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 9, 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 August 9, 2021, bluebird bio, Inc. ("bluebird" or the "Company") announced its financial results for the three months ended June 30, 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on August 9, 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: August 9, 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 Second Quarter Financial Results and Provides Operational Update

On track to complete planned business separation in 4Q 2021; each company launching with approximately 24 months of runway following separation –
– Severe genetic disease (SGD) business to scale back operations in Europe to focus on the U.S. market –
– ABECMA generates strong performance in first quarter of U.S. launch –
FDA has placed studies of elivaldogene autotemcel (eli-cel, Lenti-D™) for cerebral adrenoleukodystrophy (CALD) *on clinical hold following safety report; other SGD and oncology programs not impacted –*
– Ended quarter with $942M in cash, cash equivalents, and marketable securities –
– Company to host conference call today, August 9, 2021 at 8:00 am ET –

CAMBRIDGE, Mass. – **August 9, 2021** – bluebird bio, Inc. (NASDAQ: BLUE) today reported financial results and business highlights for the second quarter ended June 30, 2021 and provided operational updates, including the announcement that the U.S. Food and Drug Administration (FDA) placed a clinical hold on clinical studies of elivaldogene autotemcel (eli-cel, Lenti-D™) gene therapy (licensed as SKYSONA™ in Europe) for cerebral adrenoleukodystrophy (CALD).

“I’m tremendously proud of what bluebird has accomplished this quarter both operationally and strategically to ready ourselves to launch both bluebird bio and 2seventy bio,” said Nick Leschly, chief bluebird. “Seven months after announcing our intent to split, and thanks to the incredibly hard work by our teams, we have created a solid foundation for both organizations. The ABECMA launch is exceeding expectations, the oncology INDs and severe genetic disease (SGD) biologics license application (BLA) filings are tracking for later this year, and we have established clear visions and leadership teams for each business. Importantly, we have made tough strategic decisions to reshape the overall cost structure to allow both companies to launch in a strong position to execute through important value-creating milestones.”

BUSINESS SEPARATION
In January 2021, bluebird announced its intent to separate into two independent, publicly traded companies (bluebird bio and 2seventy bio). The company expects the separation to be completed by the end of 2021 and to be tax-free to bluebird shareholders.

- Key members of the executive teams of both companies have been announced, effective upon completion of the planned separation. This includes Andrew Obenshain as CEO of bluebird and Nick Leschly as CEO of 2seventy.
- The full board of directors for both companies will be announced closer to the separation date.
- 2seventy has confidentially filed its Form 10 Registration Statement with the U.S. Securities and Exchange Commission (SEC), in which it describes the planned tax-free spin-off of 2seventy as a publicly traded company.
  - bluebird plans to distribute 100% of the outstanding shares of 2seventy common stock to bluebird’s stockholders on a pro-rata basis.
- Based on current cash position and the expected $110M upfront payment upon closing of the National Resilience, Inc. strategic collaboration, the Company anticipates having a cash balance of approximately $900M at the time of separation. Together with existing and emerging sources of revenue, we expect our cash balance will be sufficient to fund approximately 24 months of operations for bluebird and 2seventy under current business plans.

ELI-CEL SAFETY UPDATE

The company received a reported Suspected Unexpected Serious Adverse Reaction (SUSAR) of myelodysplastic syndrome (MDS), that is likely mediated by Lenti-D lentiviral vector (LVV) insertion, in a patient who was treated with eli-cel, or Lenti-D drug product for CALD over one year ago in the Phase 3 ALD-104 study. Evidence currently available suggests that specific design features of Lenti-D LVV likely contributed to this event. The company has shared this information with the independent data monitoring committee of the study and the FDA has placed the eli-cel program on a clinical hold. The company does not anticipate the clinical hold to impact its programs in sickle cell disease (SCD), β-thalassemia or oncology. Subject to resolution of the clinical hold, the company anticipates completing the submission of the rolling BLA for eli-cel in 2021.

“Our hearts go out to this patient and his family, who are dealing with a challenging diagnosis,” said Nick Leschly, chief bluebird. “Given what we know, we remain confident that eli-cel can offer hope for patients and families impacted by this devastating disease who have very few treatment options. We are committed to working with regulators and physicians in order to resolve this hold as soon as possible and bring this important therapy to patients in need.”

BLUEBIRD BIO BUSINESS UPDATE

Today, bluebird bio is announcing that the company intends to focus its SGD business on the U.S. market and on further investments in research and development to optimize its core three programs in SCD, β-thalassemia and CALD, as well as on the development of a pipeline exploring new disease indications using *in vivo* LVV technology. The company remains focused and is on track to complete the rolling submissions of the U.S. BLAs in β-thalassemia in 3Q 2021 and CALD in 2021, pending resolution of the eli-cel clinical hold.

In connection with the planned completion of the business separation in the fourth quarter of 2021 and pivot to U.S.-centric efforts for SGD, bluebird plans an orderly wind down of its operations in Europe and to explore how to give patients in Europe access to its gene therapies, including potentially out-licensing the ex-U.S. rights to its three lead products to a company with European experience and capabilities.

“bluebird’s decision to focus on the U.S. market is driven by the challenges of achieving appropriate value recognition and market access for ZYNTEGLO in Europe, which makes bringing its transformative gene therapies like ZYNTEGLO and SKYSONA to patents and physicians in Europe untenable for a small innovative company at this time,” said Andrew Obenshain, president, severe genetic diseases, bluebird bio. “While European regulators have been innovative partners in supporting accelerated regulatory paths for these therapies, European payers have not yet evolved their approach to gene therapy in a way that can recognize the innovation and the expected life-long benefit of these products. We are committed to and hope to find a potential partner who can help us carry forward our therapies in Europe.”

BLUEBIRD BIO RECENT HIGHLIGHTS

- **BB1111 AND ZYNTEGLO CLINICAL HOLD LIFT –** On June 7, 2021, bluebird announced that the FDA) has lifted the clinical holds on the Phase 1/2 HGB-206 and Phase 3 HGB-210 studies of LentiGlobin for SCD gene therapy (bb1111) for adult and pediatric patients with SCD, and the Phase 3 Northstar-2 (HGB-207) and Northstar-3 (HGB-212) studies of betibeglogene autotemcel gene therapy (beti-cel; licensed as ZYNTEGLO™ in the EU and the UK) for adult, adolescent and pediatric patients with transfusion-dependent β-thalassemia (TDT). The company is working closely with study investigators and clinical trial sites to resume all study activities as soon as possible.

β-THALASSEMIA

- **EHA DATA –** On June 11, 2021, bluebird presented data from several studies of beti-cel in adult, adolescent and pediatric patients with TDT. These data were presented during EHA2021 Virtual, the

26th Annual Congress of the European Hematology Association. With 51 patients enrolled, data from the long-term follow-up study (LTF-303) show that all patients treated with beti-cel who achieve transfusion independence (TI) remain free from transfusions, with the longest follow-up of seven years. Across Phase 3 studies, 89% (32/36) of evaluable patients across ages and genotypes achieved TI and remain transfusion free, including 91% (20/22) of evaluable pediatric patients under the age of 18. Data from bluebird bio's Phase 1/2 and Phase 3 clinical studies represent more than 220 patient-years of experience with beti-cel.

- **EU MARKETING AUTHORIZATION** – On July 9, 2021, bluebird announced that the European Medicines Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) has concluded based on the review of all available data that the benefit-risk balance of ZYNTEGLO™ (beti-cel) remains favorable. bluebird bio informed the EMA that the company has lifted the voluntary marketing suspension. Today, bluebird is announcing that on the basis of the PRAC decision, the EMA CHMP (Committee for Medicinal Products for Human Use) has endorsed the positive recommendation for ZYNTEGLO by the PRAC. A confirmatory decision by the European Commission (EC) is expected in 3Q 2021.

CEREBRAL ADRENOLEUKODYSTROPHY

- **SKYSONA EC DECISION** – On July 21, 2021, bluebird announced that the EC granted marketing authorization of SKYSONA, a one-time gene therapy for the treatment of early CALD in patients less than 18 years of age with an ABCD1 genetic mutation, and for whom a human leukocyte antigen (HLA)-matched sibling hematopoietic (blood) stem cell (HSC) donor is not available.

2SEVENTY BIO RECENT HIGHLIGHTS

- **ABECMA LAUNCH –** This quarter, bluebird and Bristol-Myers Squibb (BMS) launched ABECMA (idecabtagene vicleucel; ide-cel) in the U.S. ABECMA generated total U.S. revenues of $24 million in 2Q 2021 which bluebird shares equally with BMS. As of June 30, 2021, over 65 sites in the U.S. had been qualified to treat patients. bluebird and BMS have reported robust demand for ABECMA and are working to continue to increase manufacturing capacity over time.

- **STRATEGIC MANUFACTURING ALLIANCE** – On July 28, 2021, bluebird and National Resilience, Inc. (Resilience) announced a strategic alliance aimed to accelerate the early research, development and delivery of cell therapies. As part of the agreement, Resilience will acquire bluebird's Research Triangle (bRT) manufacturing facility located in North Carolina for $110 million and will retain all of the more than 100 highly skilled technical staff and administrators currently employed at the site. Resilience will continue to support vector supply for both bluebird and 2seventy. The two companies are also finalizing a definitive agreement to establish partner programs that will share expense and revenue for successful commercialized oncology products and in parallel establish a next-generation manufacturing R&D collaboration. Additionally, 2seventy plans to invest in internal drug product manufacturing capability and capacity to support its future clinical studies.

- **KARMMA ASCO DATA –** On May 19, 2021, bluebird and BMS announced new data and analyses from the pivotal KarMMa study evaluating ABECMA. These data showed a 24.8-month median overall survival in triple-class exposed relapsed/refractory multiple myeloma. With more than 24-month median follow-up, results represent longest follow-up to date from a global clinical trial of a CAR T cell therapy in multiple myeloma with 73% overall response rate and responses ongoing with a median duration of response in patients achieving a ≥CR of 21.5 months. Analysis of characteristics of

neurotoxicity (NT) observed in KarMMa study reinforce well-understood safety profile of ABECMA with mostly Grade 1/2 occurrences of NT having early onset and resolution.

UPCOMING ANTICIPATED MILESTONES

BLUEBIRD BIO

- bluebird anticipates the separation of its SGD and oncology businesses into two independent, publicly traded companies (bluebird bio and 2seventy bio) to be completed by the end of 2021.
- TDT: The company is on track to complete its rolling BLA submission to the FDA for beti-cel in 3Q 2021. 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: Subject to resolution of the clinical hold, the company plans to complete its rolling BLA submission to the FDA for eli-cel in 2021.
- SCD: The company is continuing to evaluate the impact of the recently-lifted clinical hold on bb1111 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 of bb1111 by year end.
- SCD: The company plans to present clinical data from its ongoing HGB-206 clinical study of bb1111 by the end of 2021.

2SEVENTY BIO

- Continued commercial launch of ABECMA in the U.S.
- Submission of 1-2 investigational new drug (IND) applications by the end of 2021.
- Presentation of clinical data from the ongoing CRB-402 study of bb21217 by the end of 2021.

SECOND QUARTER 2021 FINANCIAL RESULTS

- **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2021 and December 31, 2020 were $941.6 million 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 $7.5 million for the three months ended June 30, 2021 compared to $198.9 million for the three months ended June 30, 2020. Total revenues were $20.3 million for the six months ended June 30, 2021 compared to $220.8 million for the six months ended June 30, 2020. The decrease for both periods was primarily driven by a cumulative catch-up adjustment to revenue recorded in connection with the May 2020 BMS contract modification in the second quarter of 2020.
- **R&D Expenses:** Research and development expenses were $144.3 million for the three months ended June 30, 2021 compared to $156.3 million for the three months ended June 30, 2020. Research and development expenses were $298.8 million for the six months ended June 30, 2021 compared to $310.4 million for the six months ended June 30, 2020. The decrease for both periods was primarily driven by decreased manufacturing expenses, a decrease in license and milestone fees, and a decrease in clinical costs in light of safety events in the HGB-206 study of LentiGlobin for SCD gene therapy.
- **SG&A Expenses:** Selling, general and administrative expenses were $78.6 million for the three months ended June 30, 2021 compared to $68.6 million for the three months ended June 30, 2020. Selling, general and administrative expenses were $165.5 million for the six months ended June 30, 2021 compared to $141.9 million for the six months ended June 30, 2020. The increase for both periods was primarily driven by an increase in consulting fees associated with the ongoing project to

separate the company's severe genetic disease and oncology businesses into two independently traded companies as well as an increased employee compensation, benefit, and other headcount related expenses.

- **Net Loss:** Net loss was $241.7 million for the three months ended June 30, 2021 compared to $21.5 million for the three months ended June 30, 2020. Net loss was $447.5 million for the six months ended June 30, 2021 compared to $224.1 million for the six months ended June 30, 2020.

Investor Conference Call Information

bluebird will hold a conference call to discuss this update on Monday, August 9 at 8:00 a.m. ET. Investors may listen to the call by dialing (844) 825-4408 from locations in the United States or +1 (315) 625-3227 from outside the United States. Please refer to conference ID number 9698691.

To access the live webcast of bluebird's presentation, please visit 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 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 plans and expectations for operations including its planned wind down of operations in Europe; the Company's plans and expectations for the timing of BLA submissions; the potential for any licensing or partnership transactions; and the company's expectations for the commercialization of ABECMA through the BMS collaboration; 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 execute a planned orderly wind down of European operations with the timing that we anticipated; the Company may

not be successful in negotiating or finalizing a license or other partnership transaction for the European commercial rights to severe genetic disease programs; 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 be able to 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 beti-cel and eli-cel; 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 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 June 30,		For the six months ended June 30,	
	2021	2020	2021	2020
Revenue:				
Service revenue	$ 5,314	$ 78,357	$ 11,232	$ 95,190
Collaborative arrangement revenue	1,670	109,674	3,190	111,976
Royalty and other revenue	488	10,859	5,845	13,587
Total revenues	7,472	198,890	20,267	220,753
Operating expenses:				
Research and development	144,315	156,308	298,793	310,431
Selling, general and administrative	78,576	68,628	165,451	141,876
Share of collaboration loss	10,071	—	10,071	—
Cost of royalty and other revenue	15,301	1,554	17,582	2,579
Change in fair value of contingent consideration	47	(1,655)	416	(4,763)
Total operating expenses	248,310	224,835	492,313	450,123
Loss from operations	(240,838)	(25,945)	(472,046)	(229,370)
Interest income, net	439	2,939	1,149	8,294
Other (expense) income, net	(1,087)	1,551	23,669	(2,896)
Loss before income taxes	(241,486)	(21,455)	(447,228)	(223,972)
Income tax expense	(216)	(10)	(282)	(104)
Net loss	$ (241,702)	$ (21,465)	$ (447,510)	$ (224,076)
Net loss per share - basic and diluted:	$ (3.58)	$ (0.36)	$ (6.66)	$ (3.86)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	67,487	60,384	67,233	57,987

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

	As of June 30, 2021	As of December 31, 2020
Cash, cash equivalents and marketable securities	$ 941,629	$ 1,274,142
Total assets	$ 1,454,459	$ 1,781,252
Total liabilities	$ 469,898	$ 426,196
Total stockholders' equity	$ 984,561	$ 1,355,056