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): **June 14, 2024**

Editas Medicine, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-37687**	**46-4097528**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

11 Hurley Street

Cambridge, Massachusetts	**02141**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(617) 401-9000**

(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 Instruction 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, $0.0001 par value per share	EDIT	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 7.01 Regulation FD Disclosure.

On June 14, 2024, Editas Medicine, Inc. (the "Company") issued two press releases, one titled "Editas Medicine Reports New Safety and Efficacy Data from the RUBY Trial of Reni-cel in 18 Patients with Sickle Cell Disease, Presented at the European Hematology Association (EHA) Annual Congress," a copy of which is furnished as Exhibit 99.1 hereto, and the other titled "Editas Medicine Announces New Safety and Efficacy Data from the EdiTHAL Trial of Reni-cel in 7 Patients with Transfusion-dependent Beta Thalassemia, Presented at the European Hematology Association (EHA) Annual Congress," a copy of which is furnished as Exhibit 99.2 hereto.

The information in this Item 7.01, including Exhibit 99.1 and Exhibit 99.2 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, as amended (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, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On June 14, 2024, the Company announced new safety and efficacy data in 18 patients treated with renizgamglogene autogedtemcel ("reni-cel"; formerly known as EDIT-301) in the Company's Phase 1/2/3 clinical trial of reni-cel for the treatment of severe sickle cell disease ("SCD"), which is referred to as the RUBY trial. The data provided was as of a May 8, 2024 data cutoff date.

The Company also announced on June 14, 2024, new safety and efficacy data in seven patients treated with reni-cel in the Company's Phase 1/2 clinical trial of reni-cel for the treatment of transfusion-dependent beta thalassemia ("TDT"), which is referred to as the EdiTHAL trial. The data provided was as of a May 8, 2024 data cutoff date.

RUBY Clinical Data Update

In the RUBY clinical trial, all 18 patients are free of vaso-occlusive events since reni-cel infusion with follow-up ranging from 2.4 to 22.8 months. Patients demonstrated early normalization of total hemoglobin ("Hb") with a mean within the normal range at more than 14g/dL and rapid and sustained improvements in fetal hemoglobin ("HbF") well above levels of over 40%. Across patients with at least six months follow-up, at month six, the mean total Hb was 14.3 g/dL for nine patients with a mean HbF of 48.5% for 10 patients. The mean percentage of F-cells increased early and were sustained at over 90% from month four through subsequent follow-ups for all 12 patients with at least four months follow-up.

Mean corpuscular fetal hemoglobin of HbF-containing red cells (F-cells) was sustained above the anti-sickling threshold of 10 pg/F-cell by month three after reni-cel infusion for all 14 patients with at least three months follow-up.

All patients in the RUBY trial showed sustained high levels of editing in the *HBG1* and *HBG2* promoter regions.

Markers of hemolysis have been normalized or improved in patients treated with reni-cel.

Reni-cel was well-tolerated and demonstrated a safety profile consistent with myeloablative conditioning with busulfan, the regimen that is necessary for current gene editing therapies for SCD and TDT, and autologous hematopoietic stem cell transplant by all 18 evaluated RUBY trial patients. Patients in the RUBY trial underwent a median of two apheresis and mobilization cycles.

After reni-cel infusion, all 18 patients demonstrated successful neutrophil and platelet engraftment. Neutrophil engraftment occurred at a median of 23 days, and platelet engraftment occurred at a median of 24 days. No serious adverse events related to reni-cel treatment in the RUBY trial have been reported.

EdiTHAL Clinical Data Update

In the EdiTHAL clinical trial, patients demonstrated early and robust total Hb and HbF increases, with total Hb rising above the transfusion independence threshold of 9.0 g/dL. For the six patients with at least six months follow-up, the mean total Hb and HbF concentrations at month six were 12.1 g/dL and 10.9 g/dL, respectively, which were sustained at or above the transfusion threshold from six months through subsequent follow-ups.

All seven patients have been transfusion free for a range of 4.1 to 12.8 months after receiving the last red blood cell transfusion at 0.5-2.2 months post-reni-cel infusion.

All patients in the EdiTHAL trial showed sustained high levels of editing in the *HBG1* and *HBG2* promoter regions.

Reni-cel was well-tolerated and demonstrated a safety profile consistent with myeloablative conditioning with busulfan and autologous hematopoietic stem cell transplant by all seven evaluated EdiTHAL trial patients. All patients in the EdiTHAL trial underwent one apheresis and mobilization cycle.

After reni-cel infusion, all seven patients demonstrated successful neutrophil and platelet engraftment. Neutrophil engraftment occurred at a median of 23 days, and platelet engraftment occurred at a median of 38 days. No serious adverse events related to reni-cel treatment in the EdiTHAL trial have been reported.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on June 14, 2024*
99.2	Press release issued by the Company on June 14, 2024*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* This exhibit shall be deemed to be furnished and not filed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EDITAS MEDICINE, INC.

Date: June 14, 2024

By: /s/ Erick Lucera
Erick Lucera
Chief Financial Officer

Editas Medicine Reports New Safety and Efficacy Data from the RUBY Trial of Reni-cel in 18 Patients with Sickle Cell Disease, Presented at the European Hematology Association (EHA) Annual Congress

All patients treated in the RUBY trial are free of vaso-occlusive events post-renizgamglogene autogedtemcel (reni-cel) infusion

Patients had early normalization of total hemoglobin with a mean within the normal range at >14 g/dL and rapid and sustained improvements in fetal hemoglobin well above levels of >40%.

Reni-cel was well-tolerated and demonstrated a safety profile consistent with myeloablative conditioning with busulfan and autologous hematopoietic stem cell transplant

EHA RUBY oral presentation on Saturday, June 15 at 11:30 a.m. CEST/5:30 a.m. EDT

CAMBRIDGE, Mass., June 14, 2024 – Editas Medicine, Inc. (Nasdaq: EDIT), a clinical-stage genome editing company, today announced new safety and efficacy data in 18 patients living with sickle cell disease (SCD) treated with renizgamglogene autogedtemcel (reni-cel; formerly known as EDIT-301) in the Phase 1/2/3 RUBY clinical trial. Reni-cel, the first investigational AsCas12a gene-edited cell therapy medicine, is being studied in the RUBY trial as a potential one-time, durable medicine for people living with severe SCD. The data will be presented in an oral presentation at the European Hematology Association (EHA) Hybrid Congress in Madrid, Spain and via livestream, on Saturday, June 15 at 11:30 a.m. CEST (5:30 a.m. EDT).

In the RUBY trial to date, reni-cel was well-tolerated and continues to demonstrate a safety profile consistent with myeloablative conditioning with busulfan and autologous hematopoietic stem cell transplant by all patients (N=18). Since treatment with reni-cel, patients have been free of vaso-occlusive events (VOEs) (N=18) for up to 22.8 months of follow-up. Patients had early normalization of total hemoglobin (Hb) with a mean within the normal range at >14 g/dL and rapid and sustained improvements in fetal hemoglobin (HbF) well above levels of >40%. Patients in the RUBY trial underwent a median of 2.0 apheresis and mobilization cycles (min: 1.0, max: 4.0).

“These data confirm the observations from our prior clinical readouts and further support our belief that reni-cel has the potential to be a best-in-class and clinically differentiated, one-time, durable medicine that can provide life-changing clinical benefits to patients,” said Baisong Mei, M.D., Ph.D., Chief Medical Officer, Editas Medicine. “Importantly, we continue to make significant progress in the development of reni-cel. In the RUBY trial, we have now dosed more than 20 patients, completed adult cohort enrollment, and opened and enrolled patients in the adolescent cohort. I would like to thank the participants, their families and caregivers, clinicians, and colleagues at collaborating institutions that contribute to the RUBY trial.”

“I am encouraged by these results from the RUBY trial, demonstrating this investigational gene editing medicine has been well-tolerated and shows promising efficacy for people living with sickle cell disease. Treatment with reni-cel showed a favorable safety profile and promising preliminary efficacy, supporting further investigation as a differentiated gene-edited medicine for patients with SCD. We look forward to continuing to evaluate its effectiveness on this patient population in need of treatment options,” said Rabi Hanna, M.D., Chairman of the Division of Pediatric Hematology Oncology and Blood and Marrow Transplantation at Cleveland Clinic Children’s, and the RUBY presenting investigator.

Efficacy of reni-cel in Patients with Severe Sickle Cell Disease
All patients (N=18) are free of VOEs since reni-cel infusion with follow-up ranging from 2.4 to 22.8 months.

Reni-cel treatment drives early, robust increases and sustained levels of total Hb and HbF. Across patients with ≥6 months follow-up, at month 6, the mean (standard deviation; SD) total Hb was 14.3 g/dL (2.1 g/dL) (n=9) with a mean (SD) HbF of 48.5% (3.7%) (n=10).

The mean percentage of F-cells increased early and were sustained at >90% from month 4 through subsequent follow-ups for all patients with ≥4 months follow-up (n=12).

Mean corpuscular fetal hemoglobin (MCH-F) of HbF-containing red cells (F-cells) was sustained above the anti-sickling threshold of 10 pg/F-cell by month 3 after reni-cel infusion for all patients with ≥3 months follow-up (n=14).

All patients in the RUBY trial showed sustained high levels of editing in the *HBG1* and *HBG2* promoter regions.

Markers of hemolysis have been normalized or improved in patients treated with reni-cel.

Safety of reni-cel in Patients with Severe Sickle Cell Disease
Reni-cel was well-tolerated and demonstrated a safety profile consistent with myeloablative conditioning with busulfan and autologous hematopoietic stem cell transplant by all evaluated RUBY trial patients (N=18).

After reni-cel infusion, all patients (N=18) demonstrated successful neutrophil and platelet engraftment. Neutrophil engraftment occurred at a median of 23 days (min: 15 days, max: 29 days), and platelet engraftment occurred at a median of 24 days (min: 18 days, max: 51 days).

No serious adverse events (SAEs) related to reni-cel treatment in the RUBY trial have been reported.

EHA Presentations
In addition to the RUBY oral presentation, Editas will also present data from the EdiTHAL clinical trial of reni-cel for the treatment of transfusion-dependent beta thalassemia in a poster presentation on Friday, June 14.

RUBY Oral Presentation Details:
Title: Reni-cel, the first AsCas12a gene-edited cell therapy, led to hemoglobin normalization and increased fetal hemoglobin in severe sickle cell disease patients in an interim analysis of the RUBY trial
Presenting Author: Rabi Hanna, M.D., Department of Pediatric Hematology Oncology and Blood and Marrow Transplantation, Cleveland Clinic Children's, Cleveland, OH, United States
Date/Time: Saturday, June 15, 2024, 11:30 a.m. – 12:45 p.m. CEST/ 5:30 – 6:45 a.m. EDT
Location: Hall Velasquez, IFEMA MADRID Recinto Ferial (Fairgrounds)
Session: s425 Gene therapy, cellular immunotherapy and vaccination – Clinical

EdiTHAL Poster Presentation Details:
Title: Reni-cel, the first AsCas12a gene-edited cell therapy, shows promising preliminary results in key clinical outcomes in transfusion-dependent beta thalassemia patients treated in the EdiThal trial
Presenting Author: Haydar Frangoul, M.D., M.S., Medical Director, Sarah Cannon Pediatric Hematology/Oncology & Cellular Therapy at TriStar Centennial, Nashville, TN, United States
Date/Time: Friday, June 14, 2024, 6:00 – 7:00 p.m. CEST / Noon – 1:00 p.m. EDT
Location: Hall 7, IFEMA MADRID Recinto Ferial (Fairgrounds)
Session: Poster Session

The abstracts can be accessed on the EHA website and the presentations can be accessed on the Editas Medicine website in the posters and presentations section.

Reni-cel is currently being investigated in a clinical study in patients with severe sickle cell disease (RUBY trial, NCT04853576) and transfusion-dependent beta thalassemia (EDITHAL trial, NCT05444894). In addition to the clinical data update from the RUBY and EdiTHAL trials at EHA, the Company will present a further clinical update from both trials by year-end 2024.

About renizgamglogene autogedtemcel (reni-cel)
Reni-cel, formerly known as EDIT-301, is an experimental gene editing medicine under investigation for the treatment of severe sickle cell disease (SCD) and transfusion-dependent beta thalassemia (TDT). Reni-cel consists of patient-derived $CD34^+$ hematopoietic stem and progenitor cells edited at the gamma globin gene (*HBG1* and *HBG2*) promoters, where naturally occurring fetal hemoglobin (HbF) inducing mutations reside, by AsCas12a, a novel, proprietary, highly efficient, and specific gene editing nuclease. Red blood cells derived from reni-cel $CD34^+$ cells demonstrate a sustained increase in fetal hemoglobin production, which has the potential to provide a one-time, durable treatment benefit for people living with severe SCD and TDT.

About the RUBY Trial
The RUBY trial is a single-arm, open-label, multi-center Phase 1/2/3 study designed to assess the safety and efficacy of reni-cel in patients with severe sickle cell disease. Enrolled patients will receive a single administration of reni-cel. The RUBY trial marks the first time AsCas12a was used to successfully edit human cells in a clinical trial. Additional details are available on www.clinicaltrials.gov (NCT04853576).

About the EdiTHAL Trial
The EdiTHAL trial is a single-arm, open label, multi-center Phase 1/2 study designed to assess the safety and efficacy of reni-cel in patients with transfusion-dependent beta thalassemia. Patients will receive a single administration of reni-cel. Additional details are available on www.clinicaltrials.gov (NCT05444894).

About Editas Medicine
As a clinical-stage gene editing company, Editas Medicine is focused on translating the power and potential of the CRISPR/Cas12a and CRISPR/Cas9 genome editing systems into a robust pipeline of treatments for people living with serious diseases around the world. Editas Medicine aims to discover, develop, manufacture, and commercialize transformative, durable, precision genomic medicines for a broad class of diseases. Editas Medicine is the exclusive licensee of Broad Institute's Cas12a patent estate and Broad Institute and Harvard University's Cas9 patent estates for human medicines. For the latest information and scientific presentations, please visit www.editasmedicine.com.

Forward-Looking Statements
This press release contains forward-looking statements and information within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "target," "should," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements in this press release include statements regarding the timing for the Company's receipt and presentation of data from its clinical trials, including presenting additional clinical data from the RUBY and EdiTHAL trials by year-end 2024, and the potential of, and expectations for, the Company's product candidates. The Company may not actually achieve the plans, intentions, or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including: uncertainties inherent in the initiation and completion of clinical trials, including the RUBY and EdiTHAL trials, and clinical development of the Company's product candidates, including reni-cel; availability and timing of results from clinical trials; whether interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; expectations for regulatory approvals to conduct trials or to market products and availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure

requirements. These and other risks are described in greater detail under the caption “Risk Factors” included in the Company’s most recent Annual Report on Form 10-K, which is on file with the Securities and Exchange Commission, as updated by the Company’s subsequent filings with the Securities and Exchange Commission, and in other filings that the Company may make with the Securities and Exchange Commission in the future. Any forward-looking statements contained in this press release speak only as of the date hereof, and the Company expressly disclaims any obligation to update any forward-looking statements, whether because of new information, future events or otherwise.

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Media and Investor Contact:
Cristi Barnett
(617) 401-0113
cristi.barnett@editasmed.com

Editas Medicine Announces New Safety and Efficacy Data from the EdiTHAL Trial of Reni-cel in 7 Patients with Transfusion-dependent Beta Thalassemia, Presented at the European Hematology Association (EHA) Annual Congress

All patients treated in the EdiTHAL trial maintained hemoglobin levels above the transfusion threshold and are transfusion-free post-renizgamglogene autogedtemcel (reni-cel) infusion

Reni-cel was well-tolerated and demonstrated a safety profile consistent with myeloablative conditioning with busulfan and autologous hematopoietic stem cell transplant

EHA EdiTHAL poster presentation on Friday, June 14 at 6 p.m. CEST/Noon EDT

CAMBRIDGE, Mass., June 14, 2024 – Editas Medicine, Inc. (Nasdaq: EDIT), a clinical-stage genome editing company, today announced new safety and efficacy data in 7 patients with transfusion-dependent beta thalassemia (TDT) treated with renizgamglogene autogedtemcel (reni-cel; formerly known as EDIT-301) in the Phase 1/2 EdiTHAL clinical trial. Reni-cel, the first investigational AsCas12a gene-edited cell therapy medicine, is being studied in the EdiTHAL trial as a potential one-time, durable gene editing medicine for people living with TDT. The data will be presented in a poster presentation at the European Hematology Association (EHA) Hybrid Congress in Madrid, Spain, on Friday, June 14 at 6:00 p.m. CEST (Noon EDT).

In the EdiTHAL trial to date, reni-cel was well-tolerated and continues to demonstrate a safety profile consistent with myeloablative conditioning with busulfan and autologous hematopoietic stem cell transplant by all patients (N=7). Following treatment with reni-cel, all EdiTHAL patients had early and robust increase of total hemoglobin (Hb) and fetal hemoglobin (HbF) and remain transfusion-free at last follow-up for a range of 4.1 to 12.8 months (N=7). All patients in the EdiTHAL trial underwent 1.0 apheresis and mobilization cycle.

“We continue to make significant progress in the development of reni-cel for transfusion-dependent beta thalassemia. In these new data at EHA, we demonstrate that all patients experienced early increases in fetal hemoglobin, maintained hemoglobin levels above the transfusion threshold and are free from red blood cell transfusions following reni-cel infusion. These data further support our belief that reni-cel has the potential to be a clinically differentiated, one-time, durable medicine that can provide life-changing clinical benefits to patients,” said Baisong Mei, M.D., Ph.D., Chief Medical Officer, Editas Medicine. “I would like to thank the participants, their families and caregivers, clinicians, and colleagues at collaborating institutions that contribute to the EdiTHAL trial.”

“The preliminary safety and efficacy results from the EdiTHAL trial demonstrate this investigational medicine has been well-tolerated and shows promising efficacy for patients. Reni-cel has the potential to be a functional cure for people living with transfusion-dependent beta thalassemia, and we look forward to continuing to evaluate its effectiveness for these

patients," said Haydar Frangoul, M.D., M.S., Medical Director, Pediatric Hematology and Oncology, Sarah Cannon Research Institute and HCA Healthcare's TriStar Centennial Children's Hospital.

Efficacy of reni-cel in Patients with Transfusion-dependent Beta Thalassemia
In the EdiTHAL trial, patients demonstrated early and robust total Hb and HbF increases, with total Hb rising above the transfusion independence threshold of 9.0 g/dL. For patients with ≥6 months follow-up, the mean (standard deviation; SD) total Hb and HbF concentrations at month 6 were 12.1 g/dL (1.3 g/dL) and 10.9 g/dL (1.5 g/dL) (n=6), respectively, which were sustained at or above the transfusion threshold from 6 months through subsequent follow-ups.

All patients (N=7) have been transfusion free for a range of 4.1 to 12.8 months after receiving the last red blood cell transfusion at 0.5–2.2 months post-reni-cel infusion.

All patients in the EdiTHAL trial showed sustained high levels of editing in the *HBG1* and *HBG2* promoter regions.

Safety of reni-cel in Patients with Transfusion-dependent Beta Thalassemia
Reni-cel was well-tolerated and demonstrated a safety profile consistent with myeloablative conditioning with busulfan and autologous hematopoietic stem cell transplant by all evaluated EdiTHAL trial patients (N=7).

After reni-cel infusion, all patients (N=7) demonstrated successful neutrophil and platelet engraftment. Neutrophil engraftment occurred at a median of 23 days (min: 16 days, max: 30 days), and platelet engraftment occurred at a median of 38 days (min: 24 days, max: 49 days).

No serious adverse events (SAEs) related to reni-cel treatment in the EdiTHAL trial have been reported.

EHA Presentations
In addition to the EdiTHAL poster presentation, Editas will also present data from the RUBY clinical trial of reni-cel for the treatment of severe sickle cell disease in an oral presentation on Saturday, June 15.

EdiTHAL Poster Presentation Details:
Title: Reni-cel, the first AsCas12a gene-edited cell therapy, shows promising preliminary results in key clinical outcomes in transfusion-dependent beta thalassemia patients treated in the EdiThal trial
Presenting Author: Haydar Frangoul, M.D., M.S., Medical Director, Sarah Cannon Pediatric Hematology/Oncology & Cellular Therapy at TriStar Centennial, Nashville, TN, United States
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RUBY Oral Presentation Details:
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About the EdiTHAL Trial
The EdiTHAL trial is a single-arm, open label, multi-center Phase 1/2 study designed to assess the safety and efficacy of reni-cel in patients with transfusion-dependent beta thalassemia. Patients will receive a single administration of reni-cel. Additional details are available on www.clinicaltrials.gov (NCT05444894).

About the RUBY Trial
The RUBY trial is a single-arm, open-label, multi-center Phase 1/2/3 study designed to assess the safety and efficacy of reni-cel in patients with severe sickle cell disease. Enrolled patients will receive a single administration of reni-cel. The RUBY trial marks the first time AsCas12a was used to successfully edit human cells in a clinical trial. Additional details are available on www.clinicaltrials.gov (NCT04853576).

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Media and Investor Contact:
Cristi Barnett
(617) 401-0113
cristi.barnett@editasmed.com