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 21, 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 (Address of Principal Executive Offices)		02142 (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. ☐

Item 2.02 Results of Operations and Financial Condition

On February 21, 2019, bluebird bio, Inc. announced its financial results for the year and three months ended December 31, 2018. 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 February 21, 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: February 21, 2019

bluebird bio, Inc.

By: /s/ Jeffrey T. Walsh
Jeffrey T. Walsh
Chief Strategy Officer and
Principal Financial Officer

Exhibit 99.1

bluebird bio Reports Fourth Quarter and Full Year 2018 Financial Results and Highlights Operational Progress

– Strong 2018 marked by the company's first European Marketing Authorization Application for LentiGlobin in transfusion-dependent β-thalassemia (TDT) –
– Data across LentiGlobin studies in TDT and sickle cell disease (SCD) and bb21217 in multiple myeloma presented at American Society of Hematology (ASH) Annual Meeting –
– Ended year with $1.9 billion in cash, cash equivalents and marketable securities –

CAMBRIDGE, Mass. – February 21, 2019 – bluebird bio, Inc. (NASDAQ: BLUE) today reported financial results and business highlights for the fourth quarter and full year ended December 31, 2018.

"2018 was a critical year for bluebird as the growing body of clinical data from our four lead programs, as well as the investments in our research and development strategy have allowed us to outline a bold vision for the future," said Nick Leschly, chief bluebird. "We have an unprecedented opportunity in front of us where we anticipate that all four lead programs will have an initial filing or launch by 2022, and we are developing a deep pipeline enabled by our core technologies and our partnerships. Our first approval for LentiGlobin in TDT is anticipated this year and will be a country-by-country progressive European launch. Our strategy is to set ourselves up for long term success – through the development of a seamless delivery network, adoption of value-based payment models and by our continued focus on putting patients first through the entire process. Our goal is to ensure that lives can be lived fully – and I'm confident that our caring and committed team of bluebirds across the U.S. and Europe is up to the task."

Recent Highlights

TDT

- **UPDATED LENTIGLOBIN DATA –** At the American Society of Hematology (ASH) Meeting in December 2018, bluebird bio presented new data from its studies of LentiGlobin in patients with transfusion-dependent β-thalassemia (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 the first data from the Phase 3 Northstar-3 study (HGB-212) in patients with β^0/β^0 genotypes or an IVS-I-110 mutation.

SCD

- **UPDATED LENTIGLOBIN DATA –** At the ASH Meeting in December 2018, bluebird bio presented new data from patients in Groups A, B and C in the Phase 1/2 HGB-206 study in patients with sickle cell disease (SCD). Group C patients are being treated under an updated study protocol, which includes the implementation of

mobilization and apheresis with plerixafor. The estimated enrollment in Group C has now been increased from 20 patients to up to 41 patients.

MULTIPLE MYELOMA

- **KARMMA ENROLLMENT COMPLETE –** In November 2018, bluebird bio and Celgene Corporation announced the completion of enrollment for the KarMMa pivotal study of bb2121, the companies' lead investigational anti-BCMA CAR T cell therapy candidate for patients with relapsed/refractory multiple myeloma. KarMMa is a pivotal, open-label, single-arm, multi-center Phase 2 study evaluating the efficacy and safety of bb2121 in patients with relapsed/refractory multiple myeloma. Celgene and bluebird anticipate potential approval of bb2121 in relapsed/refractory multiple myeloma in the second half of 2020.

- **BB21217 DATA –** At the ASH meeting in December 2018, bluebird bio and Celgene Corporation announced initial data from the ongoing Phase 1 clinical study of bb21217 (CRB-402). bb21217 is an investigational next-generation anti-BCMA CAR T cell therapy being evaluated in the ongoing dose escalation part of the Phase 1 CRB-402 study in adults with relapsed/refractory multiple myeloma who have received at least three prior treatments, including a proteasome inhibitor and immunomodulatory agent (or are double refractory).

COMPANY

- **MANAGEMENT APPOINTMENTS –** In February 2019, bluebird bio announced the appointment of Chip Baird as chief financial officer. Jeff Walsh, who has held various roles over the last eight years at bluebird bio — including chief operating officer and, most recently, chief financial and strategy officer — will assume the new dedicated role of chief strategy officer to drive corporate development and the company's overall growth strategy. In addition, Jason Cole, who has served as general counsel since 2014 and chief legal officer since 2016, will assume the new and expanded role of chief operating and legal officer overseeing both operations and legal functions for the company.

- **INHIBRX LICENSE** – In January 2019, bluebird bio and Inhibrx, Inc. announced that they have entered into an exclusive license agreement to research, develop and commercialize CAR T cell therapies using Inhibrx, Inc.'s proprietary single domain antibody (sdAb) platform to multiple cancer targets.

Upcoming Anticipated Milestones

- **TDT**
  - European approval of LentiGlobin in patients with TDT and non-β^0/β^0 genotypes by the end of 2019
  - Filing for U.S. approval of LentiGlobin in patients with TDT and non-β^0/β^0 genotypes by the end of 2019
  - Presentation of LentiGlobin 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 LentiGlobin 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**
  - Led by Celgene Corporation, initiation of KarMMa-2 and KarMMa-3 studies in patients with second- and third-line multiple myeloma, respectively, in 1H 2019
  - Presentation of bb2121 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
- **Company**
  - Analyst/Investor Day to be held in the first half of 2019

Fourth Quarter and Full Year 2018 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2018 and December 31, 2017 were $1.9 billion and $1.6 billion, respectively. The increase in cash, cash equivalents and marketable securities is primarily related to the completion of a public offering of common stock in July 2018, which raised net proceeds of approximately $600.6 million, the receipt of a $100.0 million investment from Regeneron Pharmaceuticals, Inc. in August 2018, and the completion of a public offering of common stock in January 2018, which raised net proceeds of approximately of $48.7 million (the result of the sale of overallotment shares from the December 2017 financing). The overall increase in cash, cash equivalents and marketable securities was offset by 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 $19.2 million for the three months ended December 31, 2018 compared to $4.2 million for the three months ended December 31, 2017, and $54.6 million for the year ended December 31, 2018 compared to $35.4 million for the year ended December 31, 2017. Effective January 1, 2018, bluebird bio adopted Accounting Standards Codification, Topic 606, *Revenue from Contracts with Customers* ("Topic 606"), using the modified retrospective transition method. The increase in both periods was primarily attributable to the adoption of Topic 606 and, to a lesser extent, increased manufacturing services under the company's agreement with Celgene Corporation. The overall increase is offset by decreased license and royalty revenue in both periods.
- **R&D Expenses:** Research and development expenses were $119.7 million for the three months ended December 31, 2018 compared to $92.6 million for the three months ended December 31, 2017. Research and development expenses were $448.6 million for the year ended December 31, 2018 compared to $273.0 million for the year ended December 31, 2017. The increase in both periods was driven by costs incurred to advance and expand the company's pipeline and is attributable to increased clinical trial-related costs and manufacturing costs for development programs, increased laboratory expenses, increased employee-related costs due to headcount growth, and increased facility related costs.
- **G&A Expenses:** General and administrative expenses were $53.5 million for the three months ended December 31, 2018 compared to $29.1 million for the three months ended December 31, 2017. General and administrative expenses were $174.1 million for the year ended December 31, 2018 compared to $93.6 million for the year ended December 31, 2017. The increase in both periods was attributable to increases in employee-related costs due to increased headcount to support overall growth, commercial-readiness activities, and professional and consulting fees.
- **Net Loss:** Net loss was $149.0 million for the three months ended December 31, 2018 compared to $117.2 million for the three months ended December 31, 2017. Net loss was $555.6 million for the year ended December 31, 2018 compared to $335.6 million for the year ended December 31, 2017.

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.

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 LentiGlobin 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)

	Three months ended December 31,		Year ended December 31,	
	2018	2017	2018	2017
Revenue:				
Collaboration revenue	$ 18,382	$ 4,018	$ 52,353	$ 22,207
License and royalty revenue	861	150	2,226	13,220
Total revenues	19,243	4,168	54,579	35,427
Operating expenses:				
Research and development	119,722	92,576	448,589	273,040
General and administrative	53,508	29,087	174,129	93,550
Cost of license and royalty revenue	818	7	885	1,527
Change in fair value of contingent consideration	2,156	(730)	2,999	(525)
Total operating expenses	176,204	120,940	626,602	367,592
Loss from operations	(156,961)	(116,772)	(572,023)	(332,165)
Interest income (expense), net	6,209	(159)	14,624	(2,001)
Other income (expense), net	1,916	(87)	1,961	(1,267)
Loss before income taxes	(148,836)	(117,018)	(555,438)	(335,433)
Income tax (expense) benefit	(187)	(210)	(187)	(210)
Net loss	$ (149,023)	$ (117,228)	$ (555,625)	$ (335,643)
Net loss per share - basic and diluted:	$ (2.72)	$ (2.52)	$ (10.68)	$ (7.71)
Weighted-average number of common shares used in computing net loss per share - basic and diluted	54,711	46,534	52,032	43,535

bluebird bio, Inc.

Condensed Consolidated Balance Sheet Data

(in thousands)

(unaudited)

	As of December 31, 2018	As of December 31, 2017
Cash, cash equivalents and marketable securities	$ 1,891,427	$ 1,614,302
Total assets	$ 2,242,844	$ 1,900,567
Total liabilities	$ 357,774	$ 277,135
Total stockholders' equity	$ 1,885,070	$ 1,623,432

Investors & Media
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