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): March 26, 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 March 26, 2020, bluebird bio, Inc. (“bluebird”) issued a press release to provide a business update in light of the evolving situation related to the coronavirus ("COVID-19") global pandemic.

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 March 26, 2020.
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: March 26, 2020

bluebird bio, Inc.

By: /s/ Jason F. Cole

Jason F. Cole

Chief Operating and Legal Officer

Exhibit 99.1

bluebird bio Provides Assessment of Impact of COVID-19, Update on Business Operations and Clinical Program Development

– Company to hold investor conference call today, March 26, 2020 at 8:30 am ET –

CAMBRIDGE, Mass. – **March 26, 2020** – bluebird bio, Inc. (NASDAQ: BLUE) today provided an update in response to the global COVID-19 pandemic. The company has taken steps to ensure the safety of its patients and employees, while working to ensure the sustainability of its business operations as this unprecedented situation continues to evolve.

“The COVID-19 pandemic has created new challenges for bluebird, the broader biotech community, and society as a whole. During this unprecedented time, we remain focused on caring for the patients who rely on us,” said Nick Leschly, chief bluebird. “In addition, we are prioritizing the safety and well-being of our employees, making a positive impact as a member of our local community, and continuing to execute on our business strategy. While we all face tremendous challenges and uncertainty at this time, I am confident in bluebird’s ability to face these headwinds with ingenuity, empathy, and a relentless commitment to the people we serve.”

bluebird bio continues to evaluate the impact of COVID-19 on the healthcare system and work with healthcare providers supporting its clinical studies to mitigate risk to patients while taking into account regulatory, institutional, and government guidance and policies. The company remains committed to maintaining its development plans but acknowledges the potential impact on clinical studies given the rapidly evolving global environment. Generally, the company expects the COVID-19 pandemic to shift the timing of enrollment and completion of clinical studies by at least three months and expects timing shifts to vary by clinical trial and by program.

Regulatory Activities

- Ide-cel (bb2121): In partnership with Bristol-Myers Squibb (BMS), the companies’ previously announced plans to submit the U.S. Biologics License Application (BLA) for ide-cel in the first half of 2020 remain on track. The clinical trials that form the basis for this application have completed enrollment.
- LentiGlobin for β-thalassemia: As part of the rolling BLA submission for LentiGlobin for β-thalassemia, the company has been engaged in discussions with the U.S. Food and Drug Administration (FDA) regarding the requirements and timing of certain information related to release assays that would be provided as part of its rolling BLA submission. These assays are advancing through development and validation for use in the commercial setting and are likely to be impacted by the COVID-19 situation.
    - Additionally, based on continued and ongoing discussions with the FDA in the context of bluebird bio’s Fast Track and Breakthrough Therapy designations, the company and the FDA have not been able to agree on bluebird bio providing data regarding these assays to the FDA during review of the BLA. Based on the status of these ongoing discussions and the expected COVID-19 related shifts, bluebird bio does not anticipate completing the rolling BLA submission for LentiGlobin for β-thalassemia until mid-2021 (Q2/Q3). If completion of the BLA for LentiGlobin for β-thalassemia is shifted until mid-2021, bluebird bio may have the opportunity to seek approval for a broader patient population, including patients with β^0/β^0 genotypes in addition to pediatric patients.
- Lenti-D for Cerebral Adrenoleukodystrophy (CALD): bluebird bio is currently on track to submit the Marketing Authorization Application (MAA) in the EU for Lenti-D for CALD by year-end 2020.

Based on the implications of our recent discussions with the FDA on LentiGlobin for β-thalassemia and the impacts of the COVID-19 pandemic on the business, the company now estimates that it will be able to submit the BLA for Lenti-D in CALD in mid-2021.

- LentiGlobin for Sickle Cell Disease (SCD): bluebird bio continues to engage in discussions with the FDA about the regulatory path for LentiGlobin for SCD. The company reiterates guidance for a regulatory update by the end of 2020.

Commercial Launch of ZYNTEGLO®

- In January 2020, the company announced the availability of ZYNTEGLO™ in Germany. While the process of consenting, preparing, and treating patients with ZYNTEGLO in Germany remains ongoing, given the evolving COVID-19 situation, the company expects the treatment of the first commercial patient in Germany to be shifted to the second half of 2020.
- During this time, bluebird bio plans to continue to engage in reimbursement discussions and undertake commercial preparation activities in the priority launch markets in Europe. The company expects the COVID-19 pandemic to impact its ability to achieve market access and reimbursement in Europe.

Operating Plan

In light of the impacts of the COVID-19 pandemic on the business and the anticipated changes to commercial, regulatory and development timelines, the company is currently re-evaluating its operating plan. The company will be adjusting priorities and overall expenses. An update will be provided by the company's Q1 2020 earnings release.

Ongoing Programs and Clinical Studies

Below is the current status of bluebird bio sponsored clinical trials:

- Ongoing clinical studies of LentiGlobin for β-thalassemia, LentiGlobin for SCD, Lenti-D for CALD as well as the study of bb21217 for multiple myeloma all currently remain active, but the effects of the COVID-19 pandemic is resulting in disruptions to study conduct across these programs.
    - The company has provided new guidance to investigators for all clinical studies in response to the COVID-19 pandemic to ensure extra precautions and communications are in place.
- As our partner in development of ide-cel, BMS has disclosed, it has have temporarily suspended screening, enrollment and apheresis in their cellular therapy clinical studies, which includes the KarMMa-2, KarMMa-3 and KarMMa-4 studies. The decision to temporarily suspend further screening, enrollment and apheresis is not considered an urgent safety measure and does not impact the ongoing BLA activities with the FDA for ide-cel.
- Planned data disclosures for 2020 remain on track.

Our People and Business

bluebird bio is evaluating all business-critical actions to determine how best to mitigate risk while being as minimally disruptive as possible. Safety of bluebird bio employees remains a top priority for the company. As of March 10, the company transitioned to a global work from home policy. Business-critical laboratory, manufacturing and related support activities continue and have been subject to heightened precautions to ensure safety of employees and the continuation of highest priority activities. The company continues to assess company policies, business continuity plans and employee support.

Conference Call Details
Investors may listen to the call on March 26, 2020 at 8:30 am ET by dialing (844) 825-4408 from locations in the United States or +1 (315) 625-3227 from outside the United States. Please refer to conference ID number 2666529.

To access the live webcast of bluebird bio's presentation, please visit the "Events & Presentations" page within the Investors & Media section of the bluebird bio website at http://investor.bluebirdbio.com. Replays of the webcast will be available on the bluebird bio website for 90 days following the event.

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.

ZYNTEGLO, LentiGlobin, Lenti-D and bluebird bio are trademarks of bluebird bio, Inc.

The full common name for ZYNTEGLO: A genetically modified autologous CD34+ cell enriched population that contains hematopoietic stem cells transduced with lentiviral vector encoding the $\beta^{A\text{-}T87Q}$-globin gene.

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 financial condition, results of operations, as well as statements regarding the plans for development and commercialization for ZYNTEGLO and the company's product candidates, including plans for our ongoing clinical trials, expectations regarding timing for the first patient treated with ZYNTEGLO in the commercial context, our plans and timing expectations for regulatory submissions for ide-cel, LentiGlobin for β-thalassemia, LentiGlobin for SCD, and Lenti-D for CALD, our plans for data disclosures in 2020, and our plans and expectations in light of and in response to the COVID-19 pandemic and its impacts on global healthcare systems and our business. 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 COVID-19 pandemic may disrupt our business and/or the global healthcare system more severely than we have anticipated, which may have the effect of further delaying our ability to enroll and complete our ongoing clinical trials (which may include potential delays of the ide-cel clinical trials beyond April 13, 2020), further delaying our ability to treat the first patient in the commercial context and obtaining market access and reimbursement for our approved product, and further delaying our timelines for regulatory submissions for

our product candidates; the risk that we will encounter further challenges in the commercial launch of ZYNTEGLO in the European Union, including in managing our complex supply chain for the delivery of drug product, in the adoption of value-based payment models, or in obtaining sufficient coverage or reimbursement for our products; the risk that our collaborations, including the collaborations with Bristol-Myers Squibb, will not continue or will not be successful; 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-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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