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): December 14, 2023

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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.)**

455 Grand Union Boulevard, Somerville, MA	**02145**
(Address of Principal Executive Offices)	**(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 7.01 Regulation FD Disclosure.

Following the FDA approval of LYFGENIA on December 8, 2023 for sickle cell disease in patients 12 and older with a history of vaso-occlusive events, bluebird bio, Inc. (the "Company") has signed an outcomes-based agreement with an organization representing approximately 100 million covered lives in the U.S. Additionally, the Company is in advanced discussions with a number of the nation's other large commercial payers and more than 15 Medicaid agencies collectively representing 80% of individuals with sickle cell disease in the U.S. The Company anticipates 85 to 105 patient starts (cell collections) combined across all three of its commercial products (LYFGENIA, ZYNTEGLO, SKYSONA) in 2024.

The information in Item 7.01 of this Current Report on Form 8-K ("Current Report") is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Forward Looking Statements

This Current Report 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 the Company's statements regarding the commercialization of LYFGENIA, including without limitation, the Company's ability to successfully partner with payers and Medicaid agencies, including by executing binding agreements with such parties and the anticipated number of patient starts in 2024. Such forward-looking statements are based on historical performance and current expectations and projections about the Company's 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 the Company's control and could cause the Company's 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 Current Report should be evaluated together with the many risks and uncertainties that affect the Company's business, particularly those identified in the risk factors discussion in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, as updated by subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission. These risks include, but are not limited to: delays and challenges in bluebird's commercialization and manufacturing of its products; the risk that the Company may not sign additional payers, which could have a negative impact on the amount of patient starts; the internal and external costs required for the Company's ongoing and planned activities, and the resulting impact on expense and use of cash, has been and may in the future be, higher than expected, which has caused the Company, and may in the future cause it, to use cash more quickly than it expects or change or curtail some of its plans or both; the Company's expectations as to expenses, cash usage and cash needs may prove not to be correct for other reasons such as changes in plans or actual events being different than its assumptions; the risk that the efficacy and safety results from the Company's prior and ongoing clinical trials will not continue or be seen in additional patients treated with its product candidates; the risk of insertional oncogenic or other reportable events associated with lentiviral vector, drug product, or myeloablation; and the risk that any one or more of the Company's products or product candidates will not be successfully commercialized. The forward-looking statements included in this Current Report are made only as of the date hereof and except as otherwise required by applicable law, the Company 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.

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: December 14, 2023

bluebird bio, Inc.

By: /s/ Joseph Vittiglio
Name: Joseph Vittiglio
Title: *Chief Legal & Business Officer and Secretary*