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 6, 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))

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 (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 6, 2019, bluebird bio, Inc. ("bluebird") issued a press release announcing that new and updated data from its investigational gene and cell therapy programs for multiple myeloma, sickle cell disease (SCD) and transfusion-dependent β-thalassemia (TDT) will be presented at the 61st Annual Meeting of the American Society of Hematology taking place in Orlando, Florida on December 7 - 10, 2019.

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 6, 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 6, 2019

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

Exhibit 99.1

bluebird bio to Present New Data from Gene and Cell Therapy Programs at 61st American Society of Hematology Annual Meeting and Exposition

Updated safety and efficacy results from ongoing Phase 1 CRB-402 study of bb21217 in relapsed/refractory multiple myeloma

Updated results from ongoing Phase 1/2 (HGB-206) study of LentiGlobin™ gene therapy for patients with sickle cell disease

New data from ongoing Phase 3 studies of LentiGlobin™ gene therapy for β-thalassemia in pediatric, adolescent and adult patients

CAMBRIDGE, Mass.— (BUSINESS WIRE)— November 6, 2019 - bluebird bio, Inc. (Nasdaq: BLUE) announced today that new and updated data from its investigational gene and cell therapy programs for multiple myeloma, sickle cell disease (SCD) and transfusion-dependent β-thalassemia (TDT) will be presented at the 61st American Society of Hematology (ASH) Annual Meeting and Exposition in Orlando, Florida, December 7 - 10.

bluebird bio will present updated safety and efficacy data from the ongoing Phase 1 clinical study (CRB-402) of bb21217. bb21217 is an investigational BCMA-targeted chimeric antigen receptor (CAR) T cell therapy being studied, in partnership with Celgene, in patients with relapsed/refractory multiple myeloma (RRMM).

In addition, data from clinical studies of LentiGlobin™ gene therapy for β-thalassemia, including results up to 61 months from the long-term follow-up study (LTF-303) and updated results from the completed Phase 1/2 Northstar (HGB-204) study, will be presented at ASH. The company will also present new data from the ongoing Phase 3 Northstar-2 (HGB-207) study in pediatric, adolescent and adult patients who do not have a β^0/β^0 genotype and from the ongoing Phase 3 Northstar-3 (HGB-212) study in pediatric, adolescent and adult patients who have β^0/β^0 genotype or an IVS-I-110 mutation at both alleles of the β-globin gene.

New data from the company's Phase 1/2 HGB-206 study of LentiGlobin gene therapy for SCD will include additional patients treated in the study and updated data for those previously reported. The company will also present data from exploratory assays designed to assess the relationship between drug product characteristics and red blood cell physiology in patients treated with LentiGlobin for SCD.

Updated Data from Ongoing Phase 1 Clinical Study (CRB-402) of bb21217

Updated Results from an Ongoing Phase 1 Clinical Study of bb21217 Anti-BCMA CAR T Cell Therapy
Presenting Author: Jesus G. Berdeja, M.D., Sarah Cannon Center for Blood Cancers, Nashville, Tenn.
Date & Time: Oral #927, Monday, December 9, 2019, 6:45 p.m. ET

bb21217, an investigational BCMA-targeted CAR T cell therapy being developed in partnership with Celgene, is one of bluebird bio's lead oncology programs. bb21217 uses the idecabtagene vicleucel CAR

molecule (formerly referred to as bb2121) and is manufactured with a process intended to increase the *in vivo* persistence of CAR T cells.

This presentation will include updated data from the Phase 1 CRB-402 study, the first-in-human study of bb21217 in patients with RRMM, designed to assess the primary endpoint of safety as well as other pre-defined endpoints including efficacy and pharmacokinetics measurements. CRB-402 is a two-part (dose escalation and dose expansion), open-label, multi-site Phase 1 study of bb21217 in adults with RRMM with a projected final enrollment of 74 patients.

Data in the abstract include results as of the data cutoff date of April 20, 2019 for 22 patients who have received bb21217 at three dose levels (12 at 150 x 10^6 CAR+ T cells; six at 300 x 10^6 CAR+ T cells; and four at 450 x 10^6 CAR+ T cells). These patients had a median of seven prior lines of therapy (min-max: 4 – 17 lines), 18 patients had a prior autologous stem cell transplant, 19 patients received daratumumab and 13 patients received prior treatment with bortezomib, lenalidomide, carfilzomib, pomalidomide and daratumumab.

As of the data cutoff, the adverse events observed were consistent with known toxicities of CAR T therapies. Thirteen of 22 patients developed cytokine release syndrome (CRS); five Grade 1, seven Grade 2, and one Grade 3 case. All 13 patients responded to supportive care, tocilizumab and/or corticosteroids. Five of 22 patients developed neurotoxicity; one Grade 1, two Grade 2, one Grade 3 (vertigo/dizziness), and one Grade 4 (encephalopathy, previously reported). For the one patient previously reported with Grade 4 neurotoxicity, Grade 3 CRS was also reported, and both have resolved.

Eighteen patients were evaluable for clinical response with $\geq$ two months of follow-up or progressive disease within two months. Eighty-three percent (n=15/18) of evaluable patients demonstrated clinical response per the International Myeloma Working Group Uniform Response Criteria for multiple myeloma. As of the data cutoff, with the median follow-up after bb21217 infusion of five months (min-max: <1 – 18 months), nine patients remained in response, including two patients with ongoing response at 15 and 18 months.

Evidence of myeloma in the bone marrow, known as minimal residual disease, was undetectable by next-generation sequencing at a sensitivity level of 10^{-5} or better in all responders who had evaluable bone marrow samples (n=10) at Month 1. CAR T cell persistence was observed in six of eight patients evaluable at six months and in two of two patients evaluable at 12 months.

This study is ongoing to evaluate the potential safety and efficacy of treatment with bb21217, and updated results, including early clinical and CAR T cell persistence data, will be shared at the ASH conference.

Multiple Myeloma Presentations at ASH

Markers of Initial and Long-Term Responses to Idecabtagene Vicleucel (Ide-Cel; bb2121) in the CRB-401 Study in Relapsed/Refractory Multiple Myeloma
Presenting Author: Ethan G. Thompson, Ph.D., Celgene, Seattle, Wash.
Date & Time: Poster #4328, Monday, December 9, 2019, 6:00 – 8:00 p.m. ET

Updated Results from an Ongoing Phase 1 Clinical Study of bb21217 anti-BCMA CAR T Cell Therapy
Presenting Author: Jesus G. Berdeja, M.D., Sarah Cannon Center for Blood Cancers, Nashville, Tenn.
Date & Time: Oral #927, Monday, December 9, 2019, 6:45 p.m. ET

SCD Presentations at ASH

The Relationships Between Target Gene Transduction, Engraftment of HSCs and RBC Physiology in Sickle Cell Disease Gene Therapy
Presenting Author: Melissa Bonner, Ph.D., bluebird bio, Cambridge, Mass.
Date & Time: Oral #206, Saturday, December 7, 2019, 2:15 p.m.

Exploring the Drivers of Clinical Benefit in Initial Patients Treated in the HGB-206 Study of LentiGlobin for Sickle Cell Disease (SCD) Gene Therapy
Presenting Author: Mark Walters, M.D., Benioff Children's Hospital, Oakland, Calif.
Date & Time: Poster #2061, Saturday, December 7, 2019, 5:30 – 7:30 p.m.

Resolution of Sickle Cell Disease Manifestations in Patients Treated with LentiGlobin Gene Therapy: Updated Results from the Phase 1/2 HGB-206 Group C Study
Presenting Author: Julie Kanter, M.D., University of Alabama at Birmingham, Birmingham, Ala.
Date & Time: Poster #990, Saturday, December 7, 2019, 5:30 – 7:30 p.m.

TDT Presentations at ASH

Clinical Outcomes after Allogeneic Hematopoietic Stem Cell Transplantation in Patients with Transfusion-Dependent β-Thalassemia Treated at the Bambino Gesù Children's Hospital, Rome, Italy
Presenting Author: Pietro Merli, M.D., IRCCS Ospedale Pediatrico Bambino Gesù, Rome, Italy
Date & Time: Poster #969, Saturday, December 7, 2019, 5:30 – 7:30 p.m.

Northstar-3: Interim Results from a Phase 3 Study Evaluating LentiGlobin Gene Therapy in Patients with Transfusion-Dependent β-Thalassemia and Either a β^0 or IVS-I-110 Mutation at Both Alleles of the *HBB* Gene
Presenting Author: Ashutosh Lal, M.D., UCSF Benioff Children's Hospital, Oakland, Calif.
Date & Time: Oral #815, Monday, December 9, 2019, 5:30 p.m.

Northstar-2: Updated Safety and Efficacy Analysis of LentiGlobin Gene Therapy in Patients with Transfusion-Dependent β-Thalassemia and Non-β^0/β^0 Genotypes
Presenting Author: Alexis Thompson, M.D., MPH, Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, Ill.
Date & Time: Poster #3543, Monday, December 9, 2019, 6:00 – 8:00 p.m.

Long-Term Clinical Outcomes of LentiGlobin Gene Therapy for Transfusion-Dependent β-Thalassemia in the Northstar (HGB-204) Study
Presenting Author: Janet Kwiatkowski, M.D., MSCE, Children's Hospital of Philadelphia, Philadelphia, Pa.
Date & Time: Poster #4628, Monday, December 9, 2019, 6:00 – 8:00 p.m.

Routine Management, Healthcare Resource Use and Patient/Caregiver-Reported Outcomes of Patients with Transfusion-Dependent β-Thalassaemia in the United Kingdom: A Mixed Methods Observational Study
Presenting Author: Farrukh Shah, MBBS, FRCP, FRCPath, M.D., Whittington Hospital, London, U.K.
Date & Time: Poster #3550, Monday, December 9, 2019, 6:00 – 8:00 p.m.

SCD and TDT Presentation at ASH

Results from the Completed HGB-205 Trial of LentiGlobin for β-Thalassemia and LentiGlobin for Sickle Cell Disease Gene Therapy
Presenting Author: Elisa Magrin, Ph.D., Necker Children's Hospital, Assistance Publique-Hôpitaux de Paris, Paris, France
Date & Time: Poster #3358, Sunday, December 8, 2019, 6:00 – 8:00 p.m.

Abstracts outlining bluebird bio's accepted data at ASH will be available on the ASH conference website at 9 a.m. EDT today.

About ide-cel and bb21217 for Multiple Myeloma
bluebird bio's lead oncology programs, idecabtagene vicleucel (ide-cel, formerly referred to as bb2121) and bb21217, are investigational BCMA-targeted chimeric antigen receptor (CAR) T cell therapies being studied in a broad clinical development program for patients with multiple myeloma. ide-cel and bb21217 are being developed in partnership with Celgene.

KarMMa is a registration-enabling, open-label, single-arm, multi-center Phase 2 study evaluating the efficacy and safety of ide-cel in patients with relapsed/refractory multiple myeloma. In November 2018, bluebird bio announced completion of enrollment in the trial. ide-cel was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration and Priority Medicines (PRIME) eligibility by the European Medicines Agency in November 2017 based on preliminary clinical data from the Phase 1 CRB-401 study.

bluebird bio's clinical development program for bb21217 includes the ongoing Phase 1 CRB-402 study. CRB-402 is the first-in-human study of bb21217 in patients with RRMM, designed to assess safety, pharmacokinetics, efficacy and duration of effect. CRB-402 is a two-part (dose escalation and dose expansion), open-label, multi-site Phase 1 study of bb21217 in adults with RRMM with a projected final enrollment of 74 patients. For more information visit: clinicaltrials.gov using identifier NCT03274219.

ide-cel and bb21217 are not approved for any indication in any geography.

About LentiGlobin for Sickle Cell Disease
LentiGlobin for sickle cell disease is an investigational gene therapy being studied as a potential treatment for SCD. bluebird bio's clinical development program for LentiGlobin for SCD includes the ongoing Phase 1/2 HGB-206 study.

SCD is a serious, progressive and debilitating genetic disease caused by a mutation in the β-globin gene that leads to the production of abnormal sickle hemoglobin (HbS), causing red blood cells (RBCs) to become sickled and fragile, resulting in chronic hemolytic anemia, vasculopathy and painful vaso-occlusive events (VOEs). For adults and children living with SCD, this means unpredictable episodes of

excruciating pain due to vaso-occlusion as well as other acute complications—such as acute chest syndrome (ACS), stroke, and infections, which can contribute to early mortality in these patients.

LentiGlobin for SCD received Orphan Medicinal Product designation from the European Commission for the treatment of SCD.

The U.S. Food and Drug Administration granted Orphan Drug status and Regenerative Medicine Advanced Therapy designation for LentiGlobin for the treatment of SCD.

bluebird bio is conducting a long-term safety and efficacy follow-up study (LTF-303) for people who have participated in bluebird bio-sponsored clinical studies of LentiGlobin for SCD. For more information visit: **https://www.bluebirdbio.com/medical-professionals/our-clinical-trials/** or clinicaltrials.gov and use identifier NCT02633943 for LTF-303.

About LentiGlobin for β-Thalassemia
The European Commission granted conditional marketing authorization for LentiGlobin for TDT, to be marketed as ZYNTEGLO™ (autologous CD34+ cells encoding $\beta^{A\text{-}T87Q}$-globin gene) gene therapy, for patients 12 years and older with TDT who do not have a β^0/β^0 genotype, for whom hematopoietic stem cell (HSC) transplantation is appropriate, but a human leukocyte antigen (HLA)-matched related HSC donor is not available.

TDT is a severe genetic disease caused by mutations in the β-globin gene that result in reduced or absent hemoglobin (Hb). In order to survive, people with TDT maintain Hb levels through lifelong chronic blood transfusions. These transfusions carry the risk of progressive multi-organ damage due to unavoidable iron overload.

LentiGlobin adds functional copies of a modified form of the β-globin gene ($\beta^{A\text{-}T87Q}$-globin gene) into a patient's own hematopoietic (blood) stem cells (HSCs). Once a patient has the $\beta^{A\text{-}T87Q}$-globin gene, they have the potential to produce HbA^{T87Q}, which is gene therapy-derived-hemoglobin, at levels that may eliminate or significantly reduce the need for transfusions.
Non-serious adverse events (AEs) observed during clinical studies that were attributed to LentiGlobin for TDT were hot flush, dyspnoea, abdominal pain, pain in extremities and non-cardiac chest pain. One serious adverse event (SAE) of thrombocytopenia was considered possibly related to LentiGlobin for TDT.
Additional AEs observed in clinical studies were consistent with the known side effects of HSC collection and bone marrow ablation with busulfan, including SAEs of veno-occlusive disease.

The conditional marketing authorization for ZYNTEGLO is only valid in the 28 member states of the EU as well as Iceland, Liechtenstein and Norway. For details, please see the Summary of Product Characteristics (SmPC).
The U.S. Food and Drug Administration granted LentiGlobin for β-thalassemia Orphan Drug status and Breakthrough Therapy designation for the treatment of TDT.

LentiGlobin for β-thalassemia continues to be evaluated in the ongoing Phase 3 Northstar-2 and Northstar-3 studies. For more information about the ongoing clinical studies, visit

www.northstarclinicalstudies.com or **clinicaltrials.gov** and use identifier NCT02906202 for Northstar-2 (HGB-207), NCT03207009 for Northstar-3 (HGB-212).

bluebird bio is conducting a long-term safety and efficacy follow-up study (LTF-303) for people who have participated in bluebird bio-sponsored clinical studies of LentiGlobin for TDT. For more information visit: **https://www.bluebirdbio.com/medical-professionals/our-clinical-trials/** or clinicaltrials.gov and use identifier NCT02633943 for LTF-303.

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 including cerebral adrenoleukodystrophy, sickle cell disease, 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**.

ZYNTEGLO, LentiGlobin, bluebird bio are trademarks of bluebird bio, Inc.

The full common name for ZYNTEGLO: A genetically modified autologous CD34+ cell enriched population that contains hematopoietic stem cells transduced with lentiviral vector encoding the $\beta^{A\text{-}T87Q}$-globin gene.

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 Company's views with respect to the potential for LentiGlobin to treat transfusion-dependent β-thalassemia and sickle cell disease, the potential for the bb21217 product candidate to treat relapsed/ refractory multiple myeloma. 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 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 or in the commercial context, 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 US and EU, and the risk that any one or more of 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.

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