

**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): **January 9, 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)

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 7.01 Regulation FD Disclosure.

From time to time, the Company presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. The Company is posting to the “Investors & Media” portion of its website at <http://ir.blueprintmedicines.com/> a copy of its current corporate slide presentation. A copy of the presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 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
<u>99.1</u>	<u>Corporate slide presentation of Blueprint Medicines Corporation dated January 9, 2023</u>
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: January 9, 2023

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

precision at scale™

KATE HAVILAND, PRESIDENT AND CEO

J.P. MORGAN HEALTHCARE CONFERENCE – JANUARY 10, 2023



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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, statements regarding plans, strategies, timelines and expectations for interactions with the U.S. Food and Drug Administration (FDA) and other regulatory authorities; statements regarding the benefits and expectations of AYVAKIT in treating patients with non-advanced systemic mastocytosis (SM); statements regarding the plans and potential benefits of AYVAKIT in treating patients with indolent SM; plans and timing for presenting detailed data from the SYMPHONY trial of BLU-945 in patients with advanced EGFR-mutant non-small cell lung cancer; statements regarding plans and expectations for the company's current or future approved drugs and drug candidates; the potential benefits of any of the company's current or future approved drugs or drug candidates in treating patients; and the company's 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 the company's business, operations, strategy, goals and anticipated milestones, including the company's 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; the company's ability and plans in continuing to establish and expand a commercial infrastructure, and successfully launching, marketing and selling current or future approved products; the company's 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 the company's current or future drug candidates; the company's advancement of multiple early-stage efforts; the company's 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 the company's 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; the company's ability to obtain, maintain and enforce patent and other intellectual property protection for AYVAKIT/AYVAKYT, GAVRETO or any drug candidates it is developing; the company's ability to develop and commercialize companion diagnostic tests for AYVAKIT/AYVAKYT, GAVRETO or any of its current and future drug candidates; the company's ability to successfully expand its operations, research platform and portfolio of therapeutic candidates, and the timing and costs thereof; the company's ability to realize the anticipated benefits of its executive leadership transition plan; and the success of the company's 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 the company's filings with the Securities and Exchange Commission (SEC), including the company's 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 the company has made or may make with the SEC in the future. The forward-looking statements in this presentation are made only as of the date hereof, and except as required by law, the company undertakes no obligation 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 place undue reliance on these forward-looking statements.

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

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OUR MISSION


Make real the promise of precision therapy to extend and improve life for as many people as possible






Suki
patient with indolent systemic mastocytosis

Blueprint's strategy to achieve Precision at Scale by 2027

APPROACH

-  Start with genetic drivers of disease
-  Design highly potent and selective medicines
-  Select the right patients
-  Drive transformative outcomes with high POS

FOCUS

-  Mast cell disorders
-  Lung cancer
-  Breast cancer

ASPIRATION



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POS, probability of success.

Blueprint has a compelling value proposition

1

FOUNDATION OF SUCCESS

Differentiated scientific platform, development and business execution

2

COMMERCIAL PORTFOLIO

Doubling product revenue in 2022

3

NEAR-TERM REVENUE GROWTH

Anticipated expansion into indolent SM, a ~15x larger patient opportunity

4

ROBUST CLINICAL PIPELINE

Diverse set of programs targeting compelling peak revenue opportunities

Blueprint's proven track record of R&D success



14 development candidates nominated



80% success rate from IND to clinical POC



5 breakthrough therapy designations



~4 years from IND to first approval



2 approved medicines



5 FDA approved indications

Our scientific platform is a competitive advantage



SELECTIVE SMALL MOLECULE PRECISION THERAPIES

DURABILITY

Potent target inhibition
leading to rapid and deep
responses

TOLERABILITY

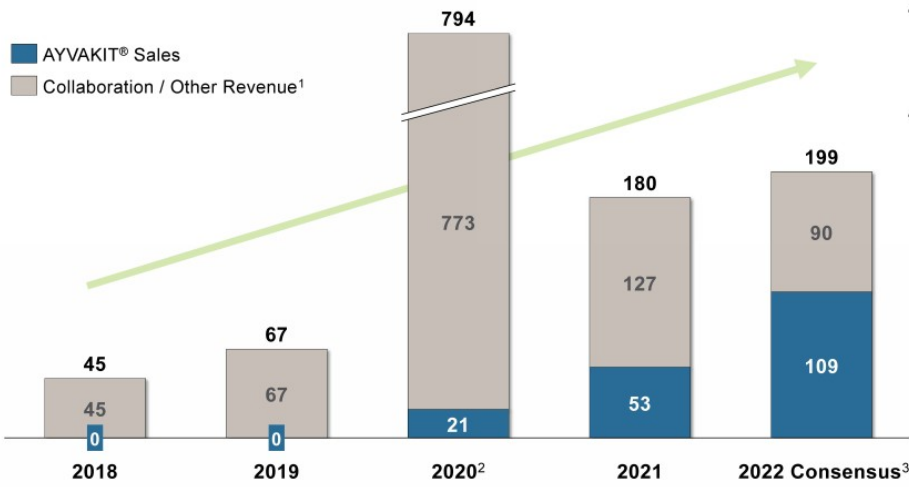
Limit side effects driven by
off-target activity

COMBINABILITY

Combine therapies to shut
down disease drivers and
resistance

Consistent business execution resulting in balance sheet strength and diversity of revenue

BLUEPRINT MEDICINES NET REVENUE (\$M)



- Entering 2023 with >\$1B in cash
- On track to achieve high-end of 2022 total revenue guidance of \$180M-\$200M and AYVAKIT revenue guidance of \$108M-\$111M
- Strong product revenue growth anticipated over the next few years



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1 Includes Gavreto sales booked as revenue in 2020 and 2021. 2 Includes Roche collaboration payments. 3 2022 Ayvakit sales represents full year 2022 FactSet consensus as of 1/4/2023. 2022 Collaboration / Other Revenue represents 2022 FactSet consensus total revenue as of 1/4/2023 less 2022 Ayvakit sales.

Strong track record of business development enabling corporate strategy



>\$1.1B of capital brought in to-date inclusive of upfront, milestones and royalties

Strong foundation of enterprise capabilities and infrastructure



KNOWLEDGE & LEADERSHIP

Precision medicine and therapeutic area leadership



EXPERIENCED TEAM

Track record of bringing innovation from discovery to commercial



GLOBAL INFRASTRUCTURE

Established U.S. and EU operations, with global partner network

Blueprint has a compelling value proposition

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ROBUST CLINICAL PIPELINE

Diverse set of programs targeting compelling peak revenue opportunities

Commercial portfolio of transformative medicines



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AYVAKIT is the first precision therapy to target the underlying cause of SM



~540 PATIENT YEARS OF SM CLINICAL DATA DEMONSTRATING



Reduced mast cell burden



Improved disease symptoms



Improved quality of life



Deep and durable clinical responses



Positive benefit-risk profile



One pill, once daily dosing

Currently FDA and EMA approved for advanced SM • sNDA submitted to FDA for indolent SM in Q4 2022

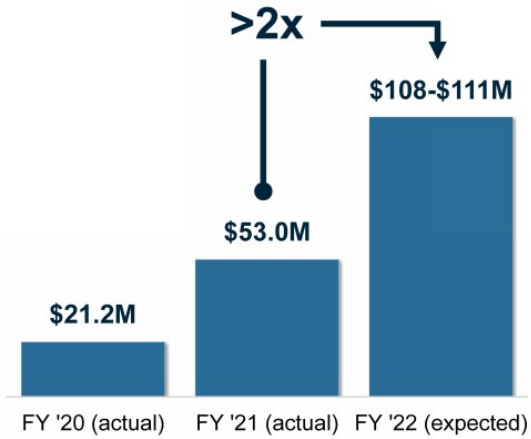


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EMA, European Medicines Agency. sDNA, supplemental new drug application.

AYVAKIT is the standard of care for advanced SM in the U.S.

AYVAKIT NET REVENUE GROWTH



AVYAKIT is the preferred treatment for advanced SM

- ~75% of new patient starts / switches

Total number of patients on therapy continues to grow

- Anticipate continued growth with expansion of SM-AHN* treatment rate

Increasing healthcare provider experience

- >350 new U.S. accounts since launch

Favorable patient access achieved

- 100% coverage with rapid average time to fill of 4.9 days

Blueprint has a compelling value proposition

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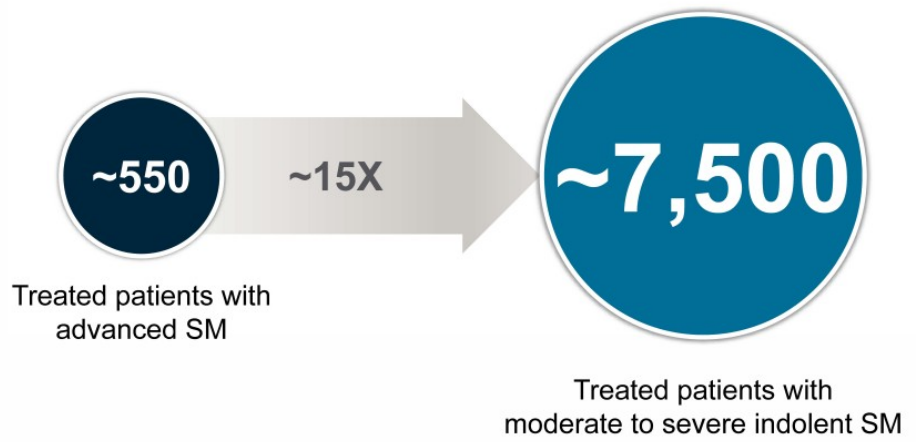
ROBUST CLINICAL PIPELINE

Diverse set of programs targeting compelling peak revenue opportunities



Indolent SM opportunity is orders of magnitude larger than advanced SM

Among ~16,000 SM patients diagnosed and observable in U.S. claims data¹



Estimated >\$1.5B global peak revenue opportunity in SM²



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¹ U.S. claims data analyses on file. ² Blueprint Medicines estimate.



HEREDITARY ANGIOEDEMA

- Rare disorder characterized by anaphylaxis, attacks of swelling
- Treated by allergist immunologists
- New specialty market established with the approval of disease modifying therapies
- Market is continuing to grow today, with >35% 3-year growth rate (2019-2021)

~7,500

patients diagnosed and treated in U.S.¹

~\$1.5B

sales of prophylactic therapies in 2021²



Blueprint is positioned for success in indolent SM, a tractable specialty market



HIGH MEDICAL NEED

Debilitating symptoms, poor quality of life and high polypharmacy burden, with no available disease modifying therapy



MOTIVATED & IDENTIFIABLE PATIENTS

7,500 patients with moderate to severe ISM diagnosed, treated with polypharmacy and observable in U.S. claims data



PRESCRIBER CONCENTRATION

Top 350 allergist immunologists and hematologist oncologists actively manage ~1,500 patients



ESTABLISHED COMMERCIAL PRESENCE IN ADVANCED SM

Fully integrated team in the field today engaging with healthcare providers, payers and the patient community

Plan to initiate U.S. launch of AYVAKIT in indolent SM in the middle of 2023



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ISM, indolent SM.

Blueprint has a compelling value proposition

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ROBUST CLINICAL PIPELINE

Diverse set of programs targeting compelling peak revenue opportunities

Pipeline targeting prevalent diseases with high medical need



MAST CELL
DISORDERS

AYVAKIT: KIT D816V

Elenestinib: KIT D816V¹

Research: wild-type KIT



LUNG
CANCER

GAVRETO: RET

BLU-945: EGFR

BLU-525: EGFR

BLU-451: EGFR exon 20



BREAST
CANCER

BLU-222: CDK2

Multiple additional undisclosed research programs in areas of medical need



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¹ Elenestinib was formerly known as BLU-263.

Comprehensive and modular EGFR portfolio strategy

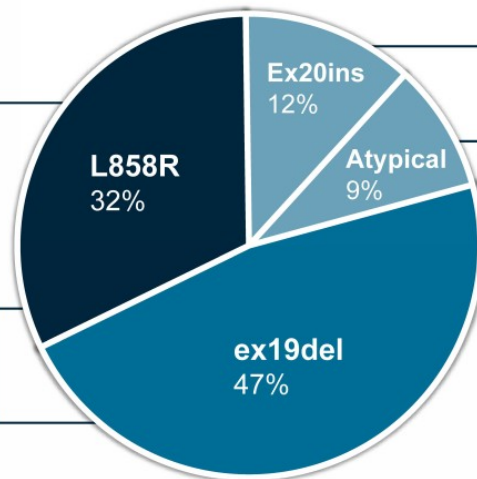
FULL SPECTRUM COVERAGE¹ OF EGFR DRIVERS²

BLU-945

- More potent on L858R than ex19del
- Covers T790M and C797X resistance
- Selectivity profile: best-in-class potential

BLU-525

- Potent coverage of L858R and ex19del
- Covers C797X resistance
- CNS penetration: best-in-class potential



BLU-451

- Potent coverage of all common ex20ins, plus atypical mutations (e.g., G719X, L861Q, etc.)
- CNS penetration: best-in-class potential

Randomized SYMPHONY trial expansion designed to de-risk combination development in 1L EGFR L858R mutant NSCLC

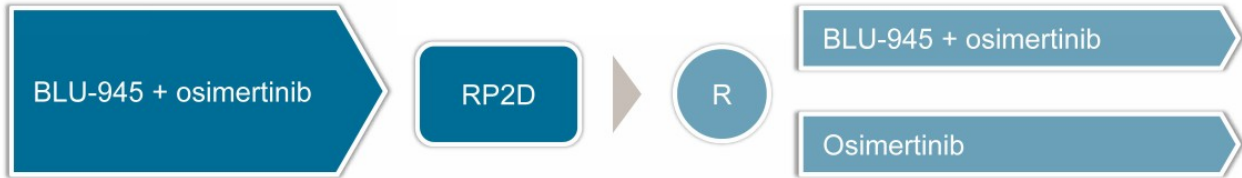


ONGOING DOSE ESCALATION

- Late-line EGFR mutant NSCLC

PLANNED EXPANSION

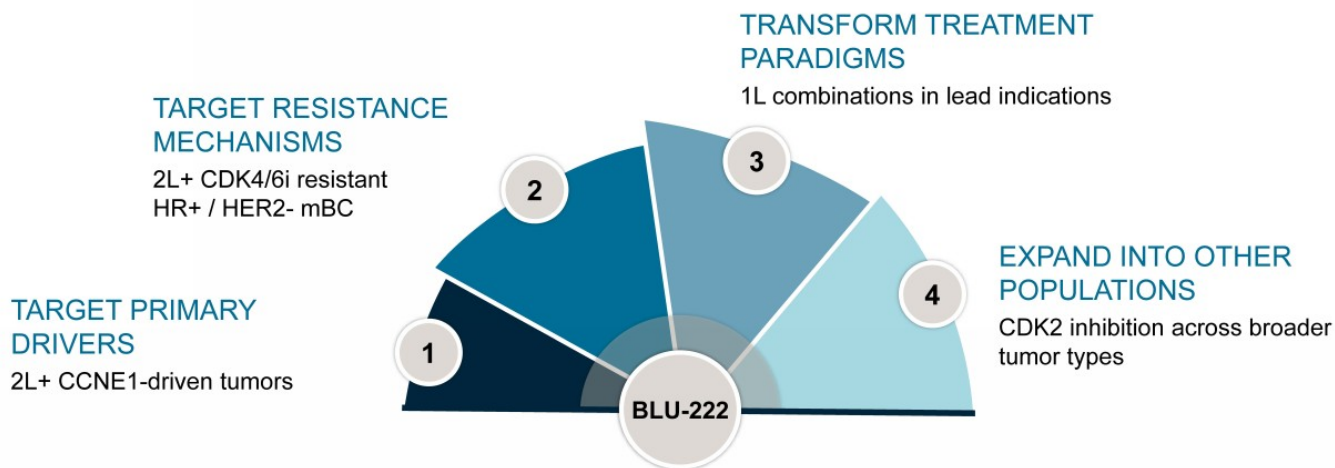
- 1L EGFR L858R mutant NSCLC



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1L, first-line. ctDNA, circulating tumor DNA. NSCLC, non-small cell lung cancer. R, randomized. RP2D, recommended Phase 2 dose.

Our goal is to establish BLU-222 as the essential component of treatment paradigms for cancers vulnerable to CDK2 inhibition



VELA trial dose escalation data, including RP2D, translational and initial combination safety, anticipated in 1H 2023



Blueprint is uniquely positioned with a diversity of significant growth drivers



SYSTEMIC
MASTOCYTOSIS

>\$1.5B

estimated global peak
revenue opportunity¹



LUNG
CANCER

~\$5B

osimertinib global
sales in 2021²



BREAST
CANCER

~\$8B

CDK4/6 inhibitor global
sales in 2021²



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¹ Blueprint Medicines estimate. ² Based on company reports.



Key anticipated portfolio milestones in 2023

Area	Program	Milestone	Timing
Mast cell disorders	AYVAKIT	Present registrational PIONEER trial data in indolent SM at AAAAI Annual Meeting	Feb 2023
	AYVAKYT	Achieve EMA validation of a type II variation MAA for indolent SM	1H 2023
	AYVAKIT	Achieve FDA approval and initiate U.S. launch in indolent SM	Mid 2023
	Research	Nominate a development candidate targeting wild-type KIT for chronic urticaria	Mid 2023
	Elenestinib	Present Part 1 HARBOR trial data in indolent SM	2H 2023
EGFRm NSCLC	BLU-525	Submit IND to FDA	1H 2023
	BLU-451	Present initial CONCERTO trial dose escalation data in EGFR exon 20 NSCLC	1H 2023
	BLU-945	Provide initial update on SYMPHONY trial expansion in 1L L858R	2H 2023
CDK2 vulnerable cancers	BLU-222	Present initial VELA trial dose escalation data	1H 2023



Blueprint 2027: Doubling our impact, in half the time



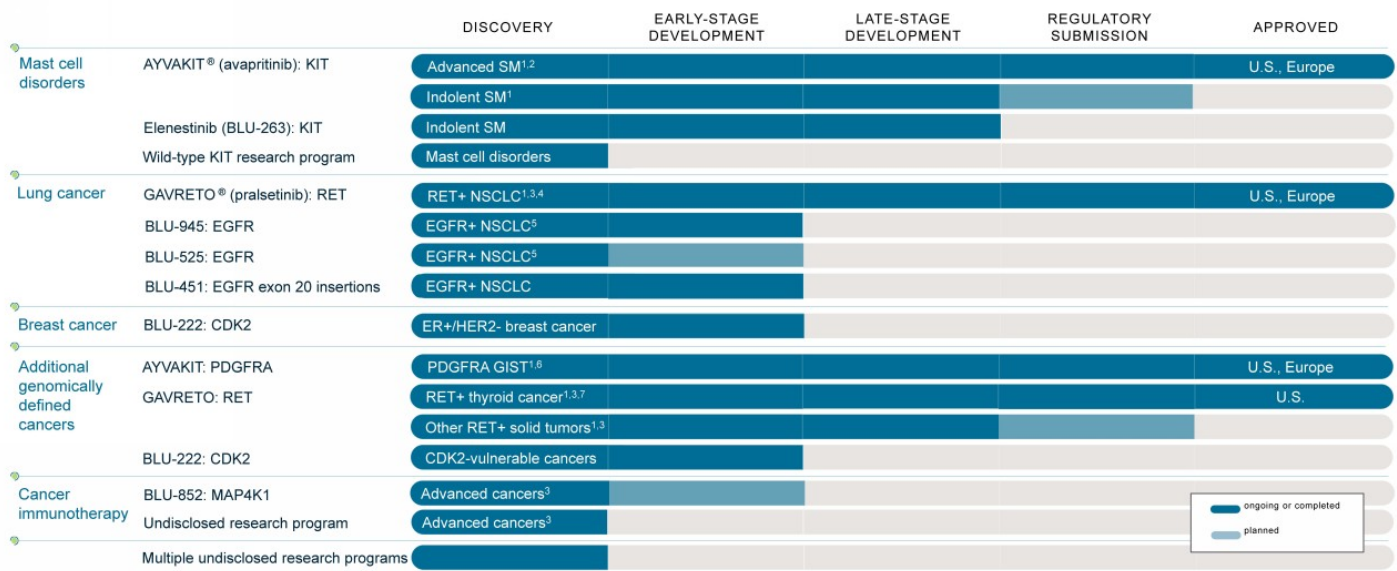
	2011-2022		Planned 2022-2027
Approved medicines	2	▶	4+
Disease leadership areas	1		3+
Late-stage clinical programs	2		4+
Research platforms	1		2
Cumulative development candidates	14		25+



precision at scale™



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1. CStone Pharmaceuticals has exclusive rights to develop and commercialize avapritinib and pralsetinib in Greater China. 2. Approved in the U.S. for adults with advanced SM, including aggressive SM (ASM), SM with an associated hematological neoplasm (SM-AHN) and mast cell leukemia (MCL). Approved in Europe (AYVAKIT®) for adults with ASM, SM-AHN or MCL, after at least one systemic therapy. 3. In collaboration with Roche. 4. Received U.S. accelerated approval for adults with metastatic RET fusion-positive NSCLC. Received conditional marketing authorization in Europe for adults with advanced RET fusion-positive NSCLC not previously treated with a RET inhibitor. 5. Zai Lab has exclusive rights to develop and commercialize BLU-945 and BLU-525 in Greater China. 6. Approved in the U.S. for adults with unresectable or metastatic GIST harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. Approved in Europe (AYVAKIT®) for adults with unresectable or metastatic GIST harboring the PDGFRA D842V mutation. 7. Received U.S. accelerated approval for advanced or metastatic RET-mutant medullary thyroid cancer and RET fusion-positive thyroid cancer.

