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, 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 August 2, 2018, bluebird bio, Inc. announced its financial results for the three months ended June 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 August 2, 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: August 2, 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 Second Quarter 2018 Financial Results and Highlights Operational Progress

- Lenti-D™ granted Priority Medicines (PRIME) designation from European Medicines Agency (EMA) and Breakthrough Designation from U.S. Food and Drug Administration (FDA) in cerebral adrenoleukodystrophy (CALD) –
- LentiGlobin™ in transfusion-dependent β-thalassemia (TDT) granted accelerated assessment of Marketing Authorization Application (MAA) from EMA -
- Ended quarter with $1.46 billion in cash, cash equivalents and marketable securities –
- Completed public offering of common stock in July 2018, raising net proceeds of approximately $600.6 million –

CAMBRIDGE, Mass. – August 2, 2018 – bluebird bio, Inc. (NASDAQ: BLUE) today reported financial results and business highlights for the second quarter ended June 30, 2018.

"The clinical data presented this spring across our development programs in TDT, SCD and multiple myeloma have further reinforced the strength of our gene and cell therapy platforms, and we are putting tremendous effort towards bringing all four of our clinical programs to patients as soon as possible," said Nick Leschly, chief bluebird. "In the second half of the year, we anticipate reaching a significant milestone for bluebird, by filing for our first potential regulatory approval in Europe with LentiGlobin to treat TDT. As we prepare to make this important transition to a commercial company, with the potential for three initial product approvals by the end of 2020, our readiness and implementation plans are well underway. We are also investing and building for our next phase of growth through a sustainable innovation engine, and a strong development and commercial infrastructure to allow us to bring more transformative therapies to patients."

Recent Highlights

TDT

- **LENTIGLOBIN ACCELERATED ASSESSMENT** – In July 2018, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) granted an accelerated assessment to LentiGlobin in transfusion-dependent β-thalassemia (TDT). The company is on track to submit a Marketing Authorization Application (MAA) to the EMA for LentiGlobin in 2018.

- **NEW DATA FROM NORTHSTAR AND NORTHSTAR-2 PRESENTED** – At the Annual Congress of the European Hematology Association (EHA) in June 2018, bluebird bio presented new data from its studies of LentiGlobin in patients with TDT: Northstar (HGB-204) and Northstar-2 (HGB-207). As of the data cutoff, 7/8 non-β^0/β^0 patients with ≥ 6 months follow-up were producing normal or near-normal amounts of total hemoglobin (11.1 – 13.3 g/dL) and were transfusion free in Northstar-2. 8/10 of non-β^0/β^0 patients achieved and maintained transfusion independence for up to 3 years in

Northstar. Across both studies, the safety profile was consistent with myeloablative conditioning.

- **FIRST PEDIATRIC PATIENT TREATED** – In April 2018, the first pediatric patient was treated in Northstar-3 (HGB-212), bluebird bio's Phase 3 study of LentiGlobin in patients with β^0/β^0 genotypes.

SCD

- **NEW DATA FROM HGB-206 PRESENTED –** At EHA in June 2018, bluebird bio presented new data from the HGB-206 study of LentiGlobin in patients with severe sickle cell disease (SCD). As of the data cutoff, all patients (n=4) in Group C with ≥ 3 months follow-up were consistently producing ≥ 30% anti-sickling HbA^{T87Q}. The first Group C patient was generating a normal total hemoglobin of 14.2 g/dL with over 60% anti-sickling HbA^{T87Q} at 6 months. Across all patients in the study, the safety profile was consistent with myeloablative conditioning.

MULTIPLE MYELOMA

- **NEW DATA FROM CRB-401 PRESENTED –** At the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2018, bluebird bio and Celgene Corporation presented new data from the ongoing CRB-401 Phase 1 clinical study of bb2121, an investigational anti-B-cell maturation antigen (BCMA) CAR T cell therapy, in 43 patients with late-stage relapsed/refractory multiple myeloma. Deep and durable responses were observed at active doses (≥150 × 10^6 CAR+ T cells). A median progression-free survival (PFS) of approximately one year was achieved in heavily pre-treated patients in the active doses of the dose escalation cohort. Consistent response rates were observed for both low and high BCMA expression levels. Adverse events have been manageable across doses.

CALD

- **PRIME DESIGNATION FOR LENTI-D** – In July 2018, the EMA granted access to its Priority Medicines (PRIME) scheme for Lenti-D for the treatment of patients with cerebral adrenoleukodystrophy (CALD). The PRIME initiative provides enhanced support and increased interaction to companies, with the goal of optimizing development plans and speeding regulatory evaluations to potentially bring innovative medicines to patients more quickly. To be accepted for PRIME, a therapy must demonstrate potential to benefit patients with unmet medical need through early clinical data or nonclinical data.

- **BREAKTHROUGH DESIGNATION FOR LENTI-D –** In May 2018, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to Lenti-D for the treatment of patients with CALD. Lenti-D previously was granted Orphan Drug

designation by the FDA and EMA, as well as Rare Pediatric Disease designation by the FDA.

COMPANY

- **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.

Second Half 2018 Anticipated Milestones

TDT

- Submission of a MAA to the EMA for LentiGlobin in patients with TDT and non-β^0/β^0 genotypes
- Submission of LentiGlobin clinical data from the Northstar-2 (HGB-207) clinical study in patients with TDT and non-β^0/β^0 genotypes to the American Society of Hematology (ASH) Annual Meeting
- Submission of LentiGlobin clinical data from the Northstar-3 (HGB-212) clinical study in patients with TDT and the β^0/β^0 genotype to the ASH Annual Meeting

SCD

- Update on the clinical development plan and registration strategy for LentiGlobin in SCD
- Submission of LentiGlobin clinical data from the HGB-206 clinical study in patients with SCD to the ASH Annual Meeting

Multiple Myeloma

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

CALD

- Presentation of Lenti-D clinical data from the ongoing Starbeam clinical study in patients with CALD in the second half of 2018

Second Quarter 2018 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2018 and December 31, 2017 were $1.46 billion and $1.61 billion, respectively.

- **Revenues:** Total revenues were $7.9 million for the three months ended June 30, 2018 compared to $16.7 million for the three months ended June 30, 2017. The decrease of approximately $8.9 million was primarily attributable to license revenue recognized in the second quarter of 2017 as a result of out-licensing arrangements entered into during that quarter. Total revenues were $23.8 million for six months ended June 30, 2018 compared to $23.5 million for six months ended June 30, 2017. The increase of $0.3 million was primarily attributable to an overall increase in collaboration revenue for the bb2121 license and manufacturing services under the company's agreement with Celgene, offset by a decrease in license and royalty revenue.

- **R&D Expenses:** Research and development expenses were $115.0 million for the three months ended June 30, 2018 compared to $63.9 million for the three months ended June 30, 2017. Research and development expenses were $212.1 million for six months ended June 30, 2018 compared to $118.9 million for six months ended June 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 $41.2 million for the three months ended June 30, 2018 compared to $21.2 million for the three months ended June 30, 2017. General and administrative expenses were $76.1 million for six months ended June 30, 2018 compared to $41.5 million for six months ended June 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 $146.0 million for the three months ended June 30, 2018 compared to $70.9 million for the three months ended June 30, 2017. Net loss was $261.1 million for six months ended June 30, 2018 compared to $139.6 million for six months ended June 30, 2017.

About bluebird bio, Inc.
With its lentiviral-based gene therapies, T cell immunotherapy expertise and gene editing capabilities, bluebird bio (NASDAQ: BLUE) 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 severe 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.

LentiGlobin and Lenti-D are trademarks of bluebird bio, Inc.

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 and sufficiency of its cash, cash equivalents and marketable securities to fund its planned operations, as well as statements regarding the anticipated development and regulatory milestones and plans for the Company's product candidates and clinical studies and statements regarding the Company's plans to provide 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-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

(in thousands, except per share data)

(unaudited)

	For the three months ended June 30,		For the six months ended June 30,	
	2018	2017	2018	2017
Revenue:				
Collaboration revenue	$ 7,437	$ 6,146	$ 23,045	$ 12,978
License and royalty revenue	414	10,570	763	10,570
Total revenues	7,851	16,716	23,808	23,548
Operating expenses:				
Research and development	115,014	63,891	212,123	118,919
General and administrative	41,168	21,197	76,094	41,481
Cost of license and royalty revenue	21	420	36	420
Change in fair value of contingent consideration	262	(970)	796	463
Total operating expenses	156,465	84,538	289,049	161,283
Loss from operations	(148,614)	(67,822)	(265,241)	(137,735)
Interest income (expense), net	2,436	(2,242)	3,824	(687)
Other income (expense), net	182	(834)	297	(1,189)
Loss before income taxes	(145,996)	(70,898)	(261,120)	(139,611)
Net loss	$ (145,996)	$ (70,898)	$ (261,120)	$ (139,611)
Net loss per share - basic and diluted:	$ (2.91)	$ (1.73)	$ (5.22)	$ (3.41)
Weighted-average number of common shares used in computing net loss per share - basic and diluted:	50,153	41,035	50,038	40,936

bluebird bio, Inc.

Condensed Consolidated Balance Sheet Data

(in thousands)

(unaudited)

	As of June 30, 2018	As of December 31, 2017
Cash, cash equivalents and marketable securities	$ 1,457,243	$ 1,614,302
Total assets	1,761,511	1,900,567
Total liabilities	303,977	277,135
Total stockholders' equity	1,457,534	1,623,432

Investors & Media
Investors:
bluebird bio
Elizabeth Pingpank, 617-914-8736
epingpank@bluebirdbio.com

Media:
bluebird bio
Stephanie Fagan, 201-572-9581
sfagan@bluebirdbio.com