bluebird bio, Inc.
Form 8-K
June 03, 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): June 3, 2015

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:

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

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

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

o 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

Amended Collaboration Agreement with Celgene Corporation

On June 3, 2015, bluebird bio, Inc. ("bluebird") and Celgene Corporation ("Celgene") amended and restated their existing master collaboration agreement focused on the discovery, development and commercialization of novel disease-altering gene therapies in oncology. The collaboration agreement, initiated in 2013, is focused on applying gene therapy technology to genetically modify a patient's own T-cells, known as chimeric antigen receptor (CAR) T-cells, to target and destroy cancer cells. Such CAR T cells have been shown to have beneficial effects in human clinical trials for patients with B cell lymphomas. Under the amended collaboration agreement, the parties will now focus the collaboration exclusively on anti-BCMA product candidates for an additional three-year term. B-cell maturation antigen, or BCMA, is a cell surface protein that is expressed in normal plasma cells and in most multiple myeloma cells, but is absent from other normal tissues. BCMA is the first target selected to advance to the clinic under the original collaboration agreement.

In connection with the amended collaboration agreement, bluebird will receive an upfront, one-time, non-refundable, non-creditable payment of $25 million to fund research and development under the collaboration. A Phase 1 clinical trial for the lead anti-BCMA product candidate under the amended collaboration is expected to be initiated in early 2016. The parties will also work collaboratively on potential next-generation anti-BCMA product candidates under the amended collaboration. The collaboration is governed by a joint steering committee, or JSC, formed by representatives from bluebird and Celgene. The JSC will, among other activities, review the collaboration program, review and evaluate product candidates and approve regulatory plans.

Under the terms of the amended collaboration, for up to two product candidate selected for development under the collaboration, bluebird is responsible for conducting and funding all research and development activities performed up through completion of the initial Phase 1 clinical study, if any, of such product candidate, provided that Celgene has agreed to reimburse bluebird a specified amount per patient in the event the parties mutually agree to expand any Phase 1 clinical trial for any product candidate under the collaboration beyond a specified number of patients per clinical trial.

On a product candidate-by-product candidate basis, up through a specified period following enrollment of the first patient in an initial Phase I clinical study for such product candidate, bluebird has granted Celgene an option to obtain an exclusive worldwide license to develop and commercialize such product candidate pursuant to a written agreement, the form of which bluebird has already agreed upon, provided that, if Celgene does not exercise its option with respect to the first product candidate under the amended collaboration then it will not be permitted to exercise its option with respect to any future product candidates under the amended collaboration. In the event that Celgene exercises its option with respect to any product candidate, bluebird may elect to co-develop and co-promote the product candidate in the United States, provided that, if bluebird does not exercise its option co-develop and co-promote the first product candidate in-licensed by Celgene under the amended collaboration agreement, 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 Celgene elects to exercise its option to exclusively in-license a product candidate, it must pay bluebird an option fee in the amount of $10.0 million for the first product candidate and $15.0 million for any additional product candidates, plus an additional fee in the amount of $10 million in the event bluebird does not exercise its option to co-develop and co-promote that product candidate in the United States. In addition to the applicable option fee, for each product candidate that is in-licensed by Celgene, and for which bluebird does not exercise its option to co-develop and co-promote 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. Bluebird will also be eligible to receive a percentage of net sales as a royalty in a range from the mid-single digits to mid-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. Celgene will assume certain development obligations and must report on their progress in achieving these milestones on a quarterly basis.

If bluebird elects to co-develop and co-promote a product candidate licensed by Celgene, then bluebird and Celgene would share equally in all costs incurred relating to the development, commercialization and manufacture of the product candidate within the United States and share equally in the profits generated by such product candidate in the United States. Additionally, if bluebird elects to co-develop and co-promote a product candidate, then the milestones and royalties would decrease compared to those described above. Under this scenario, bluebird would receive per product 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 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 mid-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 is solely responsible for the manufacture and supply of drug product for any optioned product candidate. Under the amended collaboration, 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 the optioned product candidate.

Celgene would reimburse bluebird for its costs to manufacture and supply such vectors and associated payloads, plus a modest mark-up.

If Celgene does not exercise its option with respect to any product candidate prior to expiration of the applicable option period, then bluebird has the right to develop that product candidate outside the scope of the collaboration.

Either party may terminate the amended collaboration agreement upon written notice to the other party in the event of the other party's uncured material breach. Celgene may terminate the agreement for any reason upon prior written notice to bluebird. If the agreement is terminated, rights to product candidates in development at the time of such termination will be allocated to the parties through a mechanism included in the agreement. In addition, if Celgene terminates the agreement for our breach, any then- existing co-development and co-promotion agreement will be automatically terminated and replaced with a license agreement for such product candidate and any amounts payable by Celgene under any then-existing product license agreements will be reduced.

Under the amended collaboration agreement, the so-called "call option" under the prior collaboration agreement, pursuant to which Celgene had the option to terminate the collaboration agreement and obtain fully paid-up licenses to product candidates in the event of a change of control transaction involving bluebird, has been eliminated.

Under the amended collaboration agreement, bluebird will continue to have access to certain intellectual property rights in-licensed to Celgene pursuant to its collaboration agreement with the Baylor College of Medicine, which was first established in connection with the initiation of original collaboration agreement between bluebird and Celgene.

The foregoing description of the amended collaboration agreement does not purport to be a complete statement of the parties' rights under the amended and restated collaboration agreement and is qualified in its entirety by reference to the full text of the amended and restated collaboration agreement, a copy of which will be filed as an Exhibit to bluebird's quarterly report on Form 10-Q for the quarter ended June 30, 2015.

Item 8.01 Other Events.

On June 3, 2015, bluebird issued a press release announcing the amended collaboration agreement with Celgene and its plans with respect to future research and development in oncology. 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 June 3, 2015, 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: June 3, 2015 bluebird bio, Inc.

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

EXHIBIT INDEX

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