
**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

(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))
-
-

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 I 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 I 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 I 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

<u>Exhibit No.</u>	<u>Description</u>
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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on June 3, 2015, furnished herewith.



FOR IMMEDIATE RELEASE

Celgene and bluebird bio to Develop Anti-BCMA Product Candidates; bluebird bio Regains Rights to CAR T Programs Outside of BCMA

Celgene to Pay bluebird \$25 Million in New Research Funding

bluebird bio to Independently Invest in and Pursue a Broad T cell Based Immuno-oncology Strategy

Investor Conference Call Scheduled for Wednesday, June 3, 2015 at 4:30 p.m. ET

CAMBRIDGE, Mass., June 3, 2015 – bluebird bio, Inc. (Nasdaq: BLUE), a clinical-stage company committed to developing potentially transformative gene therapies for severe genetic and rare diseases and T cell-based immunotherapies, today announced that its existing global collaboration agreement with Celgene Corporation (Nasdaq: CELG) has been amended and restated to focus on developing product candidates targeting B-cell maturation antigen (BCMA) during a three-year collaboration term. The original collaboration, initiated in 2013, was focused on applying gene therapy technology to genetically modify a patient’s own T cells to target and destroy cancer cells. BCMA is the first target selected to advance to the clinic under this collaboration. 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.

Celgene and bluebird bio will work collaboratively on the initial, lead anti-BCMA product candidate (bb2121), with a Phase 1 clinical trial expected to begin enrollment in early 2016, and develop next-generation anti-BCMA product candidates. bluebird bio retains sole rights to develop all other chimeric antigen receptor (CAR) T cell programs developed by bluebird bio under the collaboration, including ongoing undisclosed preclinical programs with opportunities in both solid tumors and hematologic malignancies.

Under the terms of the amended and restated collaboration agreement:

- bluebird bio will receive a \$25 million payment to develop the lead anti-BCMA product candidate through a Phase 1 clinical trial and develop next-generation anti-BCMA product candidates.
 - bluebird bio will be responsible for the development of all anti-BCMA product candidates through the completion of Phase 1 studies.
 - Additionally, on a product-by-product basis within the anti-BCMA product program, Celgene has an option to develop and commercialize each product candidate worldwide, and bluebird bio has the option to share equally in the development, promotion and profits of each product candidate in the United States. In addition to the payments described above and consistent with the prior agreement, Celgene would also pay
-

bluebird bio specified development and regulatory milestone payments as well as royalty payments on net sales.

“We have successfully achieved the initial goal of our collaboration with Celgene —identifying a promising lead development candidate in the CAR T cell field — and we are excited to focus our Celgene collaboration on the development of anti-BCMA products,” said Nick Leschly, chief bluebird. “Celgene is a leader in developing and commercializing therapies for multiple myeloma, and we believe they are the best global partner for our first CAR T program. Together we look forward to entering the clinic early next year with bb2121 and continuing our collaboration around next-generation BCMA products.”

“Our collaboration with bluebird bio has collectively made strong progress advancing a lead product candidate, targeting BCMA, toward the clinic in hematologic malignancies. We look forward to continuing to work with bluebird and build on the recent success to advance the anti-BCMA program and ultimately, to succeed on the goal of delivering a high-impact therapeutic in the CAR T arena,” said Tom Daniel, M.D., President of Research and Early Development at Celgene.

A Unique Position in Immuno-oncology

Outside of BCMA, bluebird bio is independently pursuing the development of a broad portfolio of novel immuno-oncology therapeutics. This portfolio will leverage bluebird bio technology, including its lentiviral vector platform, gene editing capabilities and internal gene therapy and immuno-oncology expertise.

“Consistent with the long-term vision for bluebird bio, we are expanding our immuno-oncology T cell based efforts in parallel with our late-stage hematopoietic stem cell-based programs,” said Rob Ross, M.D., senior vice president, clinical development, bluebird bio. “Our goal is to initiate multiple clinical trials over the next several years against novel targets in both solid and hematologic malignancies by integrating our proprietary lentiviral and gene editing platforms with our immuno-oncology expertise and experience in implementing multi-center, industry-sponsored gene therapy studies. This is an exciting step in bluebird bio’s evolution and an opportunity for us to further realize the value that gene therapy can bring to patients and families in need.”

Currently, bluebird bio has active pre-clinical research programs targeting multiple different, novel oncology antigens, including BCMA. These programs include various T cell therapies with significant academic and industry collaborations. bluebird bio recently announced a strategic collaboration with Five Prime Therapeutics, which marries Five Prime’s antigen discovery platform and certain human antibodies with bluebird bio’s immuno-oncology and gene therapy capabilities, with the potential for development candidates in both hematologic malignancies and solid tumors.

Investor Conference Call and Webcast Information

bluebird bio will host a conference call and webcast on at 4:30 p.m. ET on Wednesday, June

3rd to review its strategy and development plans in immuno-oncology. The event will be webcast live and can be accessed under "Calendar of Events" in the Investors and Media section of the company's website at www.bluebirdbio.com. Alternatively, investors may listen to the call by dialing (844) 825-4408 from locations in the United States or (315) 625-3227 from outside the United States.

About bluebird bio, Inc.

With its lentiviral-based gene therapy and gene editing capabilities, bluebird bio has built an integrated product platform with broad potential application to severe genetic diseases and T cell-based immunotherapy. bluebird bio's clinical programs include Lenti-D™, currently in a Phase 2/3 study, called the Starbeam Study, for the treatment of childhood cerebral adrenoleukodystrophy, and LentiGlobin®, currently in three clinical studies: a global Phase 1/2 study, called the Northstar Study, for the treatment of beta-thalassemia major; a single-center Phase 1/2 study in France (HGB-205) for the treatment of beta-thalassemia major or severe sickle cell disease; and a separate U.S. Phase 1 study for the treatment of sickle cell disease (HGB-206). bluebird bio also has ongoing preclinical CAR T immuno-oncology programs, as well as discovery research programs utilizing megaTALs/homing endonuclease gene editing technologies.

bluebird bio has operations in Cambridge, Massachusetts, Seattle, Washington, and Paris, France. For more information, please visit www.bluebirdbio.com.

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 research, development and advancement of bluebird bio's immuno-oncology product candidates and CAR T research programs. 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 bluebird bio's immuno-oncology research programs will be unsuccessful and not identify any viable product candidates or will not be safe or effective in clinical trials, the risk of cessation or delay of any of the planned clinical studies and/or our development of our immuno-oncology product candidates, the risk of a delay in the enrollment of patients in the Company's clinical studies, the risk that our collaboration with Celgene around anti-BCMA product candidates 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 annual 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.

Availability of other information about bluebird bio

Investors and others should note that we communicate with our investors and the public using our company website (www.bluebirdbio.com), our investor relations website (<http://www.bluebirdbio.com/investor-splash.html>), including but not limited to investor presentations and FAQs, Securities and Exchange Commission filings, press releases, public conference calls and

webcasts. You can also connect with us on Twitter [@bluebirdbio](#), [LinkedIn](#) or our [YouTube](#) channel. The information that we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in bluebird bio to review the information that we post on these channels, including our investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include other social media channels than the ones described above. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

Investor Relations:

Manisha Pai
bluebird bio, inc.
(617) 245-2107
mpai@bluebirdbio.com

Media:

Dan Budwick
Pure Communications
(973) 271-6085