

**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): November 12, 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 November 12, 2019, bluebird bio, Inc. (“bluebird”) issued a press release announcing that bluebird entered into a clinical research collaboration with Forty Seven, Inc. (“Forty Seven”) to pursue proof-of-concept for Forty Seven’s exploratory antibody-based conditioning regimen, FSI-174 plus magrolimab, with bluebird’s ex vivo lentiviral vector hematopoietic stem cell (LVV HSC) gene therapy platform.

The full text of bluebird’s 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

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on November 12, 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: November 12, 2019

By: /s/ Jason F. Cole

Jason F. Cole

Chief Operating and Legal Officer

bluebird bio and Forty Seven Announce a Research Collaboration to Study an All Antibody Conditioning Regimen for Use in Combination with Autologous Lentiviral Vector Hematopoietic Stem Cell Gene Therapy

CAMBRIDGE, Mass. and MENLO PARK, Calif. —(BUSINESS WIRE)—Nov. 12, 2019— [bluebird bio, Inc.](#) (Nasdaq: BLUE) and [Forty Seven, Inc.](#) (Nasdaq:FTSV) announced today that they have entered into a research collaboration to pursue clinical proof-of-concept for Forty Seven’s novel antibody-based conditioning regimen, FSI-174 (anti-cKIT antibody) plus magrolimab (anti-CD47 antibody), with bluebird’s ex vivo lentiviral vector hematopoietic stem cell (LVV HSC) gene therapy platform. This collaboration will focus on a conditioning approach aimed to deliver reduced toxicity and will initially target diseases that have the potential to be corrected with transplantation of autologous gene-modified blood-forming stem cells. If successful, the new conditioning regimen could allow for more patients to undergo gene therapy.

Autologous hematopoietic stem cell transplantation (HSCT) and most ex vivo LVV HSC gene therapies require that a patient’s own stem cells first be depleted from the bone marrow to facilitate the engraftment of the new (or gene-modified) HSCs through a process called conditioning. Conditioning is performed using chemotherapy or radiation, which can place patients at risk for infection and require hospitalization until bone marrow cells have recovered. In addition, conventional conditioning can place patients at risk for secondary malignancy and infertility. As a result, the overall toxicity profile of current conditioning regimens limits the types of patients who are eligible for gene therapy. It is hoped that novel antibody based conditioning regimens could avoid these toxicities.

“We are excited about this collaboration, combining our industry-leading LVV HSC gene therapy platform with Forty Seven’s novel antibody-based conditioning regimen,” said Philip Gregory, chief scientific officer, bluebird bio. “We believe that, if successful, this novel conditioning modality could not only increase the number of patients and physicians who may consider gene therapy but also improve the overall risk benefit profile for stem cell-based gene therapy, as well as potentially reduce time and costs associated with hospital visits.”

“Forty Seven is advancing the pioneering work on CD47 and cKIT from our scientific founder, Irv Weissman’s lab. We have shown that antibody blockade of CD47 can synergize with other antibodies targeting cancer to promote tumor engulfment. Based on this experience, coupled with the results of preclinical studies, we are eager to explore this dual-antibody approach for the potential treatment of non-malignant diseases,” says Jens Peter Volkmer, M.D., Founder and Vice President of Research and Development at Forty Seven.

Forty Seven’s President and Chief Executive Officer, Mark McCamish, M.D., Ph.D., commented, “bluebird is a leading gene therapy company and we are excited to collaborate with them. Stem cell transplantation is potentially curative for a variety of blood diseases, including genetic blood disorders like sickle cell disease and beta-thalassemia. If successful, we believe our chemo- and radiation-free, all-antibody approach could expand transplantation beyond genetic blood disorders to a range of



indications for which current transplantation approaches are suboptimal. In 2020, we plan to evaluate FSI-174 in healthy volunteers, before initiating a combination study of Forty Seven’s novel all-antibody conditioning regimen and bluebird’s gene therapy product.”

Under the terms of the agreement, bluebird bio will provide its ex vivo LVV HSC gene therapy platform and Forty Seven will contribute its innovative antibody-based conditioning regimen for the collaboration.

About FSI-174 and Magrolimab

FSI-174 is a humanized monoclonal antibody targeting cKIT, which is a receptor that is highly expressed on hematopoietic stem cells. Magrolimab is a humanized monoclonal antibody targeting CD47, which is a “don’t eat me” signal to macrophages and is expressed on all cells. Magrolimab is currently being investigated in Phase 2 clinical trials to treat cancer and has established clinical efficacy in four indications, including myelodysplastic syndrome, acute myeloid leukemia, diffuse large B cell lymphoma and follicular lymphoma, with a favorable safety profile in over 350 patients treated, including some patients treated continuously for over two years. When combined, FSI-174 sends a positive signal to macrophages to target blood forming stem cells for removal and magrolimab disengages inhibitory signals that block phagocytosis. Combination of these antibodies has shown efficient removal of blood forming stem cells, allowing for transplantation in pre-clinical models.

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 Forty Seven Inc.

Forty Seven, Inc. is a clinical-stage immuno-oncology company that is developing therapies targeting cancer immune evasion pathways based on technology licensed from Stanford University. Forty Seven’s lead program, magrolimab, is a monoclonal antibody against the CD47 receptor, a “don’t eat me” signal that cancer cells commandeer to avoid being ingested by macrophages. This antibody is currently being evaluated in multiple clinical studies in patients with myelodysplastic syndrome, acute myeloid leukemia, non-Hodgkin’s lymphoma, ovarian cancer and colorectal carcinoma.

www.bluebirdbio.com

For more information, please visit www.fortyseveninc.com or contact info@fortyseveninc.com.

Follow Forty Seven on social media: [@FortySevenInc](#), [LinkedIn](#)

Forward-Looking Statements

This release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “may,” “will,” “potentially,” and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These statements include those related to the research and development plans for bluebird bio’s and Forty Seven’s respective platforms and product candidates, the timing and success of Forty Seven’s collaboration with bluebird bio, Forty Seven’s plans to pursue clinical proof-of-concept for FSI-174 plus magrolimab with the LVV HSC gene therapy platform, the focus on diseases that have the potential to be corrected with transplantation of autologous gene-modified blood-forming stem cells, the tolerability and efficacy of FSI-174 and magrolimab, Forty Seven’s plans to continue development of FSI-174 plus magrolimab, as well as related timing for clinical trials of the same.

Any forward-looking statements are based on the companies’ 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 the exploratory antibody-based conditioning platform will not be successful or will not be safe or effective in clinical trials, the risks that the collaboration between bluebird bio and Forty Seven will not continue or be successful, and the risk that the parties will not be successful in advancing the collaboration in development, the risk that potential product candidates that bluebird bio and Forty Seven develop may not progress through clinical development or receive required regulatory approvals within expected timelines or at all, the risk that clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release and the risk that such product candidates may not be beneficial to patients or successfully commercialized. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the companies’ actual results to differ from those contained in the forward-looking statements, see the section entitled “Risk Factors” in each company’s most recent Form 10-K as well as discussions of potential risks, uncertainties and other important factors in subsequent filings with the Securities and Exchange Commission at www.sec.gov. All information contained in this press release are not guarantees of future performance and speak only as of the date hereof, and each of bluebird bio and Forty Seven disclaims any obligation to update this information to reflect future events or circumstances unless required by law.

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