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): May 2, 2019

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))

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. ☐

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 Global Select Market LLC

Item 2.02 Results of Operations and Financial Condition

On May 2, 2019, bluebird bio, Inc. announced its financial results for the three months ended March 31, 2019. 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 May 2, 2019.

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: May 2, 2019

bluebird bio, Inc.

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

Exhibit 99.1

bluebird bio Reports First Quarter 2019 Financial Results and Highlights Operational Progress

- Received positive opinion from CHMP for ZYNTEGLO™ (autologous CD34+ cells encoding βA-T87Q-globin gene) gene therapy for patients 12 years and older with transfusion-dependent β-thalassemia (TDT) who do not have β^0/β^0 genotype -
- Company hosting Analyst Day on May 9, 2019 focused on research and commercial strategies -
- Ended quarter with $1.73 billion in cash, cash equivalents and marketable securities -

CAMBRIDGE, Mass. – May 2, 2019 – bluebird bio, Inc. (NASDAQ: BLUE) today reported financial results and business highlights for the first quarter ended March 31, 2019.

"In the first quarter, we came one step closer to bringing ZYNTEGLO™, the first gene therapy for transfusion-dependent β-thalassemia (TDT), to patients with a positive opinion from the CHMP and potential approval in Europe anticipated in the second quarter," said Nick Leschly, chief bluebird. "We look forward to providing more detail on our commercial plans and launch expectations at our upcoming Analyst Day, including how our initial country-by-country launch in TDT will lay the foundation for our future launches. Our Analyst Day will also delve into our progress toward our stated goals of 1-2 new INDs per year beginning in 2020, and a deep pipeline by 2022. While the research and commercial engines are revving, our clinical development programs continue to progress at full speed, with the next data from our programs in TDT and sickle cell disease (SCD) anticipated in mid-year, and studies in earlier lines of multiple myeloma adding to the robust ide-cel (bb2121) development plan. Our team of bluebirds and our partners have been working relentlessly to get us to this point – and we're only just getting started on our journey to help patients and their families."

Recent Highlights

TDT

- **CHMP POSITIVE OPINION –** In March 2019, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending conditional marketing authorization for ZYNTEGLO™ (autologous CD34+ cells encoding β A-T87Q-globin gene), a gene therapy for patients 12 years and older with transfusion-dependent β-thalassemia (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. If approved, ZYNTEGLO, formerly referred to as LentiGlobin™ for TDT, will be the first commercially available gene therapy to treat TDT. The CHMP's positive opinion will now be reviewed by the European Commission (EC), which has the authority to grant marketing authorization for ZYNTEGLO in the European Union (EU).

CALD

- **ALD-104 –** In April 2019, bluebird bio treated the first patient in ALD-104, the company's international, non-randomized, open-label, multi-site Phase 3 study of Lenti-D Drug Product after myeloablative conditioning using busulfan and fludarabine in patients ≤17 years of age with cerebral adrenoleukodystrophy (CALD). The study will enroll approximately 20 patients. The primary endpoint of the study is the proportion of patients who are alive and do not have any of the 6 major functional disabilities (MFDs) at Month 24.

MULTIPLE MYELOMA

- **NEJM PUBLICATION –** In May 2019, bluebird bio and Celgene announced that the *New England Journal of Medicine* (NEJM) has published interim results from CRB-401, the ongoing phase 1 study of idecabtagene vicleucel (ide-cel, formerly known as bb2121), the companies' lead investigational BCMA-targeted chimeric antigen receptor (CAR) T-cell therapy candidate for patients with relapsed and refractory multiple myeloma.

COMPANY

- **MANAGEMENT APPOINTMENT –** In April 2019, bluebird bio announced that Joanne Smith-Farrell has been appointed chief business officer. In this role, Joanne will lead corporate development and strategy, alliance management, and she will also continue to serve as our oncology franchise leader. Joanne has been promoted to chief business officer after joining bluebird in April 2017 as our senior vice president, corporate development and strategy.

- **bRT OPENING –** In March 2019, bluebird bio announced the official opening of its first wholly owned manufacturing facility in Durham, N.C., that will produce lentiviral vector for the company's investigational gene and cell therapies, including: ide-cel and bb21217 for the treatment of multiple myeloma and potentially LentiGlobin™ for the treatment of TDT and SCD. bluebird bio purchased the facility in November 2017.

Upcoming Anticipated Milestones

- **TDT**
  - European approval of ZYNTEGLO in patients with TDT and non-β^0/β^0 genotypes in Q2
  - Submission of Biologics Licensing Application to the U.S. FDA for ZYNTEGLO in patients with TDT and non-β^0/β^0 genotypes by the end of 2019
  - Presentation of ZYNTEGLO clinical data from the Northstar-2 (HGB-207) clinical study in patients with TDT and non-β^0/β^0 genotypes by mid-2019 and by end of 2019

- Presentation of ZYNTEGLO clinical data from the Northstar-3 (HGB-212) clinical study in patients with TDT and the β^0/β^0 genotype by mid-2019 and by end of 2019

- **SCD**
  - Initiation of Phase 3 HGB-210 study of LentiGlobin in patients with SCD by end of 2019
  - Presentation of LentiGlobin clinical data from the HGB-206 clinical study in patients with SCD by mid-2019 and by end of 2019

- **Multiple Myeloma**
  - Presentation of ide-cel clinical data from the registration-enabling KarMMa study and CRB-401 study in patients with relapsed/refractory multiple myeloma by end of 2019
  - Presentation of bb21217 clinical data from the CRB-402 clinical study in patients with relapsed/refractory multiple myeloma by the end of 2019

First Quarter 2019 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities as of March 31, 2019 and December 31, 2018 were $1.73 billion and $1.89 billion, respectively. The decrease in cash, cash equivalents and marketable securities is primarily related to cash used in support of normal operating activities and cash used to purchase property, plant and equipment as the company continues the buildout of its manufacturing facility in Durham, North Carolina.

- **Revenues:** Total revenues were $12.5 million for the three months ended March 31, 2019 compared to $16.0 million for the three months ended March 31, 2018. The decrease was primarily attributed to decreased manufacturing services under the company's agreement with Celgene Corporation, offset by increased license and royalty revenue.
- **R&D Expenses:** Research and development expenses were $122.6 million for the three months ended March 31, 2019 compared to $97.1 million for the three months ended March 31, 2018. The increase was primarily driven by costs incurred to advance and expand the company's pipeline.
- **G&A Expenses:** General and administrative expenses were $60.3 million for the three months ended March 31, 2019 compared to $34.9 million for the three months ended March 31, 2018. The increase was largely attributable to overall growth of the pipeline as well as commercial-readiness activities.
- **Net Loss:** Net loss was $164.4 million for the three months ended March 31, 2019 compared to $115.1 million for the three months ended March 31, 2018.

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 by researching cerebral adrenoleukodystrophy, sickle cell disease, transfusion-dependent 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 $\beta^{A\text{-}T87Q}$-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 anticipated development for the company's product candidates, including anticipated regulatory milestones, potential commercial launches, planned clinical studies, as well as the company's intentions regarding the timing for providing further updates on the development and commercialization of its 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 of our product candidates will not continue or be repeated in our ongoing 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, risks 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 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 or in the adoption of value-based payment models or in obtaining sufficient coverage or reimbursement for our products if approved, the risk that our collaborations, including the collaboration with Celgene, 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.

Consolidated Statements of Operations

(in thousands, except per share data)

(unaudited)

	For the three months ended March 31,	
	2019	**2018**
Revenue:		
Collaboration revenue	$ 11,177	$ 15,608
License and royalty revenue	$ 1,294	349
Total revenues	12,471	15,957
Operating expenses:		
Research and development	122,640	97,109
General and administrative	60,279	34,926
Cost of license and royalty revenue	430	17
Change in fair value of contingent consideration	296	534
Total operating expenses	183,645	132,586
Loss from operations	(171,174)	(116,629)
Interest income, net	10,102	1,388
Other (expense) income, net	(3,389)	115
Loss before income taxes	(164,461)	(115,126)
Income tax benefit	15	-
Net loss	$ (164,446)	$ (115,126)
Net loss per share - basic and diluted:	$ (2.99)	$ (2.31)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	54,957	49,923

bluebird bio, Inc.

Condensed Consolidated Balance Sheet Data

(in thousands)

(unaudited)

	As of March 31, 2019	As of December 31, 2018
Cash, cash equivalents and marketable securities	$ 1,730,766	$ 1,891,427
Total assets	2,138,615	2,242,844
Total liabilities	366,516	357,774
Total stockholders' equity	1,772,099	1,885,070

Investors & Media
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