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): September 23, 2020

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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, $0.01 par value per share	BLUE	The NASDAQ Stock 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 September 23, 2020, bluebird bio, Inc. ("bluebird") issued a press release announcing that its investigational treatment for sickle cell disease (SCD), LentiGlobin™ for SCD Gene Therapy (bb1111), was granted eligibility to the Priority Medicines (PRIME) program from the European Medicines Agency (EMA).

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 September 23, 2020.
	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 hereunto duly authorized.

Date: September 23, 2020

bluebird bio, Inc.

By: /s/ Jason F. Cole

Jason F. Cole

Chief Operating and Legal Officer

Exhibit 99.1

bluebird bio's LentiGlobin™ for Sickle Cell Disease Gene Therapy (bb1111) Granted Priority Medicines (PRIME) Designation by European Medicines Agency

EMA's PRIME program designed to optimize development and expedite evaluation of innovative medicines for patients with high unmet need

CAMBRIDGE, Mass.— (BUSINESS WIRE)— September 23, 2020 - bluebird bio, Inc. (Nasdaq: BLUE) announced today that its investigational treatment for sickle cell disease (SCD), LentiGlobin™ for SCD gene therapy (bb1111), was granted eligibility to the Priority Medicines (PRIME) program by the European Medicines Agency (EMA).

The EMA's PRIME initiative provides enhanced support and increased interaction to companies, with the goal of optimizing development plans and speeding regulatory evaluations to potentially bring innovative medicines to patients more quickly. To be accepted for PRIME, a therapy must demonstrate potential to benefit patients with unmet medical need through early clinical data. Clinical data from the completed Phase 1/2 HGB-205 study, the ongoing Phase 1/2 HGB-206 study and ongoing long-term safety and efficacy follow-up study LTF-303 supported the PRIME application for LentiGlobin for SCD.

"Even with recent progress to deliver new medicines for sickle cell disease, there remains a profound unmet need for people living with SCD. SCD is a progressive disease that frequently leads to organ damage and early death, and whose hallmarks are hemolytic anemia, painful vaso-occlusive crises (VOCs) and stroke," said Anne-Virginie Eggimann, M.Sc., SVP, Regulatory Science, bluebird bio. "Based on the results from our clinical studies to date, we believe LentiGlobin for SCD has the potential to provide truly meaningful outcomes for people living with SCD. The PRIME designation shows that the EMA recognizes the importance of bringing innovative medicines to patients with SCD efficiently and will allow us to work even more closely with the Agency to help expedite the development and review of LentiGlobin for SCD."

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). HbS causes red blood cells to become sickled and fragile, resulting in chronic hemolytic anemia, vasculopathy and unpredictable, painful VOCs. For adults and children living with SCD, this means painful crises and other life altering or life-threatening acute complications—such as acute chest syndrome (ACS), stroke and infections. If patients survive the acute complications, vasculopathy and end-organ damage, resulting complications can lead to pulmonary hypertension, renal failure and early death.

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 red blood cells can produce anti-sickling hemoglobin, HbA^{T87Q}, which decreases the proportion of HbS, with the goal of reducing sickled red blood cells, hemolysis and other complications.

bluebird bio's clinical development program for LentiGlobin for SCD includes the completed Phase 1/2 HGB-205 study, the ongoing Phase 1/2 HGB-206 study and the ongoing Phase 3 HGB-210 study. 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 betibeglogene autotemcel for β-thalassemia or LentiGlobin for SCD. For more information visit: **www.bluebirdbio.com/our-science/clinical-trials** or **clinicaltrials.gov**.

LentiGlobin for SCD received orphan medicinal product designation from the European Commission for the treatment of SCD.

The U.S. FDA granted orphan drug designation, fast track designation, regenerative medicine advanced therapy (RMAT) designation and rare pediatric disease designation for LentiGlobin for SCD.

LentiGlobin for SCD is investigational and has not been approved in any geography.

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**.

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 company's development and regulatory plans for the LentiGlobin for SCD product candidate. 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 COVID-19 pandemic and resulting impact on our operations and healthcare systems will affect the execution of our development plans or the conduct of our clinical studies; the risk that even if LentiGlobin for SCD addresses ACS and VOC events, that it may not address progressive organ damage experienced by patients with SCD; the risk that the efficacy and safety results observed in the patients treated in our prior and ongoing clinical trials of LentiGlobin for SCD may not persist or be durable; the risk that the efficacy and safety results from our prior and ongoing clinical trials will not continue or be repeated in when treating additional patients in our ongoing or planned clinical trials; the risk that the HGB-206 and HGB-210 clinical studies as currently contemplated may be insufficient to support regulatory submissions or marketing approval in the United States and European Union; the risk that our plans for demonstrating comparability of the suspension manufacturing process for lentiviral vector will not be accepted by regulatory authorities and may delay our submissions for regulatory approval; the risk that regulatory authorities will require additional information regarding our product candidate, resulting in a delay to our anticipated timelines for regulatory submissions, including our application for marketing approval. 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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