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): December 7, 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 December 7, 2019, bluebird bio, Inc. ("bluebird") issued a press release announcing data presented at the 61st Annual Meeting of the American Society of Hematology ("ASH") from its ongoing Phase 1/2 HGB-206 study of investigational LentiGlobin product candidate in patients with sickle cell disease.

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 December 7, 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: December 9, 2019

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

Exhibit 99.1

bluebird bio Presents New Data from Ongoing Phase 1/2 HGB-206 Study of LentiGlobin™ Gene Therapy for Sickle Cell Disease (SCD) at 61st ASH Annual Meeting and Exposition

99% reduction in annualized rate of vaso-occlusive crises (VOC) and acute chest syndrome (ACS) in Group C patients with history of VOCs and ACS who had at least six months follow-up, no reports of ACS or serious VOCs at up to 21 months post-treatment

Group C patients at six months post-treatment produced consistent median levels of gene therapy-derived anti-sickling hemoglobin (HbA^{T87Q}) ranging from 44 – 59% (Month 6 – 21), reducing the median level of abnormal sickle hemoglobin (HbS)

Continued improvement in key markers of hemolysis in Group C patients demonstrates the potential of LentiGlobin for SCD to modify the underlying pathophysiology of sickle cell disease

CAMBRIDGE, Mass.— (BUSINESS WIRE)— December 7, 2019 - bluebird bio, Inc. (Nasdaq: BLUE) announced new data from its ongoing Phase 1/2 HGB-206 study of investigational LentiGlobin™ gene therapy for sickle cell disease (SCD), including additional patients treated in the study and updated data for those previously reported. These data, as well as results from exploratory assays designed to assess the relationship between drug product characteristics and red blood cell physiology, were presented at the 61st American Society of Hematology (ASH) Annual Meeting and Exposition in Orlando, Florida.

"At ASH, the growing body of data from our clinical studies of LentiGlobin for SCD reflects results from 26 treated patients with up to four years of follow-up," said David Davidson, M.D., chief medical officer, bluebird bio. "We continue to observe patients treated in Group C producing high levels of gene-therapy derived anti-sickling hemoglobin, HbA^{T87Q}, accounting for at least 40% of total hemoglobin in those with six or more months of follow-up, and exploratory assays show that HbA^{T87Q} is present in most red blood cells of treated patients. The robust production of HbA^{T87Q} was associated with substantial reductions of sickle hemoglobin, HbS, as well as improvement in key markers of hemolysis. Most importantly, patients in Group C have not experienced any episodes of acute chest syndrome or serious vaso-occlusive crises following LentiGlobin for SCD treatment."

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 crises (VOCs). 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 was designed to add 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 patients have

the $\beta^{A\text{-}T87Q}$-globin gene, their RBCs can produce anti-sickling hemoglobin that decreases the proportion of sickled hemoglobin, with the goal of reducing sickled RBCs, hemolysis and other complications.

“People living with sickle cell disease face a lifetime of unpredictable pain, hospitalizations and increased risk of stroke and premature death,” said Julie Kanter, M.D., University of Alabama at Birmingham. “It is so exciting to see the Group C results from the HGB-206 study. The data continue to demonstrate sustained expression of gene therapy-derived hemoglobin in patients treated with LentiGlobin for SCD, which resulted in significantly improved hemoglobin (>2g/dl/patient), near-normalization of markers of hemolysis and no reports of acute chest syndrome, stroke or serious vaso-occlusive crises in these patients.”

HGB-206 Updated Results
HGB-206 is an ongoing, Phase 1/2 open-label study designed to evaluate the efficacy and safety of LentiGlobin gene therapy for SCD that includes three treatment cohorts: Groups A, B and C. All results are as of the data cutoff date of August 26, 2019.

Group C
As of the data cutoff date, 17 patients were treated with LentiGlobin for SCD in Group C, with the longest follow-up at 21 months; none required regular RBC transfusions post-treatment.

In patients with six or more months of follow-up (n=12), median levels of gene therapy-derived anti-sickling hemoglobin, HbA^{T87Q}, were at least 40% of total hemoglobin. Total hemoglobin and HbA^{T87Q} levels ranged from 9.3 – 15.2 g/dL and 2.7 – 9.0 g/dL, respectively, at last visit.

Treatment with LentiGlobin for SCD reduced key markers of hemolysis, including reticulocyte counts, lactate dehydrogenase (LDH) levels and total bilirubin concentration, which suggests that treatment is improving biological markers of the disease.

Among the nine patients with at least six months of follow-up who had four or more VOC or ACS events in the two years prior to treatment, there was a 99% reduction in annualized rate of VOC and ACS. There were no reports of ACS or serious VOC at up to 21 months post-treatment in these patients. As previously reported, there was one non-serious Grade 2 VOC was observed in a patient approximately 3.5 months post-LentiGlobin for SCD treatment.

A refined manufacturing process that increases vector copy number (VCN) and improves engraftment potential of gene-modified stem cells was used for Group C. Group C patients also received LentiGlobin for SCD made from HSCs collected from peripheral blood after mobilization with plerixafor, rather than via bone marrow harvest, which was used in Group A and Group B.

Groups A and B
As of the data cutoff date, seven out of nine total patients in Groups A and B (five out of seven in Group A and two out of two in Group B) did not require regular RBC transfusions post-treatment.

All seven patients in Group A had reached at least three years of post-treatment follow-up. Levels of HbA^{T87Q} and total hemoglobin remained durable in all seven patients. At last evaluable visit, median HbA^{T87Q} levels were 0.9 g/dL and total hemoglobin was 9.0 g/dL.

Of the two patients in Group B, levels of HbA^{T87Q} and total hemoglobin remained durable at two years of post-treatment follow-up. At last visit, HbA^{T87Q} levels were 3.6 g/dL and 7.1 g/dL, and total hemoglobin was 11.3 g/dL and 13.0 g/dL.

Overall, patients in Groups A and B experienced a reduction, but not complete elimination of VOC and ACS events at two years post-treatment, suggesting that the levels of gene therapy-derived hemoglobin may have been sufficient to reduce but not eliminate continued sickle-related disease manifestations.

HGB-206 Exploratory Assays
bluebird bio presented results from exploratory assays in samples from a subset of patients treated with LentiGlobin for SCD from Groups A, B and C, to assess the relationship between drug product characteristics and RBC physiology.

To demonstrate the pancellular expression of the gene therapy derived anti-sickling Hb, HbA^{T87Q}, bluebird bio developed an assay that enables detection of HbA^{T87Q} and HbS protein in individual RBCs. In 12 patients who had at least six months of follow-up, the proportion of RBCs positive for HbA^{T87Q} at the last study visit was more than 70% in all cases; with more than 90% of RBCs positive for HbA^{T87Q} in four patients.

On average, HbA^{T87Q} present in RBCs of patients treated with LentiGlobin for SCD was within the range of non-sickling adult Hb, HbA, present in the RBCs from people with sickle cell trait. The RBCs also resembled sickle cell trait RBCs with regard to propensity to sickle under low oxygen conditions. Sickling of RBCs from patients treated with LentiGlobin for SCD was significantly less than that seen in untreated patients with SCD.

HGB-206: Safety
As of the data cutoff date, the safety data from all patients in HGB-206 are reflective of underlying SCD, the known side effects of hematopoietic stem cell collection and myeloablative conditioning. There have been no serious adverse events related to LentiGlobin for SCD. One mild, non-serious event of hot flush was reported that the investigator considered to be related to LentiGlobin for SCD; it occurred and resolved on the day of drug product infusion and did not require treatment.

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 and the planned Phase 3 HGB-210 study, which is expected to be open and enrolling patients by early 2020.

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 crises (VOCs). 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/our-science/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**.

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 sickle cell disease. 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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