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 5, 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 November 5, 2015, bluebird bio, Inc. ("bluebird") issued a press release announcing its abstract presentations at the 57th Annual Meeting of the American Society of Hematology in Orlando, Florida on December 5-8, 2015. 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 5, 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.

bluebird bio, Inc.

Date: November 5, 2015

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 November 5, 2015.

Exhibit 99.1

bluebird bio to present LentiGlobin® BB305 Clinical Data and bb2121 Preclinical Data at Annual Meeting of the American Society of Hematology

– Six abstracts accepted for presentation –
– Interim data on LentiGlobin in beta-thalassemia show six of six evaluable non-β^0/β^0 patients are transfusion-independent as of July 31st data cut-off; β^0/β^0 patients have achieved varying degrees of transfusion reduction as of data cut-off –
– Median production of corrected HbA^{T87Q} globin: 5.2 g/dL among patients of all genotypes followed for at least six months in HGB-204 study, as of July 31st data cut-off –
– Patient with sickle cell disease from HGB-205 study producing 51.5% anti-sickling hemoglobin at nine months post-treatment –
– Company will discuss ASH abstract data in a conference call today at 8:30 a.m. ET –

CAMBRIDGE, Mass. November 5, 2015 – 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, announced that data from its ongoing clinical studies of LentiGlobin BB305 in beta-thalassemia major and severe sickle cell disease (SCD) will be highlighted in oral and poster presentations at the 57th Annual Meeting of the American Society of Hematology (ASH). The company will also present preclinical data from its lead oncology program, bb2121, in three posters at ASH. bluebird bio is developing bb2121 as an anti-BCMA oncology therapy in collaboration with Celgene Corporation. Preliminary data from all six of these abstracts will become available on the ASH conference web site at 9:00 a.m. ET today.

“Our expanding clinical experience with LentiGlobin continues to show promising clinical benefit in patients with beta-thalassemia major and severe sickle cell disease,” said David Davidson, M.D., chief medical officer, bluebird bio. “We are pleased to see a median HbA^{T87Q} level of 5.2 g/dL in the seven Northstar patients with beta-thalassemia major of all genotypes followed for six months or more, as this represents a substantial proportion of their total hemoglobin. It is exciting that transfusion independence has been achieved in all of our patients with beta-thalassemia major with non-β^0/β^0 genotypes followed for at least six months in Northstar and HGB-205. Varying degrees of transfusion reduction have been observed in patients with β^0/β^0 genotypes. As would be expected, longer follow-up is required to assess the extent of HbA^{T87Q} production and the impact on transfusion requirements in these patients with β^0/β^0 genotypes since they produce no functional beta-globin at baseline. Turning to sickle cell disease, our first treated patient is producing increased levels of HbA^{T87Q} since we last reported on this study in June. HbA^{T87Q} represented 48 percent of total hemoglobin at nine months post-infusion, and the patient remains transfusion independent without sickle cell-related adverse events as of the data cut-off. These results support the transformative potential of gene therapy, and we look forward to sharing more data at ASH.”

“The three accepted oncology abstracts represent the great progress we have made building our immuno-oncology business,” said Rob Ross, M.D., head of oncology, bluebird bio. “These posters describe the encouraging pre-clinical data supporting the development of bb2121 in multiple myeloma, including our

robust manufacturing platform, and key scientific insights into engineering more potent CARs that are applicable across our planned oncology portfolio."

LentiGlobin Presentations

Update of 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 Beta AT87Q-Globin Vector (LentiGlobin BB305 Drug Product) (Abstract #201)

Presenter: Mark C. Walters, M.D., UCSF Benioff Children's Hospital, Oakland, CA

Date: Sunday, December 6, 2015

Abstract Results, as of July 31st Data Cut-off:

- Seven subjects have been monitored for at least six months post-infusion: three of the β^0/β^0 genotype and four of the non-β^0/β^0 genotype.
- The median level of HbA^{T87Q} expression among these seven subjects is 5.2 g/dL (range 1.9 to 8.2 g/dL), with total hemoglobin ranging from 8.5 to 11.1 g/dL at last visit.
- All four non-β^0/β^0 subjects have been transfusion-free for at least 90 days, with a median of 287 days transfusion-free (range: 171 to 396 days).
- Two of the β^0/β^0 subjects have received a single transfusion post-discharge, and one remains transfusion-dependent.
- All subjects engrafted.
- The safety profile was consistent with autologous transplantation. No Grade 3 or higher drug-product related adverse events have been observed, and there is no evidence of clonal dominance after a median follow-up of 198 days (range: 65 to 492 days).

Outcomes of Gene Therapy for Severe Sickle Disease and Beta-Thalassemia Major via Transplantation of Autologous Hematopoietic Stem Cells Transduced *Ex Vivo* with a Lentiviral Beta AT87Q-Globin Vector (Abstract #202)

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

Date: Sunday, December 6, 2015

Abstract Results, as of July 31st Data Cut-Off:

- The subject with severe SCD is producing approximately 51.5% anti-sickling hemoglobin (48 percent HbA^{T87Q}, 1.8 percent HbF, 1.7 percent HbA2) at nine months post-infusion.
- The subject with severe SCD remains free of transfusions.
- The subject with severe SCD has not had a post-treatment hospitalization for a disease-related event despite ceasing chronic transfusions on Day +88.
- Both subjects with beta-thalassemia major have remained transfusion-free for at least 15 months post-infusion, with consistent expression of HbA^{T87Q} – both subjects are β^0/β^E genotype.
- One additional subject with beta-thalassemia major had one month follow-up post-infusion.
- No subject has experienced a drug product-related adverse event, and there is no evidence of clonal dominance.

Initial Results from Study HGB-206: A Phase 1 Study Evaluating Gene Therapy by Transplantation of Autologous CD34+ Stem Cells Transduced *Ex Vivo* with the LentiGlobin BB305 Lentiviral Vector in Subjects with Severe Sickle Cell Disease (Abstract #3233)

Presenter: John F. Tisdale, M.D., National Institutes of Health, Bethesda, MD

Date: Sunday, December 6, 2015

Abstract Results, as of July 31st Data Cut-Off:

- LentiGlobin BB305 drug product has been manufactured for 2 subjects with severe SCD and 1 subject has been infused.
- The safety profile has been consistent with autologous transplantation, with no Grade 3 or higher drug product-related adverse events.

bb2121 Presentations

Manufacturing an Enhanced CAR T Cell Product by Inhibition of the PI3K/Akt Pathway During T Cell Expansion Results in Improved *In Vivo* Efficacy of Anti-BCMA CAR T Cells (Abstract #1893)

Presenter: Molly Perkins, D.Phil., bluebird bio, Cambridge, MA

Date: Saturday, December 5, 2015

Abstract Results, as of July 31st Data Cut-Off:

- In an *in vivo* aggressive lymphoma model, mice treated with anti-BCMA CAR T cells cultured with IL-2 and an inhibitor of PI3K experienced complete and long-term tumor regression; mice treated with anti-BCMA CAR T cells cultured only with IL-2 experienced no effect on tumor growth and succumbed to the tumors within two weeks after treatment; anti-BCMA CAR T cells grown in IL-7 and IL-15 also did not affect tumor growth.
- In an *in vivo* multiple myeloma model, mice received a single administration of anti-BCMA CAR T cells cultured under various conditions; all treatment groups demonstrated tumor regression regardless of culture conditions. In a model of tumor relapse, two weeks after tumor clearance, surviving mice were re-challenged with the same multiple myeloma model on the opposite flank; only animals that had been treated with anti-BCMA CAR T cells cultured with the PI3K inhibitor were able to resist subsequent tumor challenge.
- These data suggest that inhibition of PI3K during *ex vivo* expansion may generate a superior anti-BCMA CAR T cell product for clinical use; this approach could potentially be used in manufacture of other anti-tumor CAR therapies.

A Novel and Highly Potent CAR T Cell Drug Product for Treatment of BCMA-Expressing Hematological Malignancies (Abstract #3094)

Presenter: Alena Chekmasova, Ph.D., bluebird bio, Cambridge, MA

Date: Sunday, December 6, 2015

Abstract Results, as of July 31st Data Cut-Off:

- bluebird bio has developed a chimeric antigen receptor (CAR) targeting BCMA (bb2121) that consists of extracellular single chain variable fragment scFv antigen recognition domain derived from antibodies to BCMA linked to CD137 (4-1BB) co-stimulatory and CD3zeta chain signaling domains.
- Based on receptor density quantification bb2121 can recognize tumor cells expressing less than 800 BCMA molecules per cell.

- In a BCMA+ MM xenograph model, treatment with bb2121 resulted in rapid and sustained elimination of the tumors and 100 percent survival.

Characterization of Lentiviral Vector Derived Anti-BCMA CAR T Cells Reveals Key Parameters for Robust Manufacturing of Cell-Based Gene Therapies for Multiple Myeloma (Abstract #3243)

Presenter: Graham W.J. Lilley, M.Sc., bluebird bio, Cambridge, MA

Date: Sunday, December 6, 2015

Abstract Results, as of July 31st Data Cut-Off:

- Successful personalized medicine will require robust and reproducible cell manufacturing. A series of experiments were conducted to determine whether variations in anti-BCMA CAR surface expression resulted in changes in the activity of CAR T cells.
- The potency of the final drug product was shown to be independent of total anti-BCMA CAR expression on the cell surface.
- T cells transduced with varying MOIs to yield different amounts of CAR surface expression were diluted with donor-matched untransduced cells to achieve a uniform population of T cells containing 26 $\pm$ 4 percent anti-BCMA CAR T cells. When exposed to tumor, these CAR T cell populations exhibited no difference in cytotoxicity against BCMA-expressing cells. All T cell productions easily achieved a level of anti-BCMA CAR expression that resulted in potent anti-BCMA activity.
- These data show that our manufacturing platform has been optimized to overcome significant challenges associated with personalized medicine by reducing the effects of variability while maintaining potency in autologous cellular drug product manufacturing.

Investor Conference Call and Webcast Information
bluebird bio will host a conference call and webcast at 8:30 a.m. ET today, November 5th, 2015, to discuss the ASH abstract data and business updates. 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. The webcast will be available for replay for 30 days on the company website. Alternatively, investors may listen to the call by dialing (844) 825-4408 from locations in the United States or (315) 625-3227 from outside the United States. Please refer to conference ID number 71389854**.**

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™ product candidate currently in a Phase 2/3 study, called the Starbeam Study, for the treatment of childhood cerebral adrenoleukodystrophy, and LentiGlobin® BB305 product candidate, 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 severe sickle cell disease (HGB-206). bluebird bio also has ongoing preclinical CAR T immuno-oncology programs, 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.

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 in subjects with beta thalassemia major and severe sickle cell disease, including statements concerning the production of HbA^{T87Q} and the reduced or eliminated need for transfusion support for the study subjects with beta thalassemia major, statements regarding the potential efficacy and safety of the Company's bb2121 product candidate, statements concerning the Company's future plans with respect to LentiGlobin, bb2121 and its other product candidates. It should be noted that the data announced for LentiGlobin are preliminary in nature and the Northstar, HGB-205 and HGB-206 studies of LentiGlobin are not completed. There is limited data concerning long-term safety and efficacy following treatment with LentiGlobin. 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 sickle cell disease. It is possible that subjects for whom transfusion support has been reduced or 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 that the preclinical efficacy and safety data for our bb2121 product candidate will not be observed in our planned clinical studies, 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 our clinical studies, the risk that our collaboration with Celgene Corporation 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.

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