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): November 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 November 5, 2021, bluebird bio, Inc. ("bluebird" or the "Company") announced its financial results for the three months ended September 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 November 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: November 5, 2021

bluebird bio, Inc.

By: /s/ Gina Consylman

Gina Consylman

Chief Financial Officer and Principal Financial Officer

Exhibit 99.1

bluebird bio Reports Third Quarter Financial Results and Recent Operational Progress

– Company separation completed on November 4, 2021 –

CAMBRIDGE, Mass. – **November 5, 2021** – bluebird bio, Inc. (NASDAQ: BLUE) today reported financial results and business highlights for the third quarter ended September 30, 2021.

“This quarter was about preparing for the completion of the separation of bluebird bio and 2seventy bio and realizing the value of two independent companies," said Andrew Obenshain, chief executive officer, bluebird bio. "Notably this quarter, we secured additional capital through the close of a private financing and completion of the sale of our manufacturing facility in North Carolina and continued to make meaningful progress with our product pipeline, including filing the US biologics licensing application for beti-cel for beta-thalassemia. I am excited for what lies ahead for both bluebird and 2seventy bio, and the impact that both companies will have for patients and their families.”

BUSINESS SEPARATION RECENT HIGHLIGHTS

- **COMPLETION OF SEPARATION** – On November 4, 2021, bluebird bio completed the tax-free spin-off of its oncology business, 2seventy bio, Inc. bluebird bio will continue its work focused on severe genetic diseases, with three near-term opportunities to bring transformative gene therapies to patients and their families in the U.S. 2seventy began regular-way trading on the NASDAQ under the stock ticker symbol “TSVT” on November 5, 2021. bluebird bio will continue to trade under the stock ticker symbol “BLUE”.

- **PRIVATE FINANCING** – Prior to the separation on September 8, 2021, bluebird bio announced that it has entered into an agreement for a $75 million private placement of common stock and common stock equivalents with a healthcare investment fund selected as part of a competitive process.

- **STARTING CASH POSITION -** As of completion of the separation, bluebird’s restricted cash, cash and cash equivalents and marketable securities balance is approximately $518.5M. Increased fiscal discipline, including through projected real estate savings with the move of the Company’s headquarters to Assembly Row in Somerville, Massachusetts, and the wind down of European operations, together with the potential sale of priority review vouchers that would be issued with anticipated U.S. regulatory approvals of biologics licensing applications for beti-cel and eli-cel will be sufficient to fund operations for bluebird bio into 2023 under current business plans.

RECENT HIGHLIGHTS

β-THALASSEMIA

- **BETI-CEL SUBMISSION –** On September 21, 2021, bluebird bio announced it completed the rolling submission of its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for betibeglogene autotemcel (beti-cel) gene therapy in adult, adolescent and pediatric patients with β-thalassemia who require regular red blood cell transfusions, across all genotypes. If approved, beti-cel will be the first hematopoietic (blood) stem cell (HSC) ex-vivo gene therapy for patients in the United States.

COMPANY

- **NEW HEADQUARTERS –** Today, bluebird bio announced its new headquarters in Assembly Row, designed to reflect modern ways of working and estimated to result in more than $120 million in cost savings over the next six years for the company. bluebird signed a long-term lease with Federal Realty Investment Trust (FRIT) for the 61,000 square foot facility located at 455 Grand Union in Somerville, MA.

- **BOARD OF DIRECTORS –** This quarter, bluebird bio announced the appointment of Najoh Tita-Reid (Logitech) and Lis Leiderman, M.D. (Decibel Therapeutics) to its board of directors. They are joined on the bluebird bio board of directors by Mark Vachon (chairman – formerly of GE), John Agwunobi, M.D. (Herbalife Nutrition), Wendy Dixon, Ph.D. (formerly of Bristol-Myers Squibb), Nick Leschly (2seventy bio) and Andrew Obenshain (bluebird bio).

- **EUROPE WIND DOWN –** Following the August 9, 2021 announcement that it intended to wind down operations in Europe, on October 21, bluebird bio announced that it will withdraw its regulatory marketing authorization for SKYSONA from the European Union, and its marketing application for SKYSONA from the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (UK). bluebird bio, Inc. also anticipates withdrawing marketing authorizations for ZYNTEGLO from both the EU and the UK by early 2022. The company expects to continue activities for the long-term follow-up of patients previously enrolled within the European clinical trial programs as planned, but does not intend to initiate any new clinical trials in Europe for the beta-thalassemia, cerebral adrenoleukodystrophy or sickle cell disease programs.

- **MANAGEMENT APPOINTMENT –** On November 4, 2021, bluebird bio announced the appointment of Gina Consylman as Chief Financial Officer, effective upon the completion of the spin-off transaction of 2seventy bio.

UPCOMING ANTICIPATED MILESTONES

- beti-cel: Acceptance of the BLA to the US Food and Drug Administration for beti-cel for beta-thalassemia expected this month.
- eli-cel: The BLA filing for elivaldogene autotemcel (eli-cel, Lenti-D™) for patients with cerebral adrenoleukodystrophy (CALD) is on track for the end of 2021.
- eli-cel: The company is in active communication with the FDA to resolve the clinical hold.
- bb1111: The company plans to host an investor event on November 18th, 2021, to share further detail on its sickle cell disease program and path to regulatory approval.
- American Society of Hematology Annual Meeting: bluebird will present new data on beti-cel and bb1111 at ASH 2021, including long-term results for beti-cel in adult and pediatric patients with beta-thalassemia, new analyses from Groups A&C of the ongoing Phase 1/2 HGB 206 study of bb1111 for sickle cell disease, and sustained improvements in patient reported quality of life in Group C.

THIRD QUARTER 2021 FINANCIAL RESULTS

- **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2021, and December 31, 2020, were $970.7 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 $22.7 million for the three months ended September 30, 2021, compared to $19.3 million for the three months ended September 30, 2020. Total revenues were $42.9 million for the nine months ended September 30, 2021, compared to $240.0 million for the nine months ended September 30, 2020. The increase for the three-month period was primarily

driven by our collaborative arrangement revenue recognized under our collaboration arrangement with BMS. The decrease for the nine-month period 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.

- **ABECMA Revenue:** This quarter Bristol-Myers Squibb (BMS) reported total U.S. revenues of $67 million for ABECMA (idecabtagene vicleucel; ide-cel). bluebird bio reported a net collaboration revenue of $14.8 million for 3Q, which includes the company's share of revenue and costs associated with the commercialization of ABECMA in the U.S.
- **R&D Expenses:** Research and development expenses were $131.4 million for the three months ended September 30, 2021, compared to $140.4 million for the three months ended September 30, 2020. Research and development expenses were $429.6 million for the nine months ended September 30, 2021, compared to $450.9 million for the nine months ended September 30, 2020. The decrease for the three-month period was primarily driven by decreased collaboration research funding costs resulting from a decrease in expense recognized under our collaboration arrangement with BMS. The decrease for the nine-month period was primarily driven by decreased manufacturing expenses.
- **SG&A Expenses:** Selling, general and administrative expenses were $68.3 million for the three months ended September 30, 2021, compared to $68.0 million for the three months ended September 30, 2020. Selling, general and administrative expenses were $229.7 million for the nine months ended September 30, 2021, compared to $210.0 million for the nine months ended September 30, 2020. The increase for both periods was primarily driven by an increase in fees associated with the spinoff of 2seventy bio as well as increased employee compensation, benefit, and other headcount related expenses.
- **Restructuring Expenses:** Restructuring expenses were $20.2 million and $24.8 million for the three months and nine months ended September 30, 2021, respectively. These costs are related to a reduction in the workforce, primarily driven by the wind down of operations in Europe.
- **Net Loss:** Net loss was $216.8 million for the three months ended September 30, 2021, compared to $194.7 million for the three months ended September 30, 2020. Net loss was $664.3 million for the nine months ended September 30, 2021, compared to $418.8 million for the nine months ended September 30, 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.

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 wind down

of operations in Europe; the Company's plans and expectations for the timing of BLA submissions; and the impact of the separation of 2seventy bio. 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 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 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

For bluebird bio
Investors:
Courtney O'Leary, 978-621-7347
coleary@bluebirdbio.com

Media:
Sarah Alspach, 857-299-6198
sarah.alspach@bluebirdbio.com

bluebird bio, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2021	2020	2021	2020
Revenue:				
Service revenue	$ 6,312	$ 13,352	$ 17,544	$ 108,542
Collaborative arrangement revenue	14,831	2,422	18,020	114,398
Royalty and other revenue	1,534	3,499	7,379	17,086
Total revenues	22,677	19,273	42,943	240,026
Operating expenses:				
Research and development	131,427	140,431	429,614	450,862
Selling, general and administrative	68,277	68,046	229,708	209,922
Share of collaboration loss	—	—	10,071	—
Cost of royalty and other revenue	19,704	1,318	37,286	3,897
Restructuring expense	20,175	—	24,800	—
Change in fair value of contingent consideration	48	(828)	464	(5,591)
Total operating expenses	239,631	208,976	731,943	659,090
Loss from operations	(216,954)	(189,694)	(689,000)	(419,064)
Interest income, net	319	1,964	1,468	10,258
Other income (expense), net	(294)	(6,686)	23,375	(9,582)
Loss before income taxes	(216,929)	(194,416)	(664,157)	(418,388)
Income tax (expense)	113	(329)	(169)	(433)
Net loss	$ (216,816)	$ (194,745)	$ (664,326)	$ (418,821)
Net loss per share - basic and diluted:	$ (3.16)	$ (2.94)	$ (9.81)	$ (6.89)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	68,621	66,251	67,701	60,762

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

	As of September 30, 2021	As of December 31, 2020
Cash, cash equivalents and marketable securities	$ 970,730	$ 1,274,142
Total assets	$ 1,339,644	$ 1,781,252
Total liabilities	$ 469,117	$ 426,196
Total stockholders' equity	$ 870,527	$ 1,355,056