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 4, 2017

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 1.01 Entry into a Materials Definitive Agreement

On October 4, 2017, bluebird bio, Inc. (“bluebird”) issued a press release announcing the publication of interim data from the Starbeam Study of bluebird’s Lenti-D drug product in patients with cerebral adrenoleukodystrophy in the New England Journal of Medicine, and the presentation of additional follow-up data at the Child Neurology Society Annual Meeting. 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 October 4, 2017

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 4, 2017

bluebird bio, Inc.

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

Exhibit 99.1

bluebird bio Announces Publication of Interim Data from Starbeam Study of Lenti-D™ Drug Product in Patients with Cerebral Adrenoleukodystrophy (CALD) in The New England Journal of Medicine

- *Additional follow-up data to be included in poster presentation at Child Neurology Society (CNS) Annual Meeting –*
- *15/17 (88%) of the patients infused with Lenti-D drug product remain alive and free of major functional disabilities (MFDs), the primary efficacy endpoint of the trial –*
- *No engraftment failure, graft versus host disease (GVHD) or life-threatening infections occurred; no evidence of insertional oncogenesis –*

CAMBRIDGE, Mass., October 4, 2017 – bluebird bio, Inc. (Nasdaq: BLUE), a clinical-stage company committed to developing potentially transformative gene therapies for serious genetic diseases and T cell-based immunotherapies for cancer, today announced that interim data from an initial cohort of 17 patients in the ongoing Phase 2/3 Starbeam Study (ALD-102) evaluating Lenti-D™ investigational gene therapy in boys with cerebral adrenoleukodystrophy (CALD) were published in the New England Journal of Medicine (NEJM).

“I have seen firsthand the devastation that CALD can inflict on these young boys and their families,” said David A. Williams, M.D., chief scientific officer and senior vice-president for research at Boston Children’s Hospital and president of Dana-Farber/Boston Children’s Cancer and Blood Disorders Center, and the principal investigator of the Starbeam study. “However, when cerebral disease is detected early, it is possible to slow or stop the progression of disease. Currently, allogeneic hematopoietic stem cell transplant is the only available therapy – but one that presents challenges for patients without a matched sibling donor. These data suggest that Lenti-D may also be a viable option for patients, and one that, being autologous, could potentially overcome some of the challenges associated with allogeneic stem cell transplantation. The results of this study represent the continued development of effective gene therapy approaches to human disease treatments.”

The New England Journal of Medicine: Hematopoietic Stem Cell Gene Therapy for Cerebral Adrenoleukodystrophy

The Starbeam Study is a global, multi-center study assessing the efficacy and safety of an investigational gene therapy in boys up to 17 years of age with CALD. As of the April 25, 2017 data cut off for the publication, 16 of the 17 patients had completed the primary analysis period (24 months or discontinuation).

The primary efficacy endpoint for the Starbeam Study is the proportion of patients who are alive and have no major functional disabilities (MFDs) at 24 months post drug

product infusion. MFDs are the six severe disabilities commonly attributed to CALD that, if present, would have a profound negative impact on patients' lives: loss of communication, cortical blindness, tube feeding, total incontinence, wheelchair dependence and complete loss of voluntary movement. The primary safety endpoint is the proportion of patients who experience Grade 2+ acute GVHD or chronic GVHD at 24 months post-treatment. Secondary and exploratory assessments include Neurologic Function Score (NFS; a scoring system of 15 symptoms/signs across multiple domains used to evaluate the severity of gross neurologic dysfunction), gadolinium enhancement on MRI (an indicator of neuroinflammation), MRI Loes score (a method for quantifying brain lesions in patients with CALD using brain MRI), and additional safety assessments.

As of the April 25, 2017 data cut-off, 15/17 (88%) (95% confidence interval [CI]: 64% to 99%) of the patients infused with Lenti-D drug product remain alive and free of MFDs, the primary efficacy endpoint of the trial. Median follow-up at the time of data analysis was 29.4 months (range: 21.6 to 42.0 months). This exceeds the pre-defined efficacy success benchmark for the study of 76% MFD-free survival at 24 months for this initial subset of patients. Most adverse events occurred during the 2 weeks post-transplant and most were associated with myeloablative chemotherapy. One possibly drug related serious adverse event occurred (viral cystitis) and resolved with standard measures. There was no engraftment failure, graft versus host disease (GVHD) or life-threatening infections. There was no evidence of insertional oncogenesis.

Additional secondary and exploratory endpoints as of the data cut-off include:

- 15/17 patients maintained NFS ≤ 1.
- Loes score has stabilized in 12/17 evaluable patients (71%). Stabilization is characterized as maintaining a Loes score ≤9 or not increasing a Loes score by ≥6 points.
- Gadolinium enhancement, positive in all patients at baseline, was negative in 16/17 patients by month 6. Diffuse gadolinium enhancement re-emerged in 6 patients at month 12. Subsequent fluctuations in gadolinium enhancement were observed, with 11/17 patients negative for gadolinium enhancement at their last follow-up. In all patients showing gadolinium re-emergence, the enhancement was less extensive compared to baseline. Initial results suggest that re-emergence of gadolinium enhancement does not correlate with clinical outcome.

Two patients did not meet the primary efficacy endpoint:

- Patient 2016 had not experienced an MFD, but withdrew from the study due to radiographic progression of disease and underwent allogeneic hematopoietic stem cell transplantation (HSCT). He subsequently died from complications of the allogeneic transplantation.
- Patient 2018, as previously reported in April 2016, had rapid disease progression beginning early in his participation in the study, resulting in multiple MFDs and an NFS of 15. The rapidity of his disease progression suggests it would have been difficult to alter his early neurological decline given that Lenti-D treatment takes months to exert a therapeutic effect in CALD.

“The founding of bluebird bio was based in large part on the potential for Lenti-D to benefit boys with CALD,” said David Davidson, M.D., chief medical officer, bluebird bio. “It is encouraging to see patients doing clinically well more than three years following treatment for this rare and devastating disease, and we are excited to have achieved excellent Lenti-D drug product vector copy numbers for the first 4 patients treated in the expansion cohort. We are pleased to share the progress of the ALD-102 study in NEJM, and look forward to providing further updates this week at the CNS Annual Meeting.”

CNS Presentation: Autologous hematopoietic stem cell gene therapy for cerebral adrenoleukodystrophy – Interim results and initial long-term follow-up of an international clinical study (Poster #133)

An update of the Starbeam study data will be presented at the CNS Annual Meeting. As of August 25, 2017:

- The final patient in the initial cohort of 17 patients has achieved 24 months of post-treatment follow-up
- 15 of the first 17 patients (88%) (95% CI: 64% to 99%) infused with Lenti-D drug product remain alive and free of major functional disabilities (MFDs), the primary efficacy endpoint of the trial
- An additional 4 patients have been infused with Lenti-D drug product with a median drug product vector copy number (VCN) of 1.4 (range 1.2-1.9)
- The safety profile in 21 treated patients remains consistent with the previously reported safety profile
- Secondary and exploratory outcome measures in the initial cohort of 17 patients were generally consistent with data as reported in the publication in the *New England Journal of Medicine:*
    - 15/17 patients maintained NFS ≤ 1 at 24 months. Loes score is stable at 24 months in 12/17 patients defined as maintaining a Loes score of ≤ 9 or not increasing by ≥ 6 from baseline.
    - 14/17 patients negative for gadolinium enhancement at their last follow-up

About the Starbeam (ALD-102) Study

The Starbeam Study is assessing the efficacy and safety of an investigational gene therapy in boys up to 17 years of age with CALD. It involves transplantation with a patient’s own stem cells, which are modified to contain functional copies of the ABCD1 gene. This gene addition should result in the production of functional adrenoleukodystrophy protein (ALDP), a protein critical for the breakdown of very long chain fatty acids (VLCFAs). Buildup of VLCFAs in the central nervous system contributes to neurodegeneration in CALD.

Subjects enrolled in the study:

- Are eligible for allogeneic HSCT but with no matched sibling donor

- Have confirmed early-stage, active CALD as indicated by:
    - Gadolinium enhancement on MRI
    - Loes score between 0.5 and 9.0
    - NFS of one or less

Patients in the Starbeam study have been treated at Boston Children's Hospital, Massachusetts General Hospital, University of Minnesota Children's Hospital, UCLA and UCL Great Ormond Street Hospital, London.

About CALD

Also known as Lorenzo's Oil disease, adrenoleukodystrophy (ALD) is estimated to affect one in every 21,000 male births worldwide. The cerebral form of the disease, cerebral adrenoleukodystrophy (CALD), is a potentially fatal form of ALD. CALD involves a breakdown of the protective sheath of the nerve cells in the brain that are responsible for thinking and muscle control. Currently, the only effective treatment option for patients with CALD is allogeneic hematopoietic stem cell transplant (HSCT). Potential complications of allogeneic HSCT, which can be fatal, include graft failure, graft versus host disease (GVHD) and opportunistic infections, particularly in patients who undergo allogeneic HSCT using cells from a donor who is not a matched, unaffected sibling.

Early diagnosis of CALD is important, as the outcome of HSCT varies with clinical stage of the disease at the time of transplant. Favorable outcomes have been observed in patients who undergo transplant in the early stages of cerebral disease. Newborn screening for ALD is a critical enabler of early diagnosis and successful treatment of ALD. In the United States, newborn screening for ALD was added to the Recommended Universal Screening Panel (RUSP) in February 2016. Newborn screening for ALD is active in a limited number of states in the US.

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 three clinical studies 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. bb2121 and bb21217 are each currently being studied in Phase 1 trials 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 Europe.

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 clinical and market potential of the Company's Lenti-D product candidate. 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 efficacy and safety data for our Lenti-D product candidate from the Starbeam Study will not continue or persist, the risk of cessation or delay of any of the ongoing clinical studies and/or our development of Lenti-D, the risks regarding future potential regulatory approvals of Lenti-D, 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 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.

Contact:
Investors & Media:
Elizabeth Pingpank, 617-914-8736
epingpank@bluebirdbio.com