

**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): **August 2, 2022**

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 August 2, 2022, Blueprint Medicines Corporation announced its financial results for the quarter ended June 30, 2022 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 August 2, 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: August 2, 2022

By: /s/ Kathryn Haviland
Kathryn Haviland
Chief Executive Officer

Blueprint Medicines Reports Second Quarter 2022 Results

-- Achieved \$36.5 million in total revenues, including \$28.5 million in AYWAKIT[®] (avapritinib) net product revenues representing 20 percent AYWAKIT revenue growth from Q1 2022 --

-- Plan to report topline data for registration-enabling PIONEER trial of AYWAKIT in non-advanced SM in August 2022 --

-- Licensed KIT exon 13 inhibitor to IDRx in exchange for a 15 percent Series A preferred equity investment, and the potential to receive up to \$217.5 million in development, regulatory, and sales-based milestones and tiered percentage royalties --

-- Investor Day planned for November 1, 2022 in New York, NY --

CAMBRIDGE, Mass., August 2, 2022 – Blueprint Medicines Corporation (NASDAQ: BPMC) today reported financial results and provided a business update for the second quarter ended June 30, 2022.

“We are now one year into the AYWAKIT launch in advanced systemic mastocytosis (SM) and continue to see a significant expansion of our prescriber base as well as strong patient demand, reinforcing our conviction in the growth opportunity in SM.” said Kate Haviland, Chief Executive Officer of Blueprint Medicines. “We are on track to announce topline data from our registration-enabling PIONEER trial in August, which will catalyze our ability to bring AYWAKIT’s transformative potential to patients living with non-advanced SM. In addition, we continue to make significant progress across our pipeline of innovative investigational medicines in EGFR-mutant and CDK2-vulnerable cancers. We look forward to sharing more about our strategic vision, including the opportunities we see in SM, EGFR-mutant lung cancer, and CDK2-vulnerable cancers, and how our expanding research platform will continue to drive innovation at an Investor Day on November 1, 2022 in New York, NY. With our strong revenue performance, a clinical-stage pipeline of five significant assets, and well over \$1 billion in cash on our balance sheet as of today, we are uniquely positioned to drive near- and long-term value for all of our stakeholders by delivering transformative precision medicines to patients around the world.”

Second Quarter 2022 Highlights and Recent Progress

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

- Reported global net product revenues of \$28.5 million for the second quarter of 2022.
- Presented new retrospective analyses at the European Hematology Association (EHA) 2022 Congress, showing that AYWAKIT significantly improved overall survival in patients with advanced SM when compared to real-world data for prior best available therapies, including midostaurin and cladribine. Read the press release [here](#).
- Upon request by the FDA, changed the primary endpoint for the registrational PIONEER Part 2 trial of AYWAKIT in patients with non-advanced SM to the mean change in total symptom score (TSS).

GAVRETO[®] (pralsetinib): RET-altered cancers

- As previously recorded and reported by Roche, GAVRETO global product sales were 7 million CHF, which excludes sales in the Greater China territory driven by CStone Pharmaceuticals.
 - Received approval in Hong Kong, China, via the collaboration with CStone Pharmaceuticals, for the treatment of RET fusion-positive non-small cell lung cancer (NSCLC).
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Corporate

- Announced strategic financing collaborations with Sixth Street and Royalty Pharma plc (Royalty Pharma) (NASDAQ: RPRX) for up to \$1.25 billion, of which \$175 million was funded as of June 30, 2022, and an additional \$400 million funded in July 2022. Read the press release [here](#).
- Licensed a development candidate-stage KIT exon 13 inhibitor, and licensed the compound to IDRx, Inc., a recently launched clinical-stage biopharmaceutical company, in exchange for a 15 percent Series A preferred equity investment and up to \$217.5 million in future milestone payments and tiered percentage royalty payments.
- Published an inaugural Corporate Responsibility Report, highlighting the company's long-standing commitment to delivering sustainable value to patients with cancer and blood disorders, as well as the communities in which Blueprint Medicines operates. Read the press release [here](#) and access the report [here](#).
- Announced the appointment of Habib Dable, former Chief Executive Officer of Acceleron Pharma, Inc., to the company's Board of Directors. Read the press release [here](#).

Key Upcoming Milestones

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

- Present topline data from the registrational PIONEER Part 2 trial for avapritinib in non-advanced SM in August 2022 and submit a supplemental new drug application to the FDA for AYVAKIT in non-advanced SM in the second half of 2022.
- Share the strategic vision for Blueprint, including opportunities in SM, EGFR-mutant lung cancer, and CDK2-vulnerable cancers, and how our expanding research platform has the potential to deliver the promise of precision medicine to more patients at an Investor Day on November 1, 2022 in New York, NY.
- Present updated BLU-945 monotherapy data and initial dose escalation data for BLU-945 in combination with osimertinib from the Phase 1/2 SYMPHONY trial in EGFR-mutant NSCLC in the second half of 2022.
- Present initial clinical data from the Phase 1/2 HARMONY trial of BLU-701 in EGFR-mutant NSCLC in the second half of 2022.
- Present initial data from the HARBOR trial of BLU-263 in non-advanced SM in the second half of 2022.
- Present initial clinical data from the Phase 1/2 CONCERTO trial of BLU-451 in EGFR-mutant NSCLC in the first half of 2023.
- Present initial clinical data from the Phase 1/2 VELA trial of BLU-222 in CDK2-vulnerable cancers in the first half of 2023.

Second Quarter 2022 Results

- **Revenues:** Revenues were \$36.5 million for the second quarter of 2022, including \$28.5 million of net product revenues from sales of AYVAKIT/AYVAKYT and \$8.0 million in collaboration revenues. Blueprint Medicines recorded revenues of \$27.3 million in the second quarter of 2021, including \$8.5 million of net product revenues from sales of AYVAKIT/AYVAKIT, \$2.9 million of net product revenues from sales of GAVRETO and \$15.9 million in collaboration revenues.
 - **Cost of Sales:** Cost of sales was \$4.9 million for the second quarter of 2022, as compared to \$6.5 million for the second quarter of 2021.
 - **R&D Expenses:** Research and development expenses were \$128.5 million for the second quarter of 2022, as compared to \$80.0 million for the second quarter of 2021. This increase was primarily due to increased costs associated with the progression of our clinical trials and increased costs related to early discovery effort. Research and development expenses included \$10.5 million in stock-based compensation expenses for the second quarter of 2022.
 - **SG&A Expenses:** Selling, general and administrative expenses were \$58.7 million for the second quarter of 2022, as compared to \$49.3 million for the second quarter of 2021. This increase was primarily due to increased costs associated with expanding our commercial infrastructure for commercialization of AYVAKIT/AYVAKYT. General and administrative expenses included \$14.9 million in stock-based compensation expenses for the second quarter of 2022.
 - **Net Loss:** Net loss was \$159.7 million for the second quarter of 2022, or a net loss per share of \$2.68, as compared to a net loss of \$108.4 million for the second quarter of 2021, or a net loss per share of \$1.86.
 - **Cash Position:** As of June 30, 2022, cash, cash equivalents and investments were \$947.2 million, as compared to \$1,034.6 million as of December 31, 2021. Cash as of June 30, 2022, does not include \$400 million gross proceeds received from our strategic non-dilutive financing agreements with Sixth Street, which closed and was funded in July 2022.
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Financial Guidance

Blueprint Medicines anticipates approximately \$180M to \$200M in total revenues in 2022, including approximately \$115M to \$130M in AYWAKIT 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 8:00 a.m. ET today to discuss second quarter 2022 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 694684. 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.

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 interactions with the FDA and other regulatory authorities; plans and timelines to update the primary endpoint of the registrational PIONEER trial of AYWAKIT in patients with non-advanced SM; expectations regarding the potential benefits of AYWAKIT in treating patients with non-advanced SM; and the potential benefits of Blueprint Medicines' collaborations; 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, 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 AYWAKIT/AYVAKYT and GAVRETO or obtain marketing approval for AYWAKIT/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 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; 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 AYWAKIT/AYVAKYT, GAVRETO or any drug candidates it is developing; Blueprint Medicines' ability to develop and commercialize companion diagnostic tests for AYWAKIT/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 executive leadership transition plan; and the success of Blueprint Medicines' current and future collaborations, financing arrangements, 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)

	<u>June 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Cash, cash equivalents and investments	\$ 947,159	\$ 1,034,643
Working capital (1)	793,419	404,260
Total assets	1,192,446	1,252,225
Deferred revenue (2)	22,139	36,576
Liability related to the sale of future royalties (2)	171,254	-
Total liabilities	444,696	281,490
Total stockholders' equity	747,750	970,735

(1) Blueprint 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, June 30		Six Months Ended, June 30	
	2022	2021	2022	2021
Revenues:				
Product revenue, net	\$ 28,454	\$ 11,433	\$ 52,295	\$ 20,388
Collaboration revenue	8,093	15,862	46,983	28,483
Total revenues	36,547	27,295	99,278	48,871
Cost and operating expenses:				
Cost of sales	4,886	6,493	9,964	6,595
Collaboration loss sharing	2,145	----	5,410	----
Research and development	128,466	80,027	231,599	159,738
Selling, general and administrative	58,688	49,286	115,747	91,288
Total cost and operating expenses	\$ 194,185	135,806	362,720	257,621
Other income (expense):				
Interest income (expense), net	427	633	869	1,371
Other income (expense), net	632	(373)	177	(587)
Total other income (expense)	\$ 1,059	260	1,046	784
Loss before income taxes	\$ (156,579)	(108,251)	(262,396)	(207,966)
Income tax expense	(3,130)	(193)	(3,313)	(193)
Net loss	\$ (159,709)	\$ (108,444)	\$ (265,709)	\$ (208,159)
Net loss per share — basic and diluted	\$ (2.68)	\$ (1.86)	\$ (4.47)	\$ (3.58)
Weighted-average number of common shares used in net loss per share — basic and diluted	59,617	58,406	59,465	58,216

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