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): April 18, 2018

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)**	**(IRS Employer Identification No.)**
60 Binney Street, Cambridge, MA (Address of Principal Executive Offices)		**02142 (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 (see General Instructions A.2. below):

☐ 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On April 18, 2018, bluebird bio, Inc. ("bluebird") issued a press release announcing interim data published in the *New England Journal of Medicine* (NEJM) from two separate clinical studies of its LentiGlobin product candidate to treat patients with transfusion-dependent β-thalassemia (TDT). The full text of the press release 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 April 18, 2018.

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: April 18, 2018

bluebird bio, Inc.

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

EXHIBIT 99.1

bluebird bio Announces *New England Journal of Medicine* Publication of Interim Data from Two Phase 1/2 Clinical Studies of LentiGlobin™ Gene Therapy in Patients with Transfusion-Dependent β-Thalassemia

– Majority (12/13) of patients with non-β^0/β^0 genotypes were transfusion-free at median 27 months following LentiGlobin treatment –

CAMBRIDGE, Mass. – APRIL 18, 2018 – bluebird bio, Inc. (Nasdaq: BLUE) today announced interim data published in the *New England Journal of Medicine* (NEJM) from two separate two-year clinical studies investigating the potential for LentiGlobin™ gene therapy to eliminate or reduce chronic blood transfusions in patients with transfusion-dependent β-thalassemia (TDT). Both studies, Northstar (HGB-204), which recently was completed, and HGB-205, which is ongoing, are evaluating the safety and efficacy of one-time treatment with LentiGlobin gene therapy and the interim results showed that a majority of the 22 patients in the two Phase 1/2 studies followed for two years or longer remained free from transfusions.

Interim results also showed that all but one patient with a non-β^0/β^0 genotype (12 of 13 patients) stopped receiving regular red blood cell (RBC) transfusions, with a median time since last transfusion of 27 months. In the nine patients with a β^0/β^0 genotype or similar severity, median transfusion volume decreased by 73 percent, and RBC transfusions were stopped in three patients. Treatment with LentiGlobin requires an autologous stem cell transplant. The safety profile of LentiGlobin has been consistent with myeloablative conditioning with the chemotherapy agent busulfan.

“These interim data demonstrate the potential of LentiGlobin gene therapy to address the underlying genetic cause of TDT and increase production of functional red blood cells,” said Dave Davidson, M.D., chief medical officer, bluebird bio. “Nearly all patients in the two studies with a non-β^0/β^0 genotype achieved freedom from chronic blood transfusions and, importantly, several of these patients reached normal or near-normal total hemoglobin levels and sustained those levels throughout the interim study period. We hope the refined manufacturing process implemented in our ongoing pivotal trials of LentiGlobin will translate into further normalization of total hemoglobin levels across genotypes.”

“We look forward to our first filing in the European Union (EU) this year and continue to work closely with investigators and regulatory authorities to complete our trials and bring this important treatment option to patients as soon as possible,” said Davidson.

Transfusion-dependent thalassemia is a severe genetic disease characterized by reduced or absent hemoglobin production that results in severe anemia and ineffective red blood cell production. People with TDT need regular blood transfusions to survive, but chronic transfusions lead to unavoidable iron overload that can result in multi-organ damage and shortened life span.

“One-time treatment with LentiGlobin gene therapy resulted in positive outcomes for patients with TDT, with the majority of the 22 patients in the two Phase 1/2 studies followed for two years or longer maintaining independence from transfusion without unexpected or unmanageable

side effects," said Dr. Alexis Thompson, Head of Hematology and Director of the Comprehensive Thalassemia Program at Ann & Robert H. Lurie Children's Hospital of Chicago, and Professor of Pediatrics at Northwestern University Feinberg School of Medicine and one of the lead authors of the *NEJM* paper. "People with TDT cannot make enough hemoglobin in their red blood cells and rely on frequent transfusions to survive, which can cause serious complications. Most will not have a suitable donor for conventional allogeneic stem cell transplant. These results suggest that gene therapy could become an effective treatment for TDT."

Interim Efficacy Results of the Northstar and HGB 205-Studies

The recently completed Northstar study (HGB-204) is an open-label, single-dose, non-randomized, multi-center Phase 1/2 study designed to evaluate the safety and efficacy of LentiGlobin for the treatment of patients with TDT. HGB-205 is an ongoing, open-label, single-dose, non-randomized, single-center Phase 1/2 study designed to evaluate the safety and efficacy of LentiGlobin for the treatment of patients with TDT and severe sickle cell disease (SCD).

Through June 2, 2017, 18 patients (ages 12 to 35) in the Northstar study, and four patients with TDT (ages 16 to 19) in HGB-205 had received LentiGlobin. Ten of the 18 patients in the Northstar study and three of the four patients in HGB-205 have non-β^0/β^0 genotypes. One patient in HGB-205 is homozygous for the IVS1-110 mutation and has a severe clinical presentation similar to that seen in β^0/β^0 genotypes. Interim results published in *NEJM* from all 22 patients with TDT in the two studies showed:

- At baseline, all 13 patients with non-β^0/β^0 genotypes were transfusion-dependent. With a median time since last transfusion of 27 months (range: 11-42 months), all but one of these 13 patients had stopped receiving regular RBC transfusions. These patients had a median level of gene therapy-derived hemoglobin (known as HbA^{T87Q}) of 6.0 (3.4-10.0) g/dL and total hemoglobin of 11.2 (8.2-13.7) g/dL at the last study visit (12 to 36 months post-treatment).
- At baseline, all nine patients with genotypes that completely or nearly completely eliminate production of functional adult hemoglobin (β^0/β^0 genotypes or IVS1-110/IVS1-110 genotype) were transfusion-dependent. Three of these patients had stopped regular transfusions, with 14, 14 and 21 months having elapsed since their last transfusions, respectively. At the most recent study visit (12 to 30 months), these patients had 8.2, 6.8 and 6.6 g/dL HbA^{T87Q} and 9.0, 10.2 and 8.3 g/dL total hemoglobin, respectively.
- The six remaining patients with β^0/β^0 genotypes continued to receive RBC transfusions; they had a median of 4.2 (0.3-8.7) g/dL HbA^{T87Q} at last study visit. All but one of these patients had clinically meaningful reductions in the number and volume of transfusions compared with the two years prior to study enrollment.

Additionally, in the HGB-205 study, after the four patients with TDT ceased RBC transfusions following LentiGlobin therapy, the degree of hemolysis fully corrected in two patients by 36 months after treatment. After treatment with LentiGlobin, three patients with non-β^0/β^0 genotypes were able to transition to therapeutic phlebotomy (in which 200 ml of blood was withdrawn each month) to reduce the iron overload they had developed from chronic RBC transfusions. In these three patients, blood hemoglobin levels were stable despite a cumulative phlebotomy volume of over 1 liter per patient. One patient no longer had evidence of clinically

meaningful iron overload and stopped receiving both iron chelation therapy and therapeutic phlebotomy.

Interim Safety Results of the Northstar and HGB 205-Studies
The safety profile of LentiGlobin in TDT continues to be consistent with myeloablative conditioning with the chemotherapy agent busulfan. In the Northstar study, five mild adverse events (AEs), all Grade 1, were characterized as possibly or probably related to LentiGlobin. Nine serious adverse events (SAEs) were reported, including two episodes of veno-occlusive liver disease; none were considered related to LentiGlobin. In HGB-205, there were three SAEs, all Grade 2 or 3. For both studies, all adverse events were treated with standard measures. There was no evidence of a single gene clone becoming dominant or of any patient developing a replication-competent strain of the viral vector. All patients who were engrafted survived.

About the Northstar (HGB-204) Study
The recently completed Phase 1/2 Northstar study is an open-label, single-dose, non-randomized, multi-center study conducted in the United States, Australia and Thailand. It was designed to evaluate the safety and efficacy of LentiGlobin in increasing hemoglobin production and eliminating or reducing transfusion dependence in subjects with transfusion dependent beta-thalassemia. The study treated 18 adults and adolescents who are being followed to evaluate safety and efficacy post-LentiGlobin infusion. 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 HGB-205 study is being conducted at a single site in France. It is designed to evaluate the safety and efficacy of LentiGlobin in the treatment of subjects with TDT and SCD. The study has enrolled seven subjects. Efficacy in subjects with TDT includes evaluation of transfusion requirements post-treatment and level of hemoglobin. For patients with SCD, efficacy is being measured based on the number of vaso-occlusive crises or acute chest syndrome events pre- and post-treatment. For more information on the HGB-205 study, please visit clinicaltrials.gov using identifier NCT02151526.

The principal investigator of the HGB-205 study is Marina Cavazzana, M.D., Ph.D., Professor of Hematology at Paris Descartes University, Director Biotherapy Department, Necker Hospital, AP-HP, and Co-director of the Human Lympho-hematopoiesis Inserm laboratory at Imagine Institute for Genetic Diseases, Paris, France, in collaboration with Philippe Leboulch, M.D., Professor of Medicine at the University Paris-Sud and High Counselor and Honorary Scientific Director at France's Commissariat à l'énergie atomique et aux énergies alternatives (CEA) and visiting faculty at Harvard Medical School in the Genetics Division of Brigham & Women's Hospital, Boston, MA. Dr. Leboulch was a scientific founder of bluebird bio and serves as the co-chairman of its Scientific Advisory Board.

Dr. Leboulch and his team led the development of the HbA^{T87Q} LentiGlobin vector.

About LentiGlobin
bluebird bio is developing LentiGlobin with a goal of filing for regulatory approval in the United States and the EU for TDT and for severe SCD. The company is currently conducting four ongoing clinical studies of LentiGlobin with a fifth that has recently completed. Studies

currently ongoing include HGB-205, a single center Phase 1/2 study in both TDT and SCD; Northstar-2 (HGB-207) and Northstar-3 (HGB-212), both multi-center, international Phase 3 studies for the treatment of patients with both non-β^0/β^0 and β^0/β^0 TDT genotypes, respectively; and HGB-206, a multicenter Phase 1 study in the United States for the treatment of patients with severe SCD. In addition, bluebird is conducting a long-term safety and efficacy follow-up study (LTF-303) for subjects with hemoglobinopathies (TDT or severe SCD) who have been treated with LentiGlobin in bluebird bio-sponsored clinical studies.

LentiGlobin was granted Orphan Drug status by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of β-thalassemia and SCD. The FDA granted Breakthrough Therapy designation to LentiGlobin for the treatment of transfusion-dependent patients with β-thalassemia major and Fast-Track Designation for the treatment of beta-thalassemia major and for the treatment of certain patients with severe SCD. bluebird bio is participating in the EMA's Adaptive Pathways pilot program, which is part of the EMA's effort to improve timely access for patients to new medicines. The EMA granted Priority Medicines (PRIME) eligibility to LentiGlobin for the treatment of TDT.

About TDT
Transfusion-dependent β-thalassemia (TDT) is a severe genetic disease characterized by reduced or absent hemoglobin levels that results in severe anemia and ineffective red blood cell production. Supportive care for people with TDT consists of a lifelong regimen of chronic blood transfusions to enable survival and suppress symptoms of the disease, and iron chelation therapy to manage iron overload that results from the transfusions. Despite the availability of supportive care, many people with TDT experience serious complications and organ damage due to underlying disease and iron overload.

Allogeneic hematopoietic stem cell transplantation (HSCT) is currently the only available option to address the underlying genetic cause of TDT, though it carries significant risks. Complications of allogeneic HSCT include a risk of treatment-related mortality, graft failure, graft versus host disease (GvHD) and opportunistic infections, particularly in patients who undergo non-sibling matched allogeneic HSCT.

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 for the treatment of cerebral adrenoleukodystrophy, and its LentiGlobin™ product candidate for the treatment of transfusion-dependent β-thalassemia, also known as β-thalassemia major, 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 programs, bb2121 and bb21217, are anti-BCMA CAR T programs partnered with Celgene. bluebird bio also has discovery research programs utilizing megaTAL/homing endonuclease gene editing technologies with the potential for use across the company's pipeline.

bluebird bio has operations in Cambridge, Massachusetts, Seattle, Washington, Durham, North Carolina and Zug, Switzerland.

LentiGlobin and Lenti-D are trademarks of bluebird bio, Inc.

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. 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 risks that the preliminary positive efficacy and safety 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, and the risk that any one or more of our product candidates, including our bb2121 product candidate, 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 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.

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