
**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 9, 2015

bluebird bio, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of
incorporation)

001-35966

(Commission File Number)

13-3680878

(I.R.S. Employer
Identification No.)

**150 Second Street
Cambridge, MA**

(Address of principal executive offices)

02141

(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))
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Item 8.01 Other Events

On June 9, 2015, bluebird bio, Inc. (“bluebird”), issued a press release announcing the outcome from the National Institutes of Health Recombinant DNA Advisory Committee review of the protocol from bluebird’s proposed HGB-208 clinical trial of its LentiGlobin product candidate in pediatric subjects with Beta-thalassemia Major. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on June 9, 2015, furnished herewith.

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 9, 2015

bluebird bio, Inc.

By: /s/ Jason F. Cole

Jason F. Cole

Senior Vice President, General Counsel

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on June 9, 2015, furnished herewith.



bluebird bio Completes NIH RAC Review of HGB-208 Pediatric Study Protocol

CAMBRIDGE, Mass., June 9, 2015 – bluebird bio, Inc. (Nasdaq: BLUE), a clinical-stage company committed to developing potentially transformative gene therapies for severe genetic and rare diseases and T cell-based immunotherapies, announced today the completion of the National Institutes of Health (NIH) Recombinant DNA Advisory Committee’s (RAC) public review of the HGB-208 pediatric study protocol for bluebird bio’s LentiGlobin BB305 product candidate in beta-thalassemia major. The RAC recommendation was to delay initiation of the study in the United States for one to two years. This recommendation has no effect on the HGB-207 protocol plan.

“We appreciate the recommendations from the RAC members regarding the HGB-208 pediatric study protocol,” said David Davidson, M.D., chief medical officer. “We will take the RAC feedback on the timing of initiating HGB-208 under advisement as we advance the clinical development of our LentiGlobin BB305 product candidate for patients with beta-thalassemia major. The HGB-207 trial protocol did not require further review by the RAC, and we will continue to work closely with the regulatory authorities and our clinical study sites to pursue appropriate accelerated regulatory approval pathways in the U.S. and the EU.”

Background on RAC Process

The outcome of RAC review is a series of recommendations and advice. RAC review does not constitute a formal approval of a proposed protocol. The recommendations are captured in a summary letter, which will be sent to the institutional review boards (IRBs) reviewing the protocol in the United States. The recommendations are non-binding.

Background on HGB-207 and HGB-208 Clinical Studies

In May, bluebird bio announced that it had reached general agreement with the U.S. Food and Drug Administration (FDA) on the design of its planned clinical trials HGB-207 and HGB-208. Based on its discussions with the FDA, bluebird bio believes that data from these trials, together with data from the ongoing beta-thalassemia major clinical studies (Northstar and HGB-205), could form the basis for a Biologics License Application (BLA) submission for LentiGlobin BB305. HGB-207 and HGB-208 share similar trial designs and are differentiated primarily by patient age. HGB-207 will enroll adult and adolescent patients; HGB-208 is planned to enroll pediatric patients.

Highlights:

- Sample size: 15 patients per trial
- Duration: 24 months of follow-up per patient
- Primary endpoint: 12 months of transfusion independence

The RAC had previously notified bluebird bio that only HGB-208 required a public RAC discussion.

bluebird bio also announced in May that it is one of the first companies to participate in the European Medicines Agency's (EMA) Adaptive Pathways (formerly referred to as Adaptive Licensing) pilot program, which is part of the EMA's efforts to improve timely access for patients to new medicines. Based on several discussions involving the EMA, European Health Technology Assessment (HTA) agencies and patient advocacy organizations as part of this program, bluebird bio believes it is possible to seek conditional approval for the treatment of adults and adolescents with beta-thalassemia major on the basis of the totality of clinical data, in particular reduction in transfusion need, from the ongoing Northstar Study and supportive HGB-205 study. Conversion to full approval will be subject to the successful completion of the HGB-207 and HGB-208 clinical trials, supportive long-term follow-up data and "real-life" post-approval monitoring data.

About bluebird bio, Inc.

With its lentiviral-based gene therapy and gene editing capabilities, bluebird bio has built an integrated product platform with broad potential application to severe genetic diseases and T cell-based immunotherapy. bluebird bio's clinical programs include Lenti-D™, currently in a Phase 2/3 study, called the Starbeam Study, for the treatment of childhood cerebral adrenoleukodystrophy, and LentiGlobin®, currently in three clinical studies: a global Phase 1/2 study, called the Northstar Study, for the treatment of beta-thalassemia major; a single-center Phase 1/2 study in France (HGB-205) for the treatment of beta-thalassemia major or severe sickle cell disease; and a separate U.S. Phase 1 study for the treatment of sickle cell disease (HGB-206). bluebird bio also has ongoing preclinical CAR T immuno-oncology programs, as well as discovery research programs utilizing megaTALs/homing endonuclease gene editing technologies.

bluebird bio has operations in Cambridge, Massachusetts, Seattle, Washington, and Paris, France. For more information, please visit www.bluebirdbio.com.

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 Company's global development and regulatory strategy for LentiGlobin BB305, including the expected protocols for planned clinical trials and the timing of these clinical trials, whether these planned clinical trials will be sufficient to support regulatory submissions for marketing approval and the expected timing of any such

submissions and decisions. In particular, it should be noted that the FDA normally requires two pivotal clinical studies to approve a drug or biologic product. Whether the planned HGB-207 and HGB-208 trials will be sufficient to support submission of a BLA for LentiGlobin BB305 will likely be a review issue to be discussed with FDA following completion of the trials. In addition, it should be noted that the EMA Adaptive Pathways program is a pilot program, and as such there is limited information and precedent regarding the potential outcomes for sponsors that participate in this program. 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 of cessation or delay of any of the ongoing or planned clinical studies and/or our development of our product candidates, the risk of a delay in the enrollment of patients in the Company's clinical studies, actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and regulatory submissions, the risk that the results of previously conducted studies involving similar product candidates will not be repeated or observed in ongoing or future studies involving current product candidates, 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 annual report on 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.

Availability of other information about bluebird bio

Investors and others should note that we communicate with our investors and the public using our company website (www.bluebirdbio.com), our investor relations website (<http://www.bluebirdbio.com/investor-splash.html>), including but not limited to investor presentations and FAQs, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. You can also connect with us on Twitter [@bluebirdbio](#), [LinkedIn](#) or our [YouTube](#) channel. The information that we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in bluebird bio to review the information that we post on these channels, including our investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include other social media channels than the ones described above. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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