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): May 9, 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	02142
(Address of Principal Executive Offices)	(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. ☐

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	BLUE	The NASDAQ Global Select Market LLC

Item 8.01 Other Events.

On May 9, 2019, bluebird bio, Inc. (“bluebird”) issued a press release announcing its research and development strategies, highlighting its oncology and severe genetic disease programs in Merkel cell carcinoma, diffuse large B-Cell lymphoma, MAGE-A4 positive solid tumors, acute myeloid leukemia, and the severe form of mucopolysaccharidosis (MPSI), also known as Hurler syndrome. 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 May 9, 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: May 9, 2019

bluebird bio, Inc.

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

Exhibit 99.1

bluebird bio's Analyst Day Highlights Commercial Path to Patients and Research Engine Focused on Next-Generation Gene and Cell Therapies

New Collaboration with Seattle Children's Research Institute Targets New Immunotherapy Approaches to Acute Myeloid Leukemia

Phase 1/2 Study for Merkel Cell Carcinoma Planned with Fred Hutchinson Cancer Research Center

Additional Preclinical Programs Across Both the Severe Genetic Disease and Oncology Therapeutic Areas Support IND Goals

Company Will Webcast Live from the Event Beginning at 8:30 a.m. EDT

CAMBRIDGE, Mass. -- May 9, 2019 -- bluebird bio, Inc. (Nasdaq: BLUE) today will host an Analyst Day in New York that will highlight significant progress in the company's emerging immuno-oncology and severe genetic disease pipeline, provide updates on launch expectations for its first gene therapy product and share key aspects of its long-term growth strategy. The company also is announcing a new research collaboration with Seattle Children's Research Institute in Acute Myeloid Leukemia (AML), a Phase 1/2 study planned in Merkel Cell Carcinoma (MCC) with the Fred Hutchinson Cancer Research Center and programs in Diffuse Large B-cell Lymphoma (DLBCL) and MAGE-A4 positive solid tumors.

"bluebird is at a significant inflection point, with the potential approval and launch of our first gene therapy product this year and submissions for regulatory approval for potentially three additional products through 2022," said Nick Leschly, chief bluebird. "We have the opportunity to leverage our gene and cell therapy expertise across our platform and enable a steep innovation curve for next-generation products. We are fueled by what is just the beginning of our efforts to recode the science, systems and status quo to reach new innovation frontiers and make a significant impact on patients' lives."

Further strengthening its leadership position in developing transformative first-in-class and best-in-class gene and cell therapies, bluebird bio will discuss several key milestones and collaboration updates across its research pipeline, which is focused on next-generation, disruptive solutions for devastating diseases. In addition to the two clinic-ready programs planned for 2019, the company is on track to submit 1-2 investigational new drug applications in 2020 and beyond.

"Relentless innovation is in our DNA at bluebird. Our 1-to-Many research strategy rapidly integrates and iterates our tools and technologies across our core platforms of gene editing, gene addition and cellular immunotherapy, to develop the next generation of gene and cell therapies with the potential to improve patients' lives," said Philip Gregory, D. Phil., chief scientific officer, bluebird bio. "Our research engine, in partnership with our network of academic and industry collaborations, is designed to take on big problems that, if successful, will disrupt our field."

Research highlights include:

- **AML Research Collaboration with Seattle Children's Research Institute:** The research collaboration is intended to address two challenges of tackling AML, specifically the heterogeneity of the disease as well as the salvage of normal tissues with the potential for on-target/off-tumor targeting. Our T cell immunotherapy approach is expected to leverage technology that enables T cells to target multiple antigens on the surface of cancer cells as well as bluebird's proprietary Dimerizing Agent Regulated Immunoreceptor Complex (DARIC) platform. By utilizing the DARIC platform in potential product candidates, we expect to be able to exert pharmacologic control of CAR T cell activity *in vivo*, allowing the investigator to switch on and switch off the activity of the engineered T cells in the patient as needed by administering a small molecule drug. Combined with Seattle Children's world-class bench-to-bedside expertise in the arena of oncology cell therapies, the research collaboration's goal is to rapidly accelerate development of potential new therapies for patients with AML.
- **Phase 1/2 Trial for Merkel Cell Carcinoma:** An academic, proof-of-concept phase 1/2 single-arm study evaluating Merkel Cell Polyomavirus (MCPyV) TCR-engineered autologous T cells in combination with avelumab (anti-PDL1) is FDA-approved and in the final initiation stages of trial approval at the Fred Hutchinson Cancer Research Center for the treatment of MCC, a rare neuroendocrine cancer. Exploratory clinical data generated by researchers at the Fred Hutchinson Cancer Research Center exploring patient derived MCPyV reactive T cells in combination with PD1 axis blockade has shown promising depth and durability of response. Results from the academic phase 1/2 single-arm study are expected to inform next-generation T cell approaches including TCR engineering and checkpoint inhibition.
- **MAGE-A4:** Through its collaboration with Medigene, bluebird has developed a next-generation MAGE-A4 TCR expected to enter the clinic for solid tumors in 2020. This co-receptor-independent TCR candidate has shown robust anti-tumor activity controlling tumors in a subcutaneous melanoma xenograft model as a single agent. Moreover, this highly active TCR can be combined with bluebird's chimeric TGF-β receptor signal converter technology to "flip" the immunosuppressive signals present in the tumor microenvironment toward T cell stimulation and proliferation. This is the first collaboration target with Medigene of a potential six TCR products that the companies have agreed to work on together.
- **Diffuse Large B-cell Lymphoma Candidate:** Our DLBCL preclinical program builds on the knowledge gained from the current generation of CD19-targeting cell therapies by incorporating multiple next-generation technologies to potentially address both the depth and durability of response. Specifically, our potential DLBCL product candidate combines (i) dual-targeting directed to two novel antigens; (ii) within a unique CAR construction that is designed to enhance T cell activation; and (iii) gene editing for potential potency and durability enhancements, all in a single product candidate.
- **Mucopolysaccharidosis (MPSI):** Our MPSI program is focused on the severe form of MPSI, an ultra-rare metabolic condition that causes severe neurologic impairment and organ damage, also referred to as Hurler Syndrome. In our academic collaboration with

the University of Minnesota, we expect to leverage key learnings from our hematopoietic stem cell lentiviral vector (HSC LVV) platform technology to deliver gene-modified cells that can potentially cross the blood-brain barrier and express high and sustained levels of therapeutic enzyme. Preclinical data in the MPS1 mouse model demonstrates full molecular correction of the disease across all critical organs impacted by the disease, including the brain, following administration of an HSC LVV-gene-modified stem cell product. These robust preclinical data support the potential clinical application of this product candidate.

Webcast

To access the live webcast of bluebird bio's Analyst Day presentation, please visit the "Events & Presentations" page within the Investors & Media section of the bluebird bio website at http://investor.bluebirdbio.com. A replay of the webcast will be available on the bluebird bio website for 90 days following the meeting.

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 plans for the potential commercial launch of the Company's product candidates, as well as the advancement of the Company's research and development plans. 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 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; the risk that our collaborations with third parties will not be successful; the risk that our planned clinical studies may be delayed or not be initiated at all; 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-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.

Investors & Media

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