

FIVE PRIME THERAPEUTICS INC
Form 8-K
October 15, 2015

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 14, 2015

Five Prime Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

001-36070
(Commission

File Number)

26-0038620
(I.R.S. Employer

Identification No.)

Two Corporate Drive

94080

South San Francisco, California
(Address of principal executive offices) **(Zip Code)**
Registrant's telephone number, including area code: (415) 365-5600

(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 (see General Instruction A.2. below):

- .. 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))

Item 1.01 Entry into a Material Definitive Agreement

License and Collaboration Agreement

On October 14, 2015, Five Prime Therapeutics, Inc. (FivePrime) entered into a License and Collaboration Agreement (the Agreement) with Bristol-Myers Squibb Company (BMS), pursuant to which BMS acquired exclusive global rights to develop and commercialize certain colony stimulating factor-1 receptor (CSF1R) antibodies, including FivePrime's FPA008 antibody, and all modifications, derivatives, fragments or variants of such antibodies (each, a Licensed Antibody).

Under the terms of the Agreement, BMS will be responsible, at its expense, for developing products containing Licensed Antibodies (each, a Licensed Product) under a development plan (the Development Plan), subject to FivePrime's option, at its own expense (FivePrime Development Expenses), to conduct certain future studies, including registration-enabling studies to support approval of FPA008 in pigmented villonodular synovitis (PVNS) and in combination with FivePrime's proprietary internal or in-licensed compounds, including in oncology (each, a FivePrime Independent Development Path). BMS will have the option prior to FivePrime's commencement of a clinical trial with respect to a FivePrime Independent Development Path to include any such clinical trial in the Development Plan, and BMS would thereafter bear the associated development costs and milestone payments to FivePrime with respect to BMS's development of such FivePrime Independent Development Path. If BMS elects to include in the Development Plan what would have been a FivePrime Independent Development Path clinical trial, BMS would reimburse the FivePrime Development Expenses incurred since the Effective Date (defined below) with respect to such FivePrime Independent Development Path.

If BMS does not add a Five Prime Independent Development Path to the Development Plan before the review of any efficacy data from the first Phase 3 or registration-enabling clinical trial in such Five Prime Independent Development Path, and such Five Prime Independent Development Path indication achieves regulatory approval in the United States or marketing approval in the European Union or Japan, then BMS will reimburse FivePrime an amount equal to 125% of the FivePrime Development Expenses with respect to such Five Prime Independent Development Path.

FivePrime will continue to conduct the current Phase 1a/1b clinical trial to evaluate the safety, tolerability and preliminary efficacy of combining *Opdivo*® (nivolumab), BMS's programmed-death 1 (PD-1) immune checkpoint inhibitor, with FPA008 in six tumor types (the Current Trial), which FivePrime is currently conducting under the Clinical Trial Collaboration Agreement, effective November 21, 2014, between FivePrime and BMS (the Existing Clinical Agreement). BMS will bear all costs and expenses relating to the Current Trial including manufacturing costs for the supply of FPA008, except that FivePrime will be responsible for its own internal costs, including internal personnel costs.

BMS will be responsible for manufacturing and commercialization of each Licensed Product, with FivePrime retaining rights to a minority co-promotion option in the U.S.

Pursuant to the Agreement, BMS will make an upfront payment of \$350 million to FivePrime within 30 days after the Effective Date. Additionally, with respect to each Licensed Product, FivePrime will be eligible to receive up to (i) \$505.0 million in specified developmental and regulatory milestone payments for all combination therapies of such Licensed Product with *Opdivo*®; (ii) \$542.5 million in specified developmental and regulatory milestone payments for combination therapies of such Licensed Product with one or more BMS or FivePrime proprietary products, at least one of which is not *Opdivo*®, in the field of oncology; and (iii) \$340.0 million in specified developmental and regulatory milestone payments for therapeutic uses of such Licensed Product in PVNS and non-oncology indications.

In the event that a milestone with respect to a particular disease or combination (other than any PVNS-related milestones) is achieved by FivePrime acting within its development rights under the Agreement, the milestone payment associated with such milestone would be deferred and become payable by BMS to Five Prime after

achievement of regulatory approval in the United States or marketing approval in the European Union or Japan of the Licensed Product in such disease or combination.

BMS will also be obligated to pay FivePrime, with respect to each Licensed Product in each country, tiered percentage royalties ranging from the high teens to the low twenties, subject to reduction in certain circumstances, on worldwide net sales of such Licensed Product until the latest of (i) the expiration of certain patents covering such Licensed Product in such country, (ii) the date on which any applicable regulatory, pediatric, orphan drug or data exclusivity with respect to such Licensed Product expires in such country, (iii) the date of the first commercial sale in such country of a biosimilar product with respect to such Licensed Product or (iv) 12 years after the first commercial sale of such Licensed Product in such country. Under the Agreement, BMS will be obligated to pay FivePrime an additional low single-digit percentage royalty on net sales in the U.S. in the event FivePrime exercises its co-promotion option. FivePrime cannot determine the date on which BMS's potential royalty payment obligations to FivePrime would expire because BMS has not yet developed any Licensed Products under the Agreement and therefore FivePrime cannot identify the date of the first commercial sale or any related patents covering or regulatory exclusivity periods with respect to such Licensed Product.

Unless earlier terminated by either party, the Agreement will expire on a Licensed Product-by-Licensed Product and country-by-country basis upon the expiration of BMS' s payment obligations with respect to each Licensed Product under the Agreement. BMS may terminate the Agreement in its entirety or on a region-by-region basis at any time with advance written notice. BMS may also terminate the Agreement in its entirety (or on a Licensed Product-by-Licensed Product basis) upon written notice based on certain safety reasons. Either party may terminate the Agreement in its entirety with written notice for the other party' s material breach if such party fails to cure the breach. FivePrime may terminate the Agreement in its entirety with written notice for BMS' s material breach of its diligence obligations with respect to development and obtaining marketing approval, and may terminate the agreement on a region-by-region basis for BMS' s breach of its diligence obligations with respect to timely commercialization of a Licensed Product in a region following marketing approval. Either party also may terminate the Agreement in its entirety upon certain insolvency events involving the other party.

The Agreement is subject to clearance under the Hart-Scott-Rodino Antitrust Improvements Act and will become effective on the date of such clearance (the Effective Date). The Existing Clinical Agreement will terminate upon the Effective Date. If the Effective Date has not occurred within three months after October 14, 2015, the Agreement may be terminated by either party upon written notice.

The foregoing description of the Agreement is only a summary and is qualified in its entirety by reference to the Agreement, a copy of which will be filed as an exhibit to FivePrime' s Annual Report on Form 10-K for the fiscal year ending December 31, 2015.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Words such as *may*, *will*, *expect*, *plan*, *anticipate*, *estimate*, *intend* and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on FivePrime' s expectations and assumptions as of the date of this Current Report on Form 8-K. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this Current Report on Form 8-K include statements regarding the (i) the development of FPA008, including in combination with *Opdivo*[®]; and (ii) FivePrime' s potential receipt of upfront and milestone payments and royalties. Many factors may cause differences between current expectations and actual results including unexpected safety or efficacy data observed during clinical studies, changes in expected or existing competition, changes in the regulatory, pricing or reimbursement environment, and unexpected litigation or other disputes. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this Current Report on Form 8-K are discussed in FivePrime' s most recent Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission, including the *Risk Factors* contained therein. Except as required by law, FivePrime assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
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99.1

Press Release issued October 15, 2015

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: October 15, 2015

Five Prime Therapeutics, Inc.

By: /s/ Francis Sarena
Francis Sarena
Executive Vice President, General Counsel and
Secretary

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release issued October 15, 2015