

**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): August 6, 2018 (August 3, 2018)

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

(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 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 3.02 Unregistered Sales of Equity Securities.

On August 3, 2018, bluebird bio, Inc. (“bluebird”) entered into a Share Purchase Agreement with Regeneron Pharmaceuticals, Inc. (“Regeneron”) pursuant to which bluebird agreed to sell 420,000 shares of its common stock, par value \$0.01 per share, to Regeneron for an aggregate cash price of approximately \$100 million, or \$238.10 per share. The closing of the stock sale is subject to the satisfaction or waiver of customary closing conditions, including the expiration or early termination of the applicable pre-merger waiting period under the HSR Act. The offer, sale, and issuance of the shares is exempt from registration pursuant to Section 4(a)(2) of the Securities Act of 1933, as amended, as a transaction by an issuer not involving a public offering.

Item 8.01 Other Events.

On August 6, 2018, bluebird issued a press release announcing that bluebird has entered into a collaboration agreement with Regeneron focused on the discovery, development and potential commercialization of novel immune cell therapies for the treatment of cancer.

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 August 6, 2018. |

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: August 6, 2018

bluebird bio, Inc.

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

bluebird bio and Regeneron Announce Collaboration to Discover, Develop and Commercialize New Cell Therapies for Cancer

CAMBRIDGE, Mass. and Tarrytown, NY – August 6, 2018 – bluebird bio, Inc. (NASDAQ: **BLUE**) and Regeneron Pharmaceuticals, Inc. (NASDAQ: **REGN**) today announced a collaboration to apply their respective technology platforms to the discovery, development and commercialization of novel immune cell therapies for cancer. The collaborators will specifically leverage Regeneron’s *VelociSuite*® platform technologies for the discovery and characterization of fully human antibodies, as well as T cell receptors (TCRs) directed against tumor-specific proteins and peptides, and bluebird bio will contribute its field-leading expertise in gene transfer and cell therapy.

“The collaboration with Regeneron complements bluebird bio’s growing immuno-oncology development portfolio, which includes clinical and pre-clinical CAR T and T cell receptor programs,” said Philip Gregory, D.Phil., Chief Scientific Officer of bluebird bio. “With Regeneron’s proven targeting technologies, in combination with our deep expertise in cell biology and vector technology, as well as clinical experience with leading CAR T cell drug products, we hope to rapidly advance novel cellular therapies with the potential to transform the lives of people with cancer.”

“Like Regeneron, bluebird is a science-focused company looking to push the limits of what novel technologies can do in drug discovery and development,” said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron. “We believe that the tremendous synergies between Regeneron’s proven technologies and bluebird’s toolbox of advanced cell and gene therapy technologies create a promising opportunity to help people with cancer by developing innovative new treatments. This collaboration adds yet another dimension to our rapidly advancing portfolio of immuno-oncology candidates and combination approaches.”

The collaborators have jointly selected six initial targets and will equally share the costs of research and development up to the point of submitting an Investigational New Drug (IND) application. Additional targets may be selected over the five-year research collaboration term. When an IND is submitted for a potential cell therapy product, Regeneron will have the right to opt-in to a co-development/co-commercialization arrangement for certain collaboration targets, with 50/50 cost and profit sharing. If Regeneron does not opt-in, the company is eligible to receive milestone payments and royalties from bluebird bio on any potential resulting products.

Regeneron will also make a \$100 million investment in bluebird bio common stock at a price of \$238.10 per share, which represents a premium of 59 percent over the \$150 closing price on August 3, 2018. This approximately \$37 million premium will be credited against Regeneron’s initial 50 percent funding obligation for basic collaboration research, after which the collaborators will fund ongoing research equally. The transaction

is subject to preclearance by the Federal Trade Commission under applicable antitrust laws.

Cell-based immunotherapies such as chimeric antigen receptor T cells (CAR Ts) use human immune cells (typically T cells derived from the patient with cancer) that are modified and returned to the patient to serve as therapeutic agents that specifically target and kill cancer cells. In advanced clinical studies, researchers have shown that modified T cells are highly active therapies in patients with a variety of blood cancers even after other treatment approaches have failed, and there are existing FDA-approved medicines that utilize this approach.

bluebird bio's technologies use a customized lentiviral vector to modify T cells so that they can recognize tumor-specific proteins expressed by cancer cells and kill them upon engagement. Regeneron's *VelociSuite*[®] technologies, including *VelocImmune*[®] and *Veloci-T*, enable the creation of fully-human antibodies and T cell receptors. These complementary technologies have the potential to expand the types of tumors that modified T cells can safely and effectively target by enabling the T cells to reach both extracellular and intracellular tumor antigens.

About bluebird bio, Inc.

With its lentiviral-based gene therapies, T cell immunotherapy expertise and gene editing capabilities, bluebird bio (NASDAQ: BLUE) has built a pipeline with broad potential application in severe genetic diseases and cancer.

bluebird bio's gene therapy clinical programs include investigational treatments for cerebral adrenoleukodystrophy, transfusion-dependent β -thalassemia, also known as β -thalassemia major, and severe sickle cell disease.

bluebird bio's oncology pipeline is built upon the company's 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. The company's lead oncology programs are anti-BCMA CAR T programs partnered with Celgene.

bluebird bio's discovery research programs include utilizing megaTAL/homing endonuclease gene editing technologies with the potential for use across the company's pipeline.

bluebird bio has operations in Cambridge, Massachusetts; Seattle, Washington; Durham, North Carolina and Zug, Switzerland.

About Regeneron Pharmaceuticals, Inc.

Regeneron (NASDAQ: REGN) is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to six FDA-approved treatments and numerous product candidates in development, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye disease, heart disease, allergic and inflammatory diseases, pain, cancer, infectious diseases and rare diseases.

Regeneron is accelerating and improving the traditional drug development process through our proprietary *VelociSuite*[®] technologies, including *VelocImmune*[®] (a genetically-

engineered mouse model that has a genetically-humanized B cell immune system that produces optimized fully-human antibodies) and *Veloci-T* (a genetically-engineered mouse model that has genetically-engineered T cell immunity). Regeneron scientists are also conducting ambitious research initiatives such as the Regeneron Genetics Center®, which is conducting one of the largest genetics sequencing efforts in the world.

For additional information about the company, please visit www.regeneron.com or follow @Regeneron on Twitter.

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 Regeneron, and the benefits of each company’s strategic plans and focus. 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 Regeneron 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.

Regeneron Forward-Looking Statements and Use of Digital Media

This news release includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. (“Regeneron” or the “Company”), and actual events or results may differ materially from these forward-looking statements. Words such as “anticipate,” “expect,” “intend,” “plan,” “believe,” “seek,” “estimate,” variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the nature, timing, and possible success and therapeutic applications of Regeneron’s products, product candidates, and research and clinical programs now underway or planned, including without limitation the discovery and development of novel immune cell therapies for cancer; the likelihood and timing of achieving any of Regeneron’s anticipated clinical development milestones; unforeseen safety issues resulting from the administration of products and product candidates in patients, including serious complications or side effects in connection with the use of Regeneron’s product candidates in clinical trials; the likelihood and timing of possible regulatory approval and commercial launch of Regeneron’s late-stage product candidates

and new indications for marketed products; the extent to which the results from the research and development programs conducted by Regeneron or its collaborators (such as bluebird bio, Inc.) may be replicated in other studies and lead to therapeutic applications; ongoing regulatory obligations and oversight impacting Regeneron's marketed products, research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's products and product candidates; competing drugs and product candidates that may be superior to Regeneron's products and product candidates; uncertainty of market acceptance and commercial success of Regeneron's products and product candidates; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron's collaborators, suppliers, or other third parties to perform filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's products and product candidates; coverage and reimbursement determinations by third-party payers, including Medicare and Medicaid; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), as well as the collaboration with bluebird bio, Inc. discussed in this news release, to be cancelled or terminated without any product success; and risks associated with intellectual property of other parties and pending or future litigation relating thereto, including without limitation the patent litigation proceedings relating to Praluent® (alirocumab) Injection, the ultimate outcome of any such litigation proceedings, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission. Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update publicly any forward-looking statement, whether as a result of new information, future events, or otherwise.

Regeneron uses its media and investor relations website and social media outlets to publish important information about the Company, including information that may be deemed material to investors. Financial and other information about Regeneron is routinely posted and is accessible on Regeneron's media and investor relations website (<http://newsroom.regeneron.com>) and its Twitter feed (<http://twitter.com/regeneron>).

###

bluebird bio Investor Relations

Elizabeth Pingpank

Tel: + (617) 914-8736

epingpank@bluebirdbio.com

bluebird bio Media Relations

Stephanie Fagan

Tel: + (201) 572-9581

sfagan@bluebirdbio.com

Regeneron Investor Relations

Manisha Narasimhan, Ph.D.

Tel: +1 (914) 847-5126

manisha.narasimhan@regeneron.com

Regeneron Media Relations

Alexandra Bowie

Tel: +1 (202) 213-1643

alexandra.bowie@regeneron.com