

**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): January 11, 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.)

**60 Binney Street,
Cambridge, MA**
(Address of Principal Executive Offices)

02142
(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 2.02 Results of Operations and Financial Condition.

On January 11, 2022, bluebird bio, Inc. (the “Company”) issued a press release announcing its planned corporate updates to be presented at the 40th Annual J.P. Morgan Healthcare Conference including 2022 program milestones and financial outlook, which included its preliminary unaudited cash, cash equivalents and marketable securities balance was approximately \$442 million, including restricted cash of approximately \$46 million, as of December 31, 2021. This information is unaudited and does not present all information necessary for an understanding of the Company’s financial condition as of December 31, 2021 and its results of operations for the twelve months ended December 31, 2021. The Company expects to announce its full results for the twelve months ended December 31, 2021 on or before March 1, 2022. A copy of the press release is furnished with this Current Report on Form 8-K as Exhibit 99.1

The information contained in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 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, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on January 11, 2022.
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: January 11, 2022

bluebird bio, Inc.

By: /s/ Helen C. Fu
Helen C. Fu
Senior Vice President, General Counsel and Secretary

**bluebird bio to Provide Update on Program Milestones and 2022 Financial Outlook
at the 40th Annual J.P. Morgan Healthcare Conference**

CAMBRIDGE, Mass. — (BUSINESS WIRE) — January 11, 2021— bluebird bio, Inc. (Nasdaq: BLUE) today announced planned updates to be presented at the 40th Annual J.P. Morgan Healthcare conference including 2022 program milestones and financial outlook.

In 2022, bluebird is focused on the FDA review of two gene therapies – betibeglogene autotemcel (beti-cel), for beta-thalassemia and elivaldogene autotemcel (eli-cel), for cerebral adrenoleukodystrophy (CALD) – and is prepared to launch both beti-cel and eli-cel for patients in the U.S. in mid-2022, if approved by the FDA. An FDA Advisory Committee to discuss the Biologics License Application (BLA) for beti-cel is anticipated on March 9, 2022.

Additionally, bluebird bio expects to complete the manufacturing of commercial drug product validation lots for its third gene therapy, lovotibeglogene autotemcel (lovo-cel), for sickle cell disease in mid-2022. The Company is evaluating what impact, if any, the ongoing partial clinical hold of lovo-cel for patients under the age of 18 may have on the projected timing of the first quarter of 2023 for the submission of the BLA.

“In 2021, bluebird bio relaunched as an independent company focused on severe genetic diseases,” said Andrew Obenshain, chief executive officer, bluebird bio. “We believe in the potential of our one-time therapies to transform the lives of patients and their families and to give them more bluebird days together. This year, we intend to realize the promise of lentiviral vector gene therapy in the US with the launch of beti-cel for beta-thalassemia and eli-cel for cerebral adrenoleukodystrophy, and to lay the foundation for lovo-cel to be the first gene therapy for people living with sickle cell disease.”

2022 Financial Outlook

The Company’s preliminary unaudited restricted cash, cash and cash equivalents and marketable securities balance was approximately \$442 million, including restricted cash of approximately \$46 million, as of December 31, 2021. As bluebird bio advances its late-stage pipeline assets to the commercial setting, full-year 2022 cash burn is expected to be less than \$400 million. The Company plans to explore the sale of priority review vouchers which would be expected to be issued with the U.S. approvals of BLAs for beti-cel and eli-cel. Approximately \$150-200 million in non-dilutive cash inflows could potentially be realized from the sales, which would extend the current cash runway into 2023. The Company is also exploring multiple additional financing opportunities, while focusing on further cost efficiencies.

Presentation at the 2022 J.P. Morgan Healthcare Conference

The bluebird bio management team will present on Wednesday, January 12, at 3:45 p.m. ET. A live webcast of the presentation will be available on the “Events & Presentations” page within the Investors & Media section of the bluebird bio website at <http://investor.bluebirdbio.com>. A replay of the webcast will be available on the bluebird bio website for 30 days following the event.

About bluebird bio, Inc.

bluebird bio is pursuing curative gene therapies to give patients and their families more bluebird days.

With a dedicated focus on severe genetic diseases, bluebird has industry-leading clinical and research programs for sickle cell disease, β -thalassemia and cerebral adrenoleukodystrophy and is advancing research to apply new technologies to these and other diseases. We custom design each of our therapies to address the underlying cause of disease and have developed in-depth and effective analytical methods to understand the safety of our lentiviral vector technologies and drive the field of gene therapy forward.

Founded in 2010, bluebird has the largest and deepest ex-vivo gene therapy data set in the world—setting the standard for industry. Today, bluebird continues to forge new paths, combining our real-world experience with a deep commitment to patient communities and a people-centric culture that attracts and grows a diverse flock of dedicated birds.

For more information, visit bluebirdbio.com or follow us on social media at @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 our statements regarding our projected financial position and performance in 2022 including expected cash burn and potential cash inflows, the timing and expectations for potential regulatory approvals of beti-cel and eli-cel and the associated commercial launches, and our expectations for manufacturing and validation activities for lovo-cel. Such forward-looking statements are based on historical performance and current expectations and projections about our future 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 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, particularly those identified in the risk factors discussion 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. These risks and uncertainties include, but are not limited to: the risk that regulatory approval of beti-cel and/or eli-cel will not be obtained on the timing that we expect or at all; the partial clinical hold of lovo-cel will not be resolved on the timeframe that we expect or at all; our plans and expectations with respect to our operations and financial performance, the potential commercial launches, and our ability to execute on our strategy will be negatively impacted by the ongoing COVID-19 pandemic and the effects on us and the third parties upon which we depend, including our contract manufacturing organizations and clinical trial sites. 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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