
**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 8, 2014

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 8, 2014, bluebird bio, Inc. (“bluebird”) issued a press release announcing clinical data from its Northstar (HGB-204) and HGB-205 clinical trials of its LentiGlobin product candidate presented at the 56th Annual Meeting of the American Society of Hematology in San Francisco, CA on December 8, 2014. 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 8, 2014.

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: December 8, 2014

By: /s/ Jason F. Cole

Jason Cole

Senior Vice President, General Counsel

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on December 8, 2014.



bluebird bio Announces Data Demonstrating First Four Patients with β -Thalassemia Major Treated with LentiGlobin™ are Transfusion-Free

- Data Presented at ASH; Company to Host Investor Call on December 10 -

CAMBRIDGE, Mass. – December 8, 2014 – bluebird bio, Inc. (Nasdaq: BLUE) today announced data from eight subjects treated with LentiGlobin BB305 drug product. In the first four subjects, each of whom had at least three months of follow up, treatment with LentiGlobin BB305 drug product 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 include the first five subjects treated in bluebird bio's ongoing Phase 1/2 Northstar (HGB-204) Study and the first three subjects from its HGB-205 study. These studies include the first subjects with the beta-0/beta-0 genotype of beta-thalassemia major treated with LentiGlobin BB305 drug product and the first subject with sickle cell disease treated with gene therapy. These data are being presented today at the 56th Annual Meeting of the American Society of Hematology (ASH) in San Francisco.

"Beta-thalassemia major is a devastating disease that affects 40,000 newborn children globally every year, and the existing treatment options for these patients have significant side effects and limitations," said Alexis A. Thompson, M.D., M.P.H., professor of pediatrics at Northwestern University Feinberg School of Medicine, director of the Comprehensive Thalassemia Program at Ann & Robert H. Lurie Children's Hospital of Chicago and lead investigator of the Northstar Study, who presented the data in an oral presentation. "Data from the Northstar Study presented today further demonstrate the potential for a one-time gene therapy treatment to transform the lives of patients with beta-thalassemia major, including those with the most severe genotype of beta-thalassemia major, beta-0/beta-0, also known as Cooley's Anemia."

LentiGlobin BB305 drug product aims to treat beta-thalassemia major and severe sickle cell disease by inserting a fully functional human beta-globin gene into the patient's own hematopoietic stem cells *ex vivo* and then transplanting those modified cells into the patient through infusion, also known as autologous stem cell transplantation.

"We are very encouraged to see that each of the first four beta-thalassemia major subjects treated with LentiGlobin who had at least three months of follow up is producing robust levels of beta-T87Q-globin and is transfusion-free," said David Davidson, M.D., chief medical officer, bluebird bio. "We are on track to complete patient enrollment for the Northstar and HGB-205 studies in 2015, and as the clinical data continue to mature, we will work closely with medical experts, patient communities and regulatory authorities to define the regulatory path forward for LentiGlobin."

Northstar Study Data

The Northstar Study is an ongoing, open-label, single-dose, international, multicenter Phase 1/2 study designed to evaluate the safety and efficacy of LentiGlobin BB305 drug product for the treatment of subjects with beta-thalassemia major. As of December 1, 2014, five subjects with beta-thalassemia major have undergone infusion with LentiGlobin BB305 drug product in the Northstar Study. The first two subjects treated in the Northstar Study are producing steadily increasing amounts of beta-T87Q-globin and have been free from the need for transfusions for the past five months and three months, respectively. Three additional subjects have been infused, but it is too early to draw any meaningful conclusions on clinical efficacy.

	1102	1104	1106	1107	1108
Patient					
Age/Sex	18/F	21/F	20/F	26/F	18/F
Country of birth	USA	Thailand	Pakistan	Australia	USA
Genotype	B0/BE	B0/BE	B0/B0	B0/B0	B0/B+
Transfusion requirements (mls/kg/year)	137	153	197	223	144
CD34+ VCN	1.0/1.1*	0.7/0.7*	1.5	1.0	0.9
CD34+ cell count (x10 ⁶ /kg)	6.5	5.4	13.5	15.0	7.9
Days to neutrophil engraftment	Day +17	Day +18	Day +29	Day +14	NA
HbAT87Q/total Hb (g/dL)	3.8/8.6	0.27/9.8	6.8/9.6	0.34/9.6	NA
Last study follow up (months)	6	1**	3	1	<1

*If more than one drug product was manufactured for a subject, the VCN of each drug product lot is quantified and the cell count is combined.

**Data includes two months of follow-up on safety only.

HGB-205 Study Data

HGB-205 is an ongoing, open-label, single-center Phase 1/2 study designed to evaluate the safety and efficacy of LentiGlobin BB305 drug product in the treatment of subjects with beta-thalassemia major and severe sickle cell disease. As of December 1, 2014, two subjects with beta-thalassemia major have undergone infusion with LentiGlobin BB305 drug product. Both of these subjects achieved rapid transfusion independence with near-normal hemoglobin levels, similar to what may be expected from a successful allogeneic transplant, and have been free from the need for transfusions for the past 12 months and nine months, respectively. The third treated subject, the first individual with sickle cell disease ever to be treated with gene therapy, has achieved neutrophil engraftment, but it is too early post-transplant to draw any meaningful conclusions on clinical efficacy.

	Beta Thalassemia Major		Severe Sickle Cell Disease
Patient	1201	1202	1204
Enrolment age/Sex	18/F	16/M	13/M
Country of birth	Syria	France	France
Genotype	B0/BE	B0/BE	BS/BS
Transfusion requirements (mls/kg/year)	139	188	170
CD34+ VCN	1.5	2.1	1.2/1.0*
CD34+ cell count(x10 ⁶ /kg)	8.9	13.6	5.6
Days to neutrophil engraftment	Day +13	Day +15	Day +37
HbAT87Q/total Hb (g/dL)	7.7/11.0	9.6/13.4**	NA
Last study follow up (months)	12	9	1

*If more than one drug product was manufactured for a subject, the VCN of each drug product lot is quantified and the cell count is combined.

**Hemoglobin levels represent data from the six-month follow up visit. Nine-month visit hemoglobin data not yet available.

In both studies, treatment with LentiGlobin BB305 drug product has been well tolerated to date, with no gene therapy-related Grade 3 or greater adverse events observed. All integration site analyses that have been performed to date show a polyclonal reconstitution without any evidence of clonal dominance.

“Today’s data demonstrate the potential benefit of gene therapy across beta-hemoglobinopathies as we begin gaining insights into its therapeutic potential for patients with severe sickle cell disease,” said Marina Cavazzana, M.D., Ph.D., professor of medicine at Paris Descartes University and research director at the Centre for Clinical Research in Biotherapy, Necker Hospital, and at the Institute of Genetic Diseases, *Imagine*, Paris, France. “Sickle cell disease affects millions of people around the world, significantly impacting their quality of life. The only currently available curative treatment for sickle cell disease is an allogeneic hematopoietic stem cell transplant, which is not accessible to most patients due to lack of suitable donors, so we are eager to explore LentiGlobin’s potential as a one-time therapy.”

Investor Conference Call and Webcast Information

bluebird bio will host a conference call and webcast on Wednesday, December 10, 2014 at 8:00 am EST to review the data presented at ASH. The event will be webcast live and can be accessed under "Calendar of Events" in the Investors and Media section of the company's website at www.bluebirdbio.com. Alternatively, investors may listen to the call by dialing (844) 825-4408 from locations in the United States and (315) 625-3227 from outside the United States.

About Beta-Thalassemia

Beta-thalassemia is an inherited blood disease that can cause severe anemia. Patients with beta-thalassemia cannot make enough of the beta-globin part of hemoglobin, the protein used by red blood cells to carry oxygen throughout the body. Approximately 40,000 children are born with a serious form of the disease every year, making it one of the most common genetic diseases in the world. In its most severe form, beta-thalassemia is fatal if not treated.

Treating beta-thalassemia includes frequent and lifelong blood transfusions, which deliver red blood cells to the body to correct the anemia. However, blood transfusions also cause excess iron to build up in the body, which can damage organs and cause additional issues, such as abdominal pain, weakness, fatigue, joint pain, endocrine dysfunction, liver cirrhosis and heart failure. Patients who receive ongoing blood transfusions must also receive treatment to remove the excess iron. The only currently available curative treatment option for beta-thalassemia is allogeneic hematopoietic stem cell transplant. However, these transplants are only offered to pediatric patients with matched sibling donors (occurring in less than 25 percent of all cases), due to the significant risk of transplant-related morbidity and mortality.

About the Northstar (HGB-204) Study

Northstar is an ongoing, open-label, single-dose, international, multicenter Phase 1/2 study designed to evaluate the safety and efficacy of LentiGlobin BB305 drug product in the treatment of subjects with beta-thalassemia major. The study is designed to enroll up to 15 subjects who will be evaluated for safety and efficacy post-transplant. For more information on the Northstar Study, please visit www.northstarstudy.com or clinicaltrials.gov using identifier NCT01745120.

About the HGB-205 Study

HGB-205 is an ongoing, open-label Phase 1/2 study designed to evaluate the safety and efficacy of LentiGlobin BB305 drug product in the treatment of subjects with beta-thalassemia major and severe sickle cell disease. The study is designed to enroll up to seven subjects who will be followed to evaluate safety and transfusion requirements post-transplant. Among patients with sickle cell disease only, efficacy will also be measured based on the number of vaso-occlusive crises or acute chest syndrome events. For more information on the HGB-205 study, please visit clinicaltrials.gov using identifier NCT02151526.

About bluebird bio, Inc.

bluebird bio is a clinical-stage company committed to developing potentially transformative gene therapies for severe genetic and orphan diseases. bluebird bio has two clinical-stage programs in development. The most advanced product candidate, Lenti-D, is in a Phase 2/3 study, the Starbeam Study, for the treatment of childhood cerebral adrenoleukodystrophy (CCALD), a rare, hereditary neurological disorder affecting young

boys. The next most advanced product candidate, LentiGlobin, is currently in two Phase 1/2 studies for the treatment of beta-thalassemia major, one in the United States, Australia and Thailand (the Northstar Study) and one in France (HGB-205). The Phase 1/2 HGB-205 study also allows enrollment of patient(s) with sickle cell disease, and bluebird bio has initiated a separate U.S. sickle cell disease trial (HGB-206). bluebird bio also has an early-stage chimeric antigen receptor-modified T cell (CAR-T) program for oncology in collaboration with Celgene Corporation.

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, 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. 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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