

bluebird bio, Inc.
Form 8-K
July 12, 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): July 12, 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)

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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.

Celgene Corporation (“Celgene”) has amended the study protocol for the KarMMa study, an ongoing Phase 2 study of the bb2121 product candidate in patients with relapsed and refractory multiple myeloma. Under the amended study protocol, the dose range for the KarMMa study will be 150 to 450 x 10⁶ CAR+ T cells and the enrollment will increase to up to 140 patients. This change in dosing is based on the totality of the clinical data for the bb2121 product candidate to date.

In addition, Celgene has amended the study protocol for CRB-401, an ongoing Phase I study of the bb2121 product candidate in patients with relapsed and refractory multiple myeloma. Under the amended study protocol, the enrollment for the study will be increased by up to 20 patients, with a dose range of 150 to 450 x 10⁶ CAR+ T cells.

bluebird bio, Inc. (“bluebird”) and Celgene are co-developing and co-promoting the bb2121 product candidate in the United States, and Celgene has exclusively licensed the development and commercialization rights for the bb2121 product candidate outside of the United States. bluebird and Celgene continue to anticipate a potential approval of the bb2121 product candidate in relapsed and refractory multiple myeloma in 2020.

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: July 12, 2018 bluebird bio,
Inc.

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