
**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): November 3, 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 November 3, 2016, bluebird bio, Inc. (“bluebird”) issued a press release announcing its abstract presentations at the 58th Annual Meeting of the American Society of Hematology taking place in San Diego, California on December 3 – 6, 2016.

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 November 3, 2016, furnished herewith.

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: November 3, 2016

bluebird bio, Inc.

By: /s/ Jason F. Cole

Jason F. Cole

Chief Legal Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on November 3, 2016, furnished herewith.

bluebird bio to Present New Data from Three LentiGlobin™ Clinical Studies at American Society of Hematology (ASH) Annual Meeting

- Data from the Northstar (HGB-204) study of LentiGlobin drug product in transfusion-dependent β -thalassemia (TDT) show that all five patients with non- β^0/β^0 genotypes and ≥ 12 months of follow-up remained free of transfusions and patients with β^0/β^0 genotypes and ≥ 12 months of follow-up ($n=5$) had a median reduction in transfusion volume of 60%–*
- The median HbAT^{87Q} level at six months in Northstar was 4.7 g/dl across all genotypes and levels were generally sustained over the second year of follow-up –*
- All patients with TDT from the HGB-205 study remained free of transfusions, including two who have completed two-year primary follow-up period –*
- Patient with severe sickle cell disease (SCD) from HGB-205 study producing 53 percent HbAT^{87Q} at 18 months post-treatment, free from clinical symptoms of SCD –*
- Interim results from seven subjects in HGB-206 study in severe SCD support need for recently implemented study protocol amendments –*

CAMBRIDGE, Mass., November 3, 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, announced that data from its ongoing clinical studies of LentiGlobin drug product in transfusion-dependent β -thalassemia (TDT) and severe sickle cell disease (SCD) will be highlighted in oral and poster presentations at the 58th Annual Meeting of the American Society of Hematology (ASH). Preliminary data in these abstracts became available on the ASH conference website at 9:00 am ET today.

“In Northstar, the largest study of gene therapy in patients with TDT to date, all patients have demonstrated robust expression of therapeutic hemoglobin, or HbAT^{87Q}, with a safety profile that is consistent with autologous transplantation. We are particularly pleased to see that, across the Northstar and HGB-205 studies, all patients with non- β^0/β^0 genotypes and at least 12 months of follow-up remained free of transfusions for up to 31 months, adding to the growing body of evidence supporting the potential for LentiGlobin to become a transformative therapy for these patients. Additionally, we have seen clinically meaningful reductions in transfusions for patients with β^0/β^0 genotypes. We believe that the implementation of manufacturing process 2 going forward has the potential to further reduce transfusion requirements for patients with β^0/β^0 genotypes, and we will evaluate that hypothesis in our planned Phase 3 HGB-212 trial,” said David Davidson, M.D., chief medical officer, bluebird bio. “In SCD, the therapeutic promise of LentiGlobin is demonstrated by the sustained benefit observed in patient 1204 in the HGB-205 study, and we have implemented numerous protocol modifications to optimize outcomes in patients treated in the HGB-206 study. As we highlighted at our recent Gene



Therapy Day, we believe amendments to the study protocol aimed at optimizing cell dose, transduction efficiency and myeloablation will improve engraftment of gene-modified cells – and ultimately increase HbAT^{87Q} production in patients with SCD. All patients treated in the HGB-206 study going forward will be treated under this modified protocol, and we look forward to seeing initial clinical results in 2017 reflecting these changes.”

bluebird bio Presentations

LentiGlobin Gene Therapy for Transfusion-Dependent β -Thalassemia: Update from the Northstar (HGB-204) Phase 1/2 Clinical Study (Abstract #1175)

Presenter: Alexis Thompson, M.D., M.P.H., Ann & Robert H. Lurie Children’s Hospital of Chicago, Chicago, IL

Date: Monday, December 5, 2016, 5:30 pm PT

Session: 801. Gene Therapy and Transfer: Gene Therapy for Benign Hematologic Diseases

Abstract Results, as of June 27, 2016 Data Cut-off:

- Eighteen patients have received LentiGlobin drug product: eight with β^0/β^0 genotypes and 10 with non- β^0/β^0 genotypes
 - The median vector copy number (VCN) in drug product (DP) was 0.7 (range: 0.3 – 1.5 copies/diploid genome) and the median cell dose was 8.1×10^6 CD34+ cells/kg (range: 5.2 – 18.1×10^6 cells/kg)
 - The median *in vivo* VCN in patients with at least six months of follow-up was 0.4 copies/diploid genome (range: 0.2-1.0; n=13)
 - Patients of all genotypes with at least six months of follow-up (n=14) achieved a median HbAT^{87Q} level of 4.7 g/dl and robust HbAT^{87Q} production was sustained in the 10 patients with ≥ 12 months of follow-up
 - All patients with non- β^0/β^0 genotypes and at least 12 months follow-up (n=5) have discontinued transfusions and remain free of transfusions (median 19.4 months without transfusion; range: 15.3 to 24.0 months)
 - All patients with β^0/β^0 genotypes have considerably reduced transfusion requirements (from median 171.9 ml/kg/year at baseline [range: 168.1- 223.2 ml/kg/year] to 67.8 ml/kg/year post-treatment [range: 14.8 to 123.7 ml/kg/year])
 - The safety profile remains consistent with autologous stem cell transplantation with no \geq Grade 3 drug product-related adverse events (AEs) reported
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Update from the HGB-205 Phase 1/2 Clinical Study of LentiGlobin Gene Therapy: Sustained Clinical Benefit in Severe Hemoglobinopathies (Abstract #2311)

Presenter: Marina Cavazzana, M.D., Ph.D., Hôpital Universitaire Necker – Enfants Malades, Paris, France

Date: Saturday, December 3, 2016, 5:30 – 7:30 pm PT

Poster Session: 801. Gene Therapy and Transfer: Poster I

Abstract Results, as of July 2016 Data Cut-off:

- One patient with severe SCD (male; 13 years old) and four patients with TDT (two male, two female; 16-19 years old) have received LentiGlobin drug product
- The median LentiGlobin drug product cell dose was 8.9 (range: 5.6 – 13.6) x 10⁶ CD34+ cells/kg with a median DP VCN of 1.2 (range: 0.8 – 2.1) vector copies/diploid genome. *In vivo* VCN remained generally consistent from Month 3 in all patients with a median of 1.9 copies/diploid genome (range: 0.3 - 3.3) at last follow-up.
- Subject 1204 with severe SCD is producing 53 percent HbAT87Q at 18 months post-infusion (6.6 g/dL). This subject has experienced no hospitalizations or vaso-occlusive crises (VOCs) since treatment in October 2014, despite discontinuing transfusions three months after LentiGlobin drug product infusion.
- The two TDT patients who completed the two-year primary follow-up period have remained transfusion-free for 31 and 28 months, with HbAT87Q expression of 7.7 and 10.1 g/dL, respectively. Both subjects have the β^0/β^E genotype.
- The remaining patient with TDT with the β^0/β^E genotype has nine months of follow-up and has not required transfusions since four days after LentiGlobin drug product infusion
- One patient homozygous for the severe β^+ mutation IVS1-110 has 12 months of follow-up, and has been free of transfusions for nine months. Patients with this mutation make almost no endogenous β -globin.
- No patient has experienced a drug product-related AE in this study, and there has been no evidence of clonal dominance

Interim Results from a Phase 1/2 Clinical Study of LentiGlobin Gene Therapy for Severe Sickle Cell Disease (Abstract #1176)

Presenter: Julie Kanter, M.D., Medical University of South Carolina, Charleston, SC

Date: Monday, December 5, 2016, 5:45 pm PT

Session: 801. Gene Therapy and Transfer: Gene Therapy for Benign Hematologic Diseases

Abstract Results, as of July 2016 Data Cut-off:

- All seven treated subjects successfully engrafted
 - The median LentiGlobin drug product cell dose was 2.1 x 10⁶ CD34+ cells/kg (range: 1.6 – 5.1)
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- Median DP VCN was 0.6 (range: 0.3–1.3) vector copies/diploid genome, while median *in vivo* VCN measured in peripheral blood was 0.08 (range: 0.05–0.13) vector copies/diploid genome at last measurement
- All subjects express HbA^{T87Q}, with a median of 0.4g/dL (range: 0.1–1.0 g/dL, n=7) at three months
- The relatively low *in vivo* VCN in this study compared to other studies appears to result in the lower HbA^{T87Q} expression seen to date
- Protocol amendments have been implemented with the goal of increasing *in vivo* VCN in patients with SCD, such as increasing the transduced cell dose through alternate hematopoietic stem cell procurement methods, increasing the percentage of transduced cells through manufacturing improvements, increasing target busulfan area under the curve (AUC), and instituting blood transfusions prior to stem cell collection and conditioning

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-DTM product candidate, currently in a Phase 2/3 study, called the Starbeam Study, for the treatment of cerebral adrenoleukodystrophy, and its LentiGlobinTM BB305 product candidate, currently in four 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 Company's research, development, manufacturing and regulatory approval plans for its LentiGlobin product candidate to treat transfusion-dependent β -thalassemia and severe sickle cell



disease, including statements whether the planned manufacturing process changes for LentiGlobin will improve outcomes of patients with transfusion-dependent β -thalassemia and severe sickle cell disease and whether the planned changes to the HGB-206 clinical trial protocol will improve outcomes in patients with 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 positive results from our prior and ongoing clinical trials of LentiGlobin will not continue or be repeated in our ongoing or planned clinical trials of LentiGlobin, the risks that the changes we have made in the LentiGlobin manufacturing process or the HGB-206 clinical trial protocol will not result in improved patient outcomes, risks that the current or planned clinical trials of LentiGlobin will be insufficient to support regulatory submissions or marketing approval in the US and EU, the risk of a delay in the enrollment of patients in our clinical studies, 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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