

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): December 15, 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 7.01 Regulation FD Disclosure

On December 15, 2016, bluebird bio, Inc. (“bluebird”) issued a press release that bluebird and Apceth Biopharma GmbH, have entered into a strategic manufacturing agreement providing for the anticipated future European commercial production of bluebird’s Lenti-D product candidate for cerebral adrenoleukodystrophy and bluebird’s LentiGlobin product candidate for transfusion-dependent β -thalassemia. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 7.01 of this Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

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 December 15, 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: December 15, 2016

bluebird bio, Inc.

By: /s/ Jason F. Cole

Jason Cole

Chief Legal Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on December 15, 2016.

**bluebird bio and apceth Biopharma
Establish Commercial Drug Product Manufacturing Agreement**

Cambridge, Mass., (USA) and Munich, Germany, December 15, 2016 – bluebird bio, Inc. ([Nasdaq: BLUE](http://Nasdaq:BLUE)), a clinical-stage company committed to developing potentially transformative gene therapies for severe genetic diseases and T cell-based immunotherapies for cancer and apceth Biopharma GmbH (www.apceth.com), the global innovator and leader in the development of engineered mesenchymal stem cell (MSC) therapeutics and a successful and established contract development and manufacturing organization in the field of cell and gene therapy, announced today that they have entered into a strategic manufacturing agreement providing for the future European commercial production of bluebird bio's Lenti-D™ product candidate for cerebral adrenoleukodystrophy and its LentiGlobin™ product candidate for transfusion-dependent β-thalassemia.

This agreement follows a successful multi-year manufacturing relationship and provides bluebird bio with European commercial manufacturing capabilities, including dedicated production suites within apceth Biopharma's state-of-the-art GMP facility.

Under this multi-year agreement, apceth Biopharma will perform clinical manufacturing, process validation activities and commercial manufacturing for LentiGlobin and Lenti-D drug product to support the treatment of European patients with transfusion-dependent beta thalassemia and cerebral adrenoleukodystrophy, respectively.

“At bluebird, we are committed to not only developing potentially transformative therapies, but ensuring that we can deliver them to patients. For this reason, we are committed to investing in the capabilities and infrastructure necessary to support commercialization both in the U.S. and Europe,” said Nick Leschly, chief bluebird. “By partnering with multiple organizations, including our valued partner apceth Biopharma, we are able to develop integrated capabilities in manufacturing that can position us to effectively bring our future commercial products to patients in need.”

"We are very pleased to continue our successful contract manufacturing relationship with bluebird bio and plan to be the right partner in the future to enable product supply to European patients for clinical development and commercialization", said Christine Guenther, apceth Biopharma's CEO. "This long-term agreement confirms that apceth Biopharma is a valuable and reliable partner for our clients in the field of clinical and commercial cell and gene therapy manufacturing." Ulrike Verzetnitsch, apceth Biopharma's CTO, added: "We are very proud that our customized GMP manufacturing solutions and our deep commitment to the client's needs and expectations are recognized

by bluebird bio, leading to a long-term strategic manufacturing relationship between our companies".

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 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.

bluebird bio has operations in Cambridge, Massachusetts; Seattle, Washington; and Paris, France.

About apceth Biopharma GmbH

apceth Biopharma is a pioneering biopharmaceutical company with a pipeline of cell-based gene therapeutics for the treatment of major chronic diseases (chronic lung disease, metabolic and autoimmune diseases) and solid cancer. The company's proprietary platform technology is based on state-of-the-art genetic engineering of mesenchymal stem cells. apceth Biopharma is also a successful Contract Development and Manufacturing Organization for complex cell and gene therapy products with a high international reputation. Based in Munich (Germany) in the heart of Europe, apceth Biopharma provides its proven expertise and state-of-the-art GMP facilities to the clients from around the world. apceth Biopharma was founded as apceth GmbH & Co. KG in 2007. The company is privately owned by its founders and private investors (Santo Holding GmbH and FCP Biotech Holding GmbH).



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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 bluebird bio’s LentiGlobin and Lenti-D product candidates and plans for their commercial manufacture in Europe. 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 or planned clinical trials, the risk of cessation or delay of any of the ongoing or planned clinical studies or the development of our product candidates, the risk of a delay in the enrollment of patients in our clinical studies 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.