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): June 26, 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 8.01 Other Events

On June 26, 2017, bluebird bio, Inc. reported updated clinical data from the Starbeam Study clinical study of its Lenti-D product candidate. The full text of bluebird bio, Inc.'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 June 26, 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: June 26, 2017

bluebird bio, Inc.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on June 26, 2017

Exhibit 99.1

bluebird bio Announces Topline Interim Clinical Data from Starbeam Study of Lenti-D™ Drug Product in Cerebral Adrenoleukodystrophy (CALD)

- *15/17 patients (88%) in initial study cohort remain free of major functional disabilities (MFDs) at 24 months –*
- *Expansion cohort enrolling additional patients to gain European manufacturing experience –*

CAMBRIDGE, Mass., June 26, 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, announced topline interim data from the initial cohort of 17 patients in the ongoing Phase 2/3 Starbeam Study (ALD-102) evaluating Lenti-D™ investigational gene therapy in boys under 18 years old with cerebral adrenoleukodystrophy (CALD).

"The hope that Lenti-D may benefit boys facing such a devastating disease inspires all of us at bluebird," said David Davidson, M.D., chief medical officer, bluebird bio. "Having this proportion of the initial cohort of patients meet the primary endpoint is truly gratifying, bringing us one step closer to our goal of making Lenti-D available for patients with CALD. The two patients who did not meet the primary endpoint underscore the devastating nature of CALD, the importance of early diagnosis through newborn screening, and the challenges of the current standard of care with allogeneic hematopoietic stem cell transplant (HSCT). Patient 2016 had not experienced an MFD, but withdrew from the study due to radiographic progression of disease and underwent an allogeneic 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 a neurological function score (NFS) of 5. The rapidity of his disease progression suggests it would have been difficult to alter his early neurological decline given that transplant takes months to exert a therapeutic effect in CALD. Our hearts go out to these two boys and their families. Our program would not be possible without our brave patients and their families, and we are tremendously grateful for their participation."

As of June 13, 2017, 17 patients with CALD have completed 2 years of follow-up post-Lenti-D treatment, with 15/17 (88%) remaining free of major functional disabilities (MFDs), the primary endpoint of the trial. This exceeds the pre-defined interim efficacy benchmark for the study of MFD-free survival of 76%, derived from the literature and based on clinical data from an earlier observational study describing that natural history of CALD and outcomes from allogeneic HSCT.

In the Starbeam Study, the safety profile of Lenti-D was consistent with myeloablative conditioning. No patients treated with Lenti-D had graft versus host disease (GvHD), and there was no graft rejection or clonal dominance.

In December 2016, bluebird bio announced that the Starbeam study had been expanded to treat eight additional patients at sites in Europe and the US, and the study is currently enrolling the additional patients. The expansion of the study is intended to enable the first manufacture of Lenti-D in Europe, the subsequent treatment of subjects in Europe, and to bolster the overall clinical data package for potential future regulatory filings in the United States and Europe.

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 hematopoietic stem cell transplant (HSCT) 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, 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 that affects the nervous system of boys. 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. 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™ product candidate, currently in four clinical studies for the treatment of transfusion-dependent β-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 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 and Europe.

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.

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