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): March 24, 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 March 29, 2023, bluebird bio, Inc. (the "Company") announced its financial results for the year and three months ended December 31, 2022. 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On March 24, 2023, the Company's board of directors (the "Board") appointed Richard Paulson to the Board as a Class III director, effective April 3, 2023.

Mr. Paulson is eligible to participate in the Company's Non-Employee Director Compensation Policy, including receipt of an annual retainer of $45,000 for his Board service, and an initial award, effective April 3, 2023, of (i) a stock option to purchase 7,500 shares of the Company's common stock, par value $0.01 per share ("Common Stock"), at a purchase price equal to the closing price per share of the Common Stock on the Nasdaq Global Select Market on April 3, 2023, and (ii) 4,663 restricted stock units. The stock options and restricted stock units will vest ratably over three years in annual installments.

Mr. Paulson will also enter into the Company's standard indemnification agreement for directors and officers. Mr. Paulson is not a party to any transaction with the Company that would require disclosure under Item 404(a) of Regulation S-K, and there are no arrangements or understandings between Mr. Paulson and any other persons pursuant to which he was selected as a director.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on March 29, 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: March 29, 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 Fourth Quarter and Full Year 2022 Financial Results and Highlights Operational Progress

– Continued strong commercial launch for ZYNTEGLO® and SKYSONA®; 7 patient starts (cell collections) across both programs to date –

– Update on Biologics License Application (BLA) submission for lovo-cel for sickle cell disease (SCD) –

– Management to host conference call today, March 29, 2023 at 8:00AM ET –

SOMERVILLE, Mass. – March 29, 2023 – bluebird bio, Inc. (NASDAQ: BLUE) ("bluebird bio" or the "Company") today reported financial results and business highlights for the fourth quarter and full year ended December 31, 2022 including recent commercial and operational progress, and regulatory updates.

"Following two milestone FDA approvals in 2022, bluebird is now emerging as a commercial gene therapy leader, fueled by strong momentum and uptake for both ZYNTEGLO and SKYSONA across patients, payers and providers," said Andrew Obenshain, chief executive officer, bluebird bio. "We also remain laser focused on our lovo-cel BLA for sickle cell disease. Following feedback from the FDA in February, bluebird submitted additional information related to CMC comparability analyses to the FDA in early March; we anticipate a response from the Agency within a matter of weeks. Lovo-cel is the most deeply studied gene therapy in development for sickle cell disease, with more than 50 patients treated and multiple patients followed for more than six years. We remain extremely confident in the quality of our BLA submission. Most importantly, we know that patients and their families are waiting, and we will move quickly to expedite our BLA submission, pending alignment with FDA on product comparability."

RECENT HIGHLIGHTS

lovo-cel (lovotibeglogene autotemcel) BLA Submission Progressing

- In early March, the Company responded to feedback from the FDA on vector and drug product analytical comparability evaluations completed in December 2022; bluebird expects a response from the FDA within a matter of weeks and will move quickly to expedite its BLA submission, pending alignment with FDA on product comparability.

- The Company plans to request priority review for patients 12 and older with a history of vaso-occlusive events. If approved, bluebird continues to anticipate a commercial launch in early 2024.

Momentum Continues in ZYNTEGLO® (betibeglogene autotemcel) Commercial Launch

- bluebird has made significant progress in the launch of ZYNTEGLO, with five patient starts (cell collections) for patients with beta-thalassemia to date.

- As launch continues to progress, bluebird is advancing plans to expand manufacturing capacity to meet growing projected demand.

- On average, prior authorization for the therapy remains at just two weeks, a strong indicator of payer acceptance for ZYNTEGLO; to date, there have continued to be zero ultimate denials for payer coverage.

- bluebird's qualified treatment center (QTC) network continues to scale as planned with 12 activated QTCs (defined as a signed master service agreement or MSA) and approximately 30 QTCs in the on-boarding or MSA negotiation phase; the Company remains on track to scale to 40-50 centers by the end of 2023.

- As previously announced, during ZYNTEGLO's 2023 launch year, the Company expects to report key metrics, including the number of patient starts. bluebird does not expect to provide ZYNTEGLO revenue projections for 2023.

SKYSONA® (elivaldogene autotemcel) Commercial Launch Continues on Track

- Cell collection has been completed for two patients to be treated with SKYSONA and the first commercial infusion has been completed.

- Since approval, bluebird has activated three QTCs to treat patients with cerebral adrenoleukodystrophy (CALD).

Richard Paulson, MBA appointed to bluebird bio Board of Directors

- On March 24, 2023, Richard Paulson was appointed to bluebird bio's Board of Directors, effective April 3, 2023. Mr. Paulson is currently President and Chief Executive Officer of Karyopharm Therapeutics. He was previously Executive Vice President and Chief Executive Officer of Ipsen North America, where he focused on innovative therapies and specialty care for oncology, neuroscience and rare diseases. An experienced global biotech and pharmaceutical leader, Mr. Paulson has served in a number of leadership roles across multiple continents, including general management, marketing, sales and market access.

UPCOMING ANTICIPATED MILESTONES

LOVO-CEL
- BLA submission anticipated following response from FDA on analytical comparability data in the coming weeks.
- The Company continues to anticipate commercial launch in early 2024, if approved.

ZYNTEGLO
- The Company is on track to scale to 40-50 centers by the end of 2023.

SKYSONA
- The Company remains on track for 5-10 patient starts this year as previously guided.

FOURTH QUARTER AND FULL YEAR 2022 FINANCIAL RESULTS

- **Cash Position:** The Company's cash and cash equivalents, marketable securities and restricted cash balance was approximately $227 million, as of December 31, 2022. 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, including the net proceeds from the sale of its second priority review voucher (PRV) of $93 million and net proceeds of $131 million from its public offering in January, 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 Annual Report filed on Form 10-K for further information regarding our cash runway guidance and other financial results.

- **Revenues:** Total revenue was $0.06 million for the three months ended December 31, 2022, compared to $1.6 million for the three months ended December 31, 2021. Total revenue was $3.6 million for the twelve months ended December 31, 2022, compared to $3.7 million for the twelve months ended December 31, 2021. The Company anticipates reporting commercial revenue in its Q1 2023 financial statement, as previously guided.

- **R&D Expenses:** Research and development expenses from continuing operations were $45.9 million for the three months ended December 31, 2022, compared to $79.4 million for the three months ended December 31, 2021. Research and development expenses from continuing operations were $240.8 million for the twelve months ended December 31, 2022, compared to $320.0 million for the twelve months ended December 31, 2021. The decrease in both periods were primarily due to decreased employee compensation, benefits, other head-count related expenses, information technology and facility-related costs, clinical trial costs, and laboratory costs.

- **SG&A Expenses:** Selling, general and administrative expenses from continuing operations were $30.7 million for the three months ended December 31, 2022, compared to $53.2 million for the three months ended December 31, 2021. Selling, general and administrative expenses from continuing operations were $136.9 million for the twelve months ended December 31, 2022, compared to $210.0 million for the twelve months ended December 31, 2021. The decrease in both periods were primarily due to decreased employee compensation, benefit, and other head-count related expenses and decreased commercial readiness activities due to the Company's decision to focus its efforts on the U.S. market.

- **Gain from sale of priority review voucher**: The increase in gain from sale of priority review voucher, net was related to the sale of a priority review voucher for $102 million in the fourth quarter of 2022.

- **Net Income/Loss:** Net income from continuing operations was $32.2 million for the three months ended December 31, 2022, compared to a loss of $132.3 million for the three months ended December 31, 2021. Net loss from continuing operations was $266.6 million for the twelve months ended December 31, 2022, compared to $562.6 million for the twelve months ended December 31, 2021.

CONFERENCE CALL DETAILS

bluebird will hold a conference call to discuss fourth quarter and full year 2022 financial results and operational progress on Wednesday, March 29 at 8:00 am ET.

To access the call via telephone please follow this link https://register.vevent.com/register/BI0a0b3cf9c17a46cbbabcc02f50c3f12e to register online and 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—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, 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, plans for future regulatory submissions, our expectations regarding the timing for a potential BLA submission for lovo-cel, timing of the FDA's response to our comparability analyses for lovo-cel, our plans to request priority review for lovo-cel and timing of commercial launch of lovo-cel, if approved; and 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, 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; 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.

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

	For the three months ended December 31,		For the twelve months ended December 31,	
	2022	2021	2022	2021
Revenue:				
Product revenue	$ -	$ 1,358	$ 2,739	$ 2,850
Other revenue	62	248	858	812
Total revenues	62	1,606	3,597	3,662
Operating expenses:				
Research and development	45,899	79,384	240,764	319,946
Selling, general and administrative	30,706	53,206	136,908	209,969
Cost of product revenue	22	3,682	10,077	38,857
Restructuring expenses	-	1,001	4,940	25,801
Total operating expenses	76,627	137,273	392,689	594,573
Gain from sale of priority review voucher, net	102,000	-	102,000	-
Gain (loss) from operations	25,435	(135,667)	(287,092)	(590,911)
Interest income, net	369	146	1,032	879
Other (expense) income, net	6,538	3,283	19,599	27,652
Gain (loss) before income taxes	32,342	(132,238)	(266,461)	(562,380)
Income tax (expense) benefit	(110)	(89)	(117)	(258)
Net gain (loss) from continuing operations	32,232	(132,327)	(266,578)	(562,638)
Net loss from discontinued operations	—	(22,725)	—	(256,740)
Net gain (loss)	$ 32,232	$ (155,052)	$ (266,578)	$ (819,378)
Net loss per share from continuing operations - basic and diluted	$ 0.38	$ (1.83)	$ (3.39)	$ (8.16)
Net loss per share from discontinued operations - basic and diluted	$—	$ (0.31)	-	$ (3.73)
Net loss per share - basic and diluted	$ 0.38	$ (2.14)	$ (3.39)	$ (11.89)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	85,182	72,498	78,585	68,910

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

	As of December 31, 2022	As of December 31, 2021
Cash, cash equivalents and marketable securities	$ 181,741	$ 396,617
Restricted Cash	$ 45,439	$ 45,500
Total assets	$ 554,902	$ 593,795
Total liabilities	$ 358,559	$ 219,518
Total stockholders' equity	$ 196,343	$ 374,277