# **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 25, 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)

**150 Second Street** Cambridge, MA

(Address of principal executive offices)

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))

13-3680878

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

02141

(Zip Code)

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

On February 25, 2015, bluebird bio, Inc. announced its financial results for the year and three months ended December 31, 2014. 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 February 25, 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: February 25, 2015

#### bluebird bio, Inc.

By:<u>/s/ James M. DeTore</u> James M. DeTore *Chief Financial Officer and Principal Financial Officer* 

# EXHIBIT INDEX

Exhibit No.Description99.1Press release issued by bluebird bio, Inc. on February 25, 2015, furnished herewith.



#### bluebird bio Reports Fourth Quarter and Full Year 2014 Financial Results and Recent Operational Progress

CAMBRIDGE, Mass., February 25, 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 fourth quarter and full year ended December 31, 2014.

"Over the last year, bluebird bio's efforts advanced the field of gene therapy, driving us closer to our goal of transforming the lives of patients with severe genetic and rare diseases," said Nick Leschly, chief bluebird. "In 2014, we presented groundbreaking clinical data in treating beta-thalassemia and were the first in the field to use gene therapy to treat a patient with sickle cell disease. We also acquired gene editing capabilities, strengthened our team and added a substantial amount of cash to our balance sheet, positioning us well to advance to our next stage of development. In 2015, our priorities include completing patient enrollment and obtaining more data from our ongoing clinical programs, defining the regulatory pathways to bring our product candidates to patients and continuing to advance our pipeline of promising immunotherapy and gene therapy programs."

#### **Recent bluebird Highlights**

- Presented data from beta-thalassemia program at the American Society of Hematology (ASH) annual meeting. In December 2014, bluebird bio presented data from its Northstar and HGB-205 studies demonstrating that the first four beta-thalassemia major patients treated with LentiGlobin® were transfusion free. The Northstar Study is an ongoing, open-label, single-dose, international, multi-center Phase 1/2 study designed to evaluate the safety and efficacy of LentiGlobin for the treatment of subjects with beta-thalassemia major. The HGB-205 study is an ongoing, open-label, single-center Phase 1/2 study designed to evaluate the safety and efficacy of LentiGlobin for the treatment of subjects with beta-thalassemia major. The HGB-205 study is an ongoing, open-label, single-center Phase 1/2 study designed to evaluate the safety and efficacy of LentiGlobin in the treatment of subjects with beta-thalassemia major and severe sickle cell disease. The data presented at ASH build upon data presented in June 2014 from the HGB-205 study at the European Hematology Association (EHA) annual meeting.
- Advanced sickle cell disease program. In October 2014, as part of the HGB-205 study, bluebird bio became the first company to treat a sickle cell disease patient with gene therapy. The company also initiated the HGB-206 study, an open-label, multi-center, U.S.-based Phase 1 study designed to evaluate the safety and efficacy of LentiGlobin for the treatment of subjects with severe sickle cell disease.
- Received Breakthrough Therapy designation for LentiGlobin. In January 2015, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to LentiGlobin for the treatment of transfusion-dependent patients with beta-thalassemia major. The Breakthrough Therapy designation is supported by data from the ongoing Phase 1/2 Northstar and HGB-205 studies of LentiGlobin.
- Advanced enrollment in CCALD trial. bluebird bio continued to enroll patients in its Starbeam Study, a Phase 2/3 study designed to evaluate the safety and efficacy of Lenti-D<sup>™</sup> in the treatment of subjects with childhood cerebral adrenoleukodystrophy (CCALD).
- Strengthened balance sheet. In 2014, bluebird bio raised approximately \$353 million in net proceeds to fund operations, including an equity financing in December 2014 that raised approximately \$243 million and an equity financing in July 2014 that raised approximately \$110 million.

- Acquired new gene editing capabilities. In June 2014, bluebird bio acquired Precision Genome Engineering, Inc., or Pregenen, a privately held biotechnology company headquartered in Seattle. This acquisition provides bluebird bio with cutting-edge gene editing capabilities, including expertise in homing endonucleases and MegaTALs.
- Expanded the bluebird leadership team. In 2014, bluebird bio expanded its executive team with the appointments of Jason Cole as senior vice president and general counsel, and James M. DeTore as chief financial officer and treasurer. The company also added two independent members to its board of directors: James Mandell, M.D., former chief executive officer of Boston Children's Hospital and Mark Vachon, former president and chief executive officer of GE Healthcare Americas. Additionally, bluebird bio announced that Mitchell Finer, Ph.D. would transition from his role as chief scientific officer to a role as a member of the company's scientific advisory board.
- Continued to advance Celgene/Baylor CAR T program. bluebird bio continued to make progress under its broad, global strategic collaboration with Celgene Corporation, which is focused on discovering, developing and commercializing novel disease-altering gene therapies in oncology by utilizing a patient's own genetically modified T cells, known as chimeric antigen receptor (CAR) T cells, to selectively target and destroy cancer cells. The company expects the first product candidate from this program to enter the clinic in early 2016.

## **Upcoming Anticipated Milestones**

bluebird bio has outlined certain key goals for 2015, including:

- Completing enrollment for the Starbeam Study, as well as the Northstar and HGB-205 studies. Continuing enrollment for the HGB-206 study and presenting early clinical efficacy and safety data in patients with severe sickle cell disease at a major medical conference.
- Presenting additional data on beta-thalassemia major from the Northstar and HGB-205 studies at a major medical conference. Based on
  these additional data, the company looks forward to defining the regulatory path forward for LentiGlobin in beta-thalassemia major this year.

#### Fourth Quarter and Full Year 2014 Financial Results and Financial Guidance

- Cash Position: Cash, cash equivalents and marketable securities as of December 31, 2014 were \$492.0 million, compared to \$206.3 million as of December 31, 2013. The increase was primarily driven by net proceeds of \$353.0 million from equity financings partially offset by cash used to fund operations.
- **Revenues:** Collaboration revenue was \$6.3 million for the fourth quarter of 2014 and \$25.0 million for the year ended December 31, 2014, compared to \$6.3 million and \$19.8 million in the comparable periods in 2013. Collaboration revenue is primarily comprised of the amortization of deferred revenue related to the \$75 million upfront payment received in 2013 under bluebird bio's collaboration agreement with Celgene.
- **R&D Expenses:** Research and development expenses were \$20.5 million in the fourth quarter of 2014 and \$62.6 million for the year ended December 31, 2014, compared to \$9.8 million and \$31.0 million in the comparable periods in 2013. The increase in research and development expenses was largely due to increased spending on clinical and manufacturing activities related to the LentiGlobin and Lenti-D product candidates, as well as research and development efforts on the CAR T and gene editing programs.
- **G&A Expenses:** General and administrative expenses were \$5.3 million in the fourth quarter of 2014 and \$23.2 million in the year ended December 31, 2014, compared to \$4.7 million and \$14.1 million in the comparable periods in 2013. The increase in general and administrative expenses was largely due to incremental expenses to support public company operations and additional expenses associated with the acquisition of Pregenen.
- Net Loss: Net loss was \$19.5 million for the fourth quarter of 2014 and \$48.7 million for the year ended December 31, 2014, compared to net loss of \$8.1 million and \$25.3 million for the comparable periods in 2013.
- Financial Guidance: bluebird bio expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operations through 2017.

#### 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<sup>™</sup>, currently in a Phase 2/3 study, called the Starbeam Study, for the treatment of childhood cerebral adrenoleukodystrophy, and LentiGlobin<sup>®</sup>, 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 a preclinical CAR T cancer immunotherapy program in collaboration

with Celgene Corporation, 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. For more information, please visit www.bluebirdbio.com.

#### 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 milestones related to the Company's product candidates and clinical studies, and anticipated milestones related to the Company's product candidates and clinical studies, and anticipated milestones for 2015. 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 and/or our development of 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 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 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

#### 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 (<u>www.bluebirdbio.com</u>), our investor relations website (<u>http://www.bluebirdbio.com/investor-splash.html</u>), 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 (<u>bluebirdbio, LinkedIn</u> or our <u>YouTube</u> 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.

#### **Investor Relations:**

Jim DeTore, Chief Financial Officer bluebird bio, Inc. (339) 499-9355

Media:

Dan Budwick Pure Communications, Inc. (973) 271-6085

# bluebird bio, Inc.

# Consolidated Statements of Operations Data (unaudited) (in thousands, except per share data)

Υ.	December 31,				Year ended December 31,			
		2014		2013		2014		2013
Revenue:								
Collaboration revenue	\$	6,281	\$	6,250	\$	25,031	\$	19,792
Research and license fees		105		85		390		389
Total revenue		6,386		6,335		25,421		20,181
Operating expenses:								
Research and development		20,531		9,765		62,574		31,002
General and administrative		5,303		4,685		23,227		14,126
Change in fair value of contingent consideration		168				246		_
Total operating expenses		26,002		14,450		86,047		45,128
Loss from operations		(19,616)		(8,115)		(60,626)		(24,947)
Total other income (expense), net		72		34		120		(374)
Loss before income taxes		(19,544)		(8,081)		(60,506)		(25,321)
Benefit from income taxes		_				11,797		
Net loss	\$	(19,544)	\$	(8,081)	\$	(48,709)	\$	(25,321)
Net loss per share - basic and diluted:	\$	(0.67)	\$	(0.34)	\$	(1.83)	\$	(2.02)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	_	29,373	_	23,740	_	26,546		12,555

# bluebird bio, Inc.

# Consolidated Balance Sheets Data (unaudited) (in thousands, except par value amounts)

(in thousands, except par value amount	s)	2014	2013
Assets		<u> </u>	 
Current assets:			
Cash and cash equivalents	\$	347,845	\$ 206,279
Marketable securities		125,710	_
Deferred tax assets		1,913	693
Prepaid expenses and other current assets		4,521	 5,015
Total current assets		479,989	 211,987
Marketable securities		18,448	_
Property and equipment, net		15,740	10,920
Intangible assets, net		28,219	—
Goodwill		13,128	
Restricted cash and other non-current assets		1,215	 1,483
Total assets	\$	556,739	\$ 224,390
Liabilities and stockholders' equity			
Current liabilities:			
Accounts payable	\$	2,954	\$ 4,359
Accrued expenses and other current liabilities		14,649	5,175
Deferred revenue, current portion		25,375	 25,340
Total current liabilities		42,978	34,874
Deferred rent, net of current portion		8,674	6,740
Deferred revenue, net of current portion		5,302	30,208
Contingent consideration, net of current portion		6,321	_
Deferred tax liabilities		1,913	693
Other non-current liabilities		294	 208
Total liabilities		65,482	72,723
Stockholders' equity:			
Common stock, \$0.01 par value, 125,000 shares authorized;			
32,340 and 23,940 shares issued and outstanding at December 31, 2014			
and December 31, 2013, respectively		323	239
Additional paid-in capital		638,389	250,103
Accumulated other comprehensive loss		(71)	—
Accumulated deficit		(147,384)	 (98,675)
Total stockholders' equity		491,257	 151,667
Total liabilities and stockholders' equity	\$	556,739	\$ 224,390