FIVE PRIME THERAPEUTICS INC
Form 8-K
November 24, 2014

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 21, 2014

Five Prime Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36070**	**26-0038620**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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):

q Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

q Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

q Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

q 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

On November 21, 2014, Five Prime Therapeutics, Inc. (FivePrime) entered into a Clinical Trial Collaboration Agreement (the Agreement) with Bristol-Myers Squibb Company (BMS) pursuant to which FivePrime and BMS will collaborate under a development plan (the Development Plan) to evaluate the safety, tolerability and preliminary efficacy of combining Opdivo (nivolumab), BMS s investigational PD-1 immune checkpoint inhibitor, with FPA008, FivePrime s monoclonal antibody that inhibits colony stimulating factor-1 receptor (CSF1R) (together, the Combined Therapy). Under the Development Plan, BMS and FivePrime plan to initially study the Combined Therapy as a potential treatment for patients with non-small cell lung cancer (NSCLC), melanoma, head and neck cancer, pancreatic cancer, colorectal cancer and malignant glioma in a Phase 1a/1b study, which FivePrime expects to commence by the second half of 2015. BMS and FivePrime may, by mutual agreement, expand the scope of the Development Plan to study the Combined Therapy in clinical studies in additional tumor types under the Agreement. FivePrime is responsible for conducting the clinical study of the Combined Therapy under the Development Plan.

The Agreement provides for exclusivity with respect to the development, with a collaborative partner, of combination regimens of an anti-PD-1 or PD-L1 antagonist together with an anti-CSF1R antagonist (any such combination, a Restricted Combination). If either party would like to conduct a clinical trial to study a Restricted Combination in a particular tumor type that the parties are not then developing or preparing to develop under the Development Plan (a Proposed New Tumor Type), then that party may propose that the parties conduct the clinical trial to study the Combined Therapy under the Development Plan under the Agreement. The non-proposing party will have the right to review such proposed clinical trial and a limited period of time to elect to conduct the clinical trial under the Agreement, which election period will not begin in any event until after (i) certain dose escalation and pharmacodynamic conditions are met in the planned Phase 1a portion of the first clinical study of the Combined Therapy; or (ii) the first subject is dosed in the Phase 1b portion of the first clinical study of the Combined Therapy, whichever is earlier (such earlier date, the Initial Results Date). If the non-proposing party does not elect to conduct the clinical trial under the Agreement within the limited review and election period, the original proposing party may thereafter conduct such clinical trial to study a Restricted Combination in the Proposed Tumor Type and such Proposed Tumor Type would thereafter no longer be exclusive under the Agreement.

Under the terms of the Agreement, BMS will pay FivePrime a one-time fee of $30,000,000. If a change of control of FivePrime closes prior to the Initial Results Date, then if

- immediately prior to such change of control, the acquirer in such change of control (or any of its affiliates) owns or controls an anti-PD-1 or anti-PD-L1 antagonist that is then in clinical development for use in treating cancer or is then being commercialized for use in treating cancer,
- BMS is using commercially reasonable efforts in the performance and fulfillment of its activities under this Agreement,
- the parties are developing or pursuing the development of the Combined Therapy under the Agreement and a change of control of BMS has not occurred,

FivePrime would be obligated to pay to BMS the lesser of (x) $30,000,000 or (y) 10% of the aggregate purchase price paid to FivePrime or the stockholders of FivePrime at the closing of such change of control (with any contingent consideration being risk-adjusted and discounted).

BMS will be responsible for all third party expenses that are directly attributable to the conduct of activities under the Development Plan, other than manufacturing activities. For manufacturing costs related to FPA008, FivePrime will be responsible for the full expense of the manufacture and supply of FPA008 for any Phase 1a clinical study under the Development Plan and FivePrime and BMS shall each be responsible for one half of the full expense of the manufacture and supply of FPA008 for any other clinical study under the Development Plan. BMS is responsible for the full expense of the manufacture and supply of Opdivo for any clinical study under the Collaboration Agreement.

BMS and FivePrime will each be responsible for their own internal costs, including internal personnel costs, incurred in the conduct of activities under the Development Plan.

If FivePrime wishes to out-license the right to commercialize FPA008 in any territory at any time on or before the date that is 90 days after the Initial Results Date (the ROFR Offer Period), then for a period of three months BMS will have the exclusive right to negotiate an exclusive license to develop and commercialize FPA008 in such territory (the Right of First Refusal). If BMS does not exercise its Right of First Refusal or if BMS and FivePrime do not reach an agreement for such exclusive license within the three-month negotiation period, then FivePrime would be free to negotiate the out-license of such rights to FPA008 in such territory; provided that FivePrime must provide BMS 10 business days to match any offer from a third party for such rights received prior to the date that is 90 days after the end of the ROFR Offer Period.

After the ROFR Offer Period, if FivePrime wishes to out-license the right in any territory to commercialize FPA008 for use in cancer, then BMS will have a three-month right of first negotiation to obtain exclusive rights to FPA008 for such territory. If BMS does not exercise its right of first negotiation or if an agreement is not reached between BMS and FivePrime for such rights within such three-month period, then FivePrime would be free to out-license any and all rights to FPA008 for such territory.

Unless earlier terminated by either party, the Agreement will continue until the date that is 90 days after the completion of all clinical trials under the Agreement, the delivery of all study data by both parties and the completion of all obligations under the Development Plan. Either party may terminate the Agreement with written notice (i) if the other party is in material breach and such breach has not been cured within the applicable cure period, (ii) if either party deems it necessary to protect the safety, health or welfare of the subjects enrolled in a clinical trial or (iii) 90 days following the commencement of a clinical hold. Upon any termination of the Agreement, depending upon the circumstances, the parties have varying rights and obligations regarding the completion of any ongoing clinical trials.

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 FivePrime intends to file as an exhibit to its Annual Report on Form 10-K for its fiscal year ending December 31, 2014.

FivePrime issued a press release on November 24, 2014 announcing the Agreement, a copy of which is attached to this Current Report on Form 8-K as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release, dated November 24, 2014.

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.

Five Prime Therapeutics, Inc.

By: /s/ Francis Sarena
Francis Sarena

Senior Vice President, General Counsel & Secretary

Dated: November 24, 2014

EXHIBIT INDEX

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