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 5, 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 August 5, 2020, bluebird bio, Inc. announced its financial results for the three months ended June 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 August 5, 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: August 5, 2020

bluebird bio, Inc.

By: /s/ Chip Baird

Chip Baird

Chief Financial Officer and Principal Financial Officer

Exhibit 99.1

bluebird bio Reports Second Quarter 2020 Financial Results and Recent Operational Progress

– First sickle cell patient treated with drug product manufactured with suspension-based lentiviral vector in HGB-206 –
– Elivaldogene autotemcel (eli-cel, Lenti-D gene therapy) in cerebral adrenoleukodystrophy (CALD) granted accelerated assessment of Marketing Authorization Application (MAA) from EMA –
– In partnership with Bristol-Myers Squibb, completed submission of Biologics License Application (BLA) to FDA for ide-cel –
– Ended quarter with $1.6 billion in cash, cash equivalents and securities, extending cash runway into 2023 –

CAMBRIDGE, Mass. – **August 5, 2020** – bluebird bio, Inc. (NASDAQ: BLUE) today reported financial results and business highlights for the second quarter ended June 30, 2020 and shared recent operational progress.

“I am incredibly proud of the progress made at bluebird this quarter, and the way in which our employees have continued to execute on behalf of patients in the midst of an ongoing global pandemic,” said Nick Leschly, chief bluebird. “It is especially gratifying that despite these challenges, we have continued to treat patients in our clinical studies at levels consistent with prior quarters. Within the quarter, we presented compelling clinical data across three of our core four programs: sickle cell disease, β-thalassemia, and multiple myeloma, and made important progress across all of our programs. In sickle cell disease, we reached an important milestone on our transition to commercial manufacturing process with the successful dosing of the first sickle cell patient using drug product manufactured with suspension-based lentiviral vector. The European launch of ZYNTEGLO continues to progress, with positive ongoing discussions with payers across Europe and we expect to treat our first commercial patients in the second half of this year. Additionally, our multiple myeloma program, partnered with BMS, continues to advance with our submission of the BLA to the FDA and BMS’ validated MAA submission in Europe. With this foundation and additional cash runway, we are confident in our ability to bring our core four programs to patients in the commercial setting by 2022 and grow our sustainable pipeline of transformative gene and cell therapies. All of this progress is made possible by our undaunted bluebirds, who have shown time and again their resourcefulness and ingenuity even under the most challenging of circumstances to bring our therapies to patients.”

RECENT HIGHLIGHTS

- **SUSPENSION LVV MANUFACTURING FOR SCD -** Today, bluebird bio announced that it has treated the first sickle cell patient with drug product manufactured with suspension-based lentiviral vector (sLVV). This process is intended to allow for larger scale and more efficient manufacturing of LVV. The company intends to submit data supporting the use of sLVV to the FDA as part of its submission for regulatory approval of LentiGlobin™ gene therapy for SCD in the second half of 2021.

- **ELI-CEL ACCELERATED ASSESSMENT –** In July 2020, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) granted an accelerated assessment to elivaldogene autotemcel (eli-cel, Lenti-D gene therapy) for the treatment of cerebral adrenoleukodystrophy (CALD). The company plans to submit a Marketing Authorization Application (MAA) to the EMA for eli-cel in 2020. Accelerated assessment reduces the timeframe for the EMA to review an MAA to 150 evaluation days rather than 210. The CHMP grants review under the accelerated assessment procedure if the medicinal product is of major interest for public health, especially from the point of view of therapeutic innovation.

- **NEW ZYNTEGLO QTC –** Today, bluebird bio announced that it has contracted with a second qualified treatment center for ZYNTEGLO. The center, in Essen, Germany, is prepared to treat patients with β-thalassemia in 2020.

- **IDE-CEL BIOLOGICS LICENSE APPLICATION (BLA) SUBMISSION –** On July 29, 2020, bluebird bio and BMS announced the submission of their Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for idecabtagene vicleucel (ide-cel; bb2121), the companies' investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy. This submission provides further details on the Chemistry, Manufacturing and Controls (CMC) module to address the outstanding regulatory requests from the FDA in May 2020 following the original BLA submission.

- **SCD DATA AT EHA** – On June 12, 2020, bluebird bio presented new data showing a near elimination of sickle cell disease-related vaso-occlusive crises and acute chest syndrome in the phase 1/2 clinical study of bluebird bio's LentiGlobin™ gene therapy for sickle cell disease at 25th EHA Congress. The company plan to submit its BLA to the FDA based on an analysis of clinical data from this study using complete resolution of severe vaso-occlusive events (VOEs) as the primary endpoint with at least 18 months of follow-up post-treatment with LentiGlobin for SCD. The company continues to plan to submit the U.S. BLA for SCD in the second half of 2021.

- **TDT DATA AT EHA –** On June 12, 2020, bluebird bio presented new data showing that the majority of evaluable patients across genotypes achieve transfusion independence and maintain it with near-normal hemoglobin levels in phase 3 Studies of betibeglogene autotemcel (beti-cel; formerly LentiGlobin™ for β-thalassemia) gene therapy presented at EHA Congress. The company presented data from the Northstar-2 (HGB-207) clinical study of beti-cel in patients with transfusion-dependent β-thalassemia who do not have a β^0/β^0 genotype and the Northstar-3 (HGB-212) clinical study of beti-cel in patients with transfusion-dependent β-thalassemia who have a β^0/β^0 genotype or IVS-I-110 mutation.

- **IDE-CEL MARKETING AUTHORIZATION APPLICATION (MAA) VALIDATION** – On May 22, 2020, BMS announced that the European Medicines Agency (EMA) has validated its Marketing Authorization Applications (MAA) for ide-cel. Validation of the application confirms the submission is complete and begins the EMA's centralized review process.

- **KARMMA DATA AT ASCO** – On May 13, 2020, Bristol Myers Squibb (NYSE: BMY) and bluebird announced positive updated results from the pivotal, Phase 2 KarMMa study evaluating the efficacy and safety of the companies' investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy, ide-cel, in patients with relapsed and refractory multiple myeloma. The data from this study formed the basis of recent regulatory submissions.

- **EXTENDED CASH RUNWAY –** In June 2020, bluebird bio raised approximately $541.5 million in net proceeds through a public equity offering. bluebird bio anticipates that its cash, cash equivalents and marketable securities as of June 30, 2020, together with projected revenue generated under our collaborative arrangements and projected sales of products, will be sufficient to fund operations into 2023 based on the company's current business plan.

UPCOMING ANTICIPATED MILESTONES

Regulatory

- Submission of a Marketing Authorization Application to the European Medicines Agency for eli-cel in patients with cerebral adrenoleukodystrophy by the end of 2020.

Clinical

- Updated data presentation from HGB-206 clinical study in patients with SCD by the end of 2020.
- Presentation of ide-cel clinical data from the CRB-401 study in patients with multiple myeloma in 2020, in partnership with BMS.
- Updated data presentation from ALD-102 clinical study in patients with CALD by the end of 2020.

Commercial and Foundation Building

- ZYNTEGLO first commercial patients treated in Europe in the second half of 2020.
- ZYNTEGLO access and reimbursement in additional EU countries established by the end of 2020.

SECOND QUARTER 2020 FINANCIAL RESULTS

- **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2020 and December 31, 2019 were $1.60 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 $198.9 million for the three months ended June 30, 2020 compared to $13.3 million for the three months ended June 30, 2019. Total revenues were $220.8 million for the six months ended June 30, 2020 compared to $25.8 million for the six months ended June 30, 2019. The increase for both periods was primarily attributable to 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. Deferred revenue under our BMS collaboration will be recognized over time as the associated obligation to provide vector manufacturing through development is satisfied.
- **R&D Expenses:** Research and development expenses were $156.3 million for the three months ended June 30, 2020 compared to $146.5 million for the three months ended June 30, 2019. Research and development expenses were $310.4 million for the six months ended June 30, 2020 compared to $269.2 million for the six months ended June 30, 2019. The increase in both periods was primarily driven by costs incurred to advance and expand the company's pipeline.
- **SG&A Expenses:** Selling, general and administrative expenses were $68.6 million for both the three months ended June 30, 2020 and June 30, 2019. Selling, general and administrative expenses were $141.9 million for the six months ended June 30, 2020 compared to $128.9 million for the six months ended June 30, 2019. The increase in the six month period was largely attributable to costs incurred to support the Company's ongoing operations and growth of its pipeline as well as commercial-readiness activities.
- **Net Loss:** Net loss was $21.5 million for the three months ended June 30, 2020 compared to $195.8 million for the three months ended June 30, 2019. Net loss was $224.1 million for the six months ended June 30, 2020 compared to $360.2 million for the six months ended June 30, 2019.

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 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 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 June 30,		For the six months ended June 30,	
	2020	2019	2020	2019
Revenue:				
Service revenue	$ 78,357	$ 11,093	$ 95,190	$ 20,304
Collaborative arrangement revenue	109,674	465	111,976	2,431
Royalty and other revenue	10,859	1,738	13,587	3,032
Total revenues	198,890	13,296	220,753	25,767
Operating expenses:				
Research and development	156,308	146,540	310,431	269,180
Selling, general and administrative	68,628	68,631	141,876	128,910
Cost of royalty and other revenue	1,554	613	2,579	1,043
Change in fair value of contingent consideration	(1,655)	214	(4,763)	510
Total operating expenses	224,835	215,998	450,123	399,643
Loss from operations	(25,945)	(202,702)	(229,370)	(373,876)
Interest income, net	2,939	9,387	8,294	19,489
Other income (expense), net	1,551	(2,936)	(2,896)	(6,325)
Loss before income taxes	(21,455)	(196,251)	(223,972)	(360,712)
Income tax (expense) benefit	(10)	469	(104)	484
Net loss	$ (21,465)	$ (195,782)	$ (224,076)	$ (360,228)
Net loss per share - basic and diluted:	$ (0.36)	$ (3.55)	$ (3.86)	$ (6.54)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	60,384	55,165	57,987	55,062

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

	As of June 30, 2020	As of December 31, 2019
Cash, cash equivalents and marketable securities	$ 1,598,793	$ 1,237,966
Total assets	$ 2,107,790	$ 1,727,424
Total liabilities	$ 425,759	$ 442,431
Total stockholders' equity	$ 1,682,031	$ 1,284,993