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): April 20, 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 April 20, 2021, bluebird bio, Inc. (the "Company") issued a press release announcing business and program updates across its severe genetic disease portfolio including a revised diagnosis of transfusion-dependent anemia for a case that was initially reported as myelodysplastic syndrome (MDS) in the HGB-206 study of LentiGlobin for sickle cell disease (bb1111), removal of Zynteglo (betibeglogene autotemcel, beti-cel) for β-thalassemia from the German market due to the outcome of reimbursement negotiations in Germany, and a reduction in workforce intended to enable the Company to advance its late-stage gene therapy programs.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on April 20, 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: April 20, 2021

bluebird bio, Inc.

By: /s/ Jason F. Cole

Jason F. Cole

Chief Operating and Legal Officer

Exhibit 99.1

bluebird bio Provides Update on Severe Genetic Disease Programs and Business Operations

CAMBRIDGE, Mass. – (BUSINESS WIRE) – April 20, 2021 – bluebird bio, Inc. (Nasdaq: BLUE) announced today business and program updates across its severe genetic disease portfolio including a revised diagnosis for the previously reported case of myelodysplastic syndrome (MDS) in its Phase 1/2 study of LentiGlobin for sickle cell disease (SCD) (bb1111), the company's decision to withdraw ZYNTEGLO™ (betibeglogene autotemcel, beti-cel) for transfusion-dependent β-thalassemia (TDT) from the German market and a targeted reshaping of its workforce intended to enable the company to advance its late-stage gene therapy programs.

The case of MDS reported in February in a patient from Group C of the Phase 1/2 HGB-206 study of LentiGlobin gene therapy for SCD has been further assessed following the review of results from additional tests. The treating investigator has concluded this is not a case of MDS and has revised the diagnosis to transfusion-dependent anemia. bluebird bio has reported this update to regulatory agencies and study investigators. The company continues to work with the treating investigator to determine the potential cause of this patient's anemia.

Last month, the company 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). This assessment, along with the re-classification of the originally reported MDS case to transfusion-dependent anemia are important steps in bluebird bio's path to seeking removal of the clinical hold on studies HGB-206 and HGB-210 of LentiGlobin for SCD. bluebird bio continues to work with regulators to resume its clinical studies in sickle cell disease as well as to remove the clinical hold for HGB-207 and HGB-212 clinical studies of beti-cel for β-thalassemia, with potential lift of all clinical holds in mid-2021.

In Europe, reimbursement negotiations in Germany did not result in a price for ZYNTEGLO that reflects the value of this one-time gene therapy with potential life-long benefit for people living with TDT. The price proposed by the German health authorities fails to recognize the severe burden of living with TDT or the innovation and benefit ZYNTEGLO brings to patients who are impacted every day, throughout their lives by this severe genetic disease.

bluebird bio continues with productive negotiations across countries in Europe and we plan to continue to provide updates on the negotiation processes in the second half of 2021.

In response to these and other events and shifts related to the business over the past year, bluebird bio plans to reduce and reshape its workforce, primarily in Europe. This reduction and reallocation of resources will allow the company to focus on priority European markets and streamline global operations going forward to ensure its ability to deliver gene therapies to patients based on bluebird bio's current business plans.

"We remain committed to our pioneering mission to deliver one-time gene therapies with life-long benefits to our patients. We are grateful for the clinical investigators and healthcare providers helping us better understand the recent safety events in our sickle cell disease studies. We are confident that working with the FDA and EMA, we will be able to determine a positive path forward as we seek to re-open our clinical studies Further, through our continued engagement across Europe, we are optimistic that countries will reach pricing decisions that recognize the value of one-time gene therapies and provide the necessary access to the people who need them," said Andrew Obenshain, president, severe genetic diseases, bluebird bio. "In terms of operations, we have faced challenges over the last year that

have resulted in the difficult decision to reduce our workforce and say goodbye to some valued bluebirds. We want to express our gratitude for their contributions and commitment to patients. As we move into the future, we look forward to bluebird bio advancing as a strong, thriving organization that is dedicated to developing treatments for rare genetic diseases."

About HGB-206 and HGB-210

HGB-206 is a Phase 1/2 open-label study designed to evaluate the efficacy and safety of LentiGlobin gene therapy for sickle cell disease (SCD) that includes three treatment cohorts: Groups A, B and C. A refined manufacturing process designed to increase vector copy number (VCN) and further protocol refinements made to improve engraftment potential of gene-modified stem cells were 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 Groups A and B of HGB-206.

HGB-210 is a Phase 3 single-arm open-label study designed to evaluate the efficacy and safety of LentiGlobin gene therapy for SCD in patients between two years and 50 years of age with sickle cell disease.

About LentiGlobin for SCD (bb1111)

LentiGlobin gene therapy for sickle cell disease (bb1111) is an investigational treatment being studied as a potential treatment for SCD. bluebird bio's clinical development program for LentiGlobin for SCD includes the completed Phase 1/2 HGB-205 study, the Phase 1/2 HGB-206 study, and the Phase 3 HGB-210 study.

The U.S. Food and Drug Administration (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 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.

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 visit: https://www.bluebirdbio.com/our-science/clinical-trials or clinicaltrials.gov and use identifier NCT04628585 for LTF-307.

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

About Zynteglo (betibeglogene autotemcel)

Betibeglogene autotemcel (beti-cel) is a one-time gene therapy that adds functional copies of a modified form of the β-globin gene (βA-T87Q-globin gene) into a patient's own hematopoietic (blood) stem cells (HSCs). Once a patient has the βA-T87Q-globin gene, they have the potential to produce HbAT87Q, which is gene therapy-derived adult 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 transfusion-dependent β-thalassemia (TDT) who do not have a β0/β0 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 European Medicines Agency (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.

The U.S. Food and Drug Administration (FDA) granted beti-cel Orphan Drug status and Breakthrough Therapy designation for the treatment of TDT. 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 ZYNTEGLO.

About bluebird bio, Inc.

bluebird bio 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: cerebral adrenoleukodystrophy, sickle cell disease, β-thalassemia and multiple myeloma, using gene and cell therapy technologies including gene addition, 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 timing and expectations regarding regulatory interactions to lift the clinical hold on its HGB-206 and HGB-210 studies, anticipated timing for the submission of the BLA to the FDA for LentiGlobin for SCD in the United States, ongoing pricing & reimbursement negotiations for Zynteglo in Europe, and regarding the Company's business strategy and investments, including the cause and impact of the Company's reduction in force and

related activities. 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, many of which are beyond the Company's control. These risks and uncertainties include, but are not limited to: the risk that we may not be able to address regulatory authorities' concerns quickly or at all regarding the risk of insertional oncogenesis or MDS from the use of our product candidates; 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 we may not reach agreement with payors in Europe on the price for Zynteglo; the risk that we may not be able to execute on our business plans, including our commercialization plans, meeting our expected or planned regulatory milestones, submissions, and timelines, research and clinical development plans, and in bringing our product candidates to market; the difficulties in and effect of implementing the Company's reduction in force, such as claims arising out of the reduction; the risk that the planned reduction in force does not have the anticipated outcomes or impacts, including the risk that the actual financial and other impacts of the reduction could vary materially from the outcomes or impacts anticipated; 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 programs into an independent publicly-traded entity. 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-K, 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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