

**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): **October 15, 2019**

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 1.01 Entry into a Material Definitive Agreement.

On October 15, 2019, Blueprint Medicines Corporation (the “Company”) entered into a license agreement (the “Agreement”) with Clementia Pharmaceuticals, Inc. (“Clementia”), a wholly-owned subsidiary of Ipsen S.A. Under the Agreement, the Company granted an exclusive, worldwide, royalty-bearing license to Clementia to develop and commercialize BLU-782, the Company’s oral, highly selective investigational ALK2 inhibitor in Phase 1 clinical development for the treatment of fibrodysplasia ossificans progressiva (“FOP”), as well as specified other compounds related to the BLU-782 program (the “Licensed Products”).

Subject to the terms of the Agreement, the Company will be eligible to receive up to \$535.0 million in upfront, milestone and other payments, including an upfront cash payment of \$25.0 million and up to \$510.0 million in other payments and potential development, regulatory and sales-based milestone payments for Licensed Products. In addition, Clementia is obligated to pay to the Company royalties on aggregate annual worldwide net sales of Licensed Products at tiered percentage rates ranging from the low- to mid-teens, subject to adjustment in specified circumstances under the Agreement, and to purchase specified manufacturing inventory from the Company.

Under the terms of the Agreement, the Company will be responsible for specified activities during a transition period, including the completion of all activities necessary for database lock for its ongoing Phase 1 clinical trial in healthy volunteers, and Clementia will be responsible for conducting all other development and commercialization activities related to the Licensed Products, including the design, timing and conduct of any Phase 2 clinical trial evaluating BLU-782 for the treatment of FOP.

During the term of the Agreement, the Company has agreed not to exploit any compound covered by the licensed patents for the treatment of FOP or multiple osteochondromas (“MO”). In addition, with respect to any small molecule compound not covered by the licensed patents, the Company has agreed not to research, develop or manufacture any small molecule compound for the treatment of FOP or MO for a period of five years from the effective date of the Agreement and not to commercialize any small molecule compound for the treatment of FOP or MO for a period of seven years from the effective date of the Agreement.

Unless earlier terminated in accordance with the terms of the Agreement, the Agreement will expire on a country-by-country, Licensed Product-by-Licensed Product basis on the date when no royalty payments are or will become due. Clementia may terminate the Agreement at any time on or after the second anniversary of the effective date of the Agreement upon at least 12 months’ prior written notice to the Company, which cannot be delivered before the first anniversary of the effective date of the Agreement. Either party may terminate the Agreement for the other party’s uncured material breach or insolvency and in certain other circumstances agreed to by the parties. In certain termination circumstances, the Company is entitled to retain specified licenses to be able to continue to exploit the Licensed Products.

The foregoing description of the material terms of the Agreement is qualified in its entirety by reference to the complete text of the Agreement, which the Company intends to file, with confidential terms redacted, with the SEC as an exhibit to the Company’s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2019.

Item 7.01 Regulation FD Disclosure.

On October 16, 2019, the Company issued a press release regarding the 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 and 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.

Based on its current operating plans, the Company expects that its cash, cash equivalents and investments of \$667.3 million as of June 30, 2019, together with the \$25.0 million upfront cash payment but excluding any potential option fees, milestone payments or other payments under its existing collaborations or the Agreement, will be sufficient to enable it to fund its operating expenses and capital expenditure requirements into the second half of 2021.

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 potential development and commercialization of BLU-782 or any other Licensed Products by Clementia under the Agreement; potential payments under the Agreement, including the upfront payment and any milestone, royalty or other payments; potential benefits of the Agreement between the Company and Clementia; expectations regarding the Company's existing and future cash, cash equivalents and investments; and the Company's strategy, goals and anticipated milestones, 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, without limitation, risks and uncertainties related to the delay of any current or planned clinical trials or the development of the Company's drug candidates or the Licensed Products, including BLU-782; the ability of the Company and Clementia to terminate the Agreement under specified circumstances; preclinical and clinical results for BLU-782 that may not support further development of such drug candidate, including expectations that such results may be predictive of the results in future clinical trials; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials or the regulatory pathway for the Licensed Products; and Clementia's ability to successfully develop and commercialize the Licensed Products, including BLU-782. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Blueprint Medicines' filings with the SEC, including the Company's 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. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Blueprint Medicines Corporation on October 16, 2019
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: October 16, 2019

By: /s/ Jeffrey W. Albers

Jeffrey W. Albers

Chief Executive Officer

Ipsen and Blueprint Medicines announce exclusive global license agreement to develop and commercialize BLU-782 for the treatment of fibrodysplasia ossificans progressiva (FOP)

-- Expands Ipsen's Rare Diseases portfolio to include BLU-782, a highly selective investigational ALK2 inhibitor for the treatment of FOP --

-- Accelerates global development of BLU-782 through Ipsen's clinical expertise in rare diseases and global infrastructure --

-- Blueprint Medicines is eligible to receive up to \$535 million, including a \$25 million upfront payment and up to \$510 million in potential development, regulatory and sales-based milestones and other payments, plus tiered percentage royalties --

PARIS, France and CAMBRIDGE, Mass., USA, OCTOBER 16, 2019 /PRNewswire/ -- Ipsen (Euronext: IPN; ADR: IPSEY) and Blueprint Medicines Corporation (NASDAQ: BPMC) today announced Ipsen, through its subsidiary Clementia Pharmaceuticals, and Blueprint Medicines have entered into an exclusive, worldwide license agreement for the development and commercialization of BLU-782, an oral, highly selective investigational ALK2 inhibitor being developed for the treatment of fibrodysplasia ossificans progressiva (FOP).

The agreement enhances Ipsen's Rare Diseases portfolio and advances Blueprint Medicines' goal of rapidly and efficiently developing BLU-782 as a potential treatment for patients with FOP. Ipsen has demonstrated its commitment to leadership in this complex ultra-rare genetic disorder through the ongoing late-stage clinical development of palovarotene, an investigational retinoic acid receptor gamma (RAR γ) agonist. With the addition of BLU-782, which recently completed dosing in a Phase 1 study in healthy volunteers, Ipsen has the potential to offer the broadest possible suite of treatment options for patients with FOP.

"Our strategy has been to build a leading Rare Diseases franchise, and through the recent acquisition of Clementia, we gained a first-in-class asset in palovarotene. Now, with the addition of Blueprint Medicines' BLU-782, we have two strong complementary drug candidates. We will continue to develop and deliver valuable treatments for patients around the world living with FOP and other rare diseases," said David Meek, CEO, Ipsen.

"We admire Ipsen's track record of successful global clinical development in this complex, ultra-rare genetic disorder and believe this expertise, combined with Ipsen's global infrastructure and commitment to transforming the treatment of FOP, will accelerate the development of BLU-782 globally," said Jeff Albers, CEO, Blueprint Medicines. *"We are inspired by the FOP community, including the patients, families, clinicians and advocacy groups we have had the fortune to work with, as we have advanced this program from an idea to BLU-782, the first investigational therapy targeting ALK2, the genetic driver of FOP, to enter clinical development. We are also grateful for the dedication and drive of our team at Blueprint Medicines whose tireless commitment has brought BLU-782 this far."*

Subject to the terms of the license agreement, Blueprint Medicines will be eligible to receive up to \$535 million in upfront, milestone and other payments, including an upfront cash payment of \$25 million and up to \$510 million in potential milestone payments related to specified development, regulatory and sales-based milestones for licensed products in up to two indications, including FOP. In addition, Ipsen will pay Blueprint Medicines tiered percentage royalties ranging from the low- to mid-teens on worldwide aggregate annual net sales of licensed products, subject to adjustment in specified circumstances under the license agreement.

About BLU-782

BLU-782 was designed by Blueprint Medicines to selectively target mutant ALK2, the underlying cause of FOP, using Blueprint Medicines' proprietary scientific platform. Blueprint Medicines recently completed dosing in a Phase 1 clinical trial of BLU-782 in healthy volunteers and reported preliminary data at the American Society of Bone and Mineral Research Annual Meeting in September 2019, which showed that BLU-782 was well-tolerated at all doses tested. Previously reported preclinical data in a well-characterized, genetically accurate

FOP model showed that BLU-782 prevented injury- and surgery-induced heterotopic ossification, reduced edema and restored healthy tissue response to muscle injury. The FDA has granted a rare pediatric disease designation, orphan drug designation and fast track designation to BLU-782.

About fibrodysplasia ossificans progressiva (FOP)

FOP is a rare, severely disabling genetic disorder characterized by progressive heterotopic ossification (HO), or the abnormal transformation of muscle, ligaments and tendons into bone. HO may be spontaneous or associated with painful episodic disease flare-ups that are usually precipitated by soft tissue injury. As the disease progresses, extra-skeletal bone increasingly restricts joints, resulting in severe disability and loss of mobility, compromised respiratory function and increased risk of early death. FOP is caused by a mutation in the gene for ALK2, which is known as ACVR1, leading to inappropriate activation of the bone morphogenetic pathway.

About Ipsen

Ipsen is a global specialty-driven biopharmaceutical group focused on innovation and Specialty Care. The Group develops and commercializes innovative medicines in three key therapeutic areas – Oncology, Neuroscience and Rare Diseases. Its commitment to oncology is exemplified through its growing portfolio of key therapies for prostate cancer, neuroendocrine tumors, renal cell carcinoma and pancreatic cancer. Ipsen also has a well-established Consumer Healthcare business. With total sales over €2.2 billion in 2018, Ipsen sells more than 20 drugs in over 115 countries, with a direct commercial presence in more than 30 countries. Ipsen's R&D is focused on its innovative and differentiated technological platforms located in the heart of the leading biotechnological and life sciences hubs (Paris-Saclay, France; Oxford, UK; Cambridge, US). The Group has about 5,700 employees worldwide. Ipsen is listed in Paris (Euronext: IPN) and in the United States through a Sponsored Level I American Depository Receipt program (ADR: IPSEY). For more information on Ipsen, visit www.ipsen.com.

About Blueprint Medicines

Blueprint Medicines is a precision therapy company striving to improve human health. With a focus on genomically defined cancers, rare diseases and cancer immunotherapy, we are developing transformational medicines rooted in our leading expertise in protein kinases, which are proven drivers of disease. Our uniquely targeted, scalable approach empowers the rapid design and development of new treatments and increases the likelihood of clinical success. We are currently advancing three investigational medicines in clinical development, along with multiple research programs. For more information, visit www.BlueprintMedicines.com and follow us on Twitter (@BlueprintMeds) and LinkedIn.

Ipsen—Cautionary Note Regarding Forward-Looking Statements

The forward-looking statements, objectives and targets contained herein are based on the Group's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. All of the above risks could affect the Group's future ability to achieve its financial targets, which were set assuming reasonable macroeconomic conditions based on the information available today. Use of the words "believes", "anticipates" and "expects" and similar expressions are intended to identify forward-looking statements, including the Group's expectations regarding future events, including regulatory filings and determinations. Moreover, the targets described in this document were prepared without taking into account external growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by the Group. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties, notably the fact that a promising product in early development phase or clinical trial may end up never being launched on the market or reaching its commercial targets, notably for regulatory or competition reasons. The Group must face or might face competition from generic products that might translate into a loss of market share. Furthermore, the Research and Development process involves several stages each of which involves the substantial risk that the Group may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Group cannot be certain that favorable results obtained during pre-clinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the product concerned. There can be no guarantees a product will receive the necessary regulatory approvals or that the product will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or

uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements. Other risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Group's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the Group's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions. The Group also depends on third parties to develop and market some of its products which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to the Group's activities and financial results. The Group cannot be certain that its partners will fulfil their obligations. It might be unable to obtain any benefit from those agreements. A default by any of the Group's partners could generate lower revenues than expected. Such situations could have a negative impact on the Group's business, financial position or performance. The Group expressly disclaims any obligation or undertaking to update or revise any forward-looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. The Group's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers. The risks and uncertainties set out are not exhaustive and the reader is advised to refer to the Group's 2018 Registration Document available on its website (www.ipсен.com).

Blueprint Medicines—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 Ipsen's plan to develop and commercialize BLU-782 or any other licensed products under the license agreement; potential payments under the license agreement, including the upfront payment and any milestone or royalty payments; potential benefits of the license agreement between Blueprint Medicines and Ipsen; the potential benefits of BLU-782 or any other licensed product in treating patients, including patients with FOP; and Blueprint Medicines' strategy, goals and anticipated milestones, 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 or the licensed products, including BLU-782; the ability of Blueprint Medicines and Ipsen to terminate the license agreement under specified circumstances; preclinical and clinical results for BLU-782 that may not support further development of such drug candidate, including expectations that such results may be predictive of the results in future clinical trials; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials or the regulatory pathway for the licensed products; and Ipsen's ability to successfully develop and commercialize the licensed products. 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 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.

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