

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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FORM 8-K

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**CURRENT REPORT**  
**Pursuant to Section 13 or 15(d)**  
**of the Securities Exchange Act of 1934**

Date of Report (Date of Earliest Event Reported): **June 1, 2018**

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**Blueprint Medicines Corporation**  
(Exact name of registrant as specified in its charter)

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**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)

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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.

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### **Item 1.01 Entry into a Material Definitive Agreement.**

On June 1, 2018, Blueprint Medicines Corporation (the “Company”) entered into a Collaboration and License Agreement (the “CStone Collaboration Agreement”) with CStone Pharmaceuticals (“CStone”), pursuant to which the Company granted CStone exclusive rights to develop and commercialize the Company’s drug candidates avapritinib, BLU-554 and BLU-667, including back-up forms and certain other forms thereof (the “Licensed Products”), in Mainland China, Hong Kong, Macau and Taiwan (each, a “region” and collectively, the “Territory”), either as a monotherapy or as part of a combination therapy. The Company will retain exclusive rights to the Licensed Products outside the Territory.

Subject to the terms of the CStone Collaboration Agreement, the Company will receive an upfront cash payment of \$40.0 million and will be eligible to receive up to approximately \$346.0 million in milestone payments, including \$118.5 million related to development and regulatory milestones and \$227.5 million related to sales-based milestones. In addition, CStone will be obligated to pay the Company tiered percentage royalties on a Licensed Product-by-Licensed Product basis ranging from the mid-teens to low twenties on annual net sales of each Licensed Product in the Territory, subject to adjustment in specified circumstances. CStone will be responsible for costs related to the development of the Licensed Products in the Territory, other than specified costs related to the development of BLU-554 as a combination therapy in the Territory that will be shared by the Company and CStone.

Pursuant to the terms of the CStone Collaboration Agreement, CStone will be responsible for conducting all development and commercialization activities in the Territory related to the Licensed Products, and the Company and CStone plan to conduct a proof-of-concept clinical trial in China evaluating BLU-554 in combination with CS1001, a clinical stage anti-programmed death ligand-1 (“PD-L1”) immunotherapy being developed by CStone, as a first-line therapy for the treatment of patients with hepatocellular carcinoma (“HCC”).

Subject to specified exceptions, during the term of the CStone Collaboration Agreement, each party has agreed that neither it nor its affiliates will conduct specified development and commercialization activities in the Territory related to selective inhibitors of FGFR4, KIT, PDGFR $\alpha$  and RET. In addition, under the CStone 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 CStone Collaboration Agreement, including license grants to enable each party to conduct research, development and commercialization activities pursuant to the terms of the CStone Collaboration Agreement.

The CStone Collaboration Agreement will continue 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 and (ii) the date of expiration of the last valid patent claim related to the Company’s patent rights or any joint collaboration patent rights for the Licensed Product that covers the composition of matter, method of use or method of manufacturing such Licensed Product in such region. Subject to the terms of the CStone Collaboration Agreement, CStone may terminate the CStone Collaboration Agreement in its entirety or with respect to one or more Licensed Products for convenience by providing written notice to the Company after June 1, 2019, and CStone may terminate the CStone Collaboration Agreement with respect to a Licensed Product for convenience at any time by providing written notice to the Company following the occurrence of specified events. In addition, the Company may terminate the CStone Collaboration Agreement under specified circumstances if CStone or certain other parties challenges the Company’s patent rights or any joint collaboration patent rights or if CStone 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 CStone 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 CStone for the Company’s uncured material breach, the Company will be obligated to pay CStone 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 CStone Collaboration Agreement is qualified in its entirety by reference to the complete text of the CStone 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 Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018.

**Item 7.01 Regulation FD Disclosure.**

On June 4, 2018, the Company and CStone issued a joint press release regarding the CStone 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 8.01 Other Events.**

In the second quarter of 2018, the Company achieved a \$10.0 million research milestone under its Collaboration and License Agreement (the “Roche Collaboration Agreement”) with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. (collectively, “Roche”), which the Company expects to receive by the end of the second quarter of 2018.

The Company expects that its cash, cash equivalents and investments of \$621.1 million as of March 31, 2018, together with the \$10.0 million milestone payment under the Roche Collaboration Agreement and the \$40.0 million upfront cash payment under the CStone Collaboration Agreement but excluding any potential additional option fees, milestone payments or other payments under the Roche Collaboration Agreement and the CStone Collaboration Agreement, will be sufficient to enable it to fund its operating expenses and capital expenditure requirements into the second half of 2020.

**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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#"><u>Press release issued by Blueprint Medicines Corporation and CStone Pharmaceuticals on June 4, 2018</u></a>

**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 CStone Collaboration Agreement, including anticipated milestone and other payments under the CStone Collaboration Agreement; plans and timelines for initiating a proof-of-concept clinical trial in China evaluating BLU-554 in combination with CS1001, CStone’s clinical-stage anti-PD-L1 immunotherapy, as a first-line therapy for patients with HCC; statements about the Company’s expectations regarding the Company’s ability to fund its operating expenses and capital expenditure requirements into the second half of 2020; 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 Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, as filed with the SEC on May 2, 2018, and any other filings that the Company has made or may make with the SEC in the future. 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: June 4, 2018

By: /s/ Jeffrey W. Albers

Jeffrey W. Albers

Chief Executive Officer



**Blueprint Medicines and CStone Pharmaceuticals Announce Exclusive Collaboration and License Agreement to Develop and Commercialize Avapritinib, BLU-554 and BLU-667 in Greater China**

- Combines Blueprint Medicines' Lead Clinical Programs with CStone Pharmaceutical's Regional Expertise --
- Expands BLU-554 Development Program in Hepatocellular Carcinoma with Plans to Bring Ongoing Monotherapy Trial to China and Initiate Proof-of-Concept Combination Trial with CS1001 in China --
- Blueprint Medicines to Receive \$40 Million Upfront Payment and is Eligible to Receive Up to \$346 Million in Potential Development, Regulatory and Sales-Based Milestones --

CAMBRIDGE, Mass. and SUZHOU, China, June 4, 2018 – Blueprint Medicines Corporation (NASDAQ:BPMC), a leader in discovering and developing targeted kinase medicines for patients with genomically defined diseases, and CStone Pharmaceuticals, a privately-held biopharmaceutical company devoted to developing a new generation of innovative drugs, today announced an exclusive collaboration and license agreement for the development and commercialization of avapritinib, BLU-554 and BLU-667 in Mainland China, Hong Kong, Macau and Taiwan, either as monotherapies or combination therapies. Discovered and developed by Blueprint Medicines, avapritinib, BLU-554 and BLU-667 are potent and highly selective investigational kinase medicines that have each demonstrated clinical proof-of-concept in genomically defined subsets of patients with cancer. Blueprint Medicines will retain all rights to the licensed products in the rest of the world.

The collaboration strengthens CStone Pharmaceuticals' portfolio with exclusive rights in the territory to three clinical-stage targeted therapies and expands Blueprint Medicines' global efforts to address patient populations with high unmet needs. CStone Pharmaceuticals will lead clinical development of the licensed products in the territory by leveraging its regulatory expertise and broad local network, with the goal of commercializing the licensed products in the territory either as monotherapies or combination therapies. In addition, the companies plan to initiate a proof-of-concept clinical trial in China evaluating BLU-554 in combination with CS1001, a clinical-stage anti-programmed death ligand-1 (PD-L1) immunotherapy being developed by CStone Pharmaceuticals, as a first-line therapy for patients with hepatocellular carcinoma (HCC).

"Founded by seasoned executives with deep global and regional development experience and with a growing portfolio of potentially complementary cancer therapies, CStone Pharmaceuticals is an ideal partner in China," said Jeff Albers, Chief Executive Officer of Blueprint Medicines. "With recent regulatory reforms in China and the emergence of innovative companies like CStone Pharmaceuticals, we believe this forward-looking collaboration has the potential to expand our ability to address significant patient needs in Greater China while supporting global development of avapritinib, BLU-554 and BLU-667. In particular, we are excited to announce the expansion of the BLU-554 clinical development program in China, where more than half of all new cases of hepatocellular carcinoma worldwide occur each year."

"We are thrilled to enter into this collaboration with Blueprint Medicines, a leader in the discovery and development of highly selective kinase medicines, as the first step in a potentially long-term strategic partnership," said Frank Jiang, Chief Executive Officer of CStone Pharmaceuticals. "Based on the compelling clinical data reported to date, we believe Blueprint Medicines' targeted therapies – avapritinib, BLU-554 and BLU-667 – hold promise for dramatically altering the treatment landscape for patients in China with gastrointestinal stromal tumors, hepatocellular carcinoma, non-small cell lung cancer and other cancers. In addition, our rich pipeline of investigational cancer medicines enables exploration of combination treatment approaches with the potential to further improve patient outcomes worldwide."

Subject to the terms of the agreement, Blueprint Medicines will receive an upfront cash payment of \$40.0 million and will be eligible to receive up to approximately \$346.0 million in potential milestone payments, including \$118.5 million related to development and regulatory milestones and \$227.5 million related to sales-based milestones. In addition, CStone Pharmaceuticals will be obligated to pay Blueprint Medicines tiered percentage royalties on a

licensed product-by-licensed product basis ranging from the mid-teens to low twenties on annual net sales of each licensed product in the territory, subject to adjustment in specified circumstances.

Pursuant to the terms of the agreement, CStone Pharmaceuticals will be responsible for conducting all development and commercialization activities in the territory related to the licensed products. In addition, CStone Pharmaceuticals will be responsible for costs related to the development of the licensed products in the territory, other than specified costs related to the development of BLU-554 as a combination therapy in the territory that will be shared by the companies.

#### **About Avapritinib**

Avapritinib is an orally available, potent and highly selective inhibitor of KIT and PDGFR $\alpha$ . Preclinical data have shown that avapritinib is active across a broad spectrum of KIT and PDGFR $\alpha$  mutations, including KIT D816V, PDGFR $\alpha$  D842V and KIT exon 17 mutations, for which there are limited or no effective treatment options. Blueprint Medicines is initially developing avapritinib, an investigational medicine, for the treatment of patients with advanced gastrointestinal stromal tumors (GIST) and advanced systemic mastocytosis.

In June 2017, avapritinib received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the treatment of patients with unresectable or metastatic GIST harboring the PDGFR $\alpha$  D842V mutation. Previously, the FDA granted orphan drug designation and fast track designation to avapritinib. In addition, the European Commission has granted orphan drug designation to avapritinib. In May 2018, Blueprint Medicines announced plans to submit a New Drug Application to the FDA for avapritinib for the treatment of PDGFR $\alpha$  D842V-driven GIST in the first half of 2019.

#### **About BLU-554**

BLU-554 is an orally available, potent, irreversible inhibitor of FGFR4. BLU-554 was specifically designed by Blueprint Medicines to inhibit FGFR4 with exquisite selectivity, thereby sparing the paralogs FGFR1, FGFR2 and FGFR3. Blueprint Medicines is developing BLU-554, an investigational medicine, for the treatment of patients with FGFR4-activated HCC. Blueprint Medicines estimates that approximately 30 percent of patients with HCC have tumors with aberrantly activated FGFR4 signaling. The FDA has granted orphan drug designation to BLU-554.

#### **About BLU-667**

BLU-667 is an orally available, potent and highly selective inhibitor designed to target RET fusions, mutations and predicted resistance mutations. Blueprint Medicines is developing BLU-667, an investigational medicine, for the treatment of patients with RET-altered non-small cell lung cancer (NSCLC), medullary thyroid cancer and other solid tumors. BLU-667 was discovered by Blueprint Medicine's research team leveraging its proprietary compound library. The FDA has granted orphan drug designation to BLU-667.

#### **About CS1001**

CS1001 is an investigational monoclonal antibody directed against PD-L1 being developed by CStone Pharmaceuticals. Authorized by the U.S.-based Ligand Corporation, CS1001 is a monoclonal antibody developed by the OMT transgenic animal platform, which can generate fully human antibodies in one step. As a fully human, full-length anti-PD-L1 monoclonal antibody, CS1001 mirrors natural G-type immune globulin 4 (IgG4) human antibody, which could reduce the risk of immunogenicity and potential toxicities in patients, a unique advantage over similar drugs.

A first-in-human Phase I study (CS1001-101) has been conducted by CStone Pharmaceuticals since October 2017 to evaluate the safety, tolerability, pharmacokinetics and anti-tumor activity of CS1001 in patients with advanced tumors in China. The Phase Ia (dose escalation) portion was completed in May 2018, and the Phase Ib (dose

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expansion) portion has recently started patient recruitment. In parallel, several pivotal studies are underway, including tumor types with high incidence and prevalence rates in China.

### **About Blueprint Medicines**

Blueprint Medicines is developing a new generation of targeted and potent kinase medicines to improve the lives of patients with genomically defined diseases. Its approach is rooted in a deep understanding of the genetic blueprint of cancer and other disease driven by the abnormal activation of kinases. Blueprint Medicines is advancing multiple programs in clinical development for subsets of patients with gastrointestinal stromal tumors, hepatocellular carcinoma, systemic mastocytosis, non-small cell lung cancer, medullary thyroid cancer and other advanced solid tumors, as well as multiple programs in research and preclinical development. For more information, please visit [www.blueprintmedicines.com](http://www.blueprintmedicines.com).

### **About CStone Pharmaceuticals**

CStone Pharmaceuticals is a clinical stage biopharmaceutical company devoted to the development of innovative drugs. With a broad pipeline, the company engages in the development of cancer therapeutics with a special focus on immunoncology based combination therapies. All members of the management team are seasoned executives from top multinational pharmaceutical companies. CStone has successfully built up its core competency in clinical development and translational medicine. The company is backed by prestigious VC/PE funds via two financing rounds to date, raising \$150 million in a Series A round in July 2016, followed by \$260 million in a Series B round in May 2018. With an experienced team, a rich pipeline, a robust R&D model, and substantial funding, CStone is well positioned as the partner of choice for multinational pharmaceutical / biotech companies to develop drugs in China and the Asia-Pacific region. For more information about CStone Pharmaceuticals, please visit: [www.cstonepharma.com](http://www.cstonepharma.com)

### **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 the collaboration and license agreement between Blueprint Medicines and CStone Pharmaceuticals, including anticipated milestone and other payments under the collaboration; expectations regarding Blueprint Medicines' ability to expand its programs for avapritinib, BLU-554 and BLU-667 globally and in the territory; the potential benefits of Blueprint Medicines' or CStone Pharmaceuticals' current and future drug candidates, whether as a monotherapy or combination therapy, in treating patients, including patients in the territory; expectations regarding the impact of current or future regulatory reforms in the territory; plans and expectations regarding combination treatment approaches with CStone Pharmaceuticals' current or future drug candidates; plans and timelines for expanding Blueprint Medicines' ongoing Phase 1 clinical trial for BLU-554 to the territory; plans and timelines for initiating a proof-of-concept clinical trial in China evaluating BLU-554 in combination with CS1001 as a first-line therapy for patients with HCC; expectations regarding Blueprint Medicines' global efforts to address patient populations with high unmet needs; and Blueprint Medicines' 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 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 delay of any current or planned clinical trials or the development of Blueprint Medicines' drug candidates, including avapritinib, BLU-554, BLU-667 and BLU-782; Blueprint Medicines' advancement of multiple early-stage efforts; Blueprint Medicines' ability to successfully demonstrate the safety and efficacy of its drug candidates; 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 develop and commercialize companion diagnostic tests for its current

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and future drug candidates, including companion diagnostic tests for BLU-554 for FGFR4-driven HCC, avapritinib for PDGFR $\alpha$  D842V-driven GIST and BLU-667 for RET-driven NSCLC; the success of Blueprint Medicines' current and future collaborations, including its cancer immunotherapy collaboration with F. Hoffmann-La Roche Ltd and Hoffmann-La Roche Inc. and its collaboration with CStone Pharmaceuticals. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Blueprint Medicines' Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, as filed with the Securities and Exchange Commission (SEC) on May 2, 2018, 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.

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