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): **November 8, 2021**

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 1.01 Entry into a Material Definitive Agreement.

On November 8, 2021, Blueprint Medicines Corporation (the "Company") entered into an exclusive Collaboration and License Agreement (the "Zai Lab Collaboration Agreement") with Zai Lab (Shanghai) Co. Ltd ("Zai Lab"), pursuant to which the Company granted Zai Lab rights to develop and exclusively commercialize the Company's drug candidates BLU-945 and BLU-701 and certain other forms thereof, including back-up compounds (the "Licensed Products"), in Mainland China, Hong Kong, Macau and Taiwan (each, a "region" and collectively, the "Territory"), either as a monotherapy or in combinations together or with other agents. The Company will retain exclusive rights to the Licensed Products outside the Territory.

Subject to the terms of the Zai Lab Collaboration Agreement, the Company will receive an upfront cash payment of $25.0 million and will be eligible to receive up to $590.0 million in contingent milestone payments. In addition, Zai Lab will be obligated to pay the Company tiered percentage royalties on a Licensed Product-by-Licensed Product basis ranging from the low-teens to mid-teens on annual net sales of each Licensed Product in the Territory, subject to adjustment in specified circumstances. Royalties will be payable on a Licensed Product-by-Licensed Product and region-by-region basis until the later of (i) 12 years after the first commercial sale of a Licensed Product in a region in the Territory, (ii) the date of expiration of the last valid patent claim of the Company's patent rights or any joint collaboration patent rights related to the Licensed Product that covers the Licensed Product (including any use thereof that is on the approved label in such region or manufacture thereof) in such region and (iii) the expiration of the last regulatory exclusivity for the Licensed Product in such region. Zai Lab will be responsible for costs related to the development of the Licensed Products in the Territory.

Pursuant to the terms of the Zai Lab Collaboration Agreement, Zai Lab will be responsible for conducting all development and commercialization activities in the Territory related to the Licensed Products. Under the Zai Lab Collaboration Agreement, each party has granted the other party specified intellectual property licenses to enable the other party to perform its obligations and exercise its rights under the Zai Lab Collaboration Agreement, including license grants to enable each party to conduct research, development and commercialization activities pursuant to the terms of the Zai Lab Collaboration Agreement.

The Zai Lab Collaboration Agreement will continue on a Licensed Product-by-Licensed Product and region-by-region basis until the expiration of all payment obligations under the agreement. Subject to the terms of the Zai Lab Collaboration Agreement, Zai Lab may terminate the Zai Lab Collaboration Agreement in its entirety for convenience by providing written notice to the Company after November 8, 2023. In addition, the Company may terminate the Zai Lab Collaboration Agreement under specified circumstances if Zai Lab or certain other parties challenge the Company's patent rights or any joint collaboration patent rights or if Zai Lab or its affiliates do not conduct any material development or commercialization activities with respect to one or more Licensed Products for a specified period of time, subject to specified exceptions. Either party may terminate the Zai Lab Collaboration Agreement for the other party's uncured material breach or insolvency. In certain termination circumstances, the parties are entitled to retain specified licenses to be able to continue to exploit the Licensed Products, and in the event of termination by Zai Lab for the Company's uncured material breach, the Company will be obligated to pay Zai Lab a low single digit percentage royalty on a Licensed Product-by-Licensed Product on annual net sales of such Licensed Product in the Territory, subject to a cap and other specified exceptions.

The foregoing description of the material terms of the Zai Lab Collaboration Agreement is qualified in its entirety by reference to the complete text of the Zai Lab Collaboration Agreement, which the Company intends to file, with confidential terms redacted, with the Securities and Exchange Commission ("SEC") as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2021.

Item 7.01 Regulation FD Disclosure.

On November 9, 2021, the Company and Zai Lab issued a joint press release regarding the Zai Lab Collaboration Agreement, a copy of which is being furnished as Exhibit 99.1 to this Current Report on Form 8-K (this "Form 8-K"). The information in this Item 7.01, 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 7.01 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 and Zai Lab (Shanghai) Co. Ltd dated November 9, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and incorporated as Exhibit 101)

Forward-Looking Statements

This Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the Zai Lab Collaboration Agreement, including anticipated milestone and other payments under the Zai Lab Collaboration Agreement; and the Company's strategy, business plans and focus. The words "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 Form 8-K 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 Form 8-K, including the risk factors discussed 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. Any forward-looking statements contained in this Form 8-K represent the Company's 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, the Company explicitly disclaims any obligation to update any forward-looking statements.

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: November 9, 2021

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

Exhibit 99.1

Blueprint Medicines and Zai Lab Announce Strategic Collaboration and License Agreement for BLU-945 and BLU-701 in Greater China

-- Zai Lab obtains exclusive rights to develop and commercialize BLU-945 and BLU-701 in Greater China --

-- Collaboration accelerates and expands global development of Blueprint Medicines' next-generation EGFR inhibitors with plans to bring clinical trials of BLU-945 and BLU-701 to Greater China --

-- Blueprint Medicines to receive $25 million upfront payment, up to $590 million in potential future milestone payments, and royalties --

CAMBRIDGE, Mass., SHANGHAI and SAN FRANCISCO, November 9, 2021 – Blueprint Medicines Corporation (NASDAQ: BPMC) and Zai Lab Limited (NASDAQ: ZLAB; HKEX: 9688) today announced an exclusive collaboration and license agreement for the development and commercialization of BLU-945 and BLU-701 for the treatment of patients with epidermal growth factor receptor (EGFR) -driven non-small cell lung cancer (NSCLC) in Greater China, including mainland China, Hong Kong, Macau and Taiwan. Discovered by Blueprint Medicines, BLU-945 and BLU-701 are investigational next-generation EGFR inhibitors with first-in-class potential.

By combining Blueprint Medicines' precision therapy expertise with Zai Lab's development capabilities and established lung cancer franchise in Greater China, the collaboration aims to accelerate global development of BLU-945 and BLU-701 while addressing significant medical needs in China, where 40-50 percent of patients with NSCLC are believed to harbor EGFR mutations.[1,2,3] Blueprint Medicines will retain all rights to BLU-945 and BLU-701 in the rest of the world.

"With deep development and commercial expertise in oncology across a broad portfolio including multiple precision therapies for lung cancer, Zai Lab is the ideal partner to help us bring to China our vision for transforming the care of patients with EGFR-driven lung cancer," said Jeff Albers, Chief Executive Officer of Blueprint Medicines. "Through this collaboration, we will also propel forward our development program for BLU-945 and BLU-701 with a broad clinical trial footprint in Greater China that complements our development efforts."

"We are excited to enter into this collaboration with Blueprint Medicines, a leader in precision medicine, to bring forward two potential first-in-class EGFR inhibitors exquisitely designed to treat or prevent on-target resistance," said Dr. Samantha Du, Founder, Chairwoman and Chief Executive Officer of Zai Lab. "With more than 800,000 newly diagnosed lung cancer patients annually, one of the highest EGFR mutation rates in the world, and with no available therapies to address on-target resistance to early-generation EGFR therapies, we believe we have a tremendous opportunity to improve patient care in China." [1-4]

While targeted therapies have improved treatment for patients with EGFR-driven NSCLC, resistance inevitably emerges, with the T790M and C797S mutations being highly common on-target resistance mechanisms. Designed to address these challenges, BLU-945 and BLU-701 have the potential to be used either as a monotherapy or in combination, together or with other agents, to overcome or prevent on-target resistance across multiple lines of treatment. In addition, this collaboration enables opportunities to combine BLU-945 or BLU-701 with other Zai Lab lung cancer drug candidates to address off-target resistance mutations.

BLU-945 is a selective, potent EGFR tyrosine kinase inhibitor with activity against EGFR activating mutations combined with the T790M and C797S resistance mutations. It is highly selective over wild-type EGFR and off-target kinases, highlighting its potential to enable tolerable combinations. BLU-945 is currently being evaluated in the Phase 1/2 SYMPHONY trial in patients with previously treated EGFR-driven NSCLC (NCT04862780). BLU-701 is a selective, potent EGFR tyrosine kinase inhibitor with activity against EGFR activating mutations combined with the C797S resistance mutation. It has shown significant central nervous system (CNS) penetration in preclinical studies, which is meaningful because in EGFR-mutant NSCLC patients with baseline brain metastases, up to 40 percent of disease progressions involve CNS metastases.[5]

Subject to the terms of the agreement, Blueprint Medicines will receive an upfront cash payment of $25 million and will be eligible to receive up to $590 million in potential development, regulatory and sales-based milestone payments, and tiered royalties on a product-by-product basis ranging from the low-teens to mid-teens on annual net sales of BLU-945 and BLU-701 in Greater China, subject to adjustment in specified circumstances. In addition, Zai Lab will be responsible for all the development costs for BLU-945 and BLU-701 occurring in Greater China and will receive the rights to develop and exclusively commercialize BLU-945 and BLU-701 in the region.

About EGFR-Driven NSCLC in China

Lung cancer is the most commonly diagnosed cancer type and the leading cause of cancer death in China.[1] Annually, there are more than 800,000 new cases of lung cancer in China, of which approximately 85 percent are NSCLC.[1,6] EGFR mutations are more common in China than in the United States, occurring in 40-50 percent of NSCLC patients.[1] Third-generation EGFR-tyrosine kinase inhibitors, including osimertinib, are commonly prescribed in China and have emerged as the standard of care for the first-line setting. However, resistance inevitably emerges, leading to disease progression. There are no approved therapies for patients with disease progression following third-generation EGFR treatment.

About BLU-945 and BLU-701

Derived from Blueprint Medicines' proprietary research platform, BLU-945 and BLU-701 are investigational next-generation EGFR non-covalent tyrosine kinase inhibitors. Both treatments are specifically designed to provide comprehensive coverage of the most common activating and on-target resistance mutations, spare wild-type EGFR and other kinases to limit off-target toxicities and enable a range of combination strategies, and treat or prevent central nervous system metastases. BLU-945 is currently being evaluated in the Phase 1/2 SYMPHONY trial in patients with previously treated EGFR-driven NSCLC (NCT04862780). In addition, Blueprint Medicines plans to initiate a Phase 1/2 trial of BLU-701 in the fourth quarter of 2021.

About Blueprint Medicines

Blueprint Medicines is a global precision therapy company that invents life-changing therapies for people with cancer and hematologic 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 genomically defined cancers, systemic mastocytosis, and cancer immunotherapy. For more information, visit www.BlueprintMedicines.com and follow us on Twitter (@BlueprintMeds) and LinkedIn.

About Zai Lab

Zai Lab (NASDAQ: ZLAB; HKEX: 9688) is a patient-focused, innovative, commercial-stage, global biopharmaceutical company focused on developing and commercializing therapies that address medical conditions with unmet needs in oncology, autoimmune disorders and infectious disease. To that end, our experienced team has secured partnerships with leading global biopharmaceutical companies in order to generate a broad pipeline of innovative marketed products and product candidates. We have also built an in-house team with strong product discovery and translational research capabilities and are establishing a pipeline of proprietary product candidates with global rights. Our vision is to become a leading global biopharmaceutical company, discovering, developing, manufacturing and commercializing our portfolio in order to impact human health worldwide.

For additional information about the company, please visit www.zailaboratory.com or follow us at www.twitter.com/ZaiLab_Global.

Cautionary Note Regarding Blueprint Medicines' 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 and approvals, the initiation of clinical trials or the results of ongoing and planned clinical trials; Blueprint Medicines' plans, strategies and timelines to nominate development candidates; 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; and Blueprint Medicines' strategy, goals and anticipated financial performance, 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; 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.

Zai Lab Forward-Looking Statements

This press release contains statements about future expectations, plans and prospects, including, without limitation, statements relating to the potential, benefits, safety and efficacy of BLU-945 and BLU-701; the clinical development of BLU-945 and BLU-701; the potential treatment of epidermal growth factor receptor (EGFR) -driven non-small cell lung cancer (NSCLC) in Greater China; the potential of Zai Lab's commercial business and pipeline programs; the anticipated benefits and potential of Zai Lab's collaboration arrangement with Blueprint Medicines Corporation and other risks and uncertainties associated with drug development and commercialization. These forward-looking statements may contain words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "will," "would" and other similar expressions. Such statements constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are not statements of historical fact nor are they guarantees or assurances of future performance. Forward-looking statements are based on our expectations and assumptions as of the date of this press release and are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including but not limited to (1) our ability to successfully commercialize and generate revenue from our approved products; (2) our ability to finance our operations and business initiatives and obtain funding for such activities, (3) our results of clinical and pre-clinical development of our product candidates, (4) the content and timing of decisions made by the relevant regulatory authorities regarding regulatory approvals of our product candidates, (5) the effects of the novel coronavirus (COVID-19) pandemic on our business and general economic, regulatory and political conditions and (6) the risk factors identified in our most recent annual or quarterly report and in other reports we have filed with the U.S. Securities and Exchange Commission. We anticipate that subsequent events and developments will cause our expectations and assumptions to change and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

References

[1] Zhang YL, Yuan JQ, Wang KF, et al. “The prevalence of EGFR mutation in patients with non-small cell lung cancer: a systematic review and meta-analysis”. *Oncotarget*. 2016;7(48):78985-78993. doi:10.18632/oncotarget.12587

[2] Zhou J, Song XB, He H, et al. “Prevalence and Clinical Profile of EGFR Mutation In Non- Small-Cell Lung Carcinoma Patients in Southwest China”. *Asian Pac J Cancer Prev*. 2016;17(3):965-71. doi: 10.7314/apjcp.2016.17.3.965. PMID: 27039821.

[3] Wen S, Dai L, Wang L, et al. “Genomic Signature of Driver Genes Identified by Target Next-Generation Sequencing in Chinese Non-Small Cell Lung Cancer”. *Oncologist*. 2019 Nov;24(11):e1070-e1081. doi: 10.1634/theoncologist.2018-0572. Epub 2019 Mar 22. PMID: 30902917; PMCID: PMC6853120.

[4] International Agency for Research on Cancer, Estimated New Incidence in 2020, lung, both sexes, all ages. https://gco.iarc.fr/today/online-analysis-pie?v=2020&mode=population&mode_population=countries&population=900&populations=900&key=total&sex=0&cancer=15&type=0&statistic=5&prevalence=0&population_group=0&ages_group%5B%5D=0&ages_group%5B%5D=1 Accessed November 6, 2021.

[5] Rangachari D, Yamaguchi N, VanderLaan PA, et al. “Brain metastases in patients with EGFR-mutated or ALK-rearranged Non-Small Cell lung cancers”. *Lung Cancer* 2015;88:108-11.

[6] Govindan R, Page N, Morgensztern D, et al. “Changing epidemiology of small-cell lung cancer in the United States over the last 30 years: analysis of the surveillance, epidemiologic, and end results database.” *J Clin Oncol*. 2006 Oct 1;24(28):4539-44. doi: 10.1200/JCO.2005.04.4859. PMID: 17008692.

Trademarks

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