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): November 1, 2018

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 November 1, 2018, bluebird bio, Inc. ("bluebird") announced its financial results for the three months ended September 30, 2018. 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 November 1, 2018.

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: November 1, 2018

bluebird bio, Inc.

By: /s/ Jeffrey T. Walsh

Jeffrey T. Walsh
Chief Financial & Strategy Officer and
Principal Financial Officer

Exhibit 99.1

bluebird bio Reports Third Quarter 2018 Financial Results and Highlights Operational Progress

– Company plans to pursue accelerated development pathway for LentiGlobin™ in sickle cell disease (SCD) –

– Ended quarter with $2.0 billion in cash, cash equivalents and marketable securities –

– Company to hold conference call and webcast to discuss ASH abstracts and development plans for SCD tomorrow, November 2, 8:00 a.m. ET –

CAMBRIDGE, Mass. – November 1, 2018 – bluebird bio, Inc. (NASDAQ: BLUE) today reported financial results and business highlights for the third quarter ended September 30, 2018.

"2018 has been a year of tremendous growth and transition at bluebird, notably exemplified by the filing of our first regulatory application for LentiGlobin in transfusion dependent β-thalassemia (TDT) with the European Medicines Agency (EMA)," said Nick Leschly, chief bluebird. "As we prepare to serve patients with LentiGlobin first in Europe, and later in the U.S., we are advancing the development of our programs in SCD and multiple myeloma, the latter in collaboration with Celgene. We have outlined an accelerated development plan utilizing a surrogate endpoint that we believe allows us to continue to evolve our understanding of the potential of LentiGlobin in patients with SCD. In cerebral adrenoleukodystrophy (CALD), we have regulatory alignment on the path forward and are on track. In multiple myeloma, we and Celgene have begun to lay the plans to bring bb2121 into earlier lines of therapy, while building for the future with bb21217. We look forward to sharing clinical and pre-clinical data across our portfolio – a breadth of progress that is a testament to the tireless work of the bluebird flock."

"The emerging data from our LentiGlobin program in SCD demonstrate the potential to rapidly produce high levels of anti-sickling HbA^{T87Q} that we hope will fundamentally reduce sickling and hemolysis, thereby providing a meaningful increase in total hemoglobin and leading to a reduction in clinical events," said David Davidson, M.D., chief medical officer, bluebird bio. "We continue to have ongoing dialogue with the U.S. Food and Drug Administration (FDA), in the context of our Regenerative Medicine Advanced Therapy (RMAT) designation, and now plan to pursue an accelerated development path that may allow us to initially validate, and then leverage these clinically meaningful biomarkers to form the primary endpoint of a registration-enabling study for patients with a history of vaso-occlusive events (VOEs). We also plan to conduct future clinical investigation of LentiGlobin in patients with other SCD phenotypes, including those at risk of stroke."

Recent Highlights

TDT

- **LENTIGLOBIN MAA ACCEPTANCE** – In October 2018, the EMA accepted for review the company's marketing authorization application (MAA) for its investigational

LentiGlobin gene therapy for the treatment of adolescents and adults with TDT and a non-β^0/β^0 genotype. LentiGlobin was previously granted an accelerated assessment by the Committee for Medicinal Products for Human Use (CHMP) of the EMA in July 2018, potentially reducing the EMA's active review time of the MAA from 210 days to 150 days.

SCD

- **LENTIGLOBIN DEVELOPMENT STRATEGY** – Based on ongoing discussions with the FDA, bluebird bio is modifying and expanding its clinical development plans to explore efficacy endpoints that may allow the company to pursue a more accelerated development path in the United States for the treatment of patients with SCD who have a history of VOEs. Enrollment of the HGB-206 study has been expanded to enroll up to 50 adult and adolescent patients. The expanded HGB-206 study has a new primary efficacy endpoint based on $HbAT^{87}Q$ and total hemoglobin, and a key secondary endpoint of frequency of VOEs. As modified, the HGB-206 study will increase the overall set of clinical data regarding the relationship between anti-sickling hemoglobin and clinical outcomes and has the potential to validate the new primary efficacy endpoint as a surrogate endpoint for other SCD clinical outcomes such as VOEs. In 2019, bluebird bio intends to initiate a multi-site, international Phase 3 study of LentiGlobin for the treatment of patients with SCD and a history of VOEs with the same primary and secondary endpoints, and comparable design, as the HGB-206 study. bluebird bio is also engaged in ongoing discussions with the EMA regarding proposed development plans for LentiGlobin in SCD in Europe.

CALD

- **UPDATED DATA AT THE SOCIETY FOR THE STUDY OF INBORN ERRORS OF METABOLISM SYMPOSIUM** – In September 2018, bluebird bio announced updated results from the Phase 2/3 Starbeam study (ALD-102) of its investigational Lenti-D™ gene therapy in boys 17 years of age and under with CALD, and initial data from ALD-103, the ongoing observational study of outcomes from allogeneic hematopoietic stem cell transplant (allo-HSCT) in boys 17 years of age and under with CALD. bluebird bio has also reached general agreement with the FDA and the EMA to use data from ALD-102 and ALD-103 to support future marketing applications for Lenti-D in CALD.

- **ALD-104 STUDY –** In early 2019, bluebird bio intends to initiate a multi-site Phase 3 study of the Lenti-D product candidate for the treatment of patients with CALD to enable access following completion of enrollment in the Starbeam study, and to evaluate the suitability of additional conditioning regimens for use with the Lenti-D product candidate.

COMPANY

- **REGENERON COLLABORATION** – In August 2018, bluebird bio and Regeneron Pharmaceuticals, Inc. (Regeneron) announced a collaboration to apply their respective technology platforms to the discovery, development and commercialization of novel immune cell therapies for cancer. The collaborators will specifically leverage Regeneron's VelociSuite® technology platforms for the discovery and characterization of fully human antibodies, as well as T cell receptors (TCRs) directed against tumor-specific proteins and peptides, and bluebird bio will contribute its field-leading expertise in gene transfer and cell therapy.

- **GRITSTONE COLLABORATION** – In August 2018, bluebird bio and Gritstone Oncology, Inc. (Gritstone) announced a collaboration to utilize Gritstone's proprietary technology platform to identify and validate tumor-specific targets and provide TCRs directed to selected targets for use in bluebird's gene therapy products. bluebird bio will conduct all development, manufacturing and commercial activities.

- **STRENGTHENED BALANCE SHEET** – In July 2018, bluebird bio raised approximately $600.6 million in net proceeds through a public equity offering. bluebird bio anticipates that its cash, cash equivalents and marketable securities will be sufficient to fund operations into 2022 based on the company's current business plan.

Upcoming Anticipated Milestones

- **TDT**
  - Presentation of LentiGlobin clinical data from the Northstar (HGB-204) clinical study in patients with TDT at the American Society of Hematology (ASH) Annual Meeting
  - Presentation of LentiGlobin clinical data from the Northstar-2 (HGB-207) clinical study in patients with TDT and non-β^0/β^0 genotypes at the ASH Annual Meeting
  - Presentation of LentiGlobin clinical data from the Northstar-3 (HGB-212) clinical study in patients with TDT and the β^0/β^0 genotype at the ASH Annual Meeting

- **SCD**
  - Presentation of LentiGlobin clinical data from the HGB-206 clinical study in patients with SCD at the ASH Annual Meeting
  - Presentation early data from the investigator-initiated Phase 1 study of shRNA^{miR} lentiviral vector targeting BCL11A for autologous gene therapy in SCD at the ASH Annual Meeting

- **Multiple Myeloma**
  - Presentation of bb21217 clinical data from the CRB-402 clinical study in patients with relapsed/refractory multiple myeloma at the ASH Annual Meeting
  - Initiation by Celgene of a Phase 3 clinical study of bb2121 in third line multiple myeloma

Third Quarter 2018 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2018 and December 31, 2017 were $2.0 billion and $1.6 billion, respectively. The increase in cash, cash equivalents and marketable securities is primarily related to the completion of a public offering of common stock in July 2018, which raised net proceeds of approximately $600.6 million, and the receipt of $100.0 million from Regeneron made in connection with the company's collaboration with Regeneron which was entered into in August 2018. The overall increase in cash, cash equivalents and marketable securities was offset by $40.0 million paid to Gritstone in connection with the company's collaboration with Gritstone, which was also entered into in August 2018, and cash used in operating activities.

- **Revenues:** Total revenues were $11.5 million for the three months ended September 30, 2018 compared to $7.7 million for the three months ended September 30, 2017. Total revenues were $35.3 million for the nine months ended September 30, 2018 compared to $31.3 million for the nine months ended September 30, 2017. The increase in both periods was primarily attributable to increased manufacturing services under the company's collaboration agreement with Celgene, offset by decreased license and royalty revenue.
- **R&D Expenses:** Research and development expenses were $116.7 million for the three months ended September 30, 2018 compared to $61.5 million for the three months ended September 30, 2017. Research and development expenses were $328.9 million for the nine months ended September 30, 2018 compared to $180.5 million for the nine months ended September 30, 2017. The increase in both periods was driven by costs incurred to advance and expand the company's pipeline and is attributable to increased clinical trial-related costs and manufacturing costs for development programs, increased laboratory expenses, increased employee-related costs due to headcount growth, and increased license milestones and fees under the company's strategic collaboration and license agreements.
- **G&A Expenses:** General and administrative expenses were $44.5 million for the three months ended September 30, 2018 compared to $23.0 million for the three months ended September 30, 2017. General and administrative expenses were $120.6 million for the nine months ended September 30, 2018 compared to $64.5 million for the nine months ended September 30, 2017. The increase in both periods was attributable to increases in employee-related costs due to increased headcount to support overall growth, commercial-readiness activities, and professional and consulting fees.
- **Net Loss:** Net loss was $145.5 million for the three months ended September 30, 2018 compared to $78.8 million for the three months ended September 30, 2017. Net loss was $406.6 million for the nine months ended September 30, 2018 compared to $218.4 million for the nine months ended September 30, 2017.

Conference Call & Webcast Information

bluebird bio will host a conference call and live webcast at 8:00 a.m. ET on Friday, November 2, 2018. The live webcast can be accessed under "Events & Presentations" in the Investors & Media section of the company's website at www.bluebirdbio.com. Alternatively, investors may

listen to the call by dialing (844) 825-4408 from locations in the United States or (315) 625-3227 from outside the United States. Please refer to conference ID number 5595967.

About bluebird bio, Inc.
With its lentiviral-based gene therapies, T cell immunotherapy expertise and gene editing capabilities, bluebird bio has built a pipeline with broad potential application in severe genetic diseases and cancer.

bluebird bio's gene therapy clinical programs include investigational treatments for cerebral adrenoleukodystrophy, transfusion-dependent β-thalassemia, also known as β-thalassemia major, and sickle cell disease.

bluebird bio's oncology pipeline is built upon the company's 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. The company’s lead oncology programs are anti-BCMA CAR T programs partnered with Celgene.

bluebird bio’s discovery research programs include 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; Durham, North Carolina and Zug, Switzerland.

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 the Company's product candidates, including anticipated regulatory milestones, planned clinical studies, as well as the Company's intentions regarding the timing for providing further updates on the development of its 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 of our product candidates will not continue or be repeated in our ongoing 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, the risk of a delay in the enrollment of patients in our clinical studies, risks that the current or planned clinical trials of our LentiGlobin, Lenti-D, bb2121 or bb21217 product candidates will be insufficient to support regulatory submissions or marketing approval in the United States and European Union, 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-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.

bluebird bio, Inc.

Condensed 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,	
	2018	2017	2018	2017
Revenue:				
Collaboration revenue	$ 10,926	$ 5,211	$ 33,971	$ 18,189
License and royalty revenue	$ 602	2,500	$ 1,365	13,070
Total revenues	11,528	7,711	35,336	31,259
Operating expenses:				
Research and development	116,744	61,545	328,867	180,464
General and administrative	44,527	22,982	120,621	64,463
Cost of license and royalty revenue	29	1,100	67	1,520
Change in fair value of contingent consideration	47	(258)	843	205
Total operating expenses	161,347	85,369	450,398	246,652
Loss from operations	(149,819)	(77,658)	(415,062)	(215,393)
Interest income (expense), net	4,591	(1,155)	8,415	(1,842)
Other income (expense), net	(252)	8	45	(1,180)
Loss before income taxes	(145,480)	(78,805)	(406,602)	(218,415)
Net loss	$ (145,480)	$ (78,805)	$ (406,602)	$ (218,415)
Net loss per share - basic and diluted:	$ (2.73)	$ (1.73)	$ (7.95)	$ (5.14)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	53,277	45,648	51,130	42,524

bluebird bio, Inc.

Condensed Consolidated Balance Sheet Data

(in thousands)

(unaudited)

	As of September 30, 2018	As of December 31, 2017
Cash, cash equivalents and marketable securities	$ 1,999,050	$ 1,614,302
Total assets	2,351,789	1,900,567
Total liabilities	350,999	277,135
Total stockholders' equity	2,000,790	1,623,432

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