

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 29, 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 September 29, 2016, bluebird bio, Inc. and Medigene Immunotherapies GmbH, a wholly owned affiliate of Medigene AG, issued a joint press release announcing that the parties have entered into a strategic research collaboration and licensing agreement to research, develop and commercialize T cell receptor immunotherapies against four undisclosed targets. 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 September 29, 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: September 29, 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 September 29, 2016



Press Release

bluebird bio and Medigene establish strategic T cell receptor (TCR) alliance in cancer immunotherapy

- T cell receptor (TCR) therapeutic candidates against four targets to be generated using Medigene's proprietary TCR technology platform and bluebird bio's lentiviral vector, genome editing, synthetic biology, and manufacturing capabilities
- Medigene responsible for the generation and delivery of the TCRs to bluebird bio
- Joint preclinical development of all product candidates
- bluebird bio responsible for clinical development and commercialization of resulting products
- Medigene to receive an upfront payment of USD 15 million, R&D funding, potential preclinical, clinical and commercial milestone payments, which together could total over USD 1 billion, in addition to royalties on net sales
- bluebird bio will hold worldwide development and commercial rights and exclusive license for IP covering the TCRs
- Medigene conference call and webcast (in English) today, 29 September 2016, at 3:00 pm CEST (9:00 am EDT)

Martinsried/Munich and Cambridge, MA, 29 September 2016. Medigene AG (MDG1, Frankfurt, Prime Standard), Germany, and bluebird bio, Inc. (Nasdaq: BLUE), USA, today announced the signing of a strategic research and development collaboration and licensing agreement encompassing T cell receptor (TCR) immunotherapies against four targets.

"We are delighted to collaborate with bluebird bio, a leader in the field of cell and gene therapy, including cancer immunotherapy," said Dolores J. Schendel, chief executive officer and chief scientific officer, Medigene. "With its T cell immunotherapy expertise and outstanding gene delivery and genome editing capabilities, bluebird bio is an ideal partner for us to jointly discover and develop a new generation of T cell therapeutics to treat unmet oncology indications."

"Medigene's proprietary technology to generate highly active natural TCRs makes them an ideal partner, enabling us to broaden our pipeline with TCR-based product candidates against four new targets and continue to build our leadership in immuno-oncology," said Rick Morgan, Ph.D., vice president of immunotherapy, bluebird bio. "This agreement exploits our core expertise in lentiviral gene transfer, genome editing and synthetic biology, and leverages our manufacturing and clinical development capabilities to build a broad, fully integrated immuno-oncology franchise."

"Our first commercial agreement based on Medigene's TCR technology is testimony to our rapid progress as an immuno-oncology company," added Dave Lemus, chief operating officer, Medigene. "Furthermore, the agreement provides Medigene with significant additional financial resources for both the short term and potentially the long term as we participate in the value creation of the cell therapeutics that we jointly create."

Under the terms of the agreement, Medigene will be responsible for the generation and delivery of the TCRs using its TCR isolation and characterization platform. Following the collaborative preclinical development, bluebird bio will assume sole responsibility for the clinical development and commercialization of the TCR product candidates and will receive an exclusive license for the intellectual property covering the resulting TCRs.



Medigene will receive an upfront payment of USD 15 million as well as potential preclinical, clinical, regulatory and commercial milestone payments, which together could total over USD 1 billion in the aggregate for the four potential TCR products across several indications. Additionally, Medigene will receive R&D funding for all work performed in the collaboration and is eligible for tiered royalty payments on net sales up to a double-digit percentage.

Contractual parties to the agreement are Medigene Immunotherapies GmbH, a wholly owned affiliate of Medigene AG, and bluebird bio, Inc.

Press and analysts' conference call: Medigene will hold a press and analysts conference call (in English) today at 3:00 pm CEST / 9:00 am EDT and will webcast the call live via Medigene's website, www.medigene.com.

About Medigene's TCR technology: The TCR technology aims at arming the patient's own T cells with tumor-specific T-cell receptors. The receptor-modified T cells are then able to detect and efficiently kill tumor cells. This immunotherapy approach attempts to overcome the patient's tolerance towards cancer cells and tumor-induced immunosuppression by activating and modifying the patient's T cells outside the body (ex-vivo).

TCR therapy is developed to detect a greater number of potential tumor antigens than other T cell-based immunotherapies, such as chimeric antigen receptor T cell (CAR T) therapy. Medigene is preparing the clinical development of its first TCR candidates and is establishing a library of recombinant T cell receptors, and has established Good Manufacturing Practice (GMP)-compliant processes for their combination with patient-derived T cells. The start of a clinical Phase I TCR investigator-initiated trial (IIT) with Medigene participation is expected in 2017. Medigene plans to commence its own first clinical TCR trial in 2017 and a second trial in 2018.

Medigene's TCR technology for adoptive T-cell therapy is one of the company's three highly innovative and complementary immunotherapy platforms in immuno-oncology.

About bluebird bio: 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 four 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.

Medigene AG is a publicly listed (Frankfurt: MDG1, prime standard) biotechnology company headquartered in Martinsried near Munich, Germany. The company is developing highly innovative complementary treatment platforms to target various types and stages of cancer with candidates in clinical and pre-clinical development. Medigene concentrates on the development of personalized T cell-based immunotherapies. For more information, please visit www.medigene.com



This press release contains forward-looking statements representing the opinion of Medigene as of the date of this release. The actual results achieved by Medigene may differ significantly from the forward-looking statements made herein. Medigene is not bound to update any of these forward-looking statements. Medigene® is a registered trademark of Medigene AG. This trademark may be owned or licensed in select locations only.

bluebird bio 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 research, development and advancement of bluebird bio's product candidates and immuno-oncology research program, including its TCR research program and those shared with Medigene. 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 that the research programs for these targets will be unsuccessful and not identify any viable product candidates, the risk that our collaboration with Medigene will not continue or will not be successful, the risk of cessation or delay of any planned clinical studies and/or our development of our 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 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.*

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Should you no longer wish to receive any information about Medigene, please inform us by e-mail (investor@medigene.com). We will then delete your address from our distribution list.