# 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 2, 2017**

# 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) | (IRS Employer Identification No.) |
| 60 Binney Street, Cambridge, MA (Address of Principal Executive Offices) | | 02142 (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 (see General Instructions A.2. below):

☐ 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

On August 2, 2017, bluebird bio, Inc. announced its financial results for the three months ended June 30, 2017. 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 August 2, 2017 |

**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 2, 2017

**bluebird bio, Inc.**

By:/s/ Jeffrey T. Walsh
Jeffrey T. Walsh
*Chief Financial & Strategy Officer and Principal Financial Officer*

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Press release issued by bluebird bio, Inc. on August 2, 2017 |

**Exhibit 99.1**

**bluebird bio Reports Second Quarter 2017 Financial Results and Recent Operational Progress**

- *Completed enrollment in Northstar-2, Phase 3 study of LentiGlobin drug product in patients with transfusion-dependent β-thalassemia (TDT) and non-$\beta^0/\beta^0$ genotypes –*
- *Presented updated clinical results from studies in relapsed/refractory multiple myeloma, TDT and severe sickle cell disease (SCD) at American Society of Clinical Oncology (ASCO) Annual Meeting and European Hematology Association (EHA) Annual Meeting –*
- *Announced topline interim clinical data from Starbeam Study of Lenti-D™ drug product in cerebral adrenoleukodystrophy (CALD) –*
- *Appointed John O. Agwunobi, M.D. and Douglas A. Melton, Ph.D. to Board of Directors –*
- *Completed public offering of common stock, raising net proceeds of $436.8 million; ended quarter with $1.2 billion in cash, cash equivalents and marketable securities –*

**CAMBRIDGE, Mass., August 2, 2017** – 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, 2017.

"In the first half of 2017, we've made tremendous progress against our stated goals and continue to build momentum to the end of the year. New data from our bb2121 anti-BCMA CAR T program reinforced our confidence in this program, and we and Celgene are moving full speed ahead to continue to the next stage of development. We presented early data demonstrating the impact of manufacturing improvements for LentiGlobin, with our first patients with TDT in Northstar-2 showing significantly higher drug product VCNs than we saw in previous studies. We also announced interim data from the first 17 patients in the Starbeam study of Lenti-D that showed 88% of those patients met the primary endpoint," said Nick Leschly, chief bluebird. "We look forward to sharing more of our progress later this year at ASH, where we will provide updated data on our TDT and multiple myeloma programs, as well as a first look at the progress made in the HGB-206 study in severe SCD with changes in the study protocol. For the rest of the year, we're remaining laser-focused on the execution of our clinical development goals across our programs to bring our transformative therapies to patients and on preparing our organization to bring our gene therapy products to many more patients in a commercial setting."

**Recent Highlights**

- **COMPLETED ENROLLMENT IN NORTHSTAR-2 –** In June, bluebird bio completed the enrollment of the adult and adolescent patient cohort in the Northstar-2 study of LentiGlobin drug product in patients with TDT and non-$\beta^0/\beta^0$ genotypes.

- **UPDATED DATA FROM BB2121 ANTI-BCMA CAR T PROGRAM PRESENTED** – At ASCO in June, bluebird bio presented updated results from the ongoing CRB-401 Phase 1 clinical study of bb2121, an investigational anti-BCMA CAR T cell therapy, in 18 patients with relapsed/refractory multiple myeloma. 100% of the 15 evaluable patients in active dose cohorts (doses above 50 x $10^6$) achieved an objective response; overall response rate (ORR) across all cohorts (n=18) was 89%. 73% of evaluable patients in active dose cohorts achieved a very good partial response (VGPR) or better; 27% complete response (CR) rate across active dose cohorts. All patients tested for minimal residual disease (MRD) status (n=4) were found to be MRD-negative. No disease progression had been observed in active dose cohorts as of the May 4, 2017 data cut-off; range of follow-up was 8 to 54 weeks. No dose-limiting toxicities had been observed. The objective of this Phase 1 dose-escalation study is to evaluate the safety and efficacy of bb2121 and determine a recommended Phase 2 dose. bluebird bio and Celgene are jointly developing bb2121.

- **EARLY DATA FROM NORTHSTAR-2 PRESENTED** – At EHA in June, bluebird bio presented early data from its Phase 3 Northstar-2 (HGB-207) study of LentiGlobin drug product in patients with transfusion-dependent β-thalassemia (TDT) and non-$\beta^0/\beta^0$ genotypes. Drug product vector copy number (DP VCN) and percentage of lentiviral vector positive cells (LVV+) for the initial 7 drug product lots manufactured in Northstar-2 were consistently higher than in Northstar (HGB-204), with a median DP VCN of 3.0. Initial results show that the three patients treated to date had achieved in vivo VCN and $HbA^{T87Q}$ production as good as or better than patients achieving transfusion independence in Northstar. The first patient treated in Northstar-2 with 6 months of follow-up achieved normal levels of total hemoglobin (13.3 g/dL) after discontinuing transfusions, producing 9.5 g/dl of $HbA^{T87Q}$ at last follow-up. The safety profile was consistent with autologous transplantation.

- **NEW DATA FROM HGB-205 PRESENTED -** At EHA in June, bluebird bio presented new data from the HGB-205 study of LentiGlobin drug product in patients with TDT and severe sickle cell disease (SCD). Ongoing transfusion independence up to 3.5 years was observed in patients with TDT; three patients have discontinued iron chelation. The first patient with SCD treated with gene therapy (Patient 1204) continues to show clinically meaningful improvement in symptoms of SCD and stable vector copy number and $HbA^{T87Q}$ in peripheral blood. Two recently treated patients with severe SCD show increasing levels of $HbA^{T87Q}$

and stable *in vivo* VCN. As with Patient 1204, the first patient with SCD treated in HGB-205, these two patients received a more stringent busulfan conditioning regimen and regular blood transfusions prior to stem cell harvest.

- **TOPLINE INTERIM LENTI-D DATA ANNOUNCED –** In June, bluebird bio announced topline interim clinical data on the initial 17 patients treated in the Starbeam study of Lenti-D drug product in CALD. As of June 13, 15/17 patients (88%) in initial study cohort remain free of major functional disabilities (MFDs) at 24 months, the primary endpoint of the trial. This exceeds bluebird's pre-defined interim efficacy benchmark for the study of MFD-free survival of 76%, derived from the literature and based on clinical data from an earlier observational study describing that natural history of CALD and outcomes from allogeneic hematopoietic stem cell transplant. The safety profile of Lenti-D was consistent with myeloablative conditioning. No patients treated with Lenti-D had graft versus host disease, and there was no graft rejection or clonal dominance. An expansion cohort is enrolling additional patients to gain European manufacturing experience.

- **NEW BOARD APPOINTMENTS –** In June, bluebird bio appointed John O. Agwunobi, M.D. and Douglas A. Melton, Ph.D. to its Board of Directors.

- **DUKE COLLABORATION –** In May, bluebird bio announced that it has entered into a collaboration with Duke University's Robert J. Margolis, MD, Center for Health Policy to develop a broadly-supported path for value-based payment reform models for gene therapies and other innovative treatments.

- **STRENGTHENED BALANCE SHEET –** In June, bluebird raised $436.8 million in net proceeds in an equity financing. The company's cash, cash equivalents and marketable securities are sufficient to fund operations into 2020 based on the company's current business plan. Proceeds from the equity financing will fund the potential exercise of the option to co-develop and co-promote bb2121; planned clinical studies in oncology and severe genetic diseases; and to further expand the company's manufacturing platform and capabilities to support ongoing and anticipated product development efforts and in anticipation of a potential commercial launch; and general and administrative expenses.

**Second Quarter 2017 Financial Results and Financial Guidance**

- **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2017 were $1.2 billion, compared to $884.8 million as of December 31, 2016, an increase of $312.2 million.
- **Revenues:** Total revenue was $16.7 million for the second quarter of 2017 compared to $1.6 million for second quarter of 2016. The increase is primarily attributable to revenue recognized under bluebird bio's out-licensing agreements with Novartis Pharma AG and GlaxoSmithKline Intellectual Property

Development Limited (GSK) and the commencement of revenue recognition for the bb2121 license and manufacturing services under the company's agreement with Celgene.

- **R&D Expenses:** Research and development expenses were $64.3 million for the second quarter of 2017 compared to $41.8 million for the second quarter of 2016. The increase in research and development expenses was primarily attributable to increased manufacturing expenses, clinical trial expenses, and employee-related costs due to increased headcount to support overall growth.
- **G&A Expenses:** General and administrative expenses were $21.2 million for the second quarter of 2017 compared to $18.4 million for the second quarter of 2016. The increase in general and administrative expenses was primarily attributable to increased employee-related costs due to increased headcount, and increased facility-related expenses to support overall growth.
- **Net Loss:** Net loss was $70.9 million for the second quarter of 2017 compared to $58.8 million for the second quarter of 2016.
- **Financial Guidance:** bluebird bio expects that its cash, cash equivalents and marketable securities of $1.2 billion as of June 30, 2017 will be sufficient to fund its current operations into 2020.

**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 megaTAL/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 Europe.

**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, 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 studies, 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 studies 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 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 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.**
**Condensed Consolidated Statements of Operations Data**
**(unaudited)**
**(in thousands, except per share data)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Revenues: | | | | |
| License revenue | $ 10,570 | $ — | $ 10,570 | $ — |
| Collaboration revenue | 6,146 | 1,552 | 12,978 | 3,051 |
| Total revenues | 16,716 | 1,552 | 23,548 | 3,051 |
| Operating expenses: | | | | |
| Research and development | 64,311 | 41,760 | 119,339 | 83,671 |
| General and administrative | 21,197 | 18,363 | 41,481 | 34,318 |
| Change in fair value of contingent consideration | (970) | 1,404 | 463 | 2,417 |
| Total operating expenses | 84,538 | 61,527 | 161,283 | 120,406 |
| Loss from operations | (67,822) | (59,975) | (137,735) | (117,355) |
| Interest (expense) income, net | (2,242) | 981 | (687) | 1,932 |
| Other (expense) income, net | (834) | (76) | (1,189) | (66) |
| Loss before income taxes | (70,898) | (59,070) | (139,611) | (115,489) |
| Income tax benefit | — | 226 | — | 371 |
| Net loss | $ (70,898) | $ (58,844) | $ (139,611) | $ (115,118) |
| Net loss per share - basic and diluted: | $ (1.73) | $ (1.59) | $ (3.41) | $ (3.12) |
| Weighted-average number of common shares used in computing net loss per share - basic and diluted: | 41,035 | 36,954 | 40,936 | 36,937 |

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

| | As of June 30, 2017 | As of December 31, 2016 |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 1,197,059 | $ 884,830 |
| Total assets | 1,457,130 | 1,118,122 |
| Total liabilities | 257,111 | 248,682 |
| Total stockholders' equity | 1,200,019 | 869,440 |

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