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): May 9, 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 May 9, 2024, bluebird bio, Inc. (the "Company") announced its financial results for the three months ended 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on May 9, 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: May 9, 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 First Quarter 2024 Results and Highlights Operational Progress and 2024 Guidance

– First patient start (cell collection) for LYFGENIA completed –

– 15 patient starts to date in 2024 (11 ZYNTEGLO, 3 SKYSONA, 1 LYFGENIA); 85 to 105 patient starts anticipated across the portfolio in 2024 –

– First quarter 2024 net revenue of $18.6 million –

– Management to host conference call today, May 9, 2024 at 8:00 am ET –

SOMERVILLE, Mass. – May 9, 2024 – bluebird bio, Inc. (NASDAQ: BLUE) ("bluebird bio" or the "Company") today reported first quarter results and business highlights for the quarter ended March 31, 2024, including recent commercial and operational progress.

"bluebird has built a solid commercial gene therapy foundation, with an unparalleled network of qualified treatment centers (QTCs), proven access and reimbursement for patients, and demonstrated demand from both patients and providers," said Andrew Obenshain, chief executive officer, bluebird bio. "Following the completion of the first LYFGENIA patient start earlier this month, and with the continued momentum behind our ongoing launches, we believe we are poised for accelerated growth through the remainder of 2024."

COMMERCIAL LAUNCH UPDATES

Continued commercial momentum for LYFGENIA™ (lovotibeglogene autotemcel), ZYNTEGLO™ (betibeglogene autotemcel) and SKYSONA™ (elivaldogene autotemcel)

- First LYFGENIA patient start completed in May 2024.
- 14 patient starts completed for ZYNTEGLO and SKYSONA since the beginning of 2024 (11 ZYNTEGLO, 3 SKYSONA).

Validated access and reimbursement strategy is driving favorable coverage landscape

- Successfully confirmed prior authorization approval for commercial and Medicaid-insured patients for LYFGENIA.
- Multiple outcomes-based agreements in place for LYFGENIA with national commercial payer organizations; published coverage policies are in place for more than 200 million U.S. lives.
- Discussions ongoing with Medicaid agencies representing 80% of Medicaid-insured individuals with sickle cell disease in the U.S.
- 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 64 QTCs for LYFGENIA and ZYNTEGLO (defined as a signed MSA).

- Six centers are also activated to administer SKYSONA for patients with cerebral adrenoleukodystrophy (CALD).

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, as well as utilization of outcomes-based agreements for LYFGENIA and ZYNTEGLO.
- Based on projected timelines from cell collection to infusion, the Company anticipates recognizing revenue from its first infusion of LYFGENIA in the third quarter of 2024.

FIRST QUARTER FINANCIAL HIGHLIGHTS

- Cash Position: The Company's cash, cash equivalents and restricted cash balance was approximately $264 million, including restricted cash of approximately $52 million, as of March 31, 2024.

  Based on current business plans, which assumes the Company's ability to achieve certain commercial revenue targets, bluebird expects its cash and cash equivalents, excluding restricted cash and assuming the remaining two tranches totaling $50 million in proceeds from its term loan facility with Hercules Capital are executed, will be sufficient to meet bluebird's planned operating expenses and capital expenditure requirements through Q1 2026.

- **Revenue, net:** Total revenue, net was $18.6 million for the three months ended March 31, 2024, compared to $2.4 million for the three months ended March 31, 2023. The increase of $16.2 million was due to increased ZYNTEGLO product revenue.

On March 26, 2024, bluebird announced that it will restate its consolidated financial statements as of and for the year ended December 31, 2022, and for each of the first three quarters of 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. The restatement is not expected to impact the Company's cash position or revenue. As a result of the restatement, the Company is delayed in filing its 2023 Form 10-K and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 (the "Q1 2024 Form 10-Q"). The Company is continuing to work expeditiously to complete these filings.

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 Q1 2024 Form 10-Q 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 review of its consolidated financial statements for the quarter ended March 31, 2024.

CONFERENCE CALL DETAILS

bluebird will hold a conference call to discuss its first quarter 2024 results and business updates today, Thursday, May 9, 2024, at 8:00 am ET.

To participate in the conference call, please dial +1 (800) 715-9871 (U.S. and Canada) and ask to be joined into the bluebird call or provide the Conference ID 9768329.

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, 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 gross-to-net discounts for its products and the commercialization of LYFGENIA, including without limitation, the timing of revenue recognition, patient demand for the therapy, bluebird's ability to establish favorable coverage for its therapies, including its ability to successfully partner with payers, and expectations regarding the Company's restatement of certain historical financial statements and the timing for filing of its 2023 Form 10-K and Q1 2024 Form 10-Q. 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, including our Prospectus Supplement, dated December 22, 2023. These risks and uncertainties include, but are not limited to: delays and challenges in bluebird's commercialization and manufacturing of its products, including challenges in manufacturing vector for ZYNTEGLO and SKYSONA to meet current demand; 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; risks related to bluebird's loan agreement, including the risk that operating restrictions could adversely affect bluebird's ability to conduct its business, the risk that bluebird will not achieve milestones required to access future tranches under the agreement, and the risk that bluebird will fail to comply with covenants under the agreement, including with respect to required revenue levels, which could result in an event of default; 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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