

**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 3, 2017**

**bluebird bio, Inc.**

(Exact name of Registrant as Specified in Its Charter)

**DELAWARE**

(State or Other Jurisdiction  
of Incorporation)

**60 Binney Street,  
Cambridge, MA**

(Address of Principal Executive Offices)

**001-35966**

(Commission File Number)

**13-3680878**

(IRS Employer  
Identification No.)

**02142**

(Zip Code)

**Registrant's Telephone Number, Including Area Code: (339) 499-9300**

(Former Name or Former Address, if Changed Since Last Report)

Indicate by check mark whether the registrant is an emerging growth company as defined in 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.

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))

**Item 2.02 Results of Operations and Financial Condition**

On May 3, 2017, bluebird bio, Inc. announced its financial results for the three months ended March 31, 2017. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on May 3, 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: May 3, 2017

**bluebird bio, Inc.**

By: /s/ Jeffrey T. Walsh

Jeffrey T. Walsh

*Chief Financial and Strategy Officer and Principal  
Financial Officer*

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**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on May 3, 2017, furnished herewith.



**Exhibit 99.1**

**bluebird bio Reports First Quarter 2017 Financial Results and Recent Operational Progress**

*-Case study on first patient with severe sickle cell disease (SCD) treated with gene therapy published in New England Journal of Medicine –*

*-Appointed Derek Adams, Ph.D. Chief Technology and Manufacturing Officer and Joanne Smith-Farrell, Ph.D. Senior Vice President, Corporate Development and Strategy –*

*-Refined regulatory path for LentiGlobin™ in transfusion-dependent  $\beta$ -thalassemia (TDT) in Europe –*

*-Announced licensing of lentiviral vector patent rights for development and commercialization of cell therapies to GlaxoSmithKline and Novartis –*

*-Ended quarter with \$799.9 million in cash, cash equivalents and marketable securities –*

**CAMBRIDGE, Mass., May 3, 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 first quarter ended March 31, 2017.

“In the first quarter of 2017, we have been laser-focused on continuing to develop our commercial and manufacturing infrastructure and ensuring that we are prepared for future MAA and BLA filings,” said Nick Leschly, chief bluebird. “Throughout 2017, we will be presenting data across all four of our clinical programs. On our two most advanced programs in TDT and cerebral adrenoleukodystrophy, these data will dictate the timing and path for future regulatory submissions in the US and Europe. For our Phase 1/2 programs in SCD and multiple myeloma, the 2017 data will dictate the timing and path for our planned Phase 3 trials. I’m enthusiastic about the progress our teams are making, and look forward to continuing to move our programs forward through the second half of 2017.”

**Recent Highlights**

- **CASE STUDY PUBLISHED IN NEJM** - In March, bluebird announced the publication in the *New England Journal of Medicine* of a case study on Patient 1204, the first patient with SCD to be treated with gene therapy. This patient, who was 13 years old at the time of treatment, was treated with LentiGlobin drug product in the HGB-205 clinical study conducted in Necker Hospital, Assistance Publique-Hôpitaux de Paris, Paris, France. The data in the publication reflect 15 months of follow-up, and in that time, no SCD-related clinical events or hospitalizations have occurred, contrasting favorably with the period before the patient began regular
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transfusions. Adverse events (AEs) were consistent with busulfan conditioning, and no AEs related to LentiGlobin drug product had been observed.

- **APPOINTMENT OF NEW SENIOR EXECUTIVES** – In March, bluebird announced that Derek Adams, Ph.D. joined the company as its Chief Technology and Manufacturing Officer and Joanne Smith-Farrell, Ph.D., joined as Senior Vice President, Corporate Development and Strategy.
- **REFINED REGULATORY PATH IN EU** – In April, bluebird met with the European Medicines Agency (EMA) regarding the regulatory path for LentiGlobin in TDT as part of its participation in the Adaptive Pathways Program. Based on this meeting, bluebird believes that it is possible to seek conditional approval for our LentiGlobin product candidate, with our improved manufacturing process, for the treatment of patients with TDT and a non- $\beta^0/\beta^0$  genotype on the basis of the totality of the clinical data from our ongoing Northstar Study in patients with TDT and supportive ongoing HGB-205 study, our single-center study in patients with TDT and SCD, together with the data available from our ongoing Northstar-2 Study in patients with TDT and non- $\beta^0/\beta^0$  genotypes at the time of filing. This plan is contingent upon these studies demonstrating acceptable safety and efficacy, and in particular transfusion independence as the primary endpoint and a reduction in transfusion requirements as a secondary endpoint for efficacy analyses.
- **LICENSED LENTIVIRAL VECTOR PATENT RIGHTS** – In May, bluebird announced that it has entered into worldwide license agreements around its proprietary lentiviral vector platform with Novartis Pharma AG and GlaxoSmithKline Intellectual Development Property Limited (GSK). Financial terms of the agreements include an upfront payment to bluebird as well as potential future milestone and royalty payments.

**Upcoming Anticipated Milestones:**

- Presentation of updated bb2121 clinical data from the CRB-401 study in relapsed/refractory multiple myeloma at the American Society of Clinical Oncology (ASCO) Annual Meeting
  - Presentation of early LentiGlobin clinical data from the Northstar-2 study in patients with TDT and non- $\beta^0/\beta^0$  genotypes, as well as data from additional patients in the HGB-205 single-center study in patients with TDT and SCD at the European Hematology Association (EHA) Annual Meeting
  - Initiation of a Phase 1 clinical study of bb21217 anti-BCMA CAR T product candidate in patients with relapsed/refractory multiple myeloma
  - Initiation of HGB-212, a Phase 3 clinical study of LentiGlobin in patients with TDT and the  $\beta^0/\beta^0$  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
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- Presentation of early LentiGlobin clinical data from the HGB-206 study in patients with SCD conducted under the amended study protocol at the American Society of Hematology (ASH) Annual Meeting

#### **First Quarter 2017 Financial Results and Financial Guidance**

- **Cash Position:** Cash, cash equivalents and marketable securities as of March 31, 2017 were \$799.9 million, compared to \$884.8 million as of December 31, 2016, a decrease of \$84.9 million.
- **Revenues:** Collaboration revenue was \$6.8 million for the first quarter of 2017 compared to \$1.5 million for the first quarter of 2016. The increase is the result of the commencement of revenue recognition for the bb2121 license and manufacturing services under our agreement with Celgene.
- **R&D Expenses:** Research and development expenses were \$55.0 million for the first quarter of 2017 compared to \$41.9 million for the first quarter of 2016. The increase in research and development expenses was primarily attributable to increased employee compensation and facilities costs due to increased headcount, and increased manufacturing, clinical, research, and information technology costs to support the advancement of our clinical and pre-clinical programs.
- **G&A Expenses:** General and administrative expenses were \$20.3 million for the first quarter of 2017 compared to \$16.0 million for the first quarter of 2016. The increase in general and administrative expenses was primarily attributable to increased employee compensation expense due to increased headcount and costs to support our pre-commercial efforts.
- **Net Loss:** Net loss was \$68.7 million for the first quarter of 2017 compared to \$56.3 million for the first quarter of 2016.

#### **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  $\beta$ -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.

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

### **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, as well as the advancement of, and anticipated development and regulatory milestones and plans related to the Company’s product candidates and clinical studies. 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 Form 10-Q, 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.*

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**bluebird bio, Inc.**  
**Condensed Consolidated Statements of Operations Data**  
**(unaudited)**  
**(in thousands, except per share data)**

	Three months ended March 31,	
	2017	2016
Revenue:		
Collaboration revenue	\$ 6,832	\$ 1,499
Total revenue	<u>6,832</u>	<u>1,499</u>
Operating expenses:		
Research and development	55,028	41,911
General and administrative	20,284	15,955
Change in fair value of contingent consideration	1,433	1,013
Total operating expenses	<u>76,745</u>	<u>58,879</u>
Loss from operations	(69,913)	(57,380)
Other income, net	1,201	961
Loss before income taxes	(68,712)	(56,419)
Income tax benefit	—	145
Net loss	<u>\$ (68,712)</u>	<u>\$ (56,274)</u>
Net loss per share - basic and diluted:	<u>\$ (1.68)</u>	<u>\$ (1.52)</u>
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	<u>40,836</u>	<u>36,920</u>



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

	<u>March 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Cash, cash equivalents and marketable securities	\$ 799,869	\$ 884,830
Total assets	1,072,570	1,118,122
Total liabilities	257,191	248,682
Total stockholders' equity	815,379	869,440

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