
**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): March 26, 2018

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.)

**60 Binney St.
Cambridge, MA**
(Address of principal executive offices)

02142
(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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Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement.

Amended and Restated Co-Development, Co-Promote and Profit Share Agreement with Celgene Corporation

On March 26, 2018, bluebird bio, Inc. (“bluebird”), Celgene Corporation, and Celgene European Investment Company LLC (collectively, “Celgene”) entered into an amended and restated co-development, co-promote and profit share agreement (the “CCPS Agreement”). We and Celgene are parties to a 2013 master collaboration agreement, subsequently amended and restated in 2015, and amended again in February 2016 and in September 2017 (“the Master Collaboration Agreement”), pursuant to which the parties are collaborating to apply gene therapy technology to develop anti-BCMA product candidates. We advanced the development of our bb2121 product candidate from our collaboration with Celgene into clinical trials in February 2016. In February 2016, we exclusively licensed to Celgene the worldwide rights to develop and commercialize our bb2121 product candidate and retained an option to co-develop and co-commercialize this product candidate in the United States (the “bb2121 License Agreement”).

Pursuant to the Master Collaboration Agreement, we exercised our option to co-develop and co-commercialize the bb2121 product candidate in the United States, and effective upon the execution the CCPS Agreement, bluebird and Celgene have terminated the bb2121 License Agreement. Under the terms of the CCPS Agreement, we will share equally in all costs relating to development (including further costs and expenses associated with the ongoing CRB-401 clinical study of bb2121 after April 1, 2018), commercialization and manufacturing of bb2121 within the United States and we will share equally in the United States profits from the potential commercialization of bb2121. Under the terms of the CCPS Agreement, we may receive up to \$70.0 million in development milestone payments for the first indication to be addressed by the bb2121 product candidate, with the ability to obtain additional milestone payments for a second indication and modified licensed products. To the extent the bb2121 product candidate is commercialized outside of the United States, we are entitled to receive tiered royalty payments from Celgene ranging from the mid-single digits to low-teens based on a percentage of net sales generated outside of the United States, with the royalties payable to us subject to certain reductions. In accordance with the CCPS Agreement, Celgene is assuming responsibility for manufacturing bb2121 for development and commercialization on a global basis. We continue to have the sole right (with “back-up” and/or “second source” supply rights for Celgene under certain circumstances) to manufacture or have manufactured supplies of vectors and associated payloads for the development and commercialization of bb2121 worldwide. The cost to Celgene of the vector supply for commercialization outside of the United States will be costs plus a modest markup. The cost of vector supply for development and commercialization within the United States will be included in the cost and profit share calculation in the CCPS Agreement. Under the terms of the CCPS Agreement, we and Celgene will assume joint responsibility for all regulatory matters with respect to bb2121 in the United States. Celgene will assume responsibility for regulatory matters with respect to bb2121 outside the United States. The co-development and co-promotion relationship is governed by a joint governance committee, or JGC, formed by representatives from us and Celgene. The JGC, among other activities, will supervise the overall performance of the development and commercialization of bb2121 in the U.S., including making all decisions regarding the parties’ performance under the U.S. development and commercialization program.

Absent early termination, the CCPS Agreement will continue on a country-by-country basis, until there are no more payments owed to one or the other party on a licensed product in such country. Celgene has the right to terminate the CCPS Agreement at its discretion upon 180-day notice, beginning with the 18-month anniversary of the effective date of the CCPS Agreement. bluebird has the right to terminate the profit & loss share at its discretion upon 90-day notice, with the parties to promptly enter into a license agreement with respect to the United States and the rest of the world. Each party may terminate the CCPS Agreement upon prior notice for an uncured material breach that fundamentally frustrates the transactions contemplated by the CCPS Agreement.

The foregoing description of the CCPS Agreement does not purport to be a complete statement of the parties’ rights thereunder and is qualified in its entirety by reference to the full text of the CCPS Agreement, a copy of which will be filed as an Exhibit to bluebird’s quarterly report on Form 10-Q for the quarter ended March 31, 2018.

Item 1.02 Termination of a Material Definitive Agreement

Effective upon the CCPS Agreement effective date, and in accordance with the terms of the Master Collaboration Agreement, bluebird and Celgene terminated the bb2121 License Agreement. The disclosure under Item 1.01 is hereby incorporated under this Item 1.02.

Item 8.01 Other Events.

On March 28, 2018, bluebird issued a press release announcing that bluebird and Celgene entered into an agreement to co-develop and co-promote bb2121 in the United States. 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 March 28, 2018.

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: March 28, 2018

bluebird bio, Inc.

By: /s/ Jason F. Cole
Jason F. Cole
Chief Legal Officer



bluebird bio and Celgene Corporation Enter into Agreement to Co-Develop and Co-Promote Anti-BCMA CAR T Cell Therapy bb2121 in the United States

- *bluebird and Celgene will share 50% of U.S. costs and profits -*
- *bluebird to receive milestones and royalties on ex-U.S. sales -*

Cambridge, MA and Summit, NJ, March 28, 2018 – bluebird bio, Inc. (Nasdaq: BLUE) and Celgene Corporation (Nasdaq: CELG) today announced that the companies have entered into an agreement to co-develop and co-promote bb2121, an investigational anti-B-cell maturation antigen (BCMA) chimeric antigen receptor (CAR) T cell therapy for the potential treatment of patients with relapsed/refractory multiple myeloma in the United States.

“Entering into this co-development and co-promotion partnership with Celgene is a significant step forward in building a fully integrated oncology franchise for bluebird and together, we are committed to rapidly advancing development of bb2121 for patients,” said Joanne Smith-Farrell, Ph.D., oncology franchise leader and senior vice president, corporate development and strategy, bluebird bio. “The collaboration builds upon our extensive research and development capabilities in oncology and is a testament to the strong partnership that exists between our two companies.”

The companies originally entered into a broad, global strategic research collaboration in 2013 to discover, develop and commercialize novel therapies in oncology, which included bb2121.

“We are extremely pleased to advance our collaboration with bluebird on bb2121 and we believe this therapy has the potential to create significant impact on the treatment approach and outcomes for patients with multiple myeloma,” said Nadim Ahmed, President, Hematology and Oncology for Celgene.

About the bluebird bio-Celgene Collaboration

bluebird bio and Celgene are collaborating to develop CAR T cell therapies targeting BCMA. The collaboration’s lead oncology program, bb2121, is currently being studied for the treatment of relapsed and refractory multiple myeloma. For bb2121, bluebird and Celgene have joint responsibility for development, manufacturing and commercialization in the United States. Celgene will assume sole responsibility for drug product manufacturing and commercialization outside the United States.



bluebird bio and Celgene are also working together to develop a second clinical-stage anti-BCMA CAR T program, bb21217.

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 for the treatment of cerebral adrenoleukodystrophy, and its LentiGlobin® product candidate 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 programs, bb2121 and bb21217, are anti-BCMA CAR T programs partnered with Celgene. bluebird bio also has discovery research programs utilizing megaTAL/homing endonuclease gene editing technologies with the potential for use across the company's pipeline.

bluebird bio has operations in Cambridge, Massachusetts, Seattle, Washington, Durham, North Carolina and Zug, Switzerland.

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

About Celgene

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, please visit www.celgene.com. Follow Celgene on Social Media: [@Celgene](#), [Pinterest](#), [LinkedIn](#), [Facebook](#) and [YouTube](#).

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the potential benefits of, and plans relating to the collaboration between bluebird bio and Celgene; the potential of bb2121 as a therapeutic drug; and the benefit of each company's strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope" and similar expressions are intended to identify



forward-looking statements, although not all forward-looking statements contain these identifying words. 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, risks that the preliminary results from our clinical trials of bb2121 will not continue or be repeated in ongoing or planned clinical trials of bb2121, the risk of cessation or delay of any of the ongoing or planned clinical studies and/or our development of the bb2121 or bb21217 product candidates, risks that the current or planned clinical trials of the bb2121 product candidate will be insufficient to support regulatory submissions or marketing approval in the United States, European Union or other countries, the risk that our collaboration with Celgene will not continue or will not be successful, and the risk that the bb2121 product candidate will not be successfully commercialized. These and other risks are described in greater detail under the caption "Risk Factors" included in each company's public filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and neither company has any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

Hyperlinks are provided as a convenience and for informational purposes only. Neither Celgene nor bluebird bio bears responsibility for the security or content of external websites or websites outside of their respective control.

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