

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

(State or other jurisdiction of
incorporation)

001-35966

(Commission File Number)

13-3680878

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

**150 Second Street
Cambridge, MA**

(Address of principal executive offices)

02141

(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))
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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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on February 17, 2016, furnished herewith

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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on February 17, 2016, furnished herewith



bluebird bio Announces First Patient Treated with bb2121 in CRB-401 Phase 1 Study in Patients with Relapsed/Refractory Multiple Myeloma

Celgene has agreed to exercise its option to exclusively license bb2121 under global strategic collaboration bluebird bio to receive \$10 million option exercise payment from Celgene

Cambridge, MA, February 17, 2016 – bluebird bio, Inc. (Nasdaq: BLUE), a clinical-stage company committed to developing potentially transformative gene therapies for severe genetic diseases and T cell-based immunotherapies for cancer, announced treatment of the first patient in a Phase 1 study of its product candidate bb2121 in patients with relapsed/refractory multiple myeloma. bb2121 is a chimeric antigen receptor T cell (CAR T) therapy targeting B cell maturation antigen (BCMA), and bluebird bio is developing bb2121 in collaboration with Celgene Corporation. bluebird bio also announced today that Celgene has exercised its option to exclusively license bb2121, under the terms of the collaboration agreement between the two companies.

“bb2121 is bluebird bio’s first oncology program to enter the clinic, and the treatment of this first patient marks an important milestone for us as we build a broad, fully integrated T cell immunotherapy franchise,” said Nick Leschly, chief bluebird. “We are pleased that Celgene has exercised their option to license bb2121. We believe our combined manufacturing, development and commercial expertise will enable us to rapidly advance bb2121 through clinical trials.”

“Despite many recent advances in the field, multiple myeloma remains incurable, with almost all patients becoming refractory to therapy eventually,” said James N. Kochenderfer, M.D., National Cancer Institute, an investigator for the CRB-401 study. “BCMA is one of the most exciting targets in multiple myeloma, and we are eager to explore the potential of bb2121 to become an important new treatment option for patients living with multiple myeloma.”

bluebird bio and Celgene amended and restated their collaboration agreement in June 2015 to focus on developing product candidates targeting BCMA during a three-year collaboration term. By exercising its exclusive option under the terms of the agreement, Celgene will be responsible for worldwide development and commercialization of bb2121 after Phase 1. bluebird bio is responsible for the development of bb2121 through the completion of the CRB-401 Phase 1 study and has an option to share in the development, promotion and profits in the United States. bluebird bio will receive a \$10 million option exercise payment from Celgene, and bluebird bio is also eligible to receive specified development and regulatory and commercial milestone payments and royalty payments on net sales.



About the CRB-401 Study

The primary objective of the CRB-401 study is to evaluate the maximum tolerated dose of bb2121 and determine the recommended Phase 2 dose. The secondary objective is patient response, measured using the International Myeloma Working Group (IMWG) Response Criteria for Multiple Myeloma. The first portion of the study includes a dose-escalation phase in which cohorts of patients will receive ascending doses of bb2121 to determine the maximum tolerated dose and establish a recommended Phase 2 dose. The second portion of the study is a dose expansion phase where patients will receive bb2121 to further evaluate the safety, tolerability and clinical activity at the recommended Phase 2 dose.

About bluebird bio, Inc.

With its lentiviral-based gene therapies, T cell immunotherapy expertise and gene editing capabilities, bluebird bio has built an integrated product platform with broad potential application to severe genetic diseases and cancer. bluebird bio's gene therapy clinical programs include its Lenti-D™ product candidate, currently in a Phase 2/3 study, called the Starbeam Study, for the treatment of cerebral adrenoleukodystrophy, and its LentiGlobin® BB305 product candidate, currently in three clinical studies for the treatment of transfusion-dependent β -thalassemia, also known as β -thalassemia major, and severe sickle cell disease. bluebird bio's oncology pipeline is built upon the company's leadership in lentiviral gene delivery and T cell engineering, with a focus on developing novel T cell-based immunotherapies, including chimeric antigen receptor (CAR T) and T cell receptor (TCR) therapies. bluebird bio's lead oncology program, bb2121, is an anti-BCMA CAR T program partnered with Celgene. bb2121 is currently being studied in a Phase 1 trial for the treatment of relapsed/refractory multiple myeloma. bluebird bio also has discovery research programs utilizing megaTALs/homing endonuclease gene editing technologies with the potential for use across the company's pipeline.

bluebird bio has operations in Cambridge, Massachusetts, Seattle, Washington, and Paris, France.

LentiGlobin and Lenti-D are trademarks of bluebird bio, Inc.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the clinical and market potential of the Company's anti-BCMA oncology program, including its bb2121 product candidate. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but



are not limited to, the risk that the preclinical efficacy and safety data for our bb2121 product candidate will not be observed in the CRB-401 clinical study, the risk of cessation or delay of any of the ongoing or planned clinical studies and/or our development of our product candidates, the risk of a delay in the enrollment of patients in our clinical studies, the risk that our collaboration with Celgene Corporation will not continue or will not be successful, and the risk that any one or more of our product candidates will not be successfully developed and commercialized. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and bluebird bio undertakes no duty to update this information unless required by law.

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