

bluebird bio, Inc.
Form 8-K
September 05, 2018

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): September 5, 2018

bluebird bio, Inc.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE
(State or Other Jurisdiction

001-35966

13-3680878
(IRS Employer

of Incorporation)

(Commission File Number) 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 September 5, 2018, bluebird bio, Inc. (“bluebird”) issued a press release announcing updated data results from the Phase 2/3 Starbeam study (ALD-102) of its investigational Lenti-D gene therapy product candidate in boys 17 years of age and under with cerebral adrenoleukodystrophy (CALD), and initial data from ALD-103, the ongoing observational study of outcomes from allogeneic hematopoietic stem cell transplant (allo-HSCT) in boys 17 years of age and under with CALD. The data results were presented at the Society for the Study of Inborn Errors of Metabolism (SSIEM) 2018 Symposium in Athens, Greece.

bluebird also announced that it has reached general agreement with the U.S. Food and Drug Administration and the European Medicines Agency on the clinical development program to support future marketing applications for the Lenti-D product candidate in the treatment of CALD.

The full text of the 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 | <u>Press release issued by bluebird bio, Inc. on September 5, 2018.</u> |

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: September 5, 2018 bluebird bio,
Inc.

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