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): February 2, 2015

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)	(I.R.S. Employer Identification No.)

150 Second Street Cambridge, MA	**02141**
(Address of principal executive offices)	(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))

Item 8.01 Other Events.

On February 2, 2015, bluebird bio, Inc. ("bluebird") issued a press release announcing that the U.S. Food and Drug Administration has granted Breakthrough Therapy Designation to bluebird's LentiGlobin® product candidate for the treatment of transfusion-dependent patients with beta-thalassemia major. 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

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on February 2, 2015.

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: February 2, 2015

bluebird bio, Inc.

By: /s/ Jason F. Cole
Jason F. Cole
Senior Vice President, General Counsel

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on February 2, 2015.

Exhibit 99.1

NEWS RELEASE

FDA Grants Breakthrough Therapy Designation to LentiGlobin for Treatment of Beta-Thalassemia Major

CAMBRIDGE, Mass., February 2, 2015 – bluebird bio, Inc. (Nasdaq: BLUE) a clinical-stage company committed to developing potentially transformative gene therapies for severe genetic and rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to LentiGlobin® BB305 Drug Product for the treatment of transfusion-dependent patients with beta-thalassemia major.

LentiGlobin BB305 Drug Product aims to treat beta-thalassemia major and severe sickle cell disease by inserting a functional human beta-globin gene into the patient's own hematopoietic stem cells *ex vivo* and then returning those modified cells to the patient through an autologous stem cell transplantation.

"The FDA's Breakthrough designation of LentiGlobin highlights that new therapies are needed for the treatment of patients with beta-thalassemia major, especially treatments with the potential to meaningfully reduce or liberate patients from transfusion dependence," said David Davidson, M.D., chief medical officer of bluebird bio. "Our early clinical data investigating the use of LentiGlobin in patients with multiple genotypes of beta-thalassemia major, including beta-0/beta-0, the most severe genotype, are very encouraging, and we remain on track to complete enrollment in the Northstar and HGB-205 studies in 2015. In light of the Breakthrough designation, we look forward to working even more closely with the FDA to expedite the development of LentiGlobin for the treatment of beta-thalassemia major."

The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a drug candidate that is planned for use to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. The benefits of Breakthrough Therapy designation include the same benefits as Fast Track designation, plus an organizational commitment involving FDA's senior managers with more intensive guidance from the FDA. Breakthrough Therapy designation does not however change the standards for approval.

The Breakthrough Therapy designation is supported by data from the ongoing Phase 1/2 Northstar (HGB-204) and HGB-205 studies of LentiGlobin. Findings in eight subjects with beta-thalassemia major were presented at the 56th Annual Meeting of the American Society of Hematology (ASH) in December 2014. In the first four subjects, each of whom had at least three months of follow up, treatment resulted in sufficient hemoglobin production to reduce or eliminate the need for transfusion support among patients with beta-thalassemia major who would otherwise require chronic blood transfusions. These data consisted of the first five subjects treated in bluebird bio's ongoing Northstar Study and the first three subjects from its HGB-205 study. These included the first beta-thalassemia subjects with the beta-0/beta-0 genotype to be treated with LentiGlobin BB305 drug product. The HGB-205 study also included the first subject with sickle cell disease to be treated with gene therapy.

About bluebird bio, Inc.

With its lentiviral-based gene therapy and gene editing capabilities, bluebird bio has built an integrated product platform with broad potential application to severe genetic diseases and T cell-based immunotherapy. bluebird bio's clinical programs include Lenti-D™, currently in a Phase 2/3 study, called the Starbeam Study, for the treatment of childhood cerebral adrenoleukodystrophy, and LentiGlobin®, currently in three clinical studies: a global Phase 1/2 study, called the Northstar Study, for the treatment of beta-thalassemia major; a single-center Phase 1/2 study in France (HGB-205) for the treatment of beta-thalassemia major or severe sickle cell disease; and a separate U.S. Phase 1 study for the treatment of sickle cell disease (HGB-206). bluebird bio also has a preclinical CAR T cancer immunotherapy program in collaboration with Celgene Corporation, as well as discovery research programs utilizing megaTALs/homing endonuclease gene editing technologies.

bluebird bio has operations in Cambridge, Massachusetts, Seattle, Washington, and Paris, France. For more information, please visit www.bluebirdbio.com.

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 potential efficacy and safety of the Company's LentiGlobin product candidate and the regulatory pathway afforded by Breakthrough Designation by the FDA, in particular statements concerning the reduced or eliminated need for transfusion support in the four initial subjects treated with LentiGlobin drug product, statements concerning the Company's future plans with respect to LentiGlobin and its other product candidates and statements concerning anticipated enrollment rates and clinical milestones in 2015. It should be noted that the data for LentiGlobin announced from the Northstar and HGB-205 studies at the ASH Annual Meeting are preliminary in nature and the Northstar and HGB-205 studies are not completed. There is limited data concerning long-term safety and efficacy following treatment with LentiGlobin drug product. These data may not continue for these subjects or be repeated or observed in ongoing or future studies involving our LentiGlobin product candidate, including the HGB-205 Study, the Northstar Study or the HGB-206 study in sickle cell disease. It is possible that subjects for whom periodic transfusion support has been reduced or temporarily eliminated may receive transfusion support in the future. It should also be noted that Breakthrough designation does not change the standards for approval and is not a guarantee of success. 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 preliminary results from our clinical trials will not continue or be repeated in our ongoing clinical trials, the risk that previously conducted studies involving similar product candidates will not be repeated or observed in ongoing or future studies involving current product candidates, 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 the Company's clinical studies, the risk that our collaboration with Celgene 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.

Availability of other information about bluebird bio

Investors and others should note that we communicate with our investors and the public using our company website (www.bluebirdbio.com), our investor relations website (http://www.bluebirdbio.com/investor-splash.html), including but not limited to investor presentations and FAQs, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. You can also connect with us on Twitter @bluebirdbio, LinkedIn or our *YouTube* channel. *The information that we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in bluebird bio to review the information that we post on these channels, including our investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include other social media channels than the ones described above. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.*

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