

**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): September 13, 2017

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

**(IRS Employer
Identification No.)**

**60 Binney Street,
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 (see General Instructions A.2. below):

- 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 7.01 Regulation FD Disclosure

On September 13, 2017, bluebird bio, Inc. (“bluebird”) issued a press release announcing the initiation of the expansion cohort of CRB-401, the Phase 1 study for bluebird’s anti-BCMA CAR T cell therapy partnered with Celgene Corporation. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

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 September 13, 2017

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: September 13, 2017

bluebird bio, Inc.

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on September 13, 2017

bluebird bio Announces First Patient Treated in Expansion Cohort of CRB-401, Phase 1 Study of Anti-BCMA CAR T Therapy bb2121

CAMBRIDGE, Mass., September 13, 2017 – [bluebird bio, Inc.](#) (NASDAQ: BLUE), a clinical-stage company committed to developing potentially transformative gene therapies for serious genetic diseases and T cell-based immunotherapies for cancer, today announced that the expansion cohort of the CRB-401 Phase 1 study of bb2121, an anti-BCMA CAR T therapy, has been initiated. The objective of the CRB-401 study is to evaluate the safety and efficacy of bb2121 in patients with relapsed/refractory multiple myeloma and determine a recommended Phase 2 dose. bluebird bio and Celgene Corp. are jointly developing bb2121.

“The high response rate and sustained benefit seen with bb2121 in the recent data presented at the ASCO annual meeting in June are particularly gratifying given the limited therapeutic options available for the heavily pretreated patients with relapsed/refractory multiple myeloma participating in our study,” said David Davidson, MD, chief medical officer, bluebird bio. “In the expansion stage of the CRB-401 study, we will be treating an additional cohort of patients with a dose range shown to be active in the prior dose escalation stage of the study to gain more experience with the safety, efficacy and durability of response of bb2121.”

Patients in the expansion cohort will be treated at a dose range of 150 to 450 x 10⁶ CAR+ T cells and will be required to have prior exposure to a proteasome inhibitor, an immunomodulatory agent and daratumumab.

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™ product candidate, currently in four clinical studies for the treatment of transfusion-dependent β-thalassemia, 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 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 and Europe.

About the bluebird bio-Celgene Collaboration

In March 2013, bluebird bio and Celgene entered into a collaboration to develop chimeric antigen receptor (CAR) T cell therapies to target and destroy cancer cells. In June 2015, the collaboration was amended and restated to focus on developing product candidates targeting B-cell maturation antigen (BCMA). bluebird bio and Celgene are working together on the initial, lead anti-BCMA product candidate (bb2121), and are developing next-generation anti-BCMA product candidates, including bb21217.

Forward-Looking Statements

This press release contains forward-looking statements, which are generally statements that are not historical facts, including statements regarding the potential of the bb2121 product candidate to treat relapsed/refractory multiple myeloma and future clinical development plans of the Company and Celgene. Forward-looking statements can be identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans," "will," "outlook" and similar expressions. Forward-looking statements are based on management's current plans, estimates, assumptions and projections, and speak only as of the date they are made. Neither Celgene nor bluebird bio undertake any obligation to update any forward-looking statement in light of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond each company's control. These risks and uncertainties include, but are not limited to, the risk that the bb2121 product candidate will not be successfully developed, approved or commercialized in relapsed/refractory multiple myeloma, or the risk that the bb2121 product candidate will be safe and efficacious in other disease settings. Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in the section entitled "Risk Factors" of the Annual Report on Form 10-K and other reports of each company filed with the Securities and Exchange Commission.

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