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)

April 25, 2017

CAPRICOR THERAPEUTICS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware	**001-34058**	**88-0363465**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

8840 Wilshire Blvd., 2nd Floor, Beverly Hills, CA	**90211**
(Address of principal executive offices)	**(Zip Code)**

(310) 358-3200
(Registrant's telephone number, including area code)

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:

☐ 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 Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 April 25, 2017, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), provided an update on the Company's recently announced top-line six-month results from the randomized Phase I/II HOPE clinical trial, in the form of a slide presentation. The slide presentation is located on the "Investors" section of the Company's website at www.capricor.com. A copy of the slide presentation is also attached hereto as Exhibit 99.1 and is incorporated by reference into this Item 7.01 of this Current Report on Form 8-K.

The information contained in this Form 8-K (including Exhibit 99.1 attached hereto) is being furnished and shall not be deemed to be "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 and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Capricor Therapeutics, Inc. slide presentation dated April 25, 2017.

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.

CAPRICOR THERAPEUTICS, INC.

Date: April 25, 2017

By: /s/ Linda Marbán, Ph.D.
Linda Marbán, Ph.D.
Chief Executive Officer

Exhibit 99.1


Capricor Therapeutics™
a translational medicine company
Conference Call to Discuss
Top-Line Six-Month Results of the HOPE-Duchenne Trial
NASDAQ: CAPR
April 25, 2017

Forward-Looking Statements

This presentation contains forward-looking statements and information that are based on the beliefs of the management of Capricor Therapeutics, Inc. (Capricor) as well as assumptions made by and information currently available to Capricor. All statements other than statements of historical fact included in this presentation are forward-looking statements, including but not limited to statements identified by the words "anticipates," "believes," "estimates," and "expects" and similar expressions. Such forward-looking statements also include any expectation of or dates for commencement of clinical trials, IND filings, similar plans or projections and other matters that do not relate strictly to historical facts. These statements reflect Capricor's current views with respect to future events, based on what we believe are reasonable assumptions; however, the statements are subject to a number of risks, uncertainties and assumptions. There are a number of important factors that could cause actual results or events to differ materially from those indicated by such forward-looking statements. More information about these and other risks that may impact Capricor's business is set forth in Capricor's Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the Securities and Exchange Commission on March 16, 2017, and in its Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on September 28, 2015, together with prospectus supplements thereto. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those in the forward-looking statements. Further, Capricor's management does not intend to update these forward-looking statements and information after the date of this presentation.

Positive Top-Line Six-Month Safety and Exploratory Efficacy Data

Capricor to Advance Clinical Development of CAP-1002 as a Treatment for the Skeletal and Cardiac Manifestations of DMD

- Statistically-significant improvements were observed in exploratory efficacy measures of cardiac and upper limb function in patients who received CAP-1002
- Clinical results recapitulate pre-clinical data in cardiac and skeletal muscle
- CAP-1002 was generally safe and well-tolerated
- Capricor has submitted a meeting request to the FDA to discuss potential product registration strategies for CAP-1002 in the DMD indication
- Plan to submit HOPE data to FDA in support of potential Breakthrough Therapy and Regenerative Medicine Advanced Technology (RMAT) designations

Duchenne Muscular Dystrophy (DMD) and CAP-1002

— **DMD is a genetic disorder characterized by progressive and debilitating muscle weakness**

- Results from a lack of functional dystrophin
- Affects cardiac muscle and all skeletal muscle
- Muscle cell death due to increased fragility
- Capacity of muscle to regenerate diminishes over time, then is lost
- Replacement of muscle with scar and fat

— **In studies in Mdx mice, CDCs improve:**

- Cardiac performance and scar
- Running speed and distance
- Contractile force of isolated skeletal muscles

About CAP-1002 (allogenic cardiosphere-derived cells)

— **CAP-1002 is a cardiac progenitor cell therapeutic candidate**

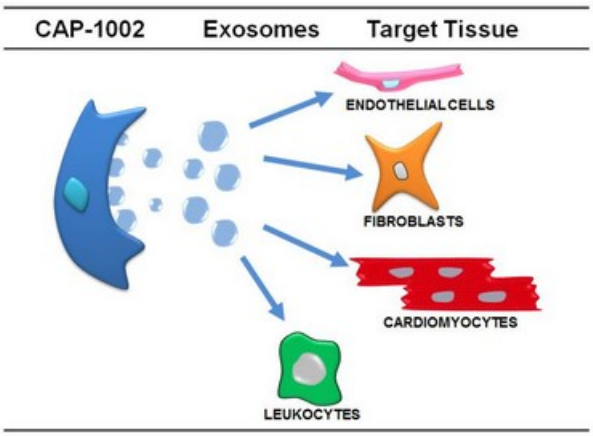
- CDCs have been shown to lead to scar regression and generate functional cardiac muscle

— **Mechanisms of action of CAP-1002:**

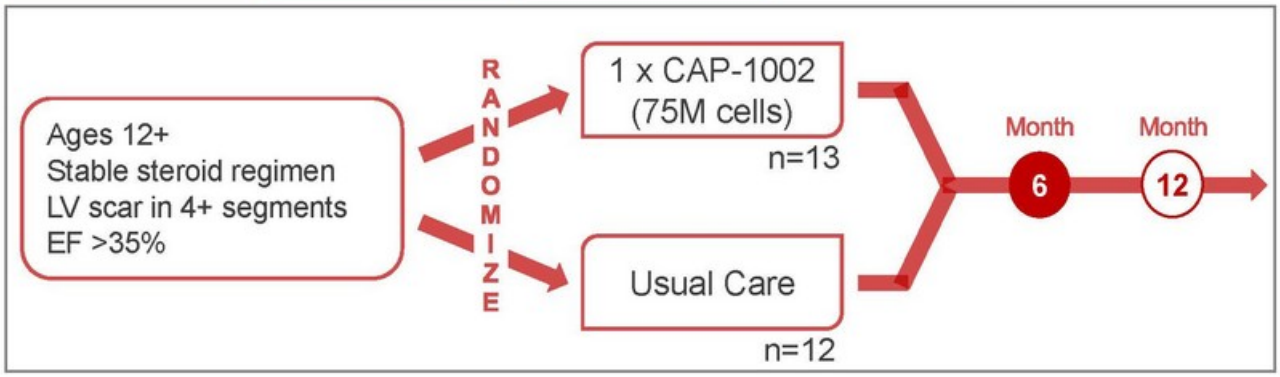
- Anti-inflammatory, anti-fibrotic, and anti-apoptotic
- Affect mitochondrial structure, oxidative function and cell morphology
- Pre-print manuscript available at http://biorxiv.org/content/early/2017/04/20/128900

CAP-1002: Mechanism of Action via Exosomes

- Cells release exosomes – particles comprised of RNAs and proteins
- Exosomes act on target cells to epigenetically alter gene expression
- Exosomes isolated from CDCs recapitulate their actions



The Randomized Phase I/II HOPE-Duchenne Clinical Trial



- Single dose coronary infusion, once at baseline
- Safety trial with multiple exploratory efficacy endpoints
- Three U.S. sites: Cedars-Sinai Medical Center
  Cincinnati Children's Hospital Medical Center
  University of Florida

Capricor Therapeutics

Baseline Characteristics

- Population characterized by advanced disease; majority are non-ambulant
- Essentially all DMD clinical development has been conducted in less sick patients

	Usual Care (n=12)	CAP-1002 (n=13)
Age (median, range)	17.5 (12–20)	18 (14–25)
Wheelchair Use Always	7 (58%)	10 (77%)
Scar Size (SD)	21.4 (10.8)	17.6 (6.8)
LV Ejection Fraction (SD)	48.4 (7.5)	49.6 (6.7)
DMD Genetic Analysis		
Exon Deletion	5	12
Exon Duplication	5	1

Patients were all male, were all receiving chronic treatment with systemic steroids, and were mostly Caucasian.

Safety Outcome Measures

	Usual Care (n=12)	CAP-1002 (n=13)
Peri-procedural TIMI grade flow 0-2	0	0
Peri-procedural sudden unexpected death	0	0
Peri-procedural major adverse cardiac events (MACE)	0	0
Sudden unexpected death	0	0
MACE	0	0
CV hospitalization	0	0
Ventricular tachycardia ≥ 30 seconds	0	0
Cardiac enzyme elevation[1]	2	13
Donor-specific antibodies, MFI ≥ 1,000	0	1
Donor-specific antibodies, MFI ≥ 5,000	0	0

[1] No clinical events associated with cardiac enzyme elevations; Peri-procedural Trop elevations: n=13 (all had CKMB > 5x ULN and 8 had Trop > 2x ULN pre-infusion); On study Trop elevation: CAP-1002 n=2 and Usual Care n=2 [Trop elevation: > 5x composite 99th percentile (0.03 pg/mL) or ≥ 20% of elevated baseline]

Peri-procedural = within 72 hours of infusion; MFI = mean fluorescence intensity

Capricor Therapeutics

Safety and Tolerability

	Usual Care (n=12)	CAP-1002 n=13)
Any treatment-emergent adverse event (TEAE)	10 (83%)	11 (85%)
Severe TEAE	2 (17%)	1 (8%)
Serious Adverse Events (SAE)	1 (8%)	3 (23%)
Any drug-related TEAE	n/a	8 (62%)
Any procedure-related TEAE	n/a	7 (54%)
Discontinuation due to TEAE	0 (0%)	0 (0%)
Deaths	0 (0%)	0 (0%)

The majority of TEAEs were rated as mild or moderate.
The most common TEAEs were atrial fibrillation (20%) and nasopharyngitis (16%).
All atrial fibrillation episodes were asymptomatic, self-limited, and occurred only during the infusion procedure.

Usual Care SAE	Related to treatment?
Femoral fracture	No

CAP-1002 SAE	Related to procedure?	Related to product?
Urinary tract infection	No	No
Fever and confusion	Uncertain	Uncertain
Ventricular fibrillation	Yes	No

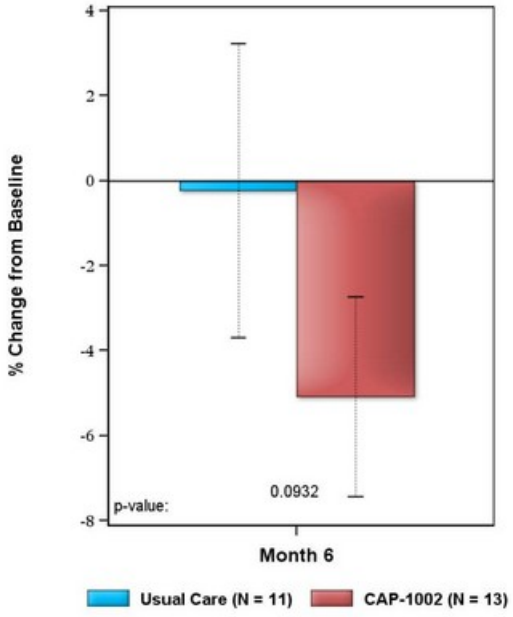
Capricor Therapeutics

Exploratory Efficacy Endpoints

		Baseline	Week 6	Month 3	Month 6	Month 12
Imaging	Cardiac magnetic resonance (cMRI)	●			●	○
Functional Tests	Performance of the Upper Limb (PUL)	●	●	●	●	○
	6-Minute Walk Test	●	●	●	●	○
	Spirometry	●	●	●	●	○
Quality of Life	Pediatric QL Inventory	●	●	●	●	○
	PODCI Adolescent Questionnaire	●	●	●	●	○
Biomarkers	Osteopontin, ST2, IL-10, Galectin-3	●	●	●	●	○

Reduced Cardiac Scar in CAP-1002 Treated Patients

Spontaneous scar reduction is not observed in DMD

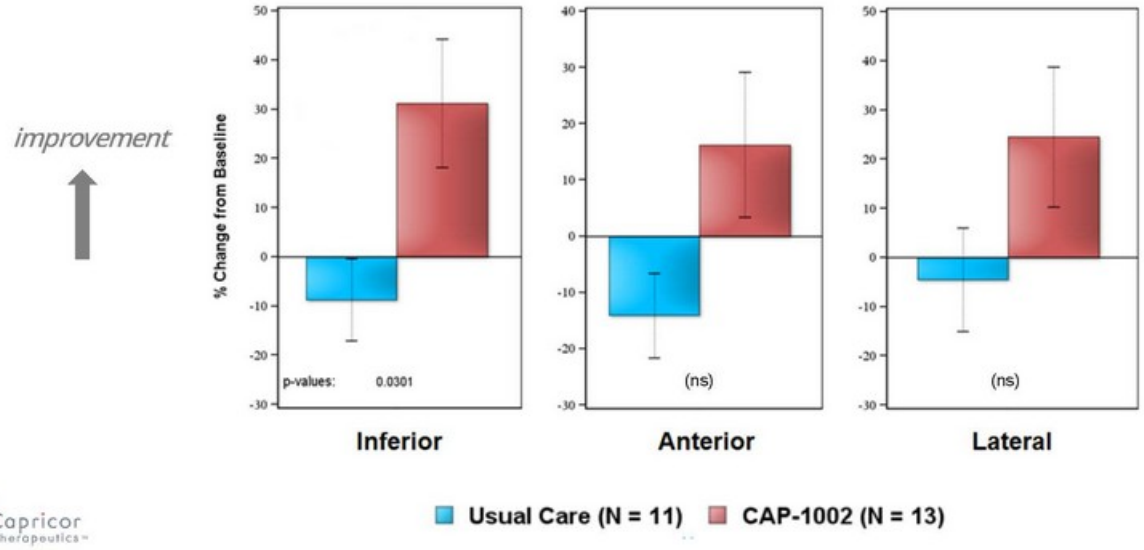


improvement

Capricor Therapeutics

Improved Systolic Wall Thickening in CAP-1002 Treated Patients

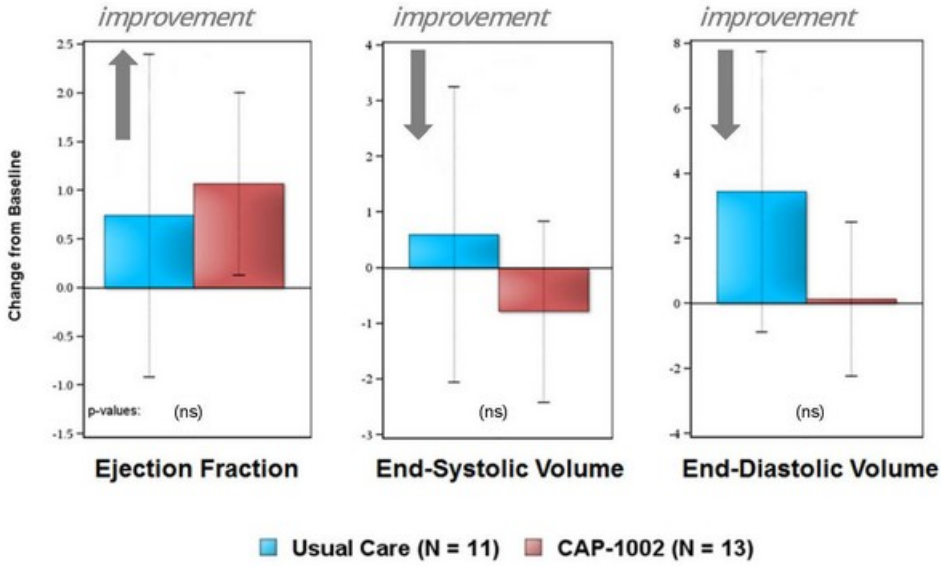
Systolic thickening is a principal mechanism of cardiac output generation in DMD



Capricor Therapeutics

Results of Ejection Fraction and Cardiac Volumes

Patients had near-normal ejection fraction and low volumes at baseline

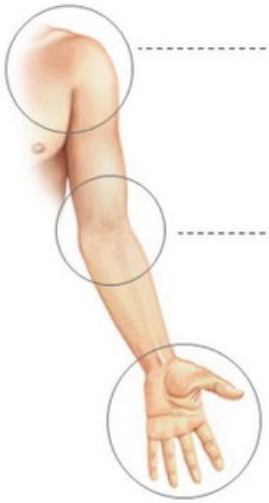


Capricor Therapeutics

Performance of the Upper Limb (PUL) Test

- The Performance of the Upper Limb (PUL) test was designed specifically for use in the DMD setting
- Evaluates a variety of manual tasks, such as lifting cans, tearing paper, and removing a container lid, which simulate activities of daily living
- Boys and young men with advanced DMD have difficulty with such common activities as feeding themselves and brushing their teeth
- The PUL was selected for the HOPE trial as a validated test to evaluate skeletal muscle performance in a DMD population with advanced disease (more than two-thirds are non-ambulant)

Performance of the Upper Limb (PUL) Test



Shoulder Level
4 items

- Lifting upper extremity weights
  - Shoulder height
  - Above shoulder height

Middle Level
9 items

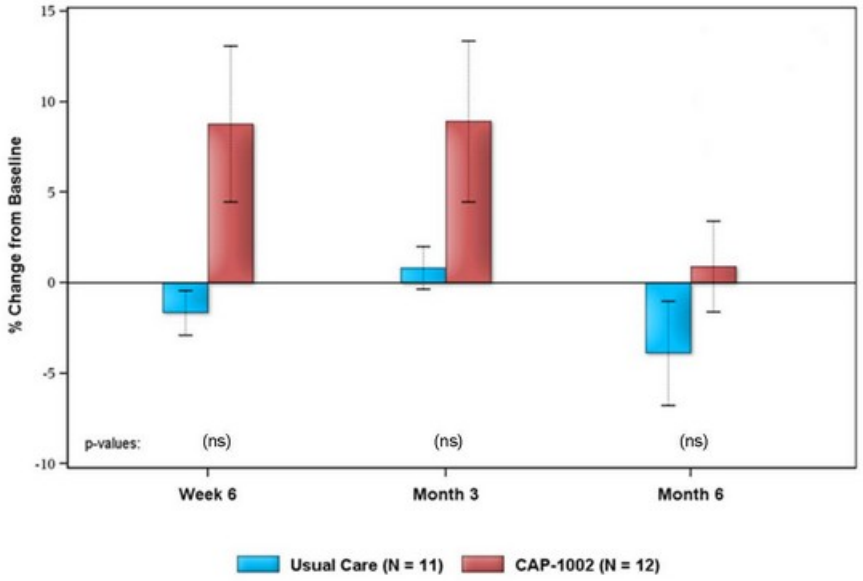
- Hand to mouth w/w/o weights
- Hand to table
- Stack light and heavy cans
- Moving weights on table
- Remove container lid
- Lift light and heavy cans
- Tearing paper

Distal Level
8 items

- Tracing a path
- Supination
- 3-point grip
- Push on a light
- Pick up coins
- Finger pinch
- Place fingers on diaphragm
- Thumb (key) grip

Capricor Therapeutics™

Mid- and Distal-Level PUL Results

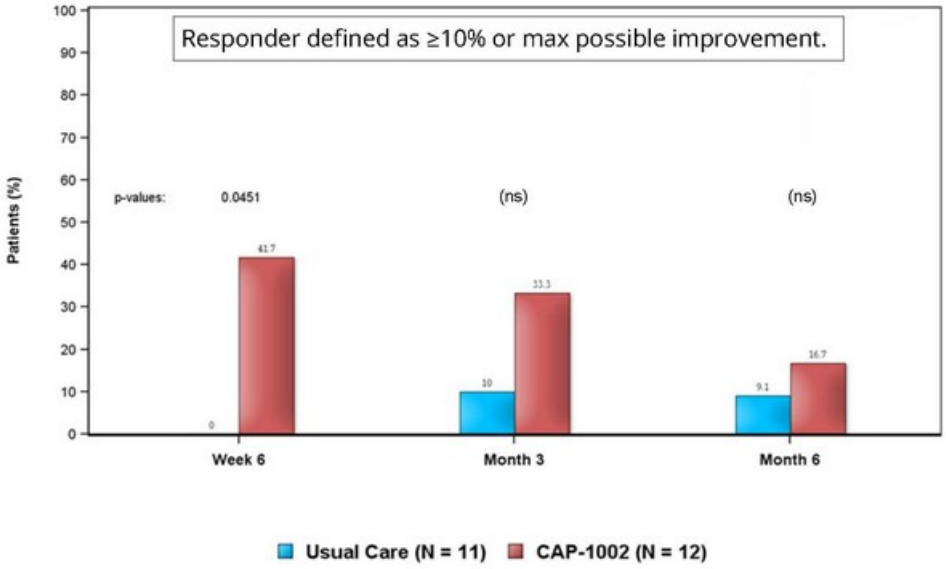


improvement

Capricor Therapeutics™

Responder Analysis on Mid- and Distal-Level PUL

Potential functional improvement in skeletal muscle

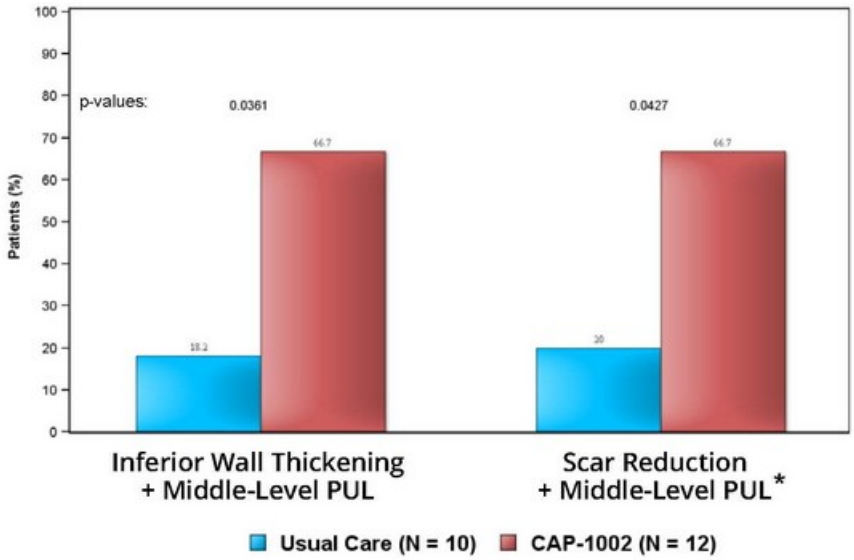


improvement

Capricor Therapeutics

Cardiac and Skeletal Muscle Effects Seen in the Same Patients

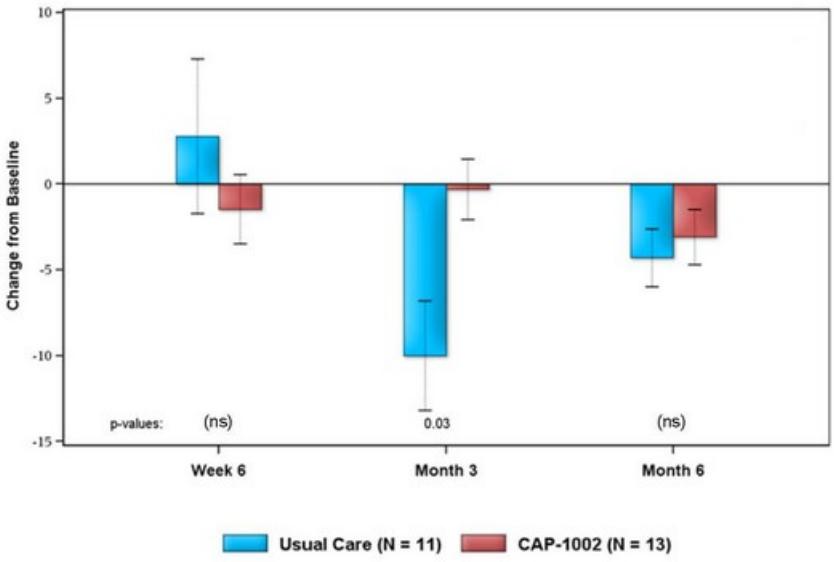
Supportive of a treatment effect



Capricor Therapeutics™

* Analysis excluded one subject due to uninterpretable imaging data.

Quality of Life (PODCI Adolescent Questionnaire)



improvement

Capricor Therapeutics

Key Conclusions from Six-Month HOPE Data

- Clinical results are in line with preclinical data that illustrate the bioactivity of CAP-1002 on both cardiac and skeletal muscle in DMD
- Exploratory efficacy analyses support the potential benefit of CAP-1002 to boys and young men with advanced Duchenne muscular dystrophy
- CAP-1002 was generally safe and well-tolerated
- Limited duration of effect following a single dose indicates that sustained benefit will require repeat administration

Next Steps for Capricor's Duchenne Muscular Dystrophy Program

- **Requested FDA meeting to review HOPE data and discuss development toward potential registration**
- **Plan to submit applications for Breakthrough Therapy or Regenerative Medicine Advanced Therapy (RMAT) designations**

- **Repeat dosing via systemic delivery anticipated for next trial**
  - Paradigm for chronic administration to achieve potential long-term benefit
  - Systemic delivery supported by studies in several models