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): October 3, 2018

Sarepta Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-14895**	**93-0797222**
(State or other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

215 First Street
Suite 415
Cambridge, MA 02142
(Address of principal executive offices, including zip code)

(617) 274-4000
(Registrant's Telephone Number, Including Area Code)

(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 7.01. Regulation FD Disclosure.

On October 3, 2018, Sarepta Therapeutics, Inc. issued a press release announcing that at the 23rd International Congress of the World Muscle Society, Jerry Mendell, M.D. presented positive updated results from the four children dosed in the gene therapy micro-dystrophin trial to treat patients with Duchenne Muscular Dystrophy. A copy of the press release and the presentation of Jerry Mendell, M.D. are furnished as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

The information in this report furnished pursuant to Item 7.01, including Exhibits 99.1 and 99.2 attached hereto, 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. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 7.01 of this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release dated October 3, 2018.
99.2	Precision Genetic Medicine for Neuromuscular Diseases, October 4, 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.

Sarepta Therapeutics, Inc.

By: /s/ Douglas S. Ingram
Douglas S. Ingram
President and Chief Executive Officer

Date: October 3, 2018

Sarepta Therapeutics Announces that at the 23rd International Congress of the World Muscle Society, Jerry Mendell, M.D., Presented Positive Updated Results from the Four Children Dosed in the Gene Therapy Micro-dystrophin Trial to Treat Patients with Duchenne Muscular Dystrophy

— Biopsy of fourth patient showed robust micro-dystrophin expression as measured by Western blot and immunohistochemistry —

— Positive functional improvements shown across all measures —

— No serious adverse events (SAEs) observed —

CAMBRIDGE, Mass., October 3, 2018 (GLOBE NEWSWIRE) — Sarepta Therapeutics, Inc. (NASDAQ:SRPT), a commercial-stage biopharmaceutical company focused on the discovery and development of precision genetic medicine to treat rare neuromuscular diseases, announced that at the 23rd International Congress of the World Muscle Society in Mendoza, Argentina, Jerry Mendell, M.D., of Nationwide Children's Hospital presented positive updated results from its gene therapy clinical trial assessing AAVrh74.MHCK7.micro-Dystrophin in individuals with Duchenne muscular dystrophy (DMD). Dr. Mendell presented the following updated data on the four patients enrolled in the study:

- All patients showed robust expression of transduced micro-dystrophin, which is properly localized to the muscle sarcolemma, as measured by immunohistochemistry. Mean gene expression for the study, as measured by percentage of micro-dystrophin positive fibers was 81.2% and the mean intensity of the fibers was 96.0% compared to normal control. All post-treatment biopsies showed robust levels of micro-dystrophin as measured by Western blot, with a mean of 74.3% compared to normal utilizing Sarepta's method, or 95.8% compared to normal pursuant to Nationwide Children's quantification of Sarepta's method that adjusts for fat and fibrotic tissue.
- Gene expression for the fourth patient was robust, as follows:
    - As measured by immunohistochemistry, micro-dystrophin positive fibers was 96.2% and the mean intensity of the fibers was 160.0% compared to normal control.
    - As measured by Western blot, patient 4 showed robust levels of micro-dystrophin, with a mean of 182.7% compared to normal utilizing Sarepta's method, or 222% compared to normal pursuant to Nationwide Children's quantification of Sarepta's method that adjusts for fat and fibrotic tissue.

- In all patients, expression of micro-dystrophin was associated with significant expression and up-regulation of the dystrophin-associated protein complex, an additional indication of functionality of dystrophin.
- All patients showed significant decreases of serum creatine kinase (CK) levels at last measure, with a mean reduction of CK of over 78% from baseline.
- Dr. Mendell also provided an update on functional endpoints for all four patients, including North Star Ambulatory Assessment (NSAA), Time to Rise, 4 Stairs Up, and 100M. Patients showed improvements across all measured functions, with boys showing an average NSAA raw score improvement of 6.5 points from baseline to last measure, or on a linearized NSAA basis, 12 points of improvement in the first 90 days. While results suggest functional improvements across all measures significantly greater than natural history predictions, it should be cautioned that this is a small, uncontrolled data set and these positive results must be reconfirmed in the larger, controlled registration trial.
- No serious adverse events (SAEs) were observed in the study. Three patients had elevated gamma-glutamyl transferase (GGT) that resolved with increased steroids within a week. There were no other significant laboratory findings. Patients had transient nausea generally during the first week of therapy coincident with increased steroid dosing.

Dr. Mendell, the study's principal investigator, in collaboration with Louise Rodino-Klapac, Ph.D., empirically optimized the AAVrh74.MHCK7 specifically for DMD:

- The AAVrh74 vector is designed to be systemically and robustly delivered to skeletal, diaphragm and cardiac muscle without promiscuously crossing the blood brain barrier, making it an ideal candidate to treat peripheral neuromuscular diseases.
- As a rhesus monkey-derived AAV vector, AAVrh74 has lower immunogenicity rates than reported with other common human AAV vectors.
- The MHCK7 promoter has been chosen for its ability to robustly express in the heart, which is critically important for patients with DMD, who typically die from pulmonary or cardiac complications. In pre-clinical models, micro-dystrophin expression in the heart was observed to be up to 120% of the micro-dystrophin levels observed in skeletal muscles.
- The transgene was designed to maintain spectrin-like repeats 2 and 3, which has been reported to be critical to maintaining the protective functional characteristics of dystrophin.

Dr. Mendell stated, "The goal of this study was to validate what we observed in pre-clinical models. We observed efficient transduction of our vector, AAVrh74, to all muscle types; robust expression in skeletal muscles via the MHCK7 promoter; a reduction in creatine kinase levels; and a favorable safety profile. Similar to pre-clinical models, we also observed in this early study that robust expression has the potential to positively impact the natural course of disease progression."

Doug Ingram, Sarepta's president and chief executive officer, added, "The encouraging results that we previously saw and reinforced in the fourth patient strengthen our resolve to rapidly move to a confirming trial and, assuming successful, to bring this therapy to the Duchenne community around the world with a sense of urgency."

Mr. Ingram continued, "These results create for us an obligation to patients around the globe living with and being damaged by this cruel disease. We are investing our energy, resources and creativity to moving the development forward, planning meetings with the FDA and other agencies around the world to take their input, building a compelling access and reimbursement package, and establishing sufficient manufacturing capacity to fully serve the community if our program is successful."

About Sarepta Therapeutics

Sarepta Therapeutics is a commercial-stage biopharmaceutical company focused on the discovery and development of precision genetic medicine to treat rare neuromuscular diseases. The Company is primarily focused on rapidly advancing the development of its potentially disease-modifying Duchenne muscular dystrophy (DMD) drug candidates. For more information, please visit www.sarepta.com.

Forward-Looking Statements

This press release contains "forward-looking statements." Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements regarding the results suggesting functional improvements across all measures significantly greater than natural history projections; the potential of the AAVrh74 vector to systemically and robustly be delivered to skeletal, diaphragm and cardiac muscle without promiscuously crossing the blood brain barrier, making it an ideal candidate to treat peripheral neuromuscular diseases; the ability of the MHCK7 promoter to robustly express in the heart; the potential of the transgene to maintain spectrin-like repeats 2 and 3; the potential of robust micro-dystrophin expression to positively impact the natural course of DMS progression; Sarepta's intention to rapidly move the micro-dystrophin gene therapy program to a confirming trial, and, if successful, to bring this therapy to the Duchenne community around the world with a sense of urgency; and Sarepta's plans to move the development forward, meet with the FDA and other agencies around the world to take their input, build a compelling access and reimbursement package, and establish sufficient manufacturing capacity to fully serve the community if the program is successful.

These forward-looking statements involve risks and uncertainties, many of which are beyond Sarepta's control. Known risk factors include, among others: success in preclinical testing and early clinical trials, especially if based on a small patient sample, does not ensure that later clinical trials will be successful, and initial results from a clinical trial do not necessarily predict final results; different methodologies, assumptions and applications Sarepta utilizes to assess particular safety or efficacy parameters may yield different statistical results, and even if Sarepta believes the data collected from clinical trials of its product candidates are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities; Sarepta's ongoing research and development efforts may not result in any viable treatments suitable for clinical research or commercialization due to a variety of reasons, some of which may be outside of Sarepta's control, including possible limitations of Company financial and other resources, manufacturing limitations that may not be anticipated or resolved for in a timely manner, and regulatory, court or agency decisions, such as decisions by the United States Patent and Trademark Office with respect to patents that cover our product candidates; and even if Sarepta's programs result in new commercialized products, Sarepta may not achieve any significant revenues from the sale of such products; and those risks identified under the heading "Risk Factors" in Sarepta's most recent Annual Report on Form 10-K for the year ended December 31, 2017 and most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) as well as other SEC filings made by the Company which you are encouraged to review.

Any of the foregoing risks could materially and adversely affect the Company's business, results of opera-tions and the trading price of Sarepta's common stock. For a detailed description of risks and uncertainties Sarepta faces, you are encouraged to review Sarepta's 2017 Annual Report on Form 10-K and most recent Quarterly Report on Form 10-Q filed with the SEC as well as other SEC filings made by Sarepta. We caution investors not to place considerable reliance on the forward-looking statements contained in this press re-lease. Sarepta does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.

Internet Posting of Information

We routinely post information that may be important to investors in the 'For Investors' section of our website at www.sarepta.com. We encourage investors and potential investors to consult our website regularly for important information about us.

Source: Sarepta Therapeutics, Inc.

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Exhibit 99.2

Precision Genetic Medicine for Neuromuscular Diseases

23rd International Congress of the World Muscle Society

Mendoza, Argentina
4 October 2018

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Forward-Looking Statements

This presentation contains "forward-looking statements." Any statements that are not statements of historical fact may be deemed to be forward-looking statements. Words such as “believe,” “anticipate,” “plan,” “expect,” “will,” “may,” “intend,” “prepare,” “look,” “potential,” “possible” and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements relating to the goal of the AAVrh74.MHCK7 micro-dystrophin study 1, its design and endpoints; and the expectations from the study, including AAVrh74 efficient transduction to all muscle types, MHCK7 selective for cardiac and skeletal transgene muscle expression, widespread micro-dystrophin expression in all biopsied muscles, reduction in CK levels and favorable safety profile with no unexpected immunological responses.

These forward-looking statements involve risks and uncertainties, many of which are beyond Sarepta’s control. Actual results could materially differ from those stated or implied by these forward-looking statements as a result of such risks and uncertainties. Known risk factors include the following: success in preclinical testing and early clinical trials, especially if based on a small patient sample, does not ensure that later clinical trials will be successful, and initial results from a clinical trial do not necessarily predict final results; different methodologies, assumptions and applications Sarepta utilizes to assess particular safety or efficacy parameters may yield different statistical results, and even if Sarepta believes the data collected from clinical trials of its product candidates are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities; Sarepta’s ongoing research and development efforts may not result in any viable treatments suitable for clinical research or commercialization due to a variety of reasons, some of which may be outside of Sarepta’s control, including possible limitations of Company financial and other resources, manufacturing limitations that may not be anticipated or resolved for in a timely manner, and regulatory, court or agency decisions, such as decisions by the United States Patent and Trademark Office with respect to patents that cover our product candidates; and even if Sarepta’s programs result in new commercialized products, Sarepta may not achieve any significant revenues from the sale of such products; if the actual number of patients suffering from DMD is smaller than estimated, Sarepta’s revenue and ability to achieve profitability may be adversely affected; and those risks identified under the heading “Risk Factors” in Sarepta’s most recent Annual Report on Form 10-K for the year ended December 31, 2017 or most recently filed Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) as well as other SEC filings made by the Company which you are encouraged to review.

Any of the foregoing risks could materially and adversely affect the Company’s business, results of operations and the trading price of Sarepta’s common stock. You should not place undue reliance on forward-looking statements. Sarepta does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof, except to the extent required by applicable law or SEC rules.

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Precision Genetic Medicine

23rd International Congress of the World Muscle Society

Welcome and Introduction

Doug Ingram

President and CEO

Sarepta Therapeutics, Inc.

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Precision Genetic Medicine

23rd International Congress of the World Muscle Society

Clinical Update: AAVrh74.MHCK7.Micro-dystrophin Program

Jerry Mendell, MD

The Ohio State University College of Medicine

Paul D Wellstone Muscular Dystrophy Cooperative Research Center

Nationwide Children's Hospital

Columbus, OH

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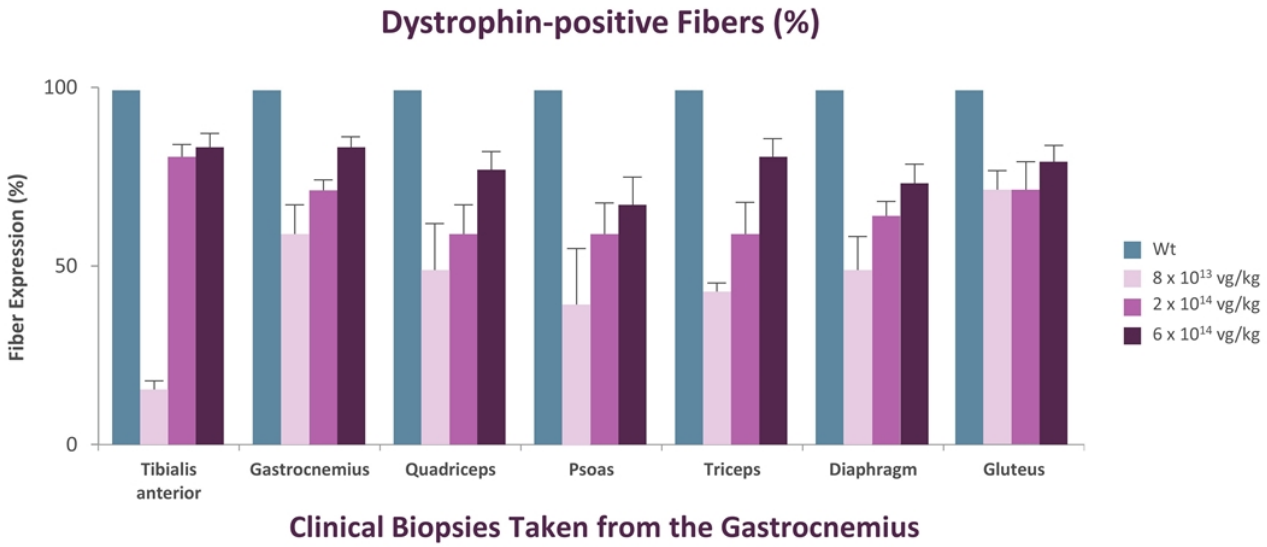
AAVrh74.MHCK7.Micro-dystrophin: Goal of Study 1 was to Validate Pre-clinical Results

Expectations based on pre-clinical models
AAVrh74 efficient transduction to all muscle types
MHCK7 selective for cardiac and skeletal transgene muscle expression
Widespread micro-dystrophin expression in all biopsied muscles
Reduction in creatine kinase (CK)
Favorable safety profile with no unexpected immunological responses

AAVrh74.MHCK7.Micro-dystrophin Widespread Expression after Gene Delivery in *mdx* Mice



Sarepta Therapeutics Data on File. AAVrh74.MHCK7.Micro-dystrophin is investigational and not approved in Argentina.

Micro-dystrophin Clinical Trial Design

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Open-Label Trial Design

- **Cohort B**
  - 4 subjects
  - 4-7 years of age
- **Inclusion criteria**
  - Confirmed *DMD* mutation
  - Negative for AAVrh74 antibodies

ClinicalTrials.gov Identifier: NCT03375164.
Sarepta Therapeutics Data on File. AAVrh74.MHCK7.Micro-dystrophin is investigational and not approved in Argentina.

Cohort B (4-7 Years of Age) Endpoints

- **Primary endpoint**
  - Safety
- **Secondary endpoints**
  - Change in micro-dystrophin expression pre- vs post-treatment
  - Decrease in CK
  - 100-meter timed test (100 m)
  - North Star Ambulatory Assessment (NSAA; 10-meter timed test included)
  - Timed up and go (TUG)
  - Ascend and descend 4 steps
  - Hand-held dynamometry (HHD)
  - Cardiac magnetic resonance imaging (at 1 year)

ClinicalTrials.gov Identifier: NCT03375164.
Sarepta Therapeutics Data on File. AAVrh74.MHCK7.Micro-dystrophin is investigational and not approved in Argentina.

Subject Demographics at Baseline

Subject	Age (years)	CK Levels at Baseline (U/L)
1	5	20,691
2	4	23,414
3	6	34,942
4	4	29,210

ClinicalTrials.gov Identifier: NCT03375164.
Sarepta Therapeutics Data on File. AAVrh74.MHCK7.Micro-dystrophin is investigational and not approved in Argentina.

Subject 4:
Micro-dystrophin Data

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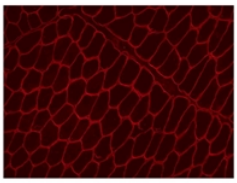
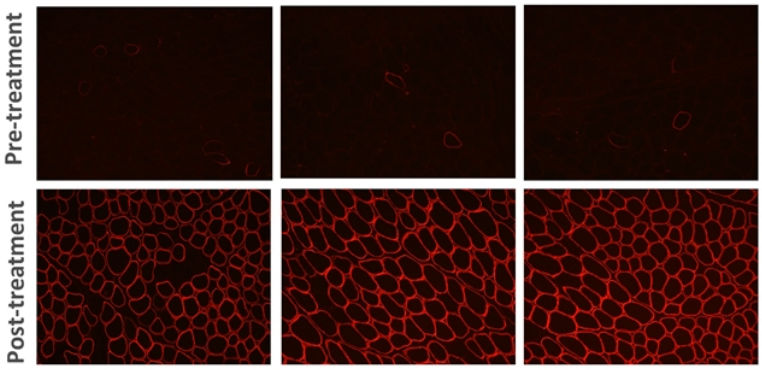
Robust Micro-dystrophin Expression in Muscle Fibers From the Gastrocnemius in Subject 4

Micro-dystrophin Expression (IHC)

Normal Control



Subject 4



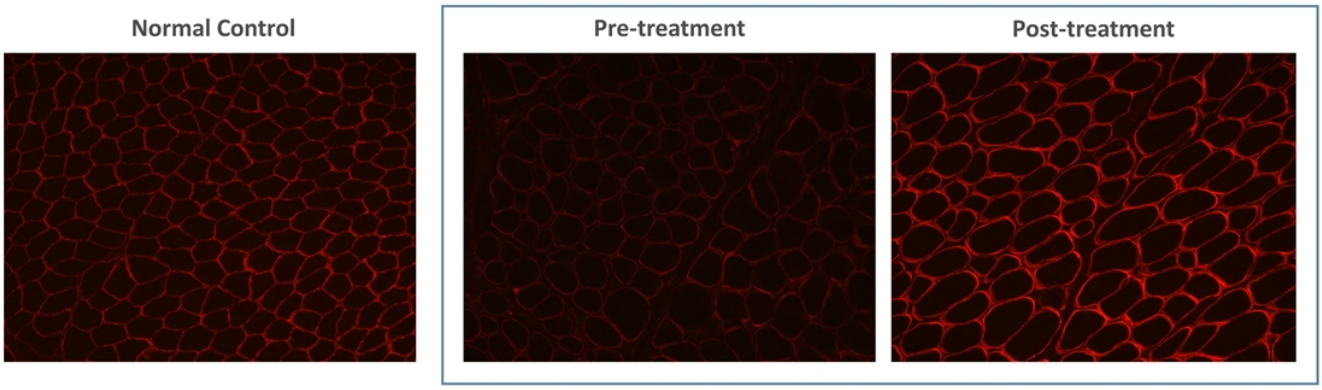
Subject	Mean Intensity	Percentage of Dystrophin-positive Fibers
4	**160.0%**	**96.2%**

ClinicalTrials.gov Identifier: NCT03375164.

Sarepta Therapeutics Data on File. AAVrh74.MHCK7.Micro-dystrophin is investigational and not approved in Argentina.

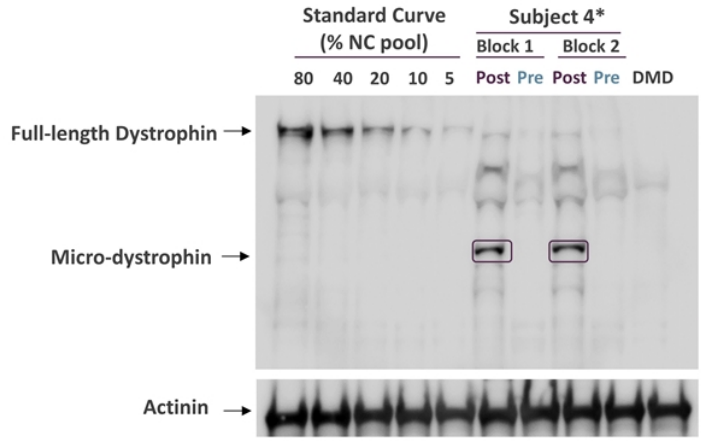
Micro-dystrophin Gene Therapy Upregulates DAPC Proteins in Subject 4

Expression of β-sarcoglycan in Muscle Fibers From the Gastrocnemius of Subject 4 (IHC)



ClinicalTrials.gov Identifier: NCT03375164.
Sarepta Therapeutics Data on File. AAVrh74.MHCK7.Micro-dystrophin is investigational and not approved in Argentina.

Detection of Micro-dystrophin Expression by Western Blot Post-treatment in Subject 4



*Samples diluted 1:4 as ULOQ (>80%) exceeded in initial analysis.

Mean values multiplied by correction factor for final value compared to normal.

Western Quantitation Method	Mean Micro-dystrophin Expression vs Normal
Sarepta	**182.7%** (not adjusted for fat and fibrotic tissue)
Nationwide	**222.0%** (adjusted for fat and fibrotic tissue)

ClinicalTrials.gov Identifier: NCT03375164.

Sarepta Therapeutics Data on File. AAVrh74.MHCK7.Micro-dystrophin is investigational and not approved in Argentina.

Micro-dystrophin Summary: All Subjects (n=4)

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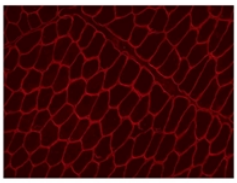
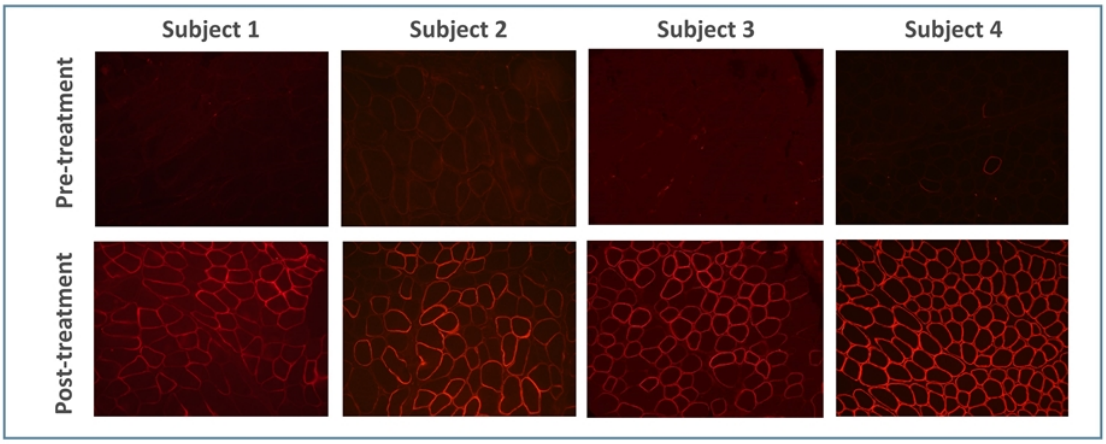
Robust Micro-dystrophin Expression in Muscle Fibers from the Gastrocnemius in All 4 Subjects

Micro-dystrophin Expression (IHC)

Normal Control



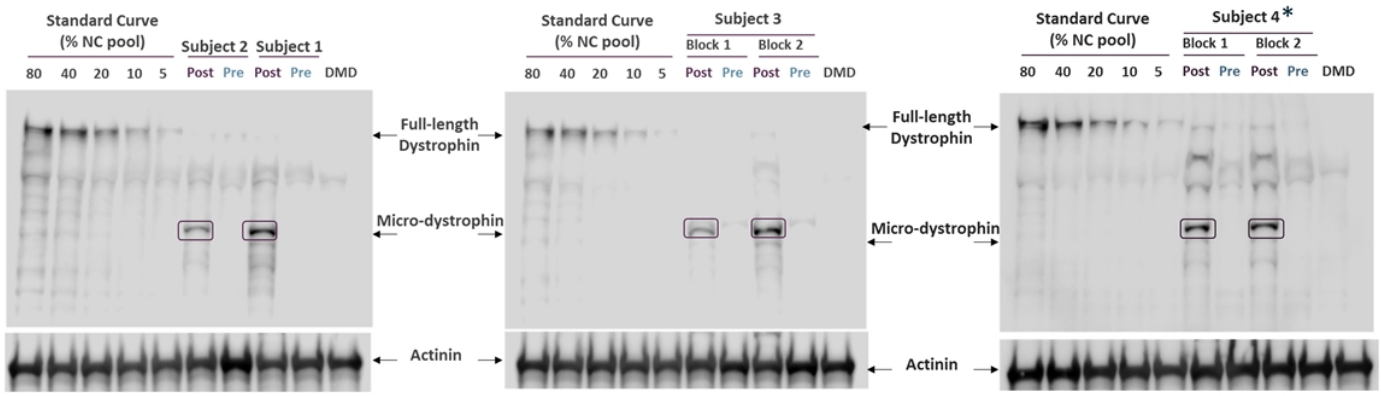


	Intensity	Percentage of Dystrophin-positive Fibers
Mean (n=4)	96.0%	81.2%

ClinicalTrials.gov Identifier: NCT03375164.

Sarepta Therapeutics Data on File. AAVrh74.MHCK7.Micro-dystrophin is investigational and not approved in Argentina.

Detection of Micro-dystrophin Expression by Western Blot Post-treatment in All 4 Subjects



Western Quantitation Method	Mean Micro-dystrophin Expression (N=4) vs Normal
Sarepta	**74.3%** (not adjusted for fat and fibrotic tissue)
Nationwide	**95.8%** (adjusted for fat and fibrotic tissue)

p-Tyr phosphotyrosine; ULOQ, upper limit of quantification.
*Samples diluted 1:4 due to sample above ULOQ.
ClinicalTrials.gov Identifier: NCT03375164.
Sarepta Therapeutics Data on File. AAVrh74.MHCK7.Micro-dystrophin is investigational and not approved in Argentina.

Robust Micro-dystrophin Expression is Supported by Vector Genome Count

Micro-dystrophin Expression (IHC)

	Intensity	Percentage of Dystrophin-positive Fibers
Mean (n=4)	**96.0%**	**81.2%**

Micro-dystrophin Expression (Western Blot)

	Sarepta (not adjusted for fat/fibrosis)	Nationwide (adjusted for fat/fibrosis)
Mean (n=4)	**74.3%**	**95.8%**

Vector Genome Number

	Vector Copies/µg DNA	Copies per Nucleus
Mean (n=4)	**$>10^5$**	**3.3**

ClinicalTrials.gov Identifier: NCT03375164.
Sarepta Therapeutics Data on File. AAVrh74.MHCK7.Micro-dystrophin is investigational and not approved in Argentina.

AAVrh74.MHCK7.Micro-dystrophin: Clinical Data Summary (n=4)

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Summary of Clinical Data

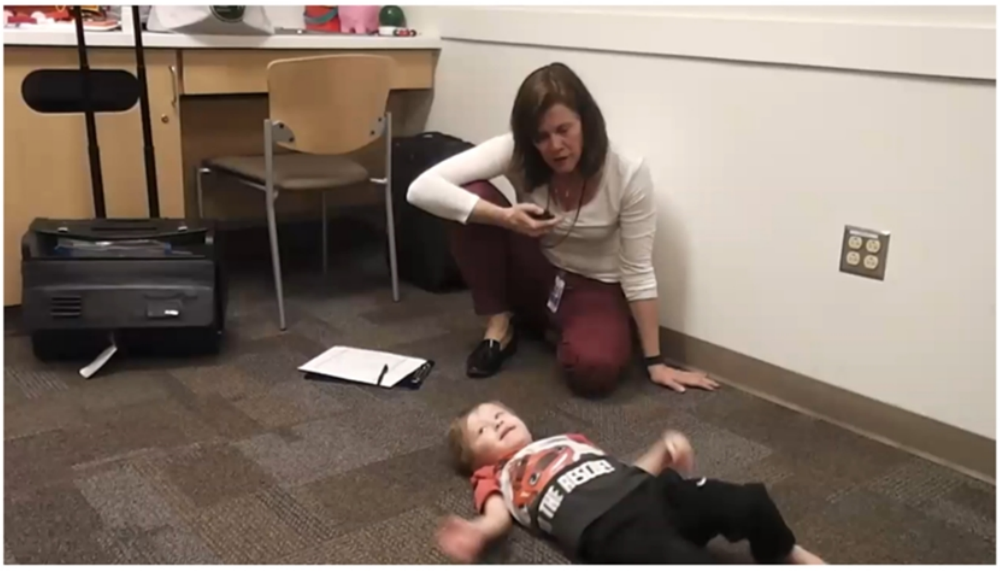
Change from Baseline to Last Assessment

Subject	Assessment	NSAA (Δ)	Time to Rise (sec)	4 Stairs Up (sec)	100 m (sec)	10 m (sec)	CK (U/L)
1	Baseline	18	3.7	3.4	49.3	5.1	20,691
	Last Visit (Day 270)	26 (+8)	3.0	2.3	43.2	4.3	6,317
2	Baseline	19	3.0	3.8	49.9	4.3	23,414
	Last Visit (Day 180)	27 (+8)	3.7	2.6	48.6	3.9	6,209
3	Baseline	26	3.9	1.9	59.3	4.7	34,942
	Last Visit (Day 180)	30 (+4)	3.4	1.8	48.4	4.1	9,650
4	Baseline	19	4.1	4.8	67.2	5.4	29,210
	Last Visit (Day 90)	25 (+6)	2.3	2.2	50.7	4.4	1,382
Average	% Change From Baseline	33% Improvement	13% Improvement	31% Improvement	14% Improvement	14% Improvement	78% Improvement

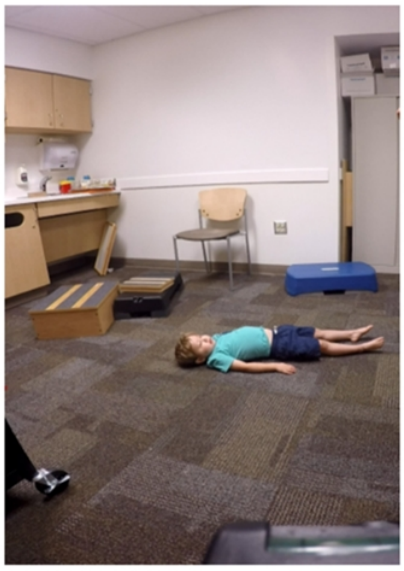
ClinicalTrials.gov Identifier: NCT03375164.

Sarepta Therapeutics Data on File. AAVrh74.MHCK7.Micro-dystrophin is investigational and not approved in Argentina.

Patient Video: Rise From Floor – Subject 4



Baseline



90 days post-treatment

Patient Video: 4-stair Climb – Subject 1

Baseline

270 days post-treatment

Safety (n=4)

- No serious adverse events in this study
- 3 subjects had elevated γ-glutamyl transpeptidase, which resolved with steroid treatment within a week
- No other clinically significant laboratory findings
- Subjects had transient nausea generally within the first week coincident with increased steroid dosing
  - Did not correlate with liver enzyme elevations or any other abnormality

ClinicalTrials.gov Identifier: NCT03375164.
Sarepta Therapeutics Data on File. AAVrh74.MHCK7.Micro-dystrophin is investigational and not approved in Argentina.

Summary

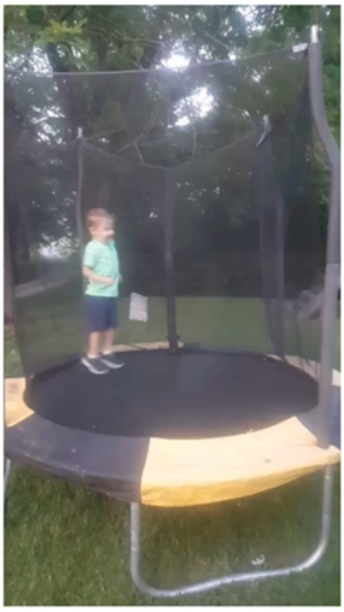
- All 4 treated subjects are doing well
  - Biomarkers show large magnitude of effect within 3 months (CK and dystrophin)
  - “Very early days" but initial functional data show improvement consistent with biomarker data
  - Early results show these boys performing in a manner unexpected for the typical boy with DMD
  - Favorable safety profile to date with up to 9 months of follow-up

Patient Home Videos: Activities of Daily Living

60 days post-treatment (Pt 1)

30 days post-treatment (Pt 2)

60 days post-treatment (Pt 3)



75 days post-treatment (Pt 4)

Question and Answer

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Thank You

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When your child needs a hospital, everything matters.℠