

**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, 2023

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.)

**455 Grand Union Boulevard,
Somerville, MA**
(Address of Principal Executive Offices)

02145
(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, 2023, bluebird bio, Inc. (the "Company") announced its financial results for the three months ended March 31, 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 May 9, 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: May 9, 2023

bluebird bio, Inc.

By: /s/ Christopher Krawtschuk

Name: Christopher Krawtschuk

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

bluebird bio Reports First Quarter 2023 Financial Results and Highlights Operational Progress

– *Biologics License Application (BLA) for lovo-cel for sickle cell disease submitted to FDA* –

– *First commercial infusions completed for both ZYNTEGLO® and SKYSONA®* –

– *Ended quarter with \$364M in cash, cash equivalents, marketable securities and restricted cash* –

SOMERVILLE, Mass. – May 9, 2023 – bluebird bio, Inc. (NASDAQ: BLUE) (“bluebird bio” or the “Company”) today reported financial results and business highlights for the first quarter ended March 31, 2023, including recent commercial and operational progress, and regulatory updates.

"The first quarter of 2023 saw us continue to establish and scale the commercial model for ex-vivo gene therapy in the US through the launches of ZYNTEGLO and SKYSONA and lay the foundation for revenue generation for years to come for bluebird," said Andrew Obenshain, chief executive officer, bluebird bio. "Additionally, with the submission of the lovo-cel BLA for sickle cell disease in April, bluebird has taken a pivotal step towards realizing its most significant opportunity yet -- bringing a transformative gene therapy to individuals living with sickle cell disease."

RECENT HIGHLIGHTS**lovo-cel (lovotibeglogene autotemcel) BLA Submitted**

- On April 24, 2023, bluebird bio announced it submitted its Biologics License Application (BLA) to the U.S. Food and Drug administration (FDA) for lovo-cel for patients with sickle cell disease (SCD) who are 12 years and older and have a history of vaso-occlusive events. The Company has requested Priority Review, which, if granted, would shorten the FDA's review of the application to six months from the time of filing, versus a standard review timeline of 10 months.

ZYNTEGLO® (betibeglogene autotemcel) Commercial Launch

- In the weeks since the Company's last commercial update, bluebird continues to build on the launch of ZYNTEGLO for beta-thalassemia. To date, there have been six patient starts (cell collections) for ZYNTEGLO.
- The first commercial ZYNTEGLO infusion has been completed and the Company anticipates recognizing revenue in Q2 2023.
- Payer uptake continues to be positive and to date, the Company has received zero ultimate denials for ZYNTEGLO; prior authorization approvals for drug product remain consistent at approximately 2 weeks.
- As previously communicated, patient starts remain the key commercial metric during the first year of the ZYNTEGLO launch. bluebird does not expect to provide ZYNTEGLO revenue projections for 2023.

SKYSONA® (elivaldogene autotemcel) Commercial Launch

- First commercial infusion with SKYSONA was completed in March 2023. In total, cell collection has been completed for three patients.
- Since approval, bluebird has activated three qualified treatment centers (QTCs) to administer SKYSONA for patients with cerebral adrenoleukodystrophy (CALD). Two additional QTCs on the West Coast are anticipated in 2023.

UPCOMING ANTICIPATED MILESTONES

LOVO-CEL

- The Company anticipates BLA acceptance of lovo-cel for SCD in Q2 2023.
- The Company continues to anticipate commercial launch in early 2024, if approved. bluebird estimates approximately 20,000 individuals living with sickle cell disease (or 1/5 of the SCD population in the US) may be eligible for gene therapy.

ZYNTEGLO

- The Company is on track to scale to 40-50 qualified treatment centers 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 sickle cell disease in anticipation of a 2024 commercial launch for lovo-cel, if approved by the FDA.

SKYSONA

- The Company continues to anticipate 5-10 patient starts this year as previously guided.

FIRST QUARTER 2023 FINANCIAL RESULTS

- **Cash Position:** The Company's cash, cash equivalents, marketable securities and restricted cash balance was approximately \$364 million, as of March 31, 2023. As bluebird bio launches two first-in-class gene therapies and readies its third investigational gene therapy for SCD for the commercial setting, full-year 2023 cash burn is expected to be in the range of \$270-\$300 million, as previously guided. Based on current operating plans, bluebird expects its cash, cash equivalents, restricted cash and marketable securities will be sufficient to meet bluebird's planned operating expenses and capital expenditure requirements into the fourth quarter of 2024. This runway includes approximately \$45 million of restricted cash, which is currently unavailable for use. Please see our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 for further information regarding our cash runway guidance and other financial results.
- **Revenue, net:** Total revenue, net was \$2.4 million for the three months ended March 31, 2023, compared to \$1.9 million for the three months ended March 31, 2022. The increase of \$0.4 million was primarily due to SKYSONA product revenue.
- **SG&A Expenses:** Selling, general and administrative expenses were \$37.4 million for the three months ended March 31, 2023, compared to \$36.1 million for the three months ended March 31, 2022. SG&A includes lease expense related to the 50 Binney Street however sublease income is presented in other income (expense), net. Excluding the lease expense for 50 Binney

St., selling, general and administrative expenses were \$27.8 million for the three months ended March 31, 2023, compared to \$36.1 million for the three months ended March 31, 2022. This decrease is mainly attributable to costs related to employee compensation, benefits, and other head-count related expenses.

- **R&D Expenses:** Research and development expenses were \$46.1 million for the three months ended March 31, 2023, compared to \$77.9 million for the three months ended March 31, 2022. The decrease of \$31.7 million was primarily due to decreased employee compensation, benefit and other headcount-related expenses and a decrease in research and development production costs in 2023.
- **Gain from sale of priority review voucher:** Operating expenses were offset by the one-time gain from sale of the Company's second priority review voucher, for \$92.9 million, net, in the first quarter of 2023.
- **Net income (loss):** Net income was \$21.2 million for the three months ended March 31, 2023, compared to a net loss of \$122.2 million for the three months ended March 31, 2022.

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—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.

bluebird bio, ZYNTGLO and SKYSONA are registered trademarks of bluebird bio, Inc. All rights reserved.

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, including restricted cash; and anticipated cash burn for 2023 as well as statements regarding the Company's plans and expectations for operations including expected timing relating to its regulatory approvals, plans to expand manufacturing capacity, anticipated growth of our QTC network and timing thereof, plans for future regulatory submissions, our expectations regarding the possible approval of lovo-cel by FDA, the expected timing relating to the potential acceptance and regulatory approval of our BLA for lovo-cel and the fact that a potential granting of Priority Review may shorten the FDA's review of the BLA to six

months, and the timing of commercial launch of lovo-cel, if approved. 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, 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, including risks associated with demonstrating analytical comparability with respect to our lovo-cel program; the risk that we may not realize expected cost savings from the restructuring, including the anticipated decrease in operational expenses, at the levels we expect; 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; 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 that additional insertional oncogenic or other reportable events associated with lentiviral vector, drug product, or myeloablation will be discovered or reported over time; the risk that our eli-cel, beti-cel and lovo-cel programs may be subject to further delays in their development, including but not limited to the imposition of new clinical holds; the risk that any one or more of our products or product candidates, including eli-cel and, beti-cel or 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 March 31,	
	2023	2022
Revenue:		
Product revenue, net	\$2,296	\$1,408
Other revenue	85	537
Total revenues	2,381	1,945
Cost of product revenue	3,376	8,310
Gross margin	(995)	(6,365)
Operating expenses:		
Selling, general and administrative	37,354	36,106
Research and development	46,144	77,875
Total operating expenses	83,498	113,981
Gain from sale of priority review voucher, net	92,930	—
Income (loss) from operations	8,437	(120,346)
Interest income, net	2,825	106
Other income (expense), net	9,978	(1,912)
Income (loss) before income taxes	21,240	(122,152)
Income tax (expense) benefit	—	—
Net income (loss)	\$21,240	\$(122,152)
Net income (loss) per share - basic	\$0.21	\$(1.66)
Net income (loss) per share - diluted	\$0.21	\$—
Weighted-average number of common shares used in computing net income (loss) per share - basic:	102,920	73,688
Weighted-average number of common shares used in computing net income (loss) per share - diluted:	103,303	—
Other comprehensive income (loss):		
Other comprehensive income (loss), net of tax benefit (expense) of \$0.0 million for the three months ended March 31, 2023 and 2022	984	(1,548)
Total other comprehensive income (loss)	984	(1,548)
Comprehensive income (loss)	\$22,224	\$(123,700)

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

	As of March 31, 2023	As of December 31, 2022
Cash, cash equivalents and marketable securities	\$ 318,257	\$ 181,741
Restricted cash	\$ 45,354	\$ 45,439
Total assets	\$ 692,736	\$ 554,902
Total liabilities	\$ 337,996	\$ 358,559
Total stockholders' equity	\$ 354,740	\$ 196,343