
**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): August 3, 2016

bluebird bio, Inc.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of
incorporation)

001-35966

(Commission File Number)

13-3680878

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

**150 Second Street
Cambridge, MA**

(Address of principal executive offices)

02141

(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))
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Item 2.02 Results of Operations and Financial Condition

On August 3, 2016, bluebird bio, Inc. announced its financial results for the three months ended June 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on August 3, 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: August 3, 2016

bluebird bio, Inc.

By: /s/ Jeffrey T. Walsh

Jeffrey T. Walsh

*Chief Financial and Strategy Officer and Principal
Financial Officer*

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by bluebird bio, Inc. on August 3, 2016, furnished herewith.

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

- *Announced long-term commercial manufacturing agreement with Lonza –*
- *Presented data on gene editing platform at American Society of Hematology (ASH) Workshop on Genome Editing –*
- *Received Orphan Drug Designation for bb2121 in Multiple Myeloma –*
- *Presented interim clinical data from Starbeam study of Lenti-D™ in cerebral adrenoleukodystrophy (CALD) at American Academy of Neurology (AAN) Annual Meeting –*
- *Presented gene therapy and oncology data at American Society for Gene and Cell Therapy (ASGCT) Meeting –*
- *Ended quarter with \$779.0 million in cash, cash equivalents and marketable securities –*

CAMBRIDGE, Mass., August 3, 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 second quarter ended June 30, 2016.

“We continue to advance our LentiGlobin™, Lenti-D and bb2121 programs through clinical trials, and in recent months, we’ve been pleased to showcase some of the innovative platform work we are doing to continuously improve upon our therapies. At the ASH Workshop on Genome Editing last month, we provided more detail on our proprietary megaTAL genome editing platform, and at the ASGCT annual meeting, we highlighted our progress in developing next-generation T cell-based immunotherapies and improving manufacturing, transduction efficiency and assay development,” said Nick Leschly, chief bluebird. “In the second half of 2016, we look forward to continued progress on our clinical programs, including initiation of the LentiGlobin HGB-207 Phase 3 study in non-β0/β0 transfusion-dependent thalassemia (TDT), the integration of manufacturing process improvements into our LentiGlobin clinical trials, and presenting updated LentiGlobin clinical data at ASH.”

Recent Highlights

- **MANUFACTURING AGREEMENT WITH LONZA** – In June, bluebird and Lonza announced a strategic manufacturing agreement providing for the future commercial production of bluebird bio's Lenti-D™ and LentiGlobin™ drug products. This agreement follows a successful multi-year clinical manufacturing relationship and provides bluebird bio with a path to commercial supply including dedicated production suites within Lonza's state-of-the-art facility. Under this multi-year agreement, Lonza will complete

the suite design, construction and validation along with process validation prior to anticipated commercial launch.

- **GENOME EDITING DATA PRESENTED AT ASH WORKSHOP ON GENOME EDITING** – In July, pre-clinical data from bluebird’s megaTAL genome editing platform was presented at the ASH Workshop on Genome Editing in Washington, DC. The data reported at the ASH workshop highlight recent progress bluebird has made in:
 - Expanding the number of megaTAL targetable sites in the genome to permit the precise placement of an editing event within a target gene
 - Refining the specificity of megaTALs to eliminate undesirable off-target activity
 - Combining megaTALs targeting different target genes to achieve the knockout of multiple genes simultaneously
- **ORPHAN DRUG DESIGNATION GRANTED FOR BB2121 IN MULTIPLE MYELOMA** – In May, the U.S. Food and Drug Administration (FDA) granted orphan drug designation for bb2121 in multiple myeloma. bb2121 is a chimeric antigen receptor T cell (CAR T) therapy targeting B cell maturation antigen (BCMA), and is being developed by bluebird bio in collaboration with Celgene Corporation. In February, the first patient was infused in the CRB-401 study of anti-BCMA CAR T therapy bb2121 in relapsed/refractory multiple myeloma. Additionally, Celgene exercised its option to exclusively license bb2121.
- **PRESENTED INTERIM DATA FROM STARBEAM STUDY AT AAN ANNUAL MEETING** – In April, Dr. Florian Eichler of Massachusetts General Hospital for Children presented interim clinical data from the Starbeam study of Lenti-D in CALD at AAN. Initial Starbeam results suggest Lenti-D gene therapy may have similar efficacy to allogeneic hematopoietic stem cell transplant (HCT), the current standard of care, with a more favorable safety profile. As of March 31, 2016, three of the 17 patients enrolled in the study have reached two years of follow-up and remain free of major functional disabilities (MFDs), the primary endpoint of the study. Sixteen of the 17 patients had stabilization of their neurological function score (NFS), and 14 of 17 had a stable Loes score. The safety profile of Lenti-D treatment appeared consistent with myeloablative conditioning.
- **TEN ABSTRACTS PRESENTED AT ASGCT 19th ANNUAL MEETING** – In April, two oral presentations given by bluebird’s academic collaborators highlighted previously presented data from bluebird bio’s ongoing gene therapy clinical trials, including interim data from the Starbeam Study of Lenti-D™ in cerebral adrenoleukodystrophy, and interim data from the HGB-205 study of LentiGlobin in severe sickle cell disease and TDT. Eight additional presentations were featured at the meeting, highlighting progress across the company’s preclinical, research and process development activities in both HSC gene therapy and T cell immunotherapy.

Second Half 2016 Anticipated Milestones

- Update on LentiGlobin process improvements
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- Initiation of the HGB-207 study in patients with TDT with the non- β^0/β^0 genotype
- Presentation of updated clinical data for LentiGlobin at the ASH annual meeting in December 2016

Second Quarter 2016 Financial Results and Financial Guidance

- **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2016 were \$779.0 million, compared to \$865.8 million as of December 31, 2015, a decrease of \$86.8 million.
- **Revenues:** Collaboration revenue was \$1.6 million for the second quarter of 2016 compared to \$4.9 million for second quarter of 2015. The decrease is a result of an amendment to our collaboration agreement with Celgene in June 2015.
- **R&D Expenses:** Research and development expenses were \$41.8 million for the second quarter of 2016 compared to \$44.3 million for the second quarter of 2015. The decrease in research and development expenses was primarily attributable to decreased in-licensing milestones and fees and stock-based compensation expense partially offset by increased employee payroll and facilities costs due to increased headcount, and increased manufacturing, clinical, and information technology costs to support the advancement of our clinical and pre-clinical programs.
- **G&A Expenses:** General and administrative expenses were \$18.4 million for the second quarter of 2016 compared to \$10.7 million for the second quarter of 2015. The increase in general and administrative expenses was primarily attributable to increased employee compensation expense due to increased headcount, and consulting costs to support our overall growth.
- **Net Loss:** Net loss was \$58.8 million for the second quarter of 2016 compared to \$51.8 million for the second quarter of 2015.
- **Financial guidance:** bluebird bio expects that its cash, cash equivalents and marketable securities of \$779.0 million as of June 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™ BB305 product candidate, currently in three 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.

LentiGlobin and Lenti-D are trademarks of bluebird bio, Inc.

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. 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 risk that our 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.

Availability of other information about bluebird bio

Investors and others should note that we communicate with our investors and the public using our company website (www.bluebirdbio.com), including but not limited to investor presentations and FAQs, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. You can also connect with us on Twitter [@bluebirdbio](https://twitter.com/bluebirdbio), [LinkedIn](https://www.linkedin.com/company/bluebirdbio) or our [YouTube](https://www.youtube.com/channel/UC...) channel. The information that we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in bluebird bio to review the information that we post on these channels, including our investor

relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include other social media channels than the ones described above. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Revenue:				
Collaboration revenue	\$ 1,552	\$ 4,940	\$ 3,051	\$ 11,284
Total revenue	<u>1,552</u>	<u>4,940</u>	<u>3,051</u>	<u>11,284</u>
Operating expenses:				
Research and development	41,760	44,266	83,671	67,985
General and administrative	18,363	10,724	34,318	18,060
Change in fair value of contingent consideration	1,404	1,973	2,417	2,188
Total operating expenses	<u>61,527</u>	<u>56,963</u>	<u>120,406</u>	<u>88,233</u>
Loss from operations	(59,975)	(52,023)	(117,355)	(76,949)
Other income, net	905	228	1,866	367
Loss before income taxes	(59,070)	(51,795)	(115,489)	(76,582)
Income tax benefit	226	-	371	-
Net loss	<u>\$ (58,844)</u>	<u>\$ (51,795)</u>	<u>\$ (115,118)</u>	<u>\$ (76,582)</u>
Net loss per share - basic and diluted:	<u>\$ (1.59)</u>	<u>\$ (1.57)</u>	<u>\$ (3.12)</u>	<u>\$ (2.34)</u>
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	<u>36,954</u>	<u>32,955</u>	<u>36,937</u>	<u>32,757</u>

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

	June 30,	December 31,
	2016	2015
Cash, cash equivalents and marketable securities	\$ 779,002	\$ 865,763
Total assets	941,667	1,002,337
Total liabilities	182,377	151,841
Total stockholders' equity	759,290	850,496

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