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 27, 2022

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.)**

10865 Road to the Cure, Suite 150, San Diego, California	**92121**
(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 June 27, 2022, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), provided an update on the Company's recently announced top-line results from the HOPE-2 open label extension trial, in the form of a slide presentation during its conference call. 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 under Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto is being furnished and shall not be deemed to be 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 incorporated by reference into any of the Company's filings under the Exchange Act, unless expressly set forth as being incorporated by reference into such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Capricor Therapeutics, Inc. slide presentation dated June 27, 2022.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).

SIGNATURES

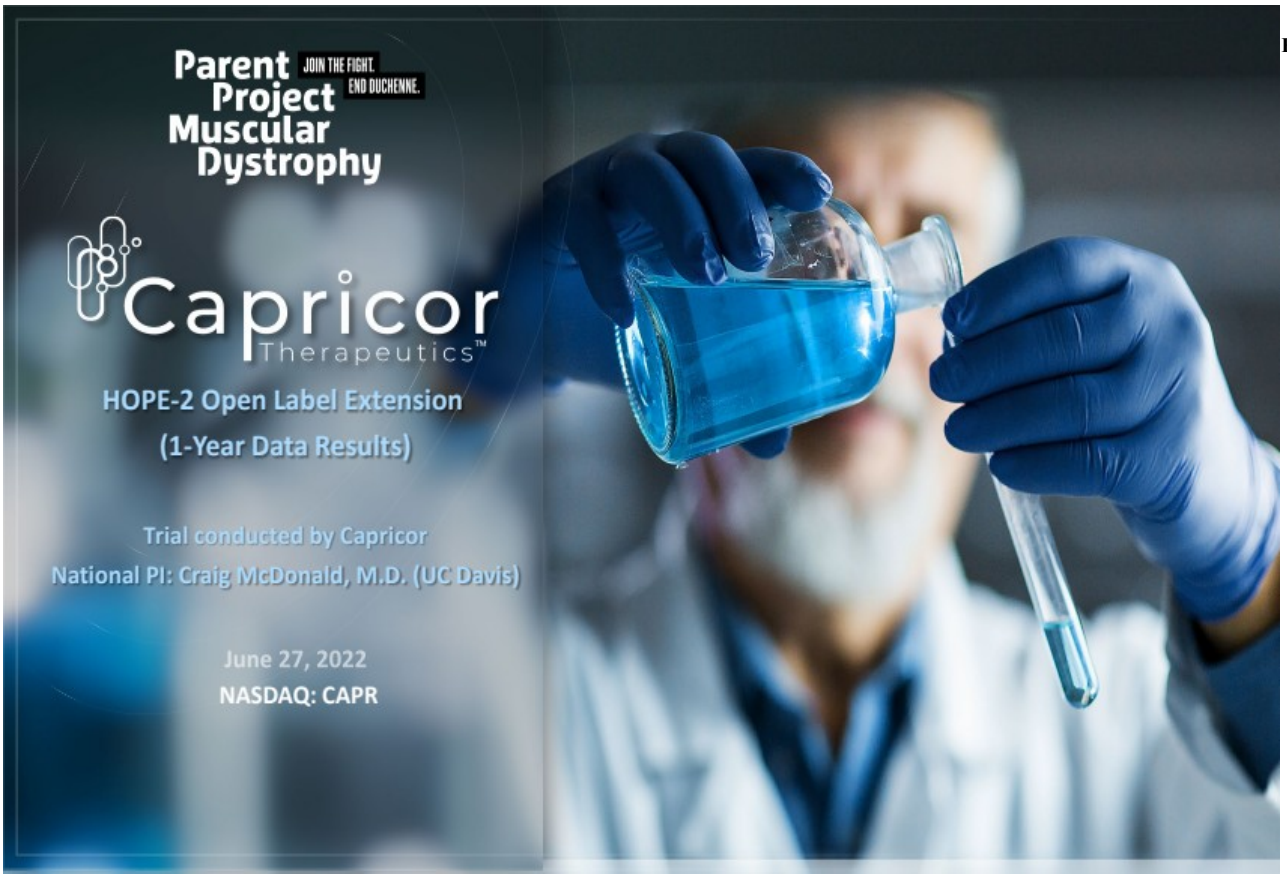
Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

CAPRICOR THERAPEUTICS, INC.

Date: June 29, 2022

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

Exhibit 99.1


Parent Project Muscular Dystrophy
JOIN THE FIGHT. END DUCHENNE.
Capricor Therapeutics™
HOPE-2 Open Label Extension
(1-Year Data Results)
Trial conducted by Capricor
National PI: Craig McDonald, M.D. (UC Davis)
June 27, 2022
NASDAQ: CAPR

Forward Looking Statements

Statements in this presentation 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; the ability to achieve product milestones and to receive milestone payments from commercial partners; 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, 2021 as filed with the Securities and Exchange Commission on March 11, 2022 and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 as filed with the Securities and Exchange Commission on May 11, 2022. 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. None of Capricor's exosome-based candidates have been approved for clinical investigation.

Call Participants

- **Linda Marban, Ph.D.** – Chief Executive Officer, Capricor Therapeutics, Inc.
- **Dan Paulson, M.D.** – Vice President of Clinical Development, Capricor Therapeutics, Inc.
- **AJ Bergmann, M.B.A.** – Chief Financial Officer, Capricor Therapeutics, Inc.
- **Craig McDonald, M.D.** – Professor and Chair of the Department of Physical Medicine and Rehabilitation and Director of the Neuromuscular Disease Clinics at the University of California, Davis. Dr. McDonald is an internationally recognized expert in the clinical management and rehabilitation of neuromuscular diseases including DMD. He is the national PI of Capricor's HOPE-2 and HOPE-3 trials.
- **Suzanne Hendrix, Ph.D.** – CEO Pentara Statistical Group, Dr. Hendrix has been instrumental in analysis and reporting for multiple regulatory submissions and authored or co-authored over 150 peer-reviewed publications related to both clinical trial results and statistical approaches for clinical trials, most of which relate to analysis and design of trials for neurodegenerative diseases.

CAP-1002 Cell Therapy

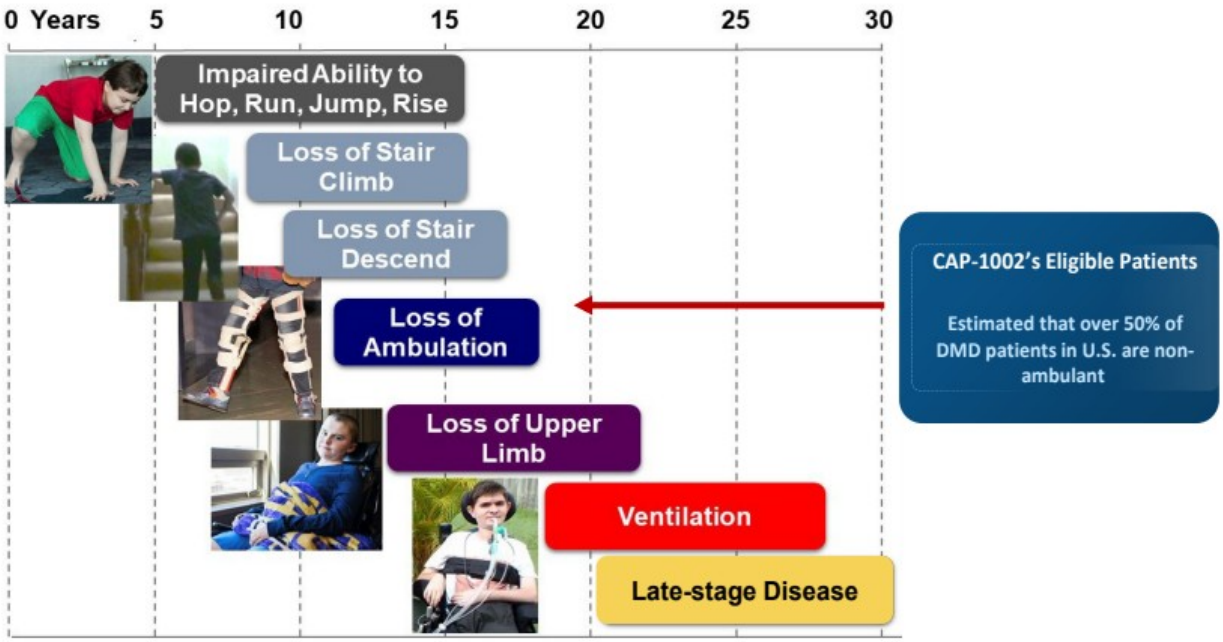
- **CAP-1002: Allogeneic Cardiosphere-Derived Cells (CDCs)**
- **Has been investigated in eight clinical trials**
- **Clinical data demonstrating skeletel and cardiac improvements in DMD**
- **Sourced from transplant qualified hearts**

- **Does not act by «stemness»**
  the cells do not engraft into host tissue
- **CAP-1002: Mechanism of action**
  Cells secrete exosomes
  - Contain miRNAs, non-coding RNAs and proteins
  - Trigger natural signaling with target cells
  - Activate changes in cellular behavior

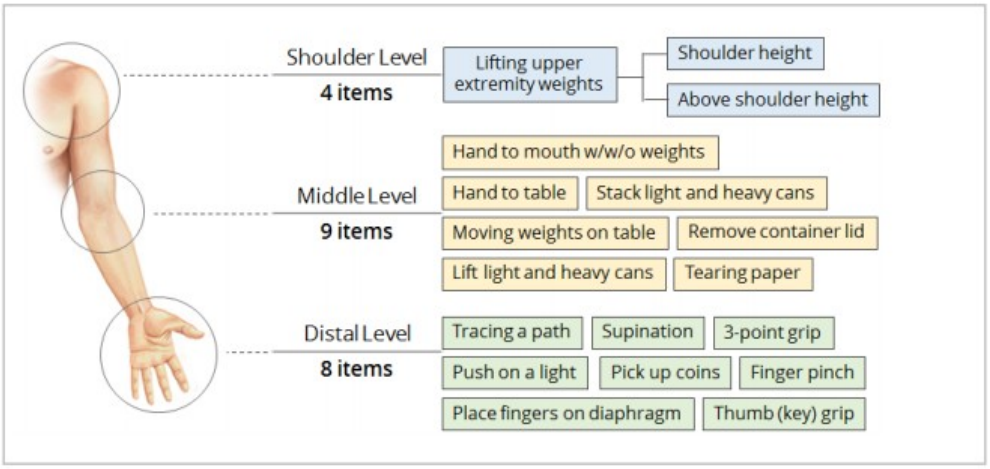
CAP-1002 Infusion Protocol is Easy

- **I.V. (intravenous) administration every 3 months – ~45 minutes Procedure**
- **Simple oral premedication regimen before infusion**
- **Safety profile: no treatment related SAEs reported through 94 infusions in ongoing HOPE-2 open label extension**
- **CAP-1002 has been administered to over 200 subjects to date across multiple clinical trials**

CAP-1002's Eligible DMD Population



Measure: Performance of Upper Limb
(PUL Test)

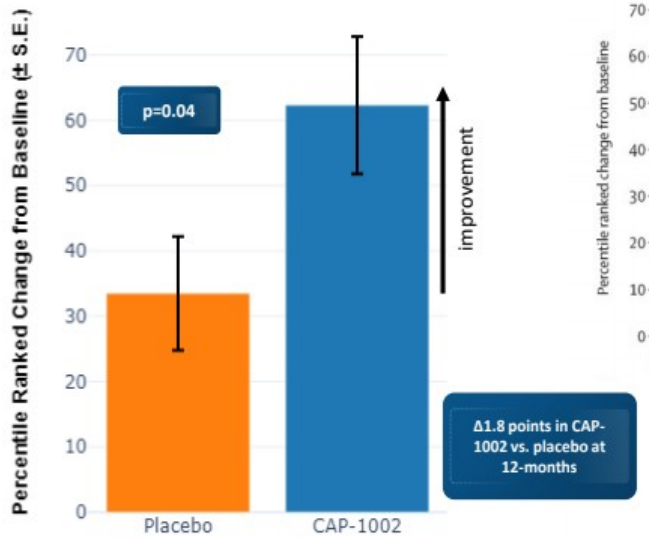


*Mayhew et al, 2019; Pane et al, 2018.

HOPE-2 Upper Limb and Cardiac Improvements

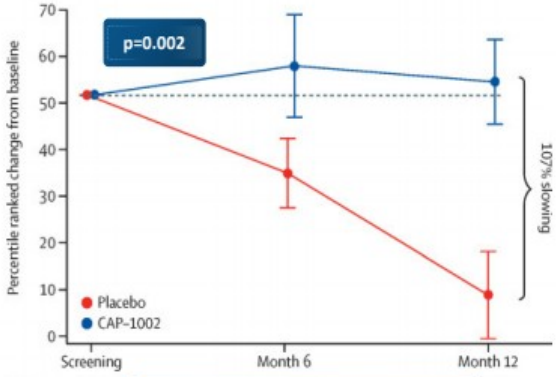
Capricor Therapeutics

Full PUL 2.0



Δ1.8 points in CAP-1002 vs. placebo at 12-months

LV Ejection Fraction



Δ=4% in LVEF by cardiac MRI

Results published in *The Lancet*, March 2022.

Mixed Model for Repeated Measures (MMRM) analysis was performed using percentile ranked change from baseline as dependent variable and percentile ranked baseline score, treatment, visit, treatment-by-visit interaction, PUL entry-item score at randomization, and site as model effects. Adjusted model outcomes are report as least-squares means (LS-Mean).

HOPE-2 Open Label Extension Overview

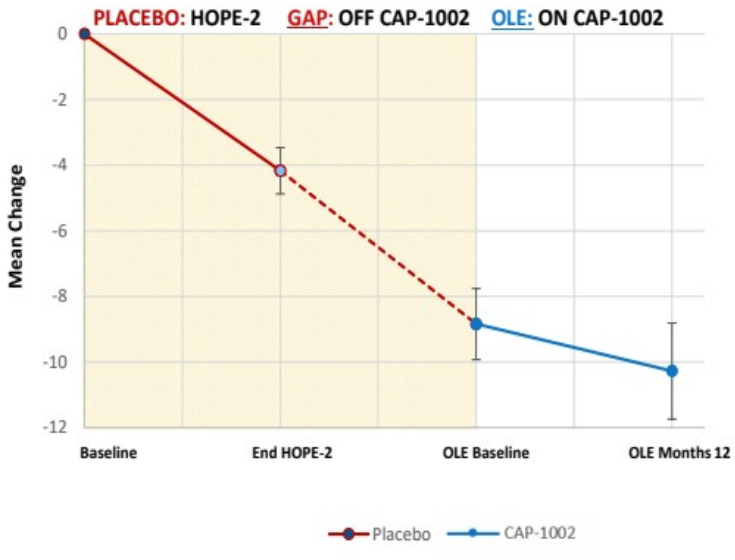
Open Label Extension Year 1 Overview

- n=13
- 6 original CAP-1002 patients
- 7 original placebo patients
- 1 patient withdrew consent

Patient Demographics

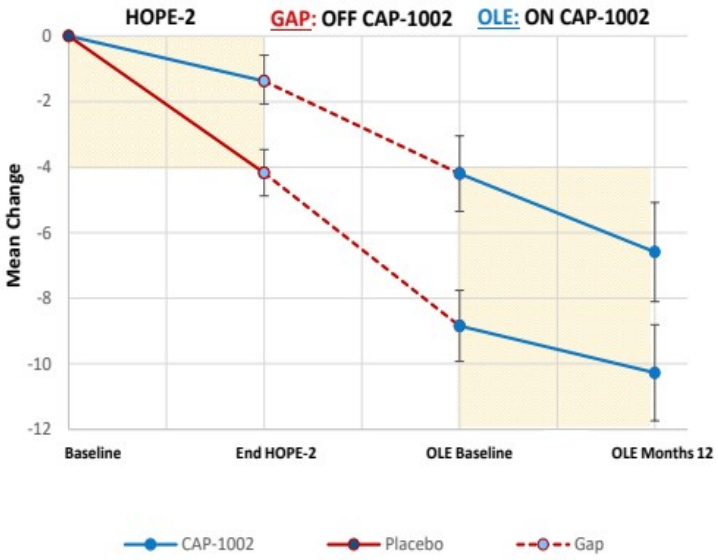
- Mean age: 13 years
- All patients were non-ambulant
- **All patients on stable regimen corticosteroids**

CAP-1002's Impact on Disease Progression



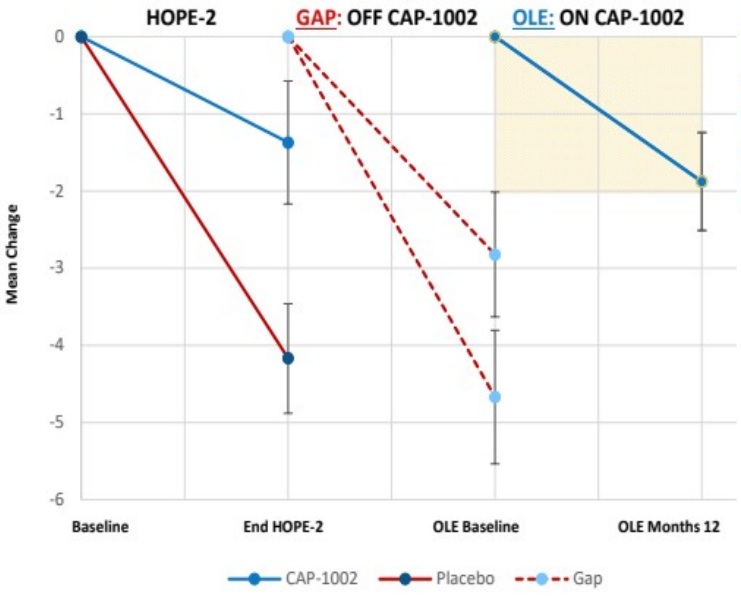
*One year change from baseline for a phase refers to a subject's change in one year during that phase.
*The linear mixed model uses all available data for all 20 subjects (12 completers).

Impact of CAP-1002 on Rate of PUL Decline



*One year change from baseline for a phase refers to a subject's change in one year during that phase.
*The linear mixed model uses all available data for all 20 subjects (12 completers).

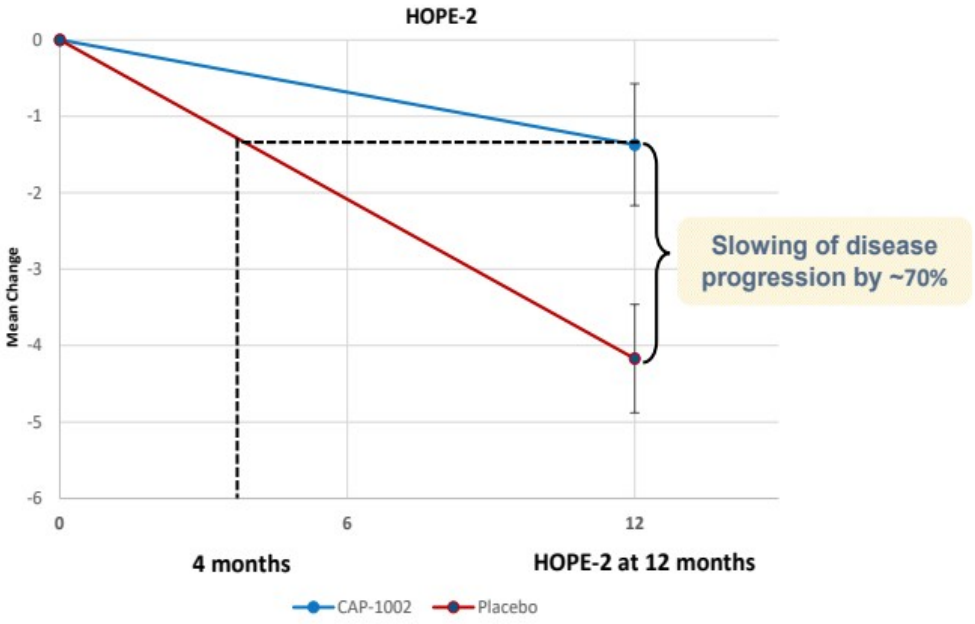
Accelerated Decline in PUL when Off-Treatment



	Difference (PUL 2.0)	p-value
OLE vs. Placebo Group from HOPE-2	2.3	0.015
OLE vs. Placebo GAP	2.8	0.006

*One year change from baseline for a phase refers to a subject's change in one year during that phase.
*The linear mixed model uses all available data for all 20 subjects (12 completers).

CAP-1002's Impact on Disease Progression

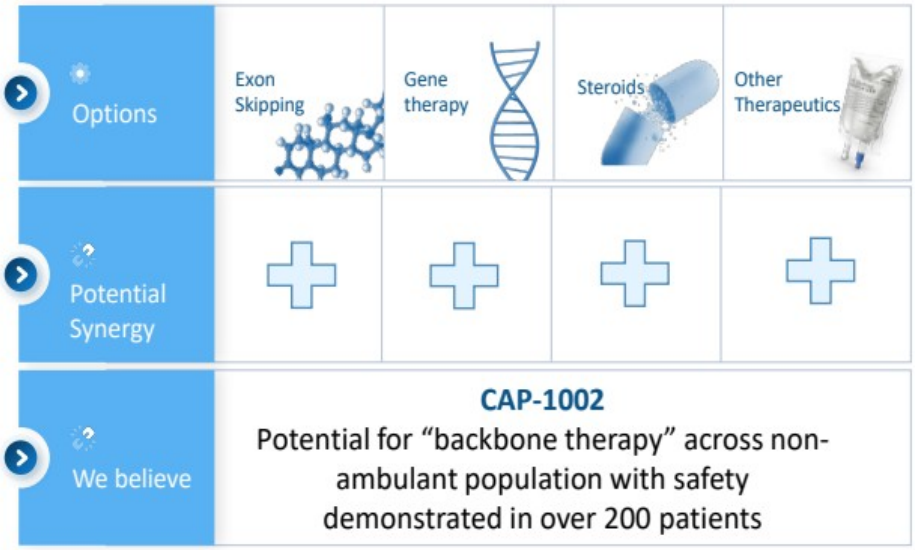


Results published in *The Lancet*, March 2022.

Time is Muscle for DMD Patients

- **CAP-1002: Potential Disease Modifying Benefit**
  - Patients on therapy experience a slower progression of their disease
  - Urgency to initiate therapy: while treatment benefits are maintained (compared to placebo patients), loss of PUL points are never recovered
  - Potential sustained benefit: durable benefit of treatment at 2 years
- **Safety profile of CAP-1002 reinforced**
- **Preserved cardiac ejection fraction shown in HOPE-2**
- **HOPE-3 pivotal Phase 3 clinical trial open for enrollment**
  - Primary efficacy endpoint: PUL 2.0 at 12 months

CAP-1002 Opportunity for "Backbone Therapy"



Acknowledgments

Patients and their families who participated in the HOPE-2 and HOPE-2 OLE Studies

- **Parent Project Muscular Dystrophy**
- **Craig McDonald, M.D. (UC Davis)**
- Coalition Duchenne
- CureDuchenne
- The Jett Foundation
- Action Duchenne
- MDA
- Casimir
- NS Pharma
- Capricor's DMD Advisory Board
- Cuixia Tian, M.D. (CCHMC)
- Russell Butterfield, M.D. (University of Utah)
- Richard Finkel, M.D. (Nemours Children's Hospital)
- Joanne Janas, M.D. (Children's Hospital of Colorado)
- Matthew Harmelink, M.D. (Children's Hospital of Wisconsin)
- Arun Varadhachary, M.D. (Washington University, Saint Louis Children's Hospital)
- Brenda Wong, M.D. (University of Massachusetts)
- Katherine Mathews, M.D. (University of Iowa, Children's Hospital)

Q&A