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): November 16, 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 8.01 Other Events

On November 16, 2017, bluebird bio, Inc. ("bluebird") reported the treatment of the first subject in the Northstar-3 study, the Phase III clinical study of the LentiGlobin product candidate in patients with transfusion-dependent β-thalassemia and a β^0/β^0 genotype (HGB-212). The full text of bluebird's 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.

Also on November 16, 2017, bluebird issued a press release announcing that bb2121, a chimeric antigen receptor T cell therapy targeting BCMA in relapsed/refractory multiple myeloma partnered with Celgene Corporation, has received Breakthrough Therapy Designation (BTD) from the U.S. Food and Drug Administration and has been granted PRIority MEdicines (PRIME) eligibility by the European Medicines Agency. The full text of the press release regarding the announcement is filed as Exhibit 99.2 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 November 16, 2017
99.2	Press release issued by bluebird bio, Inc. on November 16, 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: November 16, 2017

bluebird bio, Inc.

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

Exhibit 99.1

bluebird bio Announces First Patient Treated in Northstar-3 (HGB-212), Phase 3 Study of LentiGlobin in Patients with Transfusion-Dependent β-Thalassemia (TDT) and β^0/β^0 genotype

-Study to enroll approximately fifteen adult, adolescent and pediatric patients –

Cambridge, MA, November 16, 2017 – bluebird bio, Inc. (Nasdaq: BLUE), a clinical-stage company committed to developing potentially transformative gene therapies for severe genetic diseases and T cell-based immunotherapies for cancer, today announced that the first patient has been treated in Northstar-3 (HGB-212) the company's Phase 3 study of LentiGlobin in patients with transfusion-dependent β-thalassemia (TDT) with the β^0/β^0 genotype.

"We are excited to start our second Phase 3 study of LentiGlobin in patients with TDT," said Dave Davidson, chief medical officer. "Early data presented at the European Hematology Association annual meeting this year indicates that our refined manufacturing process, now implemented for treatment across all of our active studies of LentiGlobin, has consistently yielded improved Drug Products with higher vector copy number and an increased proportion of transduced cells. We are optimistic that these advances will improve our ability to achieve the levels of HbA^{T87Q} needed for the patients in this study, who have the β^0/β^0 genotype, to see their annual RBC transfusions dramatically reduced, if not entirely eliminated."

"Ongoing studies of LentiGlobin in patients with TDT have indicated the potential for a durable effect, with patients seeing consistent production of HbA^{T87Q} for more than three years after treatment," said Alexis Thompson, MD, MPH, Ann & Robert H. Lurie Children's Hospital of Chicago, Illinois and a primary investigator on the study. "With the introduction of the refined manufacturing process into the Northstar-2 and Northstar-3 pivotal studies, we hope our patients will produce a greater amount of hemoglobin to enhance their treatment effect, and thereby demonstrate that LentiGlobin has the potential to address the underlying genetic cause of TDT, regardless of genotype."

LentiGlobin is also being investigated in Northstar-2 (HGB-207), a Phase 3 study in patients with TDT and non-β^0/β^0 genotypes, Northstar (HGB-204), a Phase 1/2 study in patients with TDT and all genotypes, HGB-205, a Phase 1 study in patients with TDT and severe sickle cell disease (SCD), and HGB-206, a Phase 1 study in patients with SCD.

About Northstar-3 (HGB-212)
Northstar-3 is a Phase 3, global, multi-center study designed to evaluate the safety and efficacy of LentiGlobin in patients with transfusion-dependent beta-thalassemia with a β^0/β^0 genotype. In this study, the manufacturing process by which the patient's cells are transduced with the LentiGlobin viral vector has been modified, with the intent of increasing the percentage of cells successfully transduced and the average vector copy number per diploid genome.

The study’s primary endpoint is the proportion of patients who meet the definition of "transfusion reduction" (TR). TR is defined as demonstration of reduction of at least 60% in volume of red blood cell (RBC) transfusion requirements (in mL/kg) in the post-treatment time period of Months 12 to 24, as compared to the average annual transfusion requirement in the 24 months prior to enrollment. The target enrollment of the study is 15 adult, adolescent and pediatric patients.

About TDT

Transfusion-dependent β-thalassemia (TDT) is a severe genetic disease characterized by reduced or absent hemoglobin levels that results in severe anemia and ineffective red blood cell production. Supportive care for people with TDT consists of a lifelong regimen of chronic blood transfusions to enable survival and suppress symptoms of the disease, and iron chelation therapy to manage iron overload that results from the transfusions. Despite the availability of supportive care, many people with TDT experience serious complications and organ damage due to underlying disease and iron overload.

Allogeneic hematopoietic stem cell transplant (HSCT) is currently the only available option to address the underlying genetic cause of TDT, though it carries significant risks. Complications of allogeneic HSCT include a risk of treatment-related mortality, graft failure, graft vs. host disease (GvHD) and opportunistic infections, particularly in patients who undergo HSCT from a donor who is not a matched sibling.

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. 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 Company's research, development, manufacturing and regulatory approval plans for its LentiGlobin product candidate to treat transfusion-dependent ß-thalassemia, including statements whether the manufacturing process changes for LentiGlobin will improve outcomes of patients with transfusion-dependent ß-thalassemia. 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 risks that the preliminary positive efficacy and safety results from our prior and ongoing clinical trials of LentiGlobin will not continue or be repeated in our ongoing, planned or expanded clinical trials of LentiGlobin, risks that the current or planned clinical trials of LentiGlobin will be insufficient to support regulatory submissions or marketing approval in the US and EU, the risk of a delay in the enrollment of patients in our clinical studies, and the risk that any one or more of our product candidates, including our bb2121 product candidate, will not be successfully developed, approved or 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 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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Exhibit 99.2

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CELGENE CORPORATION AND BLUEBIRD BIO ANNOUNCE bb2121 ANTI-BCMA CAR-T CELL THERAPY HAS BEEN GRANTED BREAKTHROUGH THERAPY DESIGNATION FROM FDA AND PRIME ELIGIBILITY FROM EMA FOR RELAPSED AND REFRACTORY MULTIPLE MYELOMA

Designations based on preliminary clinical data from ongoing phase I study of bb2121 in heavily pre-treated multiple myeloma

SUMMIT, NJ and CAMBRIDGE, Mass. – (Nov. 16, 2017) – Celgene Corporation (NASDAQ: CELG) and bluebird bio, Inc. (NASDAQ: BLUE) today announced that bb2121, a chimeric antigen receptor T-cell (CAR-T) therapy targeting b-cell maturation antigen (BCMA) in previously treated patients with multiple myeloma, has been granted Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration (FDA) and PRIority MEdicines (PRIME) eligibility by the European Medicines Agency (EMA).

BTD designation and PRIME eligibility for bb2121 were based on preliminary clinical data from the ongoing phase 1 study CRB-401. Updated data from CRB-401 is scheduled to be presented at the 59th annual meeting of the American Society of Hematology in Atlanta during an oral presentation on Dec. 11.

“Receiving Breakthrough Therapy Designation and PRIME eligibility for bb2121 further underscores the potential of this novel cellular immunotherapy approach to multiple myeloma treatment,” said Jay Backstrom, M.D., Chief Medical Officer and Head of Global Regulatory

Affairs for Celgene. “We will work closely with these agencies as we accelerate development of bb2121, a novel technology and therapy for patients with multiple myeloma.”

“Despite recent advances, multiple myeloma remains an incurable disease, and heavily pretreated patients have limited therapeutic options,” said David Davidson, M.D., Chief Medical Officer for bluebird bio. “Early data suggest that treatment with bb2121 has the potential to induce durable responses in this patient population. It is encouraging for both the FDA and EMA to identify bb2121 as a candidate for accelerated development as we continue our work with Celgene to bring this therapy to patients in need of new options.”

Breakthrough Therapy Designation is intended to expedite the development and review of drugs that are intended to treat serious or life-threatening conditions. The criteria for breakthrough therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

PRIME is a program launched by the EMA to enhance support for the development of medicines that target an unmet medical need. This voluntary program is based on enhanced interaction and early dialogue with developers of promising medicines, to optimize development plans and speed up evaluation so these medicines can reach patients earlier. The program focuses on medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options. These medicines are considered priority medicines by EMA. To be accepted for PRIME, a medicine must show its potential to benefit patients with unmet medical needs based on early clinical data.

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.

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 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 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's lead oncology program, bb2121, is an anti-BCMA CAR T program currently being studied in a Phase 1 trial for the treatment of relapsed/refractory multiple myeloma. bluebird bio and Celgene are also working together on a second anti-BCMA CAR T program, bb21217.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those 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. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs. For example, there can be no guarantee that any product candidate will be successfully developed or complete necessary preclinical and clinical phases, or that development of any of product candidates will successfully continue. There can be no guarantee that any positive developments will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks and uncertainties relating to a number of other important factors, including: results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; the ability to obtain and maintain requisite regulatory approvals and to enroll patients in planned clinical trials; unplanned cash requirements and expenditures; competitive factors; the ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates; the ability to maintain key collaborations; and general economic and market conditions. 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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