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 5, 2021

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 5, 2021, bluebird bio, Inc. ("bluebird" or the "Company") announced its financial results for the three months ended March 31, 2021. A copy of the press release is being furnished as Exhibit 99.1 to this 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 May 5, 2021, bluebird announced the appointment of Thomas J. Klima as Chief Commercial Officer, Severe Genetic Disease, effective May 10, 2021 (the "Effective Date").

Prior to joining bluebird Mr. Klima, age 49, 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). Before that, Mr. Klima served as head of sales and commercial operations at Algeta U.S. (acquired by Bayer Healthcare) from 2012 to 2015. Before Algeta, he held various commercial leadership positions at Dendreon from 2009 to 2012. Mr. Klima began his pharmaceutical career at Eli Lilly where he held several positions of increasing responsibility from 2000 to 2009. Mr. Klima received a B.A. in Business Administration and Marketing from Western State College.

There are no family relationships between Mr. Klima and any director, executive officer or person nominated or chosen by bluebird to become a director or executive officer of bluebird within the meaning of Item 401(d) of Regulation S-K under the U.S. Securities Act of 1933 ("Regulation S-K"). Since the beginning of bluebird's last fiscal year, bluebird has not engaged in any transaction in which Mr. Klima had a direct or indirect material interest within the meaning of Item 404(a) of Regulation S-K.

In connection with Mr. Klima's appointment as Chief Commercial Officer, Severe Genetic Disease, the Company and Mr. Klima entered into an employment agreement (the "Employment Agreement"), dated April 20, 2021 and effective as of the Effective Date. Pursuant to the terms of his Employment Agreement, Mr. Klima is entitled to an initial annual base salary of $400,000 per year, and an annual discretionary cash bonus of 45% of Mr. Klima's then-current base salary. Mr. Klima's Employment Agreement also provides that, subject to approval by the Board of Directors of the Company (the "Board") (or a committee thereof), and as an inducement material to Mr. Klima entering into employment with the Company, pursuant to Nasdaq Rule 5635(c)(4), Mr. Klima shall be granted (i) a stock option to purchase 50,000 shares of the Company's common stock (the "Option"), and (ii) 25,000 restricted stock units ("RSUs"). The Option shall have an exercise price per share equal to the closing price per share on the grant date and 25% shall vest and become exercisable on the first anniversary of the Effective Date, and in equal monthly installments over the following 3 years of 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 date of grant and in three equal annual installments for the following three years on the anniversaries of the date of grant. In the event that Mr. Klima is terminated without Cause (as defined in the Employment Agreement) or resigns for Good Reason (as defined in the Employment Agreement) prior to a Change in Control (as defined in the Employment Agreement), Mr. Klima will be entitled to severance in the form of salary continuation for twelve months at his then-current base salary and will also be eligible for the continuation of Bluebird-subsidized medical and dental benefits for up to twelve months. In the event that he is terminated without Cause or resigns for Good Reason within one year following a Change of Control, Mr. Klima will be entitled to severance payable in a lump sum equal to twelve months of his then-current base salary, his target annual incentive compensation, the continuation of bluebird-subsidized medical and dental benefits for up to twelve months, and the acceleration of vesting of 100% of his outstanding unvested equity awards. Mr. Klima will also be eligible for all other compensation and benefit plans available to bluebird's employees.

The foregoing description of Mr. Klima's Employment Agreement is only a summary and it is qualified in its entirety by the Employment Agreement, a copy of which the Company expects to file as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on May 5, 2021.
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 5, 2021

bluebird bio, Inc.

By: /s/ Chip Baird

Chip Baird

Chief Financial Officer, Principal Financial Officer and Principal Accounting Officer

Exhibit 99.1

bluebird bio Reports First Quarter Financial Results and Highlights Operational Progress

CAMBRIDGE, Mass. – May 5, 2021 – bluebird bio, Inc. (NASDAQ: BLUE) today reported financial results and business highlights for the first quarter ended March 31, 2021 and shared recent operational progress.

"Undoubtedly the highlight of last quarter at bluebird was the approval of Abecma, the first and only CAR T therapy approved for the treatment of relapsed or refractory multiple myeloma," said Nick Leschly, chief bluebird. "We and our colleagues at BMS are now full speed ahead and on track to begin treating patients this quarter. It has been an amazing journey and in many ways, we're just getting started. While the oncology team has been delivering on Abecma, the severe genetic disease team met the moment. We quickly completed an investigation of the SUSAR of AML in our HGB-206 study of LentiGlobin gene therapy for SCD and determined that it was highly unlikely to be due to BB305 lentiviral vector. With these data and the other event changed from an MDS diagnosis to transfusion-dependent anemia, we are now quickly moving to engage with regulators with a goal of lifting the clinical holds in mid-2021. Amidst these challenges and work towards the planned separation, I want to commend and thank all birds for truly demonstrating anti-fragility and continuing to keep patients at the center of everything we do."

BUSINESS SEPARATION UPDATE

Today, bluebird bio is providing additional detail regarding the company's planned business separation, which is targeted for completion by year-end 2021.

bluebird bio

bluebird bio is announcing that Tom Klima will join the company as chief commercial officer. Tom brings a track record of success across multiple commercial roles in oncology and rare diseases, most recently at Gamida Cell Ltd., where he served as chief commercial officer.

Additional members of the bluebird bio leadership team focused on severe genetic diseases will include:

- Andrew Obenshain, chief executive officer (previously-disclosed)
- Jason Cole, chief business officer
- Rich Colvin, interim chief medical officer
- Anne-Virginie Eggiman, senior vice president, regulatory science

"As we move towards separation, I'm pleased to have key leadership team members in place that are poised to bring bluebird bio to its next phase of success," said Andrew Obenshain. "With the addition of Tom Klima to lead our commercial efforts, we are rounding out our team of experts with a deep level of expertise from early stage clinical development to commercial delivery. I'm excited about our path forward and look forward to continuing to expand the bluebird team to bring gene therapy to patients with severe genetic diseases."

Oncology NewCo – 2seventy bio

Today, the company is announcing that Oncology NewCo will be named 2seventy bio and members of the leadership team will include:

- Nick Leschly, chief executive officer (previously-disclosed)
- Chip Baird, chief financial officer
- Philip Gregory, chief scientific officer
- Nicola Heffron, chief operating officer

“Two hundred seventy miles per hour is the maximum speed of human thought,” said Nick Leschly, chief executive officer. “The name 2seventy was selected to signify this speed and our team’s translation of thought to action as we advance our next generation pipeline of transformative cell therapies to help cancer patients urgently in need.”

RECENT HIGHLIGHTS

MULTIPLE MYELOMA

- **ABECMA FDA APPROVAL** – On March 26, 2021, bluebird bio and Bristol-Myers Squibb announced that the U.S. Food and Drug Administration (FDA) approved Abecma (idecabtagene vicleucel; ide-cel) as the first B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Abecma is a personalized immune cell therapy approved as a one-time infusion with a recommended dose range of 300 to 460 x 10^6 CAR-positive T cells.

- **KARMMA NEJM PUBLICATION** – On February 24, 2021, bluebird bio and Bristol-Myers Squibb announced that results from the pivotal Phase 2 KarMMa study were published in The New England Journal of Medicine. The KarMMa study met its primary endpoint of overall response rate and key secondary endpoint of complete response rate. The data from the study demonstrates deep and durable responses with ide-cel treatment in triple-class exposed RRMM patients (n=128).

SICKLE CELL DISEASE

- **CLINICAL STUDIES UPDATE** – On April 20, 2021, bluebird bio announced a revised diagnosis for the previously reported case of myelodysplastic syndrome (MDS) in its Phase 1/2 study of LentiGlobin for sickle cell disease (SCD) (bb1111). Upon further assessment, the treating investigator concluded this is not a case of MDS and revised the diagnosis to transfusion-dependent anemia. In addition, on March 10, 2021, bluebird bio reported that it is very unlikely the suspected unexpected serious adverse reaction (SUSAR) of acute myeloid leukemia (AML) reported in the HGB-206 study of LentiGlobin for SCD was related to the BB305 lentiviral vector (LVV). bluebird bio continues to work with regulators to resume its clinical studies in sickle cell disease as well as to remove the clinical hold for HGB-207 and HGB-212 clinical studies of beti-cel for β-thalassemia, with potential lift of all clinical holds in mid-2021.

CEREBRAL ADRENOLEUKODYSTROPHY

- **ELI-CEL DATA AT EBMT** – On March 15, 2021, bluebird bio presented new data suggesting durability of response and a strong safety profile post elivaldogene autotemcel (eli-cel, Lenti-D™) gene therapy in patients with cerebral adrenoleukodystrophy (CALD) at the 47th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2021). Long-term results from the Phase 2/3 Starbeam study of eli-cel, showed that ninety percent of patients (27/30) are alive and free of major functional disabilities (MFDs) at 24 months or more of follow-up. In the 51 patients treated with eli-cel in clinical studies (ALD-102/LTF-304 and ALD-104) there were no reports of graft failure, graft rejection, GVHD, replication competent lentivirus or insertional oncogenesis.

PIPELINE

- **BILL & MELINDA GATES FOUNDATION GRANT TO EXPLORE IN-VIVO LVV APPLICATIONS** - bluebird bio is announcing today that it has received a grant from the Bill & Melinda Gates Foundation to explore new, potentially transformative in vivo treatments for SCD using the Company's proprietary lentiviral vector (LVV) platform. The funding will support the research and development of novel LVVs that target hematopoietic stem cells (HSCs) for in vivo administration to bring gene-based therapies for SCD and other potential indications to patients around the world who may have limited access to ex vivo and other emerging therapies. This research may also enable the application of in-vivo LVV approaches in other severe genetic diseases.

- **PSIOXUS PRE-CLINICAL DATA** - On April 14, 2021, bluebird bio and PsiOxus Therapeutics presented preclinical data at the American Association for Cancer Research (AACR) Annual Meeting 2021. The results showed synergistic activity between PsiOxus' T-SIGn vector and bluebird bio's CAR-T therapy in primary and metastatic solid tumors. A single IV cycle of PsiOxus' T-SIGn vector enabled an otherwise non-effective dose of CAR-T cell therapy to clear primary and metastatic tumors in vivo.

COMPANY

- **BUSINESS OPERATIONS** – On April 20, 2021 bluebird bio announced its decision to withdraw ZYNTEGLO™ (betibeglogene autotemcel, beti-cel) for transfusion-dependent β-thalassemia (TDT) from the German market because reimbursement negotiations in Germany did not result in a price for ZYNTEGLO that reflects the value of this one-time gene therapy with potential life-long benefit for people living with TDT. Due in part to this decision, the company also announced a targeted reshaping of its workforce intended to enable the company to advance its late-stage gene therapy programs. This reduction and reallocation of resources will allow the company to focus on priority European markets and streamline global operations going forward to ensure its ability to deliver gene therapies to patients.

UPCOMING ANTICIPATED MILESTONES

Regulatory Outlook

- SCD: The company is investigating the recently-reported safety events and plans to continue to work closely with the FDA in their review of these events to provide an update on the Company's development plan and timeline for submission for regulatory approval by year end.
- TDT: The company is on track to complete its rolling BLA submission to the U.S. FDA for beti-cel in mid-2021, contingent upon successful resolution of any U.S. FDA concerns applicable to the program arising out of the recently-reported safety events in the SCD program. This submission is anticipated to include adult, adolescent and pediatric patients with transfusion dependent β-thalassemia across all genotypes (including non-β0/β0 genotypes and β0/β0 genotypes).
- CALD: The company is on track to complete its BLA submission to the U.S. FDA for eli-cel in mid-2021. The company plans to receive European approval for eli-cel in patients with CALD in mid-2021.

Clinical Updates and Milestones

- Updated data from ongoing clinical study in patients with SCD by the end of 2021.
- Updated data from ongoing clinical studies in patients with TDT in mid-2021.
- Updated clinical data from the ongoing pivotal Phase 2 KarMMa study of Abecma (ide-cel, bb2121) in patients with relapsed and refractory multiple myeloma to be presented at the American Society of Clinical Oncology 2021 (ASCO21) Virtual Scientific Program on June 4.

- bb21217 clinical data from the ongoing CRB-402 study in patients with multiple myeloma by the end of 2021.
- Submission of 1 - 2 investigational new drug (IND) applications by the end of 2021.

Commercial and Foundation Building
- Abecma first commercial patients treated in the first half of 2021.

Company
- bluebird bio anticipates the separation of its severe genetic disease and oncology businesses into two independent, publicly traded companies (bluebird bio and 2seventy bio) to be completed by the end of 2021.

FIRST QUARTER 2021 FINANCIAL RESULTS

- **Cash Position:** Cash, cash equivalents and marketable securities as of March 31, 2021 and December 31, 2020 were $1.09 billion and $1.27 billion, respectively. The decrease in cash, cash equivalents and marketable securities is primarily related to cash used in support of ordinary course operating activities.
- **Revenues:** Total revenues were $12.8 million for the three months ended March 31, 2021 compared to $21.9 million for the three months ended March 31, 2020. The decrease was primarily driven by a decrease in ide-cel license and manufacturing services revenue and a decrease in revenue recognized in connection with treating patients in the Phase 1 CRB-402 study of bb21217 under our agreements with BMS.
- **R&D Expenses:** Research and development expenses were $154.5 million for the three months ended March 31, 2021 compared to $154.1 million for the three months ended March 31, 2020. The increase was primarily driven by increased costs incurred through the amended BMS collaboration as well as an increase in employee compensation, benefit, and other headcount related expenses. These increased costs were partially offset by a decrease in manufacturing costs.
- **SG&A Expenses:** Selling, general and administrative expenses were $86.9 million for the three months ended March 31, 2021 compared to $73.2 million for the three months ended March 31, 2020. The increase was primarily driven by increased employee compensation, benefit, and other headcount related expenses, as well as an increase in consulting fees associated with the ongoing project to separate the Company's severe genetic disease and oncology programs into two independently traded companies. These increased costs were partially offset by a decrease in costs related to commercial readiness activities due to delays in commercialization as a result of the COVID-19 pandemic and in light of safety events in the HGB-206 study of LentiGlobin gene therapy for SCD.
- **Net Loss:** Net loss was $205.8 million for the three months ended March 31, 2021 compared to $202.6 million for the three months ended March 31, 2020.

About bluebird bio, Inc.
bluebird bio is pioneering gene therapy with purpose. From our Cambridge, Mass., headquarters, we're developing gene and cell therapies for severe genetic diseases and cancer, with the goal that people facing potentially fatal conditions with limited treatment options can live their lives fully. Beyond our labs, we're working to positively disrupt the healthcare system to create access, transparency and education so that gene therapy can become available to all those who can benefit.

bluebird bio is a human company powered by human stories. We're putting our care and expertise to work across a spectrum of disorders: cerebral adrenoleukodystrophy, sickle cell disease, β-thalassemia and multiple myeloma, using gene and cell therapy technologies including gene addition, and (megaTAL-enabled) gene editing.

bluebird bio has additional nests in Seattle, Wash.; Durham, N.C.; and Zug, Switzerland. For more information, visit bluebirdbio.com.

Follow bluebird bio on social media: @bluebirdbio, LinkedIn, Instagram and YouTube.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the company's financial condition, results of operations, as well as statements regarding the Company's timing and expectations regarding its investigation of the relationship of the safety events in HGB-206 to the use of lentiviral vector BB305 in LentiGlobin gene therapy for SCD, and any regulatory interactions for lifting the clinical hold; its expectations for commercialization efforts for ZYNTEGLO in Europe; and the company's expectations for the commercialization of ABECMA through the BMS collaboration; as well as the company's expectations regarding the effects and impact of the resizing and reshaping of the workforce; the timing, leadership, structure, including the division of assets among bluebird bio and 2seventy bio, and the impact of a separation; as well as the company's intention to provide further updates on the separation and the related financing strategies for bluebird bio and 2seventy. 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 definitively determine whether the lentiviral vector BB305 used in LentiGlobin gene therapy for SCD and in beti-cel is related to the safety events in a timely manner, or at all; the risk that insertional oncogenic or other safety events associated with lentiviral vector, drug product, or myeloablation will be discovered or reported over time; the risk that we may not be able to address regulatory authorities' concerns quickly or at all and may not be able to resume our HGB-206 or HGB-210 studies in a timely manner, or at all; the risk that we may not resume patient treatment with ZYNTEGLO in the commercial context in a timely manner or at all; the risk that our lentiviral vector platform across our severe genetic disease programs may be implicated, affecting the development and potential approval elivaldogene autotemcel; the risks that we may not complete the separation on the terms or timeline currently contemplated if at all, achieve the expected benefits of a separation, and a separation could harm our business, results of operations and financial condition; the risk that the transaction might not be tax-free; we may be unable to make, on a timely or cost-effective basis, the changes necessary to operate as independent companies; 2seventy Bio's lack of independent operating history and the risk that its accounting and other management systems may not be prepared to meet the financial reporting and other requirements of operating as an independent public company; dedicated financial and/or strategic funding sources may not be available on favorable terms; a separation or announcement thereof may adversely impact our ability to attract or retain key personnel; a separation may adversely impact the effectiveness of development and commercialization efforts by us and our partners; our businesses may be disrupted as a result of the announcement or pendency of the separation; 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 our collaboration with BMS will not continue or be successful; that the commercialization of ABECMA will not be successful; 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 European Union; the risk that regulatory authorities will require additional information regarding our product candidates, resulting in delay to our anticipated timelines for regulatory submissions, including our applications for marketing approval; the risk that we will encounter further challenges in the commercial launch of ZYNTEGLO in the European Union, including in managing our complex supply chain for the delivery

of drug product, or in obtaining sufficient coverage or reimbursement for our products; 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-K, 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 March 31,	
	2021	2020
Revenue:		
Service revenue	$ 5,918	$ 16,833
Collaborative arrangement revenue	1,519	2,302
Royalty and other revenue	5,357	2,728
Total revenues	12,794	21,863
Operating expenses:		
Research and development	154,478	154,123
Selling, general and administrative	86,874	73,248
Cost of royalty and other revenue	2,281	1,025
Change in fair value of contingent consideration	369	(3,108)
Total operating expenses	244,002	225,288
Loss from operations	(231,208)	(203,425)
Interest income, net	710	5,355
Other (expense), net	24,756	(4,447)
Loss before income taxes	(205,742)	(202,517)
Income tax expense	(66)	(94)
Net loss	$ (205,808)	$ (202,611)
Net loss per share - basic and diluted:	$ (3.07)	$ (3.64)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	66,976	55,590

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

	As of March 31, 2021	As of December 31, 2020
Cash, cash equivalents and marketable securities	$ 1,093,551	$ 1,274,142
Total assets	$ 1,637,279	$ 1,781,252
Total liabilities	$ 436,946	$ 426,196
Total stockholders' equity	$ 1,200,333	$ 1,355,056