# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): November 6, 2014

# bluebird bio, Inc.

(Exact name of registrant as specified in its charter)

incorporation) Fil  150 Second Street Cambridge, MA  (Address of principal executive offices)	mmission Number)  (I.R.S. Employer Identification No.)  02141 (Zip Code)
150 Second Street Cambridge, MA (Address of principal executive offices)	02141
(Address of principal executive offices)	
` • • · · · · · · · · · · · · · · · · ·	(Zip Code)
Registrant's telephone number	
	including area code (339) 499-9300
Not	applicable
(Former name or former ad	ress, if changed since last report)
Check the appropriate box below if the Form 8-K filing is intended to simulprovisions:	aneously satisfy the filing obligation of the registrant under any of the fo
☐ Written communications pursuant to Rule 425 under the Securities Act (	7 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 November 6, 2014, bluebird bio, Inc. ("bluebird") issued a press release announcing its abstract presentations at the 56th Annual Meeting of the American Society of Hematology in San Francisco, CA on December 6th – 9th. 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 November 6, 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: November 6, 2014 By: /s/ Jason F. Cole

Jason Cole

Senior Vice President, General Counsel

# EXHIBIT INDEX

Exhibit No. 99.1 Description Press release issued by bluebird bio, Inc. on November 6, 2014.



#### bluebird bio to Present LentiGlobin Clinical Data at the American Society of Hematology Conference

-- Two abstracts accepted for presentation
-- Data to be presented from the Northstar Study and from the HGB-205 Study
-- Company to host investor call on Wednesday, December 10, 2014

CAMBRIDGE, MA, November 6, 2014 – bluebird bio, Inc. (Nasdaq: BLUE) a clinical-stage company committed to developing potentially transformative gene therapies for severe genetic and orphan diseases, today announced that data from its ongoing Phase 1/2 HGB-205 and Northstar Studies of LentiGlobin BB305 Drug Product will be presented at the 56th Annual Meeting of the American Society of Hematology (ASH) taking place December 6 – 9, 2014 in San Francisco, California.

"We are encouraged by the data generated so far from the ongoing LentiGlobin phase 1/2 studies. In the HGB-205 trial, the two subjects with beta-thalassemia previously presented at the 19th Annual Congress of the European Hematology Association (EHA) on June 14, 2014 who became transfusion independent shortly after treatment with LentiGlobin BB305 Drug Product remain transfusion independent at days 180 and 90 post-transplant, with both subjects generating over 6 g/dl of globin derived from the BB305 Drug Product transgene. At ASH we plan to present further follow up data on both of these subjects." stated David Davidson, M.D. bluebird bio's Chief Medical Officer.

"In the Northstar Study, at the time of the abstract submission, one subject had received LentiGlobin BB305 Drug Product. In this subject we have observed a monthly increase in beta-T87Q-globin levels following infusion, reaching 1.8g/dL at month 3, and we are encouraged by the trajectory of the beta-T87Q-globin increase to date. At ASH we plan to provide additional follow-up data on this subject, and early data on at least two additional subjects treated in the Northstar Study, including a subject with the beta0/beta0 genotype of beta-thalassemia," continued Dr. Davidson.

The accepted abstracts are listed below and are now available online on the ASH conference web site: www.hematology.org/Annual-Meeting. Information contained in the abstracts reflect data available as of July 31, 2014.

#### **Oral Presentation:**

**Title:** Initial Results from the Northstar Study (HGB-204): A Phase 1/2 Study of Gene Therapy for Beta-Thalassemia Major via Transplantation of Autologous Hematopoietic Stem Cells Transduced *Ex Vivo* with a Lentiviral BetaA-T87Q-Globin Vector (LentiGlobin BB305 Drug Product). A. Thompson, M.D. *et al* 

Abstract: 549

Session Name: 801. Gene Therapy and Transfer I

**Date**: Monday, December 8, 2014 **Session Time**: 2:45 PM – 4:15 PM **Oral Presentation Time**: 3:15 PM

Location: Moscone Center, South Building, Gateway Ballroom 104

#### Poster Presentation:

Title : Study HGB-205 : Outcomes of Gene Therapy for Hemoglobino pathies via Transplantation of Autologous Hematopoietic Stem Cells Transduced Ex

Vivo with a Lentiviral BetaA-T87Q-Globin Vector (Lentiglobin BB305 Drug Product). Marina Cavazzana, M.D. Ph.D et al

Abstract: 4797

Session Name: 801. Gene Therapy and Transfer: Poster III

**Date**: Monday, December 8, 2014 **Session Time**: 6:00 PM - 8:00 PM

Location: Moscone Center, West Building, Level 1

#### **Investor Conference Call and Webcast Information**

bluebird bio will host a conference call and webcast on Wednesday, December 10, 2014 at 8.00 am EDT to review data presented at ASH, including new data since the submission of the data abstracts. 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.

#### About the Northstar (HGB-204) Study

The phase 1/2 study is designed to evaluate the feasibility, 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 fifteen subjects. Subjects 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

The phase 1/2 study is designed to evaluate the safety and efficacy of LentiGlobin 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. Subjects will be followed to evaluate safety and transfusion requirements post-transplant. In sickle cell disease patients 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 recently-initiated 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, one in the US (the Northstar Study) and one in France (HGB-205), for the treatment of beta-thalassemia major. 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 BB305 product candidate, the Company's plans with respect to LentiGlobin and its other product candidates and anticipated clinical and business milestones and announcements. In addition, it should be noted that the data for LentiGlobin announced from the Northstar and HGB-205 studies are preliminary in nature and the Northstar and HGB-205 studies are not completed. 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 severe SCD. 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 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 the results of previously conducted studies involving similar product candidates will not be repeated or observed in ongoing or future studies involving current product candidates, 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 annual report on Form 10-K, 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 (<a href="http://www.bluebirdbio.com/">www.bluebirdbio.com/</a>, our investor relations website (<a href="http://www.bluebirdbio.com/">http://www.bluebirdbio.com/</a> 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.

#### **Investor Relations:**

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