31, 2020. Research and development expense for the fourth quarter of 2021 included $260.0 million incurred to acquire in-process research and development compounds through the acquisition of Lengo Therapeutics which was the primary driver of the increase in expenses over the prior year. Research and development expenses also included $10.0 million in stock-based compensation expenses for the fourth quarter of 2021 and $39.7 million in stock-based compensation for the year ended December 31, 2021.
- **SG&A Expenses:** Selling, general and administrative expenses were $54.2 million for the fourth quarter of 2021 and $195.3 million for the year ended December 31, 2021, as compared to $42.5 million for the fourth quarter of 2020 and $157.7 million for the year ended December 31, 2020. This increase was primarily due to increased costs associated with expanding our commercial infrastructure for commercialization of AYVAKIT/AYVAKYT. Selling, general and administrative expenses included $12.7 million in stock-based compensation expenses for the fourth quarter of 2021 and $52.0 million in stock-based compensation for the year ended December 31, 2021.
- **Net Income (Loss):** Net loss was $(318.7) million for the fourth quarter of 2021 and $(644.1) million for the year ended December 31, 2021, or a diluted net loss per share of $(5.40) and diluted net loss per share of $(11.01), respectively, as compared to a net loss of $(85.7) million for the fourth quarter of 2020 and a net income of $313.9 million for the year ended December 31, 2020, or a diluted net loss per share of $(1.53) and a diluted net income per share of $5.59, respectively.
- **Cash Position:** As of December 31, 2021, cash, cash equivalents and marketable securities were $1,034.6 million, as compared to $1,549.7 million as of December 31, 2020.

2022 Financial Guidance

Blueprint Medicines today announced it anticipates approximately $180M to $200M in total revenues in 2022, including approximately $115M to $130M in AYVAKIT net product revenues. The company continues to expect that its existing cash, cash equivalents and investments, together with 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 fourth quarter and full year 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 936793. A webcast of the call will also 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 Conferences

Blueprint Medicines will participate in two upcoming investor conferences:

- **11th Annual SVB Leerink Global Healthcare Conference** on Friday, February 18, 2022 at 10:40 a.m. ET.
- **Cowen 42nd Annual Health Care Conference** on Tuesday, March 8, 2022 at 9:10 a.m. ET.

A live webcast of each presentation will be available by visiting the Investors & Media section of Blueprint Medicines' website at http://ir.blueprintmedicines.com. A replay of the webcasts will be archived on Blueprint Medicines' website for 30 days following each presentation.

About Blueprint Medicines

Blueprint Medicines is a global precision therapy company that invents life-changing therapies for people with cancer and blood 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 systemic mastocytosis, lung cancer and other genomically defined cancers, 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, approvals and launches, the initiation of clinical trials or the results of ongoing and planned clinical trials, and publications; Blueprint Medicines' plans, strategies and timelines to nominate development candidates; plans regarding expansion of Blueprint Medicines' research platform, addition of new therapeutic candidates to its portfolio, and targeted sourcing of external innovation, and the anticipated benefits of these plans; 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, including its collaborations with CStone,Roche and Genentech, and Zai Lab ; and Blueprint Medicines' strategy, goals and anticipated financial performance, growth, 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; Blueprint Medicines' ability to successfully expand its operations, research platform and portfolio of therapeutic candidates and the timing and costs thereof; Blueprint Medicines' ability to realize the anticipated benefits of its succession planning process and executive leadership transition plan; 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)

	December 31, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 1,034,643	$ 1,549,722
Working capital (1)	404,260	796,957
Total assets	1,252,225	1,718,393
Deferred revenue	36,576	41,158
Total liabilities	281,490	248,305
Total stockholders' equity	970,735	1,470,088

(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 December 31,		Years Ended December 31,	
	2021	**2020**	**2021**	**2020**
Revenues:				
Product revenue, net	$ 20,029	$ 6,688	$ 57,687	$ 22,134
Collaboration revenue	86,993	27,419	122,393	771,601
Total revenues	$ 107,022	$ 34,107	$ 180,080	$ 793,735
Cost and operating expenses:				
Cost of sales	7,549	128	17,934	425
Collaboration loss sharing	4,531	-	7,801	-
Research and development	356,877	77,405	601,033	326,860
Selling, general and administrative	54,199	42,541	195,293	157,743
Total cost and operating expenses	$ 423,156	$ 120,074	$ 822,061	$ 485,028
Other income (expense):				
Interest income, net	463	936	2,386	6,599
Other income (expense), net	(381)	50	(1,489)	(366)
Total other income (expense)	$ 82	$ 986	$ 897	$ 6,233
Income (loss) before income taxes	$ (316,052)	$ (84,981)	$ (641,084)	$ 314,940
Income tax expense	2,635	688	3,001	1,058
Net income (loss)	$ (318,687)	$ (85,669)	$ (644,085)	$ 313,882
Net income (loss) per share applicable to common stockholders — basic	$ (5.40)	$ (1.53)	$ (11.01)	$ 5.76
Net income (loss) per share applicable to common stockholders —diluted	$ (5.40)	$ (1.53)	$ (11.01)	$ 5.59
Weighted-average number of common shares used in net income (loss) per share applicable to common stockholders — basic	58,985	56,072	58,518	54,534
Weighted-average number of common shares used in net income (loss) per share applicable to common stockholders —diluted	58,985	56,072	58,518	56,168

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