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): May 19, 2015

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 2.02 Results of Operations and Financial Condition

On May 19, 2015, bluebird bio, Inc. ("bluebird") issued a press release announcing its global regulatory strategy for its LentiGlobin BB305 product candidate for the treatment of beta-thalassemia major. 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	Press release issued by bluebird bio, Inc. on May 19, 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: May 19, 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 May 19, 2015, furnished herewith.

Exhibit 99.1

FOR IMMEDIATE RELEASE

bluebird bio Announces Global Regulatory Strategy for LentiGlobin BB305 in Beta-Thalassemia Major

Company Plans to Pursue Conditional and Accelerated Registration Strategies in E.U. and U.S., Respectively

Plans to Pursue Conditional Approval in E.U. Based on Data from Ongoing Northstar and HGB-205 Studies through Adaptive Pathways Pilot Program

NIH RAC Will Review HGB-208 Pediatric Study Protocol on June 9, 2015

Conference Call and Webcast Today at 8:00AM ET

CAMBRIDGE, Mass., May 19, 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, today announced that it has met with regulatory authorities in Europe and the United States to discuss potential approval pathways for its LentiGlobin BB305 product candidate for the treatment of beta-thalassemia major. These discussions have resulted in general agreement from both agencies regarding bluebird bio's development plans, which could potentially result in accelerated approvals.

"We are very pleased with the outcome of these recent regulatory interactions," commented David Davidson, M.D., chief medical officer. "We look forward to advancing our beta-thalassemia major program based on data both from our ongoing studies as well as two planned open-label studies with a sample size of 15 patients each. The EMA Adaptive Pathways pilot program will allow us to pursue conditional approval for the treatment of beta-thalassemia major on the basis of clinical data from our ongoing HGB-204 and HGB-205 studies. This feedback brings us closer to achieving our vision of delivering one-time, potentially transformative gene therapy to patients."

EMA Registration Strategy: Participate in Adaptive Pathways Pilot Program
bluebird bio 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 discussed below, supportive long-term follow-up data and "real-life" post-approval monitoring data.

FDA Registration Strategy: Pursue Accelerated Approval Based on HGB-207 (n=15) and HGB-208 (n=15)
In addition, bluebird bio has 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 will enroll pediatric patients.

bluebird bio has also reached general agreement with the FDA on:

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

In the United States, if the LentiGlobin BB305 product candidate demonstrates acceptable efficacy and safety in these patient populations, these planned clinical trials could support an accelerated approval, with post-approval confirmatory evidence to be provided with longer-term follow-up of these trials. As a result of this regulatory feedback and as required of all gene therapy clinical trials, bluebird bio has filed both clinical study protocols with the National Institutes of Health (NIH) Recombinant DNA Advisory Committee (RAC). The RAC has notified bluebird bio that HGB-207 does not require an in-depth review or public RAC discussion. The RAC has also notified bluebird bio that the HGB-208 study protocol is scheduled for public review on June 9, 2015.

"We are grateful for the collaborative regulatory feedback from the FDA and EMA on the design of our pivotal studies, as well as feedback from the European HTA agencies and patient advocacy organizations that are participating in our Adaptive Pathways pilot project," stated Anne-Virginie Eggimann, vice president of regulatory science. "We are looking forward to continuing our engagement with all of these stakeholders in the coming months to support the potential acceleration of the LentiGlobin BB305 program."

Background on the EMA's Adaptive Pathways Program
In establishing the Adaptive Pathways program, the EMA stated the following:

"The concept of Adaptive Pathways foresees either an initial approval in a well-defined patient subgroup with a high medical need and subsequent widening of the indication to a larger patient population, or an early regulatory approval (e.g. conditional approval), which is prospectively planned, and where uncertainty is reduced through the collection of post-approval data on the medicine's use in patients. This approach is particularly relevant for medicines with the potential to treat serious conditions with an unmet medical need and may reduce the time to a medicine's approval or to its reimbursement for targeted patient groups. It involves balancing the importance of timely patient access with the need for adequate, evolving information on a medicine's benefits and risks. The Adaptive Pathways approach builds on regulatory processes already in place within the existing European Union legal framework."

The pilot was initiated in March 2014 and was called "Adaptive Licensing" at the time. EMA changed the name to Adaptive Pathways "to better reflect the idea of a life-span approach to bring new medicines to patients with clinical drug development, licensing, reimbursement, and utilization in clinical practice, and monitoring viewed as a continuum."

Background on the FDA Process and NIH's RAC
FDA approval must be obtained before clinical testing of biological products. Each clinical study protocol for a gene therapy product is reviewed by the FDA and the NIH, through its Recombinant DNA Advisory Committee (RAC). Within the FDA, the Center for Biologics Evaluation and Research (CBER) regulates gene therapy products. CBER works with the NIH and its RAC, which makes recommendations to the NIH on gene therapy issues and engages in a public discussion of scientific, safety, ethical and societal issues related to proposed and ongoing gene therapy protocols.

The NIH is responsible for convening the RAC to discuss protocols that raise novel or particularly important scientific, safety or ethical considerations at one of its quarterly public meetings. The Office of Biotechnology Activities (OBA) notifies the FDA of the RAC's decision regarding the necessity for full public review of a gene therapy protocol. RAC proceedings and reports are posted to the OBA web site and may be accessed by the public.

Investor Conference Call and Webcast Information
bluebird bio will host a conference call and webcast on May 19, 2015 at 8:00 AM ET to review its LentiGlobin regulatory strategy. The event will be webcast live and can be accessed under "Calendar of Events" in the Investors and Media section of the company's website at www.bluebirdbio.com. Alternatively, investors may listen to

the call by dialing (844) 825-4408 from locations in the United States and (315) 625-3227 from outside the United States.

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 a preclinical CAR T immuno-oncology program in collaboration with Celgene Corporation, 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 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, the risk that our collaboration

with Celgene will not continue or will not be successful, 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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