# 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 1, 2019**

# 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** | | **02142** |
| **(Address of Principal Executive Offices)** | | **(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))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock (Par Value $0.01) | BLUE | The NASDAQ Global Select Market LLC |

Indicate by check mark whether the registrant is an emerging growth company 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 1, 2019, bluebird bio, Inc. announced its financial results for the three months ended June 30, 2019. 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 Number | Description |
|---|---|
| 99.1 | Press release issued by bluebird bio, Inc. on August 1, 2019. |

**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 thereunto duly authorized.

**bluebird bio, Inc.**

Date: August 1, 2019

By: /s/ Chip Baird
Chip Baird
*Chief Financial Officer and Principal Financial Officer*

**Exhibit 99.1**

**bluebird bio Reports Second Quarter 2019 Financial Results and Highlights Operational Progress**

*– Received EU conditional marketing authorization for ZYNTEGLO® (autologous CD34+ cells encoding βA-T87Q-globin gene) gene therapy for patients 12 years and older with transfusion dependent β-thalassemia (TDT) who do not have a $\beta^0/\beta^0$ genotype –*
*– Presented data across LentiGlobin® for TDT and sickle cell disease (SCD) at 2019 European Hematology Association (EHA) Annual Congress –*
*– Ended quarter with $1.54 billion in cash, cash equivalents and marketable securities –*

**CAMBRIDGE, Mass. – August 1, 2019** – bluebird bio, Inc. (NASDAQ: BLUE) today reported financial results and business highlights for the second quarter ended June 30, 2019.

"With the approval of our first gene therapy, bluebird bio has entered into an exciting, and potentially transformative time for patients and for the company. We are focused on getting our qualified treatment centers up and running in Europe, ensuring we are prepared to deliver ZYNTEGLO to patients, and advancing the implementation of our value and outcomes-based payment model," said Nick Leschly, chief bluebird. "In the weeks since announcing our approval, we have been encouraged by our progress across these fronts and by the receptivity to our payment model from payers in our initial European launch markets. In the second half of the year, we are focused on executing our clinical studies as well as initiating new studies in sickle cell disease, multiple myeloma, and early stage oncology programs. I am incredibly grateful for our amazing and growing flock of bluebirds who are working to ensure that we do our best for patients every day."

**Recent Highlights:**

**TDT**

- **EU CONDITIONAL MARKETING AUTHORIZATION –** In June 2019, bluebird bio announced that the European Commission (EC) granted conditional marketing authorization for ZYNTEGLO (autologous CD34+ cells encoding $\beta^{A-T87Q}$-globin gene, known as LentiGlobin® for TDT), a gene therapy for patients 12 years and older with transfusion-dependent β-thalassemia (TDT) who do not have a $\beta^0/\beta^0$ genotype, for whom hematopoietic stem cell (HSC) transplantation is appropriate but a human leukocyte antigen (HLA)-matched related HSC donor is not available. The PRIME and Adaptive Pathway programs allowed for early and enhanced dialogue and accelerated assessment of ZYNTEGLO, which was completed on the shortest timetable for an advanced therapy medicinal product (ATMP) by the EMA to date. ZYNTEGLO is bluebird bio's first gene therapy to gain regulatory approval. bluebird bio will continue the country-by-country reimbursement process to help ensure access to ZYNTEGLO for appropriate patients.

- **DATA FROM NORTHSTAR, NORTHSTAR-2 AND NORTHSTAR-3 PRESENTED –** At the European Hematology Association (EHA) Annual Congress
in June 2019, bluebird bio presented new data from its studies of LentiGlobin in patients with TDT: long-term data from the completed Phase 1/2 Northstar study (HGB-204), updated data from the Phase 3 Northstar-2 study (HGB-207) in patients with non-$\beta^0/\beta^0$ genotypes, and updated data from the Phase 3 Northstar-3 study (HGB-212) in patients with $\beta^0/\beta^0$ genotypes or an IVS-I-110 mutation.

**SCD**

- **DATA FROM HGB-206 PRESENTED** – At EHA in June 2019, bluebird bio presented new data from patients in Group C of its ongoing Phase 1/2 HGB-206 study of the company's investigational LentiGlobin gene therapy for sickle cell disease (SCD). Group C patients are being treated under an updated study protocol, which includes the implementation of mobilization and apheresis with plerixafor.

**TDT & SCD**

- **HGB-205 STUDY COMPLETION –** In February 2019, the final patient completed primary follow up in the HGB-205 study of patients with TDT and SCD. All patients will continue to be monitored for long term outcomes.

**COMPANY**

- **ANALYST DAY –** In May 2019, bluebird bio hosted an analyst day in New York that highlighted significant progress in the company's emerging immuno-oncology and severe genetic disease pipeline, launch plans for its first gene therapy product, and key aspects of its long-term growth strategy. bluebird bio also announced a new research collaboration with Seattle Children's Research Institute in Acute Myeloid Leukemia (AML), a planned Phase 1/2 study in Merkel Cell Carcinoma (MCC) in collaboration with the Fred Hutchinson Cancer Research Center and preclinical programs in Diffuse Large B-cell Lymphoma (DLBCL), MAGE-A4 positive solid tumors and Mucopolysaccharidosis (MPSI).

**Upcoming Anticipated Milestones:**

- **TDT**
    - Initiation of a rolling Biologics Licensing Application submission to the U.S. FDA for ZYNTEGLO in patients with TDT and non-$\beta^0/\beta^0$ genotypes by the end of 2019
    - Presentation of ZYNTEGLO clinical data from the Northstar-2 (HGB-207) clinical study in patients with TDT and non-$\beta^0/\beta^0$ genotypes by the end of 2019
    - Presentation of ZYNTEGLO clinical data from the Northstar-3 (HGB-212) clinical study in patients with TDT and a $\beta^0/\beta^0$ genotype or an IVS-I-110 mutation by the end of 2019

- **SCD**
  - Initiation of Phase 3 HGB-210 study of LentiGlobin in patients with SCD by the end of 2019
  - Presentation of LentiGlobin clinical data from the HGB-206 clinical study in patients with SCD by the end of 2019

- **Multiple Myeloma**
  - ide-cel clinical data update from the registration-enabling KarMMa study in patients with relapsed/refractory multiple myeloma by the end of 2019
  - Presentation of bb21217 clinical data from the CRB-402 clinical study in patients with relapsed/refractory multiple myeloma by the end of 2019

- **CALD**
  - Presentation of updated clinical data from the Starbeam (ALD-102) study in patients with cerebral ALD by the end of 2019

**Second Quarter 2019 Financial Results**

- **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2019 and December 31, 2018 were $1.54 billion and $1.89 billion, respectively. The decrease in cash, cash equivalents and marketable securities is primarily related to cash used in support of normal operating activities and cash used to purchase property, plant and equipment as the company continues the buildout of its manufacturing facility in Durham, North Carolina.

- **Revenues:** Collaboration and license and royalty revenues were $13.3 million for the three months ended June 30, 2019 compared to $7.9 million for the three months ended June 30, 2018. The increase of $5.4 million was primarily attributable to an increase in collaboration revenue under our arrangement with Celgene as well as an increase in license and royalty revenue. Collaboration and license and royalty revenues were $25.8 million for the six months ended June 30, 2019 compared to $23.8 million for the six months ended June 30, 2018. The increase of $2.0 million was primarily attributable to an increase in license and royalty revenue, offset by a decrease in collaboration revenue under our arrangement with Celgene.
- **R&D Expenses:** Research and development expenses were $146.5 million for the three months ended June 30, 2019 compared to $115.0 million for the three months ended June 30, 2018. Research and development expenses were $269.2 million for the six months ended June 30, 2019 compared to $212.1 million for the six months ended June 30, 2018. The increase in both periods was primarily driven by costs incurred to advance and expand the company's pipeline.
- **G&A Expenses:** General and administrative expenses were $68.6 million for the three months ended June 30, 2019 compared to $41.2 million for the three months ended June 30, 2018. General and administrative expenses were $128.9 million for the six months ended June 30, 2019 compared to $76.1 million for the six months ended June 30, 2018.

The increase in both periods was largely attributable to costs incurred to support the company's overall growth of its pipeline as well as commercial-readiness activities.

- **Net Loss:** Net loss was $195.8 million for the three months ended June 30, 2019 compared to $146.0 million for the three months ended June 30, 2018. Net loss was $360.2 million for the six months ended June 30, 2019 compared to $261.1 million for the six months ended June 30, 2018.

**About bluebird bio, Inc.**
bluebird bio is pioneering gene therapy with purpose. From our Cambridge, Mass., headquarters, we're developing gene therapies for severe genetic diseases and cancer, with the goal that people facing potentially fatal conditions with limited treatment options can live their lives fully. Beyond our labs, we're working to positively disrupt the healthcare system to create access, transparency and education so that gene therapy can become available to all those who can benefit.

bluebird bio is a human company powered by human stories. We're putting our care and expertise to work across a spectrum of disorders by researching cerebral adrenoleukodystrophy, sickle cell disease, transfusion-dependent β-thalassemia and multiple myeloma using three gene therapy technologies: gene addition, cell therapy and (megaTAL-enabled) gene editing.

bluebird bio has additional nests in Seattle, Wash.; Durham, N.C.; and Zug, Switzerland. For more information, visit bluebirdbio.com.

Follow bluebird bio on social media: @bluebirdbio, LinkedIn, Instagram and YouTube.



The full common name for ZYNTEGLO: A genetically modified autologous CD34+ cell enriched population that contains hematopoietic stem cells transduced with lentiviral vector encoding the $\beta^{A\text{-}T87Q}$-globin gene.

**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, results of operations, as well as statements regarding the anticipated development for ZYNTEGLO and the company's product candidates, including anticipated regulatory milestones, planned commercial launches, planned clinical studies, as well as the company's intentions regarding the timing for providing further updates on the development and commercialization of ZYNTEGLO and the company's product candidates. 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 risks that the preliminary positive efficacy and safety results from our prior and ongoing clinical trials will not continue or be repeated in our ongoing or future 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, risks that the current or planned clinical trials of our product candidates will be insufficient to support regulatory submissions or marketing approval in the United States and European Union, the risk that we will encounter challenges in the commercial launch of ZYNTEGLO in the European Union, including in managing our complex supply chain for the delivery of drug product or in the adoption of value-based payment models or in obtaining sufficient coverage or reimbursement for our products if approved, the risk that our collaborations, including the 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.**

**Consolidated Statements of Operations**

**(in thousands, except per share data)**

**(unaudited)**

| | For the three months ended June 30, | | For the six months ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Revenue: | | | | |
| Collaboration revenue | $ 11,558 | $ 7,437 | $ 22,735 | $ 23,045 |
| License and royalty revenue | 1,738 | 414 | 3,032 | 763 |
| Total revenues | 13,296 | 7,851 | 25,767 | 23,808 |
| Operating expenses: | | | | |
| Research and development | 146,540 | 115,014 | 269,180 | 212,123 |
| General and administrative | 68,631 | 41,168 | 128,910 | 76,094 |
| Cost of license and royalty revenue | 613 | 21 | 1,043 | 36 |
| Change in fair value of contingent consideration | 214 | 262 | 510 | 796 |
| Total operating expenses | 215,998 | 156,465 | 399,643 | 289,049 |
| Loss from operations | (202,702) | (148,614) | (373,876) | (265,241) |
| Interest income, net | 9,387 | 2,436 | 19,489 | 3,824 |
| Other (expense) income, net | (2,936) | 182 | (6,325) | 297 |
| Loss before income taxes | (196,251) | (145,996) | (360,712) | (261,120) |
| Income tax benefit | 469 | — | 484 | — |
| Net loss | $ (195,782) | $ (145,996) | $ (360,228) | $ (261,120) |
| Net loss per share - basic and diluted: | $ (3.55) | $ (2.91) | $ (6.54) | $ (5.22) |
| Weighted-average number of common shares used in computing net loss per share - basic and diluted: | 55,165 | 50,153 | 55,062 | 50,038 |

**bluebird bio, Inc.**

**Condensed Consolidated Balance Sheet Data**

**(in thousands)**

**(unaudited)**

| | As of June 30, 2019 | As of December 31, 2018 |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 1,541,802 | $ 1,891,427 |
| Total assets | 2,023,344 | 2,242,844 |
| Total liabilities | 386,970 | 357,774 |
| Total stockholders' equity | 1,636,374 | 1,885,070 |

**Investors & Media**

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