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 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 November 1, 2018, bluebird bio, Inc. issued a press release announcing its abstract presentations at the 60th Annual Meeting of the American Society of Hematology taking place in San Diego, California on December 1-4, 2018. 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 1, 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: November 1, 2018

bluebird bio, Inc.

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

Exhibit 99.1

bluebird bio to Present New Data from Early- and Late-Stage Pipeline of Investigational Gene and Cell Therapies at the American Society of Hematology Annual Meeting

– Initial data from Phase 3 studies of LentiGlobin™ gene therapy in transfusion-dependent β-thalassemia for β0/β0 genotype and updated data in non-β0/β0 genotype –

– Updated data from Phase 1 study of LentiGlobin in sickle cell disease –

– Initial efficacy and safety results from Phase 1 study of bb21217 in patients with relapsed/refractory multiple myeloma –

– First presentation of Phase 1 clinical research from collaboration with Dana-Farber/Boston Children's Cancer and Blood Disorders Center to study BCL11a shRNAmiR in patients with sickle cell disease –

– First results from bluebird bio's megaTAL engineered T cells in animal models –

– Company to webcast investor and analyst event, Monday, December 3, 8:30 p.m. PST –

CAMBRIDGE, Mass. – November 1, 2018 – bluebird bio, Inc. (Nasdaq: BLUE) today announced that new data from its early- and late-stage investigational gene and cell therapy programs will be presented during the 60th Annual Meeting of the American Society of Hematology (ASH) in San Diego, California, December 1 – 4.

"The breadth of data we are presenting at ASH illustrates the potential of our gene and cell therapies to provide meaningful benefits to people living with severe diseases," said David Davidson, M.D., chief medical officer, bluebird bio. "Our presentations will include data from the pivotal trials of LentiGlobin gene therapy in patients with transfusion-dependent β-thalassemia, bluebird bio's first treatment under review for potential approval by the European Medicines Agency. We will also share updated data from our study of LentiGlobin in patients with sickle cell disease and initial results from our next generation anti-BCMA CAR T therapy, bb21217, in patients with relapsed/refractory multiple myeloma."

bluebird bio will present initial data from patients with transfusion-dependent β-thalassemia (TDT) with a β0/β0 genotype treated with LentiGlobin™ gene therapy in the Phase 3 Northstar-3 (HGB-212) study as well as updated results, including up to 3.5 years of follow-up, from the completed Phase 1/2 Northstar study (HGB-204).

Abstracts outlining bluebird bio's accepted data at ASH will be available on the ASH conference website at 9:00 a.m. EDT today.

First Data from Clinical Programs

Initial Results from a Phase 1 Clinical Study of bb21217, a Next-Generation Anti-BCMA CAR T Therapy
Presenter: Nina Shah, M.D., University of California San Francisco, San Francisco, Calif.
Date & Time: Sunday, December 2, 2018, 4:45 p.m. PST (7:45 p.m. EST)

bluebird bio's lead oncology programs, bb2121 and bb21217, are anti-BCMA CAR T programs partnered with Celgene. bb21217 is a next-generation anti-BCMA CAR T cell therapy using the bb2121 CAR molecule with a manufacturing process designed to improve T cell persistence. bb21217 has exhibited improved persistence and increased anti-tumor activity in preclinical animal studies.

This presentation will include early data from the Phase 1 CRB-402 study of bb21217 in patients with relapsed/refractory multiple myeloma. CRB-402 is a two-part (dose escalation and dose expansion), open label, multi-site Phase 1 study of bb21217 in adults with relapsed/refractory multiple myeloma with a projected final enrollment of 50 patients.

Data in the abstract include results as of the data cutoff date of June 15, 2018 for eight patients who have received bb21217. These patients had a median of nine prior lines of therapy (4 – 17 lines) and all received a dose of 150 x 10^6 CAR+ T cells. The median follow-up after bb21217 infusion was 16 weeks (2 – 27 weeks).
The adverse events observed as of the data cut-off were consistent with known toxicities of CAR T therapies. Five of eight patients developed cytokine release syndrome (CRS); one Grade 1, three Grade 2 and one Grade 3 case. All responded to supportive care with or without tocilizumab. This included one patient with high tumor burden who experienced dose-limiting toxicity (DLT) consisting of Grade 3 CRS and Grade 4 encephalopathy with signs of posterior reversible encephalopathy syndrome on MRI. This patient received tocilizumab, corticosteroids and cyclophosphamide, improved neurologically and achieved a stringent complete response (sCR). Following this event, the dose escalation cohort was divided into two groups based on tumor burden and dosing continued at 150 x 10^6 CAR+ T cells.
Seven patients were evaluable for initial (one-month) clinical response. Six of seven patients demonstrated clinical response per the International Myeloma Working Group (IMWG) Uniform Response Criteria for multiple myeloma, including one sCR, three very good partial responses (VGPR) and two partial responses (PR). Robust CAR+ T cell expansion during the first 30 days was observed in seven of seven evaluable patients and the two patients evaluable at six months both had CAR vector copies detectable in peripheral blood.
This study is ongoing to evaluate the potential safety and efficacy of treatment with bb21217 and updated results will be shared at the ASH conference.

Flipping the Switch: Initial Results of Genetic Targeting of the Fetal to Adult Globin Switch in Sickle Cell Patients
Presenter: Erica Esrick, M.D., Pediatric Hematology and Oncology, at Dana-Farber/Boston Children's Cancer and Blood Disorders Center, Boston, Mass.
Date & Time: Monday, December 3, 2018, 6:45 p.m. PST (9:45 p.m. EST)
This presentation will include early data from the investigator-initiated Phase 1 study of shRNA^{miR} lentiviral vector (LVV) targeting BCL11A for autologous gene therapy in SCD. As of July 28, 2018, one patient had received treatment with BCL11a shRNA^{miR}. In the patient's immature red blood cells, expression of the BCL11A protein was reduced by approximately 90 percent compared to levels prior to gene therapy. At 76 days following treatment this patient had a sustained overall hemoglobin of >10 g/dL and, compared to what was observed pre-gene therapy, there was a notable absence of irreversibly sickled cells as assessed by peripheral blood smear, a blood test used to identify abnormalities in the number or shape of blood cells.
Adverse events were consistent with myeloablative conditioning, and there have been no product-related adverse events and no SCD-related complications. Updated results will be shared at the ASH conference.

Oral Presentations

LentiGlobin for Transfusion-Dependent β-Thalassemia

- **Clinical Outcomes of LentiGlobin Gene Therapy for Transfusion-Dependent β-Thalassemia Following Completion of the Northstar HGB-204 Study (Abstract #167)**
  Presenter: John Rasko, Ph.D., Central Clinical School Centenary Institute of Cancer Medicine & Cell Biology, University of Sydney, Sydney, Australia
  Date & Time: Saturday, December 1, 2018, 3:00 – 3:15 p.m. PST (6:00 – 6:15 p.m. EST), Room 30D

- **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., Department of Pediatric Hematology and Oncology, IRCCS Ospedale Pediatrico Bambino Gesù, Rome, Italy
  Date & Time: Monday, December 3, 2018, 7:15 – 7:30 p.m. PST (10:15 – 10:30 p.m. EST), Room 6B

LentiGlobin for Sickle Cell Disease

- **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.

Date & Time: Monday, December 3, 2018, 7:30 – 7:45 p.m. PST (10:30 – 10:45 p.m. EST), Room 6B

bb21217 for Relapsed/Refractory Multiple Myeloma

- **Initial Results from a Phase 1 Clinical Study of bb21217, a Next-Generation Anti-BCMA CAR T Therapy (Abstract #488)**
  Presenter: Nina Shah, M.D., University of California San Francisco, San Francisco, Calif.
  Date & Time: Sunday, December 2, 2018, 4:45 – 5:00 p.m. PST (7:45 – 8:00 p.m. EST), Room 6B

BCL11a shRNA^{miR} for Sickle Cell Disease

- **Flipping the Switch: Initial Results of Genetic Targeting of the Fetal to Adult Globin Switch in Sickle Cell Patients (Abstract #801)**
  Presenter: Erica Esrick, M.D., Pediatric Hematology and Oncology, Boston Children's Hospital, Boston, Mass.
  Date & Time: Monday, December 3, 2018, 6:45 – 7:00 p.m. PST (9:45 – 10:00 p.m. EST), Room 6B

Preclinical Presentations

- **Knockout of *CBLB* Greatly Enhances Anti-Tumor Activity of CAR T Cells (Abstract #338)**
  Presenter: Kathryn Hooper, bluebird bio, Cambridge, Mass.
  Date & Time: Sunday, December 2, 2018, 9:45 – 10:00 a.m. PST (12:45 – 1:00 p.m. EST), Room 28D

- **Persistence of CRISPR/Cas9-edited Hematopoietic Repopulating Cells with Therapeutically Relevant Reactivation of Fetal Hemoglobin in Nonhuman Primates (Abstract #806)**
  Presenter: Olivier Humbert, Fred Hutchinson Cancer Center, Seattle Children's Hospital, Seattle, Wash.
  Date & Time: Monday, December 3, 2018, 3:00 – 3:15 p.m. PST (6:00 – 6:15 p.m. EST), Grand Hall C

Poster Presentations

LentiGlobin for Sickle Cell Disease

- **Outcomes for Initial Patient Cohorts with Up To 33 Months of Follow-up in the HGB-206 Phase 1 Trial (Abstract #1080)**
  Presenter: Julie Kanter, M.D., Medical University of South Carolina, Charleston, S.C.

Date & Time: Saturday, December 1, 2018, 6:15 – 8:15 p.m. PST (9:15 – 11:15 p.m. EST), Hall GH

- **Analysis of RBC Properties in Patients with SCD Treated with LentiGlobin Gene Therapy (Abstract #2195)**
  Presenter: Nicolas Hebert, St. Anthony Research Center, Paris, France
  Date & Time: Saturday, December 1, 2018, 6:15 – 8:15 p.m. PST (9:15 – 11:15 p.m. EST), Hall GH

- **Characterizing the U.S. Population with Severe Manifestations of Sickle Cell Disease Using Real-World Evidence (Abstract #4811)**
  Presenter: Clark Paramore, bluebird bio, Cambridge, Mass.
  Date & Time: Monday, December 3, 2018, 6:00 – 8:00 p.m. PST (9:00 – 11:00 p.m. EST), Hall GH

Investor Event & Webcast Information
bluebird bio will host a live webcast of an investor and analyst event at 8:30 p.m. PST (11:30 p.m. EST) on Monday, December 3, 2018, during the ASH Annual Meeting. To access the webcast, please visit the "Events & Presentations" page within the Investors & Media section of the bluebird bio website at http://investor.bluebirdbio.com/. A replay of the webcast will be available on the bluebird bio website for 90 days following the call.

About LentiGlobin
LentiGlobin is an investigational one-time gene therapy being studied as a potential treatment to address the underlying genetic cause of transfusion-dependent β-thalassemia (TDT) and sickle cell disease (SCD).

bluebird bio's clinical development program for LentiGlobin includes ongoing studies around the world with sites in Australia, Germany, Greece, France, Italy, Thailand, the United Kingdom and the United States. In addition, bluebird bio is conducting a long-term safety and efficacy follow-up study (LTF-303) for people who have participated in bluebird bio-sponsored clinical studies of LentiGlobin for TDT and SCD.

The European Medicines Association (EMA) granted Priority Medicines (PRIME) eligibility and Orphan Medicinal Product designation to LentiGlobin for the treatment of TDT and SCD. LentiGlobin is also part of 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 U.S. Food and Drug Administration granted LentiGlobin Orphan Drug status and Breakthrough Therapy designation for the treatment of TDT and SCD.

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, also known as β-thalassemia major, 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.

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 ß-thalassemia and sickle cell disease, the potential for the bb21217 product candidate to treat relapsed/ refractory multiple myeloma, and the Company's expectations regarding the review, potential regulatory approval and potential commercial launch of its LentiGlobin product candidate in the United States and Europe. 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 our product candidates will not continue or be repeated in our ongoing or planned clinical trials, 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 our product candidates will be insufficient to support future regulatory submissions or to support marketing approval in the US and EU, 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 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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