
**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 24, 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 February 24, 2016, bluebird bio, Inc. announced its financial results for the year and three months ended December 31, 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 February 24, 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: February 24, 2016

bluebird bio, Inc.

By: /s/ James M. DeTore
James M. DeTore
Chief Financial Officer and Principal Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press release issued by bluebird bio, Inc. on February 24, 2016, furnished herewith.



bluebird bio Reports Fourth Quarter and Full Year 2015 Financial Results and Recent Operational Progress

- Treated first patient in CRB-401 study of anti-BCMA CAR T bb2121 in relapsed/refractory multiple myeloma --*
 - Announced that Celgene has exercised its option to license bb2121 --*
- Presented LentiGlobin clinical data in transfusion-dependent β -thalassemia and severe sickle cell disease at the American Society of Hematology (ASH) annual meeting --*
- Presented pre-clinical and manufacturing data from oncology pipeline at ASH annual meeting --*
 - Signed exclusive license agreement with Viomed for solid tumor CAR T target --*
 - Ended year with \$865.8 million in cash, cash equivalents, and marketable securities --*

CAMBRIDGE, Mass., February 24, 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 fourth quarter and full year ended December 31, 2015.

“In 2015 bluebird bio defined an accelerated regulatory path for LentiGlobin in β -thalassemia and established a powerful reason to believe in LentiGlobin in sickle cell disease, though there is still more to learn as we treat additional patients. We also fully enrolled our Starbeam study of Lenti-D in cerebral adrenoleukodystrophy and made significant advances in building a competitive T cell oncology franchise,” said Nick Leschly, chief bluebird. “In 2016 we are excited to learn even more across all of our programs and continue to innovate and improve. We are particularly looking forward to sharing data from the Starbeam study for the first time and presenting more data with longer follow-up from all three of our LentiGlobin clinical studies.”

Recent Highlights

- **ADVANCED FIRST ONCOLOGY PROGRAM INTO THE CLINIC** – Earlier in February, the first patient was infused in the CRB-401 study of bb2121 in relapsed/refractory multiple myeloma. Additionally, Celgene has exercised its option to exclusively license bb2121, under the terms of the collaboration agreement between the two companies. bluebird bio will receive a \$10.0 million option exercise payment from Celgene and is also eligible to receive specified development and regulatory milestone payments and royalty payments on net sales.
- **PRESENTED UPDATED CLINICAL DATA IN β -THALASSEMIA FROM HGB-204 AND HGB-205 CLINICAL STUDIES OF LENTIGLOBIN AT ASH** – In December 2015, investigators presented data from bluebird bio’s ongoing clinical

studies in transfusion-dependent β -thalassemia (TDT) and severe sickle cell disease (SCD). Data in patients with TDT from the HGB-204 and HGB-205 studies showed that 100% of patients with non- β 0/ β 0 genotypes achieved sustained transfusion independence as of the data cut-off, ranging from 7.1 months to 23.4 months. Patients with the β 0/ β 0 genotype all saw reductions in their transfusion needs, ranging from a 33% to 100% reduction.

- **PRESENTED CLINICAL DATA IN SICKLE CELL DISEASE FROM HGB-205 AND HGB-206 CLINICAL STUDIES OF LENTIGLOBIN AT ASH** – Marina Cavazzana, M.D., Ph.D., of Hospital Necker, University Paris Descartes, presented updated data on one patient with SCD from the HGB-205 study, who remained free of transfusions, hospitalizations and acute SCD-related events for more than nine months as of the data cut-off. At the 12-month post-drug infusion follow-up, the proportion of anti-sickling hemoglobin in this patient accounted for 49% (47% HbA^{T87Q} + 2% HbF) of all hemoglobin production – well above the 30% threshold anticipated to achieve a disease-modifying effect. John Tisdale, M.D., of the National Institutes of Health presented early data from the HGB-206 study, in which two patients had at least three months of post-infusion follow-up. At the three-month post-infusion follow-up for Subject 1301, anti-sickling hemoglobin accounted for 17% of all hemoglobin production (4% HbA^{T87Q} + 13% HbF). At the six-month post-infusion follow-up for subject 1303, anti-sickling hemoglobin accounted for 16 percent of all hemoglobin production (12% HbA^{T87Q} + 4% HbF).
 - **PRESENTED PRE-CLINICAL AND MANUFACTURING DATA FROM CAR T ONCOLOGY PROGRAMS AT ASH** – bluebird bio scientists presented three posters at ASH, covering critical basic research, translational and manufacturing aspects of the Company’s T cell oncology programs. One poster discussed an important observation made by bluebird bio scientists: culturing anti-BCMA CAR T cells with a PI3K inhibitor generated a product with many of the properties of younger, less differentiated T cells. Consistent with a younger T cell phenotype, this product showed improved *in vivo* efficacy and persistence in multiple model systems.
 - **SHARED DATA ON PLATFORM IMPROVEMENTS** – In an investor event at ASH, bluebird bio chief scientific officer Philip Gregory, D.Phil., presented data from ongoing research to improve the cell transduction process for LentiGlobin. The presentation showed that in preclinical experiments, adding selected compounds to the transduction process resulted in substantially increased vector copy number and transduction efficiency (i.e. percentage of corrected cells). Importantly, the new process was shown to be robust with similar improvements seen across multiple donors and vector lots.
 - **ENTERED INTO CAR T LICENSE WITH VIROMED** – Signed exclusive license agreement with Viromed Co., Ltd., to research, develop and commercialize CAR T therapies using Viromed’s proprietary humanized antibody to an undisclosed cancer target in solid tumors.
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Upcoming Anticipated Milestones

- Presentation of interim data from the Starbeam study of Lenti-D in patients with cerebral adrenoleukodystrophy (CALD) at the American Academy of Neurology annual meeting in April 2016
- Update on LentiGlobin process improvements in the second half of 2016
- Initiation of the HGB-207 study in patients with TDT with the non-β0/β0 genotype in the second half of 2016
- Presentation of updated data from the HGB-204, HGB-205 and HGB-206 studies at the ASH annual meeting in December 2016

Fourth Quarter and Full Year 2015 Financial Results and Financial Guidance

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2015 were \$865.8 million, compared to \$492.0 million as of December 31, 2014, an increase of \$373.8 million, which was primarily driven by the June 2015 equity financing partially offset by cash used to fund operations.
 - **Revenues:** Collaboration revenue was \$1.5 million for the fourth quarter of 2015 and \$14.1 million for the year ended December 31, 2015, compared to \$6.3 million and \$25.0 million in the comparable periods in 2014. The decrease is a result of an amendment to our collaboration agreement with Celgene in the second quarter of 2015.
 - **R&D Expenses:** Research and development expenses were \$35.7 million for the fourth quarter of 2015 and \$134.0 million for the year ended December 31, 2015, compared to \$20.5 million and \$62.6 million for the comparable periods in 2014. The increase in research and development expenses was primarily attributable to increased employee compensation expense due to increased headcount, in-licensing milestones and fees, and manufacturing and clinical trial-related costs to support our advancing pipeline.
 - **G&A Expenses:** General and administrative expenses were \$14.4 million for the fourth quarter of 2015 and \$46.2 million for the year ended December 31, 2015, compared to \$5.3 million and \$23.2 million for the comparable periods in 2014. The increase in general and administrative expenses was primarily attributable to increased employee compensation expense due to increased headcount, and consulting and facilities-related costs to support our overall growth.
 - **Net Loss:** Net loss was \$47.3 million for the fourth quarter of 2015 and \$166.8 million for the year ended December 31, 2015, compared to net loss of \$19.5 million and \$48.7 million for the comparable periods in 2014.
 - **Financial guidance:** bluebird bio expects that its cash, cash equivalents and marketable securities of \$865.8 million as of December 31, 2015 will be sufficient to fund its current operations through 2018.
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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, also known as β -thalassemia major, 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, 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 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), 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](#) or our [YouTube](#) 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 December 31,		Year ended December 31,	
	2015	2014	2015	2014
Revenue:				
Collaboration revenue	\$ 1,471	\$ 6,281	\$ 14,079	\$ 25,031
Research and license fees	—	105	—	390
Total revenue	<u>1,471</u>	<u>6,386</u>	<u>14,079</u>	<u>25,421</u>
Operating expenses:				
Research and development	35,659	20,530	134,038	62,574
General and administrative	14,444	5,302	46,209	23,227
Change in fair value of contingent consideration	329	168	2,869	246
Total operating expenses	<u>50,432</u>	<u>26,000</u>	<u>183,116</u>	<u>86,047</u>
Loss from operations	(48,961)	(19,614)	(169,037)	(60,626)
Total other income (expense), net	1,684	70	2,314	120
Loss before income taxes	(47,277)	(19,544)	(166,723)	(60,506)
Income tax (expense) benefit	—	—	(60)	11,797
Net loss	<u>\$(47,277)</u>	<u>\$(19,544)</u>	<u>\$(166,783)</u>	<u>\$(48,709)</u>
Net loss per share - basic and diluted:	<u>\$ (1.29)</u>	<u>\$ (0.67)</u>	<u>\$ (4.81)</u>	<u>\$ (1.83)</u>
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	<u>36,716</u>	<u>29,373</u>	<u>34,669</u>	<u>26,546</u>

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

	<u>December 31,</u> <u>2015</u>	<u>December 31,</u> <u>2014</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 164,269	\$ 347,845
Marketable securities	353,680	125,710
Prepaid expenses and other current assets	6,016	6,434
Total current assets	523,965	479,989
Marketable securities	347,814	18,448
Property and equipment, net	82,614	15,740
Intangible assets, net	24,456	28,219
Goodwill	13,128	13,128
Restricted cash and other non-current assets	10,360	1,215
Total assets	<u>\$ 1,002,337</u>	<u>\$ 556,739</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 6,334	\$ 2,954
Accrued expenses and other current liabilities	28,145	14,649
Deferred revenue, current portion	5,889	25,375
Total current liabilities	40,368	42,978
Deferred rent, net of current portion	8,294	8,674
Deferred revenue, net of current portion	35,959	5,302
Contingent consideration, net of current portion	5,082	6,321
Construction financing lease obligation	61,901	—
Other non-current liabilities	237	2,207
Total liabilities	151,841	65,482
Stockholders' equity:		
Common stock, \$0.01 par value, 125,000 shares authorized; 36,894 and 32,340 shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	369	323
Additional paid-in capital	1,166,585	638,389
Accumulated other comprehensive income (loss)	(2,291)	(71)
Accumulated deficit	(314,167)	(147,384)
Total stockholders' equity	850,496	491,257
Total liabilities and stockholders' equity	<u>\$ 1,002,337</u>	<u>\$ 556,739</u>

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