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): December 1, 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 December 1, 2018, bluebird bio, Inc. ("bluebird") issued a press release announcing data presented at the 60th Annual Meeting of the American Society of Hematology ("ASH") from the completed Phase 1/2 Northstar (HGB-204) study of investigational LentiGlobin product candidate in patients with transfusion-dependent β-thalassemia and from the ongoing Phase 1/2 HGB-206 study (Groups A and B) of LentiGlobin product candidate in patients with sickle cell disease.

On December 2, 2018, bluebird issued a press release announcing data presented at ASH from the ongoing Phase 1 clinical study of bb21217 (CRB-402) of its investigational next-generation anti-BCMA CAR T cell therapy being investigated in relapsed-refractory multiple myeloma.

The full text of bluebird's press releases regarding these announcements are filed as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K and are 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 December 1, 2018 regarding data from HGB-204 study and HGB-206 study (Groups A and B).
99.2	Press release issued by bluebird bio, Inc. on December 2, 2018 regarding data from CRB-402 clinical study.

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: December 3, 2018

bluebird bio, Inc.

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

Exhibit 99.1

bluebird bio Presents Updated Data from Clinical Studies of LentiGlobin Gene Therapy in Transfusion-Dependent β-Thalassemia and Sickle Cell Disease at 60th Annual Meeting of the American Society of Hematology

All patients with transfusion-dependent β-thalassemia and a non-β0/β0 genotype who achieved transfusion independence continue to maintain it for up to 3.5 years in Phase 1/2 Northstar (HGB-204) study

HbAT87Q levels were stable and vaso-occlusive events were reduced in most Group A and B patients with sickle cell disease in Phase 1/2 HGB-206 study following treatment with LentiGlobin

CAMBRIDGE, Mass. – December 1, 2018 – bluebird bio, Inc. (Nasdaq: BLUE) announced new long-term data from the completed Phase 1/2 Northstar (HGB-204) study of investigational LentiGlobin™ gene therapy in patients with transfusion-dependent β-thalassemia (TDT) and from the ongoing Phase 1/2 HGB-206 study of LentiGlobin in patients with sickle cell disease (SCD) today at the 60th Annual Meeting of the American Society of Hematology (ASH).

“The breadth of our LentiGlobin data at ASH across multiple clinical trials reflects the commitment of patients, families and healthcare providers to investigate the transformative therapeutic potential of gene therapy for the beta-hemoglobinopathies,” said David Davidson M.D., chief medical officer, bluebird bio. “LentiGlobin gene therapy is designed to address the underlying genetic cause of beta-thalassemia and sickle cell disease. The longer-term data emerging from our clinical trials show that most treated patients are producing sufficient amounts of engineered HbAT87Q to achieve and maintain a therapeutic benefit.”

LentiGlobin in Transfusion-Dependent β-Thalassemia
TDT is an inherited blood disorder caused by a mutation in the β-globin gene, which causes ineffective red blood cell production leading to severe anemia. People with TDT require regular transfusions to maintain hemoglobin levels in order to survive, but chronic transfusions carry risks, including iron overload that can result in multi-organ damage and shortened life expectancy.

“The Northstar study includes patients who have been transfusion independent for more than three and a half years after receiving LentiGlobin treatment,” said Dr. John Rasko, Head of Department, Cell & Molecular Therapies, Royal Prince Alfred Hospital, Australia. “These patients maintained stable hemoglobin levels of at least 9.0 g/dL without transfusions, and their HbAT87Q levels remained stable as well.”

Phase 1/2 Northstar (HGB-204) Efficacy
The results reported for the completed Phase 1/2 Northstar (HGB-204) study reflect data as of September 14, 2018.

After treatment with LentiGlobin, patients are monitored for production of HbA^{T87Q}, which is gene therapy derived-hemoglobin. The production of HbA^{T87Q} increases the overall hemoglobin level in patients with the goal of reducing or eliminating the need for transfusions.

Data showed that eight of 10 patients with TDT and a non-β^0/β^0 genotype who were treated with LentiGlobin in the Northstar study achieved transfusion independence, meaning they had not received a transfusion for at least 12 months and maintained hemoglobin >9 g/dL. These eight patients have maintained transfusion independence for a median duration of 38 months (21 – 44 months) as of September 14, 2018.

Total hemoglobin levels for the eight transfusion-independent non-β^0/β^0 genotype patients were stable and ranged from 9.7 – 14.1 g/dL at the last study visit. HbA^{T87Q} remained stable in these patients over time, for up to four years as of the time of data cut-off.

Three of the eight patients with TDT and a β^0/β^0 genotype who were treated with LentiGlobin achieved transfusion independence. Two of these patients had follow-up for more than 3.5 years and one had more than two years of follow up. All three maintained transfusion independence through their last follow up with hemoglobin ranging from 9.1 – 10.9 g/dL.

An exploratory assessment was conducted to assess liver iron concentration in the 11 patients who have become transfusion independent in the Northstar study. Increased iron levels are a consequence of frequent transfusions. High iron levels can cause organ damage, which many TDT patients are at risk for and must manage through chelation regimens. Liver iron concentrations were measured at baseline and then at every 12 months after treatment. Over time, iron concentrations began to decrease in the 11 patients, with the largest decrease observed in patients who had 48 months (n=3) of data available.

Phase 1/2 Northstar (HGB-204) Safety
The safety profile of LentiGlobin treatment in adults and adolescents with TDT in the Northstar study was generally consistent with myeloablative conditioning. The median time to platelet engraftment was 39.5 (19 – 191) days.

In the Phase 3 Northstar-2 (HGB-207) and Northstar-3 (HGB-212) studies, a refined manufacturing process was used to produce LentiGlobin to further improve the clinical results observed in the Northstar study. Data from Northstar-2 and Northstar-3 studies will be presented on Monday, December 3, 2018, 7:15 – 7:30 p.m. PST (10:15 – 10:30 p.m. EST):

- **LentiGlobin Gene Therapy for Patients with Transfusion-Dependent β-thalassemia (TDT): Results from the Phase 3 Northstar-2 and Northstar-3 Studies (Abstract #1025)**

Presenter: Franco Locatelli, M.D., Ph.D., Professor of Pediatrics, University of Pavia, Italy and Director, Department of Pediatric Hematology and Oncology, IRCCS Ospedale Pediatrico Bambino Gesù, Rome, Italy

For more information about the ongoing clinical studies of LentiGlobin in TDT visit www.northstarclinicalstudies.com or clinicaltrials.gov and use identifier NCT02906202 for Northstar-2 (HGB-207) and NCT03207009 for Northstar-3 (HGB-212).

LentiGlobin in Sickle Cell Disease
SCD is a serious, progressively debilitating and life-threatening genetic disease. SCD results from production of abnormal sickle hemoglobin (HbS), which leads to sickled red blood cells (RBCs) and hemolysis. As a result of this abnormal hemoglobin, many affected individuals live with severe anemia and vaso-occlusive events (VOE) which include severe, recurrent pain crises that lead to organ damage and shortened life span.

"In patients with sickle cell disease who underwent autologous transplant with LentiGlobin, gene therapy-derived HbA^{T87Q} levels have remained stable and we saw decreased rates of vaso-occlusive events with up to three years of follow-up," said Dr. Julie Kanter, Medical University of South Carolina, Charleston, S.C. "These results indicate that even moderate amounts of HbA^{T87Q} seem to benefit affected patients. We will continue following all treated individuals long term, to assess the potential relationship between HbA^{T87Q} levels and improved clinical outcomes including vaso-occlusive events."

The Phase 1/2 HGB-206 study is an ongoing, open-label study designed to evaluate the efficacy and safety of LentiGlobin gene therapy for the treatment of adults with SCD.

HGB-206: Groups A & B Efficacy
A total of nine patients were treated with LentiGlobin in Groups A (n=7) and B (n=2) in the HGB-206 study. As of the data cut-off date of September 14, 2018, there was up to 39 months of follow-up for the seven patients in Group A and up to 17 months of follow-up for the two patients in Group B.

In Group A patients, consistent HbA^{T87Q} production was observed ranging from 0.7 – 2.8 g/dL at last visit and patients maintained stable total hemoglobin levels ranging from 7.6 – 11.8 g/dL at last visit. HbA^{T87Q} production was higher in Group B patients, ranging from 3.4 – 6.5 g/dL and total hemoglobin levels were stable at 11.0 – 12.3 g/dL at the last visit. These higher rates of total hemoglobin and HbA^{T87Q} production in Group B are attributed to the implementation of a refined drug product manufacturing process and protocol modifications to improve engraftment of genetically modified stem cells.

In all patients who received LentiGlobin treatment, frequency of VOEs was reduced.

HGB-206: Groups A & B Safety
The safety profile of LentiGlobin remains generally consistent with underlying SCD and myeloablative conditioning. A serious adverse event (SAE) of myelodysplasia syndrome was

reported in a patient who received LentiGlobin approximately three years ago in Group A of the Phase 1/2 HGB-206 study. Analysis of the patient's cells showed no evidence of vector mediated insertional oncogenesis, and the independent data monitoring committees, along with the treating physician, agreed the SAE was unlikely related to LentiGlobin gene therapy.

In order to further improve the clinical results observed in Groups A and B, in addition to the refined manufacturing process introduced in Group B, plerixafor mobilization and apheresis-derived hematopoietic stem cells were used to produce LentiGlobin for Group C of the Phase 1/2 HGB-206 study. Data from Group C patients will be presented Monday, December 3, 2018, 7:30 – 7:45 p.m. PST (10:30 – 10:45 p.m. EST):

- **Current Results of LentiGlobin Gene Therapy in Patients with Severe Sickle Cell Disease Treated Under Refined Protocol (Abstract #1026)**
  Presenter: John Tisdale, M.D., National Heart, Lung and Blood Institute, Bethesda, Md.

For more information about the ongoing HGB-206 clinical study of LentiGlobin in SCD visit clinicaltrials.gov and use identifier NCT02140554.

About bluebird bio, Inc.
With its lentiviral-based gene therapies, T cell immunotherapy expertise and gene editing capabilities, bluebird bio has built a pipeline with broad potential application in severe genetic diseases and cancer.

bluebird bio's gene therapy clinical programs include investigational treatments for cerebral adrenoleukodystrophy, transfusion-dependent β-thalassemia and sickle cell disease.

bluebird bio's oncology pipeline is built upon the company's 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. The company's lead oncology programs are anti-BCMA CAR T programs partnered with Celgene.

bluebird bio's discovery research programs include 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. For more information, visit bluebirdbio.com.

Follow bluebird bio on social media: Twitter, LinkedIn, Instagram, YouTube.

LentiGlobin is a trademark 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 views with respect to the potential for its LentiGlobin product candidate to treat transfusion-dependent β-

thalassemia and 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 will not result in improved patient outcomes, risks that the current or planned clinical trials of LentiGlobin will be insufficient to support future regulatory submissions or to support marketing approval in the US and EU, and the risk that LentiGlobin will not be successfully developed, approved or commercialized for the treatment of either transfusion-dependent β-thalassemia or sickle cell disease. 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-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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Exhibit 99.2

bluebird bio and Celgene Corporation Present Initial Data from Ongoing Phase 1 Clinical Study of Next-Generation Anti-BCMA CAR T Cell Therapy bb21217 in Patients with Relapsed/Refractory Multiple Myeloma at ASH Annual Meeting

bb21217 early safety profile consistent with CAR T platform therapies

83 percent objective response rate in 12 heavily pretreated multiple myeloma patients at first dose level studied

Higher dose of bb21217 being assessed in the ongoing Phase 1 study

CAMBRIDGE, Mass. and SUMMIT, N.J. – December 2, 2018 – bluebird bio, Inc. (Nasdaq: BLUE) and Celgene Corporation (NASDAQ: CELG) announced initial data from the ongoing Phase 1 clinical study of bb21217 (CRB-402), an investigational next-generation anti-BCMA CAR T cell therapy being studied in patients with relapsed/refractory multiple myeloma. The data were presented by Nina Shah, M.D., University of California, San Francisco, as an oral presentation at the 60th Annual Meeting of the American Society of Hematology (ASH).

bb21217 is an investigational anti-BCMA CAR T cell therapy that uses the bb2121 chimeric antigen receptor (CAR) molecule with a manufacturing process designed to improve CAR T cell functional persistence. bb21217 has exhibited improved functional persistence and increased anti-tumor activity in preclinical animal studies.

“Anti-BCMA CAR T therapy with bb2121 has shown clinical responses in a substantial proportion of patients with relapsed/refractory multiple myeloma. With the bb21217 program we are pursuing an approach intended to improve the *in vivo* persistence of functional CAR T cells with the hope that this provides a more durable benefit for patients,” said David Davidson, M.D., chief medical officer, bluebird bio. “The safety results and promising response rate in the initial dose cohort, as well as the observation of detectable CAR T cells in the first three patients with follow up to the month 6 study visit and beyond, support advancing to a higher dose to further characterize the potential of bb21217 as a treatment option for patients with relapsed/refractory multiple myeloma.”

“The initial results of bb21217 are encouraging in terms of the adverse event profile, as well as the instances of ongoing, deep responses shown in these heavily pre-treated patients,” said Alise Reicin, M.D., President, Global Clinical Development for Celgene. “We look forward to further results from this next-generation agent in this area of continued medical need.”

bb21217 is being evaluated in the ongoing dose escalation part of the Phase 1 CRB-402 study in adults with relapsed/refractory multiple myeloma who have received at least three prior

treatments, including a proteasome inhibitor and immunomodulatory agent (or are double refractory).

“Patients with multiple myeloma often undergo multiple cycles of treatment because there is currently no known cure for this aggressive cancer,” said Nina Shah, M.D., University of California, San Francisco, San Francisco, Calif. “The early clinical data from this Phase 1 study show manageable safety findings, and most patients in this initial group achieved an objective response. Future study is needed to assess durability of response at the current dose, as well as safety and activity at higher doses of bb21217.”

Patients included in these preliminary Phase 1 results (n=12) had a median age of 63 years (min; max: 44 – 69 years). They had received a median of seven prior lines of therapy (min; max: 4 – 17 lines) and 83 percent of patients received a prior autologous stem cell transplant. Fifty-eight percent (n=7) of patients had high-risk cytogenetics.

All treated patients received a dose of 150 x 10^6 CAR+ T cells. The median follow-up after bb21217 infusion was 26 weeks (min; max: 4 – 51 weeks). The primary endpoint is safety measured by frequency of adverse events (AEs), dose limiting toxicity (DLT) and changes in laboratory results. Secondary endpoints include disease specific response criteria based on the International Myeloma Working Group (IMWG) Uniform Response Criteria for Multiple Myeloma.

Safety Results
The safety results, reported as of the data extract of October 18, 2018, were manageable and consistent with known toxicities of CAR T therapies.

Eight of the 12 patients (67 percent) treated with bb21217 developed cytokine release syndrome (CRS); four Grade 1, three Grade 2, one Grade 3 case and no Grade 4 cases. Additionally, three of the 12 patients (25 percent) experienced neurotoxicity, including one Grade 1, one Grade 2 and one Grade 4 case. All CRS and neurotoxicity events resolved and no deaths occurred on study. Following the Grade 4 neurotoxicity event, patients were divided into two groups based on tumor burden and dosing continued at 150 x 10^6 CAR+ T cells for a total of 12 subjects treated at this dose level.

Efficacy Results
Of the 12 patients who received treatment with bb21217, 83 percent (n=10) achieved an objective clinical response by IMWG criteria. As of the data extract, responses are ongoing in nine of 10 patients, including three with a complete response (CR) or stringent complete response (sCR), two with a very good partial response (VGPR) and four with a partial response (PR).

Evidence of myeloma in the bone marrow, known as minimal residual disease (MRD), was undetectable at a minimum of two time points, by next-generation sequencing at a sensitivity

level of 10^{-5} or better in all responders who had evaluable bone marrow samples (n=4) with some as early as day 15.

CAR+ T cell expansion was observed during the first 30 days following treatment in all evaluable patients (n=11) with anti-BCMA CAR+T cells showing sustained persistence in all patients (3/3) with six or more months of follow-up.

The ongoing Phase 1 CRB-402 study is assessing a higher dose of 300 $x10^6$ CAR+ T cells in both high and low tumor burden cohorts.

About bb21217
bb2121 and bb21217 are bluebird bio's lead investigational anti-BCMA CAR T therapies being developed in collaboration with Celgene.

Chimeric antigen receptors (CAR) are receptor proteins that have been engineered to give T cells the ability to target a specific protein. bb2121 and bb21217 are designed to recognize and kill plasma cells, notably malignant myeloma cells, that express the B cell maturation antigen (BCMA).

bluebird bio's clinical development program for bb21217 includes the ongoing Phase 1 CRB-402 two-part (dose escalation and dose expansion), non-randomized, open label study with sites in the United States. For more information visit: clinicaltrials.gov using identifier NCT03274219.

bb21217 is not approved for any indication in any geography.

About Multiple Myeloma
Multiple myeloma is a cancer of certain cells in the blood, called plasma cells. The cause of multiple myeloma is not known, and currently there is no cure. However, there are a number of treatment options available that can lead to remission. For some people with multiple myeloma, remission can last many years. Patients who have already been treated with some available therapies but continue to have progression of their disease have "relapsed" or "refractory" multiple myeloma, meaning their cancer has reoccurred after they have received initial treatments. Patients with relapsed/refractory multiple myeloma have fewer treatment options.

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bluebird bio has operations in Cambridge, Massachusetts; Seattle, Washington; Durham, North Carolina and Zug, Switzerland. For more information, visit www.bluebirdbio.com.

Follow bluebird bio on social media: @bluebird bio, LinkedIn, Instagram, YouTube.

About Celgene

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, please visit www.celgene.com.

Follow Celgene on Social Media: Twitter, Pinterest, LinkedIn, Facebook and YouTube.

UC Disclaimer

The information stated above was prepared by bluebird bio Inc. and reflects solely the opinion of bluebird bio. Nothing in this statement shall be construed to imply any support or endorsement of bluebird bio, or any of its products, by the Regents of the University of California, its officers, agents and employees.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those regarding the potential benefits of, and plans relating to the collaboration between bluebird bio and Celgene in the development of bb2121 and bb21217; the potential of bb2121 and bb21217 as therapeutic drugs; and the benefit of each company's strategic plans and focus. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "would," "could," "potential," "possible," "hope" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs. For example, there can be no guarantee that any product candidate will be successfully developed or complete necessary preclinical and clinical phases, or that development of any of product candidates will successfully continue, or that marketing approval will be granted. There can be no guarantee that any positive developments will result in stock price appreciation. Management's expectations and, therefore, any forward-looking statements

in this press release could also be affected by risks and uncertainties relating to a number of other important factors, including: results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies; the content and timing of decisions made by the U.S. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; the ability to obtain and maintain requisite regulatory approvals and to enroll patients in planned clinical trials; unplanned cash requirements and expenditures; competitive factors; the ability to obtain, maintain and enforce patent and other intellectual property protection for any product candidates; the ability to maintain key collaborations; and general economic and market conditions. These and other risks are described in greater detail under the caption "Risk Factors" included in each company's public filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and neither company has any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

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