

bluebird bio, Inc.
Form 8-K
February 17, 2016

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): February 16, 2016

bluebird bio, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE

001-35966

13-3680878

(State or other jurisdiction of
incorporation)

(Commission File Number)

(I.R.S. Employer
Identification No.)

150 Second Street

Cambridge, MA

02141

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (339) 499-9300

Not Applicable

(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))

Item 1.01 Entry into a Material Definitive Agreement.

On February 10, 2016, Celgene Corporation (“Celgene”) exercised its option to exclusively license bb2121 (“bb2121”), the lead anti-BCMA product candidate under the Amended and Restated Collaboration Agreement dated June 3, 2015 (the “Amended Collaboration Agreement”) between Celgene and bluebird bio, Inc. (“bluebird”). In connection with its option exercise, Celgene will pay to bluebird an option exercise payment of \$10.0 million in accordance with the terms of the Amended Collaboration Agreement. On February 16, 2016, the parties entered into the Amended and Restated License Agreement (the “License Agreement”), which provides for, among other matters, Celgene’s exclusive worldwide license to develop and commercialize bb2121. Under the License Agreement, subject to customary “back-up” supply rights granted to Celgene, bluebird has the sole right to manufacture or have manufactured supplies of vectors and associated payloads manufactured for incorporation into bb2121. Celgene will reimburse bluebird for its costs to manufacture and supply such vectors and associated payloads, plus a modest mark-up. bluebird will continue to be responsible for conducting the ongoing CRB-401 Phase 1 clinical study of bb2121 for the treatment of relapsed/refractory multiple myeloma. Following the completion of the CRB-401 Phase 1 clinical study, Celgene will be responsible for all costs and expenses for the development and commercialization of bb2121, subject to bluebird’s co-development and co-promotion option described below.

bluebird may elect to co-develop and co-promote bb2121 in the United States, provided however, if bluebird does not exercise its option to co-develop and co-promote bb2121, then bluebird will not be permitted to exercise its option to co-develop and co-promote any future product candidates under the Amended Collaboration Agreement. If bluebird does not exercise its option to co-develop and co-promote bb2121 in the United States, bluebird will be eligible to receive up to \$10.0 million in clinical milestone payments, up to \$117.0 million in regulatory milestone payments and up to \$78.0 million in commercial milestone payments, in addition to the option fee. bluebird will also be eligible to receive a percentage of net sales as a royalty in a range from the mid-single digits to low-teens. The royalties payable to bluebird are subject to certain reductions, including for any royalty payments required to be made by Celgene to acquire patent rights, with an aggregate minimum floor.

If bluebird elects to co-develop and co-promote bb2121 in the United States, then bluebird and Celgene would share equally in all costs incurred relating to the development, commercialization and manufacture of bb2121 within the United States and share equally in the profits generated by bb2121 in the United States. Additionally, if bluebird elects to co-develop and co-promote bb2121, then the milestones and royalties would decrease compared to those described above. Under this scenario, bluebird would receive up to \$10.0 million in clinical milestone payments and outside of the United States, up to \$54.0 million in regulatory milestone payments and up to \$36.0 million in commercial milestone payments, in addition to the option fee. Furthermore, to the extent any of the product candidates licensed by Celgene and co-developed and co-promoted by bluebird are commercialized, bluebird would be entitled to receive tiered royalty payments ranging from the mid-single digits to low-teens based on a percentage of net sales from sales generated outside of the United States. The royalties payable to bluebird are subject to certain reductions, including for any royalty payments required to be made by Celgene to acquire patent rights, with an aggregate minimum floor. Celgene will assume certain development obligations and must report on their progress in achieving these milestones on a quarterly basis.

Absent early termination, the License Agreement will continue on a country-by-country basis, until there are no more payments owed to bluebird on bb2121 in such country. Celgene has the right to terminate the License Agreement at its discretion upon 180-day notice, beginning with the 18-month anniversary of the effective date of the License Agreement. Each party may also terminate the License Agreement upon prior notice for an uncured material breach that fundamentally frustrates the transactions contemplated by the License Agreement. bluebird also has the right to terminate the License Agreement if Celgene or any of its affiliates challenges the validity, scope or enforceability of or otherwise opposes, any patent included within the intellectual property rights licensed to Celgene under the License Agreement.

On February 17, 2016, the parties further amended the Amended Collaboration Agreement. The amendment provides for, among other matters, updated timing for certain deliverables in connection with Celgene's option to exclusively license bb2121.

The foregoing descriptions of the License Agreement and the amendment to the Amended Collaboration Agreement do not purport to be a complete statement of the parties' rights under such agreements and are qualified in their entirety by reference to the full text of such agreements, a copy of each such agreement will be filed as an exhibit to bluebird's quarterly report on Form 10-Q for the quarter ended March 31, 2016.

Item 8.01 Other Events.

On February 17, 2016, bluebird issued a press release announcing the treatment of the first subject in the CRB-401 Phase I clinical study of bb2121 for the treatment of relapsed/refractory multiple myeloma. The full text of the press release regarding the announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 Press release issued by bluebird bio, Inc. on February 17, 2016, furnished herewith

8-K – Celgene

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.

Date: February 17, 2016 bluebird bio,
Inc.

By: /s/ Jason
F. Cole
Jason F.
Cole
Senior
Vice
President,
General
Counsel

EXHIBIT INDEX

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