
**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 15, 2024**

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 February 15, 2024, Blueprint Medicines Corporation announced its financial results for the year ended December 31, 2023 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Blueprint Medicines Corporation on February 15, 2024
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 15, 2024

By: /s/ Kathryn Haviland

Kathryn Haviland

Chief Executive Officer

Blueprint Medicines Reports Fourth Quarter and Full Year 2023 Results

-- Achieved \$204.2 million in AYVAKIT®/AYVAKYT® (avapritinib) net product revenues in 2023, including \$71.0 million in the fourth quarter --

-- Anticipate global AYVAKIT net product revenue of approximately \$360 million to \$390 million in 2024, representing >80 percent year-over-year growth at the midpoint --

-- Nine presentations highlighting AYVAKIT long-term safety and efficacy, BLU-808 preclinical profile, and additional data fortifying leadership in mast cell diseases accepted for presentation at 2024 AAAAI Annual Meeting --

CAMBRIDGE, Mass., February 15, 2024 – Blueprint Medicines Corporation (NASDAQ: BPMC) today reported financial results and provided a business update for the fourth quarter and full year ended December 31, 2023 and provided financial guidance.

“As we enter 2024, AVAYKIT continues to be the foundation of our thriving and growing commercial business. Our 2024 guidance of \$360 to \$390 million sets us up to nearly double AYVAKIT product revenue this year, driven by the launch in ISM as we focus on reaching more patients in both the U.S. and Europe. AYVAKIT’s compelling efficacy and safety profile, coupled with the chronic nature of ISM, make the cumulative effect of patients staying on therapy an important revenue driver this year, beyond and in addition to new patient starts. AYVAKIT is firmly on the path to becoming a multibillion-dollar product, providing Blueprint with durable revenue growth well into the next decade. Beyond AYVAKIT and ISM, we are balancing investment in our most compelling pipeline opportunities and maintaining financial discipline, strengthening our financial profile, and accelerating our path to profitability,” said Kate Haviland, Chief Executive Officer of Blueprint Medicines. “We are particularly excited about our expanding portfolio targeting allergic-inflammatory diseases where mast cells play a central role, and we are looking forward to sharing more on these programs throughout this year.”

Fourth Quarter 2023 Highlights and Recent Progress

Mast cell disorders

- Achieved AYVAKIT net product revenues of \$204.2 million and \$71.0 million for the full year and the fourth quarter of 2023, respectively, representing 84 percent growth year-over-year.
- Announced approval by the European Commission for AYVAKYT as the first and only treatment for indolent systemic mastocytosis (ISM). Read the press release [here](#).
- Presented data demonstrating the compelling benefit-risk profile of elenestinin in ISM from Part 1 of the HARBOR trial and analyses of real-world data highlighting the burden of and urgency to treat ISM at the 2023 American Society of Hematology annual meeting. Read the presentations [here](#).

Breast cancer and other solid tumors

- Advanced the development of BLU-222 in combination with ribociclib and fulvestrant in patients with HR+/HER2-breast cancer.
- Announced the development candidate nomination of BLU-956, a next-generation CDK2 inhibitor.

Corporate

- Presented a 2024 corporate overview and strategy at the J.P. Morgan 42nd Annual Healthcare Conference. Read the press release [here](#).
 - Identified an alternate partner for GAVRETO® (pralsetinib) in the U.S. and are working with all involved parties to enable continuity of access to GAVRETO in the U.S. The company plans to provide an update to coincide with the late February 2024 termination date of the existing collaboration agreement with Roche.
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- The company continues to expect that the wind-down of the Roche collaboration for GAVRETO and the discontinuation of global development and marketing in territories outside the U.S. and Greater China will result in significantly lower year-over-year operating expenses related to GAVRETO and will have no material impact to its overall operating expense plans in 2024.

2024 Financial Guidance

Blueprint Medicines today announced it anticipates approximately \$360 million to \$390 million in global AYVAKIT net product revenues for all approved indications in 2024. The midpoint of this range represents more than 80 percent year-over-year revenue growth, the majority of which is expected to be driven by ISM. The company continues to expect that operating expenses and cash burn will further decline in 2024, and that its existing cash, cash equivalents and investments, together with anticipated future product revenues, will maintain a durable capital position to enable the company to achieve a self-sustainable financial profile.

Key Upcoming Milestones

The company plans to achieve the following milestones in the first half of 2024:

Mast cell diseases

- Present long-term safety and efficacy data from the PIONEER trial of AYVAKIT in ISM at the 2024 American Academy of Allergy, Asthma and Immunology (AAAAI) Annual Meeting.
- Present preclinical data for BLU-808, a highly selective and potent oral inhibitor of wild-type KIT, at the 2024 AAAAI Annual Meeting.
- Submit an investigational new drug application for BLU-808 in the second quarter of 2024.

Breast cancer and other solid tumors

- Continue ongoing strategic business development discussions.
- Present data for BLU-222 in combination with ribociclib and fulvestrant in patients with HR+/HER2- breast cancer in the first half of 2024.

Fourth Quarter and Year End 2023 Results

- **Revenues:** Revenues were \$72.0 million for the fourth quarter of 2023, including \$71.0 million of net product revenues from sales of AYVAKIT/AYVAKYT and \$0.9 million in collaboration revenues. Revenues for the year ended December 31, 2023 were \$249.4 million, including \$204.2 million of net product revenues from sales of AYVAKIT/AYVAKYT, and \$45.2 million in collaboration and license revenues. Blueprint Medicines recorded \$38.8 million and \$204.0 million in revenues in the fourth quarter and year ended December 31, 2022, respectively.
 - **Cost of Sales:** Cost of sales was \$0.3 million for the fourth quarter of 2023 and \$8.5 million for the year ended December 31, 2023, as compared to \$4.8 million and \$17.8 million for the fourth quarter and year ended December 31, 2022, respectively. This decrease was mainly due to a decrease in inventory write-downs and the cost of collaboration-related sales.
 - **R&D Expenses:** Research and development expenses were \$97.5 million for the fourth quarter of 2023 and \$427.7 million for the year ended December 31, 2023, as compared to \$117.8 million and \$477.4 million for the fourth quarter and year ended December 31, 2022, respectively. This decrease was primarily due to a focused approach towards optimizing operational efficiency across Blueprint Medicine's portfolio as the company executes across its top priority programs and the timing of manufacturing of clinical trial materials. Research and development expenses also included \$10.0 million in stock-based compensation expenses for the fourth quarter of 2023 and \$41.5 million in stock-based compensation for the year ended December 31, 2023.
 - **SG&A Expenses:** Selling, general and administrative expenses were \$79.3 million for the fourth quarter of 2023 and \$295.1 million for the year ended December 31, 2023, as compared to \$64.0 million and \$237.4
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million for the fourth and year ended December 31, 2022, respectively. This increase was primarily due to an increase in compensation and personnel related costs driven by the company's first quarter 2023 field force expansion to support the AYVAKIT launch in ISM and an increase in commercial and related activities primarily related to the commercialization of AYVAKIT/AYVAKYT. Selling, general and administrative expenses included \$12.6 million in stock-based compensation expenses for the fourth quarter of 2023 and \$51.1 million in stock-based compensation for the year ended December 31, 2023.

- **Net Income (Loss):** Net loss was \$(110.9) million for the fourth quarter of 2023 and \$(507.0) million for the year ended December 31, 2023, or a diluted net loss per share of \$(1.82) and diluted net loss per share of \$(8.37), respectively, as compared to a net loss of \$(158.6) million for the fourth quarter of 2022 and a net loss of \$(557.5) million for the year ended December 31, 2022, or a diluted net loss per share of \$(2.65) and a diluted net loss per share of \$(9.35), respectively.
- **Cash Position:** As of December 31, 2023, cash, cash equivalents and marketable securities were \$767.2 million, as compared to \$1,078.5 million as of December 31, 2022. Blueprint Medicine's cash and investments provide a durable capital position which enables the company to reach a self-sustainable profile.

Conference Call Information

Blueprint Medicines will host a live conference call and webcast at 8:00 a.m. ET today to discuss fourth quarter and full year 2023 financial results and recent business activities. The conference call may be accessed by dialing 833-470-1428 (domestic) or 404-975-4839 (international), and referring to conference ID 071930. 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 one upcoming investor conference:

- **Cowen 44th Annual Health Care Conference** on Monday, March 4, 2024 at 9:10 am ET.

A live webcast of the presentation will be available under "Events and Presentations" in the Investors & Media section of the Blueprint Medicines website at <http://ir.blueprintmedicines.com>. A replay of the webcast will be archived on the Blueprint Medicines website for 30 days following the presentation.

About Blueprint Medicines

Blueprint Medicines is a fully-integrated, commercial-stage, global biopharmaceutical company that invents life-changing medicines in two core, strategic areas of allergy/inflammation and oncology/hematology. We pursue discovery, development, and commercialization of therapies that potently and selectively target known drivers of disease, with focused investment in therapeutic areas where we can leverage our core expertise and business infrastructure to bring scale to our science. We are bringing AYVAKIT®/AYVAKYT® (avapritinib) to people living with systemic mastocytosis (SM) in the U.S. and Europe. Additionally, we have a pipeline of research and development programs that range from early science to advanced clinical trials in mast cell-mediated diseases, including SM and chronic urticaria, breast cancer, and other solid tumors vulnerable to CDK2 inhibition. For more information, visit www.BlueprintMedicines.com and follow us on X (formerly 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' future business growth, including its expectations for growth in 2024;

AYVAKIT's potential as a blockbuster market opportunity in SM; whether the any of Blueprint Medicines' product candidates will address unmet medical needs; reduction of Blueprint Medicines' operating expenses and cash burn in 2024; statements regarding plans and expectations for the company's current or future approved drugs and drug candidates; the potential benefits of any of Blueprint Medicines' current or future approved drugs or drug candidates in treating patients; and Blueprint Medicines' financial performance, 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: the risk of delay of any current or planned clinical trials or the development of Blueprint Medicines' current or future drug candidates; risks related to 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; preclinical and clinical results for Blueprint Medicines' drug candidates may not support further development of such drug candidates either as monotherapies or in combination with other agents or may impact the anticipated timing of data or regulatory submissions; the timing of the initiation of clinical trials and trial cohorts at clinical trial sites and patient enrollment rates may be delayed or slower than anticipated; actions of regulatory agencies may affect the initiation, timing and progress of clinical trials; risks related to Blueprint Medicines' ability to obtain, maintain and enforce patent and other intellectual property protection for its products and current or future drug candidates it is developing; and the success of Blueprint Medicines' current and future collaborations, financing arrangements, partnerships or licensing arrangements. 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)

	<u>December 31,</u>	<u>December 31,</u>
	<u>2023</u>	<u>2022</u>
Cash, cash equivalents and investments	\$ 767,171	\$ 1,078,472
Working capital (1)	593,470	863,417
Total assets	1,049,250	1,349,902
Deferred revenue (2)	5,604	18,291
Liability related to the sale of future royalties and revenues (2)	441,625	430,330
Term loan (2)	238,813	139,083
Total liabilities	918,641	835,225
Total stockholders' equity	130,609	514,677

(1) Blueprint Medicines defines working capital as current assets less current liabilities.

(2) Includes both current and long-term portions of the balance

Blueprint Medicines Corporation
Condensed Consolidated Statements of Operations Data
(in thousands, except per share data)
(unaudited)

	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2023	2022	2023	2022
Revenues:				
Product revenue, net	\$ 71,034	\$ 30,064	\$ 204,207	\$ 110,993
Collaboration and license revenue	923	8,717	45,173	65,543
License revenue – Related Party	—	—	—	27,500
Total revenues	71,957	38,781	249,380	204,036
Cost and operating expenses:				
Cost of sales	260	4,848	8,540	17,813
Collaboration loss sharing	—	1,872	4,256	8,948
Research and development	97,537	117,840	427,720	477,419
Selling, general and administrative	79,270	64,019	295,141	237,374
Total cost and operating expenses	\$ 177,067	\$ 188,579	\$ 735,657	\$ 741,554
Other income (expense):				
Interest expense, net	(5,170)	(9,240)	(18,793)	(16,767)
Other income (expense), net	(577)	1,435	(946)	2,004
Total other expense	(5,747)	(7,805)	(19,739)	(14,763)
Loss before income taxes	(110,857)	(157,603)	(506,016)	(552,281)
Income tax expense	61	1,036	968	5,236
Net loss	\$ (110,918)	\$ (158,639)	\$ (506,984)	\$ (557,517)
Net loss per share applicable to common stockholders — basic and diluted	\$ (1.82)	\$ (2.65)	\$ (8.37)	\$ (9.35)
Weighted-average number of common shares used in net loss per share - basic and diluted	60,890	59,873	60,558	59,642

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