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)

November 14, 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, &A	**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 November 14, 2019, 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 November 14, 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: November 14, 2019

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

Exhibit 99.1


Capricor
Therapeutics™
Corporate & Investor Presentation
November 2019
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 September 30, 2019, as filed with the Securities and Exchange Commission on November 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.

Developing Therapies for Rare Diseases

RARE DISEASE FOCUS

- Advanced Clinical Program: Cell Therapy (CAP-1002) for Duchenne muscular dystrophy (DMD)
- Preclinical Stage: Exosome platform technology
- RMAT, orphan drug and rare pediatric designations for DMD

DOMAIN EXPERTISE

- Comprehensive preclinical characterization
- Expertise in cell and exosome-based therapies
- Extensive IP portfolio for core technologies

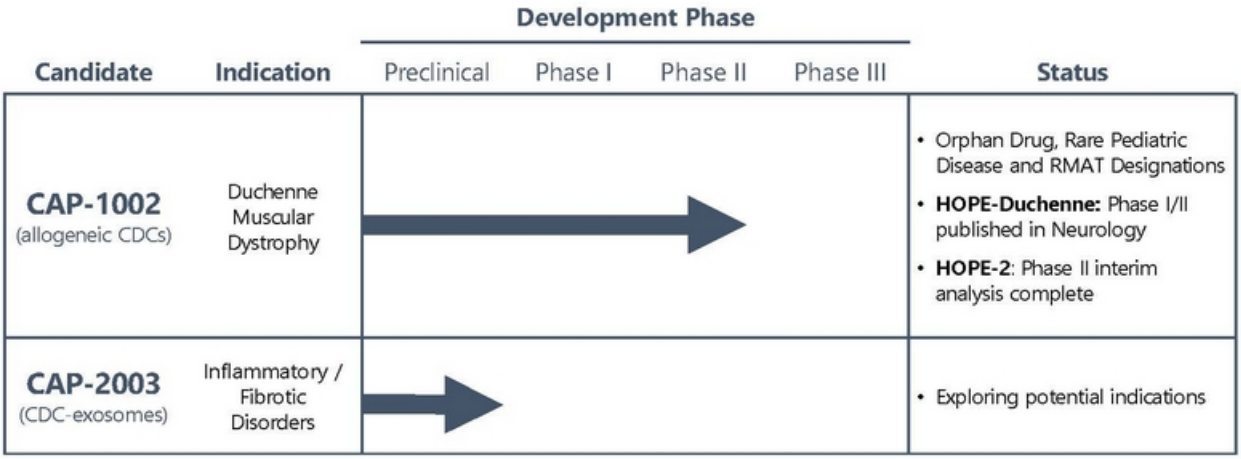
STRATEGIC COLLBORATIONS

- Potential near-term development milestones
- External collaborations: US Army, US Department of Defense, Cedars-Sinai Medical Center

FINANCIAL

- Raised over $50M in equity
- Secured over $45M in non-dilutive funding
- Clean Capital Structure

Capricor's Product Pipeline



CAP-1002 is an Investigational New Drug and is not approved for any indications.
CAP-2003, Capricor's exosomes technology, has not yet been approved for clinical investigation.
CDCs = cardiosphere-derived cells

CAP-1002 Manufacturing

CSps	CDCs	Wash	Formulate	Fill	CAP-1002
					

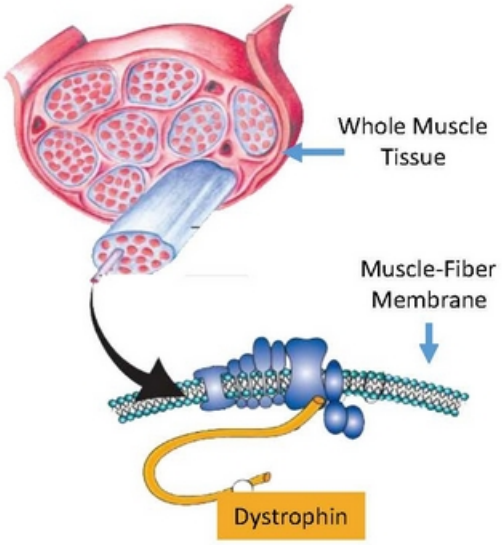
- CAP-1002 is manufactured from donor hearts via a proprietary process
- Clinical trial material currently produced at Capricor facility
- High-yield process in advanced development
- Previous 3-year collaboration with Janssen Biotech focused on chemistry, manufacturing and controls (CMC)

Capricor Therapeutics

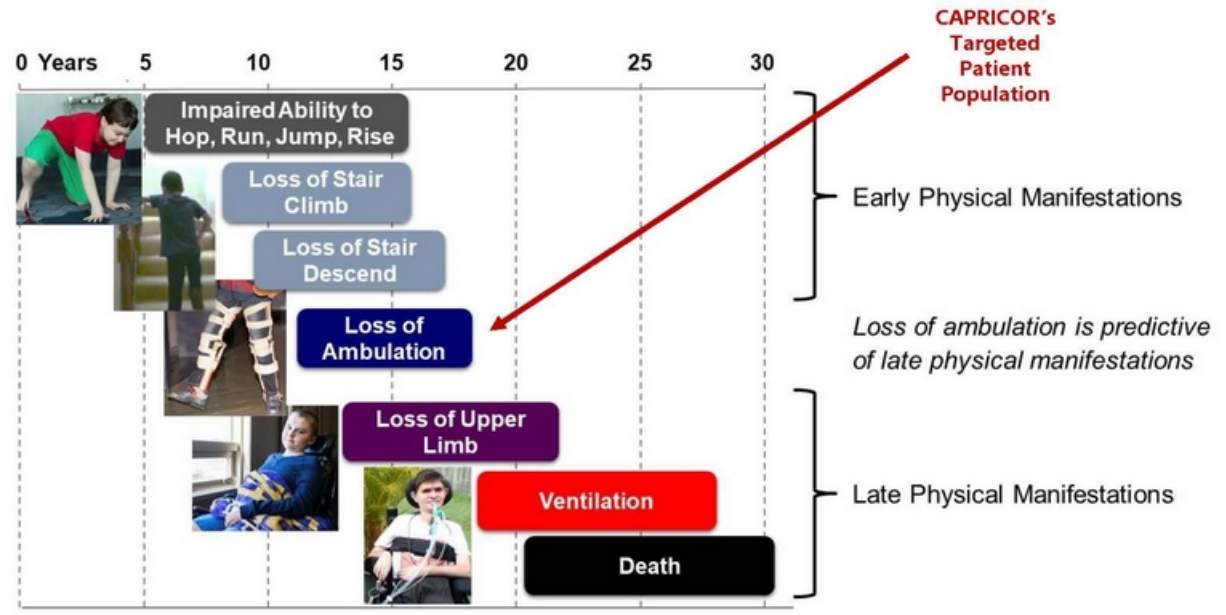

CAP-1002
Duchenne
Muscular
Dystrophy
Program

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**

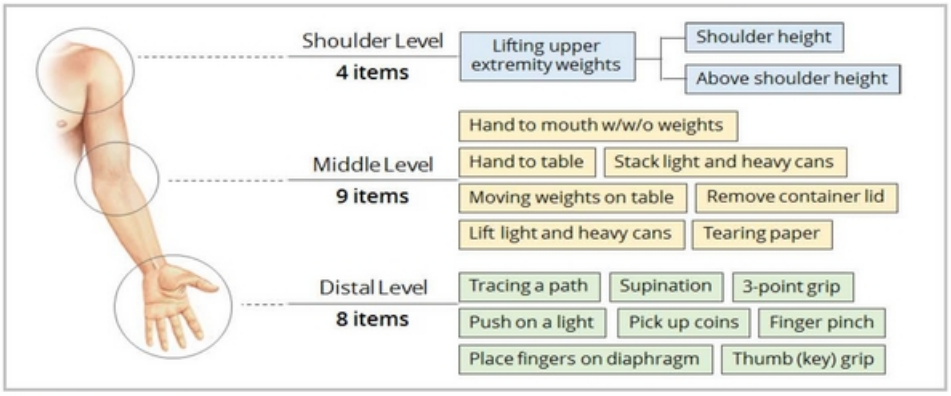


Capricor's Addressable Market



Primary Efficacy Endpoint

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



PUL v.2.0:

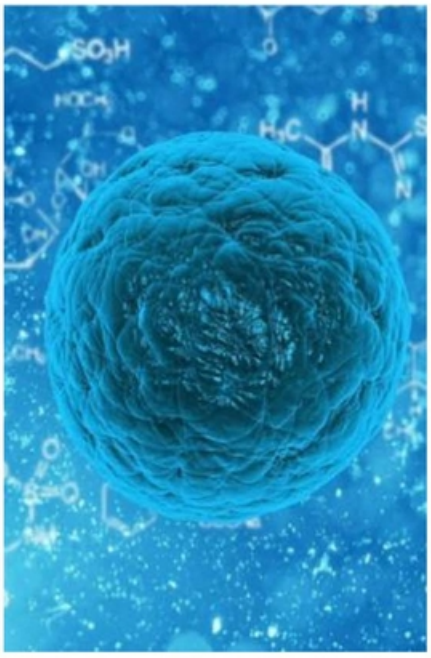
- 3-point response scale - more robust and reproducible than v1.2
- Compensatory strategies allowed to achieve tasks (not allowed in v1.2)
- v2.0: better able to detect change at 12 months at all levels of ability*

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

Capricor's CAP-1002 Technology

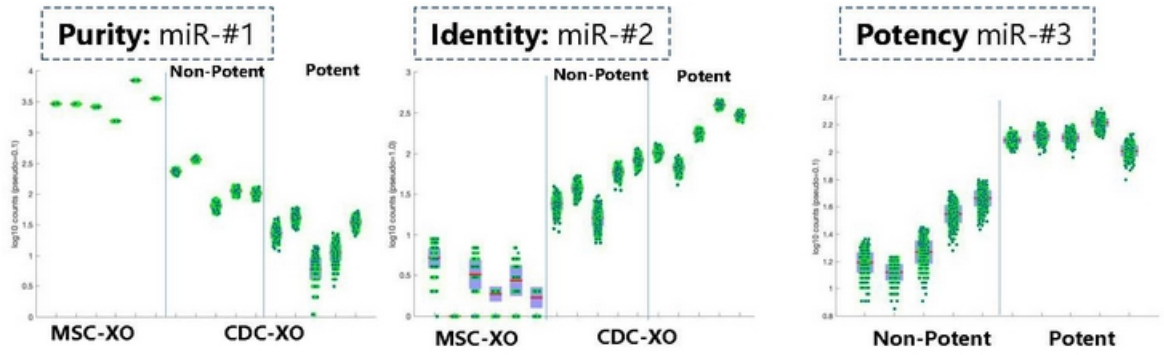
CAP-1002 is a biologic consisting of allogeneic cardiosphere-derived cells (CDCs)

- 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**



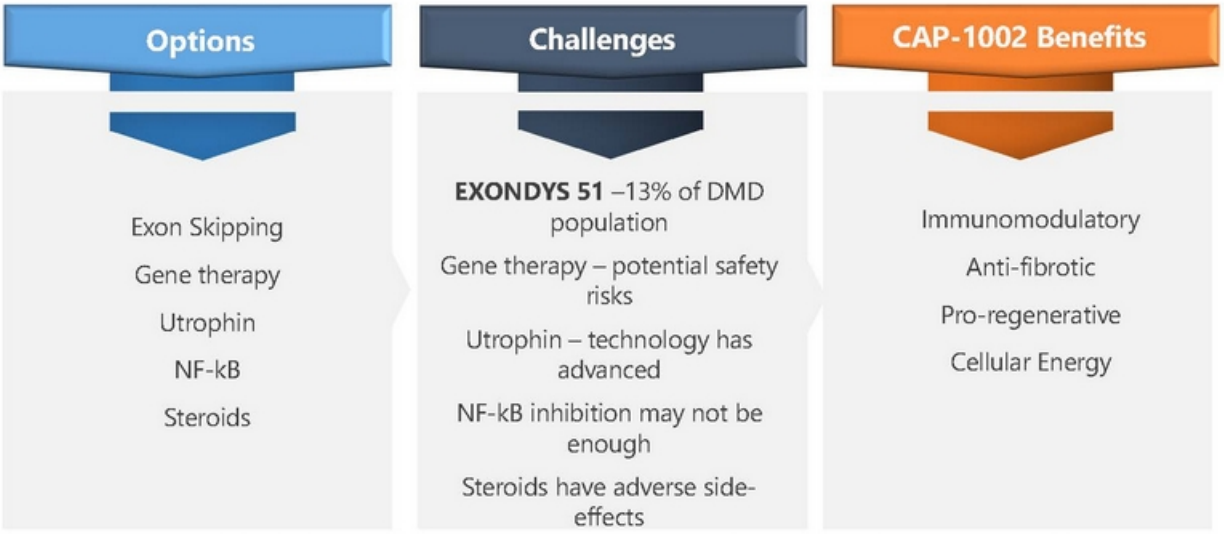
Capricor Therapeutics

CAP-1002: Supporting the Mechanism of Action



CAP-1002's purity, identity and potency can be defined by specific miRNAs

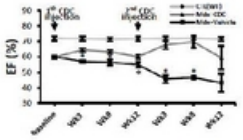
Treatment Options for DMD are Limited



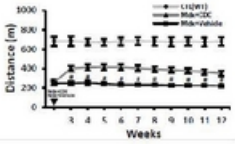
We believe CAP-1002 may be used synergistically with other therapeutics aimed to treat DMD

Trajectory of CDCs in DMD (Preclinical Data)

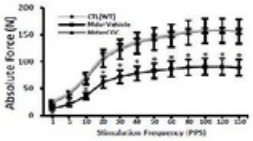
- **Hypothesis:** CDCs to treat **cardiomyopathy**
- Left ventricular ejection fraction markedly improved vs. control
  - *P*<0.05 at all timepoints through 12 weeks of follow-up*

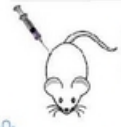


- **Hypothesis:** CDCs to treat **skeletal muscle function**
- Exercise performance approximately doubled vs. control
  - *P*<0.005 at all timepoints through 12 weeks of follow-up*

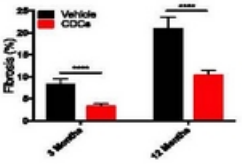


- **Hypothesis:** CDCs to treat **soleus muscle**
- Twitch force, tetanic force, and fibrosis in soleus (slow-twitch) and extensor digitorum longus (fast-twitch) muscles significantly improved vs. control
  - *P*<0.05; muscles isolated at three weeks post-treatment*





- **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



Capricor Therapeutics

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


CAP-1002:
DMD HOPE-Duchenne
TARGET: DMD-related cardiomyopathy
HYPOTHESIS: CAP-1002 may also treat skeletal muscle

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:

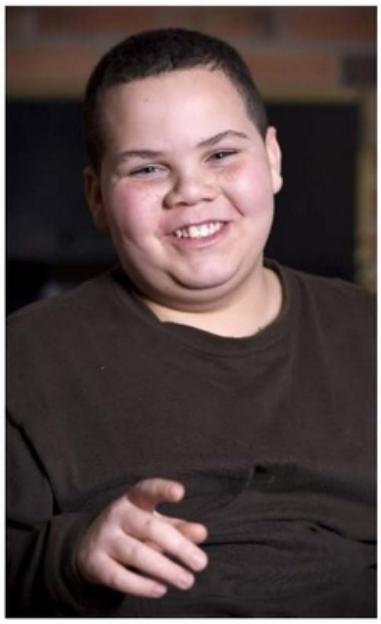
- RMAT provides benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate
- Eligibility for rolling review and priority review

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

Capricor Therapeutics

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


HOPE-2:
Phase II Clinical Study

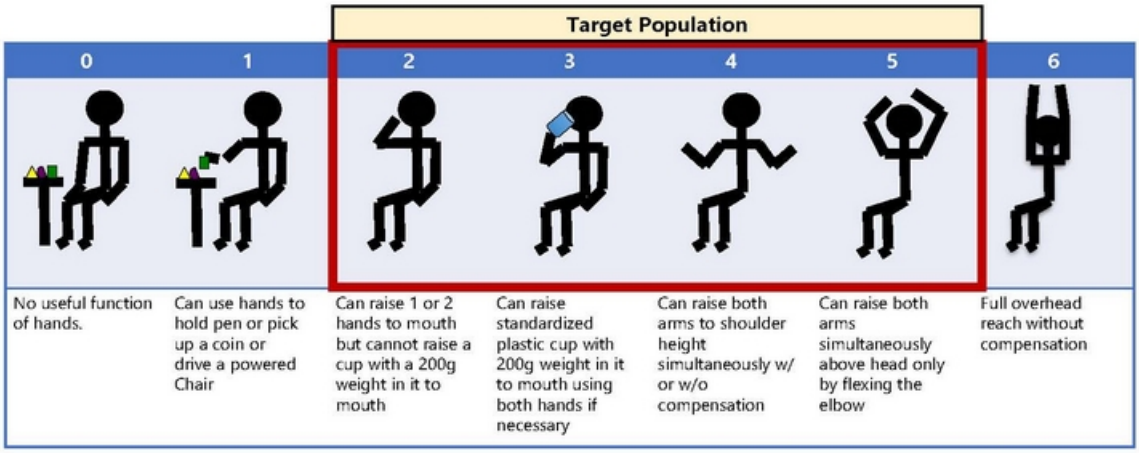
HOPE-2 Clinical Trial

- **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

Capricor Therapeutics

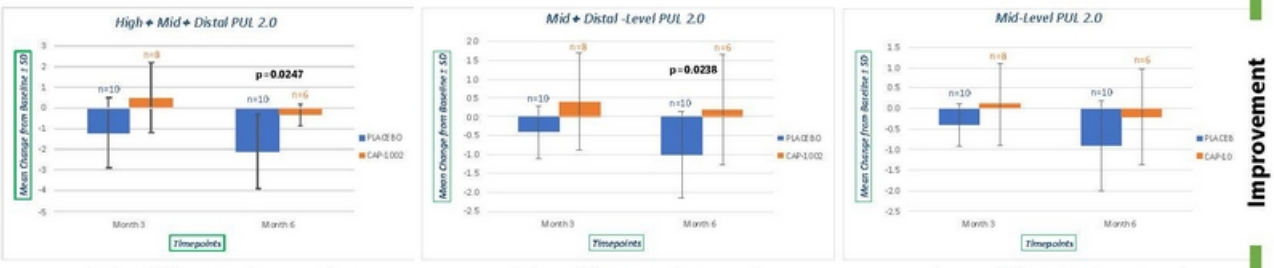
https://www.clinicaltrials.gov/ct2/show/study/NCT03406780.

Performance of the Upper Limb (Entry Items)



Improvements in PUL 2.0

CAP-1002 vs. Placebo at 6-months



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

Δ 1.2 difference in CAP-1002 vs. placebo at 6-months

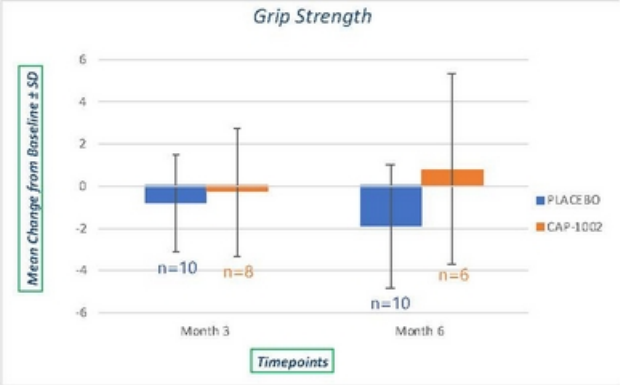
Δ 0.7 difference in CAP-1002 vs. placebo at 6-months

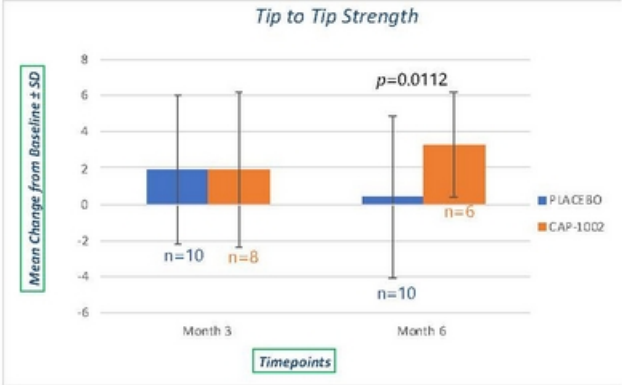
- As shown by these data, preservation of function is maintained for at least 6 months.
- CAP-1002 may offer a treatment for a *primarily non-ambulant DMD population for whom no other options currently exist.*
- A 1.0 improvement in PUL may suggest clinical relevance

Capricor Therapeutics

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 Grip Strength and Tip-to-Tip Pinch Strength Was observed at 6 months





Capricor Therapeutics

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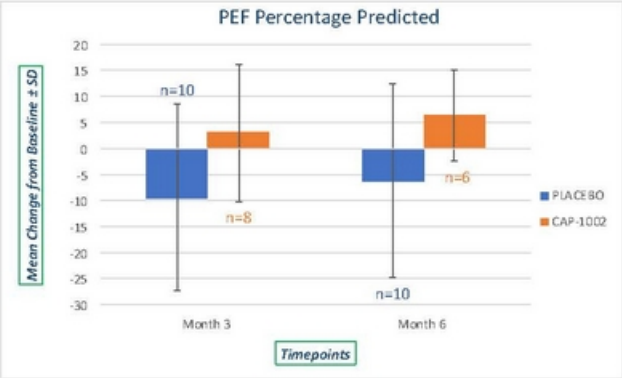
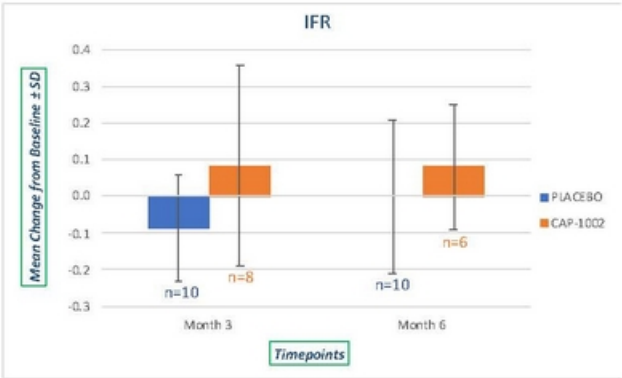
Improvements in Pulmonary Function Observed





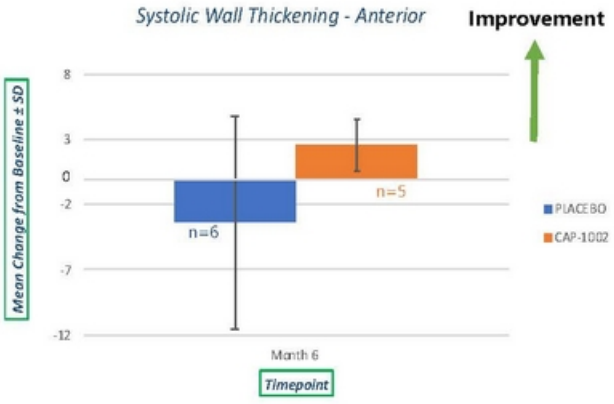
- Pulmonary endpoints are intriguing:
  - More patients and longer follow-up may potentially lead to more robust findings
- Data suggests respiratory muscle function is improved in CAP-1002 vs. placebo
- No changes in FVC observed

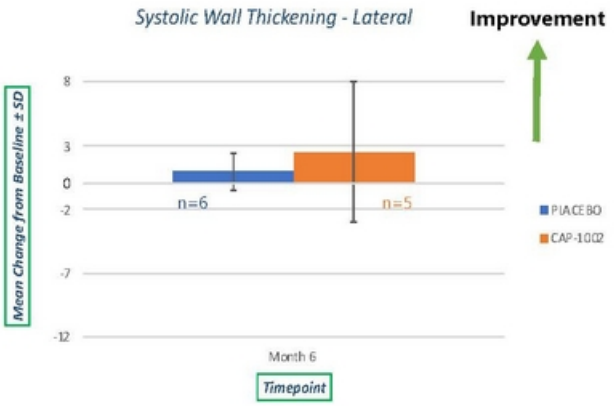
Capricor Therapeutics

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



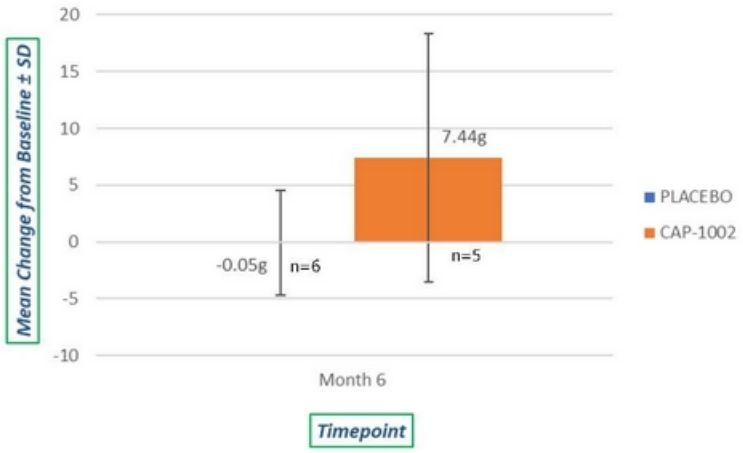


Similar improvements as shown in HOPE-Duchenne

Capricor Therapeutics

*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.

Increase in Left Ventricle Myocardium Mass



Capricor Therapeutics

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.

HOPE-2 Interim Analysis Safety Results

A total of 57 infusions were performed in HOPE-2 as of July 31, 2019

With the exception of two serious adverse events[1,2] in the form of immediate allergic reactions, no early safety signals were identified

To reduce the risk of such events, Capricor initiated a commonly used pre-medication regimen including oral steroids and antihistamines

Since initiation of the pre-treatment regimen, approximately 40 infusions of CAP-1002 or placebo have been administered with only one serious adverse event[1] reported that required an overnight observation of the patient

Capricor Therapeutics

[1]Assessed as related to either CAP-1002 or placebo administration
[2]One SAE each in HOPE-2 and HOPE-OLE

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

- Phase III clinical trial in planning stages (est. 70 pts.)
- Continue discussions with FDA regarding path forward
- 12-month data expected in Q2-2020 from HOPE-2
- Plan to announce further updates as they become available

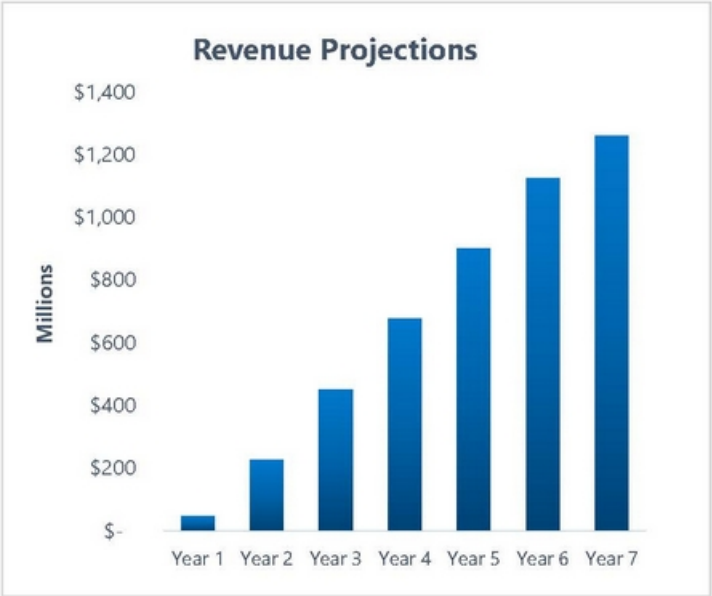
DMD Market Statistics and Revenue Projections

Patient Population

- Est. US DMD population: 15,000
- Est. non-ambulant patient population*: 50%
- Est. addressable patients*: 7,500

Estimated Target Price*

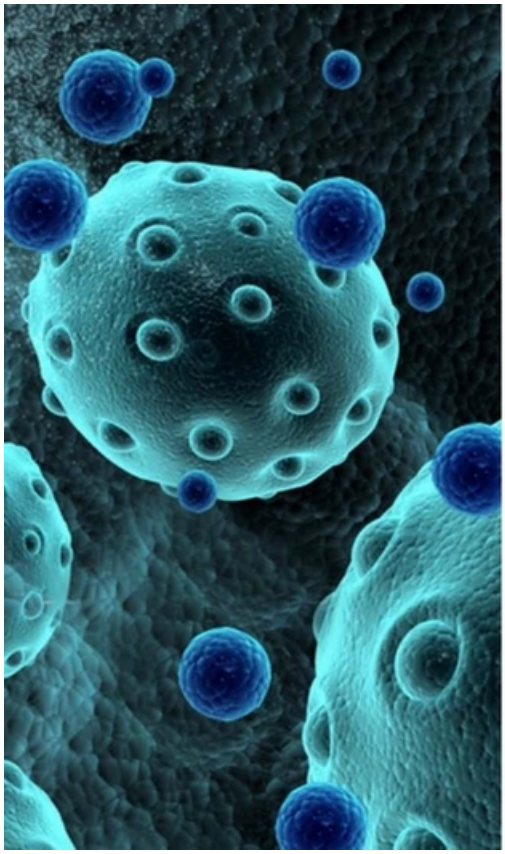
- CAP-1002 Target Price: $150,000 per dose
  - Current dosing estimate: 4 doses per year = $600,000



Capricor Therapeutics *Based on internal projections and estimates.

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)

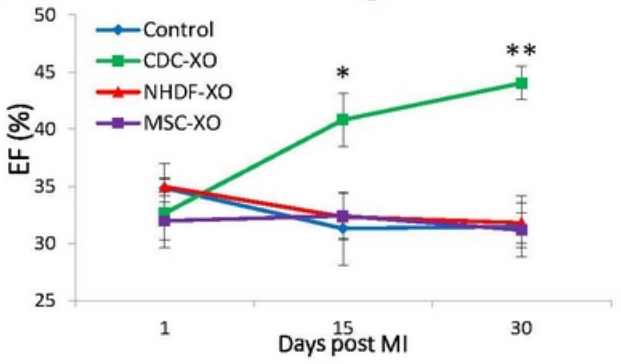


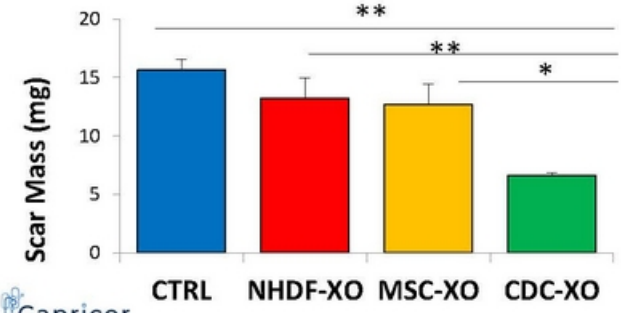
Exosomes – "Nature's Communication System"

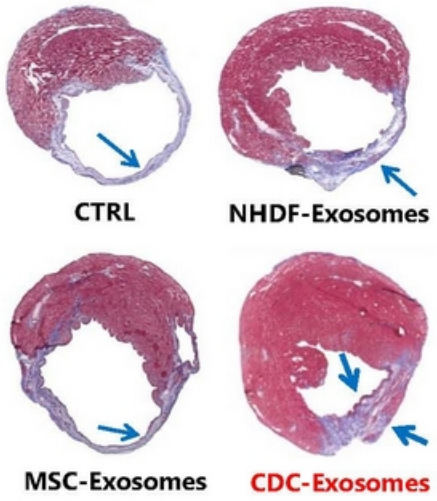
- Extracellular vesicles - term for cell-derived vesicles, includes exosomes and microvesicles

- Nanometer-sized lipid-bilayer vesicles (30-120nm)
- 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)

Exosomes Recapitulate CDC Therapeutic Effect





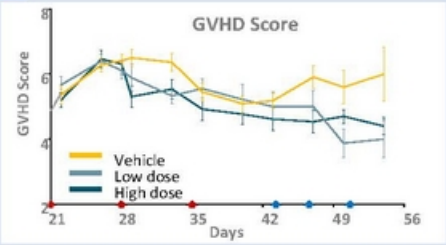


- CDC-XOs Improve Cardiac Function and Preserve Muscle Mass

Ibrahim et al, Stem Cell Reports, 2014.

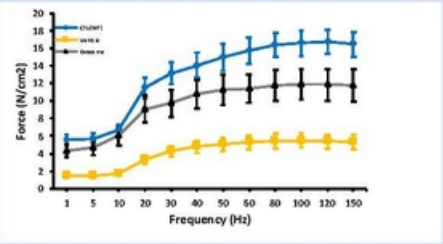
Exosomes: POC Established in Multiple Indications

GVHD



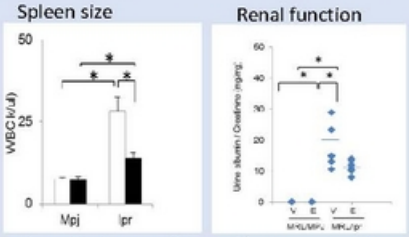
XOs reduce GVHD score and increase weight and survival

DUCHENNE MUSCULAR DYSTROPHY*



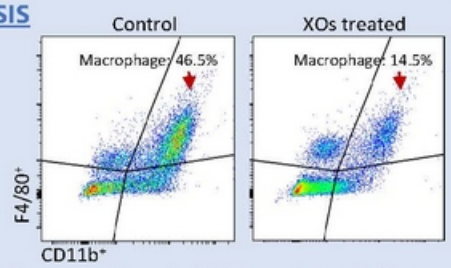
XOs improve muscle activity and exercise capability in DMD

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

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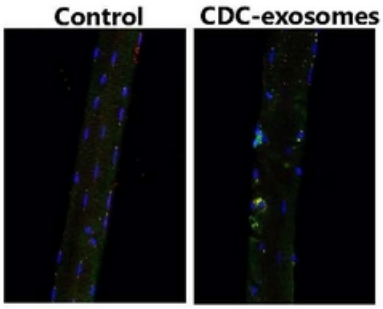
Unpublished results

*Aminzadeh et al, Stem Cell Reports 2018.

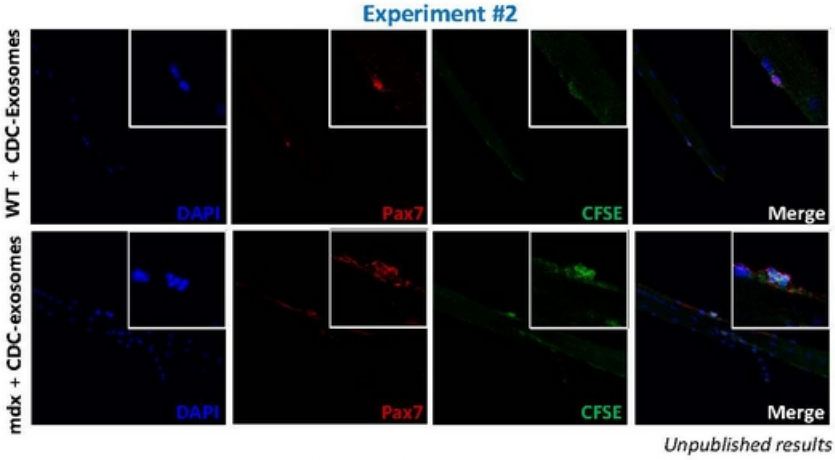
CDC-Exosomes Demonstrate Preferential Uptake by Satellite Cells

- Myofibers isolated from WT or *mdx*^{4cv} mice were incubated O/N with CFSE labeled exosomes from CDCs
- Fibers were stained for ATPB, a mitochondria marker (Exp #1) or for Pax7, satellite cells (Exp #2)

Experiment #1



Experiment #2



Unpublished results

- CDC-exosomes demonstrate preferential uptake by satellite cells on associated-myofibers
- *mdx*^{4cv} satellite cells showed a higher CDC-exosomes uptake when compared with WT satellite cells

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Investment Highlights

Innovative, Proprietary Therapeutic Platforms

- First-in-class biologics with potential to improve cardiac and skeletal muscle
- Product candidates based on cells and extracellular vesicles (exosomes)

Advanced Pipeline

- HOPE-2, Phase II trial in DMD ongoing
- Commercial manufacturing process in development
- Positive proof-of-concept clinical data in DMD

Strong Scientific Foundation & Leadership Team

- Translational approach built upon the research of leading academic scientists
- Technology initially developed at Johns Hopkins University
- Management has deep domain expertise
- Extensive IP portfolio for core technologies

Capital Efficiency

- Raised over $50M to date in equity
- Successful record of securing non-dilutive funding, over $45M to date

Regulatory Pathway

- Granted orphan drug and rare pediatric designations
- Granted RMAT designation

Senior Leadership Team

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

Under her direction, Capricor has secured over $45 million in non-dilutive funding and over $50 million in equity capital. Earlier in her career, Dr. Marbán was with Exolgen, Inc. where she was responsible for business development and operations supervising the development of gene therapy products in a joint development agreement with Genzyme Corp. Dr. Marbán began her career at the Cleveland Clinic Foundation working on the biophysical properties of cardiac musde. That work continued when she moved to a postdoctoral fellowship at Johns Hopkins University. While at JHU, she advanced to the rank of Research Assistant Professor in the Department of Pediatrics, continuing her work on the mechanism of contractile dysfunction in heart failure. Dr. Marbán earned a Ph.D. from Case Western Reserve University in cardiac physiology.

Luis Rodriguez-Borlado, Ph.D.
Vice President of Regenerative Therapies

Prior to joining Capricor, Dr. Borlado developed a scientific career in academic laboratories in Spain and in The Netherlands studying signal transduction pathways involved in cell transformation and DNA replication. Dr. R-Borlado has a Ph.D in Biochemistry and Molecular Biology from the University Autónoma of Madrid with the study of molecular bases of immune system development.

AJ Bergmann, MBA
Chief Financial Officer

Mr. Bergmann joined Capricor in 2011 and coordinated the Company's reverse merger and financings yielding over $50 million to date. Prior to joining Capricor, Mr. Bergmann had experience in accounting, finance and operations management of various companies. Mr. Bergmann graduated from Providence College and has a M.B.A. from the University of Southern California's Marshall School of Business.

Karen Krasney, JD
EVP & General Counsel

Ms. Krasney's career spans over 40 years and has been focused on 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 that develops, manufactures and sells medical devices for cardiology applications. 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.

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. He led the clinical operations team for hemophilia products at Baxter Bioscience and in this role contributed to the US and EU marketing authorization of ADVATE, now the world's most prescribed Factor VIII-replacement therapy and a cornerstone of Baxter's multibillion-dollar hemophilia franchise. He also held positions at two start-up biotech companies. At Novalar, 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.

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