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 22, 2017

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)	(I.R.S. Employer Identification No.)

150 Second Street Cambridge, MA	**02141**
(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:

☐ 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))

Item 2.02 Results of Operations and Financial Condition

On February 22, 2017, bluebird bio, Inc. announced its financial results for the year and three months ended December 31, 2016. 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 22, 2017, furnished herewith.

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 22, 2017

bluebird bio, Inc.

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on February 22, 2017, furnished herewith.

Exhibit 99.1

bluebird bio Reports Fourth Quarter and Full Year 2016 Financial Results and Recent Operational Progress

-Presented interim phase 1 dose escalation data for anti-BCMA CAR T product candidate in patients with relapsed/refractory multiple myeloma at EORTC-NCI-AACR Meeting –
-Presented data from clinical studies of LentiGlobin™ drug product in patients with transfusion-dependent β-thalassemia (TDT) and severe sickle cell disease (SCD) at ASH –
-Treated the first patients with LentiGlobin drug product manufactured with enhanced processes in HGB-207, phase 3 study in patients with TDT with non-β0/β0 genotypes, and under the amended study protocol for HGB-206, phase 1 study in patients with severe SCD –
-Reopened Starbeam study of Lenti-D™ drug product in cerebral adrenoleukodystrophy (CALD) –
-Completed successful public offering of common stock, raising net proceeds of $234.7 million; ended year with $884.8 million in cash, cash equivalents and marketable securities –

CAMBRIDGE, Mass., February 22, 2017 – bluebird bio, Inc. (Nasdaq: BLUE), a clinical-stage company committed to developing potentially transformative gene therapies for severe genetic diseases and T cell-based immunotherapies for cancer, today reported business highlights and financial results for the fourth quarter and full year ended December 31, 2016.

"We ended 2016 with momentum to drive progress in 2017 and cash to fund the business well into 2019," said Nick Leschly, chief bluebird. "2017 is a critical year for bluebird, with data readouts across all four of our clinical programs, including proof-of-concept data on manufacturing improvements for LentiGlobin; proof-of-concept data for the changes to the HGB-206 study protocol; additional data from our anti-BCMA CAR T program, bb2121; and full data from the first 17 patients in the Starbeam study of Lenti-D. Execution will also be a key theme for 2017, with a focus on laying the groundwork for future MAA and BLA filings and engagement with payors. All of these activities are building to the 2022 vision we laid out in January: to have multiple products on the market with dramatic patient impact and a deep pipeline driven by a sustainable innovation engine."

Recent Highlights

- **FIRST CLINICAL DATA FOR ANTI-BCMA CAR T PROGRAM REPORTED -** In November, bluebird bio announced interim phase 1 dose escalation data for its anti-BCMA CAR T product candidate in patients with relapsed/refractory multiple myeloma. 100% of patients in the second and third dose cohorts (n=6) achieved an objective response; two patients were MRD-negative. The overall response rate (ORR) was 78%. Two patients in the study achieved stringent complete responses, with 6 and 4 months follow-up. Among all dosed patients (n=11), no dose-limiting toxicities were observed as of the November data cut-off date, and no Grade 3 or Grade 4 cytokine release syndrome or Grade 3 or Grade 4 neurotoxicity were observed as of the data cut-off.

- **LENTIGLOBIN DATA AT ASH** – At the American Society of Hematology (ASH) Annual Meeting, bluebird provided updates across its ongoing studies of LentiGlobin in transfusion-dependent β-thalassemia (TDT) and severe sickle cell disease (SCD). Updated interim clinical data from the Northstar (HGB-204) study of LentiGlobin drug product in TDT confirmed that all patients with non-β^0/β^0 genotypes and ≥12 months of follow-up have stopped regular transfusions; patients with β^0/β^0 genotypes and ≥12 months of follow-up had a median reduction in transfusion volume of 63% as of the September 16, 2016 data cut-off. In the HGB-205 study, the first patient with SCD treated with gene therapy remains free of clinical symptoms 21 months after receiving LentiGlobin drug product, and ongoing transfusion independence and sustained production of HbA^{T87Q} were reported in patients with TDT as of the September 9, 2016 data cut-off. Updated interim clinical data from seven subjects in the HGB-206 study of LentiGlobin drug product in SCD underscore the need for recently implemented protocol amendments seeking to improve HbA^{T87Q} production in this population.

- **STUDIES OF LENTIGLOBIN DRUG PRODUCT MANUFACTURED WITH NEW PROCESS UNDERWAY** – In December, the first patient was treated with LentiGlobin drug product in the Northstar-2 (HGB-207) phase 3 clinical study of patients with TDT and non-β^0/β^0 genotypes. A LentiGlobin drug product vector copy number (DP VCN) of 2.9 copies/diploid genome was observed, with 77% of cells lentiviral vector sequence positive (LVV+). In February of 2017, the first patient was treated under the amended study protocol for the HGB-206 phase 1 clinical study of patients with SCD. A LentiGlobin DP VCN of 3.3 copies/diploid genome was observed, with 83% of cells LVV+ for this patient.

- **MANUFACTURING AGREEMENT WITH APCETH –** In December, bluebird and apceth Biopharma announced that they have entered into a strategic manufacturing agreement providing for the future European commercial production of bluebird bio's Lenti-D product candidate for cerebral adrenoleukodystropy (CALD) and its LentiGlobin product candidate for TDT. This agreement follows a successful multi-year clinical manufacturing relationship and provides bluebird bio with European commercial manufacturing capabilities, including dedicated production suites within apceth Biopharma's state-of-the-art GMP facility.

- **KEY MANAGEMENT APPOINTMENTS -** Susanna High was named chief operating officer and Andrew Obenshain was named senior vice president and head of Europe.

- **FULLY ENROLLED HGB-205 STUDY –** In February of 2017, the final patient with SCD in the HGB-205 single-center study in TDT and SCD was infused with LentiGlobin drug product.

- **REOPENED STARBEAM STUDY –** In December, bluebird bio announced plans to expand enrollment by up to eight additional patients in the ongoing Starbeam Phase 2/3 clinical study of Lenti-D drug product in patients less than 18 years of age with cerebral adrenoleukodystrophy (CALD). The expansion of the study is intended to enable the first manufacture of Lenti-D in Europe and subsequent treatment of subjects in Europe, and to bolster the overall clinical data package for potential future regulatory filings in the United States and Europe.

- **STRENGTHENED BALANCE SHEET –** In December, bluebird raised $234.7 million in net proceeds in an equity financing. The company's cash, cash equivalents and marketable securities are sufficient to fund operations into the second half of 2019 based on the company's current business plan. Proceeds from the equity financing will fund the advancement of bb2121 and other anti-BCMA product candidates for the treatment of relapsed/refractory multiple myeloma; the initiation of HGB-212, a phase 3 clinical study of LentiGlobin in patients with TDT and the β^0/β^0 genotype; the expansion of manufacturing capabilities to support product development efforts and in anticipation of a potential commercial launch; and the growth of commercial infrastructure to support conditional commercial launch of LentiGlobin in Europe pending marketing authorization in Europe.

Upcoming Anticipated Milestones:

- Presentation of updated bb2121 clinical data from the CRB-401 study at the American Society of Clinical Oncology (ASCO) Annual Meeting
- Presentation of early LentiGlobin clinical data from the HGB-207 study at the European Hematology Association (EHA) Annual Meeting

- Initiation of a phase 1 clinical study of bb21217 anti-BCMA CAR T product candidate
- Initiation of HGB-212, phase 3 clinical study of LentiGlobin in patients with TDT and the β^0/β^0 genotype in the second half of 2017
- Presentation of full data from the initial 17 patients treated in the Starbeam clinical study of Lenti-D in CALD by year end 2017
- Presentation of early LentiGlobin clinical data from the HGB-206 study conducted under the amended study protocol at ASH

Fourth Quarter and Full Year 2016 Financial Results and Financial Guidance

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2016 were $884.8 million, compared to $865.8 million as of December 31, 2015, an increase of $19.0 million, which was primarily driven by the December 2016 equity financing partially offset by cash used to fund operations.
- **Revenues:** Collaboration revenue was $1.6 million for the fourth quarter of 2016 and $6.2 million for the year ended December 31, 2016, compared to $1.5 million and $14.1 million in the comparable periods in 2015. The decrease for the full year is a result of a change in revenue recognition associated with an amendment to our collaboration agreement with Celgene in the second quarter of 2015.
- **R&D Expenses:** Research and development expenses were $57.1 million for the fourth quarter of 2016 and $204.8 million for the year ended December 31, 2016, compared to $35.7 million and $134.0 million in the comparable periods in 2015. The increase in research and development expenses was primarily attributable to increased manufacturing costs for our ongoing clinical and pre-clinical studies, increased employee compensation expense and increased information technology and facilities costs to support our overall growth.
- **G&A Expenses:** General and administrative expenses were $16.2 million for the fourth quarter of 2016 and $65.1 million for the year ended December 31, 2016, compared to $14.4 million and $46.2 million in the comparable periods in 2015. The increase in general and administrative expenses was primarily attributable to increased employee compensation expense and consulting costs to support our overall growth and pre-commercial efforts.
- **Net Loss:** Net loss was $71.4 million for the fourth quarter of 2016 and $263.5 million for the year ended December 31, 2016, compared to $47.3 million and $166.8 million in the comparable periods in 2015.
- **Financial guidance:** bluebird bio expects that its cash, cash equivalents and marketable securities of $884.8 million as of December 31, 2016 will be sufficient to fund its current operations into the second half of 2019.

About bluebird bio, Inc.
With its lentiviral-based gene therapies, T cell immunotherapy expertise and gene editing capabilities, bluebird bio has built an integrated product platform with broad potential application to severe genetic diseases and cancer. bluebird bio's gene therapy clinical programs include its Lenti-D™ product candidate, currently in a Phase 2/3 study, called the Starbeam Study, for the treatment of cerebral adrenoleukodystrophy, and its LentiGlobin™ product candidate, currently in four clinical studies for the treatment of transfusion-dependent β-thalassemia, and severe sickle cell disease. bluebird bio's oncology pipeline is built upon the company's leadership in lentiviral gene delivery and T cell engineering, with a focus on developing novel T cell-based immunotherapies, including chimeric antigen receptor (CAR T) and T cell receptor (TCR) therapies. bluebird bio's lead oncology program, bb2121, is an anti-BCMA CAR T program partnered with Celgene. bb2121 is currently being studied in a Phase 1 trial for the treatment of relapsed/refractory multiple myeloma. bluebird bio also has discovery research programs utilizing megaTAL/homing endonuclease gene editing technologies with the potential for use across the company's pipeline.

bluebird bio has operations in Cambridge, Massachusetts and Seattle, Washington.

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 and results of operations, the sufficiency of its cash, cash equivalents and marketable securities, as well as the advancement of, and anticipated development and regulatory milestones and plans related to the Company's product candidates and clinical studies, including statements regarding whether the planned manufacturing process changes for the LentiGlobin drug product will improve outcomes in patients with transfusion-dependent β-thalassemia and severe sickle cell disease, whether the planned changes to the HGB-206 clinical study protocol will improve outcomes in patients with severe sickle cell disease and plans for future clinical data disclosures. 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, risks that the preliminary results from our clinical trials 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, the risk of a delay in the enrollment of patients in our clinical studies, the risks that the changes we have made in the LentiGlobin drug product manufacturing process or the HGB-206 clinical study protocol will not result in improved patient outcomes, risks that the current or planned clinical trials of the LentiGlobin drug product will be insufficient to support regulatory submissions or marketing approval in the United States and European Union, 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 annual report on 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 Data
(unaudited)
(in thousands, except per share data)

	Three months ended December 31,		Year ended December 31,	
	2016	2015	2016	2015
Revenue:				
Collaboration revenue	$ 1,552	$ 1,471	$ 6,155	$ 14,079
Total revenue	1,552	1,471	6,155	14,079
Operating expenses:				
Research and development	57,133	35,659	204,775	134,038
General and administrative	16,178	14,444	65,119	46,209
Change in fair value of contingent consideration	576	329	4,091	2,869
Total operating expenses	73,887	50,432	273,985	183,116
Loss from operations	(72,335)	(48,961)	(267,830)	(169,037)
Other income, net	908	1,684	3,711	2,314
Loss before income taxes	(71,427)	(47,277)	(264,119)	(166,723)
Income tax benefit (expense)	63	—	612	(60)
Net loss	$ (71,364)	$ (47,277)	$ (263,507)	$ (166,783)
Net loss per share - basic and diluted:	$ (1.88)	$ (1.29)	$ (7.07)	$ (4.81)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	38,051	36,716	37,284	34,669

bluebird bio, Inc.
Consolidated Balance Sheets Data
(unaudited)
(in thousands)

	December 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 278,887	$ 164,269
Marketable securities	425,491	353,680
Prepaid expenses and other current assets	19,836	6,016
Total current assets	724,214	523,965
Marketable securities	180,452	347,814
Property and equipment, net	156,955	82,614
Intangible assets, net	20,694	24,456
Goodwill	13,128	13,128
Restricted cash and other non-current assets	22,679	10,360
Total assets	$ 1,118,122	$ 1,002,337
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 13,664	$ 6,334
Accrued expenses and other current liabilities	54,660	28,145
Deferred revenue, current portion	6,209	5,889
Total current liabilities	74,533	40,368
Deferred rent, net of current portion	10,408	8,294
Deferred revenue, net of current portion	40,204	35,959
Contingent consideration, net of current portion	3,277	5,082
Construction financing lease obligation	120,140	61,901
Other non-current liabilities	120	237
Total liabilities	248,682	151,841
Stockholders' equity:		
Common stock, $0.01 par value, 125,000 shares authorized; 40,691 and 36,894 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	407	369
Additional paid-in capital	1,447,856	1,166,585
Accumulated other comprehensive loss	(1,149)	(2,291)
Accumulated deficit	(577,674)	(314,167)
Total stockholders' equity	869,440	850,496
Total liabilities and stockholders' equity	$ 1,118,122	$ 1,002,337

Contact:
Investors:
bluebird bio, Inc.
Manisha Pai, 617-245-2107
mpai@bluebirdbio.com

Media:
bluebird bio, Inc.
Elizabeth Pingpank, 617-914-8736
epingpank@bluebirdbio.com
or
Pure Communications, Inc.
Dan Budwick, 973-271-6085