

**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): October 9, 2019

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))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock (Par Value \$0.01)	BLUE	The NASDAQ Global Select Market LLC

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 October 9, 2019, bluebird bio, Inc. (“bluebird”) issued a press release announcing that bluebird has entered into a research collaboration agreement with Novo Nordisk A/S to jointly develop next generation *in vivo* genome editing treatments for severe genetic diseases, including hemophilia.

The full text of bluebird’s press release is being furnished 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 October 9, 2019.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 thereunto duly authorized.

bluebird bio, Inc.

Date: October 9, 2019

By: /s/ Jason F. Cole

Jason F. Cole

Chief Operating and Legal Officer

bluebird bio and Novo Nordisk Enter into Research Agreement to Develop *in vivo* Genome Editing Candidates for Haemophilia and Other Severe Genetic Diseases

CAMBRIDGE, Mass. and Bagsværd, Denmark —(BUSINESS WIRE)—Oct. 9, 2019— [bluebird bio, Inc.](#) (Nasdaq: BLUE) and Novo Nordisk A/S (NVO) today announced that they have entered into a research collaboration to jointly develop next-generation *in vivo* genome editing treatments for genetic diseases, including haemophilia. During the three-year research collaboration, bluebird and Novo Nordisk will focus on identifying a development gene therapy candidate with the ambition of offering people with haemophilia A a lifetime free of factor replacement therapy.

The research collaboration will utilise bluebird bio’s proprietary mRNA-based megaTAL™ technology that has the potential to provide a highly specific and efficient way to silence, edit or insert genetic components. Aligned with Novo Nordisk’s haemophilia portfolio, the research collaboration will initially focus on correcting FVIII-clotting factor deficiency, with the potential to explore additional therapeutic targets.

“We are pleased to announce our collaboration with bluebird whose demonstrated capabilities in gene therapy will enable the next-generation of innovative products to make a significant impact on patients’ lives,” said Marcus Schindler, senior vice president for Global Drug Discovery at Novo Nordisk. “This important research collaboration aimed at addressing genetic diseases at the DNA level reflects Novo Nordisk’s enduring commitment and dedication to inventing disease-modifying medicines that can truly change the lives of people living with haemophilia and other genetic diseases.”

“bluebird has made tremendous progress on enabling an *in vivo* gene editing platform based on our megaTAL technology, including important advances in high-quality mRNA production and purification,” said Philip Gregory, D. Phil., chief scientific officer, bluebird bio. “We believe this technology has the potential to create a highly differentiated approach to the treatment of many severe genetic diseases. Moreover, we are thrilled to be able to combine this new platform technology with Novo Nordisk’s deep expertise in haemophilia research and therapeutics. We believe this collaboration will move us toward our shared goal of recoding the treatment paradigm and substantially reduce the burden of disease for patients with factor VIII deficiency.”

About megaTALs

MegaTALs are a single-chain fusion enzyme that combines the natural DNA cleaving processes of Homing Endonucleases (HEs) with the DNA binding region of transcription activator-like (TAL) effectors. TALs are easily engineered proteins that recognize specific DNA sequences. This protein fusion architecture allows the generation of extremely active and highly specific and compact nucleases that are compatible with all current viral and non-viral cell delivery methods.

About haemophilia

The incidence of haemophilia A is approximately one in 5,000 and of haemophilia B it is approximately one in 25,000 male births respectively¹. Over 400,000 males have haemophilia A or B and the disease is severely underdiagnosed in developing countries². An estimated 304,000³ people live with haemophilia A, which is a result of decreased or defective production of the blood clotting factor VIII. People with haemophilia B, of which there are some 136,000⁴ have deficiencies in producing clotting factor IX.



For people with haemophilia, bleeds often occur in the joints, particularly knees and ankles. Bleeds can also occur in the muscles, soft tissues, gastrointestinal tract or even the brain. Trauma, major surgery, tooth extractions or other minor surgical interventions require medical supervision to manage the associated bleeding. Without treatment, bleeds are painful and can cause lasting damages and lead to impaired mobility.

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](#).

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About Novo Nordisk A/S

Novo Nordisk is a global healthcare company with more than 95 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 41,600 people in 80 countries and markets its products in more than 170 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO).

For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.

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 and development plans for bluebird bio's gene therapy products and megaTAL platform. 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 risks that bluebird bio's megaTAL platform will not be successful or will not be safe or effective in clinical trials, the risks that our collaboration with Novo Nordisk A/S will not continue or be successful, and the risk that we will

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not be successful in identifying a gene therapy candidate for development. 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.

For bluebird bio

Investors:

Elizabeth Pingpank, 617-914-8736

epingpank@bluebirdbio.com

or

Media:

Jennifer Snyder, 617-448-0281

jsnyder@bluebirdbio.com

For Novo Nordisk A/S

Investors:

Peter Hugrefte Ankersen, +45 3075 9085

phak@novonordisk.com

Valdemar Borum Svarrer, +45 3079 0301

jvls@novonordisk.com

Ann Søndermølle Rendbæk, +45 3075 2253

arnd@novonordisk.com

Kristoffer Due Berg (US), +1 609 235 2989

krdb@novonordisk.com

or

Media:

Martin Havtorn Petersen, +45 3075 5246

mhpsz@novonordisk.com

Ken Inchausti (US), +1 609 240 9429

kiiau@novonordisk.com

www.bluebirdbio.com

References

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2. https://unctad.org/en/PublicationChapters/tdstat42_FS11_en.pdf
3. Stonebraker JS; Study of variations in the reported haemophilia A prevalence around the world. Haemophilia 2010; 16(1):20-32.
4. Stonebraker JS, A study of variations in the reported haemophilia B prevalence around the world. Haemophilia 2012; 18(3):e91-e94