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): November 14, 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 November 14, 2024, bluebird bio, Inc. (the "Company") announced its financial results for the three months ended September 30, 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 November 14, 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: November 14, 2024

bluebird bio, Inc.

By: /s/ O. James Sterling

Name: O. James Sterling

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

Exhibit 99.1

bluebird bio Reports Third Quarter 2024 Results and Highlights Operational Progress and 2024 Guidance

- 74 patient starts completed or scheduled to date in 2024 across bluebird's commercial portfolio -

- Third quarter 2024 net revenue of $10.6 million reflects quarter-to-quarter fluctuations in drug product infusions; anticipate at least $25 million of net revenue in the fourth quarter -

- Management to host conference call today, November 14, 2024 at 8:00 am ET -

SOMERVILLE, Mass. – November 14, 2024 – bluebird bio, Inc. (NASDAQ: BLUE) ("bluebird bio" or the "Company") today reported third quarter results and business highlights for the quarter ended September 30, 2024, including recent commercial and operational progress.

"Patient starts more than doubled from our second to third quarter update, providing clear evidence that our commercial launches continued to accelerate," said Andrew Obenshain, chief executive officer. "This momentum, coupled with steps we took in the third quarter to increase manufacturing capacity for ZYNTEGLO and optimize our cost structure, is propelling bluebird forward on our path to becoming a sustainable commercial gene therapy company. We remain focused on securing additional cash resources to extend our runway, which we believe would enable us to achieve this vision and reach cash flow break-even in the second half of 2025."

COMMERCIAL LAUNCH UPDATES

Continued commercial momentum across the portfolio

- 57 patient starts completed to date in 2024 (35 ZYNTEGLO, 17 LYFGENIA, 5 SKYSONA).
- 17 additional starts scheduled through the remainder of 2024.
- Evidence of strong commercial demand, with 30 patient starts already scheduled in 2025, supporting the potential for cash flow breakeven in the second half of 2025.
- More than 70 activated QTCs, with 40% having initiated or completed treatment for at least one patient.

Validated access and reimbursement strategy is driving favorable coverage landscape

- To date, more than half of all states have affirmed coverage for LYFGENIA through a preferred drug list or published coverage criteria.
- Nearly 50% of Medicaid-insured individuals with sickle cell disease in the U.S. live in a state that has already completed prior authorization approval for the use of LYFGENIA for at least one patient.
- Multiple outcomes-based agreements are published and in place for LYFGENIA with national commercial payer organizations, representing more than 200 million U.S. lives.

DATA PRESENTATIONS AT ASH 2024

Updated data from the Company's lentiviral vector (LVV) gene addition programs in patients with sickle cell disease who have a history of vaso-occlusive events and patients with beta-thalassemia who require regular blood transfusions will be presented at the 66th American Society of Hematology (ASH) Annual Meeting and

Exposition. The meeting will take place December 7-10, 2024 at the San Diego Convention Center and online.

SICKLE CELL DISEASE DATA

- **Oral Presentation [#511]:** An Update on Lovotibeglogene Autotemcel (lovo-cel) Clinical Trials for Sickle Cell Disease (SCD) and Analysis of Early Predictors of Response to Lovo-cel
- Presenting Author: Dr. Stacey Rifkin-Zenenberg (Hackensack)
- Date/Time: Sunday, December 8, 2024, 9:30 a.m. – 11:00 a.m. PT

- **Poster Presentation [#3576]:** Participants with a History of Stroke in Lovotibeglogene Autotemcel (lovo-cel) Clinical Trials
- Presenting Author: Dr. Jen Jaroscak (The Medical University of South Carolina)
- Date/Time: Sunday, December 8, 2024, 6:00 p.m. – 8:00 p.m. PT

BETA-THALASSEMIA DATA

- **Poster Presentation [#2194]:** Betibeglogene Autotemcel (beti-cel) Gene Addition Therapy results in durable Hemoglobin A (HbA) Production with up to 10 Years of Follow-Up in Participants with Transfusion-Dependent β-Thalassemia
- Presenting Author: Dr. Alexis A Thompson (Children's Hospital of Philadelphia)
- Date/Time: Saturday, December 7, 2024, 5:30 p.m. – 7:30 p.m. PT

Abstracts outlining bluebird bio's accepted data at ASH 2024 are available on the ASH conference website.

THIRD QUARTER FINANCIAL HIGHLIGHTS

- **Cash Position:** The Company's cash, cash equivalents and restricted cash balance was approximately $118.7 million, including restricted cash of approximately $48.0 million, as of September 30, 2024.

  bluebird and Hercules are engaging collaboratively as bluebird works to secure adequate cash runway to obtain additional financing and reach cash flow break-even. Based on current forecasts, which assume continued cost-saving initiatives, successfully renegotiating key contracts, and continued collaborative engagement from Hercules, we expect our existing cash and cash equivalents will enable us to fund our operations into the first quarter of 2025.

  The Company anticipates quarterly cash flow break-even in the second half of 2025, assuming it scales to approximately 40 drug product deliveries per quarter and obtains additional cash resources to extend its runway.

- **Revenue, net:** Total revenue, net was $10.6 million for the three months ended September 30, 2024, compared to $12.3 million for the three months ended September 30, 2023, driven by quarter-to-quarter variability in drug product infusions.

  Revenue for the third quarter includes revenue from LYFGENIA, following the completion of the first infusion for sickle cell disease.

bluebird previously guided to an anticipated reduction of net revenue in the third quarter; the Company now anticipates net revenue of at least $25 million in the fourth quarter 2024, as previously reported patient starts are infused.

- **Cost of Product Revenue:** Cost of product revenue was $11.8 million for the three months ended September 30, 2024, compared to $9.1 million for the three months ended September 30, 2023.

- **SG&A Expenses:** Selling, general and administrative expenses were $39.8 million for the three months ended September 30, 2024, compared to $40.8 million for the three months ended September 30, 2023. The decrease of $1.0 million was primarily driven by decrease in employee compensation, benefit, and other headcount related expenses, commercial expenses, and facility fees, partially offset by increased professional services fees.

- **R&D Expenses:** Research and development expenses were $23.2 million for the three months ended September 30, 2024, compared to $58.5 million for the three months ended September 30, 2023. The decrease of $35.3 million was primarily driven by material production shift to inventory and cost of product revenue as well as decreased employee compensation, benefit, and other headcount related expenses, consulting fees, and facility and information technology fees.

- **Net income (loss):** Net loss was $60.8 million for the three months ended September 30, 2024, compared to a net loss of $87.2 million for the three months ended September 30, 2023.

CONFERENCE CALL DETAILS

bluebird will hold a conference call to discuss its third quarter 2024 results and business updates today, Wednesday, November 14, 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.

To access the live webcast, please visit 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 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 future results of operations and financial position, including anticipated revenue for the fourth quarter; the number of anticipated patient starts across bluebird's portfolio of therapies; the Company's anticipated cash runway and path to cash flow breakeven in the second half of 2025, including the impact of continued cost-saving initiatives, bluebird's ability to successfully renegotiate key contracts, and continued collaborative engagement from Hercules, and the Company's ability to obtain additional cash resources; the Company's expectations with respect to the commercialization of its products, including without limitation, patient demand, the timing and amount of revenue recognition; and the Company's ability to establish favorable coverage for its therapies. 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, 2023, 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, 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; the risk that additional funding may not be available on acceptable terms, or at all; 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 cash and 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 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 ; 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; the risk that bluebird's products, including LYFGENIA, will not be successfully commercialized; and risks related to compliance with Nasdaq continued listing requirements. 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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bluebird bio, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except per share data)
(unaudited)

	For the three months ended September 30,		For the nine months ended September 30,	
	2024	2023	2024	2023
		(As Restated)		(As Restated)
Revenue:				
Product revenue, net	$ 10,612	$ 12,281	$ 45,274	$ 21,414
Other revenue	—	111	12	249
Total revenues	10,612	12,392	45,286	21,663
Cost of product revenue	11,781	9,126	66,591	21,335
Gross margin	(1,169)	3,266	(21,305)	328
Operating expenses:				
Selling, general and administrative	39,765	40,771	136,479	118,700
Research and development	23,174	58,501	73,408	131,536
Restructuring expenses	2,811	—	2,811	—
Total operating expenses	65,750	99,272	212,698	250,236
Gain from sale of priority review voucher, net	—	—	—	92,930
Loss from operations	(66,919)	(96,006)	(234,003)	(156,978)
Interest income	1,640	2,454	7,056	7,961
Interest expense	(5,778)	(4,311)	(16,875)	(12,331)
Other income, net	10,191	10,631	31,782	30,177
Loss before income taxes	(60,866)	(87,232)	(212,040)	(131,171)
Income tax (expense) benefit	58	—	37	80
Net loss	$ (60,808)	$ (87,232)	$ (212,003)	$ (131,091)
Net loss per share - basic	$ (0.31)	$ (0.80)	$ (1.10)	$ (1.23)
Net loss per share - diluted	$ (0.31)	$ (0.80)	$ (1.10)	$ (1.23)
Weighted-average number of common shares used in computing net loss per share - basic:	193,893	109,098	193,588	106,924
Weighted-average number of common shares used in computing net loss per share - diluted:	193,893	109,098	193,588	106,924
Other comprehensive income (loss):				
Other comprehensive income (loss), net of tax benefit (expense) of $0.0 million for the three and nine months ended September 30, 2024 and 2023	611	137	285	1,843
Total other comprehensive income (loss)	611	137	285	1,843
Comprehensive loss	$ (60,197)	$ (87,095)	$ (211,718)	$ (129,248)

bluebird bio, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except per share data)
(unaudited)

	As of September 30, 2024	As of December 31, 2023
Cash and cash equivalents	$70,651	$221,755
Restricted cash	48,001	52,842
Total assets	465,056	619,161
Total liabilities	470,842	424,624
Total stockholders' equity	(5,786)	194,537