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 20, 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 April 20, 2016, bluebird bio, Inc. ("bluebird") issued a press release announcing clinical data from its Starbeam clinical study of its Lenti-D product candidate, presented at the American Academy of Neurology (AAN) 2016 Annual Meeting in Vancouver, British Columbia, Canada on April 20, 2016. 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 April 20, 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.

bluebird bio, Inc.

Date: April 20, 2016

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on April 20, 2016.

Exhibit 99.1

bluebird bio Reports Interim Clinical Data from Starbeam Study of Lenti-D™ at AAN 2016 Annual Meeting

First clinical data to be presented from Phase 2/3 Starbeam Study; Company to host investor webcast and conference call today at 4:30 p.m. ET

Cambridge, Mass. April 20, 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, announced that interim data from the ongoing Phase 2/3 Starbeam Study (ALD-102) evaluating the Lenti-D™ product candidate in pediatric patients with cerebral adrenoleukodystrophy (CALD) will be presented today at the American Academy of Neurology (AAN) Annual Meeting during the Clinical Trials Plenary Session. The data will be highlighted in an oral presentation by Florian Eichler, M.D., Director of the Leukodystrophy Service at Massachusetts General Hospital for Children.

"CALD is a rare and deadly disease, and currently the only available treatment option is allogeneic hematopoietic stem cell transplant, which is often challenging for patients without a matched sibling donor," said David A. Williams, M.D., president of Dana-Farber/Boston Children's Cancer and Blood Disorders Center and the principal investigator of the Starbeam study. "It is exciting to see a potential autologous treatment option for these patients. While these study results are early, they are encouraging, and we look forward to further understanding the impact that treatment with Lenti-D gene therapy could have on patients as these data evolve."

Interim Data Summary

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 March 31, 2016, 17 patients with CALD had received Lenti-D drug product. All patients had at least six months of follow up, with eight patients having between 12 and 24 months of follow up.

The primary efficacy endpoint for the Starbeam Study is the proportion of patients with no major functional disabilities (MFDs) at 24 months post treatment. MFDs are six components of the neurological function score (NFS) 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. Secondary endpoints include Loes score (a method for quantifying

demyelination and atrophy in patients with CALD using brain MRI), NFS (a scoring system assessing clinical deficits across 15 functional domains), gadolinium enhancement on MRI (an indicator of neuroinflammation), and safety.

Data from these 17 patients as of March 31, 2016, reported today at AAN include:

- All patients remain free of MFDs.
- Sixteen of 17 patients had NFS stabilization (change of <3 points and an absolute NFS ≤ 4).
    - Two patients have an NFS of 1, due to the occurrence of stuttering in one patient, and episodic urinary incontinence in another patient.
    - One patient had an early, rapidly progressive course and has an NFS of 5, reflecting deficits in speech, vision, difficulty walking and running, and episodes of urinary incontinence.
- Fourteen of 17 patients had a stable Loes score (change of ≤ 5 points or an absolute Loes Score ≤ 9).
- Sixteen of 17 had resolution of gadolinium enhancement by month six. Re-emergence of diffuse contrast enhancement was seen in five patients at month 12. Of those five patients, the two with at least 18 months of follow up showed resolution of gadolinium enhancement at month 18.
- The safety profile of Lenti-D treatment appears consistent with myeloablative conditioning with one possibly drug-related serious adverse event (Grade 3 BK-mediated viral cystitis) and one possibly drug-related adverse event (Grade 1 tachycardia). Both resolved with standard measures.
- Integration site analyses have demonstrated polyclonal reconstitution in all subjects without evidence of clonal dominance to date.

“While the interim results from the Starbeam study are early, with only three of the 17 patients having completed the study thus far, we are pleased to see evidence of neurologic and radiographic stabilization of CALD,” said David Davidson, M.D., chief medical officer, bluebird bio. “All patients are free of MFDs and most have had no progression in NFS. Brain MRI is the primary tool to quantify disease activity, and it is encouraging that most patients in the study have had stabilization of Loes score and resolution of gadolinium enhancement. We look forward to sharing additional data from this trial as the results mature, and would like to express our gratitude to the study investigators, and especially to the patients and families who are participating in this trial.”

David Williams receives research support from bluebird bio for research related to sickle cell disease, and the company has licensed intellectual property from Boston Children’s Hospital for technology related to gene therapy for hemoglobinopathies that Williams co-invented.

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 a functioning copy 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 hematopoietic stem cell transplant (HCT) but with no matched sibling donor
- Confirmed early-stage, active CALD as indicated by gadolinium enhancement on MRI
- Have a Loes score between 0.5 – 9.0
- Have an NFS of one or less

About CALD

Also known as Lorenzo's Oil disease, cerebral adrenoleukodystrophy (CALD) is a rare and fatal, X-linked, inherited, neurodegenerative disease that primarily affects young boys. CALD involves a progressive destruction of myelin, the protective sheath of the nerve cells in the brain that are responsible for thinking and muscle control. Symptoms usually occur in early childhood and progress rapidly if untreated, leading to severe loss of neurological function and eventual death. In boys affected by CALD, learning and behavioral problems are often observed in mid-childhood between the ages of 3 and 15 years (median age 7). The worldwide incidence rate for ALD is approximately one in 21,000 male newborns; of those, 30-40 percent are affected by CALD, the cerebral form of the disease.

Currently, the only effective treatment option for patients with CALD is allogeneic HCT. Complications of allogeneic HCT include a significant risk of treatment-related mortality, graft failure, graft-versus-host disease (GvHD) and opportunistic infections, particularly in patients who undergo allogeneic HCT and do not have a matched sibling donor.

Investor Webcast Information

bluebird bio will host an investor conference call and webcast with slides today, April 20, 2016 at 4:30 p.m ET. To access the live webcast and slides, please visit the "Events & Presentations" page within the Investors and Media section of the bluebird bio website at http://investor.bluebirdbio.com. The slide presentation is not accessible until the start of the call and will be posted to the "Events & Presentations" page of the Investors and Media section for 90 days following the end of the call. Alternatively, investors may listen to the call by dialing (844) 825-4408 from locations in the United States or (315) 625-3227 from outside the United States. Please refer to conference ID number 90617203.

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 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 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 quarterly report on 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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