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, 2023

### **Blueprint Medicines Corporation**

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

001-37359 (Commission File Number)

45 Sidney Street

Cambridge, Massachusetts (Address of principal executive offices)

26-3632015 (I.R.S. Employer Identification No.)

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

Emerging growth company  $\Box$ 

of this chapter).

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, 2023, Blueprint Medicines Corporation (the "Company") announced its financial results for the quarter ended June 30, 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 7.01 Regulation FD.

On August 2, 2023, the Company is hosting an investor conference call and webcast to review its financial results and other business highlights. A copy of the presentation for the investor conference call and for the webcast is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.2 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of 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 exhibits relating to Items 2.02 and 7.01 of this Form 8-K shall be deemed to be furnished and not filed:

Exhibit	Description
No.	
<u>99.1</u>	Press release issued by Blueprint Medicines Corporation on August 2, 2023
<u>99.2</u>	Corporate slide presentation of Blueprint Medicines Corporation dated August 2, 2023
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

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

Date: August 2, 2023

### Blueprint Medicines Reports Second Quarter 2023 Results

-- Achieved \$39.9 million in AYVAKIT®/AYVAKYT® (avapritinib) net product revenues and \$57.6 million in total revenues in the second quarter of 2023 -

-- AYVAKIT approved by the FDA for the treatment of adults with indolent systemic mastocytosis on May 22, 2023 --

-- Announced development candidate BLU-808, an oral, highly potent and selective wild-type KIT inhibitor with first- and best-in-class potential, for the treatment of patients with mast cell disorders, including chronic urticaria -

CAMBRIDGE, Mass., Aug 2, 2023 - Blueprint Medicines Corporation (NASDAQ: BPMC) today reported financial results and provided a business update for the second quarter ended June 30, 2023.

"We have entered a new era at Blueprint with the launch of AYVAKIT in indolent systemic mastocytosis. In the second quarter, we delivered strong growth in AYVAKIT revenue and patients on therapy, reinforcing our belief in the blockbuster potential for AYVAKIT in systemic mastocytosis," said Kate Haviland, Chief Executive Officer of Blueprint Medicines. "We also achieved important regulatory and operational milestones, including multiple readouts from our pipeline at ASCO and the nomination of a selective and potent inhibitor of wild-type KIT which leverages our expertise and infrastructure as we build a franchise in mast cell driven diseases. Our year-to-date achievements fortify our strong foundation for near- and long-term growth."

### Second Quarter 2023 Highlights and Recent Progress

### Systemic mastocytosis (SM) and other mast cell disorders

- Announced that the U.S. Food and Drug Administration (FDA) approved AYVAKIT® (avapritinib), the first and only medicine approved for the treatment of adults with indolent systemic mastocytosis (ISM) and the only treatment approved across the spectrum of indolent and advanced SM. Read the press release <u>here</u>.
- Published detailed results from the PIONEER study in New England Journal of Medicine (NEJM) Evidence. Key results demonstrate that AYVAKIT achieved statistically significant and clinically meaningful benefits in
  overall symptoms and objective measures of mast cell burden compared to placebo at 24 weeks, with improvements deepening through 48 weeks. Data also show meaningful improvements in quality-of-life measurements.
  AYVAKIT showed a favorable safety profile compared to placebo. Read the press release <u>here</u>.
- Announced nomination of BLU-808, an oral, highly potent and selective wild-type KIT inhibitor with first- and best-in-class potential, as a development candidate for the treatment of mast cell disorders, including chronic urticaria.

#### Cancers vulnerable to CDK2 inhibition

Presented monotherapy dose escalation data from the Phase 1/2 VELA trial of BLU-222 in patients with cancers vulnerable to CDK2 inhibition at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. The
results showed evidence of favorable safety, cell cycle modulation and clinical response, supporting initiation of combination dose escalation of BLU-222 with ribociclib and fulvestrant in patients with hormone receptorpositive/HER2-negative breast cancer. Find the poster here.

### EGFR-driven non-small cell lung cancer (NSCLC)

### BLU-945

Presented dose escalation data from the Phase 1/2 SYMPHONY study of BLU-945 in patients with late-line EGFR-driven NSCLC at the 2023 ASCO Annual Meeting. BLU-945 monotherapy and in combination with
osimertinib showed evidence of clinical activity and was generally well tolerated, with infrequent adverse events associated with wild-type EGFR inhibition, supporting continued combination dose escalation. Find the poster
<u>here</u>.

### BLU-451

Presented dose escalation data from the Phase 1/2 CONCERTO study of BLU-451 in patients with NSCLC driven by EGFR exon 20 insertions and atypical mutations at the 2023 ASCO Annual Meeting. Results showed evidence of safety and clinical benefit, including central nervous system activity, supporting continued dose escalation. Find the poster here.

### **Key Upcoming Milestones**

Blueprint Medicines plans to achieve the following milestones by the end of 2023:

- Present data from Part 1 of the HARBOR trial of elenestinib in indolent SM.
- Continue AYVAKIT commercial launch execution in SM.

### Second Quarter 2023 Results

- Revenues: Revenues were \$57.6 million for the second quarter of 2023, including \$39.9 million of net product revenues from sales of AYVAKIT/AYVAKYT and \$17.7 million in collaboration revenues. Blueprint Medicines recorded revenues of \$36.5 million in 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.
- Cost of Sales: Cost of sales was \$2.3 million for the second quarter of 2023, as compared to \$4.9 million for the second quarter of 2022. The decrease was primarily due to a decrease in the cost of collaboration-related sales.
- R&D Expenses: Research and development expenses were \$110.1 million for the second quarter of 2023, as compared to \$128.5 million for the second quarter of 2022. This decrease was primarily due to continued operational efficiency gains across our portfolio as we execute across our top priority programs and the timing of manufacturing of clinical trial materials. Research and development expenses included \$10.2 million in stock-based compensation expenses for the second quarter of 2023.
- SG&A Expenses: Selling, general and administrative expenses were \$71.9 million for the second quarter of 2023, as compared to \$58.7 million for the second quarter of 2022. This increase was primarily due to an increase in compensation and personnel related costs driven by our first quarter field force expansion to support the AYVAKIT launch in ISM. Selling, general, and administrative expenses included \$13.6 million in stock-based compensation expenses for the second quarter of 2023.
- Net Loss: Net loss was \$132.8 million for the second quarter of 2023, or a net loss per share of \$2.19, as compared to a net loss of \$159.7 million for the second quarter of 2022, or a net loss per share of \$2.68.
- Cash Position: As of June 30, 2023, cash, cash equivalents and investments were \$836.6 million, as compared to \$1,078.5 million as of December 31, 2022.

### **Conference Call Information**

Blueprint Medicines will host a live conference call and webcast at 8:00 a.m. ET today to discuss second quarter 2023 financial results and recent business activities. The conference call may be accessed by dialing 833-470-1428 (domestic) or 929-526-1599 (international), and referring to conference ID 669158. A webcast of the call will also be available under "Events and Presentations" in the Investors & Media section of the Blueprint Medicines website at <a href="http://ir.blueprintmedicines.com/">http://ir.blueprintmedicines.com/</a>. 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:

### Morgan Stanley 21<sup>st</sup> Annual Global Healthcare Conference on Monday, September 11, 2023 at 11:20 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 tanslate science into a broad pipeline of precision therapies. Today, we are delivering our approved medicines to patients in the U.S. and Europe, and we are globally advancing multiple programs for systemic mastocytosis (SM), lung cancer and other genomically defined cancers, and cancer immunotherapy. For more information, visit <u>www.BlueprintMedicines.com</u> and follow us on <u>Twitter (@BlueprintMedic</u>) and <u>LinkedIn</u>.

### **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 approvals and launches, the initiation of clinical trials or the results of ongoing and planned clinical trial. Blueprint Medicines' plans, strategies and timelines to nominate development candidates; timelines and expectations for Blueprint Medicines' 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 reating 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," "protetila," "continue," "target" and similar expressions are intended to identify forward-looking statements and inportant 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: preliminary activity and safety data may not be representative of more mature data; the risk of delay of any current or planned clinical trials or the development of Blueprint Medicines' current or future drug candidates; and gain approval of its drug candidates or a timely basis, if at all; preclinical and clinical results for Blueprint Medicines' current or future drug candidates may not stereseful and other agents or is prograved and gain approval of its drug candidates or may impact the anticipated milestores business; the success of Blueprint Medicines' ability to successfully demonstrate the safety and efficacy of its drug candidates on a timely basis, if at all; preclinical and

### Trademarks

Blueprint Medicines, AYVAKIT, AYVAKYT and associated logos are trademarks of Blueprint Medicines Corporation.

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

	June 30,	December 31,	
	2023		2022
Cash, cash equivalents and marketable securities	\$ 836,566	\$	1,078,472
Working capital (1)	642,307		863,417
Total assets	1,106,445		1,349,902
Liability related to the sale of future royalties and revenues (2)	437,341		430,330
Term loan (2)	140,003		139,083
Deferred revenue (2)	8,328		18,291
Total liabilities	795,315		835,225
Fotal stockholders' equity	311,130		514,677

Blueprint Medicines defines working capital as current assets less current liabilities.
 Amount includes both current and non-current portions of the balances.

# Blueprint Medicines Corporation Condensed Consolidated Statements of Operations and Comprehensive Loss (in thousands, except per share data) (Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,				
		2023	2022		2023		2022
Revenues:							
Product revenue, net	\$	39,876	\$ 28,454	\$	78,945	\$	52,295
Collaboration and license revenue		17,694	8,093		41,912		46,983
Total revenues		57,570	36,547		120,857		99,278
Cost and operating expenses:							
Cost of sales		2,323	4,886		5,498		9,964
Collaboration loss sharing		1,234	2,145		2,530		5,410
Research and development		110,063	128,466		222,135		231,599
Selling, general and administrative		71,931	58,688		142,882		115,747
Total cost and operating expenses		185,551	 194,185		373,045	_	362,720
Other income (expense):							
Interest income (expense), net		(3,996)	427		(9,815)		869
Other income (expense), net		(626)	632		359		177
Total other income (expense), net		(4,622)	 1,059		(9,456)		1,046
Loss before income taxes		(132,603)	 (156,579)		(261,644)		(262,396)
Income tax expense		190	3,130		710		3,313
Net loss	\$	(132,793)	\$ (159,709)	\$	(262,354)	\$	(265,709)
Net loss per share - basic and diluted	\$	(2.19)	\$ (2.68)	\$	(4.35)	\$	(4.47)
Weighted-average number of common shares used in net loss per share - basic and diluted		60,516	59,617		60,322		59,465

Media Contact Sarah Mena Guerrero 617-714-6684 media@blueprintmedicines.com

Investor Contact Jenna Cohen 857-209-3147 <u>ir@blueprintmedicines.com</u>





AUGUST 2, 2023

# Agenda



INTRODUCTION

Kate Haviland Chief Executive Officer



AYVAKIT PERFORMANCE

Philina Lee, PhD Chief Commercial Officer



KEY PORTFOLIO MILESTONES

Fouad Namouni, MD President, R&D



Q2 2023 PERF(

Mike Chief Fin



### Forward-looking statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, state regarding plans, strategies, timelines and expectations for Blueprint Medicines' current or future approved drugs and drug candidates, including approvals and launches, the ini trials or the results of ongoing and planned clinical trials; Blueprint Medicines' plans, strategies and timelines to nominate development candidates; timelines and expectations fu with the FDA and other regulatory authorities; statements regarding the plans and potential benefits of AYVAKIT in treating patients with indolent systemic matocytosis; statement plans and expectations for Blueprint Medicines' current or future approved drugs and drug candidates; the potential benefits of any of Blueprint Medicines' current or future app drug candidates in treating patients; and Blueprint Medicines' financial performance, strategy, goals and anticipated milestones, business plans and focus. The words "aim," "ma "would," "should," "expect," "plan, " anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify fo statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this presentation are based on management's currer 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 looking statements contained in this presentation, including, without limitation: preliminary activity and safety data may not be representative of more mature data; the risk of de current or planned clinical trials or the development of Blueprint Medicines' current or future drug candidates; risks related to Blueprint Medicines' ability to successfully demonst 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 ma 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 submission 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 aff timing and progress of clinical trials; the success of Blueprint Medicines' current and future collaborations, financing arrangements, partnerships or licensing arrangements; Blu Medicines' ability to conduct ongoing and planned clinical trials; risks related to Blueprint Medicines' ability to obtain, maintain and enforce patent and other intellectual property its products and current or future drug candidates it is developing; and resurgence of the COVID-19 pandemic may impact Blueprint Medicines' business, operations, strategy, anticipated milestones, including ongoing and planned research and discovery activities. Any forward-looking statements contained in this presentation represent Blueprint Med 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 to update any forward-looking statements contained in this presentation as a result of new information, future events or otherwise. Accordingly, readers are cautioned not to pla reliance on these forward-looking statements.

This presentation also contains estimates, projections and other statistical data made by independent parties and by Blueprint Medicines relating to market size and growth and about Blueprint Medicines' industry. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, assumptions and estimates of Blueprint Medicines' future performance and the future performance of the markets in which the company operates are necessarily subject to a hi uncertainty and risk.

Blueprint Medicines, AYVAKIT, AYVAKYT and associated logos are trademarks of Blueprint Medicines Corporation.



### Blueprint Medicines Q2 2023 highlights new era of Precision at Scale



### **COMMERCIAL EXECUTION**

AYVAKIT U.S. ISM approval and strong Q2 performance unlocks blockbuster potential



### **PIPELINE PROGRESS**

Clear path to value creation, including best-in-class CDK2 inhibitor BLU-222



### RESEARCH EX

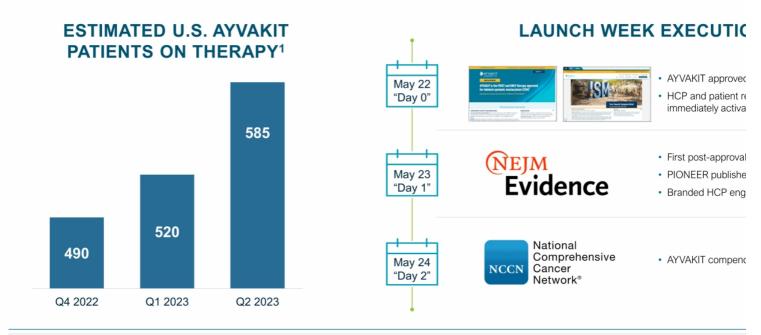
First- and best-in-classignificant market c BLU-808, an oral, hic selective wtKIT inhibi disorders, including c

### DRIVING NEAR- AND LONG-TERM VALUE WHILE BEING DISCIPLINED STEWARDS OF (



ISM, indolent systemic mastocytosis; wtKIT, wild-type KIT

# AYVAKIT update: second quarter 2023 performance



### AYVAKIT GLOBAL NET REVENUE OF \$39.9M IN Q2 2023, DRIVEN BY GROWTH IN



1. Blueprint Medicines data on file. Estimated patient numbers reflect patients on therapy at quarter exit. ISM, indolent systemic mastocytosis; Rx, prescription; HCP, healthcare provider

# Strength across all key metrics of ISM launch

### STRONG PROVIDER ENGAGEMENT



- · Hem/onc and allergist prescribing
- · Community and academic
- ~70% of SM prescriptions since ISM approval from new prescribers



SM, systemic mastocytosis; ISM, indolent systemic mastocytosis

### Not for promotional use

### ENCOURAGING PATIENT ACTIVATION



- ~585 total patients on therapy
- New patient starts heavily weighted toward June, first full month post-ISM approval

### UNENCUMBI ACCESS



- Updated policies cr with broad ISM lab;
- No denials
- No step therapy

# BLU-808 fits the target product profile of a first- and best-in-class KIT inhibitor for treatment of mast cell disorders, including chronic

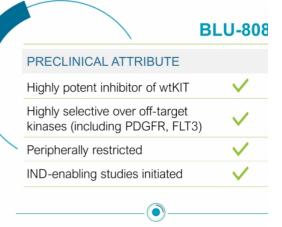


Typical presentation of hives or wheals, a common symptom in chronic urticaria<sup>1</sup>

- Patients with chronic urticaria can experience itching, hives, and swelling
- Related symptoms include anxiety and sleep loss
- · QoL similar to other severe skin diseases

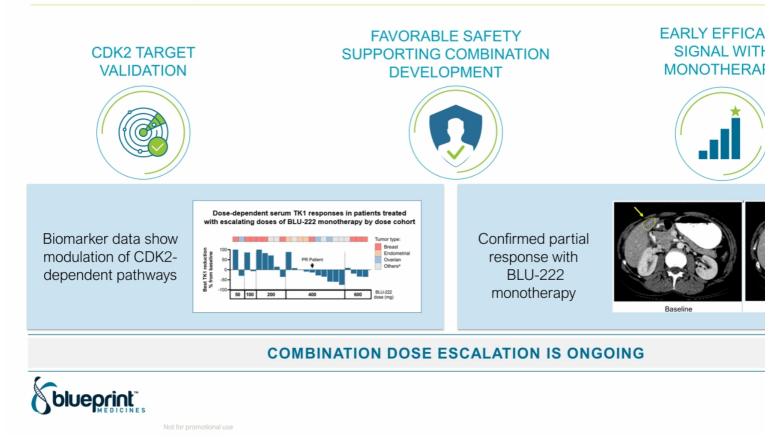


1. Nature Reviews Disease Primer (2022). QoL, quality of life



- Current treatment includes antihistamin H2 blockers, Xolair
- Unmet need for 2L+ treatment targeting underlying cause of disease

# BLU-222 has potential to be the best-in-class CDK2 inhibitor



# Financial discipline and commitment to maintaining strong casl

Statement of Operations (unaudited)	Three Months Ended 6/30/2023	Three Months Ended 6/30/2022	Six Months Ended 6/30/2023	Six I Er 6/30
Total revenue	\$57.6M	\$36.5M	\$120.9M	
Net product sales Collaboration revenue	\$39.9M \$17.7M	\$28.5M \$8.0M	\$79.0M \$41.9M	
Cost of sales	\$2.3M	\$4.9M	\$5.5M	
Collaboration loss sharing	\$1.2M	\$2.1M	\$2.5M	
Research & development expense <sup>1</sup>	\$110.1M	\$128.5	\$222.1M	
Selling, general & admin expense <sup>2</sup>	\$71.9M	\$58.7M	\$142.9M	
Net Loss	\$(132.8)M	\$(159.7)M	\$(262.4)M	
Balance Sheet (unaudited)			6/30/2023	1:
Cash, cash equivalents, and investments	S		\$836.6M	\$



1. Includes stock-based compensation expense of \$10.2M and \$20.3M for the three and six months ended 6/30/23, and \$10.5M and \$20.5M for the three and six months ended 6/30/22, respectively. 2. Inclu compensation expense of \$13.6M and \$26.7M for the three and six months ended 06/30/23, and \$14.9M and \$28.2M for the three and six months ended 6/30/22, respectively.

# Progress against key anticipated portfolio milestones in 2023

Area	Program	Milestone
	AYVAKIT	Present registrational PIONEER trial data in indolent SM at AAAAI Annual Meeting
	AYVAKYT	Achieve EMA validation of a type II variation MAA for indolent SM
Mast cell AYVAKIT		Achieve FDA approval and initiate U.S. launch in indolent SM
	Research	Nominate a development candidate targeting wild-type KIT for chronic urticaria
	Elenestinib	Present Part 1 HARBOR trial data in indolent SM
EGFRm NSCLC	BLU-525	Submit IND to FDA
	BLU-451	Present initial CONCERTO trial dose escalation data in EGFR exon 20 NSCLC
Cancers vulnerable to CDK2 inhibition	BLU-222	Present initial VELA trial dose escalation data

### CONTINUED COMMERCIAL EXECUTION FOR AYVAKIT/AYVAKYT IN SM



SM, systemic mastocytosis; AAAAI, American Academy of Allergy, Asthma & Immunology; EMA, European Medicines Agency; MAA, marketing authorization application; FDA, U.S. Food and Drug Administration; IND, investigational new drug; NSCLC, non-small cell lung cancer



# Thank You