

bluebird bio, Inc.
Form 8-K
March 28, 2018

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	001-35966	13-3680878
(State or other jurisdiction	(Commission	(I.R.S. Employer
of incorporation)	File Number)	Identification No.)

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60 Binney St.

Cambridge, MA

02142

(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))

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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

Exhibit

No.	Description
99.1	<u>Press release issued by bluebird bio, Inc. on March 28, 2018.</u>

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