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): November 2, 2016

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 November 2, 2016, bluebird bio, Inc. announced its financial results for the three months ended September 30, 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 November 2, 2016, 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: November 2, 2016

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 November 2, 2016, furnished herewith.

Exhibit 99.1

bluebird bio Reports Third Quarter 2016 Financial Results and Recent Operational Progress

-Initiated HGB-207 Phase 3 study of LentiGlobin™ drug product in patients with transfusion-dependent beta-thalassemia (TDT) with non β^0/β^0 genotypes –

-HGB-207 and all studies of LentiGlobin to incorporate manufacturing process 2 going forward –

-Provided update on manufacturing process 2, LentiGlobin drug product regulatory progress in TDT and efforts to optimize outcomes in sickle cell disease (SCD) at Gene Therapy Day –

-Established strategic T Cell Receptor (TCR) alliance in cancer immunotherapy with Medigene –

-Received PRIME designation for LentiGlobin from European Medicines Agency –

-Ended quarter with $727.6 million in cash, cash equivalents and marketable securities –

CAMBRIDGE, Mass., November 2, 2016 – 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 third quarter ended September 30, 2016.

"In recent months, we have made important advances in our gene therapy transduction and manufacturing processes, translational research and clinical development that will be critical for us to successfully bring LentiGlobin drug product to patients with transfusion-dependent β-thalassemia (TDT) and severe sickle cell disease (SCD). This includes implementing a new LentiGlobin manufacturing process that has been shown *in vitro* to consistently improve the percentage of cells transduced and vector copy number, and making a number of changes to the protocol for our ongoing severe SCD study that we believe have the potential to improve patient outcomes. We look forward to sharing initial clinical data from these improvements in 2017," said Nick Leschly, chief bluebird.

"In September we announced a strategic alliance with Medigene around TCRs against four targets, a significant step forward in our efforts to build a broad, fully integrated immuno-oncology franchise. We anticipate sharing further progress in oncology in the first half of 2017, with presentation of initial data from our Phase 1 study of bb2121, our anti-BCMA CAR T program in multiple myeloma."

Recent Highlights

- **PHASE 3 HGB-207 STUDY OF LENTIGLOBIN OPENED –** In September, bluebird bio opened the company's first Phase 3 study of LentiGlobin drug product. HGB-207 is a global, multi-center study in patients with TDT with non-β0/β0 genotypes. This study will incorporate the addition of bluebird bio's transduction enhancers to the drug product manufacturing process, and will be conducted under the same Investigational New Drug application (IND) as previous studies of LentiGlobin drug product in TDT. This study, which will include adult and adolescent patients (cohort #1) and pediatric patients (cohort #2), is intended to be pivotal in the U.S. and confirmatory in the E.U. bluebird bio plans to initiate the HGB-212 pivotal study of LentiGlobin drug product in patients with TDT with β0/β0 genotypes in 2017.

- **GENE THERAPY DAY –** In October, bluebird bio held a Gene Therapy Day to provide updates on its LentiGlobin product candidate and its research, development and commercialization strategies. Highlights included:
    - A head-to-head *in vitro* comparison of manufacturing Process 1 and Process 2 consistently improved the percentage of cells transduced and vector copy number (VCN) in cells from TDT patients of all genotypes and severe SCD patients.
    - bluebird bio has implemented several amendments to the protocol of the ongoing HGB-206 study in severe SCD, with the goal of improving patient outcomes by increasing successful engraftment of transduced cells.
    - bluebird bio has reached general agreement with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) on the regulatory paths forward for LentiGlobin in TDT in the U.S. and E.U.

- **STRATEGIC TCR ALLIANCE WITH MEDIGENE –** In September, bluebird bio and Medigene announced that they have established a strategic alliance in cancer immunotherapy focused on four TCR targets. Under the terms of the agreement, Medigene will be responsible for the generation and delivery of TCRs using its TCR isolation and characterization platform. Following collaborative preclinical development, bluebird bio will assume sole responsibility for the clinical development and commercialization of the TCR product candidates and will receive an exclusive license for intellectual property covering the resulting TCRs.

- **LENTIGLOBIN ACCEPTED INTO EUROPEAN MEDICINES AGENCY (EMA) PRIME PROGRAM –** In September, the EMA granted access to its Priority Medicines (PRIME) scheme for LentiGlobin drug product in the treatment of patients with TDT. The PRIME initiative provides enhanced support and increased interaction to companies, with the goal of optimizing development plans and speeding regulatory evaluations to potentially bring innovative

medicines to patients more quickly. To be accepted for PRIME, a therapy must demonstrate potential to benefit patients with unmet medical need through early clinical data or nonclinical data.

Upcoming Anticipated Milestones

- Presentation of updated TDT and SCD clinical data from the Northstar (HGB-204), HGB-205 and HGB-206 clinical studies at the American Society of Hematology (ASH) annual meeting in December
- Presentation of early data from CRB-401, the Phase 1 trial of bb2121 in relapsed/refractory multiple myeloma in the first half of 2017

Third Quarter 2016 Financial Results and Financial Guidance

- **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2016 were $727.6 million, compared to $865.8 million as of December 31, 2015, a decrease of $138.2 million.
- **Revenues:** Collaboration revenue was $1.6 million for the third quarter of 2016 compared to $1.3 million for third quarter of 2015.
- **R&D Expenses:** Research and development expenses were $64.0 million for the third quarter of 2016 compared to $30.4 million for the third quarter of 2015. The increase in research and development expenses was primarily attributable to increased in-licensing milestones and fees, increased manufacturing costs and increased information technology and facilities costs to support the advancement of our clinical and pre-clinical programs, and increased employee payroll costs to support our overall growth.
- **G&A Expenses:** General and administrative expenses were $14.6 million for the third quarter of 2016 compared to $13.7 million for the third quarter of 2015. The increase in general and administrative expenses was primarily attributable to increased employee compensation expense due to increased headcount, partially offset by decreased stock-based compensation expense.
- **Net Loss:** Net loss was $77.0 million for the third quarter of 2016 compared to $42.9 million for the third quarter of 2015.
- **Financial guidance:** bluebird bio expects that its cash, cash equivalents and marketable securities of $727.6 million as of September 30, 2016 will be sufficient to fund its current operations through 2018.

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 megaTALs/homing endonuclease gene editing technologies with the potential for use across the company's pipeline.

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

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, and whether the planned changes to the HGB-206 clinical study protocol will improve outcomes in patients with severe sickle cell disease. 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 quarterly report on 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.

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	**2015**	**2016**	**2015**
Revenue:				
Collaboration revenue	$ 1,552	$ 1,324	$ 4,603	$ 12,607
Total revenue	1,552	1,324	4,603	12,607
Operating expenses:				
Research and development	63,971	30,395	147,642	98,380
General and administrative	14,623	13,704	48,941	31,765
Change in fair value of contingent consideration	1,098	352	3,515	2,540
Total operating expenses	79,692	44,451	200,098	132,685
Loss from operations	(78,140)	(43,127)	(195,495)	(120,078)
Other income, net	937	263	2,803	630
Loss before income taxes	(77,203)	(42,864)	(192,692)	(119,448)
Income tax benefit (expense)	178	(60)	549	(60)
Net loss	$(77,025)	$ (42,924)	$(192,143)	$(119,508)
Net loss per share - basic and diluted:	$ (2.07)	$ (1.18)	$ (5.19)	$ (3.52)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	37,201	36,384	37,026	33,979

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

	September 30, 2016	December 31, 2015
Cash, cash equivalents and marketable securities	$ 727,641	$ 865,763
Total assets	918,262	1,002,337
Total liabilities	223,749	151,841
Total stockholders' equity	694,513	850,496

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