
**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 6, 2015

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 6, 2015, bluebird bio, Inc. announced its financial results for the three months ended June 30, 2015. 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 6, 2015, 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 6, 2015

bluebird bio, Inc.

By: /s/ James M. DeTore

James M. DeTore

Chief Financial 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 6, 2015, furnished herewith.



bluebird bio Reports Second Quarter 2015 Financial Results and Recent Operational Progress

- Presented promising new beta-thalassemia major and severe sickle cell disease data from HGB-205 study at EHA annual meeting --
- Announced global regulatory strategy for LentiGlobin BB305 in beta-thalassemia major, with plans to pursue conditional and accelerated registration strategies in the E.U. and U.S., respectively --
- Announced broad T cell oncology strategy and related collaborations --
- Hired Philip Gregory, D. Phil., as Chief Scientific Officer --
- Completed successful public offering of common stock, raising net proceeds of \$477.2 million --

CAMBRIDGE, Mass., August 6, 2015 – bluebird bio, Inc. (Nasdaq: BLUE), a clinical-stage company committed to developing potentially transformative gene therapies for severe genetic and rare diseases and T cell-based immunotherapies, today reported business highlights and financial results for the second quarter ended June 30, 2015.

“The first half of this year was a period of exceptional progress for bluebird bio across all fronts, and we made significant strides toward our goal of delivering transformative gene therapy products to change the lives of patients,” said Nick Leschly, chief bluebird. “We gained general agreement from U.S. and E.U. regulators on the path forward for LentiGlobin in beta-thalassemia major, and presented early data in severe sickle cell disease that supports the potential for LentiGlobin to make a meaningful difference for these patients. We also spoke for the first time in greater detail about our strategy to build an independent, differentiated immuno-oncology business.”

Recent Highlights

- **SICKLE CELL DISEASE (SCD) AND BETA-THALASSEMIA DATA PRESENTATION AT THE 20TH CONGRESS OF THE EUROPEAN HEMATOLOGY ASSOCIATION** – Presented positive data from two patients with beta-thalassemia major and the first patient with severe sickle cell disease ever treated with our LentiGlobin BB305 product candidate. As of May 2015, Subjects 1201 and 1202 with beta-thalassemia major remained transfusion-independent for 16 and 14 months, respectively. Subject 1204 with severe SCD demonstrated increasing HbAT87Q production at six months' follow-up and was free of transfusions for more than three months. At the six-month visit post-drug product infusion, the proportion of anti-sickling hemoglobin (HbAT87Q + HbF) in the patient with SCD accounted for 45 percent of all hemoglobin production. As of May 2015, the patient with SCD had no hospitalizations for sickle cell complications post-transplant, despite weaning of transfusions. LentiGlobin BB305 was well-tolerated, with no drug product-related adverse events observed as of the May 2015 data cut-off.
 - **LENTIGLOBIN BETA-THALASSEMIA GLOBAL REGULATORY STRATEGY** – Announced plan to pursue conditional approval of our LentiGlobin BB305 product candidate for the treatment of beta-thalassemia major in the E.U. through the Adaptive Pathways Pilot Program based on data from the ongoing Northstar and HGB-205 studies and plan to pursue
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accelerated approval in the U.S. based on our planned HGB-207 and HGB-208 studies. Completed NIH RAC review of HGB-207 and HGB-208 study protocols in adult and adolescent patients with beta-thalassemia major and pediatric patients with beta-thalassemia major, respectively.

- **IMMUNO-ONCOLOGY STRATEGY** – Announced strategy to build a broad T cell-based immuno-oncology portfolio based on our immuno-oncology, gene therapy clinical development and lentiviral vector manufacturing expertise and genome editing capabilities. Revised Celgene collaboration to focus exclusively on anti-BCMA product candidates in multiple myeloma, initiated a strategic collaboration with Kite Pharma focused on second-generation T cell receptor (TCR) therapies in HPV-associated cancers and entered into an exclusive license agreement with Five Prime Therapeutics around chimeric antigen receptor (CAR) T cell therapies against an undisclosed cancer target for hematologic malignancies and solid tumors.
- **CHIEF SCIENTIFIC OFFICER** – Hired Philip Gregory, D. Phil., as Chief Scientific Officer. Formerly Chief Scientific Officer and Senior Vice President, Research at Sangamo BioSciences, Dr. Gregory brings extensive expertise in the fields of genome editing and gene therapy.
- **STRENGTHENED BALANCE SHEET** – Raised \$477.2 million in net proceeds in an equity financing in June 2015. Our cash, cash equivalents and marketable securities are sufficient to fund our operations through 2018, based on the company's current business plan. Proceeds from the equity financing will fund advancement of our immuno-oncology programs, development of a commercial infrastructure to support a potential conditional commercial launch of LentiGlobin in Europe, expansion of manufacturing capabilities to support ongoing and anticipated development and commercial efforts, and initiation of clinical studies of LentiGlobin in adult, adolescent and pediatric subjects with beta-thalassemia major.

Second Quarter 2015 Financial Results and Financial Guidance

- **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2015 were \$936.4 million, compared to \$492.0 million as of December 31, 2014, an increase of \$444.4 million, which was primarily driven by the June 2015 equity financing.
 - **Revenues:** Collaboration revenue was \$4.9 million for the second quarter of 2015 compared to \$6.3 million for the second quarter of 2014. Collaboration revenue is primarily comprised of the amortization of deferred revenue related to our collaboration agreement with Celgene.
 - **R&D Expenses:** Research and development expenses were \$44.3 million for the second quarter of 2015, compared to \$13.9 million for the same period in 2014, an increase of \$30.4 million. The increase in research and development expenses was primarily attributable to an \$11.0 million increase in stock-based compensation expense, of which \$8.5 million is non-recurring, a \$10.7 million increase in one-time in-license milestones and fees, and an increase in expenses necessary to support the advancement of our clinical and pre-clinical programs.
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- **G&A Expenses:** General and administrative expenses were \$10.7 million for the second quarter of 2015, compared to \$5.7 million for the same period in 2014, an increase of \$5.0 million. The increase in general and administrative expenses was primarily attributable to a \$3.5 million increase in employee- and contractor-related costs to support our overall growth.
- **Net Loss:** Net loss was \$51.8 million for the second quarter of 2015, compared to net loss of \$1.5 million for the second quarter of 2014.
- **Financial guidance:** bluebird bio expects that its cash, cash equivalents and marketable securities of \$936.4 million as of June 30, 2015 will be sufficient to fund its operations through 2018, based on the company's current business plan.

About bluebird bio, Inc.

With its lentiviral-based gene therapy and gene editing capabilities, bluebird bio has built an integrated product platform with broad potential application to severe genetic diseases and T cell-based immunotherapy. bluebird bio's clinical programs include Lenti-D™, currently in a Phase 2/3 study, called the Starbeam Study, for the treatment of childhood cerebral adrenoleukodystrophy, and LentiGlobin®, currently in three clinical studies: a global Phase 1/2 study, called the Northstar Study, for the treatment of beta-thalassemia major; a single-center Phase 1/2 study in France (HGB-205) for the treatment of beta-thalassemia major or severe sickle cell disease; and a separate U.S. Phase 1 study for the treatment of sickle cell disease (HGB-206). bluebird bio also has ongoing preclinical CAR T immuno-oncology programs, as well as discovery research programs utilizing megaTALs/homing endonuclease gene editing technologies.

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. 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 risk of cessation or delay of any of the ongoing or planned clinical studies or development activities for our product candidates, the risk of a delay in the enrollment of patients in the Company's clinical studies, the risk that the results of previously conducted studies involving similar product candidates will not be repeated or observed in ongoing or future studies involving current product candidates, the risk that our collaborations with Celgene and Kite 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 and 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.

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), our investor relations website (<http://www.bluebirdbio.com/investor-splash.html>), 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.
Consolidated Statements of Operations Data
(unaudited)
(in thousands, except per share data)

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
Revenue:				
Collaboration revenue	\$ 4,940	\$ 6,250	\$ 11,284	\$ 12,500
Research and license fees	—	85	—	170
Total revenue	4,940	6,335	11,284	12,670
Operating expenses:				
Research and development	44,266	13,931	67,985	25,394
General and administrative	10,724	5,738	18,060	11,277
Change in fair value of contingent consideration	1,973	—	2,188	—
Total operating expenses	56,963	19,669	88,233	36,671
Loss from operations	(52,023)	(13,334)	(76,949)	(24,001)
Other income, net	228	11	367	69
Loss before income taxes	(51,795)	(13,323)	(76,582)	(23,932)
Benefit from income taxes	—	11,797	—	11,797
Net loss	\$ (51,795)	\$ (1,526)	\$ (76,582)	\$ (12,135)
Net loss per share - basic and diluted:	\$ (1.57)	\$ (0.06)	\$ (2.34)	\$ (0.50)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	32,955	24,474	32,757	24,312



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

	June 30,	December 31,
	2015	2014
Cash, cash equivalents and marketable securities	\$ 936,445	\$ 492,003
Total assets	999,169	556,739
Total liabilities	80,203	65,482
Total stockholders' equity	918,966	491,257

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