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 7, 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 2.02 Results of Operations and Financial Condition.

On November 7, 2023, bluebird bio, Inc. (the "Company") announced its financial results for the three months ended September 30, 2023. 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 7, 2023.
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 7, 2023

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 Third Quarter 2023 Financial Results and Highlights Operational Progress

– Continued strong commercial launch for ZYNTEGLO® and SKYSONA®; 22 patient starts across both programs to date –

– Ended quarter with $227M in cash, cash equivalents, marketable securities and restricted cash –

– Company entered into advance agreement to sell priority review voucher, if granted, for $103 million; potential non-dilutive capital would strengthen cash position –

– Management to host conference call today at 8:00AM ET –

SOMERVILLE, Mass. – November 7, 2023 – bluebird bio, Inc. (NASDAQ: BLUE) ("bluebird bio" or the "Company") today reported financial results and business highlights for the third quarter ended September 30, 2023, including recent commercial and operational progress, and regulatory updates.

"We continue to see strong, linear growth for both the ZYNTEGLO and SKYSONA launches, with patients completing the treatment process, and significant demand across our established qualified treatment center network," said Andrew Obenshain, chief executive officer, bluebird bio. "Launch preparations for lovo-cel for sickle cell disease are well underway in anticipation of our December 2023 PDUFA date. In the third quarter, we accelerated the growth of our QTC network, which is one hundred percent synergistic across ZYNTEGLO and lovo-cel, and advanced conversations with payers who recognize the value of lovo-cel and have responded favorably to our innovative contract offerings. We are confident in our commercial gene therapy experience, committed to continued partnership with the sickle cell community, and excited about the opportunity to bring gene therapy to individuals living with SCD."

RECENT HIGHLIGHTS

Commercial launches of ZYNTEGLO® (betibeglogene autotemcel) and SKYSONA® (elivaldogene autotemcel)

- Continued strong, linear growth for ZYNTEGLO with 16 patient starts (cell collections) since launch. Cell collection has been completed for 6 patients for SKYSONA to date.

- In September, bluebird announced an amendment to its agreement with Lonza, which manufactures drug product for ZYNTEGLO and SKYSONA. The amended agreement enables increased manufacturing capacity for both therapies. The agreement also included modified payment terms intended to better align with the Company's business objectives.

- Value of ZYNTEGLO and SKYSONA continues to be recognized among commercial and government payers. Recently, bluebird signed outcomes-based agreements for ZYNTEGLO with Michigan and Massachusetts state Medicaid agencies. To date, the Company has received zero ultimate denials for both therapies and prior authorization approvals for drug product remain consistent at approximately two weeks across all payers.

- bluebird's qualified treatment center (QTC) network has scaled to 29 activated centers (defined as a signed master service agreement or MSA) including both adult and pediatric centers across

16 states. Of these 29 activated QTCs, four have been activated to administer SKYSONA for patients with cerebral adrenoleukodystrophy (CALD) in addition to ZYNTEGLO. The Company remains on track to scale to 40-50 activated QTCs by the end of 2023.

lovo-cel FDA Review

- On August 16, 2023, bluebird bio announced that the U.S. Food and Drug Administration (FDA) communicated that an advisory committee meeting will not be scheduled for lovotibeglogene autotemcel (lovo-cel).

- The lovo-cel Biologics Licensing Application (BLA) review remains on track. The Agency previously accepted the lovo-cel BLA for Priority Review and set a Prescription Drug User Fee Act (PDUFA) goal date of December 20, 2023.

Advance Agreement to Sell PRV

- On October 30, 2023, bluebird entered into an agreement to sell a Rare Pediatric Disease Priority Review Voucher (PRV), if received, in connection with the potential approval of lovo-cel for sickle cell disease. Under the terms of the agreement, rights to the PRV will transfer to the buyer and the Company will receive $103 million upon closing of the sale, which is contingent upon the FDA's approval of the BLA for lovo-cel and granting of the PRV. bluebird anticipates receipt of a potential PRV should lovo-cel be approved for patients with sickle cell disease ages 12 and older. Proceeds from the potential sale of the PRV are not yet reflected in the Company's cash runway.

Data Presentations at ASH 2023

Updated long-term follow-up data from the Company's gene therapy programs in sickle cell disease and beta-thalassemia will be presented at the 65th American Society of Hematology (ASH) Annual Meeting and Exposition, taking place December 9-12, 2023 at the San Diego Convention Center and online. bluebird continues to have the most mature gene therapy programs for both SCD and beta-thalassemia, presenting up to five years and up to nine years of long-term data, respectively.

- **SICKLE CELL DISEASE DATA**
  - **Oral Presentation [#1051]:** Efficacy, Safety, and Health-Related Quality of Life (HRQOL) in Patients with Sickle Cell Disease (SCD) Who Have Received lovotibeglogene autotemcel (lovo-cel) Gene Therapy: Up to 60 Months of Follow-up
  - Presenting Author: Julie Kanter, M.D., director of the UAB Adult Sickle Cell clinic, associate professor in the Division of Hematology and Oncology, and co-director of the UAB Comprehensive Sickle Cell Disease Center at the University of Alabama in Birmingham
  - Date/Time: Monday, December 11, 2023, 4:30 p.m. PT

- **BETA-THALASSEMIA DATA**
  - **Poster Presentation [#1102]:** Sustained, Efficacy, Safety, and Improved Quality of Life in Adult and Pediatric Patients with Transfusion-Dependent β-Thalassemia up to 9 Years Post Treatment with betibeglogene autotemcel (beti-cel)

- Presenting Author: Alexis A. Thompson, M.D., M.P.H., professor of pediatrics (hematology), Perelman School of Medicine, University of Pennsylvania, Philadelphia, and chief, Division of Hematology, Children's Hospital of Philadelphia
- Date/Time: Saturday, December 9, 2023, 5:30 p.m. PT

- **Poster Presentation [#2480]:** Improvement in Iron Burden in Patients with Transfusion-Dependent β-Thalassemia (TDT) Treated with betibeglogene autotemcel (beti-cel) Gene Therapy: Up to 9 Years of Follow-up
- Presenting Author: Janet L. Kwiatkowski, M.D., MSCE, professor of pediatrics (hematology), Department of Pediatrics, Perelman School of Medicine, University of Pennsylvania, Philadelphia, and director, Thalassemia Center, Children's Hospital of Philadelphia
- Date/Time: Sunday, December 10, 2023, 6:00 p.m. PT

Abstracts outlining bluebird bio's accepted data at ASH 2023 are available on the ASH conference website.

UPCOMING ANTICIPATED MILESTONES

- For lovo-cel, the FDA has set a PDUFA goal date for December 20, 2023, and if approved, the Company anticipates commercial launch in early 2024. bluebird estimates approximately 20,000 individuals living with SCD (or one-fifth of the U.S. SCD population) may be eligible for gene therapy.
- The Company is on track to scale to 40-50 activated QTCs by the end of 2023. bluebird's QTC network is designed to maximize its commercial opportunity in beta-thalassemia and to prioritize proximity to individuals with living with SCD in anticipation of a 2024 commercial launch for lovo-cel, if approved by the FDA.
- For SKYSONA, the Company continues to anticipate 5-10 patient starts this year as previously guided.

THIRD QUARTER 2023 FINANCIAL RESULTS

- **Cash Position:** The Company's cash, cash equivalents, marketable securities and restricted cash balance was approximately $227 million, as of September 30, 2023. bluebird anticipates full-year 2023 net cash burn to be in the range of $270-$300 million, as previously guided. Based on current operating plans, bluebird expects its cash, cash equivalents and marketable securities including anticipated cash flows from operations, and excluding $53 million of restricted cash, will be sufficient to meet bluebird's planned operating expenses and capital expenditure requirements into the second quarter of 2024.

- **Revenue, net:** Total revenue, net was $12.4 million for the three months ended September 30, 2023, compared to $0.1 million for the three months ended September 30, 2022. The increase of $12.3 million was primarily due to SKYSONA and ZYNTEGLO product revenue.

- **SG&A Expenses:** Selling, general and administrative expenses were $40.7 million for the three months ended September 30, 2023, compared to $33.4 million for the three months ended September 30, 2022. SG&A includes lease expense related to 50 Binney Street; however, the associated sublease income is presented in other income (expense), net. Excluding the lease

expense for 50 Binney St., SG&A expenses were $31.1 million for the three months ended September 30, 2023, compared to $24.1 million for the three months ended September 30, 2022. This increase is mainly attributable to commercial costs driven by marketing activities for ZYNTEGLO and SKYSONA in the United States and the performance of commercial readiness activities in the United States for lovo-cel, in anticipation of potential approval, as well as increased employee compensation, benefit and other headcount-related expenses, professional fees, and information technology and facility related costs in 2023. These increased costs were partially offset by decreased consulting fees.

- **R&D Expenses:** Research and development expenses were $45.5 million for the three months ended September 30, 2023, compared to $53.1 million for the three months ended September 30, 2022. The decrease of $7.6 million was primarily due to manufacturing costs related to SKYSONA and ZYNTEGLO now being included in inventory and cost of product revenue, as well as decreased employee compensation, benefit and other headcount-related expenses, license and milestone fees, and information technology and facility related costs in 2023. These decreased costs were partially offset by increased clinical costs, lab expenses, and consulting fees.

- **Net income (loss):** Net loss was $71.7 million for the three months ended September 30, 2023, compared to a net loss of $76.5 million for the three months ended September 30, 2022.

CONFERENCE CALL DETAILS

bluebird will hold a conference call to discuss third quarter financial results and commercial launch progress on Tuesday, November 7 at 8:00 am ET.

To access the call via telephone, please register at this link https://register.vevent.com/register/BIee363f414c2f4fd19da314c2b328d635 to receive a dial in number and unique PIN to access the live conference call.

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.

With a dedicated focus on severe genetic diseases, bluebird has industry-leading 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 and is establishing the commercial model for gene therapy—setting the standard for the 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.

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 the Company's financial condition, results of operations, commercial revenue and key metrics, including the expected number of patient starts, and anticipated reporting and timing thereof; anticipated cash runway; the Company's ability to obtain additional financing options to extend its cash runway; and anticipated cash burn for 2023, as well as statements regarding the Company's plans and expectations for operations, including with respect to the therapeutic potential of the Company's products and product candidates; the potential regulatory approval, including the PDUFA acceptance, and commercial launch of lovo-cel; closing of the sale of the Company's PRV, if received in connection with the potential approval of lovo-cel; expectations regarding receipt of the PRV; plans to expand manufacturing capacity; anticipated growth of its QTC network and timing thereof; the Company's ability to pursue curative gene therapies and the expected benefits for patients; and the Company's participation in upcoming events and presentations. Such forward-looking statements are based on historical performance and current expectations and projections about our 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 our control and could cause our 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 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 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 include, but are not limited to: delays and challenges in our commercialization and manufacturing of our products; the risk that we may not receive a Priority Review Voucher upon potential approval of lovo-cel or that lovo-cel may not be approved in the timeframe we anticipate or at all; we may encounter additional delays in the development of our programs, including the imposition of new clinical holds, that may impact our ability to meet our expected timelines and increase our costs; the internal and external costs required for our 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 us, and may in the future cause us to use cash more quickly than we expect or change or curtail some of our plans or both; substantial doubt exists regarding our ability to continue as a going concern; our 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 our assumptions; the risk that the efficacy and safety results from our prior and ongoing clinical trials will not continue or be seen in additional patients treated with our product candidates; the risk of insertional oncogenic or other reportable events associated with lentiviral vector, drug product, or myeloablation; the risk that any one or more of our products or product candidates, including lovo-cel, will not be successfully developed, approved or commercialized, as applicable. 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,	
	2023	2022	2023	2022
Revenue:				
Product revenue, net	$ 12,281	$ —	$ 21,414	$ 2,739
Other revenue	111	71	249	795
Total revenues	12,392	71	21,663	3,534
Cost of product revenue	10,955	—	23,895	10,056
Gross margin	1,437	71	(2,232)	(6,522)
Operating expenses:				
Selling, general and administrative	40,703	33,402	118,406	106,201
Research and development	45,463	53,149	133,881	194,864
Restructuring expenses	—	(1,699)	—	4,940
Total operating expenses	86,166	84,852	252,287	306,005
Gain from sale of priority review voucher, net	—	—	92,930	—
Income (loss) from operations	(84,729)	(84,781)	(161,589)	(312,527)
Interest income, net	2,454	383	7,958	663
Other income (expense), net	10,544	7,885	30,152	13,061
Income (loss) before income taxes	(71,731)	(76,513)	(123,479)	(298,803)
Income tax (expense) benefit	—	(7)	80	(7)
Net income (loss)	$ (71,731)	$ (76,520)	$ (123,399)	$ (298,810)
Net income (loss) per share - basic	$ (0.66)	$ (0.94)	$ (1.15)	$ (3.91)
Net income (loss) per share - diluted	$ (0.66)	$ (0.94)	$ (1.15)	$ (3.91)
Weighted-average number of common shares used in computing net income (loss) per share - basic:	109,098	81,543	106,924	76,361
Weighted-average number of common shares used in computing net income (loss) per share - diluted:	109,098	81,543	106,924	76,361
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, 2023 and 2022	137	(214)	1,843	(1,719)
Total other comprehensive income (loss)	137	(214)	1,843	(1,719)
Comprehensive income (loss)	$ (71,594)	$ (76,734)	$ (121,556)	$ (300,529)

bluebird bio, Inc.
Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	As of September 30, 2023	As of December 31, 2022
Cash, cash equivalents and marketable securities	$ 174,293	$ 181,741
Restricted cash	$ 53,022	$ 45,439
Total assets	$ 613,608	$ 554,902
Total liabilities	$ 391,072	$ 358,559
Total stockholders' equity	$ 222,536	$ 196,343