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 7, 2024

Beam Therapeutics Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39208**	**81-5238376**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

238 Main Street **Cambridge, Massachusetts**	**02142**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 857 327-8775

(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:

☐ 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, par value $0.01 per share	BEAM	Nasdaq Global Select Market

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 December 7 and December 8, 2024, Beam Therapeutics Inc. (the "Company") issued press releases entitled, respectively, "Beam Therapeutics Announces New Data from BEACON Phase 1/2 Clinical Trial of BEAM-101 in Sickle Cell Disease at American Society of Hematology (ASH) Annual Meeting" and "Beam Therapeutics Presents New Non-human Primate (NHP) Data Demonstrating Proof-of-concept for ESCAPE, a Non-genotoxic, Antibody-based Conditioning Approach to Treating Sickle Cell Disease, at American Society of Hematology (ASH) Annual Meeting." Copies of the Company's press releases are attached as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K and incorporated herein by reference

The information under this Item 7.01, including Exhibits 99.1 and 99.2 hereto, is being furnished herewith and shall not be deemed "filed" for the 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 such information be deemed incorporated by reference into 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 December 8, 2024, the Company presented positive new clinical data from its ongoing BEACON clinical trial of BEAM-101 for the treatment of severe sickle cell disease at the American Society of Hematology ("ASH") meeting taking place in San Diego, California. The BEACON trial initially includes up to 45 patients ages 18 to 35 with severe sickle cell disease who have received prior treatment with at least one disease-modifying agent with inadequate response or intolerance. Following mobilization, conditioning and treatment with BEAM-101, patients are assessed for safety and tolerability, with safety endpoints including neutrophil and platelet engraftment. Patients are also assessed for efficacy, with efficacy endpoints including the change from baseline in severe vaso-occlusive events, transfusion requirements, hemoglobin F ("HbF") levels and quality of life assessments.

The presentation contained initial, preliminary data as of October 28, 2024 from a total of seven patients in the BEACON trial, with follow up ranging from one to 11 months. The presentation data included the following:

- All patients achieved endogenous HbF levels exceeding 60% and reduction in corresponding sickle hemoglobin S below 40% that was durable through the data cutoff date. A pancellular distribution of HbF was also observed after the elimination of transfused blood.
- Total hemoglobin levels increased rapidly with resolution of anemia in all patients after elimination of the transfused blood.
- All patients achieved the minimum target cell dose in either 1 or 2 cycles of mobilization (average: 1.4). The mean time to neutrophil engraftment was 17.1 days (range: 15–21), with a low mean duration of neutropenia (6.3 days). The mean time to platelet engraftment was 19.1 days (range: 11–34).

- Key markers of hemolysis, including indirect bilirubin, haptoglobin, lactate dehydrogenase and reticulocytes, normalized or improved in all patients following BEAM-101 treatment.
- The initial safety profile of BEAM-101 was consistent with busulfan conditioning and autologous hematopoietic stem cell ("HSC") transplantation ("HSCT"). The most common treatment-emergent adverse events were consistent with busulfan conditioning, including febrile neutropenia, stomatitis and anemia. One patient died four months after BEAM-101 infusion due to respiratory failure that was determined by the investigator to be likely related to busulfan conditioning and deemed unrelated to BEAM-101. No vaso-occlusive crises were reported post-engraftment.

As of December 2, 2024, more than thirty-five patients have cleared screening and enrolled in the BEACON trial. Of these patients, 11 have been dosed with BEAM-101. Data from the four most recently dosed patients was not included in the Company's presentation at ASH. The trial's Data Monitoring Committee and the U.S. Food & Drug Administration have cleared the trial to enroll adolescents from 12 to 17 years old.

In addition, on December 8, 2024, the Company presented new preclinical data for its Engineered Stem Cell Antibody Evasion ("ESCAPE") conditioning platform at ASH. ESCAPE is comprised of two investigational drug products: BEAM-103, an anti-CD117 monoclonal antibody ("mAb") that is designed to suppress and/or eliminate hematopoietic stem and progenitor cells ("HSPCs") that express CD117, and BEAM-104, a cell therapy that includes an edit to the promoter region of the *HBG1/2* genes intended to elevate HbF, plus an additional edit to CD117 designed to prevent binding of BEAM-103, allowing the edited cells to function normally and evade targeting by the antibody. Together, this approach aims to provide a non-genotoxic alternative to traditional transplant myeloablative conditioning ahead of HSCT.

In the preclinical study, conducted in the laboratory of John Tisdale, M.D., at the National Institutes of Health, CD34+ cells from three rhesus non-human primates ("NHPs") were multiplex base-edited *ex vivo* to introduce edits to CD117 and to HBG1/2. The NHPs were then conditioned with only a CD117 mAb at doses of either 10 mg/kg or 25 mg/kg, seven days prior to transplantation. Post-transplant, additional mAb treatments were administered to sustain a negative selective pressure on unedited cells.

The presentation data included the following:

- Administration of the BEAM-104 edited cells to antibody-conditioned NHPs demonstrated long-term engraftment of HSCs in the marrow, evidenced by the presence of edited cells in the periphery beyond six months.
- Rapid and near complete replacement of wild-type erythroid cells by edited cells was observed following dosing with the BEAM-103 mAb, with a corresponding early induction of therapeutically relevant levels of HbF. Levels of cells containing hemoglobin F reached greater than 80% post-transplant. All NHPs achieved greater than 40% g-globin, a key constituent of HbF, post-transplant.
- BEAM-103 dosing was well tolerated without the use of transfusions, antibiotics or additional supportive care. In contrast to busulfan conditioning, NHPs that received mAb administration demonstrated only minor declines in neutrophil counts and platelet levels, an expected outcome of the mAb targeting CD117 on wild-type HSPCs.
- The CD117 base-edit showed normal receptor function *in vitro* and *in vivo*. No changes to CD117 signaling, structure or expression were observed following editing. Normal hematopoietic reconstitution was observed post-transplantation.

On December 8, 2024, the Company also announced updated guidance for its Phase 1/2 open label, dose escalation study of BEAM-302 in patients with alpha-1 antitrypsin deficiency-associated lung disease. The Company now expects to report initial clinical data from multiple cohorts in the trial in the first half of 2025.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Investors are cautioned not to place undue reliance on these forward-looking statements, including, but not limited to, statements related to the therapeutic applications and potential of the Company's technology and the clinical trial designs and expectations for BEAM-101, ESCAPE and BEAM-302, including the expected timing for reporting clinical data. Each forward-looking statement is subject to important risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including, without limitation, risks and uncertainties related to: that initiation and enrollment of, and anticipated timing to advance, our clinical trials may take longer than expected; that our product candidates or the delivery modalities we rely on to administer them may cause serious adverse events; that our product candidates may experience manufacturing or supply interruptions or failures; and the other risks and uncertainties identified under the headings "Risk Factors Summary" and "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2024 and in any subsequent filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this Current Report. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by applicable law

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No	Description
99.1	Press Release Issued by Beam Therapeutics Inc. on December 7, 2024
99.2	Press Release Issued by Beam Therapeutics Inc. on December 8, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 9, 2024

Beam Therapeutics Inc.

By: /s/ John Evans
Name: John Evans
Title: Chief Executive Officer

Exhibit 99.1

Beam Therapeutics Announces New Data from BEACON Phase 1/2 Clinical Trial of BEAM-101 in Sickle Cell Disease at American Society of Hematology (ASH) Annual Meeting

All Seven Patients Treated with BEAM-101 Achieved Hemoglobin F (HbF) Induction of >60%, Hemoglobin S (HbS) Reduction to <40%, and Resolution of Anemia Post-BEAM-101 Treatment

Initial Safety Profile Consistent with Busulfan Conditioning and Autologous Hematopoietic Stem Cell Transplantation

All Seven Patients Dosed Achieved Target Cell Dose with One or Two Mobilization Cycles and Experienced Rapid Neutrophil and Platelet Engraftment

Markers of Hemolysis Normalized or Improved in All Patients

Beam to Host Investor Event on Dec. 8, 2024, at 8 p.m. PT

San Diego, December 7, 2024 – Beam Therapeutics Inc. (Nasdaq: BEAM), a biotechnology company developing precision genetic medicines through base editing, today announced new safety and efficacy data from its BEACON Phase 1/2 clinical trial of BEAM-101 in patients with sickle cell disease (SCD) with severe vaso-occlusive crises (VOCs). The data were featured today in the press program for the 66th American Society of Hematology (ASH) Annual Meeting and Exposition in San Diego and will be presented in an oral session on Sunday, Dec. 8, 2024, at 10 a.m. PT.

Consistent with Beam's previously announced data, updated data from seven patients treated with investigational base-editing therapy BEAM-101 demonstrated robust and durable increases in fetal hemoglobin (HbF) and reductions in sickle hemoglobin (HbS), rapid neutrophil and platelet engraftment, and normalized or improved markers of hemolysis. No VOCs were reported post-engraftment. A summary of the results from the ongoing clinical study is provided below.

"These initial data from the BEACON trial are very encouraging and highlight the potential of BEAM-101 to deliver meaningful clinical benefits to patients with severe sickle cell disease," said Matthew M. Heeney, M.D., associate chief of hematology at Dana-Farber/Boston Children's Cancer and Blood Disorders Center. "The data from the first seven patients demonstrate the ability for BEAM-101 to dramatically modify the hemoglobin profile to express a majority of protective fetal hemoglobin. All patients mobilized efficiently and had rapid engraftment with a low number of neutropenic days. I look forward to the continued maturation of the data to provide further insights into the long-term benefits of BEAM-101 for people living with sickle cell disease."

"It's an honor to share the initial results from BEACON with the hematology community at the ASH Annual Meeting, where there is broad recognition of the significant burden that sickle cell disease places on patients and their families," said John Evans, chief executive officer of Beam. "We believe these early data for BEAM-101 are a testament to the potential of our base-editing

technology to provide a differentiated option for sickle cell patients, having demonstrated a robust increase in fetal hemoglobin of >60%, a decrease in hemoglobin S to <40% and resolution of anemia in all patients. Additionally, the data from our ESCAPE nongenotoxic conditioning program – to be presented on Sunday – highlight our commitment to expanding access to treatment by decreasing the burden and complications patients potentially face when undergoing transplantation. We look forward to continuing to rapidly advance both programs for patients with sickle cell disease."

To date, more than 35 patients have cleared screening and enrolled in the BEACON Phase 1/2 clinical trial, and of these, 11 patients have been dosed with BEAM-101. As of an Oct. 28, 2024, data cut-off, a total of seven patients with severe SCD were treated with BEAM-101 and included in the safety and efficacy analysis with follow up ranging from 1 to 11 months.

Key highlights include the following:

- **Rapid and Sustained Increases in Protective Fetal Hemoglobin (HbF)**: All patients achieved endogenous HbF levels exceeding 60% and reduction in corresponding sickle hemoglobin (HbS) below 40% that was durable. A pancellular distribution of HbF was observed after the elimination of transfused blood.
- **Robust and Sustained Total Hemoglobin (Hb) Levels**: Total hemoglobin levels increased rapidly with resolution of anemia in patients after elimination of the transfused blood.
- **Efficient Cell Collection and Rapid Engraftment**: All patients achieved the minimum target cell dose in either 1 or 2 cycles of mobilization (average: 1.4). The mean time to neutrophil engraftment was 17.1 days (range: 15–21), with a low mean duration of neutropenia (6.3 days). The mean time to platelet engraftment was 19.1 days (range: 11–34).
- **Normalization of Hemolysis Markers**: Key markers of hemolysis, including indirect bilirubin, haptoglobin, lactate dehydrogenase and reticulocytes, normalized or improved in all patients following BEAM-101 treatment.
- **Safety Profile Consistent with Busulfan and Autologous Hematopoietic Stem Cell Transplantation (HSCT)**: The safety profile of BEAM-101 was consistent with busulfan conditioning and autologous HSCT. The most common treatment-emergent adverse events (TEAEs) were consistent with busulfan conditioning, including febrile neutropenia, stomatitis and anemia. One patient died four months after BEAM-101 infusion due to respiratory failure that was determined by the investigator to be likely related to busulfan conditioning and deemed unrelated to BEAM-101. No VOCs were reported post-engraftment.

ASH Investor Event Information

Beam will host a live and webcast investor event on Dec. 8, 2024, at 8:00 p.m. PT in San Diego to review the key presentations from this year's ASH meeting. The event will be webcast live and can be accessed under "Events & Presentations" in the Investors section of the company's website at www.beamtx.com. The archived webcast will be available on the company's website beginning approximately two hours after the event.

About BEAM-101

BEAM-101 is an investigational genetically modified cell therapy for the treatment of severe sickle cell disease (SCD). The one-time therapy consists of autologous CD34+ hematopoietic stem and progenitor cells (HSPCs) that have been base-edited in the promotor regions of the HBG1/2 genes and are administered via a hematopoietic stem cell transplant procedure. The BEAM-101 edit is designed to inhibit the transcriptional repressor BCL11A from binding to the promoter without disrupting BCL11A expression, leading to increased production of non-sickling and anti-sickling fetal hemoglobin (HbF) and thus mimicking the effects of naturally occurring variants seen in hereditary persistence of fetal hemoglobin. HbF is the predominant hemoglobin variant during development and early life. The safety and efficacy of BEAM-101 is being evaluated in the ongoing BEACON Phase 1/2 study, an open-label, single-arm, multicenter trial in adult patients with SCD with severe vaso-occlusive crises (VOCs).

About Beam Therapeutics

Beam Therapeutics (Nasdaq: BEAM) is a biotechnology company committed to establishing the leading, fully integrated platform for precision genetic medicines. To achieve this vision, Beam has assembled a platform with integrated gene editing, delivery and internal manufacturing capabilities. Beam's suite of gene editing technologies is anchored by base editing, a proprietary technology that is designed to enable precise, predictable and efficient single base changes, at targeted genomic sequences, without making double-stranded breaks in the DNA. This has the potential to enable a wide range of potential therapeutic editing strategies that Beam is using to advance a diversified portfolio of base editing programs. Beam is a values-driven organization committed to its people, cutting-edge science, and a vision of providing life-long cures to patients suffering from serious diseases.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Investors are cautioned not to place undue reliance on these forward-looking statements, including, but not limited to, statements related to: the therapeutic applications and potential of our technology, including with respect to SCD; our plans, and anticipated timing, to advance our programs; the clinical trial designs and expectations for BEAM-101 and ESCAPE; our presentations at the ASH annual meeting; and our ability to develop life-long, curative, precision genetic medicines for patients through base editing. Each forward-looking statement is subject to important risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including, without limitation, risks and uncertainties related to: our ability to develop, obtain regulatory approval for, and commercialize our product candidates, which may take longer or cost more than planned; our ability to raise additional funding, which may not be available; our ability to obtain, maintain and enforce patent and other intellectual property protection for our product candidates; the uncertainty that our product candidates will receive regulatory approval necessary to initiate human clinical trials; that preclinical testing of our product candidates and preliminary or interim data from preclinical studies and clinical trials may not be predictive of the results or success of ongoing or later clinical trials; that initiation and enrollment of, and anticipated timing to advance, our clinical trials may take longer than expected; that our product candidates or the

delivery modalities we rely on to administer them may cause serious adverse events; that our product candidates may experience manufacturing or supply interruptions or failures; risks related to competitive products; and the other risks and uncertainties identified under the headings “Risk Factors Summary” and “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2023, our Quarterly Reports on Form 10-Q for the quarterly period ended September 30, 2024 and in any subsequent filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date of this press release. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by applicable law.

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Beam Therapeutics Presents New Non-human Primate (NHP) Data Demonstrating Proof-of-concept for ESCAPE, a Non-genotoxic, Antibody-based Conditioning Approach to Treating Sickle Cell Disease, at American Society of Hematology (ASH) Annual Meeting

NHP Data Showed CD117 Monoclonal Antibody (mAb) Conditioning Successfully Achieved Long-term Engraftment of Base-edited Hematopoietic Stem Cells and Induced Robust Levels of Hemoglobin F

mAb Dosing Well Tolerated Without Need for Supportive Care

Beam on Track to Initiate Phase 1-enabling Studies by End of 2024

Beam to Host Investor Event on Dec. 8, 2024, at 8 p.m. PT

San Diego, December 8, 2024 – Beam Therapeutics Inc. (Nasdaq: BEAM), a biotechnology company developing precision genetic medicines through base editing, today announced new data for its Engineered Stem Cell Antibody Evasion (ESCAPE) conditioning platform. Presented in an oral session at the 66th American Society of Hematology (ASH) Annual Meeting and Exposition in San Diego, the data demonstrated that conditioning and *in vivo* selection with an anti-CD117 antibody enabled engraftment of base-edited hematopoietic stem cells (HSCs) and induced robust, durable production of fetal hemoglobin (HbF) in a non-human primate (NHP) model.

ESCAPE is comprised of two investigational drug products: BEAM-103, an anti-CD117 monoclonal antibody (mAb) that is designed to suppress and/or eliminate hematopoietic stem and progenitor cells that express CD117, and BEAM-104, a cell therapy that includes an edit to the promoter region of the HBG1/2 genes intended to elevate HbF, plus an additional edit to CD117 designed to prevent binding of BEAM-103, allowing the edited cells to function normally and evade targeting by the antibody. Together, this approach aims to provide a non-genotoxic alternative to traditional transplant myeloablative conditioning. The company intends to advance BEAM-103 and BEAM-104 for development in sickle cell disease (SCD) and beta-thalassemia.

“The data presented today at ASH represent a potential paradigm shift—the first in nearly 70 years—in transplant medicine,” said Giuseppe Ciaramella, Ph.D., president of Beam Therapeutics. “For decades, the field has relied on genotoxic conditioning regimens, which come with significant side effects and risks, limiting access to potentially curative therapies for many patients. With ESCAPE, we are moving toward a less toxic, more accessible approach that could expand the eligible patient population, potentially making gene editing therapies a viable option for patients with both severe and more moderate disease. These proof-of-concept data provide a strong foundation for advancing ESCAPE into the clinic, with the potential to transform transplant medicine for patients with sickle cell disease, beta-thalassemia and beyond.”

In the preclinical study, conducted in the laboratory of John Tisdale, M.D., at the National Institutes of Health, CD34+ cells from three rhesus NHPs were multiplex base-edited *ex vivo* with BEAM-104 to introduce edits to CD117 and to HBG1/2. NHPs were then conditioned with only the BEAM-103 CD117 mAb at doses of either 10 mg/kg or 25 mg/kg, seven days prior to transplantation. Post-transplant, additional BEAM-103 treatments were administered to sustain a negative selective pressure on unedited cells.

Highlights from the study include the following:

- **Administration of the BEAM-104 edited cells to antibody-conditioned animals led to long-term engraftment.**
  - Long term engraftment of HSCs in the marrow was demonstrated by the presence of edited cells in the periphery beyond 6 months.
- **Dosing with the BEAM-103 mAb led to rapid and near complete replacement of wild-type erythroid cells by edited cells, leading to early induction of therapeutically relevant levels of HbF.**
  - Levels of cells containing HbF reached >80% post-transplant.
  - All NHPs achieved >40% g-globin, a key constituent of HbF, post-transplant.
  - Rapid and sustained reactivation of HbF post-transplant showed promise of therapeutic benefit in SCD patients.
- **BEAM-103 dosing was well tolerated with no need for transfusions, antibiotics or additional supportive care.**
  - In contrast to busulfan conditioning, NHPs that received BEAM-103 demonstrated only minor decline in neutrophil counts and platelet levels, an expected outcome of the mAb targeting CD117 on wild-type hematopoietic stem and progenitor cells.
- **The CD117 base-edit showed normal receptor function *in vitro* and *in vivo.***
  - No changes to CD117 signaling, structure or expression were observed following editing.
  - In NHP studies, normal hematopoietic reconstitution was observed post-transplantation.

ASH Investor Event Information

Beam will host a live and webcast investor event at 8:00 p.m. PT on Dec. 8, 2024, in San Diego to review the key presentations from this year's ASH meeting. The event will be webcast live and can be accessed under "Events & Presentations" in the Investors section of the company's website at www.beamtx.com. The archived webcast will be available on the company's website beginning approximately two hours after the event.

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