
**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 8, 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 September 8, 2016, bluebird bio, Inc. (“bluebird”) issued a press release announcing the opening of the Phase 3 HGB-207 clinical trial of its LentiGlobin product candidate in patients with transfusion-dependent beta-thalassemia. The full text of bluebird’s press release regarding this 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 September 8, 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.

bluebird bio, Inc.

Date: September 8, 2016

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on September 8, 2016.



Exhibit 99.1

bluebird bio Opens Phase 3 Study of LentiGlobin™ Drug Product in Patients with Transfusion-Dependent Beta-Thalassemia *-- HGB-207 trial to be conducted with enhancements to transduction process under the same IND as previous studies of LentiGlobin --*

CAMBRIDGE, Mass., September 8, 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, today announced the opening of HGB-207, a Phase 3, global, multi-center study in patients with transfusion-dependent beta-thalassemia with non- β^0/β^0 genotypes. This study will incorporate the addition of bluebird bio’s transduction enhancers to the hematopoietic stem cell (HSC) manufacturing process, and will be conducted under the same Investigational New Drug application (IND) as previous studies of LentiGlobin in beta-thalassemia.

“The opening of bluebird’s first Phase 3 study for LentiGlobin, in which we are using an improved manufacturing process that increases transduction efficiency, is an exciting step forward,” said David Davidson, M.D., chief medical officer, bluebird. “The accumulating clinical data show a correlation among vector copy number, the percentage of vector-containing cells, and the amount of hemoglobin produced by patients treated with LentiGlobin. We believe that the addition of our transduction enhancers to our manufacturing process has the potential to substantially increase the hemoglobin levels in patients with transfusion dependent beta-thalassemia and increase their likelihood of achieving clinically meaningful reductions in transfusion requirements or transfusion independence, the ultimate goal of our therapy.”

In this study, the process by which the patient’s cells are transduced with LentiGlobin will be modified by the addition of two additives during the transduction step of the manufacturing process, intended to increase vector copy number and the percentage of cells successfully transduced. bluebird also intends to incorporate these transduction enhancers into the manufacturing process for HGB-206, its ongoing study of LentiGlobin in patients with severe sickle cell disease (SCD).

About the HGB-207 Study

HGB-207 is a Phase 3, global, multi-center study designed to evaluate the safety and efficacy of LentiGlobin BB305 drug product in patients with transfusion-dependent beta-thalassemia and non- β^0/β^0 genotypes. The target enrollment of the study is 15 subjects. The study’s primary endpoint is transfusion independence, defined as a 12-month transfusion free period after transplant. This study is intended to be pivotal in the U.S. and confirmatory in the E.U.



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, 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 research and development plans for the Company's LentiGlobin product candidate in transfusion-dependent β -thalassemia and severe sickle cell disease. 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 results from our prior clinical trials of LentiGlobin will not continue or be repeated in our planned HGB-207 clinical trial, the risk that the introduction of the transduction improvements to the LentiGlobin manufacturing process may have a negative or no impact on clinical outcomes in our HGB-207 and HGB-206 clinical trials, the risk of cessation or delay of any of the ongoing or planned clinical trials of LentiGlobin., 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.

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