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 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.)**

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. ☐

Results of Operations and Financial Condition.

On August 4, 2022, bluebird bio, Inc. (the "Company" or "bluebird bio") announced its financial results for the three months ended June 30, 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On August 4, 2022, the Company announced that Thomas J. Klima, 50, is being appointed as bluebird bio's Chief Commercial and Operating Officer, effective August 8, 2022. Mr. Klima has served as bluebird bio's Chief Commercial Officer since May 2021. Prior to joining bluebird bio, Mr. Klima served as Chief Commercial Officer at Gamida Cell Ltd. from January 2019 to December 2020, where he led the strategic vision and commercial growth transforming its R&D organization to a commercially ready company. In 2018, Mr. Klima served as senior vice president of global commercial planning and operations at Atara Biotherapeutics. From 2015 to 2017, Mr. Klima served as senior vice president and chief commercial officer at Navidea Biopharmaceuticals Ltd. (acquired by Cardinal Health). Mr. Klima received a B.A. in Business Administration and Marketing from Western State College.

There are no (i) family relationships, as defined in Item 401 of Regulation S-K, between Mr. Klima and any of bluebird bio’s executive officers or directors, or any person nominated to become a director or executive officer, (ii) arrangements or understandings between Mr. Klima and any other person pursuant to which Mr. Klima was appointed as Chief Commercial and Operating Officer of bluebird bio or (iii) transactions in which Mr. Klima has an interest requiring disclosure under Item 404(a) of Regulation S-K.

In connection with Mr. Klima's appointment as Chief Commercial and Operating Officer, the Compensation Committee of the Company's Board of Directors approved an increase to Mr. Klima's annual base salary to $460,000 from $422,000. In addition, Mr. Klima will receive (i) a stock option to purchase 22,000 shares (the "Option") of the Company's common stock, par value $0.01 per share ("Common Stock"), and (ii) 11,000 restricted stock units ("RSUs") on September 1, 2022 (the "Grant Date"). The Option will have an exercise price per share equal to the closing price per share of the Common Stock on the NASDAQ Global Select Market on the Grant Date and 25% shall vest and become exercisable on the first anniversary of the Grant Date and in equal installments over the following three years of Mr. Klima's continuous service thereafter. The RSUs shall vest as follows, provided that Mr. Klima continues his employment through the applicable vesting date: 25% on the first anniversary of the Grant Date and in three equal annual installments for the following three years on the anniversaries of the Grant Date.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on August 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: August 4, 2022

bluebird bio, Inc.

By: /s/ Jason F. Cole

Name: Jason F. Cole

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

Exhibit 99.1

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

- beti-cel for beta-thalassemia PDUFA goal date is set for August 19, 2022 -

- eli-cel for cerebral adrenoleukodystrophy PDUFA goal date is set for September 16, 2022 -

- Ended quarter with $218M in restricted cash, cash and cash equivalents and marketable securities -

SOMERVILLE, Mass. – **August 4, 2022** – bluebird bio, Inc. (NASDAQ: BLUE) ("bluebird bio" or the "Company") today reported financial results and business highlights for the second quarter ended June 30, 2022, and shared recent operational progress.

"The second quarter marked significant progress for bluebird bio and a precedent-setting moment for the field of gene therapy," said Andrew Obenshain, chief executive officer, bluebird bio. "With the FDA advisory committee's unanimous support for beti-cel and eli-cel for their target indications, we are now laser-focused on commercial readiness, and if approved, we anticipate launching both therapies in the fourth quarter of this year. Additionally, this quarter we advanced the remaining CMC steps ahead of our lovo-cel BLA submission, and we remain on track to submit the BLA in the first quarter of next year."

RECENT HIGHLIGHTS

BETI-CEL

- **UNANIMOUS POSITIVE VOTE AT FDA ADVISORY COMMITTEE MEETING –** On June 10, the U.S. Food and Drug Administration's (FDA) Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) voted (13-0) that the benefits of betibeglogene autotemcel (beti-cel) gene therapy outweigh the risks for people with beta-thalassemia who require regular red blood cell transfusions. If approved, beti-cel will be the first ex-vivo LVV gene therapy available in the U.S.

- **ICER REVIEW –** The Institute for Clinical and Economic Review (ICER) completed its review of beti-cel for people with beta-thalassemia and determined in its final report that beti-cel will be cost effective at a price up to $3.0 million. bluebird anticipates setting a price for beti-cel upon potential FDA approval.

ELI-CEL

- **UNANIMOUS POSITIVE VOTE AT FDA ADVISORY COMMITTEE MEETING –** On June 9, the FDA CTGTAC voted (15-0) that the benefits of elivaldogene autotemcel (eli-cel) gene therapy outweigh the risks for the treatment of any sub-population of children with early active cerebral adrenoleukodystrophy (CALD). If approved, eli-cel will be the first and only gene therapy for the treatment of early active CALD, a rare neurodegenerative disease that primarily affects young children and leads to irreversible loss of neurologic function and death.

LOVO-CEL

- **CONTINUED PROGRESS TOWARD BLA SUBMISSION** – bluebird bio remains on track to submit a biologics licensing application (BLA) to the FDA for lovotibeglogene autotemcel (lovo-cel) for sickle cell disease 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. This quarter, the Company completed manufacturing of commercial drug product validation lots, marking significant progress on CMC requirements and final steps to BLA submission. Additionally, bluebird completed enrollment of all patients in the HGB-210 study necessary to support manufacturing data requirements for the BLA submission. The remaining step prior to BLA submission is completion of vector and drug product analytical comparability, which the Company expects to complete in the fourth quarter of 2022.

The Company remains in active dialogue with the FDA about the resolution of the partial clinical hold for patients under 18. The Company is continuing to enroll and treat patients 18 and older in the HGB-210 study.

COMPANY

- **TOM KLIMA APPOINTED CHIEF COMMERCIAL & OPERATING OFFICER –** Effective August 8, Tom Klima will serve as Chief Commercial & Operating Officer. Klima joined bluebird in May 2021 as Chief Commercial Officer to hone the Company's commercial strategy and oversee launch execution plans for its gene therapy portfolio. His new role reflects expanded responsibilities for program management and patient supply chain in addition to sales, marketing and market access.

UPCOMING INVESTOR EVENT

Members of the management team will participate in the 2022 Wedbush PacGrow Virtual Healthcare Conference, Wednesday, August 10, at 9:10 a.m. ET as part of the panel titled Miss Con-GENE-iality - Updates in Gene Tx.

UPCOMING ANTICIPATED MILESTONES

BETI-CEL

- The FDA has set a PDUFA goal date for August 19, 2022, and if approved, the Company anticipates first apheresis in the fourth quarter of 2022.
- beti-cel is being reviewed under Priority Review for the treatment of beta-thalassemia in patients requiring regular red blood cell transfusions. bluebird bio anticipates receiving a Priority Review Voucher (PRV) upon potential approval of beti-cel.

ELI-CEL

- The FDA has set a PDUFA goal date of September 16, 2022, and if approved, the Company anticipates therapy availability in the fourth quarter of 2022.
- eli-cel is being reviewed under Priority Review for the treatment of cerebral adrenoleukodytrophy in patients less than 18 years of age who do not have an available and willing human leukocyte antigen (HLA)-matched sibling hematopoietic stem cell (HSC) donor. bluebird bio anticipates receiving a PRV upon potential approval of eli-cel.
- bluebird bio is in active communication with the FDA to resolve the eli-cel clinical hold and anticipates the FDA's questions may be resolved concurrent with the agency's ongoing review of the Company's BLA submission.

LOVO-CEL

- The Company is in active communication with the FDA to resolve the lovo-cel partial clinical hold and resume enrollment and treatment of patients under the age of 18.

- The Company expects to complete vector and drug product analytical comparability in the fourth quarter of 2022.
- The Company plans to submit its BLA for lovo-cel in Q1 2023.

SECOND QUARTER 2022 FINANCIAL RESULTS

- **Cash Position:** The Company's restricted cash, cash and cash equivalents and marketable securities balance was approximately $218 million, including restricted cash of approximately $45 million, as of June 30, 2022. The full-year 2022 cash burn is expected to be less than $340 million.

  As of today, the Company has raised approximately $24.7 million in gross proceeds through its At-the-Market (ATM) equity facility. Of this $24.7 million, $8.0 million in net proceeds were realized in the second quarter and are reflected in the restricted cash, cash and cash equivalents and marketable securities balanced as of June 30, 2022. The Company is exploring additional 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 $1.5 million for the three months ended June 30, 2022, compared to $0.1 million for the three months ended June 30, 2021.

- **R&D Expenses:** Research and development expenses from continuing operations were $63.8 million for the three months ended June 30, 2022, compared to $84.6 million for the three months ended June 30, 2021. The decrease of $20.8 million was primarily due to decreased employee compensation, benefits, other head-count related expenses, information technology and facility-related costs, lab expenses and clinical trial costs. These decreased costs were partially offset by increased manufacturing costs.

- **SG&A Expenses:** Selling, general and administrative expenses from continuing operations were $36.7 million for the three months ended June 30, 2022, compared to $55.0 million for the three months ended June 30, 2021. The decrease of $18.3 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. These decreased costs were partially offset by increased information technology and facility-related costs due to the addition of the Company's office lease in Somerville, Massachusetts.

- **Net Loss:** Net loss from continuing operations was $100.1 million for the three months ended June 30, 2022, compared to $155.8 million for the three months ended June 30, 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.

bluebird bio is a trademark of bluebird bio, Inc.

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, and anticipated cash burn for 2022, as well as statements regarding the Company's plans and expectations for operations including expected timing relating to its regulatory approvals, commercial launches including the initiation of patient apheresis in the commercial context following potential approval, expectations regarding the price of any therapy if approved by the FDA, plans for future regulatory submissions, expectations regarding the timing of completion of vector and drug product analytical comparability for lovo-cel, expectations regarding the receipt of any Priority Review Vouchers upon potential approval of beti-cel or eli-cel, and our expectations regarding the timing for a potential BLA submission for lovo-cel, anticipated PDUFA goal dates 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 June 30,		For the six months ended June 30,	
	2022	2021	2022	2021
Revenue:				
Product revenue	$ 1,331	$ —	$ 2,739	$ 724
Other revenue	188	143	725	313
Total revenues	1,519	143	3,464	1,037
Operating expenses:				
Research and development	63,841	84,645	141,716	167,488
Selling, general and administrative	36,694	54,984	72,800	118,553
Cost of product revenue	1,745	15,215	10,055	15,791
Restructuring expenses	6,639	—	6,639	—
Total operating expenses	108,919	154,844	231,210	301,832
Loss from operations	(107,400)	(154,701)	(227,746)	(300,795)
Interest income, net	174	218	280	573
Other (expense) income, net	7,088	(1,274)	5,176	23,027
Loss before income taxes	(100,138)	(155,757)	(222,290)	(277,195)
Income tax (expense) benefit	—	(216)	—	(282)
Net loss from continuing operations	(100,138)	(155,973)	(222,290)	(277,477)
Net loss from discontinued operations	—	(85,729)	—	(170,033)
Net loss	$ (100,138)	$ (241,702)	$ (222,290)	$ (447,510)
Net loss per share from continuing operations - basic and diluted	$ (1.36)	$ (2.31)	$ (3.02)	$ (4.13)
Net loss per share from discontinued operations - basic and diluted	$ —	$ (1.27)	$ —	$ (2.53)
Net loss per share - basic and diluted	$ (1.36)	$ (3.58)	$ (3.02)	$ (6.66)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	73,767	67,487	73,727	67,233

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

	As of June 30, 2022	As of December 31, 2021
Cash, cash equivalents and marketable securities	$ 173,150	$ 396,617
Total assets	$ 573,592	$ 593,795
Total liabilities	$ 393,476	$ 219,518
Total stockholders' equity	$ 180,116	$ 374,277