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 24, 2024

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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 2.02 Results of Operations and Financial Condition.

On March 26, 2024, bluebird bio, Inc. (the "Company") announced certain financial results for the three months and year ended December 31, 2023. When the Company files its Annual Report on Form 10-K for the year ended December 31, 2023 (the "2023 Form 10-K"), it expects to continue to report that there is substantial doubt regarding its ability to continue as a going concern. The going concern analysis is expected to be revisited when the Company files its Quarterly Report on Form 10-Q for the quarter ending March 31, 2024.

A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (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 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 4.02 Non-Reliance on Previously Issued Finance Statements or a Related Audit Report or Completed Interim Review.

In connection with the preparation of the financial statements of the Company for the year ended December 31, 2023, the Company, in consultation with its independent registered public accounting firm, Ernst & Young LLP ("EY"), identified certain accounting errors relating to the application of U.S. GAAP to certain arrangements with contract manufacturing organizations that are deemed to contain one or more leases for accounting purposes.

On March 24, 2024, the Audit Committee of the Board of Directors (the "Audit Committee") of the Company, based on the recommendation of management and after consultation with EY, concluded that the Company's previously-issued audited consolidated financial statements for each fiscal year beginning January 1, 2019 and its previously-issued unaudited interim condensed consolidated financial statements for each of the first three quarters in such years, as well as the associated earnings releases and investor presentations or other communications describing such financial statements, were materially misstated and, accordingly, should no longer be relied upon.

The Company intends to restate its consolidated financial statements as of and for the year ended December 31, 2022 in connection with the filing of its 2023 Form 10-K. Similarly, the Company will include restated unaudited financial information for each of the first three quarters of 2023 and 2022 in its 2023 Form 10-K (each such annual and quarterly period to be restated, a "Restated Period").

Specifically, the identified errors resulted from the Company's identification of embedded leases and the application of its accounting policy for the treatment of non-lease components contained in lease agreements. The Company's accounting policy required that lease and non-lease components in agreements with contract manufacturing organizations that are accounted for as leases be combined. The Company determined that it did not consistently combine such components, resulting in an estimated understatement of lease assets and lease liabilities between $100 million and $200 million in the annual Restated Period and an estimated understatement of lease assets and lease liabilities between $30 million and $125 million in each of the quarterly Restated Periods. As a result of the errors, the Company also expects to record an increase in non-cash interest expense in each Restated Period. The Company does not expect the errors to result in any impact on its cash position or revenue.

Additionally, the Company has determined that the errors resulted from the existence of a material weakness in its internal control over financial reporting that also existed during the Restated Periods and that its internal control over financial reporting was not effective as of December 31, 2023. As a result, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures were not effective as of December 31, 2023.

On March 26, 2024, the Company filed a notification of inability to timely file Form 10-K on Form 12b-25 due to additional time required for the Company to correct the errors described above and prepare restated financial statements. At this time, the Company expects to file the 2023 Form 10-K no later than April 16, 2024. However, there can be no assurance that the Company will be able to prepare restated financial statements and file the 2023 Form 10-K on the timeline anticipated, or that no additional errors will be identified.

The Company's management and Audit Committee have discussed the matters disclosed in this Current Report on Form 8-K with EY.

Cautionary Note Regarding Forward-Looking Statements

This Current Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the Company's expectations with respect to the analysis of its ability to continue as a going concern, the estimated impact of errors in the Company's previously-issued financial statements, including on its cash position and revenue, the timing of the filing of the restated financials and the Company's 2023 10-K, and the results of the Company's evaluation of its internal control over financial reporting and disclosure controls. Statements using words such as "expect", "anticipate", "believe", "may", "will" and similar terms are also forward-looking statements. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the important factors discussed under the caption "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, as updated by its subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission. Except as required by law, the Company undertakes no obligations to make any revisions to the forward-looking statements contained in this Current Report or to update them to reflect events or circumstances occurring after the date of this Current Report, whether as a result of new information, future developments or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on March 26, 2024.
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, 2024

bluebird bio, Inc.

By: /s/ Christopher Krawtschuk

Name: Christopher Krawtschuk

Title: *Chief Financial Officer, Principal Financial Officer and Principal Accounting Officer*

Exhibit 99.1

bluebird bio Reports Fourth Quarter and 2023 Annual Results and Highlights Operational Progress and 2024 Guidance

– Cash runway through Q1 2026 following announcement of a $175 million term loan facility with Hercules Capital –

– 9 patient starts to date in 2024 (7 ZYNTEGLO, 2 SKYSONA); 85 to 105 patient starts anticipated across the portfolio in 2024 –

– First government outcomes-based agreement for sickle cell disease signed with Michigan Medicaid –

– 62 qualified treatment centers (QTCs) activated –

– Full year 2023 revenue of $29.5 million with $7.8 million generated in the fourth quarter –

– Management to host conference call today, March 26, 2024 at 8:00 am ET –

SOMERVILLE, Mass. – March 26, 2024 – bluebird bio, Inc. (NASDAQ: BLUE) ("bluebird bio" or the "Company") today reported fourth quarter and annual financial results and business highlights for the year ended December 31, 2023, including recent commercial and operational progress.

"In 2023, bluebird established a validated, commercial gene therapy strategy that brought ZYNTEGLO and SKYSONA to individuals living with beta-thalassemia and cerebral adrenoleukodystrophy. Building on that foundation, today we are positioned for robust commercial uptake of LYFGENIA for sickle cell disease, with a substantial QTC network in place, favorable Medicaid coverage being established, and demonstrated strong patient demand," said Andrew Obenshain, chief executive officer, bluebird bio. "Our recent agreement with Hercules Capital meaningfully extends our cash runway, and further enables us to capitalize on our commercial head start and bring our transformative gene therapies to patients and their families. In 2024, we anticipate between 85 to 105 patient starts across our three FDA approved therapies, laying the foundation for strong revenue growth."

RECENT COMPANY HIGHLIGHTS

Up to $175 million Debt Financing with Hercules Capital

- On March 18, 2024, bluebird announced that it had entered into a five-year term loan facility with Hercules Capital. Under the terms of the agreement, the Company may draw up to $175 million, available in four tranches. The first tranche of $75 million was drawn at closing. The Company may draw upon two additional tranches of $25 million each, subject to satisfaction of certain conditions, including achievement of commercial milestones. The facility also provides for a fourth tranche of $50 million, available at the lender's discretion.
- Based on launch estimates and current business plans, and assuming three tranches totaling $125 million are executed, the transaction is projected to extend the Company's cash runway through Q1 2026.

COMMERCIAL LAUNCH UPDATES

Strong patient uptake across portfolio

- First LYFGENIA patient start imminent; multiple patients enrolled and preparing for treatment across QTC network.
- Continued strong, linear growth for ZYNTEGLO with 7 patient starts since the beginning of 2024, in addition to 20 patient starts completed for ZYNTEGLO in 2023.
- Completed 2 patient starts for SKYSONA since the beginning of 2024, in addition to 6 patient starts completed for SKYSONA in 2023.

Validated access and reimbursement strategy is driving favorable coverage landscape

- In the first quarter of 2024, bluebird signed its first Medicaid outcomes-based agreement for LYFGENIA with the state of Michigan.
- In addition to the Medicaid outcomes-based agreement, bluebird has signed four outcomes-based agreements for LYFGENIA with national commercial payer organizations and published coverage policies cover more than 200 million U.S. lives.
- Discussions are ongoing with more than 15 Medicaid agencies representing 80% of Medicaid-insured individuals with sickle cell disease in the U.S. and the Company is engaged with the Center for Medicare and Medicaid Innovation (CMMI) on its Cell and Gene Therapy Access Model demonstration.
- Timely access to ZYNTEGLO and SKYSONA has continued, with zero ultimate denials for either therapy across both Medicaid and commercial payers.

Substantial QTC footprint established

- bluebird has activated 62 QTCs for ZYNTEGLO (defined as a signed MSA); capitalizing on launch synergies, 49 centers are already receiving referrals for LYFGENIA.
- Five centers are also activated to administer SKYSONA for patients with cerebral adrenoleukodystrophy (CALD).
- The Company anticipates continued QTC network expansion across its portfolio in 2024.

LOVO-CEL CLINICAL TRIAL UPDATE

- Enrollment is ongoing for the HGB-210 study evaluating lovo-cel for patients under the age of 12. The Company anticipates enrollment to be complete in Q4 2024.

2024 GUIDANCE

- The Company anticipates 85 to 105 patient starts (cell collections) combined across all three of its FDA approved therapies (LYFGENIA, ZYNTEGLO, SKYSONA) in 2024. Consistent with previous quarters, bluebird plans to provide quarterly updates on patient starts for each of its therapies.
- Gross-to-net discounts across all three products are expected to be in the range of 20% to 25% of gross revenue in 2024 and will fluctuate based on product and payer mix, and well as utilization of outcomes-based agreements for LYFGENIA and ZYNTEGLO.
- Based on projected timelines from cell collection to infusion, the Company expects to recognize revenue from its first infusion of LYFGENIA in the third quarter of 2024.

FOURTH QUARTER AND ANNUAL FINANCIAL HIGHLIGHTS

- **Cash Position:** The Company's cash, cash equivalents and restricted cash balance was approximately $275 million, including restricted cash of approximately $53 million, as of December 31, 2023.

  Based on launch trajectory and current business plans, bluebird expects its cash and cash equivalents excluding restricted cash and assuming three tranches totaling $125 million in proceeds from its term loan facility are executed, will be sufficient to meet bluebird's planned operating expenses and capital expenditure requirements through Q1 2026.

  In the fourth quarter of 2023, the Company entered into a factoring agreement which is accelerating cash collection related to patient starts across its portfolio of approved therapies.

- **Revenue, net:** Total revenue, net was $7.8 million for the three months ended December 31, 2023, compared to $0.1 million for the three months ended December 31, 2022.

  Total revenue, net was $29.5 million for the twelve months ended December 31, 2023, compared to $3.6 million for the twelve months ended December 31, 2022. The increase of $25.9 million was primarily due to SKYSONA and ZYNTEGLO product revenue.

  For the year ended December 31, 2023, product revenues by therapy represent $16.7 million attributable to ZYNTEGLO and $12.4 million attributable to SKYSONA, with gross-to-net discounts of approximately 19% across both products.

On March 26, 2024, bluebird announced that it will restate its consolidated financial statements for 2022, and for the first three quarters of both 2022 and 2023 in its Annual Report on Form 10-K for the year ended December 31, 2023 (the "2023 Form 10-K"). The restatements relate to the identification of embedded leases and the treatment of non-lease components contained in lease agreements with contract manufacturers. As a result, the Company anticipates recording an increase in lease assets and lease liabilities, as well as an increase in non-cash interest expense in each restated period. The Company does not expect the restatement to result in any impact on its cash position or revenue. bluebird anticipates filing its 2023 Form 10-K, inclusive of the restatement no later than April 16, 2024.

The financial results included in this press release represent the most current information available to the Company's management. The Company expects that its actual results to be reported in its 2023 Form 10-K will not differ materially from the results included herein, however, these results are subject to change following the completion of the Company's financial close procedures and the audit of its consolidated financial statements for the year ended December 31, 2023.

CONFERENCE CALL DETAILS

bluebird will hold a conference call to discuss its fourth quarter and 2023 annual results and business updates today, Tuesday, March 26, 2024, at 8:00 am ET.

To access the live conference call via telephone, please register at this link to receive a dial in number and unique PIN.

The live webcast of the call may be accessed by visiting the "Events & Presentations" page within the Investors & Media section of the bluebird website at http://investor.bluebirdbio.com. A replay of the webcast will be available on the bluebird website for 90 days following the event.

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

Founded in 2010, bluebird has been setting the standard for gene therapy for more than a decade—first as a scientific pioneer and now as a commercial leader. bluebird has an unrivaled track record in bringing the promise of gene therapy out of clinical studies and into the real-world setting, having secured FDA approvals for three therapies in under two years. Today, we are proving and scaling the commercial model for gene therapy and delivering innovative solutions for access to patients, providers, and payers.

With a dedicated focus on severe genetic diseases, bluebird has the largest and deepest ex-vivo gene therapy data set in the field, with industry-leading programs for sickle cell disease, β-thalassemia and cerebral adrenoleukodystrophy. 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.

bluebird continues to forge new paths as a standalone commercial gene therapy company, 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.

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, such as statements regarding the number of anticipated patient starts across bluebird's portfolio of therapies and the timing of the first LYFGENIA patient start, expectations regarding gross-to-net discounts, the Company's anticipated cash runway, the Company's expectations regarding its ability to access future tranches of its term loan facility, the Company's expectations with respect to the commercialization of LYFGENIA, including without limitation, the potential for robust commercial uptake of LYFGENIA, the timing of revenue recognition, patient demand for the therapy, bluebird's ability to establish favorable coverage for its therapies, including its ability successfully partner with payers and its expectations for expansion of its QTC network , expectations with respect to the completion of enrollment in HGB-210, and expectations regarding the Company's restatement of certain historical financial statements and the timing for filing of its 2023 10-K. Such forward-looking statements are based on historical performance and current expectations and projections about bluebird's 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 bluebird's control and could cause bluebird's 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 for the year ended December 31, 2022, as updated by its 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: delays and challenges in bluebird's commercialization and manufacturing of its products; the internal and external costs required for bluebird'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 bluebird, and may in the future cause bluebird to use cash more quickly than it expects or change or curtail some of its plans or both; substantial doubt exists regarding bluebird's ability to continue as a going concern; bluebird'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 bluebird's assumptions; the risk that the efficacy and safety results from bluebird's prior and ongoing clinical trials will not continue or be seen in the commercial context; the risk that bluebird is not able to activate QTCs on the timeframe that it expects; the risk that the QTCs experience delays in their ability to enroll or treat patients; the risk that bluebird experiences delays in establishing operational readiness across its supply chain following approval to support treatment in the commercial context; the risk that there is not sufficient patient demand or payer reimbursement to support continued commercialization of the Company's therapies; the risk of insertional oncogenic or other safety events associated with lentiviral vector, drug product, or myeloablation, including the risk of hematologic malignancy; and the risk that bluebird's products, including LYFGENIA, will not be successfully commercialized. 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.

Investors & Media

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