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 7, 2019

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. ☐

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 $0.001 per share	CAPR	The Nasdaq Capital Market

Item 7.01 Regulation FD Disclosure.

On October 7, 2019, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), provided an update on the Company's recently announced interim results from the HOPE-2 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 October 7, 2019.

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: October 7, 2019

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

A Study of CAP-1002 in Ambulatory and Non-Ambulatory Patients with Duchenne Muscular Dystrophy **[HOPE-2]**

Updated Results from the Interim Analysis Presented at the 24th International Annual Congress of the World Muscle Society

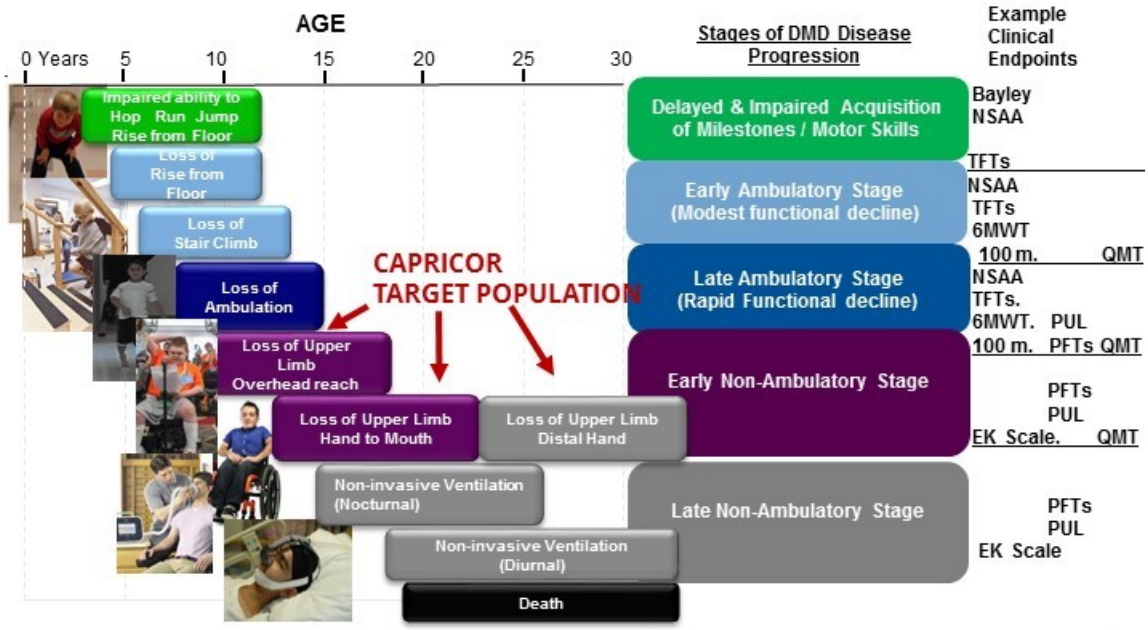
October 7, 2019 Conference Call
NASDAQ: CAPR

Forward-Looking Statements

Statements in this press release regarding the efficacy, safety, and intended utilization of Capricor's product candidates; the initiation, conduct, size, timing and results of discovery efforts and clinical trials; the pace of enrollment of clinical trials; plans regarding regulatory filings, future research and clinical trials; regulatory developments involving products, including the ability to obtain regulatory approvals or otherwise bring products to market; plans regarding current and future collaborative activities and the ownership of commercial rights; scope, duration, validity and enforceability of intellectual property rights; future royalty streams, revenue projections; expectations with respect to the expected use of proceeds from the recently completed offerings and the anticipated effects of the offerings, and any other statements about Capricor's management team's future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements that are not statements of historical fact (including statements containing the words "believes," "plans," "could," "anticipates," "expects," "estimates," "should," "target," "will," "would" and similar expressions) should also be considered to be forward-looking statements. 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, 2018 as filed with the Securities and Exchange Commission on March 29, 2019, and as amended by its Amendment No. 1 to Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on April 1, 2019, in its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019, as filed with the Securities and Exchange Commission on August 8, 2019, and in its Registration Statement on Form S-3 as filed with the Securities and Exchange Commission on October 24, 2018, and as amended by its Amendment No. 1 to Form S-3 filed with the Securities and Exchange Commission on July 17, 2019, together with prospectus supplements thereto. All forward-looking statements in this press release are based on information available to Capricor as of the date hereof, and Capricor assumes no obligation to update these forward-looking statements.

CAP-1002 is an Investigational New Drug and is not approved for any indications. CAP-2003 has not yet been approved for clinical investigation.

DMD Progression is Sequential, Non-Linear and Irreversible



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HOPE-2 Interim Analysis Breakdown

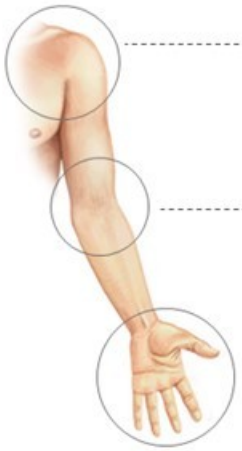
- Intent-to-Treat population = 20 subjects
- Safety population = 20 subjects
- Per Protocol population for July analysis = 17 subjects
  - 3 subjects were excluded due to missed or incomplete infusions
    - Subject 01-0009: incomplete Month 3 infusion due to acute allergic reaction and no Month 6 infusion
    - Subject 05-0002: no Month 3 infusion
    - Subject 05-0003: received Day 1 infusion only (subject withdrew consent for personal reasons)
- **CAP-1002 and Placebo groups had similar demographics and baseline characteristics**
  - Mean (SD) age = 14.3 (3.11 years)
  - All patients were on corticosteroids
  - 80% of patients were non-ambulant

Performance of the Upper Limb (Entry Items)

Target Population

0	1	2	3	4	5	6
No useful function of hands.	Can use hands to hold pen or pick up a coin or drive a powered Chair	Can raise 1 or 2 hands to mouth but cannot raise a cup with a 200g weight in it to mouth	Can raise standardized plastic cup with 200g weight in it to mouth using both hands if necessary	Can raise both arms to shoulder height simultaneously w/ or w/o compensation	Can raise both arms simultaneously above head only by flexing the elbow	Full overhead reach without compensation

Primary Efficacy Endpoint:
Performance of the Upper Limb (PUL: v1.2) to Assess Skeletal Muscle



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

PUL v.2.0:

- 3-point response scale - more robust and reproducible than v1.2
- Compensatory strategies allowed to achieve tasks (not allowed in v1.2)
- V2.0: better able to detect change at 12 months at all levels of ability*

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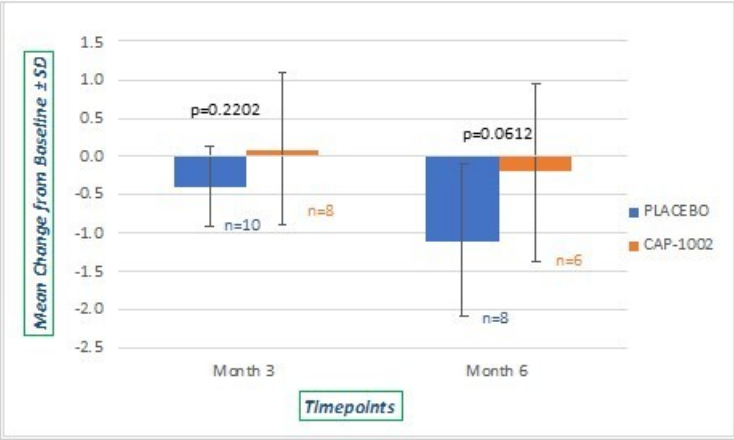
*Mayhew et al, 2019; Pane et al, 2018

Improvements in PUL 2.0 Observed

Mid-Level (Elbow) - Primary efficacy endpoint suggested by FDA (CBER)

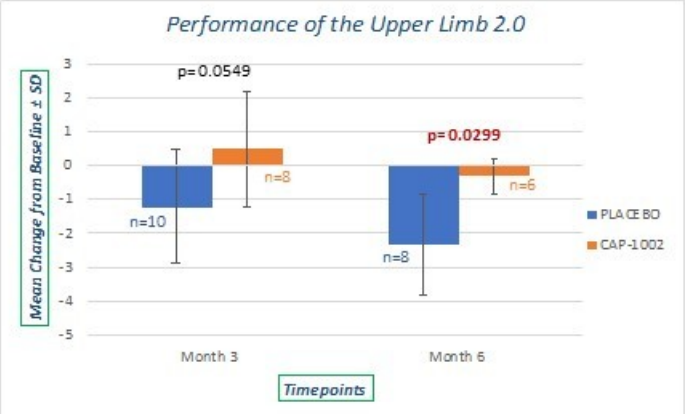
- Δ 0.9 difference in CAP-1002 vs. placebo at 6-months
- Similar improvements shown in HOPE-Duchenne



Comparisons treated vs. placebo using mixed model repeated measures ANOVA with covariates
Analysis done in Sept. ITT Population
Colored boxes heights, either positive or negative, represent mean change from baseline
Bars represent ± one standard deviation from the mean
P-values are nominal without adjustment for multiple testing or claims of statistical significance

Improvements in PUL 2.0 Observed
Shoulder + Mid + Distal

- Δ 2.0 difference in CAP-1002 vs. placebo at 6-months



Comparisons treated vs. placebo using mixed model repeated measures ANOVA with covariates
*Analysis done in Sept. **ITT** Population*
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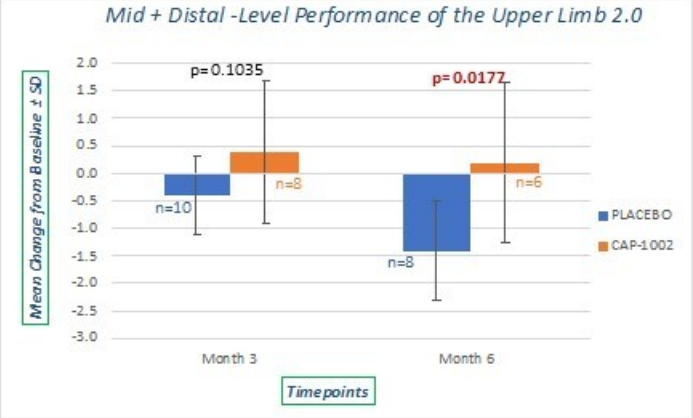
Improvements in PUL 2.0 Observed
Mid + Distal

- Δ 1.6 difference in CAP-1002 vs. placebo at 6-months
- Skeletal muscle function improved in non-ambulant patients with DMD
- Could help patients maintain independence if function is improved or decline attenuated



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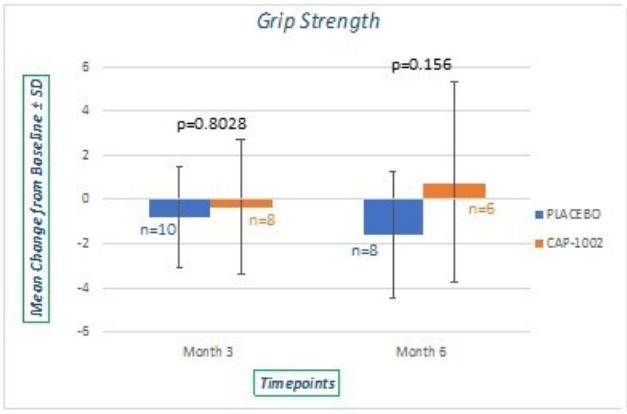
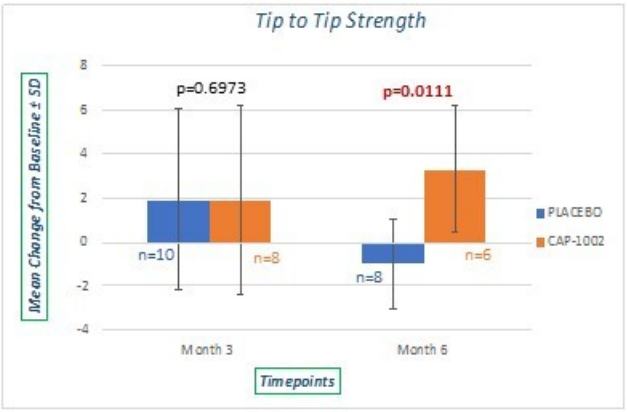
Improvements in Grip Strength and in Tip to Tip Pinch Strength was observed at 6 months





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Comparisons treated vs. placebo using mixed model repeated measures ANOVA with covariates
*Analysis done in Sept. **ITT** Population*
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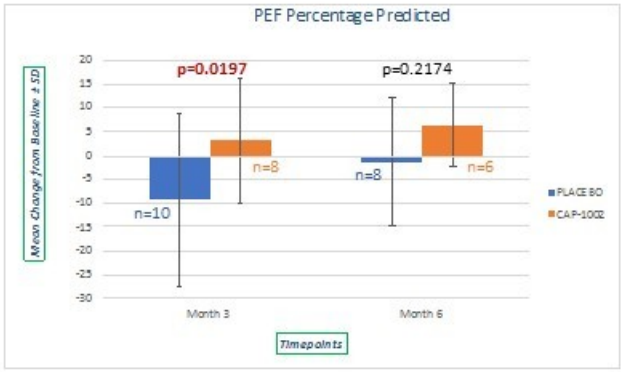
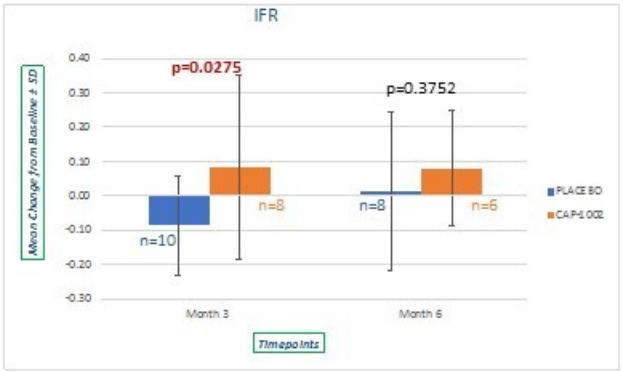
Improvements in Pulmonary Function Observed





- Pulmonary endpoints are intriguing:
  - More patients and longer follow-up may potentially lead to more robust findings
- Data suggests respiratory muscle function is improved in CAP-1002 vs. placebo
- No changes in FVC observed

Comparisons treated vs. placebo using mixed model repeated measures ANOVA with covariates
Analysis done in Sept. ITT Population
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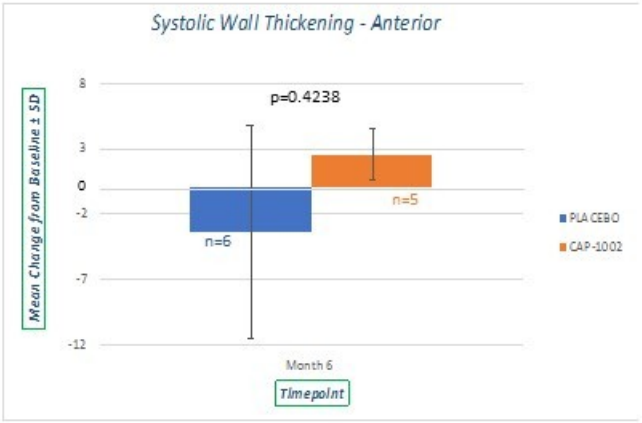
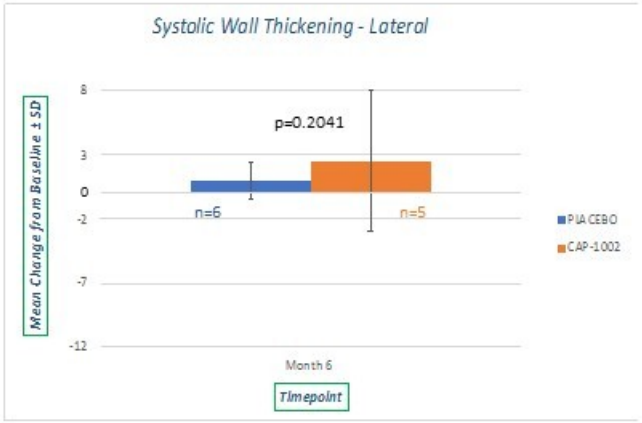
Cardiac Function as measured by MRI
Improvement in Anterior & Lateral Systolic Wall Thickening





Similar improvements as shown in HOPE-Duchenne

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Comparisons treated vs. placebo using mixed model repeated measures ANOVA with covariates
Analysis done in July ***Per Protocol*** *Population*
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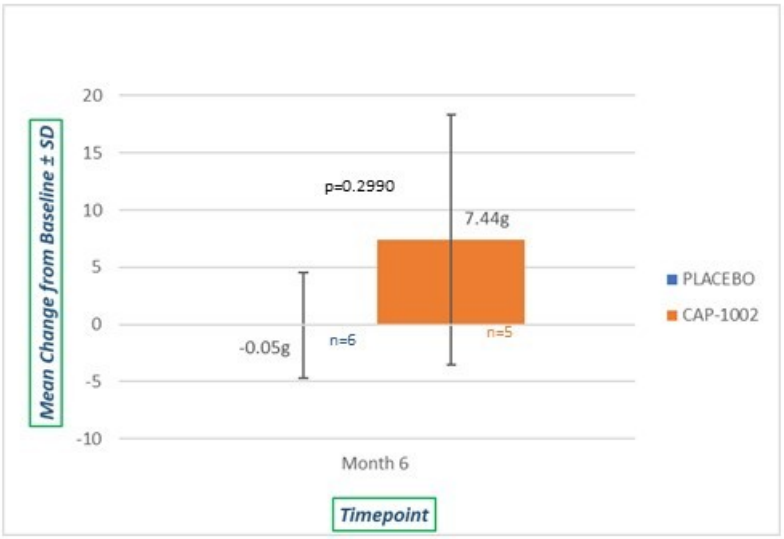
Increase in Left Ventricle Myocardium Mass



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HOPE-2 Interim Analysis Data Summary

- **Skeletal:**
  - Mid-Level PUL 2.0 at 6 months (p=0.0612) (ITT) and (p=0.0389) (July PP)
  - Shoulder + Mid + Distal Level PUL 2.0 at 6 months **(p=0.0299)** and strong signal at 3 months (p=0.0549)
  - Mid + Distal Level PUL 2.0 at 6 months **(p=0.0177)**
  - Tip to Tip strength (independent skeletal measure) at 6 months **(p=0.0111)**
- **Respiratory**
  - Trends towards improvements in PEF (% predicted) and IFR (absolute)
- **Cardiac**
  - Improvements in wall thickening (similar to positive changes seen in HOPE-Duchenne)
  - LV myocardium mass

Conclusions and Future Directions

Conclusions:

- First placebo-controlled trial in DMD to use PUL 2.0 for evaluation of efficacy
- First placebo-controlled trial showing upper limb functional improvements in **non-ambulant DMD patients**
- Directionally consistent improvements in function, strength, pulmonary and cardiac endpoints

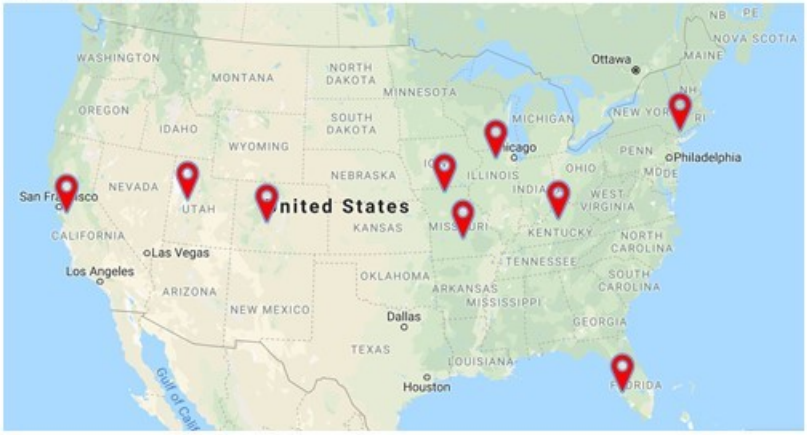
Moving Forward:

- Meet with FDA to determine if CAP-1002 potentially qualifies for accelerated approval based on RMAT standards
  - Based on *Guidance for Industry: Expedited Programs for Regenerative Medicine Therapies for Serious Conditions*

Acknowledgements

- **All patients and their families who participated in the HOPE-2 Study**
- Parent Project Muscular Dystrophy
- Coalition Duchenne
- CureDuchenne
- HOPE-Duchenne was funded with the support of CIRM

- Craig McDonald, MD (UC Davis)
- Cuixia Tian, MD (CCHMC)
- Russell Butterfield, MD (University of Utah)
- Richard Finkel, MD (Nemours Children's Hospital)
- Joanne Janas, MD (Children's Hospital of Colorado)
- Matthew Harmelink, MD (Children's Hospital of Wisconsin)
- Arun Varadhachary, MD (Washington University, Saint Louis Children's Hospital)
- Brenda Wong, MD (University of Massachusetts)
- Katherine Mathews, MD (University of Iowa, Children's Hospital)



World-Class DMD Advisory Board

Craig McDonald, M.D. (National PI)	**University of California at Davis (USA)**
Michelle Eagle, Ph.D., M.Sc., MCSP	Atom International Ltd (UK)
Pat Furlong	Parent Project Muscular Dystrophy (USA)
Kan Hor, M.D.	Nationwide Children's Hospital (USA)
Oscar Henry Mayer, M.D.	Children's Hospital of Philadelphia (USA)
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Lee Sweeney, Ph.D.	University of Florida (USA)
Michael Taylor, M.D., Ph.D.	Cincinnati Children's Hospital Medical Center (USA)