

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 21, 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 21, 2016, bluebird bio, Inc. issued a press release announcing that its LentiGlobin gene therapy for the treatment of patients with transfusion-dependent beta-thalassemia has been granted access by the European Medicines Agency (EMA) to the EMA's Priority Medicines (PRIME) program. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on September 21, 2016.

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**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 21, 2016

**bluebird bio, Inc.**

By: /s/ Jason F. Cole

Jason Cole

*Chief Legal Officer*

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**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on September 21, 2016.



**LentiGlobin™ Investigational Gene Therapy for Transfusion-Dependent Beta-Thalassemia Accepted into European Medicines Agency's PRIME Program**

**CAMBRIDGE, Mass.** – September 21, 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 that the European Medicines Agency (EMA) has granted access to its Priority Medicines (PRIME) scheme for LentiGlobin drug product in the treatment of patients with transfusion-dependent beta-thalassemia (TDT).

The PRIME initiative provides enhanced support and increased interaction to companies, with the goal of optimizing development plans and speeding regulatory evaluations to potentially bring innovative medicines to patients more quickly. To be accepted for PRIME, a therapy must demonstrate potential to benefit patients with unmet medical need through early clinical data or nonclinical data. Access to the PRIME initiative complements bluebird's ongoing participation in the EMA's Adaptive Pathways Pilot program, which also aims to expedite patient access to therapies with the potential to treat serious conditions with unmet need. It uses the existing EU regulatory framework for medicines, including conditional approval.

"PRIME designation will allow bluebird bio to further improve our communication with European regulators as we continue to refine our evidence generation plan in the context of adaptive biomedical innovation. Overall, we believe this will enable us to accelerate development of LentiGlobin drug product for patients with transfusion-dependent beta thalassemia, a life-shortening disease with significant unmet medical need," said David Davidson, M.D., chief medical officer, bluebird bio. "Earlier this year we completed enrollment in the Northstar (HGB-204) global clinical study of LentiGlobin drug product in patients with TDT, which along with the supporting HGB-205 study, will form the basis of our eventual application for conditional approval in the EU under the Adaptive Pathways Pilot program. As the data from both studies mature, we look forward to continuing to work with the EMA to bring LentiGlobin to patients who may benefit from gene therapy."

**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 four clinical studies for the treatment of transfusion-dependent  $\beta$ -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

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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 Company's EU regulatory plans for its LentiGlobin BB305 product candidate to treat transfusion-dependent  $\beta$ -thalassemia, including whether the current or planned clinical trials of LentiGlobin will be sufficient to support regulatory submissions for marketing approval, the expected timing of any such submissions and decisions, and any potential for an accelerated assessment of any future MAA for LentiGlobin. In addition, it should be noted that the EMA Adaptive Pathways program is a pilot program, and as such there is limited information and precedent regarding the potential outcomes for sponsors that participate in this program. 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 current or planned clinical trials, the risk of cessation or delay of any of the ongoing or planned clinical trials of LentiGlobin, the risk that the EMA will not deem the MAA for LentiGlobin sufficient for early or conditional approval in transfusion-dependent  $\beta$ -thalassemia. 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.*

#### **Investor Relations**

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