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 4, 2020

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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 4, 2020, bluebird bio, Inc. announced its financial results for the three months ended September 30, 2020. 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 4, 2020.
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 4, 2020

bluebird bio, Inc.

By: /s/ Chip Baird

Chip Baird

Chief Financial Officer and Principal Financial Officer

Exhibit 99.1

bluebird bio Reports Third Quarter 2020 Financial Results and Highlights Operational Progress

- Company to host conference call today, November 4, 2020 at 4:30PM ET -

CAMBRIDGE, Mass. – **November 4, 2020** – bluebird bio, Inc. (NASDAQ: BLUE) today reported financial results and business highlights for the third quarter ended September 30, 2020 and shared recent operational progress.

“While 2020 continues to present unprecedented challenges, bluebird has continued to advance our innovative cell and gene therapy programs. Looking to 2021 and beyond, this is a catalyst-rich period for bluebird as we are on the cusp of multiple approvals in the U.S. and EU,” said Nick Leschly, chief bluebird. “In the near term, we look forward to collaborating with FDA to find innovative approaches to help advance these complex therapies. We know that the role of a pioneer in science is never easy, but we are driven by the patients we hope to help. As always, I would like to thank our birds for their passion and resiliency, and for their relentless commitment to the people we serve. The way our employees continue to show up is incredibly inspiring.”

RECENT HIGHLIGHTS

SICKLE CELL DISEASE

- **BIOLOGICS LICENSE APPLICATION (BLA) SUBMISSION -** Today, bluebird bio announces confirmation of its general agreement with the U.S. Food and Drug Administration (FDA) that the clinical data package required to support a BLA submission for LentiGlobin™ for sickle cell disease (bb1111) will be based on data from a portion of patients in the HGB-206 study Group C that have already been treated. bluebird bio is also announcing today that it has reached general agreement with FDA on its path to transition to commercial manufacturing using an analytical comparability strategy, including suspension-based lentiviral vector (sLVV). These developments meaningfully de-risk the bb1111 program and bring clarity on the path to approval. However, FDA requested the use of drug product manufactured from sickle cell disease (SCD) patient cells in addition to healthy donors as well as commercial lentiviral vector to demonstrate drug product comparability. Given this feedback, alongside COVID-19 related shifts and contract manufacturing organization COVID-19 impacts, bluebird is adjusting its submission timing to late 2022. The company looks forward to continuing to work with the Agency to find an innovative approach to reviewing the CMC portion of a BLA submission and address the high unmet need in sickle cell disease.

- **LENTIGLOBIN FOR SICKLE CELL DISEASE PRIME DESIGNATION –** On September 23, 2020, bluebird bio announced that its investigational treatment for SCD, LentiGlobin for SCD gene therapy, was granted eligibility to the Priority Medicines (PRIME) program by the European Medicines Agency (EMA). The EMA’s PRIME initiative provides enhanced support and increased interaction to companies, with the goal of optimizing development plans and speeding regulatory evaluations to potentially bring innovative medicines to patients more quickly.

TRANSFUSION DEPENDENT β-THALASSEMIA

- **BIOLOGICS LICENSE APPLICATION (BLA) SUBMISSION -** Today, bluebird bio announces that based on continued and ongoing discussions with the FDA in the context of bluebird bio’s Fast Track and Breakthrough Therapy designations, the company intends to seek approval for all patients with transfusion dependent β-thalassemia across all genotypes (including non-β^0/β^0 genotypes and β^0/β^0

genotypes). The company remains on track to complete the rolling BLA submission for betibeglogene autotemcel (beti-cel; formerly LentiGlobin™ for β-thalassemia) in mid-2021.

- **HGB-212 FINAL INFUSION –** Today, bluebird bio announces the completion of treatment in the ongoing phase 3 Northstar-3 (HGB-212) clinical study of beti-cel in patients with transfusion-dependent β-thalassemia who have a β0/β0 genotype or IVS-I-110 mutation.

MULTIPLE MYELOMA

- **CRB-402 FINAL INFUSION –** Today, bluebird bio announces the completion of treatment in the ongoing Phase 1 study (CRB-402) of bb21217, an investigational BCMA-targeted chimeric antigen receptor (CAR) T cell therapy being studied in patients with relapsed/refractory multiple myeloma (R/RMM).

- **IDE-CEL BIOLOGICS LICENSE APPLICATION (BLA) ACCEPTANCE AND PRIORITY REVIEW –** On September 22, 2020, bluebird bio and BMS announced that the U.S. FDA has accepted for Priority Review their BLA for idecabtagene vicleucel (ide-cel; bb2121), the companies' investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy. The FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of March 27, 2021.

CEREBRAL ADRENOLEUKODYSTROPHY

- **ELI-CEL MARKETING AUTHORIZATION APPLICATION (MAA) VALIDATION –** On October 2, 2020, bluebird bio announced that the EMA has accepted its MAA for elivaldogene autotemcel (eli-cel, Lenti-D™). Validation of the application confirms the submission is sufficiently complete to begin the EMA's centralized review process

- **ELI-CEL DATA AT EBMT –** On August 29, 2020, bluebird bio presented new data suggesting durability of response and a strong safety profile post eli-cel gene therapy in patients with cerebral adrenoleukodystrophy (CALD) at the 46th EBMT annual meeting. Long-term results from the Phase 2/3 Starbeam study of eli-cel, showed that eighty-seven percent of patients are alive and free of major functional disabilities (MFDs) at 24 months or more of follow-up and there were no reports of graft failure, graft rejection, or GVHD.

COMPANY

- **NEW BOARD APPOINTMENT –** On August 11, 2020, bluebird bio announced the appointment of Denice Torres to its Board of Directors.

UPCOMING ANTICIPATED MILESTONES

Regulatory Outlook

- SCD: The company plans to complete the BLA submission to the U.S. FDA for LentiGlobin for SCD in 2022.
- TDT: The company is on track to complete a rolling BLA submission to the U.S. FDA for beti-cel in mid-2021. This submission will include all patients with transfusion dependent β-thalassemia across all genotypes (including non-β0/β0 genotypes and β0/β0 genotypes).
- Multiple Myeloma: The FDA has set a PDUFA goal date of March 27, 2021 for the approval of ide-cel (bb2121) in patients with relapsed and refractory multiple myeloma.
- CALD: The company is on track to complete the BLA submission to the U.S. FDA for eli-cel in mid-2021.

Clinical

- Today, bluebird bio announces its intention to present bb21217 clinical data from the ongoing CRB-402 study in patients with multiple myeloma by the end of 2020.
- bluebird bio plans to present ide-cel clinical data from the ongoing CRB-401 study in patients with multiple myeloma by the end of 2020, in partnership with BMS.
- bluebird bio plans to present updated data from the ongoing HGB-206 clinical study in patients with SCD by the end of 2020.

Commercial and Foundation Building

- ZYNTEGLO first commercial patients treated in Europe by the end of 2020.

THIRD QUARTER 2020 FINANCIAL RESULTS

- **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2020 and December 31, 2019 were $1.44 billion and $1.24 billion, respectively. The increase in cash, cash equivalents and marketable securities is primarily a result of proceeds received from the May 2020 public offering of the Company's common stock and a one-time upfront payment received in connection with the Company's amended collaboration with BMS, partially offset by cash used in support of ordinary course operating and commercial-readiness activities.
- **Revenues:** Total revenues were $19.3 million for the three months ended September 30, 2020 compared to $8.9 million for the three months ended September 30, 2019. Total revenues were $240.0 million for the nine months ended September 30, 2020 compared to $34.7 million for the nine months ended September 30, 2019. The increase for the three month period was primarily driven by an increase in ide-cel license and manufacturing services revenue and an increase in research and development revenue under our agreement with BMS. The increase for the nine months period was primarily driven by the recent amended BMS collaboration and monetization for ex-U.S. milestones and royalties from ide-cel and bb21217, with the majority of the revenue recognized relating to ide-cel license and manufacturing services.
- **R&D Expenses:** Research and development expenses were $140.4 million for the three months ended September 30, 2020 compared to $151.4 million for the three months ended September 30, 2019. Research and development expenses were $450.9 million for the nine months ended September 30, 2020 compared to $420.6 million for the nine months ended September 30, 2019. The decrease for the three month period was primarily driven by a decrease in manufacturing costs. The increase for the nine month period was primarily driven by an overall increase in costs incurred to advance and expand the company's pipeline.
- **SG&A Expenses:** Selling, general and administrative expenses were $68.0 million for the three months ended September 30, 2020 compared to $66.3 million for the three months ended September 30, 2019. Selling, general and administrative expenses were $209.9 million for the nine months ended September 30, 2020 compared to $195.2 million for the nine months ended September 30, 2019. The increase for both periods was largely attributable to costs incurred to support the Company's ongoing operations and growth of its pipeline.
- **Net Loss:** Net loss was $194.7 million for the three months ended September 30, 2020 compared to $206.0 million for the three months ended September 30, 2019. Net loss was $418.8 million for the nine months ended September 30, 2020 compared to $566.3 million for the nine months ended September 30, 2019.

CONFERENCE CALL DETAILS

bluebird bio will hold a conference call to discuss business updates and third quarter 2020 financial results on Wednesday, Nov 4 at 4:30PM 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 545-6725

To access the live webcast of bluebird bio's presentation, please visit the "Events & Presentations" page within the Investors & Media section of the bluebird bio website at http://investor.bluebirdbio.com. Replays of the webcast will be available on the bluebird bio 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 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 including cerebral adrenoleukodystrophy, sickle cell disease, β-thalassemia and multiple myeloma, using three gene therapy technologies: gene addition, cell therapy 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 plans for regulatory submissions for beti-cel (marketed as ZYTENGLO in the European Union), eli-cel, ide-cel, and LentiGlobin for SCD, including anticipated endpoints to support regulatory submissions and timing expectations; the company's expectations regarding the potential for the suspension-based manufacturing process for lentiviral vector; the company's expectations and execution under its revised operating plan, including its cash runway; its expectations for commercialization efforts for ZYNTEGLO in Europe; and the company's expectations for the amended collaboration agreement with BMS; as well as the company's intentions regarding the timing for providing further updates on the development and commercialization of ZYNTEGLO and the company's product candidates. 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 risks that the COVID-19 pandemic and resulting economic conditions will have a greater impact on the company's operations and plans than anticipated; that our amended collaboration with BMS will not continue or 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 our plans for submitting a BLA for LentiGlobin for SCD may be delayed if the FDA does not accept our comparability plans for the use of the suspension-based manufacturing process for LVV; the risk that the submission of BLA for ide-cel is not accepted for filing by the FDA or approved in the timeline we expect, or at all; the risk of cessation or delay of any of the ongoing or planned clinical studies and/or our development of our product candidates, including due to delays from the COVID-19 pandemic's impact on healthcare systems; 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 challenges in the commercial launch of ZYNTEGLO in the European Union, including in managing our complex supply chain for the delivery of drug product, in the adoption of value-based payment models, 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 September 30,		For the nine months ended September 30,	
	2020	2019	2020	2019
Revenue:				
Service revenue	$ 13,352	$ 4,598	$ 108,542	$ 24,902
Collaborative arrangement revenue	2,422	1,977	114,398	4,408
Royalty and other revenue	3,499	2,335	17,086	5,367
Total revenues	19,273	8,910	240,026	34,677
Operating expenses:				
Research and development	140,431	151,412	450,862	420,592
Selling, general and administrative	68,046	66,250	209,922	195,160
Cost of royalty and other revenue	1,318	862	3,897	1,905
Change in fair value of contingent consideration	(828)	802	(5,591)	1,312
Total operating expenses	208,967	219,326	659,090	618,969
Loss from operations	(189,694)	(210,416)	(419,064)	(584,292)
Interest income, net	1,964	8,417	10,258	27,906
Other expense, net	(6,686)	(4,298)	(9,582)	(10,623)
Loss before income taxes	(194,416)	(206,297)	(418,388)	(567,009)
Income tax (expense) benefit	(329)	264	(433)	748
Net loss	$ (194,745)	$ (206,033)	$ (418,821)	$ (566,261)
Net loss per share - basic and diluted:	$ (2.94)	$ (3.73)	$ (6.89)	$ (10.27)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	66,251	55,292	60,762	55,139

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

	As of September 30, 2020	As of December 31, 2019
Cash, cash equivalents and marketable securities	1,437,870	1,237,966
Total assets	1,945,484	1,727,424
Total liabilities	422,463	442,431
Total stockholders' equity	1,523,021	1,284,993