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, 2022

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.)**
60 Binney Street, Cambridge, MA		**02142**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (339) 499-9300

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, 2022, bluebird bio, Inc. (the "Company") announced its financial results for the three months ended March 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 this Report on Form 8-K and 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, 2022.
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, 2022

bluebird bio, Inc.

By: /s/ Jason F. Cole

Jason F. Cole

Chief Strategy & Financial Officer, Principal Financial Officer and Principal Accounting Officer

Exhibit 99.1

bluebird bio Reports First Quarter 2022 Financial Results and Highlights Operational Progress

- BLAs for beti-cel for β-thalassemia and eli-cel for cerebral adrenoleukodystrophy, to be discussed at an FDA Advisory Committee Meeting on June 9-10, 2022 -

- Company restructuring initiated in April to reduce operating costs by 35 to 40 percent by year-end 2022 -

- Ended quarter with $312M in restricted cash, cash and cash equivalents and marketable securities -

CAMBRIDGE, Mass. – **May 9, 2022** – bluebird bio, Inc. (NASDAQ: BLUE) ("bluebird bio" or the "Company") today reported financial results and business highlights for the first quarter ended March 31, 2022, and shared recent operational progress.

"For more than a decade, bluebird bio has helped chart the path for the field of gene therapy and today, we are closer than ever before to realizing our mission of bringing potentially curative gene therapies to patients and their families," said Andrew Obenshain, chief executive officer, bluebird bio. "We have taken action to sharpen our focus and our finances, as the FDA completes its review of the beti-cel and eli-cel BLAs, and we prepare for the launch of two gene therapies in the second half of the year. In parallel, we are actively collecting the manufacturing comparability data required for lovo-cel and remain focused on submitting our BLA for sickle cell disease to the FDA in Q1 2023."

RECENT HIGHLIGHTS

BETI-CEL AND ELI-CEL

- **ADVISORY COMMITTEE MEETING ON JUNE 9-10, 2022 –** On April 13, the U.S Food and Drug Administration (FDA) confirmed its plans to review betibeglogene autotemcel (beti-cel) and elivaldogene autotemcel (eli-cel) in an FDA Cellular, Tissue and Gene Therapies Advisory Committee Meeting that will take place over two days on June 9-10, 2022. The advisory committee will discuss the efficacy and safety data supporting the benefit/risk of beti-cel and eli-cel respectively, as well as safety information relevant to both therapies. If approved, beti-cel and eli-cel would be the Company's first FDA approved therapies as an independent severe genetic disease company. An overview of the agenda was included in the Federal Register announcement posted on April 13. The full agenda will be determined by the FDA and included in briefing materials that will be posted by the FDA closer to the date of the advisory committee meeting.

LOVO-CEL

- **CONTINUED PROGRESS TOWARD BLA SUBMISSION** – bluebird bio has enrolled more than half of the patients in the HGB-210 study that will be needed to support manufacturing data requirements for the lovotibeglogene autotemcel (lovo-cel) biologics licensing application (BLA) and the Company is on track to submit a BLA to the FDA for sickle cell disease (SCD) in the first quarter of 2023. As previously communicated, the Company has treated all patients in HGB-206 Group C who will form the primary basis of efficacy for BLA submission, with the demonstration of analytical comparability and validation of the commercial manufacturing process as the key remaining actions prior to submission of the planned BLA. Enrollment and dosing for patients 18 and older are continuing in the HGB-210 study and the Company remains in active dialogue with the FDA about the resolution of the partial clinical hold for patients under 18.

COMPANY

- **RESTRUCTURING UPDATE –** On April 5, 2022, bluebird bio announced a comprehensive restructuring intended to deliver up to $160 million in cost savings over the next two years,

reduce its workforce by approximately 30% and extend its cash runway into the first half of 2023. Near-term cost savings were realized in April as bluebird began implementing the restructuring. The Company continues to evaluate additional financing options, including public or private equity financings and monetizing any priority review vouchers that may be issued upon approval of beti-cel or eli-cel.

- **NEW HEADQUARTERS MOVE –**bluebird bio has begun transitioning to its new headquarters in Assembly Row. The Company's new HQ is designed to reflect modern ways of working and estimated to result in more than $120 million in cost savings over the next six years. bluebird will maintain laboratory space and operations at 60 Binney St. in Cambridge through 2023.

UPCOMING INVESTOR EVENTS

Members of the management team will participate in the following upcoming investor conferences:

- BofA Securities 2022 Health Care Conference, Wednesday, May 11, at 3:20 p.m. PT at the Encore Hotel, Las Vegas, NV
- 2022 RBC Capital Markets Global Healthcare Conference, Tuesday, May 17, at 8:00 a.m. ET at the Intercontinental NY Barclay, New York, NY
- Goldman Sachs 43rd Annual Global Healthcare Conference, Wednesday, June 15, at 4:00 p.m. PT at the Terranea Resort, Rancho Palos Verdes, CA

To access the live webcast of bluebird bio's presentations, 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 webcasts will be available on the bluebird bio website for 90 days following the event.

UPCOMING ANTICIPATED MILESTONES

LOVO-CEL

- The Company is in active communication with the FDA to resolve the partial clinical hold and resume enrollment and treatment of patients under the age of 18.
- The Company plans to complete manufacturing of commercial drug product validation lots by mid-2022.
- The Company expects to confirm vector and drug product analytical comparability by Q4 2022.
- The Company plans to submit its BLA for lovo-cel in Q1 2023.

BETI-CEL

- The FDA has set a PDUFA goal date of August 19, 2022, for a decision on the approval of beti-cel in patients with β-thalassemia with commercial launch expected to follow in the beginning of Q4 2022 if approved.
- An FDA advisory committee meeting for beti-cel and eli-cel will be held over the course of two days on June 9-10, 2022.

ELI-CEL

- The FDA has set a PDUFA goal date of September 16, 2022, for a decision on the approval of eli-cel in patients with cerebral adrenoleukodystrophy with therapy availability expected in Q4 2022 if approved.
- An FDA advisory committee meeting for beti-cel and eli-cel will be held over the course of two days on June 9-10, 2022.
- bluebird bio is in active communication with the FDA to resolve the clinical hold and anticipates the FDA's questions may be resolved concurrent with the agency's ongoing review of the Company's BLA submission.

FIRST QUARTER 2022 FINANCIAL RESULTS

- **Cash Position:** The Company's restricted cash, cash and cash equivalents and marketable securities balance was approximately $312 million, including restricted cash of approximately $45 million, as of March 31, 2022. The full-year 2022 cash burn is expected to be less than $340 million with a 35 to 40 percent reduction in operating costs anticipated by year-end 2022.

  The Company is exploring multiple financing opportunities, including public or private equity financings and monetizing any priority review vouchers that may be issued upon approval of beti-cel or eli-cel.

- **Revenues:** Total revenue was $1.9 million for the three months ended March 31, 2022, compared to $0.9 million for the three months ended March 31, 2021.

- **R&D Expenses:** Research and development expenses from continuing operations were $77.9 million for the three months ended March 31, 2022, compared to $82.8 million for the three months ended March 31, 2021. The decrease of $4.9 million was primarily due to decreased employee compensation, benefit, and other head-count related expenses, offset by increased manufacturing costs.

- **SG&A Expenses:** Selling, general and administrative expenses from continuing operations were $36.1 million for the three months ended March 31, 2022, compared to $63.6 million for the three months ended March 31, 2021. The decrease of $27.5 million was 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 for beti-cel, eli-cel, and lovo-cel.

- **Net Loss:** Net loss from continuing operations was $122.2 million for the three months ended March 31, 2022, compared to $121.5 million for the three months ended March 31, 2021.

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 clinical 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, as well as statements regarding the Company's plans and expectations for operations including expected timing relating to its manufacturing plans, regulatory approvals and commercial launches, potential cost-savings from our restructuring, expected reductions of operating expenses, our expectations that the cost savings from the restructuring will extend our cash runway into the first half of 2023, and our expectations regarding the timing for a potential BLA submission for lovo-cel, and anticipated FDA approval of the BLAs for beti-cel and eli-cel. 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: 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 or delays in resolving existing 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, may be higher than expected which may 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 eli-cel and/or beti-cel may not be approved within the priority review timeframe or at all; the risk that any one or more of our product candidates, including eli-cel and/or beti-cel, will not be successfully developed, approved or commercialized. 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,	
	2022	**2021**
Revenue:		
Product revenue	$ 1,408	$ 724
Other revenue	537	170
Total revenues	1,945	894
Operating expenses:		
Research and development	77,875	82,843
Selling, general and administrative	36,106	63,569
Cost of product revenue	8,310	576
Total operating expenses	122,291	146,988
Loss from operations	(120,346)	(146,094)
Interest income, net	106	355
Other (expense) income, net	(1,912)	24,301
Loss before income taxes	(122,152)	(121,438)
Income tax (expense) benefit		(66)
Net loss from continuing operations	(122,152)	(121,504)
Net loss from discontinued operations	—	(84,304)
Net loss	$ (122,152)	$ (205,808)
Net loss per share from continuing operations—basic and diluted	$ (1.66)	$ (1.81)
Net loss per share from discontinued operations—basic and diluted	$ —	$ (1.26)
Net loss per share—basic and diluted	$ (1.66)	$ (3.07)
Weighted-average number of common shares used in computing net loss per share—basic and diluted	73,688	66,976

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

	As of March 31, 2022	As of December 31, 2021
Cash, cash equivalents and marketable securities	$ 266,637	$ 396,617
Total assets	$ 491,071	$ 593,795
Total liabilities	$ 227,812	$ 219,518
Total stockholders' equity	$ 263,259	$ 374,277