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): June 7, 2021

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 June 7, 2021, bluebird bio, Inc. (the "Company" or "bluebird") issued a press release to announce that the U.S. Food and Drug Administration (FDA) has lifted the clinical holds on the Phase 1/2 HGB-206 and Phase 3 HGB-210 studies of LentiGlobin for sickle cell disease (SCD) gene therapy (bb1111) for adult and pediatric patients with SCD, and the Phase 3 Northstar-2 (HGB-207) and Northstar-3 (HGB-212) studies of betibeglogene autotemcel gene therapy (beti-cel; licensed as ZYNTEGLO™ in the European Union and the United Kingdom) for adult, adolescent and pediatric patients with transfusion-dependent β-thalassemia (TDT). The Company is working closely with study investigators and clinical trial sites to resume all study activities as soon as possible.

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 June 7, 2021.
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 hereunto duly authorized.

Date: June 7, 2021

bluebird bio, Inc.

By: /s/ Jason F. Cole

Jason F. Cole

Chief Operating and Legal Officer

Exhibit 99.1

bluebird bio Announces the Lifting of FDA Clinical Hold for Sickle Cell Disease and β-Thalassemia Studies

CAMBRIDGE, Mass. — (BUSINESS WIRE) — June 7, 2021— **bluebird bio, Inc.** (Nasdaq: BLUE) today announced that the U.S. Food and Drug Administration (FDA) has lifted the clinical holds on the Phase 1/2 HGB-206 and Phase 3 HGB-210 studies of LentiGlobin for sickle cell disease (SCD) gene therapy (bb1111) for adult and pediatric patients with SCD, and the Phase 3 Northstar-2 (HGB-207) and Northstar-3 (HGB-212) studies of betibeglogene autotemcel gene therapy (beti-cel; licensed as ZYNTEGLO™ in the EU and the UK) for adult, adolescent and pediatric patients with transfusion-dependent β-thalassemia (TDT). The company is working closely with study investigators and clinical trial sites to resume all study activities as soon as possible.

“Patient safety continues to be our utmost priority, and we are grateful for the close partnership with the FDA, investigators, scientists and most importantly, patients, who all contributed to the assessments of the adverse events in HGB-206 that ultimately led to today’s announcement,” said Andrew Obenshain, president, severe genetic diseases, bluebird bio. “As pioneers in gene therapy, we remain committed to advancing the field through our learnings. Over the past four months, we have gained deeper knowledge and understanding of the pathophysiology of sickle cell disease that will allow us to better serve patients and the broader community. We look forward to resuming our clinical programs and continuing to advance toward major regulatory submissions for sickle cell disease and β-thalassemia.”

Previously Reported Safety Events
On March 10, 2021, bluebird bio reported that it is very unlikely the suspected unexpected serious adverse reaction (SUSAR) of acute myeloid leukemia (AML) reported in the HGB-206 study of LentiGlobin for SCD was related to the BB305 lentiviral vector (LVV). No cases of hematologic malignancy have been reported in any patient who has received treatment with beti-cel. On April 20, 2021, bluebird bio announced a revised diagnosis for the previously reported case of myelodysplastic syndrome (MDS) in its Phase 1/2 study of LentiGlobin for SCD. Upon further assessment, the treating investigator concluded this is not a case of MDS and revised the diagnosis to transfusion-dependent anemia.

About LentiGlobin for SCD (bb1111)
LentiGlobin gene therapy for sickle cell disease (bb1111) is an investigational treatment being studied as a potential one-time therapy for SCD. bluebird bio’s clinical development program for LentiGlobin for SCD includes the completed Phase 1/2 HGB-205 and the ongoing phase 1/2 HGB-206 and Phase 3 HGB-210 studies. In addition, bluebird bio is conducting a long-term safety and efficacy follow-up study (LTF-307) for people who have participated in bluebird bio sponsored clinical studies of LentiGlobin for SCD. For more information on the studies, visit: https://www.bluebirdbio.com/our-science/clinical-trials or clinicaltrials.gov.

The FDA has 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 received orphan medicinal product designation from the European Commission for the treatment of SCD, and Priority Medicines (PRIME) eligibility by the European Medicines Agency (EMA) in September 2020.

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

About betibeglogene autotemcel (beti-cel)
Betibeglogene autotemcel (beti-cel) is a one-time gene therapy that 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 adult hemoglobin (Hb), at levels that may eliminate or significantly reduce the need for transfusions. In studies of beti-cel, transfusion independence (TI) is defined as no longer needing red blood cell transfusions for at least 12 months while maintaining a weighted average Hb of at least 9 g/dL.

The European Commission granted conditional marketing authorization (CMA) for beti-cel, marketed as ZYNTEGLO™ 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. Non-serious adverse events (AEs) observed during clinical studies that were attributed to beti-cel included abdominal pain, thrombocytopenia, leukopenia, neutropenia, hot flush, dyspnea, pain in extremity, tachycardia and non-cardiac chest pain. One serious adverse event (SAE) of thrombocytopenia was considered possibly related to beti-cel.

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. For details, please see the Summary of Product Characteristics (SmPC).

On April 28, 2020, the EMA renewed the CMA for beti-cel. The CMA for beti-cel is valid in the 27 member states of the EU as well as the UK, Iceland, Liechtenstein and Norway. In November 2020, bluebird bio submitted to the EMA an application for the second renewal of the CMA. This procedure is currently on hold while the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) reviews the safety of ZYNTEGLO. The CMA is valid while the renewal application review is ongoing by the regulatory agency.

The FDA granted beti-cel Orphan Drug status and Breakthrough Therapy designation for the treatment of TDT.

bluebird bio is on track to complete its rolling Biologics License Application (BLA) submission to the FDA for beti-cel in mid-2021. This submission is anticipated to include adult, adolescent and children with transfusion dependent β-thalassemia across all genotypes (including non-β^0/β^0 genotypes and β^0/β^0 genotypes). Beti-cel is not approved in the U.S.

Beti-cel continues to be evaluated in the ongoing Phase 3 Northstar-2 (HGB-207) and Northstar-3 (HGB-212) studies. 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 beti-cel.

About bluebird bio, Inc.
bluebird bio, Inc. (NASDAQ: BLUE) is pioneering gene therapy with purpose. From our Cambridge, Mass., headquarters, we're developing gene and cell 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, betibeglogene autotemcel, beti-cel, LentiGlobin for SCD, bb1111 and bluebird bio are trademarks of bluebird bio, Inc.

bluebird bio Cautionary Statement Regarding Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are based on historical performance and current expectations and projections about our future financial results, goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, that are difficult to predict, may be beyond our control and could cause our future financial results, goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. No forward-looking statement can be guaranteed. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect bluebird bio's business, which include but are not limited to: the risk that insertional oncogenic events associated with lentiviral vector or additional MDS events associated with transplant or myeloablation will be discovered or reported over time; the risk that insertional oncogenic events associated with lentiviral vector in other programs may result in a clinical hold of our programs in SCD, TDT or cerebral adrenoleukodystrophy; the risk that we may experience delays in our ability to restart the enrollment and conduct of our HGB-206 and HGB-210 clinical trials; the risk that we may not be able to execute on our business plans, including meeting our expected or planned regulatory milestones, submissions or timelines, such as in the completion of our BLA submission for beti-cel; the risk that LentiGlobin for SCD or beti-cel will not be approved for marketing by the FDA, and the risk that we will not successfully bring LentiGlobin for SCD or beti-cel to market in the United States; the risk that we may not resume patient treatment with ZYNTEGLO in the commercial context in a timely manner or at all; and the risk that with the impact on the execution and timing of our business plans, we may not successfully execute our previously-announced plans to spin-off our oncology portfolio and programs into an independent publicly-traded company on the timeline that we expect, or at all. 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 bluebird bio's Annual Report on Form 10-K, as updated by our subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission. The forward-looking statements included in this document are made only as of the date of this document and except as otherwise required by applicable law, bluebird bio undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise.

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