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): February 18, 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 February 18, 2020, bluebird bio, Inc. announced its financial results for the year and three months ended December 31, 2019. A copy of the press release is being furnished as Exhibit 99.1 to this Current 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 February 18, 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: February 18, 2020 bluebird bio, Inc.

By: /s/ Chip Baird
Chip Baird
Chief Financial Officer and Principal Finance Officer

Exhibit 99.1

bluebird bio Reports Fourth Quarter and Full Year 2019 Financial Results and Highlights Operational Progress

– First conditional approval of ZYNTEGLO™ (autologous CD34+ cells encoding $\beta^{A\text{-}T87Q}$-globin gene) gene therapy for patients 12 years and older with transfusion-dependent β-thalassemia who do not have β^0/β^0 genotype in Europe achieved in 2019; Germany launch underway –
– Announced positive top-line data from pivotal Phase 2 KarMMa study of ide-cel in relapsed and refractory multiple myeloma –
– Presented clinical data across studies of LentiGlobin gene therapy for β-thalassemia (betibeglogene autotemcel) and LentiGlobin gene therapy for sickle cell disease (SCD) and bb21217 in multiple myeloma at American Society of Hematology (ASH) Annual Meeting –
– Ended quarter with $1.24 billion in cash, cash equivalents and marketable securities –

CAMBRIDGE, Mass. – **February 18, 2020** – bluebird bio, Inc. (NASDAQ: BLUE) today reported financial results and business highlights for the fourth quarter and full year ended December 31, 2019.

“2019 was truly a transformative year for bluebird, with our first commercial product now launched in Europe and exciting progress across our first four clinical programs and pipeline,” said Nick Leschly, chief bluebird. “Notably, our data in SCD continues to build, and at the ASH annual meeting in December we presented data that showed a 99% reduction in the annualized rate of vaso-occlusive crises (VOC) and acute chest syndrome (ACS) in HGB-206 Group C patients with history of VOCs and ACS who had at least six months follow-up. In β-thalassemia, the consistency with which patients who do not have a β^0/β^0 genotype in our Northstar-2 (HGB-207) study are achieving transfusion independence is very encouraging – and we’re starting to see indications that we may be able to see similar outcomes with many patients with β^0/β^0 genotypes as well in our Northstar-3 (HGB-212 study). These data put us in a strong position as we progress our European launch, currently underway in Germany. At the end of 2019, we also announced positive top-line data from the pivotal KarMMa study of ide-cel. We and our partners at BMS look forward to submitting these data to the FDA in the first half of this year. Amidst all of our progress in 2019, our birds demonstrated time and again their dedication to patients and ability to meet and learn from the many challenges we have faced along the way. I look forward to facing the challenges of 2020 with this amazing flock.”

Recent Highlights:

TRANSFUSION-DEPENDENT β-THALASSEMIA

- **LAUNCH IN GERMANY –** In January 2020, bluebird bio announced the launch of ZYNTEGLO™ (autologous CD34+ cells encoding βA-T87Q-globin gene), a gene therapy for patients 12 years and older with transfusion-dependent β-thalassemia (TDT) who do not have a β0/β0 genotype, for whom hematopoietic stem cell (HSC) transplantation is appropriate but a human leukocyte antigen (HLA)-matched related HSC donor is not available in Germany. The company signed its first agreements with statutory health insurances utilizing bluebird’s innovative value-based payment model and providing coverage for ZYNTEGLO for up to 50% of patients in Germany, and the first qualified treatment center was established at University Hospital of Heidelberg to provide ZYNTEGLO to patients. The company anticipates treating the first commercial patient in the first half of 2020.

- **UPDATED LENTIGLOBIN FOR β-THALASSEMIA DATA –** At the American Society of Hematology (ASH) meeting in December 2019, bluebird bio presented new data from its studies of LentiGlobin™ gene therapy for β-thalassemia (betibeglogene autotemcel) in patients with TDT: long-term data from the completed Phase 1/2 Northstar study (HGB-204), updated data from the Phase 3 Northstar-2 study (HGB-207) in patients with non-β^0/β^0 genotypes, and updated data from the Phase 3 Northstar-3 study (HGB-212) in patients with β^0/β^0 genotypes or an IVS-I-110 mutation.

- **BIOLOGICS LICENSE APPLICATION (BLA) SUBMISSION –** bluebird bio has initiated its rolling BLA submission of LentiGlobin for β-thalassemia for approval in the U.S. and is engaged with the FDA in discussions regarding the requirements and timing of certain information to be provided in the BLA, including information regarding various release assays for LentiGlobin for β-thalassemia. Subject to these ongoing discussions, the company is currently planning to complete the BLA submission in the second half of 2020.

- **NORTHSTAR-2 FINAL INFUSION** – In January 2020, the final patient enrolled in the pediatric cohort of Northstar-2 (HGB-207) was infused with LentiGlobin for β-thalassemia.

SICKLE CELL DISEASE (SCD)

- **HGB-211 –** bluebird bio is announcing today plans to launch HGB-211, the company's second Phase 3 study of LentiGlobin for sickle cell disease (SCD). This study is expected to enroll approximately 18 patients ages 2-14 years with SCD and elevated stroke risk, stroke being one of the most severe complications during childhood and adolescence. The primary endpoint of the study will be transcranial doppler response without transfusion. HGB-211 is in addition to the company's previously announced Phase 3 study (HGB-210) and is intended to support potential approval of LentiGlobin for SCD in pediatric patients at elevated stroke risk. HGB-211 is expected to begin enrolling patients in 2020.

- **UPDATED LENTIGLOBIN FOR SCD DATA** – At the ASH meeting in December 2019, bluebird bio presented new data from patients in Groups A, B and C in the Phase 1/2 HGB-206 study in patients with SCD. Group C patients are being treated under a study protocol utilizing hematopoietic stem cell (HSC) mobilization and apheresis with plerixafor, and a refined manufacturing process to increase vector copy number and engraftment potential of gene-modified HSCs. The company also disclosed that the target enrollment in HGB-206 has been achieved.

MULTIPLE MYELOMA

- **KARMMA TOPLINE** – In December 2019, Bristol-Myers Squibb and bluebird bio announced positive top-line results from the pivotal Phase 2 KarMMa study of ide-cel in relapsed and refractory multiple myeloma. The study met its primary endpoint and key secondary endpoint, demonstrating deep and durable responses in a heavily pre-treated multiple myeloma patient population. Safety results are consistent with the data presented in CRB-401 study.

- **BB21217 DATA** – At the ASH meeting in December 2019, bluebird bio and Bristol-Myers Squibb presented updated data from ongoing CRB-402 Phase 1 study of BCMA-targeted CAR T cell therapy bb21217 in relapsed and refractory multiple myeloma. The dose escalation part of CRB-402 is complete, and the dose expansion part of the study is ongoing.

COMPANY

- **FORTY SEVEN COLLABORATION** – In November 2019, bluebird bio and Forty Seven announced that they have entered into a research collaboration to pursue clinical proof-of-concept for Forty Seven's novel antibody-based conditioning regimen, FSI-174 (anti-cKIT antibody) plus magrolimab (anti-CD47 antibody), with bluebird's ex vivo lentiviral vector hematopoietic stem cell (LVV HSC) gene therapy platform. Under the terms of the agreement, bluebird bio will provide its ex vivo LVV HSC gene therapy platform and Forty Seven will contribute its innovative antibody-based conditioning regimen for the collaboration.

Upcoming Anticipated Milestones:

- **Regulatory**
  - Submission of a BLA to the U.S. FDA for ide-cel in patients with relapsed and refractory multiple myeloma in the first half of 2020, in partnership with Bristol-Myers Squibb.
  - Submission of a BLA to the U.S. FDA and a Marketing Authorization Application to the European Medicines Agency for Lenti-D in patients with cerebral adrenoleukodystrophy by the end of 2020.

- **Clinical**
  - Submission for presentation of ide-cel clinical data from the KarMMa study in the first half of 2020, in partnership with Bristol-Myers Squibb.
  - Submission for presentation of ide-cel clinical data from the CRB-401 study in 2020, in partnership with Bristol-Myers Squibb.
  - Initiation of the Phase 3 HGB-210 study of LentiGlobin for SCD in patients with a history of vaso-occlusive crises in the first half of 2020.
  - Initiation of the Phase 3 HGB-211 study of LentiGlobin for SCD in patients at risk of stroke in 2020.
  - Updated data presentation from ALD-102 in patients with CALD by the end of 2020.
  - Updated data presentation from the Northstar-2 (HGB-207) clinical study in patients with transfusion-dependent β-thalassemia (TDT) and non-β^0/β^0 genotypes by the end of 2020.
  - Updated data presentation from the Northstar-3 (HGB-212) clinical study in patients with TDT and a β^0/β^0 genotype or an IVS-I-110 mutation by the end of 2020.
  - Updated data presentation from HGB-206 clinical study in patients with SCD by the end of 2020.

- **Commercial and Foundation Building**
  - ZYNTEGLO first commercial patients treated in the first half of 2020.
  - ZYNTEGLO access and reimbursement in additional EU countries established by the end of 2020.

Fourth Quarter and Full Year 2019 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2019 and December 31, 2018 were $1.24 billion and $1.89 billion, respectively. The decrease in cash, cash equivalents and marketable securities is primarily related to cash used in support of ordinary course operating and commercial-readiness activities.
- **Revenues:** Collaboration and license and royalty revenues were $10.0 million for the three months ended December 31, 2019 compared to $19.2 million for the three months ended December 31, 2018. Collaboration and license and royalty revenues were $44.7 million for the

year ended December 31, 2019 compared to $54.6 million for the year ended December 31, 2018. The decrease in both periods was primarily attributable to a decrease in collaboration revenue under our arrangement with Bristol-Myers Squibb, partially offset by an increase in license and royalty revenue.

- **R&D Expenses:** Research and development expenses were $161.8 million for the three months ended December 31, 2019 compared to $119.7 million for the three months ended December 31, 2018. Research and development expenses were $582.4 million for the year ended December 31, 2019 compared to $448.6 million for the year ended December 31, 2018. 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 $76.2 million for the three months ended December 31, 2019 compared to $53.5 million for the three months ended December 31, 2018. Selling, general and administrative expenses were $271.4 million for the year ended December 31, 2019 compared to $174.1 million for the year ended December 31, 2018. The increase in both periods 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 $223.3 million for the three months ended December 31, 2019 compared to $149.0 million for the three months ended December 31, 2018. Net loss was $789.6 million for the year ended December 31, 2019 compared to $555.6 million for the year ended December 31, 2018.

LentiGlobin for β-thalassemia Safety

Non-serious adverse events (AEs) observed during the HGB-204, HGB-207 and HGB-212 clinical studies that were attributed to LentiGlobin for β-thalassemia were hot flush, dyspnoea, abdominal pain, pain in extremities, thrombocytopenia, leukopenia, neutropenia and non-cardiac chest pain. One serious adverse event (SAE) of thrombocytopenia was considered possibly related to LentiGlobin for β-thalassemia for TDT.

Additional AEs observed in clinical studies were consistent with the known side effects of HSC collection and bone marrow ablation with busulfan, including SAEs of veno-occlusive disease.

With more than five years of follow-up to date, there have been no new unexpected safety events, no deaths, no graft failure and no cases of vector-mediated replication competent lentivirus or clonal dominance. In addition, there have been no new reports of veno-occlusive liver disease (VOD) as of the data cutoff presented at ASH.

About LentiGlobin for β-Thalassemia (betibeglogene autotemcel)
The European Commission granted conditional marketing authorization for LentiGlobin for β-thalassemia, to be marketed as ZYNTEGLO™ (autologous CD34+ cells encoding $\beta^{A\text{-}T87Q}$-globin gene) gene therapy, for patients 12 years and older with TDT who do not have a β^0/β^0 genotype, for whom hematopoietic stem cell (HSC) transplantation is appropriate, but a human leukocyte antigen (HLA)-matched related HSC donor is not available.

TDT is a severe genetic disease caused by mutations in the β-globin gene that result in reduced or significantly reduced hemoglobin (Hb). In order to survive, people with TDT maintain Hb levels through lifelong chronic blood transfusions. These transfusions carry the risk of progressive multi-organ damage due to unavoidable iron overload.

LentiGlobin for β-thalassemia adds functional copies of a modified form of the β-globin gene ($\beta^{A\text{-}T87Q}$-globin gene) into a patient's own hematopoietic (blood) stem cells (HSCs). Once a patient has the $\beta^{A\text{-}T87Q}$-globin gene, they have the potential to produce HbA^{T87Q}, which is gene therapy-derived hemoglobin, at levels that may eliminate or significantly reduce the need for transfusions.

The conditional marketing authorization for ZYNTEGLO is only valid in the 28 member states of the EU as well as Iceland, Liechtenstein and Norway. For details, please see the Summary of Product Characteristics (SmPC).

The U.S. Food and Drug Administration granted LentiGlobin for β-thalassemia Orphan Drug status and Breakthrough Therapy designation for the treatment of TDT.

bluebird bio has initiated its rolling BLA submission of LentiGlobin for β-thalassemia for approval in the U.S. and is engaged with the FDA in discussions regarding the requirements and timing of certain information to be provided in the BLA, including information regarding various release assays for LentiGlobin for β-thalassemia. Subject to these ongoing discussions, the company is currently planning to complete the BLA submission in the second half of 2020.

LentiGlobin for β-thalassemia continues to be evaluated in the ongoing Phase 3 Northstar-2 and Northstar-3 studies. For more information about the ongoing clinical studies, visit **www.northstarclinicalstudies.com** or **clinicaltrials.gov** and use identifier NCT02906202 for Northstar-2 (HGB-207), NCT03207009 for Northstar-3 (HGB-212).

bluebird bio is conducting a long-term safety and efficacy follow-up study (LTF-303) for people who have participated in bluebird bio-sponsored clinical studies of LentiGlobin for β-thalassemia. For more information visit: **https://www.bluebirdbio.com/our-science/clinical-trials** or clinicaltrials.gov and use identifier NCT02633943 for LTF-303.

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.

The full common name for ZYNTEGLO: A genetically modified autologous CD34+ cell enriched population that contains hematopoietic stem cells transduced with lentiviral vector encoding the βA-T87Q-globin gene.

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 and commercialization for ZYNTEGLO and the company's product candidates, including anticipated regulatory milestones, the execution of the company's commercial launch plans, planned clinical studies, 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 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 of cessation or delay of any of the ongoing or planned clinical studies and/or our development of our product candidates; 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; the risk that our collaborations, including the collaborations with Bristol-Myers Squibb and Forty Seven, will not continue or will not be successful; 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.

bluebird bio, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except per share data)

(unaudited)

	For the three months ended December 31,		For the year ended December 31,	
	2019	**2018**	**2019**	**2018**
Revenue:				
Collaboration revenue	$ 7,159	$ 18,382	$ 36,469	$ 52,353
License and royalty revenue	2,838	861	8,205	2,226
Total revenues	9,997	19,243	44,674	54,579
Operating expenses:				
Research and development	161,821	119,722	582,413	448,589
Selling, general and administrative	76,202	53,508	271,362	174,129
Cost of license and royalty revenue	1,073	818	2,978	885
Change in fair value of contingent consideration	1,435	2,156	2,747	2,999
Total operating expenses	240,531	176,204	859,500	626,602
Loss from operations	(230,534)	(156,961)	(814,826)	(572,023)
Interest income, net	6,855	6,209	34,761	14,624
Other (expense) income, net	535	1,916	(10,088)	1,961
Loss before income taxes	(223,144)	(148,836)	(790,153)	(555,438)
Income tax benefit (expense)	(203)	(187)	545	(187)
Net loss	$ (223,347)	$ (149,023)	$ (789,608)	$ (555,625)
Net loss per share - basic and diluted:	$ (4.04)	$ (2.72)	$ (14.31)	$ (10.68)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	55,344	54,711	55,191	52,032

bluebird bio, Inc.

Condensed Consolidated Balance Sheet Data

(in thousands)

(unaudited)

	As of December 31, 2019	As of December 31, 2018
Cash, cash equivalents and marketable securities	$ 1,237,966	$ 1,891,427
Total assets	$ 1,727,424	$ 2,242,844
Total liabilities	$ 442,431	$ 357,774
Total stockholders' equity	$ 1,284,993	$ 1,885,070

Investors & Media

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