

**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): December 4, 2020**

**bluebird bio, Inc.**

(Exact name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-35966**  
(Commission File Number)

**13-3680878**  
(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))

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, \$0.01 par value per share	BLUE	The NASDAQ Stock 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 8.01 Other Events.**

On December 4, 2020, bluebird bio, Inc. (“bluebird”) and Magenta Therapeutics, Inc. (“Magenta”) issued a press release announcing a phase 2 clinical trial collaboration to evaluate the utility of Magenta’s MGTA-145 candidate, in combination with plerixafor, for mobilization and collection of stem cells in adults and adolescents with sickle cell disease.

The full text of bluebird’s press release regarding the announcement is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release issued by bluebird bio, Inc. on December 4, 2020.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: December 4, 2020

**bluebird bio, Inc.**

By: /s/ Jason F. Cole  
Jason F. Cole  
*Chief Operating and Legal Officer*

**Magenta Therapeutics and bluebird bio Announce a Phase 2 Clinical Trial Collaboration to Evaluate Magenta's MGTA-145 for Mobilizing and Collecting Stem Cells in Adults and Adolescents with Sickle Cell Disease**

CAMBRIDGE, Mass. – December 4, 2020 - Magenta Therapeutics (NASDAQ: MGTA) and bluebird bio, Inc. (NASDAQ: BLUE) today announced an exclusive clinical trial collaboration to evaluate the utility of MGTA-145, in combination with plerixafor, for mobilization and collection of stem cells in adults and adolescents with sickle cell disease (SCD). The data from this clinical trial could provide proof-of-concept for MGTA-145, in combination with plerixafor, as the preferred mobilization regimen for patients with SCD. bluebird bio's experience with plerixafor as a mobilization agent in sickle cell disease aligns with Magenta's combination therapy approach, utilizing MGTA-145 plus plerixafor with potential to achieve safe, rapid and reliable mobilization of sufficient quantities of high-quality stem cells to improve outcomes associated with stem cell transplantation. Under the collaboration, the stem cells will be fully characterized, and Magenta will undertake preclinical studies to evaluate the ability of these cells to be gene corrected and engrafted in mouse models. The companies will co-fund the clinical trial and Magenta will retain all rights to its product candidate.

"We are excited to build upon our leading position in the field of ex-vivo gene therapy and the promising clinical data with LentiGlobin in SCD with a collaboration focused on achieving improved stem cell mobilization," said Dave Davidson, M.D., chief medical officer, bluebird bio. "In this initial study, we hope to establish whether the combination of plerixafor with MGTA-145 can generate appropriate CD34+ stem cells with a single round of mobilization. If successful, we hope to evaluate this novel mobilization regimen with LentiGlobin to make another step forward in the treatment of patients with SCD."

"Achieving reliable and rapid stem cell mobilization and a simplified collection process can ensure the entire patient experience is optimal with respect to therapeutic outcome. The incorporation of bluebird bio's experience in this area of treatment will be immensely valuable in further developing MGTA-145 plus plerixafor to address the remaining unmet needs in gene therapy approaches for diseases like sickle cell disease," said John Davis Jr., M.D., M.P.H., M.S., Head of Research & Development and Chief Medical Officer, Magenta Therapeutics. We look forward to collaborating with bluebird bio to evaluate MGTA-145 as the preferred mobilization option for people with sickle cell disease."

SCD is a serious, progressive and debilitating genetic disease caused by a mutation in the  $\beta$ -globin gene that leads to the production of abnormal sickle hemoglobin (HbS), causing red blood cells (RBCs) to become sickled and fragile, resulting in chronic hemolytic anemia, vasculopathy and painful vaso-occlusive events (VOEs). For adults and children living with SCD, this means unpredictable episodes of excruciating pain due to vaso-occlusion as well as other acute complications—such as acute chest syndrome (ACS), stroke, and infections, which can contribute to early mortality in these patients.

Currently available mobilization drugs, including granulocyte-colony stimulating factor (G-CSF), a commonly used mobilization agent administered over the course of five to seven days in other transplant settings, is not used in sickle cell disease because it can trigger vaso-occlusive crises and even death in adults and adolescents. Plerixafor is used to mobilize a patient's stem cells for collection prior to transplant and while an available treatment option, multiple cycles of apheresis and collection may sometimes be required to generate sufficient stem cells for gene therapy. Magenta is developing MGTA-145 in combination with plerixafor to be the preferred mobilization regimen for rapid and reliable mobilization and collection of hemopoietic stem cells to improve stem cell transplantation outcomes in multiple disease areas, including genetic diseases such as sickle cell disease, as well as blood cancers and autoimmune diseases.

## *About Magenta Therapeutic's MGTA-145*

MGTA-145, in combination with plerixafor, has demonstrated, in a recently completed Phase 1 study in healthy volunteers, it can rapidly and reliably mobilize high numbers of functional stem cells in a single day, without the need for G-CSF. MGTA-145 works in combination with plerixafor to harness a physiological mechanism of stem cell mobilization to rapidly and reliably mobilize HSCs for collection and transplant across multiple indications.

Additionally, as shown in preclinical studies, stem cells mobilized with MGTA-145 can be efficiently gene-modified and are able to engraft, potentially allowing for safer and more efficient mobilization for gene therapy approaches to treat sickle cell disease and other genetic diseases.

Magenta completed its Phase 1 trial of MGTA-145 in healthy volunteers, demonstrating MGTA-145 was well tolerated and enables same-day dosing, mobilization and simplified collection of sufficient stem cells for transplant, meeting all primary and secondary endpoints.

### **About bluebird bio, Inc.**

bluebird bio is pioneering gene therapy with purpose. From our Cambridge, Mass., headquarters, we're developing gene and cell 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: cerebral adrenoleukodystrophy, sickle cell disease,  $\beta$ -thalassemia and multiple myeloma, using gene and cell therapy technologies including gene addition, 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](http://bluebirdbio.com).

Follow bluebird bio on social media: [@bluebirdbio](https://twitter.com/bluebirdbio), [LinkedIn](https://www.linkedin.com/company/bluebirdbio), [Instagram](https://www.instagram.com/bluebirdbio) and [YouTube](https://www.youtube.com/channel/UC8vYUw1Uw1Uw1Uw1Uw1Uw1Uw).

LentiGlobin and bluebird bio are trademarks of bluebird bio, Inc.

### **About Magenta Therapeutics**

Magenta Therapeutics is a clinical-stage biotechnology company developing medicines to bring the curative power of immune system reset through stem cell transplant to more patients with autoimmune diseases, genetic diseases and blood cancers. Magenta is combining leadership in stem cell biology and biotherapeutics development with clinical and regulatory expertise, a unique business model and broad networks in the stem cell transplant world to revolutionize immune reset for more patients.

Magenta is based in Cambridge, Mass. For more information, please visit [www.magentatx.com](http://www.magentatx.com).

Follow Magenta on Twitter: [@magentatx](https://twitter.com/magentatx).

### **Forward-Looking Statement**

This press release may contain forward-looking statements and information within the meaning of The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "may," "will," "could," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "seeks," "endeavour," "potential," "continue" or the negative of such words or other similar expressions can be used to identify forward-looking statements. The express or implied forward-looking statements included in this press release are only predictions and are subject to a number of risks, uncertainties

and assumptions, including, without limitation risks set forth under the caption “Risk Factors” in Magenta’s Annual Report on Form 10-K filed on March 3, 2020, and in bluebird bio’s Annual Report on Form 10-K filed on February 18, 2020, as updated by each company’s most recent Quarterly Report on Form 10-Q and its other filings with the Securities and Exchange Commission. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although Magenta and bluebird bio believe that the expectations reflected in the forward-looking statements are reasonable, neither Magenta nor bluebird bio can guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither Magenta or bluebird bio, nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements included in this press release. Any forward-looking statement included in this press release speaks only as of the date on which it was made. Neither Magenta nor bluebird undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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