

**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 10, 2022**

**bluebird bio, Inc.**

(Exact name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-35966**  
(Commission File Number)

**13-3680878**  
(IRS Employer  
Identification No.)

**455 Grand Union Boulevard,  
Somerville, MA**  
(Address of Principal Executive Offices)

**02145**  
(Zip Code)

**(339) 499-9300**  
(Registrant's telephone number, including area code)

**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 10, 2022, bluebird bio, Inc. (“bluebird” or the “Company”) announced that the U.S. Food and Drug Administration’s (FDA) Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC) has recommended approval of betibeglogene autotemcel (beti-cel) for the treatment of people with  $\beta$ -thalassemia who require regular red blood cell transfusions. On the question: “Do the benefits of betibeglogene autotemcel for the treatment of subjects with beta-thalassemia who require regular red blood cell transfusions outweigh the risks, including the potential for insertional oncogenesis?” the CTGTAC voted 13 (yes) to 0 (no). The CTGTAC’s recommendation is based on the Biologics License Application for beti-cel currently under priority review by the FDA with a Prescription Drug User Fee Act goal date set for August 19, 2022.

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## 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 10, 2022

**bluebird bio, Inc.**

By: /s/ Jason F. Cole

Name: Jason F. Cole

Title: Chief Strategy & Financial Officer, Principal Financial Officer  
and Principal Accounting Officer