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 28, 2017

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)	(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 1.01 Entry into a Materials Definitive Agreement

On September 22, 2017, Celgene Corporation ("Celgene") exercised its option to exclusively license bb21217 ("bb21217"), the second anti-BCMA product candidate under the Amended and Restated Collaboration Agreement dated June 3, 2015 (as amended, the "Amended Collaboration Agreement") between Celgene and bluebird bio, Inc. ("bluebird"). In connection with its option exercise, Celgene will pay to bluebird an option exercise payment of $15.0 million in accordance with the terms of the Amended Collaboration Agreement. On September 28, 2017, the parties entered into the Amended and Restated License Agreement (the "License Agreement"), which provides for, among other matters, Celgene's exclusive worldwide license to develop and commercialize bb21217. Under the License Agreement, 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 bb21217. Celgene will reimburse bluebird for its costs to manufacture and supply such vectors and associated payloads, plus a modest mark-up. bluebird will continue to be responsible for conducting the ongoing CRB-402 Phase 1 clinical study of bb21217 for the treatment of relapsed/refractory multiple myeloma. Following the completion of the CRB-402 Phase 1 clinical study, Celgene will be responsible for all costs and expenses for the development and commercialization of bb21217, subject to bluebird's co-development and co-promotion option described below.

bluebird may elect to co-develop and co-promote bb21217 in the United States. If bluebird does not exercise its option to co-develop and co-promote bb21217 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, in addition to the option fee. bluebird will also be eligible to receive a percentage of net sales as a royalty in a range from the mid-single digits to low-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.

If bluebird elects to co-develop and co-promote bb21217 in the United States, then bluebird and Celgene would share equally in all costs incurred relating to the development, commercialization and manufacture of bb21271 within the United States and share equally in the profits generated by bb21217 in the United States. Additionally, if bluebird elects to co-develop and co-promote bb21217, then the milestones and royalties would decrease compared to those described above. Under this scenario, bluebird would receive 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 option fee. Furthermore, 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 low-teens based on a percentage of net sales form 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 will assume certain development obligations and must report on their progress in achieving these milestones on a quarterly basis.

Absent early termination, the License Agreement will continue on a country-by-country basis, until there are no more payments owed to bluebird on bb21217 in such country. Celgene has the right to terminate the License Agreement at its discretion upon 180-day notice, beginning with the 18-month anniversary of the effective date of the License Agreement. Each party may also terminate the License Agreement upon prior notice for an uncured material breach that fundamentally frustrates the transactions contemplated by the License Agreement. bluebird also has the right to terminate the License Agreement if Celgene or any of its affiliates challenges the validity, scope or enforceability of or otherwise opposes, any patent included within the intellectual property rights licensed to Celgene under the License Agreement.

On September 28, 2017, the parties further amended the Amended Collaboration Agreement. The amendment provides for, among other matters, updated timing for certain deliverables in connection with Celgene's option to exclusively license bb21217.

The foregoing descriptions of the License Agreement and the amendment to the Amended Collaboration Agreement do not purport to be a complete statement of the parties' rights under such agreements and are qualified in their entirety by reference to the full text of such agreements, a copy of each such agreement will be filed as an exhibit to bluebird's quarterly report on Form 10-Q for the quarter ended September 30, 2017.

Item 8.01 Other Events

On September 28, 2017, bluebird bio, Inc. ("bluebird") issued a press release announcing the treatment of the first subject in the CRB-402 Phase I clinical study of bb21217 for the treatment of relapsed/refractory multiple myeloma. 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 September 28, 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 28, 2017

bluebird bio, Inc.

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

Exhibit 99.1

bluebird bio Announces First Patient Treated with Second Anti-BCMA CAR T bb21217 in CRB-402 Phase 1 Study in Patients with Relapsed/Refractory Multiple Myeloma

-Celgene has exercised its option to exclusively license bb21217 under its collaboration with bluebird bio-
-bluebird bio to receive $15 million option exercise payment from Celgene-

Cambridge, MA, September 28, 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, announced the treatment of the first patient with relapsed/refractory multiple myeloma in a Phase 1 study of bb21217. bb21217 is an investigational chimeric antigen receptor T cell (CAR T) therapy targeting B cell maturation antigen (BCMA). bluebird bio is developing bb21217 in collaboration with Celgene Corporation. bluebird bio also announced today that Celgene has exercised its option to exclusively license bb21217, under the terms of the collaboration between the two companies.

"bb21217, bluebird's second oncology program to enter the clinic, complements bb2121, which has demonstrated encouraging safety and efficacy results in an ongoing Phase 1 trial. With bb21217, we manufacture a CAR T cell product enriched for 'memory T cells' – a long-lived, more potent T cell subtype – which in preclinical *in vivo* studies has shown improved anti-tumor activity," said Philip Gregory, chief scientific officer, bluebird bio. "While the clinical data we have shared to date from our bb2121 program have shown deep and durable responses, we know that multiple myeloma is an aggressive and historically incurable cancer. With our partners at Celgene, we are excited to bring forward a second program reflecting our commitment to exploring all avenues to deliver cutting edge therapies to patients."

"The advancement of bb21217 into the clinic builds upon the success of our first-generation program and is one more testament to bluebird's and Celgene's combined leadership in the field of anti-BCMA CAR T therapies" said Rupert Vessey, EVP and President, Global Research & Early Development, Celgene. "We look forward to our continued partnership with bluebird to unleash the full potential of anti-BCMA CAR T therapies for patients living with historically incurable cancers."

bluebird bio and Celgene's collaboration focuses on developing product candidates targeting BCMA for the treatment of patients with multiple myeloma. By exercising its exclusive option under the terms of the collaboration, Celgene will be responsible for worldwide development and commercialization of bb21217 after Phase 1. bluebird bio is responsible for the development of bb21217 through the completion of the CRB-402 Phase 1 study and has an option to share in the development, promotion and profits in the United

States. bluebird bio will receive a $15 million option exercise payment from Celgene, and bluebird bio is also eligible to receive specified development, regulatory and commercial milestone payments and royalty payments on net sales.

About the CRB-402 Study

The primary objective of the CRB-402 study is to evaluate the maximum tolerated dose of bb21217 and determine the recommended Phase 2 dose. The secondary objective is preliminary efficacy data, measured using the International Myeloma Working Group (IMWG) Response Criteria for Multiple Myeloma. The first portion of the study includes a dose-escalation phase in which cohorts of patients will receive ascending doses of bb21217 to determine the maximum tolerated dose and establish a recommended Phase 2 dose. The second portion of the study is a dose expansion phase where patients will receive bb21217 to further evaluate the safety, tolerability and clinical activity at the recommended Phase 2 dose.

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® BB305 product candidate, currently in three clinical studies 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. bb2121 and bb21217 are each currently being studied in Phase 1 trials for the treatment of relapsed/refractory multiple myeloma.

bb2121 and bb21217 are investigational therapies that have not been not been approved by any regulatory agency and for which the safety and efficacy have not been established.

bluebird bio also has discovery research programs utilizing megaTALs/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.

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 clinical and market potential of the Company's anti-BCMA oncology program, including the bb2121 and bb21217 product candidates. 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 the preclinical efficacy and safety data for our bb21217 product candidate will not be observed in the CRB-402 clinical study, the risk of cessation or delay of any of the ongoing or planned clinical studies and/or our development of our product candidates, the risk of a delay in the enrollment of patients in our clinical studies, the risk that our collaboration with Celgene Corporation 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 quarterly 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.

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