
**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 9, 2016

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 May 9, 2016, bluebird bio, Inc. (“bluebird”) issued a press release announcing its presentations at the American Society of Gene and Cell Therapy (ASGCT) 19th Annual Meeting, which took place on May 4-7, 2016 in Washington, D.C.

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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on May 9, 2016.

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 9, 2016

bluebird bio, Inc.

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on May 9, 2016.



bluebird bio Presents Oncology and Gene Therapy Data at the ASGCT 19th Annual Meeting

CAMBRIDGE, Mass. – May 9, 2016 – 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 for cancer, today announced the presentation of pre-clinical data from its immuno-oncology and hematopoietic stem cell (HSC) gene therapy programs at the American Society of Gene & Cell Therapy (ASGCT) 19th Annual Meeting, taking place May 4-7, 2016 in Washington, D.C.

Additionally, two oral presentations given by bluebird’s academic collaborators highlighted previously presented data from bluebird bio’s ongoing gene therapy clinical trials. David Williams, M.D., president of Dana-Farber/Boston Children’s Cancer and Blood Disorders Center presented interim data from the Starbeam Study of Lenti-D™ in cerebral adrenoleukodystrophy, and Marina Cavazzana, M.D., Ph.D., of Hospital Necker, University Paris Descartes, presented interim data from the HGB-205 study of LentiGlobin® in severe sickle cell disease and transfusion-dependent β -thalassemia.

“The preclinical data presented at ASGCT are testament to bluebird’s commitment to developing next-generation immuno-oncology and gene therapies. We are particularly excited about our oncology presentations, which highlighted our progress toward the generation of T cells with sustained anti-tumor activity as well as research on small-molecule regulated multi-chain chimeric antigen receptors known as Darics,” said Philip Gregory, D.Phil., chief scientific officer, bluebird bio. “For our hematopoietic stem cell programs, scalable manufacturing and transduction efficiency remain areas of focus and importance for bluebird. Multiple presentations at ASGCT discussed encouraging examples of our efforts on these fronts – with more to come as we continue to innovate in this critical direction.”

Oncology Presentations:

Oral Abstract #277: Small Molecule-regulated Antigen Recognition System for Inducible T Cell Targeting of Cancer Cells

Overview and results presented by Wai-Hang Leung, Ph.D., bluebird bio.

- bluebird bio scientists presented data on a small-molecule regulated CAR (Daric) for applications where it may be useful to turn antigen-driven T cell activity on or off, such as minimizing off-tumor activity. In addition to potentially providing an enhanced safety
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- profile for CAR T cells, this technology could be applied in other indications such as autoimmune disease.
- Daric engineered CAR T cells possess minimal activity in the absence of dimerizing agents (rapamycin / AP21967), and antigen-specific cytotoxicity and cytokine production are significantly upregulated with the addition of rapamycin / AP21967.

Oral Abstract #747: Towards the Clinical Application of BCMA CAR T cells: The Importance of Reduced Tonic Signaling and Methods to Enhance Memory T Cells

Results presented by Kevin Friedman, Ph.D., bluebird bio.

- bluebird bio has developed a potent CAR targeting BCMA (bb2121) to treat multiple myeloma and some lymphomas. The initial clinical application of this technology to treat patients with multiple myeloma began in February.
- bluebird bio scientists demonstrated that a property called tonic signaling can reduce CAR T cell durability and tumor control, but careful CAR engineering can avoid this problem. Furthermore, simple manufacturing changes involving inhibition of the PI3K pathway can significantly increase the potency and fitness of CAR T cells.

Abstract #323: Efficient Generation of CART Cells by Homology Directed Transgene Integration into the TCR-Alpha Locus

Results presented by Baeckseung Lee, Ph.D., bluebird bio.

- Homology directed transgene integration combines nuclease-mediated gene disruption with site-specific integration of novel genetic material. Using bluebird bio's proprietary gene editing technology, megaTALs, bluebird scientists demonstrated that this can be efficiently accomplished in primary human T cells by introducing a CD19 CAR into the TCR alpha gene (TRAC).
- Nuclease generated CAR T cells had similar cytotoxicity and cytokine production compared to those made by lentiviral vector transduction. These data demonstrate the potential for megaTAL-mediated targeted gene addition as a robust method for the genetic editing of CAR T cells.

HSC Gene Therapy Presentations

Abstract #221: Staurosporine Increases Lentiviral Transduction of Human CD34+ Cells

Results presented by Melissa Bonner, Ph.D., bluebird bio.

- bluebird has been evaluating numerous compounds for the potential to increase vector copy number (VCN) and enhance cell transduction in lentiviral vector (LVV)-based gene therapy.
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- Limited staurosporine treatment prior to LVV transduction can increase the proportion of modified cells, including long-term repopulating cells, in a gene modified cell product.
- This work received an “Outstanding Poster Award” from the ASGCT.

Abstract #229: PGE2 Increases Lentiviral Vector Transduction Efficiency of Human HSC

Results presented by Garrett C. Heffner, Ph.D., bluebird bio.

- As part of its work to evaluate small molecules that may increase VCN and enhance cell transduction, bluebird identified PGE2 as a VCN enhancer in CD34+ cells.
- PGE2 improves VCN approximately 2-fold from multiple healthy normal CD34+ cell donors as well as donors with primary hemoglobinopathies. These increases in VCN also result in an increased percentage of cells with integrated lentiviral vector leading to improved globin expression in in vitro preclinical models.

Abstract #458: Development of a stable producer cell line for scalable lentiviral vector production for gene therapy of hemoglobinopathies

Results presented by Sarah Slason, bluebird bio

- Current manufacturing of clinical grade lentiviral vectors commonly relies on transient infection of adherent 293T cells. An inducible producer cell line grown in suspension culture represents a potentially more scalable manufacturing process for vector production, eliminating the need for costly plasmid and transfection reagents.
- bluebird bio scientists have developed 293F-based stable packaging and producer cell lines for inducible production of LentiGlobin BB305, and reported the successful production of LentiGlobin BB305 at research scale in suspension culture.

Abstract #473: Qualification of a p24 ELISA Assay for Quantitation of Total Lentiviral Vector Concentration

Results presented by Elisabeth Boucher, bluebird bio.

- The availability of reliable analytical tools to characterize purified LVV product and in-process samples is critical to successful LVV process development. In support of late-stage process characterization, it is essential to qualify the assay and demonstrate its suitability to test in-process samples in different matrices.
- Scientists at bluebird bio reported on the qualification of a p24 ELISA assay for LVV quantitation, showing precision, repeatability, specificity and accuracy within an established range, adequate to support late-stage process characterization activities.

Abstract #709: Characterization of Nanoparticles in Lentiviral Vector Preparations

Results presented by Erik Hansen, bluebird bio.

- Progress to late-stage clinical development of lentivirus based gene therapies and CAR T therapies will require enhanced characterization of the purified lentivirus product. LVV preparations are complex and utilize host cells that produce not only the viral particles of interest, but also a variety of closely related impurities that can include microvesicles. These cell-derived impurities can overlap key biophysical and biochemical attributes of the LVV, making them challenging to analyze.
- bluebird bio scientists reported on the use of various analytical tools to further characterize LVV preparations in terms of particle size distribution and counts, as well as methods for determining the total particle to infectious particle ratio.

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™ BB305 product candidate, currently in three 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 megaTALs/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 Paris, France.

LentiGlobin and Lenti-D are trademarks of bluebird bio, Inc.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding bluebird bio's existing product candidates and research programs. 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, risks that the preliminary results from our clinical trials will not continue or be repeated in our ongoing clinical trials, the risk that

previously conducted studies involving similar product candidates will not be repeated or observed in ongoing or future studies involving current product candidates, 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 our clinical studies, 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 quarterly 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.

Contact Information

bluebird bio, Inc.

Manisha Pai, 617-245-2107

mpai@bluebirdbio.com

or

Pure Communications, Inc.

Dan Budwick, 973-271-6085

dan@purecommunicationsinc.com