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): August 8, 2023

---

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 August 8, 2023, bluebird bio, Inc. (the "Company") announced its financial results for the three months ended June 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 August 8, 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: August 8, 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 Second Quarter 2023 Financial Results and Highlights Operational Progress

– Continued strong commercial launch for ZYNTEGLO® and SKYSONA®; 16 patient starts across both programs to date –

– Biologics License Application (BLA) for lovo-cel for sickle cell disease accepted for FDA priority review; PDUFA goal date December 20, 2023 –

– Ended quarter with $291M in cash, cash equivalents, marketable securities and restricted cash –

– Management to host conference call on Q2 earnings and commercial launch progress today August 8, 2023 at 8:00AM ET –

SOMERVILLE, Mass. – August 8, 2023 – bluebird bio, Inc. (NASDAQ: BLUE) ("bluebird bio" or the "Company") today reported financial results and business highlights for the second quarter ended June 30, 2023, including recent commercial and operational progress, and regulatory updates.

"As we approach the anniversaries of the FDA approvals of ZYNTEGLO and SKYSONA, we have continued to advance our commercial strategy and prove the model for the gene therapy field on our path to profitability," said Andrew Obenshain, chief executive officer, bluebird bio. "Additionally, with the ongoing FDA review of lovo-cel and potential approval by the end of this year, bluebird is preparing for our largest opportunity yet to impact the lives of patients and families – a gene therapy for individuals living with sickle cell disease in the US."

RECENT HIGHLIGHTS

ZYNTEGLO® (betibeglogene autotemcel) Commercial Launch

- bluebird continues to build on the launch of ZYNTEGLO for beta-thalassemia. To date, there have been 11 patient starts for ZYNTEGLO.
- To date, the Company has received zero ultimate denials from commercial or government payers for ZYNTEGLO; prior authorization approvals for drug product remain consistent at approximately two weeks.
- As previously communicated, patient starts remain the key commercial metric during the first year of the ZYNTEGLO launch.

SKYSONA® (elivaldogene autotemcel) Commercial Launch

- Cell collection has been completed for 5 patients for SKYSONA to date.
- Since approval, bluebird has activated four QTCs to administer SKYSONA for patients with cerebral adrenoleukodystrophy (CALD).

lovo-cel BLA Acceptance and Priority Review

- On June 21, 2023, bluebird bio announced that the FDA accepted for priority review its BLA for lovotibeglogene autotemcel (lovo-cel), the Company's gene therapy for individuals living with sickle cell disease (SCD). bluebird is pursuing FDA approval for lovo-cel for patients ages 12 and older who have a history of vaso-occlusive events (VOEs). The agency has set a Prescription Drug User Fee Act (PDUFA) goal date of December 20, 2023.

lovo-cel ICER Review

- In its ongoing review of the cost-effectiveness of gene therapies for sickle cell disease, the Institute for Clinical and Economic Review (ICER) determined that lovo-cel will be cost effective at a price up to $2.26 million when considering the societal perspective. bluebird anticipates setting a price for lovo-cel upon potential FDA approval.

UPCOMING ANTICIPATED MILESTONES

ZYNTEGLO

- The Company is on track to scale to 40-50 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.

SKYSONA

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

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.

SECOND QUARTER 2023 FINANCIAL RESULTS

- **Cash Position:** The Company's cash, cash equivalents, marketable securities and restricted cash balance was approximately $291 million, as of June 30, 2023. The Company anticipates full-year 2023 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, marketable securities and restricted cash, inclusive of revenue will be sufficient to meet bluebird's planned operating expenses and capital expenditure requirements into the fourth quarter of 2024. Excluding $45 million of restricted cash, which is currently unavailable for use, bluebird estimates cash runway into the second quarter of 2024. Please see our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 for further information regarding our cash runway guidance and other financial results.

- **Revenue, net:** Total revenue, net was $6.9 million for the three months ended June 30, 2023, compared to $1.5 million for the three months ended June 30, 2022. The increase of $5.4 million was primarily due to SKYSONA and ZYNTEGLO product revenue.

- **SG&A Expenses:** Selling, general and administrative expenses were $40.3 million for the three months ended June 30, 2023, compared to $36.7 million for the three months ended June 30, 2022. SG&A includes lease expense related to 50 Binney Street; however, sublease income is presented in other income (expense), net. Excluding the lease expense for 50 Binney St., SG&A expenses were $30.7 million for the three months ended June 30, 2023, compared to $28.2 million for the three months ended June 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 costs related to employee compensation, benefits, and other head-count related expenses.

- **R&D Expenses:** Research and development expenses were $42.3 million for the three months ended June 30, 2023, compared to $63.8 million for the three months ended June 30, 2022. The decrease of $21.5 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 and a decrease in information technology and facility related costs in 2023.

- **Net income (loss):** Net loss was $72.9 million for the three months ended June 30, 2023, compared to a net loss of $100.1 million for the three months ended June 30, 2022.

CONFERENCE CALL DETAILS

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

To access the call via telephone, please register at this link https://register.vevent.com/register/BI4fa1d86317c74333813f6827624e43ae 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.

bluebird bio, ZYNTEGLO 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 its QTC network and timing thereof, plans for future regulatory submissions, the expected timing for the potential PDUFA acceptance and regulatory approval of lovo-cel by FDA, 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 associates with demonstrating analytical comparability with respect to our lovo-cel program; 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 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 any one or more of our products or product candidates, including eli-cel, 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

Investors:
Courtney O'Leary, 978-621-7347
coleary@bluebirdbio.com

Media:
Jess Rowlands, 857-299-6103
Jess.rowlands@bluebirdbio.com

bluebird bio, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except per share data)
(unaudited)

	For the three months ended June 30,		For the six months ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenue:				
Product revenue, net	$6,837	$1,331	$9,133	$2,739
Other revenue	53	188	138	725
Total revenues	6,890	1,519	9,271	3,464
Cost of product revenue	9,564	1,745	12,940	10,055
Gross margin	(2,674)	(226)	(3,669)	(6,591)
Operating expenses:				
Selling, general and administrative	40,349	36,694	77,703	72,800
Research and development	42,274	63,841	88,418	141,716
Restructuring expenses	—	6,639	—	6,639
Total operating expenses	82,623	107,174	166,121	221,155
Gain from sale of priority review voucher, net	—	—	92,930	—
Income (loss) from operations	(85,297)	(107,400)	(76,860)	(227,746)
Interest income, net	2,679	174	5,504	280
Other income (expense), net	9,630	7,088	19,608	5,176
Income (loss) before income taxes	(72,988)	(100,138)	(51,748)	(222,290)
Income tax (expense) benefit	80	—	80	—
Net income (loss)	$(72,908)	$(100,138)	$(51,668)	$(222,290)
Net income (loss) per share - basic	$(0.67)	$(1.36)	$(0.49)	$(3.02)
Net income (loss) per share - diluted	$(0.67)	$(1.36)	$(0.49)	$(3.02)
Weighted-average number of common shares used in computing net income (loss) per share - basic:	108,685	73,767	105,819	73,727
Weighted-average number of common shares used in computing net income (loss) per share - diluted:	108,685	73,767	105,819	73,727
Other comprehensive income (loss):				
Other comprehensive income (loss), net of tax benefit (expense) of $0.0 million for the three and six months ended June 30, 2023 and 2022	722	43	1,706	(1,505)
Total other comprehensive income (loss)	722	43	1,706	(1,505)
Comprehensive income (loss)	$(72,186)	$(100,095)	$(49,962)	$(223,795)

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

	As of June 30, 2023	As of December 31, 2022
Cash, cash equivalents and marketable securities	$ 245,303	$ 181,741
Restricted cash	$ 45,302	$ 45,439
Total assets	$ 663,393	$ 554,902
Total liabilities	$ 374,374	$ 358,559
Total stockholders' equity	$ 289,019	$ 196,343