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)

March 10, 2020

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. ☐

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 March 10, 2020, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), posted to the "Investors" section of the Company's website at *www.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 March 10, 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: March 10, 2020

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

Exhibit 99.1


Capricor
Therapeutics™
Corporate & Investor Presentation
March 2020
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; 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 September 30, 2019, as filed with the Securities and Exchange Commission on November 8, 2019, and in its Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on December 5, 2019 which was declared effective by the Securities and Exchange Commission on December 17, 2019, and the prospectus contained therein, together with any amendments and 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.

Investment Highlights

Synergistic Asset Portfolio

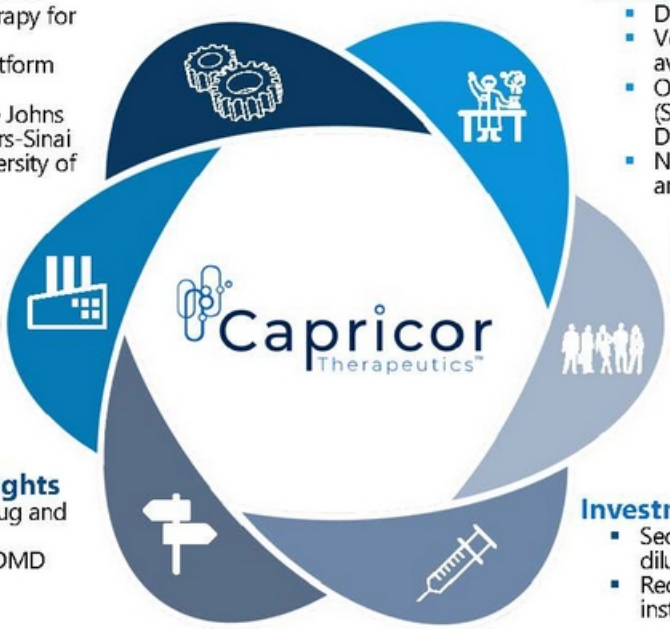
- Phase II – cardiac cell therapy for DMD
- Preclinical – exosome platform technology
- Core IP licensed from the Johns Hopkins University, Cedars-Sinai Medical Center and University of Rome

Market Opportunity

- Rare disease focus
- Duchenne muscular dystrophy (DMD) affects est. 20,000 (US)
- Est. 200,000 world-wide

Regulatory Highlights

- RMAT, orphan drug and rare pediatric designations for DMD



Unmet Medical Need

- DMD is a fatal genetic disease
- Very few treatment options available world-wide
- Only 2 approved drugs in the U.S. (SRPT) – addressing only 21% of DMD patients
- No approved treatments for non-ambulant DMD patients

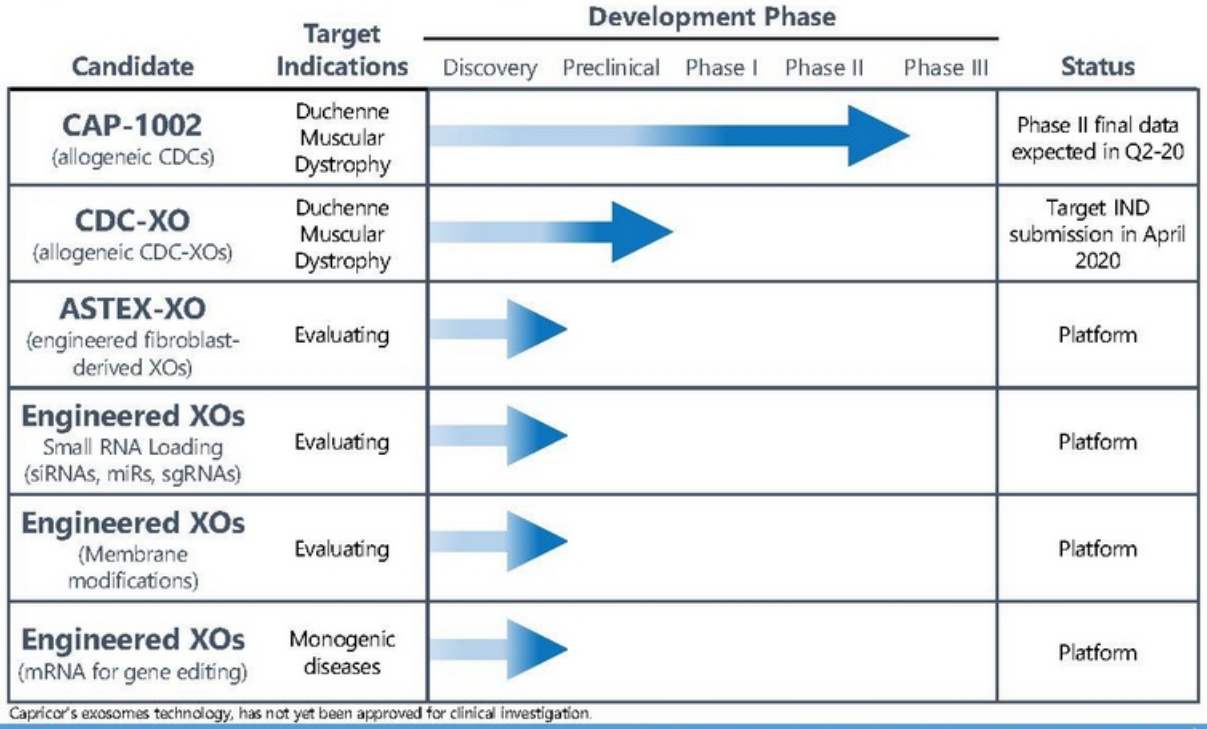
Experienced Management Team

- Members of Board and management have significant operational experience, including participating in several successful exits

Investment Highlights

- Secured over $45M in non-dilutive capital since inception
- Recent support from institutional healthcare fund

Capricor's Product Pipeline

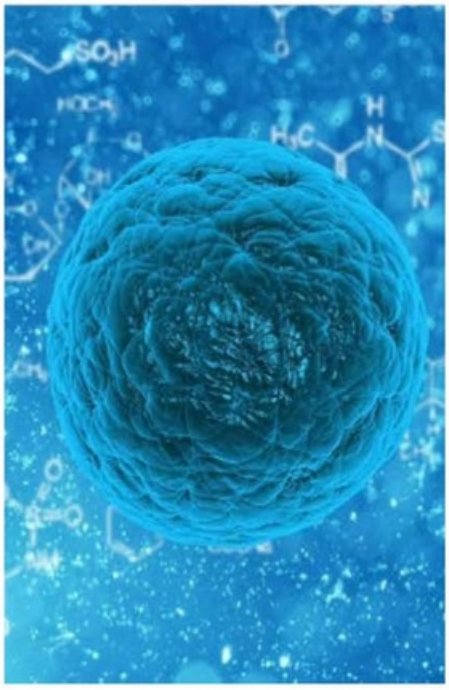


Capricor's exosomes technology, has not yet been approved for clinical investigation.

Capricor's CAP-1002 Technology

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

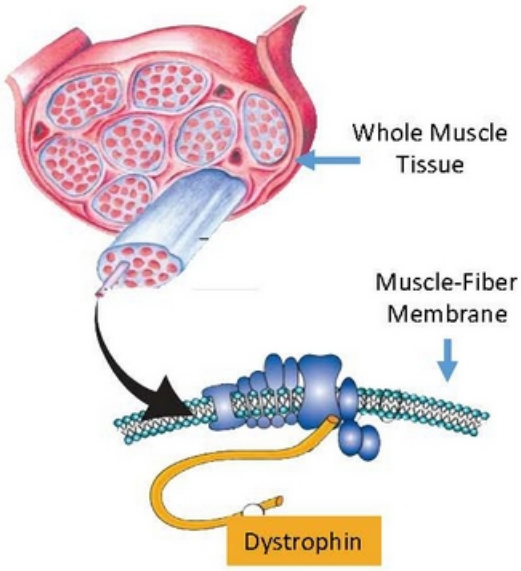
- Manufactured from donated heart muscle
- Does not act by "stemness" - the cells do not engraft into host tissue
- MOA: cells secrete exosomes:
  - Contain miRNA, non-coding RNAs and proteins
  - Internalized by target cells
  - Stimulate diverse and lasting changes in cellular behavior
  - 3 known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




CAP-1002
Duchenne
Muscular
Dystrophy
Program
6

Lack of Dystrophin Predisposes Muscle to Damage

- 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**



Mechanism of Action:
Defined in *"Stem Cell Reports"*

Capricor Therapeutics

Oxidative Stress
- ↑ phospho-Akt
- ↑ Nrf2 (cytoplasmic)
- ↑ Nrf2 (nuclear)

→
- ↑ HO-1
- ↑ GCLC cat. sub.
- ↑ catalase
- ↑ SOD-2

Inflammation
- ↓ NF-kB

→
- ↓ phospho-IkB
- ↓ p65 (nuclear)
- ↓ MCP1

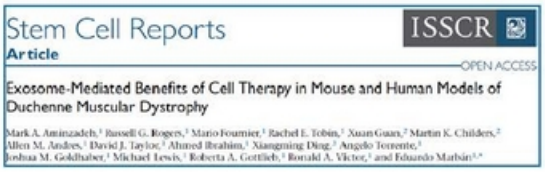
→
- ↓ CD68+ macrophages
- ↓ CD3+ T cells

Fibrosis
- ↓ collagen I
- ↓ collagen III

Cellular Energy
- ↑ mitochondrial DNA copy number
- ↑ level of respiratory chain subunits

→ **RESTORED** mitochondrial ultrastructure
NORMALIZED deficient respiratory capacity of isolated mitochondria

Muscle Cell Generation
- ↑ Ki67+ cardiomyocytes
- ↑ Aurora B cardiomyocytes

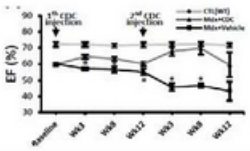

Stem Cell Reports
ISSCR
Article
OPEN ACCESS
Exosome-Mediated Benefits of Cell Therapy in Mouse and Human Models of Duchenne Muscular Dystrophy
Mark A. Aminzadeh,[1] Russell G. Rogers,[1] Mario Fournier,[1] Rachel E. Tobin,[1] Xuan Guan,[2] Martin K. Childers,[2] Allen M. Andres,[1] David J. Taylor,[3] Ahmed Ibrahim,[3] Xiangming Ding,[3] Angelo Torrente,[3] Joshua M. Goldhaber,[1] Michael Lewis,[1] Roberta A. Gottlieb,[3] Ronald A. Victor,[1] and Eduardo Marbán[1,*]

*CDCs have been the subject of >100 peer-reviewed papers since 2007.
Aminzadeh et al. *Stem Cell Reports*. 2018.

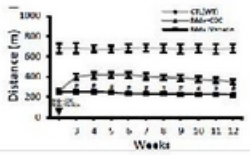
Trajectory of CDCs in DMD (Preclinical Data)

Capricor Therapeutics

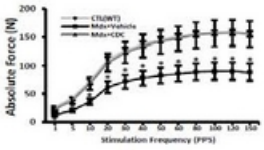
- **Hypothesis:** CDCs to treat **cardiomyopathy**
- Left ventricular ejection fraction markedly improved vs. control
  - *P*<0.05 at all timepoints through 12 weeks of follow-up*



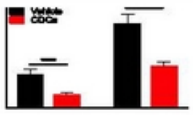
- **Hypothesis:** CDCs to treat **skeletal muscle function**
- Exercise performance approximately doubled vs. control
  - *P*<0.005 at all timepoints through 12 weeks of follow-up*



- **Hypothesis:** CDCs to treat **soleus muscle**
- Twitch force, tetanic force, and fibrosis in soleus (slow-twitch) and extensor digitorum longus (fast-twitch) muscles significantly improved vs. control
  - *P*<0.05; muscles isolated at three weeks post-treatment*

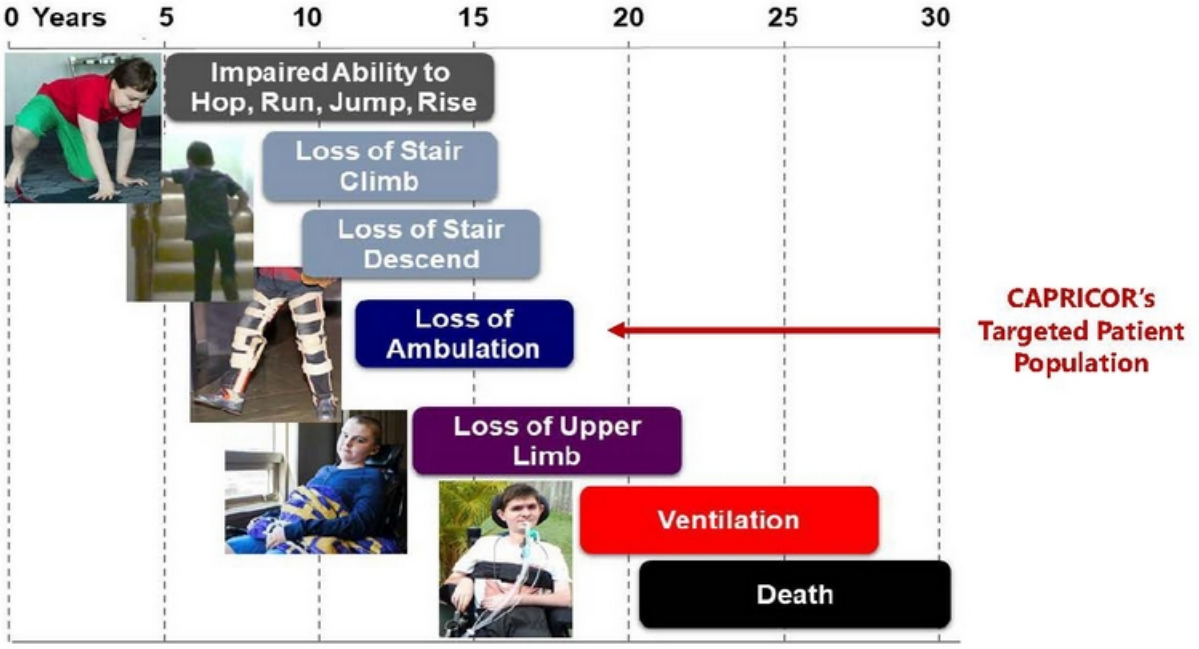


- **Hypothesis:** CDCs to treat **diaphragm muscle**
- Fibrosis in the diaphragm markedly declined vs. control
  - *P*<0.0001; muscles isolated at 3- and 12 months post-treatment



*Aminzadeh et al. *Stem Cell Reports*. 2018.

Capricor's Addressable Market

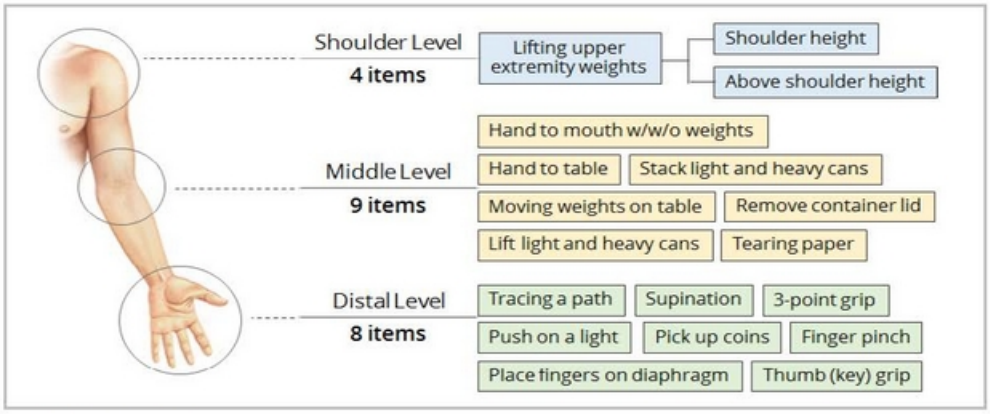


Competitive Landscape for DMD

We believe CAP-1002 may be used synergistically with other therapeutics aimed to treat DMD

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'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
- Reliance upon data obtained from a meaningful number of sites

HOPE-Duchenne Focused on Older DMD Patients

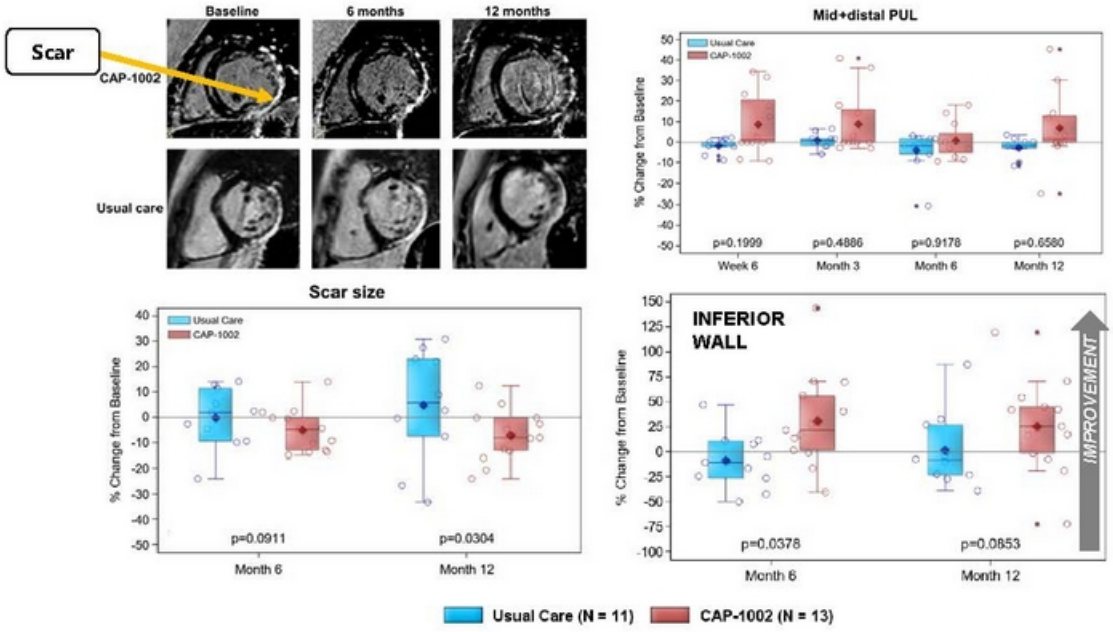
- Phase I/II study: 25 patients, randomized and open-label
- One-time, multi-vessel, intracoronary delivery of cells
- HOPE population were all on stable corticosteroids
- Very limited options for this patient population

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

https://n.neurology.org/content/92/8/e866.
Study funded with the support of CIRM
https://clinicaltrials.gov/ct2/show/NCT02485938

HOPE-Duchenne:
Reduced Cardiac Scar and Improved PUL



*p-values are based on absolute change from baseline


HOPE-2
Phase II Clinical Study
16

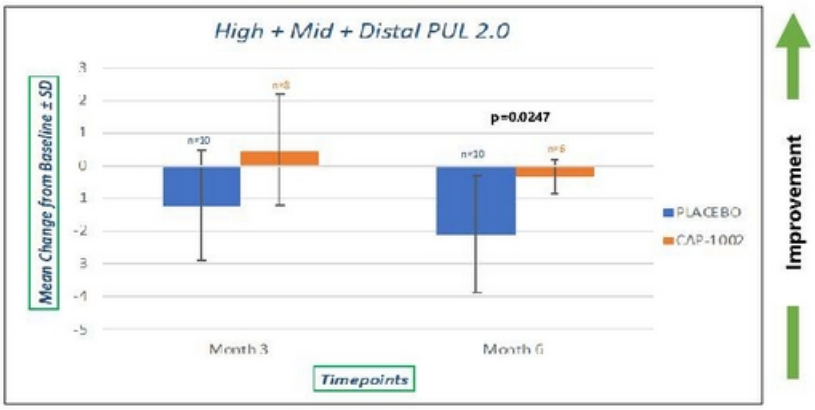
HOPE-2 Clinical Trial

- **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)
- **Interim Analysis:** 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.

Improvements in PUL 2.0

CAP-1002 vs. Placebo at 6-months

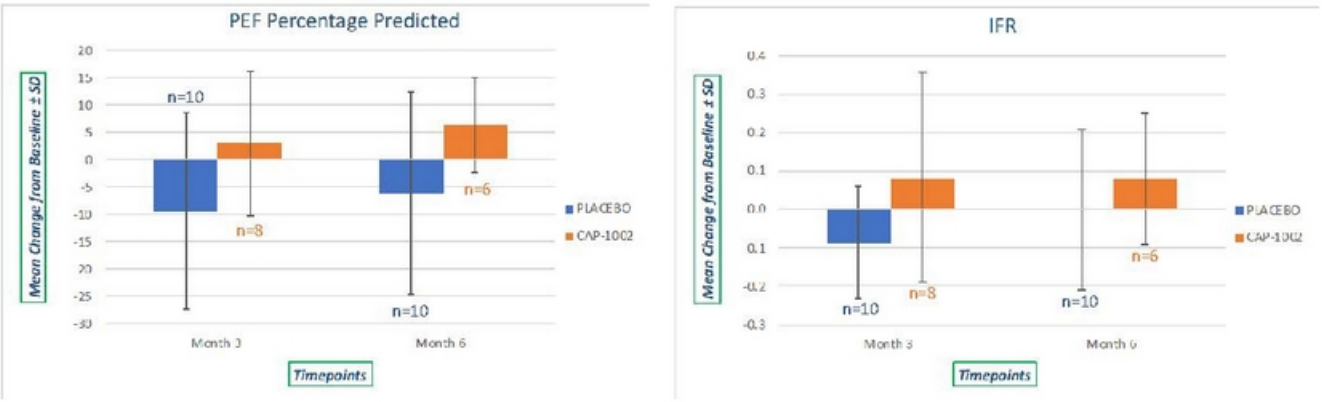


Δ 1.8 difference in CAP-1002 vs. placebo at 6-months

- As shown by these data, preservation of function is maintained for at least 6 months.
- CAP-1002 may offer a treatment for a *primarily non-ambulant DMD population for whom no other options currently exist.*
- A 1.0 improvement in PUL may suggest clinical relevance

Analysis done using Oct ITT population dataset.
Colored boxes heights either positive or negative represent mean change from baseline.
Bars represent ± one standard deviation from the mean. p-values were calculated using a mixed model repeated measures ANOVA with covariates.
p-values are nominal without adjustment for multiple testing or claims of statistical significance.

Improvements in Pulmonary Function Observed

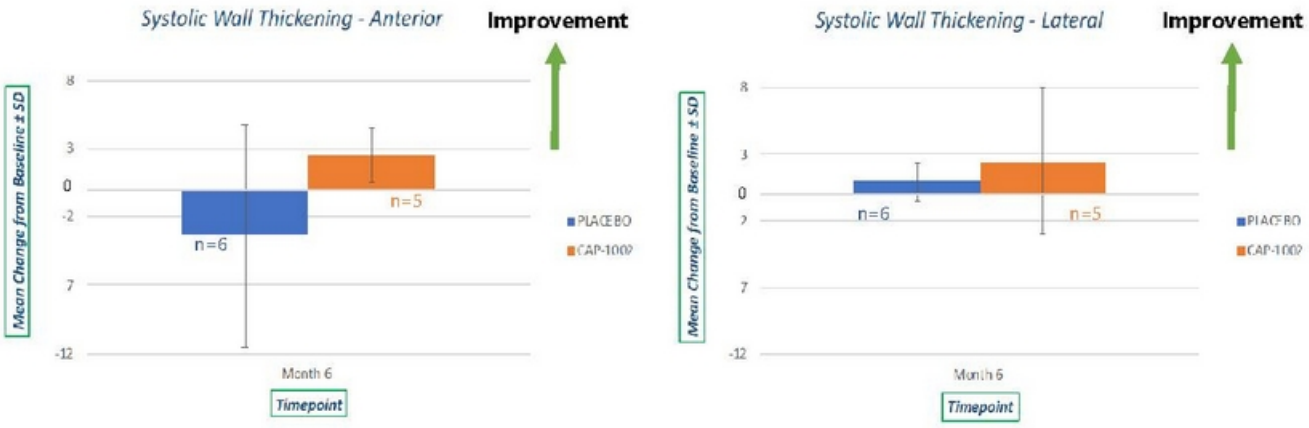


- Pulmonary endpoints are intriguing:
  - More patients and longer follow-up may potentially lead to more robust findings
- Data suggests respiratory muscle function is improved in CAP-1002 vs. placebo
- No changes in FVC observed

Analysis done using Oct ITT population dataset.
Colored boxes, heights, either positive or negative, represent mean change from baseline.
Bars represent ± one standard deviation from the mean.

Cardiac Function as Measured by MRI

Improvement in Anterior & Lateral Systolic Wall Thickening



Similar improvements as shown in HOPE-Duchenne

*Analysis done using July **Per Protocol** population dataset.*
Colored boxes heights either positive or negative represent mean change from baseline.
Bars represent ± one standard deviation from the mean.

Conclusions and Future Directions

CAP-1002 for DMD

Conclusions

- Positive outcomes from two clinical trials showing improvements in skeletal and cardiac muscle function
- 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

- Continue discussions with FDA regarding path forward
- 12-month data expected by Q2-2020 from HOPE-2
- Plan to announce further updates as they become available
- Continue development towards manufacturing scale-up
- Pursue partnership opportunities

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)
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)


Exosomes
Technology
23

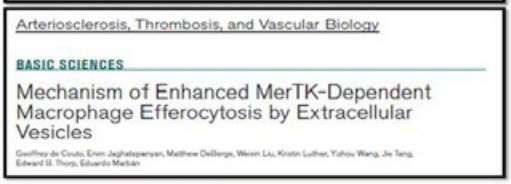
From Discovery to Platform Development

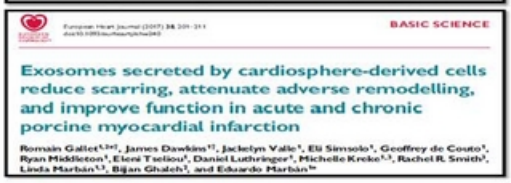
Capricor Therapeutics

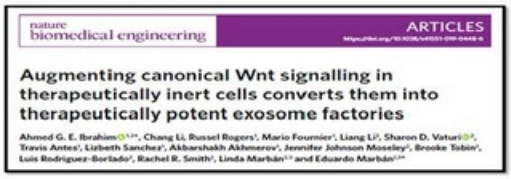
Publications covering our technology have been published by us or our collaborators in multiple peer-reviewed journals.

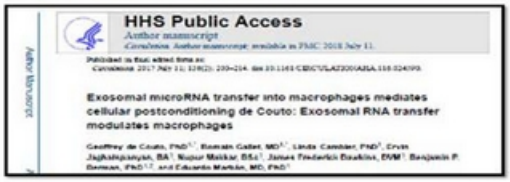

Stem Cell Reports
ISSCR
Article
OPEN ACCESS
Exosomes as Critical Agents of Cardiac Regeneration Triggered by Cell Therapy

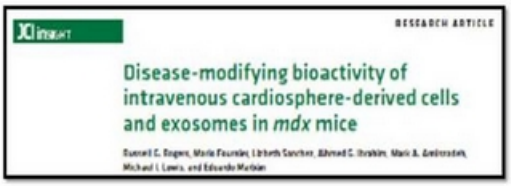

Taylor & Francis
TECHNICAL REPORT
OPEN ACCESS
A comprehensive method for identification of suitable reference genes in extracellular vesicles


Arteriosclerosis, Thrombosis, and Vascular Biology
BASIC SCIENCES
Mechanism of Enhanced MerTK-Dependent Macrophage Efferocytosis by Extracellular Vesicles


BASIC SCIENCE
Exosomes secreted by cardiosphere-derived cells reduce scarring, attenuate adverse remodelling, and improve function in acute and chronic porcine myocardial infarction


nature biomedical engineering
ARTICLES
Augmenting canonical Wnt signalling in therapeutically inert cells converts them into therapeutically potent exosome factories


HHS Public Access
Author manuscript
Exosomal microRNA transfer into macrophages mediates cellular postconditioning de Couto: Exosomal RNA transfer modulates macrophages

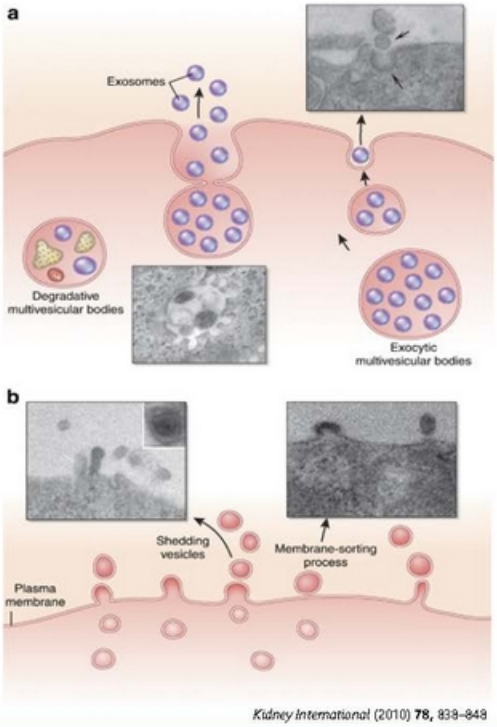

JCI insight
RESEARCH ARTICLE
Disease-modifying bioactivity of intravenous cardiosphere-derived cells and exosomes in *mdx* mice


Research Article
EMBO Molecular Medicine
Y RNA fragment in extracellular vesicles confers cardioprotection via modulation of IL-10 expression and secretion

Extracellular Vesicles (Exosomes)

Cell Free Regenerative Medicine

- Extracellular vesicles - term for cell-derived vesicles, including exosomes
- Nanometer-sized lipid-bilayer vesicles
- Rich in RNAs and proteins
- Secreted by nearly all cell types
- Cell signaling modality
- Potential for broad therapeutic applicability
- **IP**: Exclusive world-wide license agreement with Cedars-Sinai Medical Center for IP rights related to the exosomes technology originating from cardiosphere-derived cells (CDCs)



Kidney International (2010) **78,** 838–848

The Field of Exosomes:
Increasing Market Opportunity

Capricor Therapeutics

High Growth

27.7% CAGR of the global exosome diagnostic and therapeutic market through 2019 to 2027[1]

Increased Financing Activities

Over $300M raised to date in several private companies to date[2]

Large Addressable Market

The global market for exosome diagnostic and therapeutics is expected to reach revenue of $580 million by 2027[1]

Increased Strategic Transactions

M&A activity continuing to increase in delivery, oncology and manufacturing with therapeutics underrepresented in deal flow

[1] https://www.grandviewresearch.com/press-release/global-exosome-diagnostics-and-therapeutics-market-forecast?utm_source=PRN
[2] Based on public data online sources

Capricor's Potential Solutions to Complex Problems

Capricor Therapeutics

Problems	Possible Solutions
1. **Gene therapy using viral delivery (AAV)** – Immune response 2. **Delivery of RNAs** – Uptake to render biologic relevance – Therapeutic development very slow 3. **Synthetic nanoparticles have not been successful as delivery vehicles**	**Exosomes**: – nature's delivery vehicle – low immunogenicity – can deliver contents to the nucleus without integration – can be targeted (tropism) – can be lyophilized for ease of handling

Why Engineer Exosomes?
Platform Technology

Capricor Therapeutics

1

Bioactive Molecules Potentially:

- increase potency
- reduce variability
- help product development

2

Modifications Under Evaluation for:

- Cargo; nucleic acids (mRNA and miRNAs)

3

Modifications under Evaluation for:

- Membrane Modifications;
- Tropism Change, Coating with immunomodulatory markers (PD-L1)

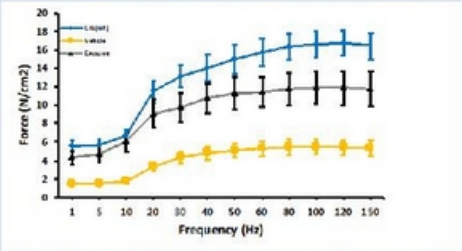
4

Preliminary Data Demonstrates:

- it is feasible to transfer mRNAs and miRNAs loaded into exosomes to target cells

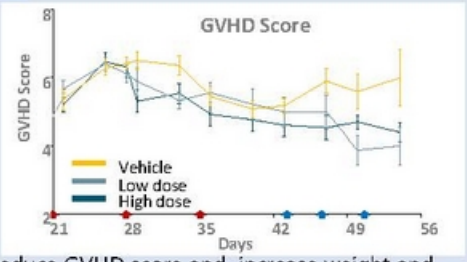
CDC-Exosomes:
POC Established in Multiple Indications

DUCHENNE MUSCULAR DYSTROPHY*



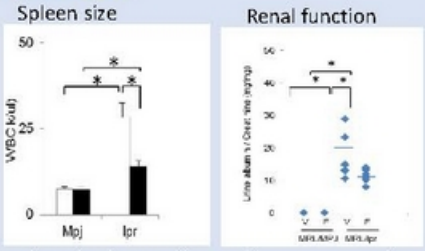
XOs improve muscle activity and exercise capability in mdx-mouse model

GVHD



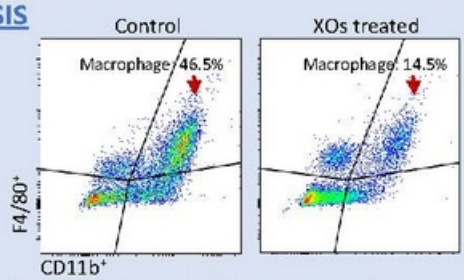
XOs reduce GVHD score and increase weight and survival in mouse model

LUPUS NEPHRITIS



XOs reduce lymphadenopathy and improve renal function in a Lupus nephritis mouse model

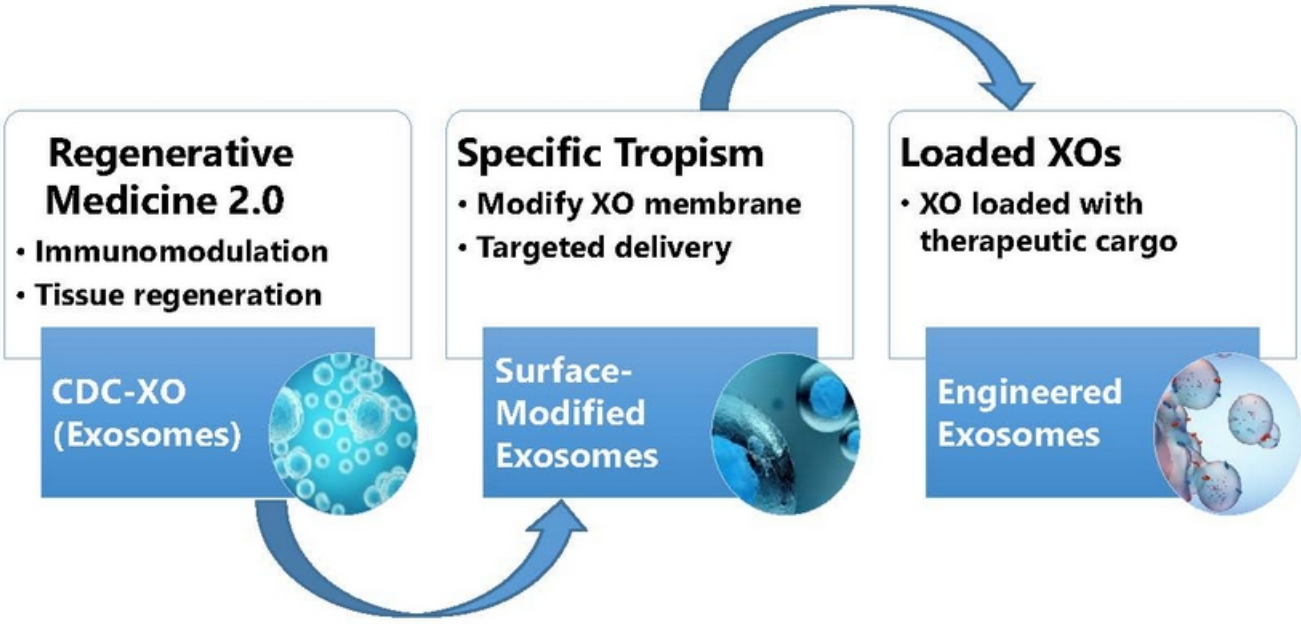
SEPSIS



XOs reduces recruitment of inflammatory cells in a mouse sepsis model

Unpublished results
*Aminzadeh et al, Stem Cell Reports 2018

Targeted Exosome Platform Allows for Broad Applicability



Recent and Targeted Catalysts in 2020

CAP-1002 in Duchenne Muscular Dystrophy

- ✓ 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
- ✓ Dec. 2019: Completed $5.1M offering (priced at-market)
- ❖ April 2020: Plan to host KOL call on cardiac complications in DMD
- ❖ Q2-2020: Plan to announce HOPE-2 final 12-month results
- ❖ Mid-2020: Plan to meet with FDA to discuss CAP-1002 in DMD
- ❖ 2H-2020: Plan to present HOPE-2 final results at medical conference
- ❖ 2020: Continue to pursue partnership opportunities for DMD program

Exosomes Platform Technology

- ❖ April-2020: Plan to submit IND for DMD
- ❖ 1H-2020: Planning key hires in R&D
- ❖ 2H-2020: Aim to publish data from exosomes technology
- ❖ 2020: Continue to advance platform opportunities

Senior Leadership Team

Linda Marbán, Ph.D.
Chief Executive Officer, Co-founder and Director

- Dr. Marbán has over 25 years of experience in the biotechnology 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.
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.

Tariq Warsi, Ph.D.
Vice President of Research and Development

- 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 degradation.

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 $50 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.