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)

May 28, 2020

CAPRICOR THERAPEUTICS, INC.

(Exact name of Registrant as Specified in its Charter)

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

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

(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 \Box

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 Common Stock, par value \$0.001 per share Trading Symbol(s) CAPR Name of Each Exchange on Which Registered The Nasdaq Capital Market

90211 (Zip Code)

(

Item 7.01 Regulation FD Disclosure.

On May 28, 2020, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), posted to the "Investors" section of the Company's website atwww.capricor.com a corporate presentation providing an update of the Company's current business and products (the "Corporate Presentation"). A copy of the Corporate Presentation is 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 Item 7.01 of this Current Report on Form 8-K 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 May 28, 2020.

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: May 28, 2020

By: /s/ Linda Marbán, Ph.D. Linda Marbán, Ph.D.

Chief Executive Officer





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; 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, 2019 as filed with the Securities and Exchange Commission on March 27, 2020 and in our Quarterly Report on Form 10-Q for the guarter ended March 31, 2020 as filed with the Securities and Exchange Commission on May 15, 2020. 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.

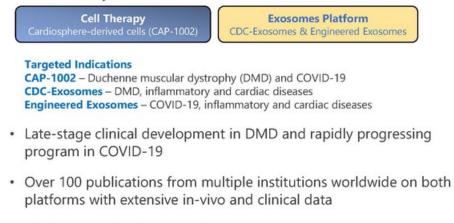
CAP-1002 is an Investigational New Drug and is not approved for any indications. None of Capricor's exosome-based candidates have been approved for clinical investigation.

Capricor Therapeutics, Inc.

Corporate Summary



• Two products with novel approaches to neuromuscular, infectious, inflammatory and cardiovascular diseases



- · Efficient use of capital including non-dilutive sources
- Experienced management team

Capricor Therapeutics, Inc.

Developing Transformative Therapics from Bench to Bedside 3

1As of 5/15/20 as reported in Form 10Q

NASDAQ CAPR

Proforma Cash (3/31/20)¹ \$26.3 million

> Common shares¹ 14.3 million

Non-Dilutive Capital \$45 million

External Collaborators US Army US Department of Defense Johns Hopkins University Cedars-Sinai Medical Center





Capricor's Product Pipeline

Candidate	Target _ Indications						
		Discovery	Preclinical	Phase I	Phase II	Phase III	Status
CAP-1002 (allogeneic CDCs)	Duchenne Muscular Dystrophy						-Positive Phase II reported -Requested End-of Phase Meeting with FDA
CAP-1002 (allogeneic CDCs)	COVID-19		-				Expanded Access
Exosome <u>VLP</u> Display Vaccine 4-part antigen design	SARS-CoV-2						In Development
Exosome <u>mRNA</u> Vaccine Tripartite mRNA design	SARS-CoV-2						In Development
CDC-Exosomes (allogeneic CDC-XOs)	Duchenne Muscular Dystrophy						IND submitted
ASTEX-Exosomes (engineered fibroblast- derived XOs)	Evaluating						Platform
Engineered Exosomes (mRNA for gene editing)	Evaluating						Platform
Cell Therapy	Exosome Platfo	orm					
							en approved for clinical investigation
cor Therapeutics, Inc.			Deve	loping Tran	sformative Th	crapics from	Bench to Bedside

Capricor's CAP-1002 Technology

CAP-1002 is a biologic consisting of allogeneic cardiosphere-derived cells (CDCs)

- · Manufactured from donated heart muscle
- Does not act by "stemness" the cells do not engraft into host tissue
- MOA: cells secrete exosomes:
 - Contain miRNAs, non-coding RNAs and proteins
 - Internalized by target cells
 - Stimulate diverse and lasting changes in cellular behavior
 - 3 known miRNAs drive CAP-1002 potency
- CAP-1002 has been investigated in multiple independent clinical trials and more than 150 human subjects to date

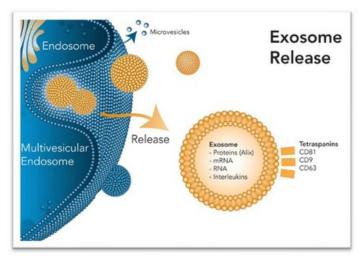
Capricor Therapeutics, Inc.



Overview of Exosome Technology



- Lipid-bilayer nanoparticles produced by most cells for inter-cellular communication
- Contain small fragment nucleic acids and proteins for cellular signaling
- Contents readily enter cytoplasm and nucleus
- Targeted to specific receptors
- May be bioengineered
- May be lyophilized



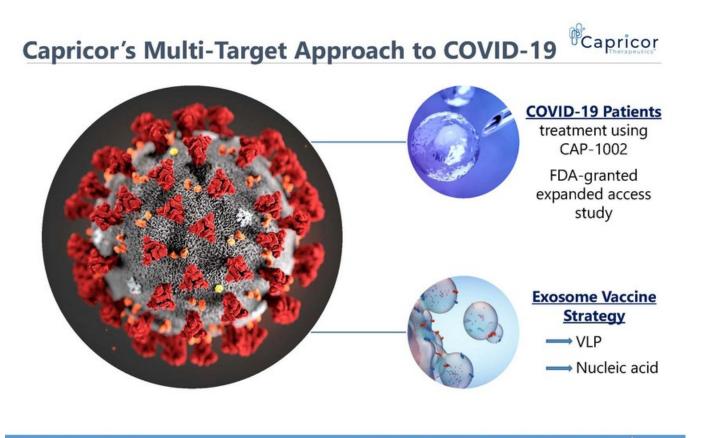
Capricor Therapeutics, Inc.

The Field of Exosomes:



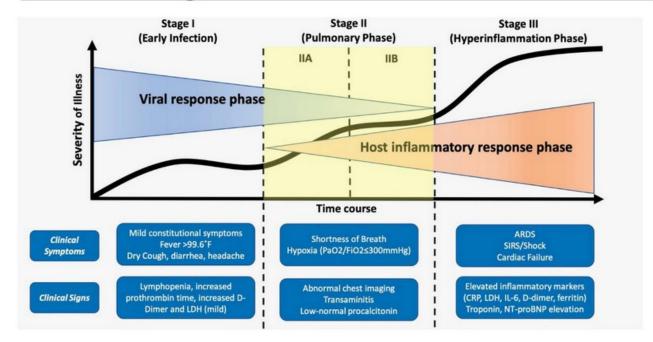
Increasing Market Opportunity





Capricor Therapeutics, Inc

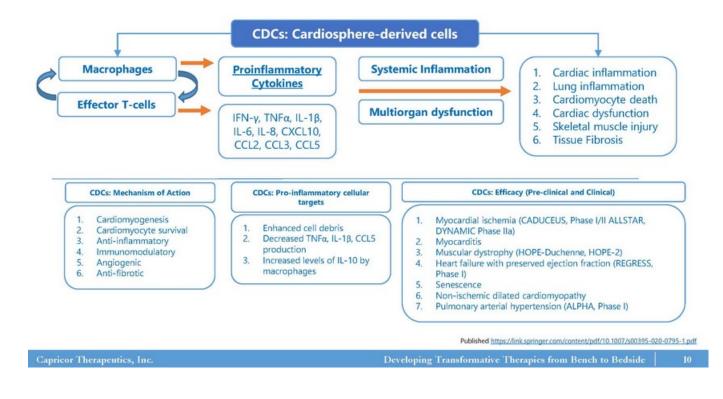
CAP-1002 Targets Severe Cases of COVID-19



Capricor Therapeutics, Inc

Immunomodulatory Effects of CAP-1002





CAP-1002: COVID-19 Preliminary Results



Six critical COVID-19 patients with ARDS*

- Treated at Cedars-Sinai Medical Center in Los Angeles, CA
- 5 males and 1 female
- Age range: 19 to 75
- 5 of 6 on mechanical ventilation prior to treatment
- Received intravenous infusions of 150 million cells of CAP-1002

Results:

- Within 1-4 days following infusion
 - 4 of 5 patients no longer required ventilator support
- 4 patients have been discharged
- 2 patients remain in ICU

Improved biomarkers:

- Ferritin, absolute lymphocyte count and CRP

No adverse events related to the administration of CAP-1002 were observed

*Published https://link.springer.com/content/pdf/10.1007/s00395-020-0795-1.pdf

Capricor Therapeutics, Inc.

CAP-1002: COVID-19 Development Plan



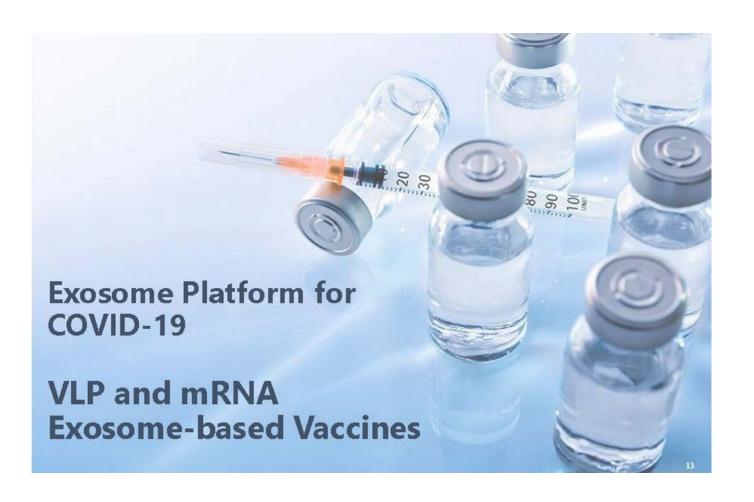
Ongoing:

FDA approved expanded access protocol to treat up to 20 COVID-19 patients (April 29, 2020)

- Emergency use in critical patients
- Amendment to expand to randomized, double-blind placebo-controlled Phase II study to treat up to 40 patients under review
- Pursuing non-dilutive funding opportunities

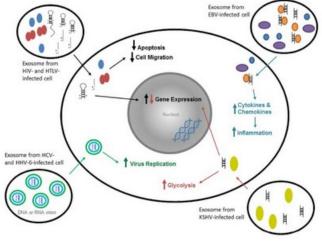
Limited options available for critical COVID-19 patients in this setting

Capricor Therapeutics, Inc.



Exosomes Target Cargo Directly to the Cell Capricor

- Exosomes serve as a natural signaling system
- CD-9, CD-81 and CD-63 are surface markers of exosomes and can serve as targeting molecules for effective delivery to cells and confirmation of exosome loading

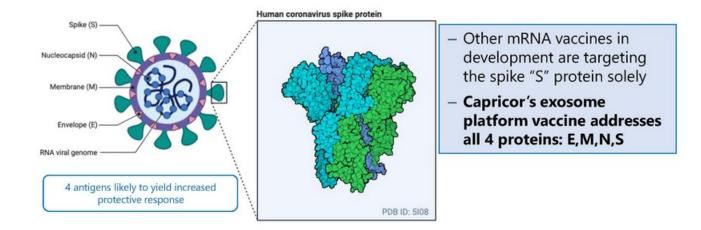


Capricor Therapeutics, Inc.

Coronavirus Structure

Unique Protein Visualization





Two unique vaccine approaches utilizing exosomes: (1) VLP & (2) mRNA vaccines

Capricor Therapeutics, Inc

Capricor's Exosome-Based Vaccine



Approach is Distinctive

Exosome-based approach

- Allows for specificity in cellular targeting
- Innovative technology yet is well characterized

Unique 4-antigen approach

- Potentially confers greater immunity by targeting all 4 antigens

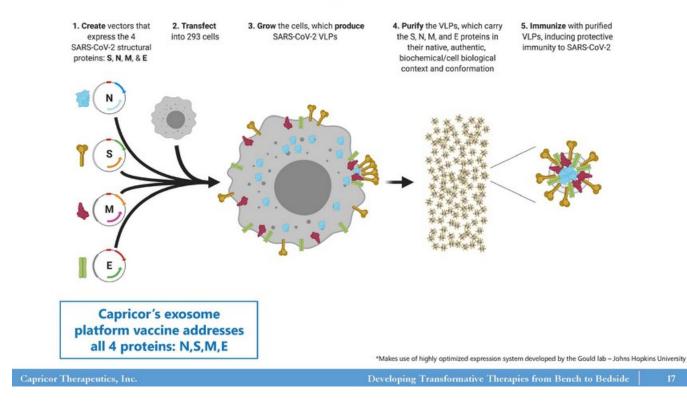
Exosomes potentially superior to liposomes

- Not recognized as foreign by immune system
- Deliver payload directly to cytoplasm or nucleus
- Superior targeting permits lower doses
- Target both T and B cells allows for immediate activity and long-term memory

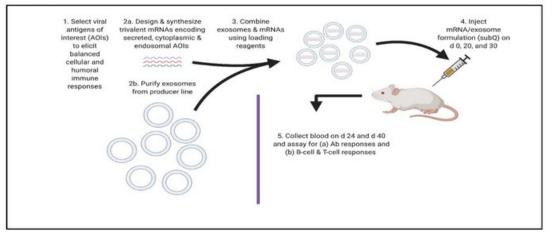
Two differentiated vaccine approaches under development

- Platform permits accelerated innovation of both VLP and mRNA vaccines

(1) Exosome VLP: Display Vaccine Approach ** Capricor



(2) Exosome mRNA Vaccine



Exosome-based mRNA vaccine can have the following potential benefits:

- Delivering payload directly to cytoplasm or nucleus
- Superior targeting may permit lower doses
- Exosome based mRNA vaccine will have all 4 proteins for better immune response
- Exosomes address the delivery problem by targeting cells of interest

Capricor Therapeutics, Inc.

Vaccine Development Planned Timeline



SARS-CoV-2 Vaccines

- Validation of multi-protein approach (4 viral proteins (S, M, E, N)) underway
- Generate exosome based VLP-based vaccine and mRNA vaccine underway

IND/Clinical Validation

- Preclinical testing underway
- Preclinical testing in non-human primates 2H 2020
- Initiate Clinical Evaluation 1H 2021

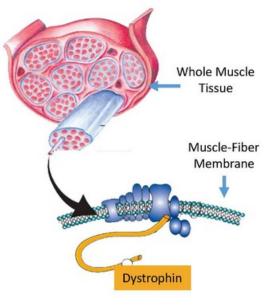
Capricor Therapeutics, Inc.



Lack of Dystrophin Predisposes Muscle to Damage

Capricor

- Dystrophin is a structural protein located within the muscle fiber membrane
- · Acts both as a cushion and a kind of glue
- Without dystrophin, muscles are unable to function properly, suffer progressive damage and eventually die
- Much of the muscle injury that occurs in dystrophin-deficiency is attributable to secondary damage caused by inflammation

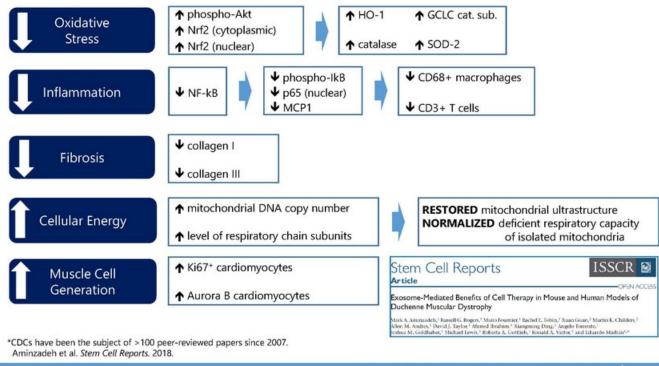


Capricor Therapeutics, Inc.

Mechanism of Action:

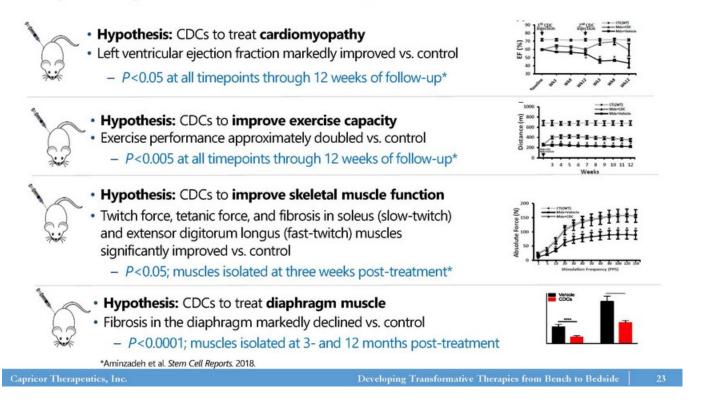


Defined in "Stem Cell Reports"



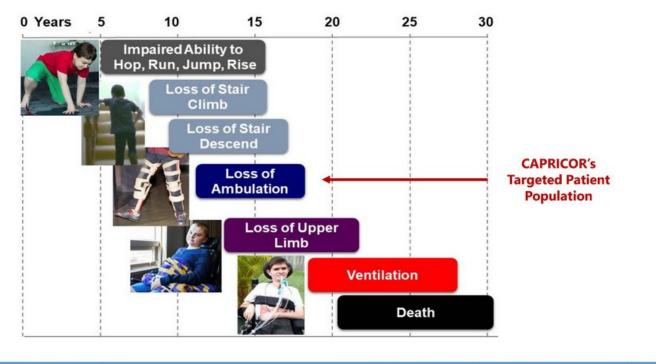
Capricor Therapeutics, Inc

Trajectory of CDCs in DMD (Preclinical Data) Capricor



Capricor's Addressable DMD Population





Capricor Therapeutics, Inc

Competitive Landscape for DMD



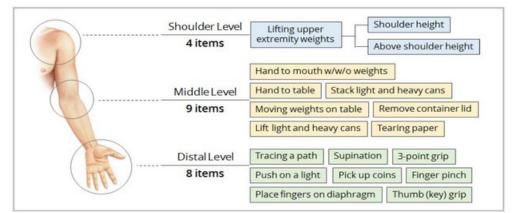
Options	Challenges	CAP-1002 Benefits
Exon Skipping Gene therapy NF-kB Steroids	Exon Skipping – treats a small portion of the DMD population Gene therapy – potential safety risks NF-kB inhibition may not be enough Steroids have adverse side- effects	Immunomodulatory Anti-fibrotic Pro-regenerative Cellular Energy
We believe CAP-1002 may	be used synergistically with oth treat DMD	ner therapeutics aimed to

Capricor Therapeutics, Inc.



Primary Efficacy Endpoint

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



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*

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

Capricor Therapeutics, Ir

Capricor's Regulatory Designations - DMD

GOAL OF FDA'S RMAT DESIGNATION

To facilitate efficient development and expedite review of a drug

Similar to breakthrough therapy designation:

- RMAT provides benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate
- · Eligibility for rolling review and priority review

Products may also be eligible for accelerated approval

 On the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit



HOPE-Duchenne Focused on Older DMD Patients

- · Phase I/II study: 25 patients, randomized and open-label
- · One-time, multi-vessel, intracoronary delivery of cells
- · HOPE population were all on stable corticosteroids
- · Very limited options for this patient population

RESULTS

- Reduction in cardiac scar at 6 and 12 months measured by MRI
- Improvement in cardiac function (systolic wall thickening) at 6 and 12 months
- · Improvements shown in PUL (mid + distal)
 - Best improvement shown within the first 3 months
- Study published in February 2019 in Journal of Neurology

Capricor Therapeutics, Inc.

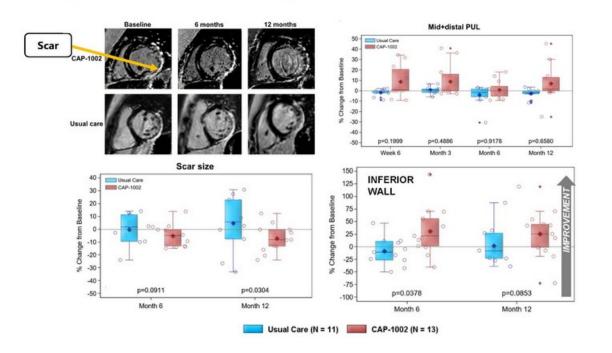






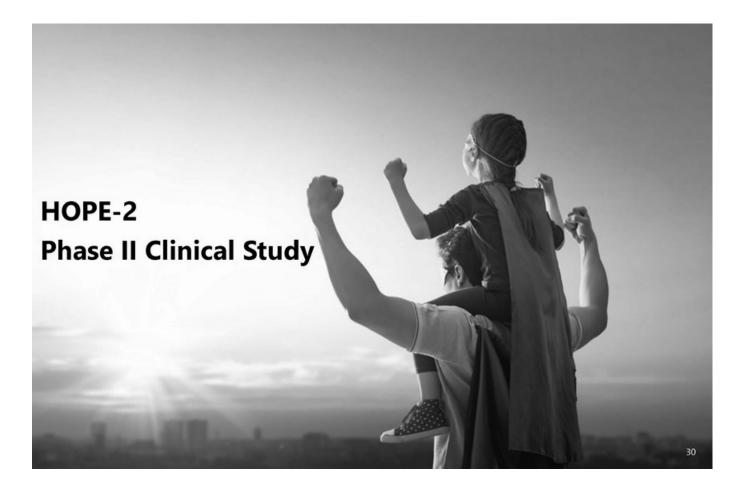
HOPE-Duchenne: Reduced Cardiac Scar and Improved PUL





Capricor Therapeutics, Inc

*p-values are based on absolute change from baseline (Transformative Therapics from Bench to Bedside 2)



HOPE-2 Clinical Trial



- **Design:** Phase II, randomized, double-blind, placebo-controlled trial in participants with DMD and reduced skeletal muscle function
- Objective: Evaluate safety and efficacy of CAP-1002
- Dosing Regimen: 150M cells delivered intravenously every 3 months
- · Sites: 9 sites (USA)
- Data: ITT population 20 subjects
- Demographics
 - Mean age: 14.3 years
 - All patients were on corticosteroids
 - ~ 80% of patients were non-ambulant

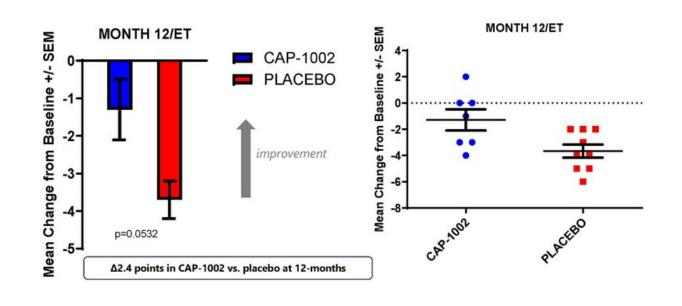


https://www.clinicaltrials.gov/ct2/show/study/NCT03406780.

Clinically Meaningful Changes Observed in PUL 2.0



(Shoulder + Mid + Distal)

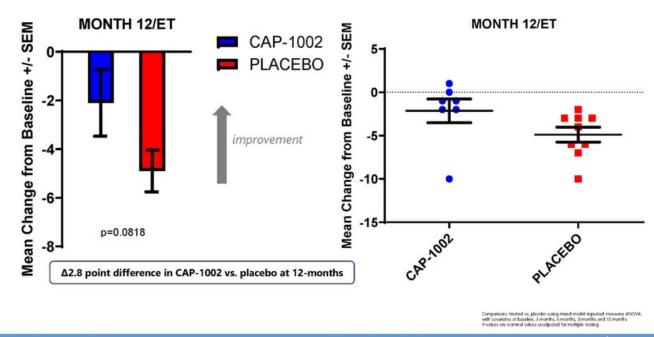


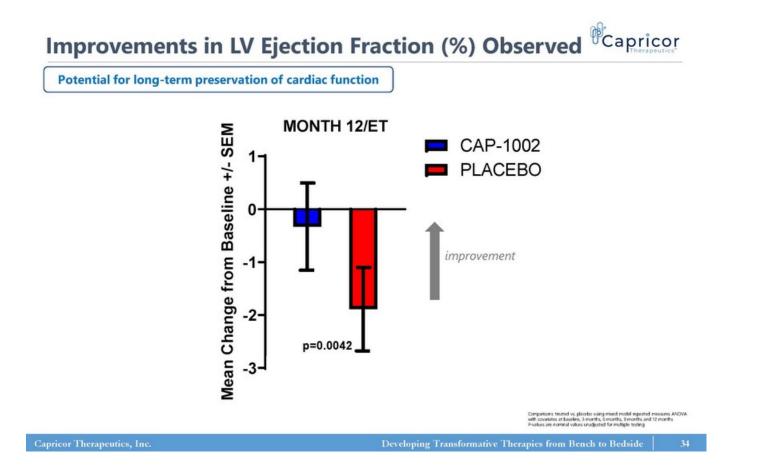
Capricor Therapeutics, Inc.

Comparisons treated vs. placebo using mixed model ingested measures ANOVA with covariates at baseline, 3 months, 6 months, 9 months and 12 months P-values are nominal values unadjusted for multiple testing

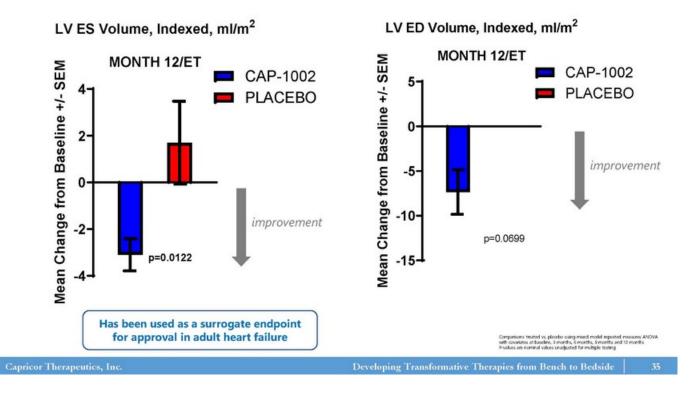
Clinically Meaningful Changes in Mid-Level PUL 1.2 Similar changes shown in HOPE-Duchenne

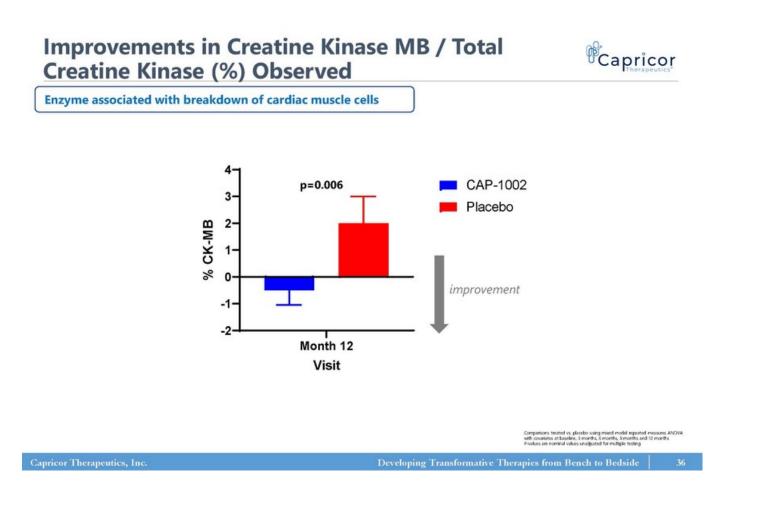






Improvements in LV End-Systolic Volume & LV End-Diastolic Volume Observed





HOPE-2 Safety Results



- A total of 69 infusions (CAP-1002 or placebo) were performed in HOPE-2
 - Generally safe and well tolerated throughout the study
 - With the exception of hypersensitivity reactions, no safety signals were identified

Capricor Therapeutics, Inc.

Conclusions and Future Directions



Conclusions:

- First placebo-controlled trial showing upper limb functional improvements in **non-ambulant DMD patients**
- Directionally consistent improvements in strength, respiratory and cardiac endpoints
- First ever study in DMD that correlates cardiac functional stabilization with reduction of a biomarker of myocardial cell damage
- Consistent results shown preclinically, Phase I/II and Phase II

Moving Forward:

- Requested End-of Phase 2 Meeting with FDA to discuss next steps and pathway to approval
- Engaged global CMO for scale-up of manufacturing of CAP-1002
- Expeditious initiation of open label extension

Capricor Therapeutics, Inc.

World-Class DMD Advisory Board



Craig McDonald, M.D. (National PI)	University of California at Davis (USA) Atom International Ltd (UK)		
Michelle Eagle, Ph.D., M.Sc., MCSP			
Richard Finkel, M.D.	Nemours Children's Hospital (USA)		
Pat Furlong	Parent Project Muscular Dystrophy (USA)		
Kan Hor, M.D.	Nationwide Children's Hospital (USA)		
John Jefferies, M.D.	Cincinnati Children's Hospital Medical Center (USA)		
Oscar Henry Mayer, M.D.	Children's Hospital of Philadelphia (USA)		
Eugenio Mercuri, M.D., Ph.D.	Catholic University of the Sacred Heart (Italy)		
Francesco Muntoni, M.D.	University College London (UK)		
Thomas Voit, M.D.	University College London (UK)		
Lee Sweeney, Ph.D.	University of Florida (USA)		
Michael Taylor, M.D., Ph.D.	Cincinnati Children's Hospital Medical Center (USA)		

Capricor Therapeutics, Inc.

Recent and Targeted Milestones in 2020



Cell Therapy (CAP-1002) Technology

- ✓ Feb. 2019: HOPE-Duchenne (Phase I/II) study published in Journal of Neurology
- ✓ Oct. 2019: Reported positive six-month results of HOPE-2 trial at World Muscle Society International Conference
- ✓ Oct. 2019: Met with FDA to discuss DMD program
- Q2 2020: Hosted a call with Dr. Taylor on cardiac complications of DMD
- ✓ Q2 2020: Announced compassionate use program for CAP-1002 to treat COVID-19 patients
- ✓ Q2 2020: Announced positive preliminary results from compassionate use program
- ✓ Q2 2020: Announced approval of expanded access program in DMD
- ✓ Q2 2020: Announced publication of COVID-19 compassionate use case series
- ✓ Q2 2020: Announced positive HOPE-2 final 12-month results
- Q3 2020: Plan to meet with FDA to discuss CAP-1002 in DMD
- 2H 2020: Plan to announce updates on expanded access program for COVID-19
- 2H 2020: Plan to present HOPE-2 final results at medical conference
- 2020: Continue to pursue partnership opportunities for DMD program

Exosomes Platform Technology

- ✓ Q1 2020: Hosted a call with Dr. Gould from JHU on vaccine development
- ✓ Q1 2020: Announced strategic plan for exosomes expansion as potential vaccine for COVID-19
- ✓ Q2 2020: Submitted IND for DMD
- 2H 2020: Plan to announce updates on vaccine program for COVID-19
- 2H 2020: Plan to publish pre-clinical data from exosomes technology
- 2020: Continue to advance platform opportunities and pursue partnership opportunities

Capricor Therapeutics, Inc.

Senior Leadership Team





Linda Marbán, Ph.D.

- Chief Executive Officer, Co-founder and Director Dr. Marbán has over 25 years of exp
- industry Been with Capricor since 2005 and CEO since 2010.
- Previous experience includes Excigen, Inc. where she was responsible for business development and operations.
- Dr. Marbán began her career in academic science at the Cleveland Clinic Foundation working on the biophysical properties of cardiac muscle and continued to a postdoctoral
- fellowship at Johns Hopkins University. Dr. Marbán earned a Ph.D. from Case Western Reserve University .

in cardiac physiology.

Karen Krasney, J.D.

Tariq Warsi, Ph.D.

Executive Vice President & General Counsel

- Ms. Krasney's has over 40 years of experience in domestic and international corporate and business law, as well as litigation.
- Ms. Krasney served as legal counsel of Biosensors International
- Group Ltd., a multinational medical device company. Ms. Krasney received her Bachelor of Arts degree from the University of California, Los Angeles and her Juris Doctorate from the University of Southern California.



Stephen Gould, Ph.D. **Executive Consultant**

- Dr. Gould is a Professor of Biological Chemistry at Johns Hopkins University and an internationally recognized exosome expert who brings an unparalleled understanding of exosome engineering to Capricor.
- Dr. Gould is co-Founder and acting President of the American Society for Exosomes and Microvesicles (ASEMV).
- Dr. Gould's team was the first to reveal the mechanistic link between exosome biogenesis and virus budding, the first to identify mechanisms of exosome engineering and the first to develop an exosome-based cancer therapeutic.
- Dr. Gould has published numerous research articles and several book chapters, received numerous public and private research grants and served on an array of NIH and other grant review panels.

AJ Bergmann, M.B.A. **Chief Financial Officer**

- Mr. Bergmann has worked in the finance industry for over a
- decade. Mr. Bergmann joined Capricor in 2011 and coordinated the
- Company's reverse merger, uplisting to NASDAQ and financings yielding over \$60 million to date. Mr. Bergmann graduated from Providence College and has a
- M.B.A. from the University of Southern California's Marshall School of Business.

Siegfried Rogy, Ph.D.

Vice President of Clinical Operations Dr. Rogy has over 25 years of clinical operations and development experience at companies including Baxter Bioscience, The Medicines Company and Maxim



- Pharmaceuticals. Dr. Rogy held positions at two start-up biotech companies including Novalar where he successfully directed a Phase I-III clinical program leading to the marketing authorization of
- OraVerse[®], a local anesthesia reversal agent. Dr. Rogy earned his Bachelor of Science and Ph.D. in Biology from the Karl-Franzens-University, Graz, Austria.

Developing Transformative Therapies from Bench to Bedside



Dr. Warsi has over 20 years of experience in cell and molecular biology. Dr. Warsi held positions at Amgen® where he performed research in cell and gene therapy, immunotherapy and large protein biologics contributing to the delivery of analytical methods, process optimization, authoring INDs and leading programs from R&D through early phase clinical studies. Dr. Warsi earned his Bachelor of Science degree in Biological Sciences from the University of California, Riverside. He conducted his postdoctoral research at Harvard Medical School, where he studied the contributions of protein structure, function and

Vice President of Research and Development

Dr. Warsi has over 20 years of experience in cell and molecular

degradation.