

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): December 14, 2016

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.)

**150 Second Street
Cambridge, MA**

(Address of principal executive offices)

02141

(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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Item 8.01 Other Events

On December 14, 2016, bluebird bio, Inc. (“bluebird”) issued a press release announcing the treatment of the first subject in the Northstar-2 Study, bluebird’s global, multi-center Phase III study of its LentiGlobin product candidate for the treatment of patients with transfusion-dependent β -thalassemia who do not have a β^0/β^0 genotype.

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.

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 December 14, 2016.

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: December 14, 2016

bluebird bio, Inc.

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on December 14, 2016.



Exhibit 99.1

bluebird bio Announces First Patient Treated with LentiGlobin™ Drug Product in Northstar-2 (HGB-207) Phase 3 Trial of Patients with Transfusion-Dependent β -Thalassemia

- *LentiGlobin drug product vector copy number (DP VCN) of 2.9 copies/diploid genome; 77% of cells lentiviral vector sequence positive (LVV+) –*

Cambridge, Mass., December 14, 2016 – 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, announced treatment of the first patient in Northstar-2, the Phase 3 study of its LentiGlobin drug product in patients with transfusion-dependent β -thalassemia (TDT) and non- β^0/β^0 genotypes. This study will use LentiGlobin drug product manufactured with the addition of transduction enhancers intended to increase the drug product vector copy number and percent of cells transduced. The study's primary endpoint is the proportion of treated subjects who meet the definition of "transfusion independence," defined as total hemoglobin levels of at least 9g/dL without any RBC transfusions for a continuous period of at least 12 months at any time during the study.

"The opening of our first Phase 3 trial in TDT is an exciting milestone for bluebird," said David Davidson, chief medical officer. "At ASH we presented interim LentiGlobin data from the Northstar study showing substantial and durable treatment effects, with all patients with non- β^0/β^0 genotypes and at least twelve months of follow-up achieving freedom from transfusions. We are hopeful that our new manufacturing process incorporating transduction enhancers will build upon these results and may provide even better outcomes for patients. It is an encouraging start for Northstar-2 to have achieved a robust drug product VCN of 2.9 c/dg and 77% LVV+ for our first treated patient. We are tremendously grateful to the patients, families, study investigators, and site staff who have participated in our LentiGlobin program and enabled progress toward our goal of improving the lives of patients with TDT."

"The current results of the HGB-204 and HGB-205 LentiGlobin studies show a reduction, and in some cases, elimination of RBC transfusions in patients with TDT," said Mark C. Walters, M.D., UCSF Benioff Children's Hospital, Oakland, a principal investigator on the study. "The current study, Northstar-2, will test a new manufacturing method to increase the VCN in the drug product. If it is successful, this new enhanced transduction method could expand the number of patients who no longer need transfusions after the gene therapy treatment."

bluebird bio is also moving forward with plans to initiate Northstar-3 (HGB-212), a Phase 3 trial of LentiGlobin drug product in patients with transfusion-dependent β -thalassemia with the β^0/β^0 genotype. This study will also be conducted under the new



manufacturing process, and is expected to begin enrolling patients in 2017. The primary endpoint of this planned study is transfusion reduction.

About Northstar-2 (HGB-207)

Northstar-2 is a Phase 3, global, multi-center study designed to evaluate the safety and efficacy of LentiGlobin drug product in patients with transfusion-dependent beta-thalassemia with non- β^0/β^0 genotypes. In this study, the manufacturing process by which the patient's cells are transduced with the LentiGlobin viral vector is modified, with the intent of increasing vector copy number and the percentage of cells successfully transduced.

The target enrollment of the study is 15 adult and adolescent patients and 8 pediatric patients. The study's primary endpoint is the proportion of treated subjects who meet the definition of "transfusion independence," defined as total hemoglobin levels of at least 9g/dL without any RBC transfusions for a continuous period of at least 12 months at any time during the study.

About TDT

Transfusion-dependent β -thalassemia (TDT), also called β -thalassemia major or Cooley's anemia, is an inherited blood disease that can cause severe anemia and can be fatal within the first few years of life if not treated. TDT is one of the most common genetic diseases in the world, and approximately 60,000 children are born every year with a serious form of the disease.

Despite advances in the supportive conventional management of the disease, which consists of frequent and lifelong blood transfusions and iron chelation therapy, there is still a significant unmet medical need, including the risk for significant morbidity and early mortality. Currently, the only advanced treatment option for TDT is allogeneic hematopoietic stem cell transplant (HSCT).

Complications of allogeneic HSCT include a significant risk of treatment-related mortality, graft failure, graft vs. host disease and opportunistic infections, particularly in patients who undergo non-sibling-matched allogeneic HSCT.

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™ drug product, 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 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 Paris, France.

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 development, manufacturing and regulatory approval plans for its LentiGlobin product candidate to treat transfusion-dependent β -thalassemia including statements whether the manufacturing process changes for LentiGlobin will improve outcomes of patients with transfusion-dependent β -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, 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, the risks that the changes we have made in the LentiGlobin manufacturing process will not result in improved patient outcomes, 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 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 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.



Contact:

Investors:

bluebird bio, Inc.

Manisha Pai, 617-245-2107

mpai@bluebirdbio.com

Media:

bluebird bio, Inc.

Elizabeth Pingpank, 617-914-8736

epingpank@bluebirdbio.com

or

Pure Communications, Inc.

Dan Budwick, 973-271-6085