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): July 9, 2021

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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 July 9, 2021, bluebird bio, Inc. ("bluebird") issued a press release announcing that the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) has concluded based on the review of all available data that the benefit-risk balance of medicinal products containing betibeglogene autotemcel (beti-cel) gene therapy (licensed as ZYNTEGLO™ in the European Union and the United Kingdom) remains favorable. Accordingly, bluebird has informed the EMA that it is lifting the voluntary marketing suspension effective today.

The full text of bluebird's press release 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 July 9, 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: July 9, 2021

bluebird bio, Inc.

By: /s/ Jason F. Cole

Jason F. Cole

Chief Operating and Legal Officer

Exhibit 99.1

bluebird bio Announces Positive Recommendation by PRAC Regarding Article 20 Safety Referral Review of ZYNTEGLO™ Gene Therapy for Transfusion-Dependent β-thalassemia and Marketing to Resume in EU

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) confirms favorable benefit-risk balance of ZYNTEGLO

Company has informed EMA of lift of voluntary temporary marketing suspension

CAMBRIDGE, Mass. — (BUSINESS WIRE) — July 9, 2021 — **bluebird bio, Inc**. (Nasdaq: BLUE) today announced that the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) has concluded based on the review of all available data that the benefit-risk balance of medicinal products containing ZYNTEGLO™ (betibeglogene autotemcel gene therapy) remains favorable. As of today, bluebird bio has informed the EMA that the company is lifting the voluntary marketing suspension.

"Patient safety remains our top priority. To this end, we are grateful to the PRAC for its comprehensive review of the available evidence and positive recommendation for ZYNTEGLO," said Andrew Obenshain, president, severe genetic diseases, bluebird bio. "We are pleased to resume offering ZYNTEGLO to patients living with transfusion-dependent β-thalassemia, offering the potential to live free from transfusions which is evidenced by our clinical studies where patients are maintaining normal or near-normal hemoglobin levels over the course of up to seven years of follow-up."

No cases of hematologic malignancy have been reported in any patient who has received treatment with ZYNTEGLO. However because it is manufactured using the same BB305 lentiviral vector used in LentiGlobin for sickle cell disease (SCD; investigational drug product bb1111), bluebird bio decided to temporarily suspend marketing of ZYNTEGLO while the root cause of the safety events reported earlier this year for LentiGlobin for SCD were investigated by the company and assessed by the PRAC.

As previously announced on June 7, 2021, the U.S. Food and Drug Administration (FDA) lifted the clinical holds on the Phase 1/2 HGB-206 and Phase 3 HGB-210 studies of LentiGlobin for SCD following the Agency's review of the data.

The recommendation from the PRAC can be viewed here on the EMA website. As a next step, the recommendation will be forwarded to the Committee for Advanced Therapies (CAT) and Committee for Medicinal Products for Human Use (CHMP) for adoption. The final stage of the review procedure is the adoption by the European Commission (EC) of a legally binding decision applicable in all EU Member States.

About ZYNTEGLO (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.

beti-cel is manufactured using the BB305 lentiviral vector (LVV), a third-generation, self-inactivating LVV. The promoter, a regulatory element of the LVV that controls the expression of the transgene, selected for BB305 is a cellular (non-viral) promoter that drives gene expression only in the erythroid lineage cells (red blood cells and their precursors).

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 product information, containing 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 Iceland, Liechtenstein and Norway. In November 2020, bluebird bio submitted to the EMA an application for the second renewal of the CMA. ZYNTEGLO also has a CMA in Great Britain, further to the grandfathering of the license by the MHRA earlier this year.

The U.S. Food and Drug Administration (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.

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, including statements regarding the company's expectations regarding the commercialization of ZYNTEGLO, and the timing of the submission of a BLA for beti-cel to the FDA. 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 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 and the renewal of the CMA 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; the risk that results seen in our clinical trials of beti-cel may not be seen in the commercial context for ZYNTEGLO; 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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