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 4, 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 March 4, 2022, bluebird bio, Inc. (the "Company") announced its financial results for the year and three months ended December 31, 2021. 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On March 4, 2022, the Company announced that its board of directors (the “Board”), upon the recommendation of the Board’s nominating and corporate governance committee, appointed Charlotte Jones-Burton, MD, MS to the Board as a Class I director, effective March 7, 2022. Dr. Jones-Burton was also appointed to serve on the nominating and corporate governance committee of the Board.

In connection with this appointment, on March 7, 2022, the Company will grant Dr. Jones-Burton 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 March 7, 2022. Dr. Jones-Burton will also be granted on March 7, 2022 restricted stock units for 4,663 shares of Common Stock. The stock options and restricted stock units will vest ratably over three years in annual installments.

Dr. Jones-Burton 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 Dr. Jones-Burton and any other persons pursuant to which she 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 4, 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: March 4, 2022

bluebird bio, Inc.

By: /s/ Gina Consylman

Gina Consylman

Chief Financial Officer and Principal Financial Officer

Exhibit 99.1

bluebird bio Reports Fourth Quarter and Full Year 2021 Financial Results, Highlights Operational Progress and Provides Corporate Update

- The Company's first two gene therapies, beti-cel for β-thalassemia and eli-cel for cerebral adrenoleukodystrophy, under review by the FDA -

- lovo-cel BLA submission for sickle cell disease remains on track for Q1 2023 -

- Ended year with $442M in restricted cash, cash and cash equivalents and marketable securities -

CAMBRIDGE, Mass. – **March 4, 2022** – 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, 2021, shared recent operational progress, and provided a corporate update.

"2022 is set up to be a landmark year for bluebird bio, with LVV gene therapies for β-thalassemia and cerebral adrenoleukodystrophy under review by the U.S. Food and Drug Administration (FDA) and plans to submit a Biologics License Application (BLA) for lovo-cel for sickle cell disease (SCD) early next year," said Andrew Obenshain, CEO, bluebird bio. "Underscoring these significant milestones is a continued focus on commercialization and financial discipline to enable the delivery of these transformative therapies to patients and their families."

RECENT HIGHLIGHTS

LOVO-CEL

- **UPDATE ON PARTIAL CLINICAL HOLD FOR PATIENTS UNDER THE AGE OF 18** – Today, bluebird bio provided an update on the FDA's partial clinical hold for the lovotibeglogene autotemcel (lovo-cel) gene therapy clinical program for patients under the age of 18 with SCD. As previously communicated, in January 2022, bluebird bio received questions from the FDA related to the partial clinical hold. Following review of the questions from the FDA and an assessment of the timeline for manufacturing drug product lots and collecting analytical comparability data in the HGB-210 study, bluebird bio is reaffirming plans to submit the BLA for lovo-cel in Q1 2023. The Company continues to work with regulators to resume treating patients under the age of 18. In the meantime, the Company is collecting comparability data from drug product lots manufactured for adult patients in the HGB-210 study. As previously communicated, bluebird bio 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 Company's commercial manufacturing process as the key remaining actions prior to submission of the planned BLA.

- **HGB-206 FINAL INFUSION** – Today, bluebird bio announced the completion of the final patient infusion in the HGB-206 study, the ongoing Phase 1/2 open-label study designed to evaluate the efficacy and safety of lovo-cel for sickle cell disease. A total of 45 patients have been treated with lovo-cel in the HGB-206 study across three treatment cohorts: Groups A (n=7), B (n=2) and C (n=36).

- **DATA AT ASH AND PUBLISHED IN THE NEW ENGLAND JOURNAL OF MEDICINE** – On December 12, 2021, at the 63rd American Society of Hematology (ASH) Annual Meeting, bluebird bio presented new data showing a complete elimination of severe vaso-occlusive events (VOEs) through up to 36 months of follow-up in 25 patients who had a history of at least four severe

VOEs and at least six months follow-up in Group C of its ongoing Phase 1/2 HGB-206 study of lovo-cel for patients with SCD. The safety data presented remain consistent with the known side effects of autologous hematopoietic stem cell collection, myeloablative single-agent busulfan conditioning and underlying SCD. Select data from the Group C cohort of the HGB-206 study were simultaneously published in The New England Journal of Medicine (NEJM).

BETI-CEL

- **BETI-CEL BLA ACCEPTANCE AND PRIORITY REVIEW -** On November 22, 2021, bluebird bio announced that the FDA accepted for priority review its BLA for betibeglogene autotemcel (beti-cel), the Company's potentially curative gene therapy for adult, adolescent and pediatric patients with β-thalassemia across all genotypes who require regular red blood cell (RBC) transfusions. On January 18, 2022, the FDA extended the review period for the BLA and revised the Prescription Drug User Fee Act (PDUFA) goal date to August 19, 2022. Under priority review, bluebird would be eligible to receive a priority review voucher upon potential approval of beti-cel in 2022.

- **DATA AT ASH AND PUBLISHED IN THE NEW ENGLAND JOURNAL OF MEDICINE** - On December 11, 2021, at the 63rd ASH Annual Meeting, bluebird bio presented new data showing that adult and pediatric patients living with β-thalassemia who require regular RBC transfusions can produce normal or near-normal levels of total hemoglobin and continue to remain transfusion-free, and achieve stable iron markers, through up to seven years of follow-up in the ongoing long-term follow-up study (LTF-303) of beti-cel. In the safety data presented there were zero deaths or vector-derived replication-competent lentivirus, and no events of insertional oncogenesis or malignancy in LTF-303. The majority of AEs and SAEs were unrelated to beti-cel and consistent with the known side effects of HSC collection and busulfan conditioning regimen. Data from the pivotal HGB-207 Northstar-2 study were also simultaneously published in an original article in the NEJM.

ELI-CEL

- **ELI-CEL CLINICAL HOLD -** The Company remains in communication with the FDA regarding the clinical hold. The FDA has notified the Company that the clinical hold on the elivaldogene autotemcel (eli-cel) program will remain in place and requested additional information about safety events and monitoring in the eli-cel clinical program.

- **ELI-CEL BLA ACCEPTANCE AND PRIORITY REVIEW -** On December 17, 2021, bluebird bio announced that the FDA accepted for priority review its BLA for eli-cel, the Company's gene therapy for cerebral adrenoleukodystrophy in patients less than 18 years of age. On January 18, 2022, the FDA extended the review period for the BLA and revised the PDUFA goal date to September 16, 2022. Under priority review, bluebird would be eligible to receive a priority review voucher upon potential approval of eli-cel in 2022.

COMPANY

- **NEW BOARD OF DIRECTORS APPOINTMENT –** Today, bluebird bio announced the appointment of Charlotte Jones-Burton, M.D., M.S., to its Board of Directors. Dr. Jones-Burton is Senior Vice President, Product Development and Strategy at Chinook Therapeutics, a clinical-stage biotechnology company discovering, developing and commercializing precision medicines for rare, severe chronic kidney diseases. With more than 20 years of experience as a clinical development leader, internal medicine and nephrology physician and academician, Dr. Jones-Burton is dedicated to creating healthier communities through drug development, patient advocacy and people engagement. Dr. Jones-Burton earned a medical degree and Master of Science degree in Epidemiology and Preventive Medicine, with a concentration in Clinical

Research, from the University of Maryland School of Medicine. Her postgraduate training included an internal medicine residency and a nephrology fellowship at the University of Maryland Medical Systems.

UPCOMING ANTICIPATED MILESTONES

LOVO-CEL

- The Company is in active communication with the FDA to resolve the partial clinical hold and resume treating 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 is on track 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 mid-2022 if approved.
- bluebird bio anticipates 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 commercial launch expected to follow by the end of 2022 if approved.
- bluebird bio anticipates 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.

FOURTH QUARTER AND FULL YEAR 2021 FINANCIAL RESULTS

- **Cash Position:** The Company's restricted cash, cash and cash equivalents and marketable securities balance was approximately $442 million, including restricted cash of approximately $46 million, as of December 31, 2021. The full-year 2022 cash burn is expected to be less than $400 million. The Company's expectation to generate operating losses and negative operating cash flows in the future and the need for additional funding to support its planned operations raise substantial doubt regarding its ability to continue as a going concern for a period of one year after the date that its consolidated financial statements for the year ended December 31, 2021 are issued.

  The Company is exploring multiple financing opportunities, including plans for the sale of priority review vouchers, which the Company would be eligible to receive upon potential approval of beti-cel and eli-cel in 2022, while focusing on further cost efficiencies.

- **Revenues:** Total revenue from continuing operations was $1.6 million and $3.7 million for the three and twelve months ended December 31, 2021, respectively. The Company did not recognize revenue from continuing operations in 2020.

- **R&D Expenses:** Research and development expenses from continuing operations were $79.4 million for the three months ended December 31, 2021, compared to $58.8 million for the three

months ended December 31, 2020. Research and development expenses were $319.9 million for the twelve months ended December 31, 2021, compared to $319.3 million for the twelve months ended December 31, 2020.

- **SG&A Expenses:** Selling, general and administrative expenses from continuing operations were $53.2 million for the three months ended December 31, 2021, compared to $80.6 million for the three months ended December 31, 2020. Selling, general and administrative expenses were $210.0 million for the twelve months ended December 31, 2021, compared to $240.0 million for the twelve months ended December 31, 2020.

- **Net Loss:** Net loss from continuing operations was $132.3 million for the three months ended December 31, 2021, compared to $136.3 million for the three months ended December 31, 2020. Net loss from continuing operations was $562.6 million for the twelve months ended December 31, 2021, compared to $561.1 million for the twelve months ended December 31, 2020.

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.

bluebird bio is a trademark of bluebird bio, Inc.

Forward-Looking Statements
This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation 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; the Company's plans and expectations for the timing of BLA submissions; the Company's plans to confirm vector and drug product analytical comparability; the timing of expected FDA advisory committee meetings; and the expectations for being granted any priority review voucher upon approval of any BLA . Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that the Company may not be able to execute an orderly wind down of European operations with the timing or at a cost that we anticipated; the risk that additional insertional oncogenic or other safety events associated with lentiviral vector, drug product, or myeloablation will be discovered or reported over time; the risk that the FDA may impose a clinical hold on additional programs utilizing lentiviral vectors; the risk that we may not address the FDA's concerns regarding eli-cel quickly or at all; the risk that the FDA may require additional information, testing, or monitoring that results in a delay to our

regulatory submission plans including our BLAs for lovo-cel, beti-cel and eli-cel; the risks that we may not achieve the expected benefits of a separation, and a separation could harm our business, results of operations and financial condition; dedicated financial and/or strategic funding sources may not be available on favorable terms; the risk that we are unable to realize the intended benefits of resizing and reshaping our workforce; the COVID-19 pandemic and resulting economic conditions will have a greater impact on the Company's operations and plans than anticipated; that preliminary positive efficacy and safety results from our prior and ongoing clinical trials will not continue or be repeated in our ongoing or future clinical trials; the risk that the current or planned clinical trials of our product candidates will be insufficient to support regulatory submissions or marketing approval in the United States; and the risk that any one or more of our product candidates, will not be successfully developed, approved or commercialized. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and bluebird bio undertakes no duty to update this information unless required by law.

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 December 31,		For the twelve months ended December 31,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Product revenue	$ 1,358	$ —	$ 2,850	$ —
Other revenue	248	—	812	—
Total revenues	1,606	—	3,662	—
Operating expenses:				
Research and development	79,384	58,815	319,946	319,309
Selling, general and administrative	53,206	80,572	209,969	239,950
Cost of product revenue	3,682	—	38,857	—
Restructuring expense	1,001	—	25,801	—
Total operating expenses	137,273	139,387	594,573	559,259
Loss from operations	(135,667)	(139,387)	(590,911)	(559,259)
Interest income, net	146	641	879	5,770
Other income (expense), net	3,283	2,678	27,652	(6,881)
Loss before income taxes	(132,238)	(136,068)	(562,380)	(560,370)
Income tax (expense) benefit	(89)	(253)	(258)	(686)
Net loss from continuing operations	(132,327)	(136,321)	(562,638)	(561,056)
Net loss from discontinued operations	(22,725)	(63,553)	(256,740)	(57,639)
Net loss	$ (155,052)	$ (199,874)	$ (819,378)	$ (618,695)
Net loss per share from continuing operations—basic and diluted	$ (1.83)	$ (2.05)	$ (8.16)	$ (9.02)
Net loss per share from discontinued operations—basic and diluted	$ (0.31)	$ (0.96)	$ (3.73)	$ (0.93)
Net loss per share—basic and diluted:	$ (2.14)	$ (3.01)	$ (11.89)	$ (9.95)
Weighted-average number of common shares used in computing net loss per share—basic and diluted:	72,498	66,395	68,190	62,178

bluebird bio, Inc.
Condensed Consolidated Balance Sheet Data
(in thousands, except per share data)
(unaudited)

	As of December 31, 2021	As of December 31, 2020
Cash, cash equivalents and marketable securities	$ 396,617	$ 741,673
Total assets	$ 593,795	$ 1,781,252
Total liabilities	$ 219,518	$ 426,196
Total stockholders' equity	$ 374,277	$ 1,355,056