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): October 13, 2016

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 October 13, 2016, bluebird bio, Inc. ("bluebird") issued a press release announcing its research and development strategies for its gene therapy programs, including bluebird's progress with manufacturing process improvements, planned changes to its HGB-206 clinical trial of its Lenti-Globin product candidate for the treatment of severe sickle cell disease, and regulatory updates for its Lenti-Globin product candidate for the treatment of transfusion-dependent beta-thalassemia.

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 October 13, 2016.

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: October 13, 2016

bluebird bio, Inc.

By:/s/ Jason F. Cole
Jason F. Cole
Chief Legal Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on October 13, 2016.

Exhibit 99.1

bluebird bio Provides Update on LentiGlobin™ Programs and Research and Development Strategy at Gene Therapy Day

– Consistently demonstrated improved vector copy number (VCN) in transfusion-dependent β-thalassemia (TDT) and severe sickle cell disease (SCD) patient cells in vitro *with manufacturing Process 2 –*

– Implementing plan to optimize patient outcomes in severe SCD –

– Achieved general agreement on regulatory path for TDT across all genotypes, ages –

– Advanced suspension manufacturing process –

NEW YORK, NY, October 13, 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, will outline today key activities underway intended to advance the company's LentiGlobin programs in transfusion-dependent β-thalassemia (TDT) and severe sickle cell disease (SCD). The presentation will focus on three key aspects of these activities: 1) potential improvements in transduction efficiency and manufacturing; 2) updates to the protocol for the company's ongoing HGB-206 clinical trial in SCD; and 3) regulatory plans for the company's LentiGlobin drug product candidate in TDT. The company will webcast its presentation beginning at 9:00 am ET today on the Investors & Media section of www.bluebirdbio.com.

"At bluebird bio we have an incredibly ambitious goal: to deliver one-time, transformative therapies to patients with rare genetic diseases and cancer. We are relentless in our efforts to continue innovating in pursuit of that goal, and we have made substantial advances in the transduction and manufacturing processes, translational research, and clinical development," said Nick Leschly, chief bluebird. "By incorporating manufacturing Process 2 into our LentiGlobin clinical trials, we believe we can achieve our ultimate goal of increasing hemoglobin production in patients treated with LentiGlobin drug product. In sickle cell disease we have used our early clinical data to identify and implement multiple distinct improvements with the potential to overcome the unique challenges presented by this complex disease. We are hopeful that the tremendous work done by our research and development teams will yield improved outcomes for patients in the clinic in 2017 and beyond, and that the regulatory progress we are making will enable us to bring these treatments to patients as quickly as possible. We anticipate seeing many catalysts across our programs in the next 15 months, including initial clinical data from our Phase 1 clinical study of our bb2121 product candidate in relapsed/refractory multiple myeloma and updates on our Lenti-D program in cerebral adrenoleukodystrophy."

LentiGlobin Manufacturing Data: A Head-to-Head *In Vitro* Comparison of Process 1 and Process 2
bluebird bio has recently modified the process by which the patient's cells are transduced in LentiGlobin clinical studies with the addition of enhancers during the manufacturing process. The goal of manufacturing Process 2 is to increase the percentage of cells successfully transduced, thereby increasing vector copy number (VCN) in the drug product that is given to the patient.

Using retained samples of CD34+ stem cells collected from patients in the HGB-204 (Northstar) and HGB-206 studies, the company was able to demonstrate in a head-to-head *in vitro* comparison that manufacturing Process 2 substantially increased the percentage of cells transduced and VCN, as compared to manufacturing Process 1.

This *in vitro* data from Process 2 showed an average increase of approximately three-fold in vector-positive cells and VCN across all patient samples tested. Process 2 has been successfully scaled up for clinical manufacturing, and all LentiGlobin clinical trials moving forward will use manufacturing Process 2, including the Phase 3 HGB-207 (Northstar-2) trial and the Phase 1 HGB-206 clinical trial.

bluebird bio also highlighted progress it has made in moving from adherent manufacturing of lentiviral vectors to potentially more efficient suspension manufacturing, consistently achieving the targeted potency, purity and VCNs at increased scale.

LentiGlobin in Sickle Cell Disease: Addressing the Challenges and Promise of Gene Therapy
Based on an assessment of patient data presented at ASH 2015 and the underlying biology of SCD, the company believes that the following specific amendments to the protocol of the ongoing HGB-206 clinical trial may lead to improved patient outcomes through:

- Improving or enhancing stem cell collection by both:
  - (i) Suppression of sickle cell bone marrow pathology through required pre-stem cell harvest red blood cell transfusions, and
  - (ii) Use of improved cell separation techniques and increase of the required minimum cell dose
- Increasing percentage of cells transduced and VCN through implementation of manufacturing Process 2 for LentiGlobin drug product
- Enhancing the engraftment of the LentiGlobin drug product by adjusting the target level of exposure to busulfan for pre-infusion conditioning; and
- Additional exploratory alternative cell collection approaches through the mobilization and apheresis of patient CD34+ cells using plerixafor

To accommodate these changes to the protocol, the study enrollment has been expanded for a total enrollment of up to 29 patients.

LentiGlobin in Transfusion-Dependent β-thalassemia: Regulatory Progress

bluebird bio is working closely with regulatory agencies in the United States and Europe to bring LentiGlobin to patients with TDT who can benefit, as quickly as possible, and has reached general agreement with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), respectively, on the regulatory paths forward. Key elements of the company's regulatory process include:

- General agreement with the FDA on pivotal clinical trial designs across patient genotypes and age groups:
    - HGB-207 (Northstar-2) Phase 3 study in 15 adult and adolescent patients with TDT who do not have β^0/β^0 genotypes, with an additional pediatric cohort of 8 patients for a total enrollment of approximately 23 patients
    - HGB-212 Phase 3 study in 15 adult, adolescent and pediatric patients with TDT who have β^0/β^0 genotypes to launch in 2017, with a primary endpoint of transfusion reduction
    - Both studies will be conducted using manufacturing Process 2 and are designed to provide the basis for BLA submissions in the United States
- Confirmation that, as part of the EMA Adaptive Pathways and PRIME programs, application for conditional approval for LentiGlobin in the EU would be based on data from the HGB-204 (Northstar) and HGB-205 studies of LentiGlobin, as well as available data from the HGB-207 (Northstar-2) and HGB-212 studies

To access the live webcast, please visit the "Events & Presentations" page within the Investors and Media section of the bluebird bio website at http://investor.bluebirdbio.com. Replays of the webcast will be available on the bluebird bio website for 90 days following the event.

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-D™ product candidate, currently in a Phase 2/3 study, called the Starbeam Study, for the treatment of cerebral adrenoleukodystrophy, and its LentiGlobin™ BB305 product candidate, currently in four clinical studies for the treatment of transfusion-dependent ß-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 ß-thalassemia and severe sickle cell disease, including statements whether the planned manufacturing process changes for LentiGlobin will reduce costs and improve outcomes of patients with transfusion-dependent ß-thalassemia and severe sickle cell disease, 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 reduced costs or 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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