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): February 21, 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 February 21, 2018, bluebird bio, Inc. announced its financial results for the year and three months ended December 31, 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 February 21, 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: February 21, 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 Fourth Quarter and Full Year 2017 Financial Results and Highlights Operational Progress

- *Company expanding organization and capabilities to prepare three programs for regulatory filing in the next two years –*
- *LentiGlobin in transfusion-dependent β-thalassemia (TDT) planned to be filed for marketing authorization in 2018 –*
- *bb2121 in relapsed/refractory multiple myeloma planned to be filed for marketing authorization in 2019 –*
- *Lenti-D in cerebral adrenoleukodystrophy (CALD) planned to be filed for marketing authorization in 2019 –*
- *Ended year with $1.6 billion in cash, cash equivalents and marketable securities –*

Cambridge, Mass., February 21, 2018 – 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 fourth quarter and full year ended December 31, 2017.

"We ended 2017 in a tremendously strong position with compelling data and progress across all four of our clinical programs. This progress brings us closer to potentially providing transformative therapies to a broader population of patients that we urgently seek to serve," said Nick Leschly, chief bluebird. "We have an aggressive plan to file three programs with regulatory authorities in the next two years: LentiGlobin in TDT in 2018, Lenti-D in CALD in 2019 and, with our partners at Celgene, bb2121 in multiple myeloma, also in 2019. The potential impact that our gene and cell therapies can bring to patients drives our commitment to execute on our strategy which is focused on operating with discipline, expanding our capabilities for commercial success, and levering our product engine to continue to grow and advance our pipeline."

Recent Highlights

- **FINAL PATIENT INFUSED IN CRB-401 –** In February 2018, the final patient to be enrolled in CRB-401, the Phase 1 study of bb2121 investigational anti-BCMA CAR T therapy in patients with relapsed/refractory multiple myeloma, was infused. A total of 43 patients (21 in the dose escalation phase and 22 in the expansion phase) have been treated in this study.

- **FIRST PATIENT TREATED IN KARMMA –** In February 2018, the first patient was infused in KarMMa, a registration-enabling study of bb2121 in patients with relapsed/refractory multiple myeloma. This study is being run by Celgene, bluebird's partner in the development of anti-BCMA CAR T therapies.

- **CHIEF COMMERCIAL OFFICER APPOINTED –** In February 2018, bluebird appointed Alison Finger as Chief Commercial Officer. In this role, Alison will be responsible for shaping and delivering an integrated global commercial strategy to make bluebird's gene therapies broadly accessible to patients. She will oversee all commercial strategy and operations, access management, including pricing, reimbursement and health outcomes, as well as patient operations. Alison joined bluebird as senior vice president, marketing and product launch in August of 2015.
- **ASH PRESENTATIONS –** At the American Society of Hematology (ASH) Annual Meeting, bluebird provided compelling clinical updates across its ongoing studies of LentiGlobin in TDT and severe sickle cell disease (SCD), and bb2121 anti-BCMA CAR T therapy. These data can be found here (HGB-204 and HGB-207 studies of LentiGlobin in TDT), here (HGB-206 study of LentiGlobin in SCD), here (HGB-205 single center study of LentiGlobin in patients with TDT or SCD) and here (bb2121). All data in these linked press releases are as of the respective data cut-off dates described in the press releases.

- **COLLABORATION WITH TC BIOPHARM –** In December 2017, bluebird and immunotherapy company TC BioPharm, Ltd., or TCB, announced the execution of a strategic collaboration and license agreement focused on gamma delta CAR T cells. Under the terms of the agreement, bluebird and TCB will collaborate to discover and develop CAR-engineered gamma delta T cells, which has the potential to be a powerful new platform for CAR T cell therapies in cancer, with potential applicability for both allogeneic and autologous therapies across liquid and solid tumors. TCB is responsible for development of all programs through Phase 1/2, at which point bluebird has the exclusive option to assume sole responsibility for further clinical development and commercialization on a global basis.

- **MANUFACTURING SITE ACQUISITION AND AGREEMENTS –** In November 2017, bluebird announced its acquisition of a 125,000 square foot manufacturing facility in Durham, North Carolina. Once construction and validation is complete, the site will produce lentiviral vector for the company's gene and cell therapies. In addition, bluebird also entered into multi-year agreements with three manufacturing partners in the United States and Europe: Brammer Bio (Cambridge, MA), Novasep (Gosselies, Belgium) and MilliporeSigma, the Life Science business of Merck KGaA (Carlsbad, CA). Each of these partners is collaborating with bluebird on production of lentiviral vector across all programs. bluebird also partners with Lonza (Houston, TX) and apceth Biopharma (Munich, Germany) to produce drug product for its product candidates.

- **BB2121 BREAKTHROUGH AND PRIME DESIGNATIONS –** In November 2017, bluebird and Celgene announced that bb2121 had been granted Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration (FDA) and PRIority MEdicines (PRIME) eligibility by the European Medicines Agency (EMA). BTD is designed to expedite the development and review of drugs that are intended to treat serious or life-threatening conditions. PRIME is a program launched by the EMA to enhance support for the development of medicines that target an unmet medical need.
- **FIRST PATIENT TREATED IN NORTHSTAR-3 (HGB-212) –** In November 2017, the first patient was infused with LentiGlobin drug product in Northstar-3, bluebird's Phase 3, global, multi-center study designed to evaluate the safety and efficacy of LentiGlobin in patients with TDT and the β^0/β^0 genotype. The target enrollment of the study is 15 adult, adolescent or pediatric patients.

- **STRENGTHENED BALANCE SHEET –** In December 2017, bluebird raised $569.8 million in net proceeds through a public equity offering. In January 2018, bluebird raised an additional $48.6 million in net proceeds pursuant to the partial exercise of the underwriters' over-allotment option in connection with this public equity offering. bluebird anticipates that its cash, cash equivalents and marketable securities as of December 31, 2017 will be sufficient to fund operations into 2021 based on the company's current business plan.

2018 Anticipated Milestones

- Filing for European approval of LentiGlobin in patients with TDT and non-β^0/β^0 genotypes in the second half of 2018
- Update on the clinical development plan and registration strategy for LentiGlobin in SCD by year end 2018
- Initiation of an investigator-led Phase 1 clinical study of a lentiviral gene therapy targeting BCL11a suppression and fetal hemoglobin upregulation in patients with SCD
- Initiation by Celgene of a Phase 3 clinical study of bb2121 in third line multiple myeloma
- Presentation of bb2121 clinical data from the CRB-401 study at the American Society of Clinical Oncology (ASCO) 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 European Hematology Association Annual Meeting
- Presentation of LentiGlobin clinical data from the HGB-206 clinical study in patients with SCD 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
- Presentation of bb21217 clinical data from the CRB-402 clinical study in patients with relapsed/refractory multiple myeloma at the ASH Annual Meeting

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

Fourth Quarter and Full Year 2017 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2017 were $1.6 billion, compared to $884.8 million as of December 31, 2016, an increase of $729.5 million, which was primarily driven by the company's June and December 2017 public equity offerings.
- **Revenues:** Total revenues were $4.2 million for the fourth quarter of 2017 compared to $1.6 million for fourth quarter of 2016, and $35.4 million for the year ended December 31, 2017 compared to $6.2 million for the year ended December 31, 2016. The increase is primarily attributable to the commencement of revenue recognition for the bb2121 license and manufacturing services under the company's agreement with Celgene and revenue recognized from the company's out-licensing agreement with Novartis Pharma AG (Novartis).
- **R&D Expenses:** Research and development expenses were $92.6 million for the fourth quarter of 2017 compared to $57.1 million for the fourth quarter of 2016, and $273.0 million for the year ended December 31, 2017 compared to $204.8 million for the year ended December 31, 2016. The increase in research and development expenses 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 our development programs, as well as increased employee-related costs due to headcount growth supporting overall research and development activities. When comparing the fourth quarter of 2017 to the fourth quarter of 2016, the increase in research and development expense was also attributable to license milestones and fees, primarily related to the company's strategic collaboration and license agreement with TCB.
- **G&A Expenses:** General and administrative expenses were $29.1 million for the fourth quarter of 2017 compared to $16.2 million for the fourth quarter of 2016, and $93.6 million for the year ended December 31, 2017 compared to $65.1 million for the year ended December 31, 2016. The increase in general and administrative expenses was attributable to increases in employee-related costs due to headcount to support overall growth, commercial-readiness activities, and facility-related expenses.
- **Cost of License and Royalty Revenue:** Cost of license and royalty revenue was less than $0.1 million for the fourth quarter of 2017 and $1.5 million for the year ended December 31, 2017 and is primarily composed of amounts payable to third party licensors in connection with amounts received under our out-license arrangement with Novartis. No similar costs were incurred during 2016.
- **Net Loss:** Net loss was $117.2 million for the fourth quarter of 2017 compared to $71.4 million for the fourth quarter of 2016, and $335.6 million for the year ended December 31, 2017 compared to $263.5 million for the year ended December 31, 2016.

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 for the treatment of cerebral adrenoleukodystrophy, and its LentiGlobin® product candidate for the treatment of 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 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 programs, bb2121 and bb21217, are anti-BCMA CAR T programs partnered with Celgene. 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, 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 to 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, risks that the preliminary results from our clinical trials 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 the LentiGlobin, Lenti-D or bb2121 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 annual report on 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. Guidance as to the

sufficiency of our cash, cash equivalents and marketable securities to fund our planned operations is based on current assumptions as of the date hereof and does not include the effect of any future potential license and collaboration agreements, business combinations or asset acquisitions. 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 amounts)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
::				
llaboration revenue	$ 4,018	$ 1,552	$ 22,207	$ 6,155
ense and royalty revenue	150	—	13,220	—
Total revenues	4,168	1,552	35,427	6,155
ıg expenses:				
search and development	92,576	57,133	273,040	204,775
neral and administrative	29,087	16,178	93,550	65,119
st of license and royalty revenue	7	—	1,527	—
ange in fair value of contingent consideration	(730)	576	(525)	4,091
Total operating expenses	120,940	73,887	367,592	273,985
Loss from operations	(116,772)	(72,335)	(332,165)	(267,830)
(expense) income, net	(159)	914	(2,001)	3,782
xpense) income, net	(87)	(6)	(1,267)	(71)
Loss before income taxes	(117,018)	(71,427)	(335,433)	(264,119)
tax benefit (expense)	(210)	63	(210)	612
Net loss	$ (117,228)	$ (71,364)	$ (335,643)	$ (263,507)
per share - basic and diluted:	$ (2.52)	$ (1.88)	$ (7.71)	$ (7.07)
d-average number of common shares used in computing net er share - basic and diluted	46,534	38,051	43,535	37,284

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

	As of December 31,	
	2017	2016
Cash, cash equivalents and marketable securities	$ 1,614,302	$ 884,830
Total assets	$ 1,900,567	$ 1,118,122
Total liabilities	$ 277,135	$ 248,682
Total stockholders' equity	$ 1,623,432	$ 869,440

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