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): March 22, 2019

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)**	**(IRS Employer Identification No.)**
60 Binney Street, Cambridge, MA (Address of Principal Executive Offices)		**02142 (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 (see General Instructions A.2. below):

☐ 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On March 22, 2019, bluebird bio, Inc. issued a press release announcing the official opening of its manufacturing facility in Durham, North Carolina. A copy of the press release 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 March 22, 2019.

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: March 22, 2019

bluebird bio, Inc.

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

Exhibit 99.1

bluebird bio Opens State-of-the-Art Gene and Cell Therapy Manufacturing Facility in Durham, North Carolina

Gov. Cooper to cut ribbon on facility that will strengthen bluebird bio's capabilities to manufacture products for clinical development and commercial supply

CAMBRIDGE, Mass. and DURHAM, N.C. -- Mar. 22, 2019 -- bluebird bio, Inc. (Nasdaq: BLUE) today announced the official opening of its first wholly owned manufacturing facility in Durham, N.C., that will produce lentiviral vector for the company's investigational gene and cell therapies, including: bb2121 and bb21217 for the treatment of multiple myeloma and potentially LentiGlobin™ for the treatment of transfusion-dependent β-thalassemia (TDT) and sickle cell disease.

Gov. Roy Cooper, Secretary of Commerce Tony Copeland and local patient advocates will join chief bluebird Nick Leschly in a ribbon cutting ceremony at the 125,000-square-foot facility. Currently, bluebird employs approximately 50 scientists, engineers, manufacturing and operations personnel at the facility and is on track to grow to approximately 70 employees by the end of 2019.

"At bluebird bio, we view every aspect of our path to helping patients as both a privilege and a responsibility. This includes the expertise that we've poured into the construction and operation of our manufacturing facility, because it is a crucial step toward our mission of bringing a new generation of treatments to people living with severe genetic diseases and cancer," said Leschly. "Our teams in North Carolina and across the globe are working to deliver treatments that will make a big difference for a lot of patients and families. This is what drives our ambition to bring four gene therapies forward in the next few years."

“North Carolina is proud to bring bluebird bio’s cutting-edge work to Durham,” Governor Cooper said. “bluebird is developing treatments for devastating diseases that could change the course of medicine. And, with the Triangle’s highly-skilled workforce, it will continue to be a leader in the biotech field.”

bluebird bio purchased the facility in November 2017. Once completed, the company will have invested more than $80 million building a world class site equipped with multiple manufacturing suites capable of producing lentiviral vector (LVV). The facility also includes warehouse and quality control testing laboratories. The facility construction is substantially complete and equipment qualification is underway. Initially, bluebird bio expects the facility to produce clinical and commercial supply of lentiviral vector, which is a critical component of the company’s gene and cell therapies. The facility is large enough to accommodate significant future expansion, including the possibility of manufacturing commercial drug product.

The goal of gene therapy is to change or replace faulty genes with functional ones in order to prevent, treat or cure a disease. Vectors are selected parts of viruses that have been genetically modified so they can deliver new genes into cells without causing an infectious disease. Prior to gene therapy treatment, copies of functional genes are added to a vector — the delivery system — in a laboratory setting. The vector, with copies of the functional gene, is added to blood stem cells collected from the patient. The cells that now have functional copies of the gene are referred to as gene-modified cells.

In addition to the Durham facility, bluebird bio also has multi-year agreements with three manufacturing partners in the United States and Europe: Brammer Bio (Cambridge, Mass.), Novasep (Gosselies, Belgium) and MilliporeSigma, the Life Science business of Merck KGaA (Carlsbad, Calif.). Each of these partners is collaborating with bluebird bio on production of lentiviral vector across all programs. bluebird bio also partners with Lonza (Houston, Texas) and apceth Biopharma (Munich, Germany) to produce drug product for Lenti-D and LentiGlobin.

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bluebird will receive an Economic Development Award from NCBiotech upon meeting job creation targets in North Carolina and will also receive life-sciences-specific employee training support through the North Carolina Community College System's Customized Training Program.

About bluebird bio, Inc.

bluebird bio is pioneering gene therapy with purpose. From our Cambridge, Mass., headquarters, we're developing gene therapies for severe genetic diseases and cancer, with the goal that people facing potentially fatal conditions with limited treatment options can live their lives fully. Beyond our labs, we're working to positively disrupt the healthcare system to create access, transparency and education so that gene therapy can become available to all those who can benefit.

bluebird bio is a human company powered by human stories. We're putting our care and expertise to work across a spectrum of disorders by researching cerebral adrenoleukodystrophy, sickle cell disease, transfusion-dependent β-thalassemia and multiple myeloma using three gene therapy technologies: gene addition, cell therapy and (megaTAL-enabled) gene editing.

bluebird bio has additional nests in Seattle, Wash.; Durham, N.C.; and Zug, Switzerland. For more information, visit bluebirdbio.com.

Follow bluebird bio on social media: @bluebirdbio, LinkedIn, Instagram and YouTube.

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 construction and manufacturing capacity of the Company's facility, and the advancement of, and anticipated development and commercialization plans for, the Company's product candidates. 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 manufacturing facility will not be completed and qualified to manufacture lentiviral vector or drug product on the timelines we

anticipate or at all; the risk that we are unable to successfully operate a manufacturing facility for clinical or commercial supply; the risks that the preliminary positive efficacy and safety results from our prior and ongoing clinical trials of our product candidates will not continue or be repeated in our ongoing or planned clinical trials; risks that the current or planned clinical trials of our product candidates will be insufficient to support future regulatory submissions or to support marketing approval in the U.S. and EU; and the risk that our product candidates will not be successfully developed, approved or 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 Form 10-K 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.

Investors & Media

Investors:
bluebird bio Elizabeth Pingpank, (617) 914-8736
epingpank@bluebirdbio.com

Media:
Jenn Snyder, (617) 448-0281
jsnyder@bluebirdbio.com