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): October 31, 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 October 31, 2019, bluebird bio, Inc. announced its financial results for the three months ended September 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 No.	Description
99.1	Press release issued by bluebird bio, Inc. on October 31, 2019.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: October 31, 2019

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

Exhibit 99.1

bluebird bio Reports Third Quarter 2019 Financial Results and Highlights Operational Progress

- Continued progress towards 2022 vision of four marketed gene and cell therapy products with robust development pipeline -
- ZYNTEGLO commercial launch advancing with European Medicines Agency approval of refined commercial manufacturing process -
- Ended quarter with $1.41 billion in cash, cash equivalents and marketable securities -

CAMBRIDGE, Mass. – October 31, 2019 – bluebird bio, Inc. (NASDAQ: BLUE) today reported financial results and business highlights for the third quarter ended September 30, 2019.

"During the third quarter we advanced our country-by-country launch plans in Europe and, with the recent approval of the commercial drug product manufacturing specifications for ZYNTEGLO, we moved one step closer to our goal of treating patients suffering from TDT in early 2020," said Nick Leschly, chief bluebird. "Also this quarter, we presented updated data from the Phase 2/3 Starbeam study in patients with CALD. To report that patients continued to be free of MFDs at up to five years of follow-up is something we're tremendously proud to do for these families, and we look forward to advancing that program in the regulatory process next year. Looking ahead, we plan to provide clinical updates for ZYNTEGLO and across the rest of our portfolio, including LentiGlobin in sickle cell disease, bb21217 in multiple myeloma, and from our registration-enabling KarMMa study of ide-cel in patients with multiple myeloma by the end of this year. I'd like to thank all the bluebirds around the globe for their tireless focus on doing the right thing for our patients – we've seen amazing progress thus far in 2019 and I look forward to ending the year on a strong note."

Recent Highlights:

TDT

- **ZYNTEGLO COMMERCIAL READINESS –** In October, bluebird bio announced that the European Medicines Agency (EMA) approved the refined commercial drug product manufacturing specifications for ZYNTEGLO™ (autologous CD34+ cells encoding βA-T87Q-globin gene), a one-time gene therapy for patients 12 years and older with transfusion-dependent β-thalassemia (TDT) who do not have a β0/β0 genotype, for whom hematopoietic stem cell (HSC) transplantation is appropriate but a human leukocyte antigen (HLA)-matched related HSC donor is not available. With this update, apceth is in the final stages of preparing to manufacture ZYNTEGLO for commercial use. The company continues to proceed with discussions on value-based payment agreements and Qualified Treatment Center contracts and expects to treat the first commercial patient in early 2020.

CALD

- **DATA FROM STARBEAM STUDY (ALD-102) AND ALD-103 PRESENTED**– At the 13th European Pediatric Neurology Society (EPNS) Congress in September 2019, bluebird bio presented new data from the clinical development program for its investigational studies of Lenti-D™ gene therapy in patients with cerebral adrenoleukodystrophy: updated data from the Phase 2/3

Starbeam study (ALD-102) in boys 17 years of age and under with CALD and updated data from the ongoing observational study (ALD-103) of allogeneic hematopoietic stem cell transplant (allo-HSCT) in boys 17 years of age and under with CALD. Long-term follow-up data as of April 2019 showed that the 88% of patients treated in the Starbeam study (ALD-102) were free of major functional disabilities (MFDs) at two years, and continued to remain MFD-free at up to five years of follow-up.

COMPANY

- **FIRST PATIENT TREATED IN PHASE 1/2 TRIAL FOR MERKEL CELL CARCINOMA (MCC)**– In August 2019, Fred Hutchinson Cancer Research Center infused the first patient in their proof-of-concept phase 1/2 single-arm study evaluating Merkel Cell Polyomavirus (MCPyV) TCR-engineered autologous T cells in combination with avelumab (anti-PDL1) for the treatment of MCC. Results from the academic phase 1/2 single-arm study are expected to inform next-generation T cell approaches including TCR engineering and checkpoint inhibition. The study will enroll approximately 16 patients. Development of this program is led by Fred Hutchinson Cancer Research Center. bluebird bio retains the exclusive option to license this program.

- **NOVO NORDISK COLLABORATION** – In October 2019, bluebird bio and Novo Nordisk announced a research collaboration to jointly develop next-generation *in vivo* genome editing treatments for genetic diseases, including hemophilia. During the three-year research collaboration, bluebird and Novo Nordisk will focus on identifying a development gene therapy candidate with the ambition of offering people with hemophilia A a lifetime free of factor replacement therapy.

- **MANAGEMENT UPDATE** – In October 2019, bluebird bio announced that Jeffrey T. Walsh, chief strategy officer, has decided to transition from his current role effective January 6, 2020. Jeff has not only built a strong foundation for bluebird's overall growth strategy but also leaves an experienced and passionate team. Both Chip Baird, chief financial officer, and Joanne Smith-Farrell, chief business officer, will assume broader corporate development and strategic responsibilities as bluebird continues to deliver on its mission for patients.

- **NEW BOARD APPOINTMENT** – In September 2019, bluebird bio announced the appointment of William R. Sellers, M.D. to its Board of Directors.

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-β^0/β^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-β^0/β^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 β/β^0 genotype or an IVS-I-110 mutation by the end of 2019

- **SCD**
  - Phase 3 HGB-210 study of LentiGlobin in patients with SCD open and enrolling 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

Third Quarter 2019 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2019 and December 31, 2018 were $1.41 billion and $1.89 billion, respectively. The decrease in cash, cash equivalents and marketable securities is primarily related to cash used in support of ordinary course operating activities and cash used to purchase property, plant and equipment, including those purchases related to the company's buildout of its manufacturing facility in Durham, North Carolina.
- **Revenues:** Collaboration and license and royalty revenues were $8.9 million for the three months ended September 30, 2019 compared to $11.5 million for the three months ended September 30, 2018. Collaboration and license and royalty revenues were $34.7 million for the nine months ended September 30, 2019 compared to $35.3 million for the nine months ended September 30, 2018.The decrease in both periods was primarily attributable to a decrease in collaboration revenue under our arrangement with Celgene, partially offset by an increase in license and royalty revenue and collaboration revenue under our arrangement with Regeneron.
- **R&D Expenses:** Research and development expenses were $151.4 million for the three months ended September 30, 2019 compared to $116.7 million for the three months ended September 30, 2018. Research and development expenses were $420.6 million for the nine months ended September 30, 2019 compared to $328.9 million for the nine months ended September 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 $66.3 million for the three months ended September 30, 2019 compared to $44.5 million for the three months ended September 30, 2018. General and administrative expenses were $195.2 million for the nine months ended September 30, 2019 compared to $120.6 million for the nine months ended September 30, 2018. The increase in both periods was largely attributable to costs incurred to support the company's ongoing operations and growth of its pipeline as well as commercial-readiness activities.
- **Net Loss:** Net loss was $206.0 million for the three months ended September 30, 2019 compared to $145.5 million for the three months ended September 30, 2018. Net loss was $566.3 million for the nine months ended September 30, 2019 compared to $406.6 million for the nine months ended September 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,

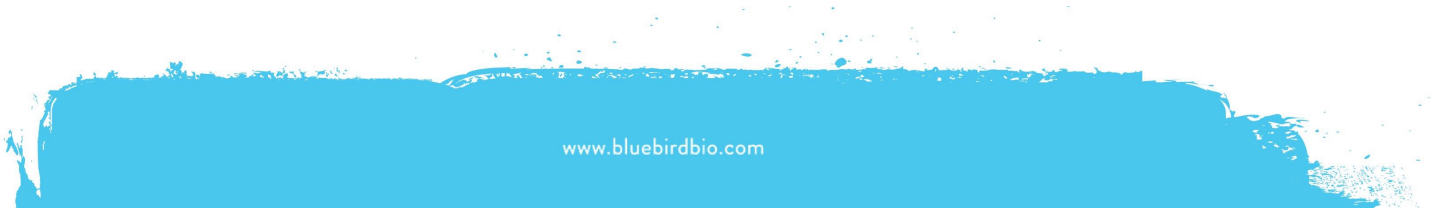
we're working to positively disrupt the healthcare system to create access, transparency and education so that gene therapy can become available to all those who can benefit.

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.

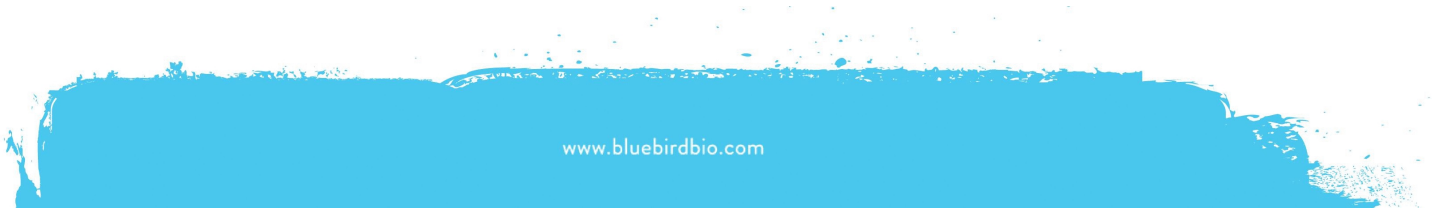
Follow bluebird bio on social media: @bluebirdbio, LinkedIn, Instagram and YouTube.

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 βA-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 plans for regulatory submissions and commercialization 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 September 30,		For the nine months ended September 30,	
	2019	2018	2019	2018
Revenue:				
Collaboration revenue	$ 6,575	$ 10,926	$ 29,310	$ 33,971
License and royalty revenue	2,335	602	5,367	1,365
Total revenues	8,910	11,528	34,677	35,336
Operating expenses:				
Research and development	151,412	116,744	420,592	328,867
General and administrative	66,250	44,527	195,160	120,621
Cost of license and royalty revenue	862	29	1,905	67
Change in fair value of contingent consideration	802	47	1,312	843
Total operating expenses	219,326	161,347	618,969	450,398
Loss from operations	(210,416)	(149,819)	(584,292)	(415,062)
Interest income, net	8,417	4,591	27,906	8,415
Other (expense) income, net	(4,298)	(252)	(10,623)	45
Loss before income taxes	(206,297)	(145,480)	(567,009)	(406,602)
Income tax benefit	264	—	748	—
Net loss	$ (206,033)	$ (145,480)	$ (566,261)	$ (406,602)
Net loss per share - basic and diluted:	$ (3.73)	$ (2.73)	$ (10.27)	$ (7.95)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	55,292	53,277	55,139	51,130

bluebird bio, Inc.

Condensed Consolidated Balance Sheet Data

(in thousands, except per share data)

(unaudited)

	As of September 30, 2019	As of December 31, 2018
Cash, cash equivalents and marketable securities	$ 1,405,887	$ 1,891,427
Total assets	1,892,218	2,242,844
Total liabilities	420,508	357,774
Total stockholders' equity	1,471,710	1,885,070

Investors & Media

Investors:
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