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)

December 16, 2019

CAPRICOR THERAPEUTICS, INC.

(Exact name of Registrant as Specified in its Charter)

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

8840 Wilshire Blvd., 2nd Floor, Beverly Hills, CA	**90211**
(Address of principal executive offices)	**(Zip Code)**

(310) 358-3200
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 December 16, 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 December 16, 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: December 16, 2019

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

Exhibit 99.1


Capricor
Therapeutics™
Corporate & Investor Presentation
December 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-1 as filed with the Securities and Exchange Commission on December 5, 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.

Developing Cell and Exosome-Based Therapies for Rare Diseases

RARE DISEASE FOCUS

- **Preclinical Stage:** Exosome platform technology in active development
- **Advanced Clinical Program:** Cell Therapy (CAP-1002) for Duchenne muscular dystrophy (DMD)
- 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

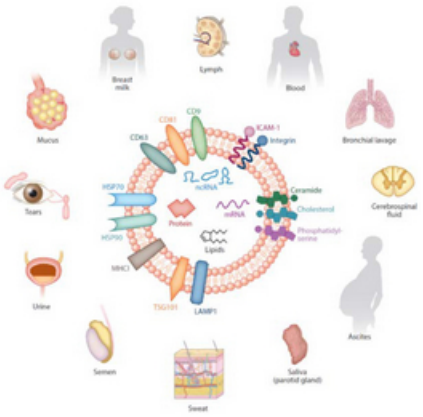
- Potential near-term development milestones
- External collaborations: US Army, US Department of Defense, Cedars-Sinai Medical Center

FINANCIAL

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

The Field of Exosomes: Increasing Market Opportunity

- **Global market size projected to grow at high rates**
- **Increasing financing activity among private companies:**
  - Over $300M raised to date in several private companies
- **M&A activity continuing to increase:**
  - **Delivery**
    - Roche collaboration with PureTech Health for up to $1.0B
      - Oral administration of antisense oligonucleotide using milk-exosomes
  - **Oncology**
    - Bio-Techne acquired Exosome Dx for up to $575M
      - Cancer detection using liquid biopsy
    - Jazz and Codiak – Strategic Collaboration with $56M upfront and additional milestone payments
  - **Manufacturing**:
    - Lonza acquired HansaBioMed Life Sciences
      - Acquisition of exosomes manufacturer
- **Therapeutics is still under-represented in deal flow**



Delivery of Gene-based Therapies to Treat Disease

Problems

- **Gene therapy using viral delivery (AAV)**
  - Immune response
- **Delivery of RNAs**
  - Uptake to render biologic relevance
  - Therapeutic development very slow
- **Synthetic nanoparticles have not been successful as delivery vehicles**

Possible Solutions

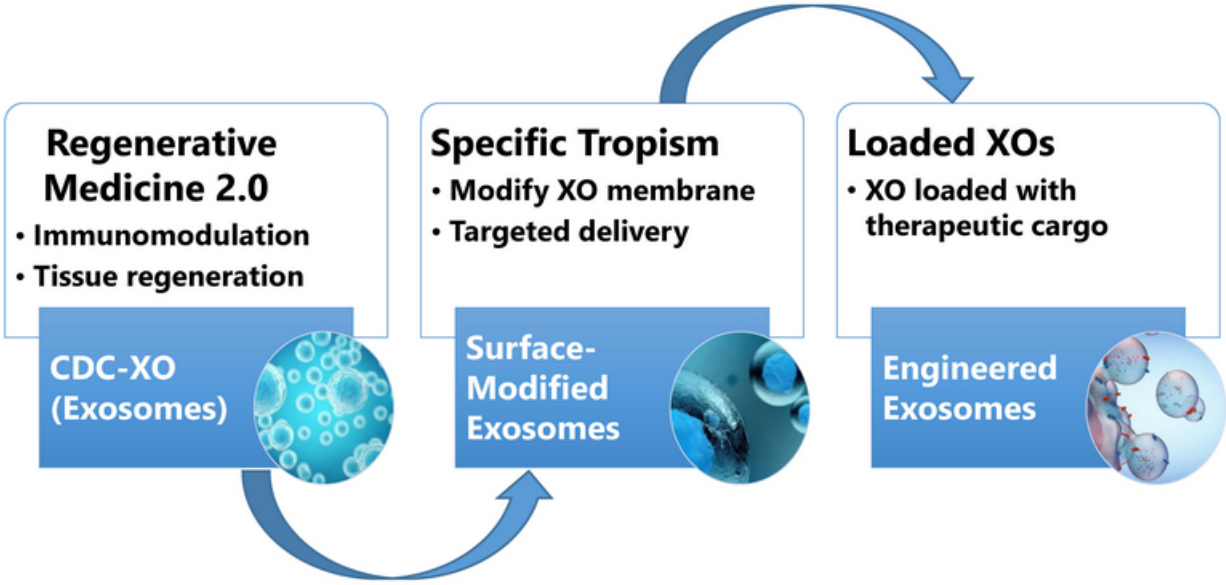
Exosomes:

- 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?

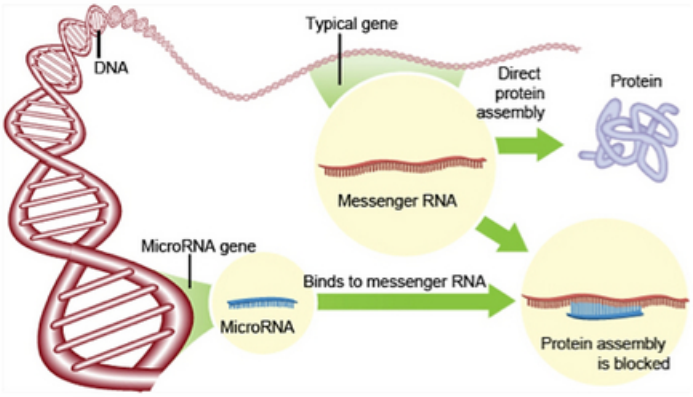
- Engineering exosomes loaded with bioactive molecules potentially will:
  - increase potency
  - reduce variability
  - eventually help during product development
- Different modifications are now under evaluation:
  - Cargo
    - Nucleic acids (mRNA or miRNAs)
  - Membrane modifications
    - Tropism change
    - Coating with immunomodulatory signals (PD-L1)
- **Preliminary data demonstrates that is feasible to transfer mRNAs and miRNAs loaded into exosomes to target cells**

Targeted Exosome Platform Allows for Broad Applicability



Loading miRNAs into Exosomes

- MicroRNAs (miRNAs) are a class of small, noncoding RNAs involved in regulation of gene expression
- Loading XOs with miRNAs may allow for tunable regulation of gene expression in target cells



Capricor's Exosome Product Pipeline

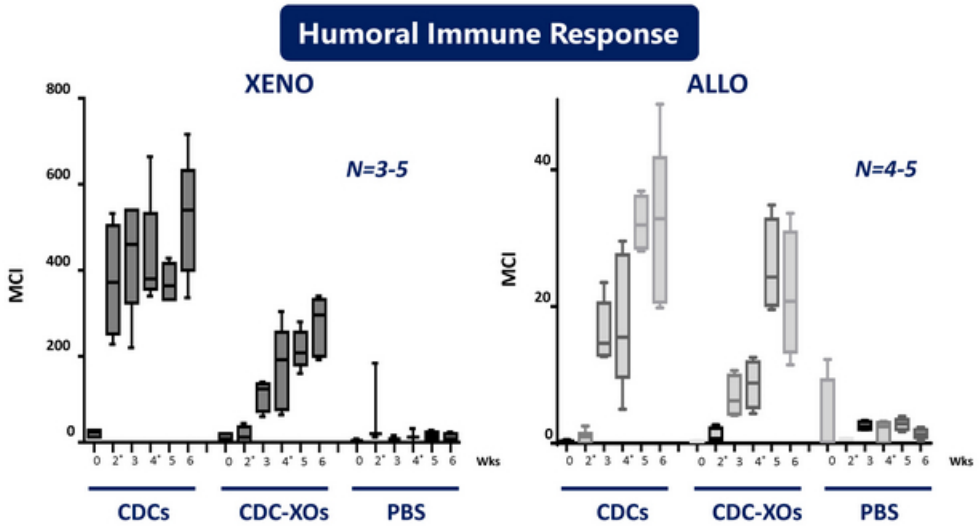
Candidate	Target Indications	Development Phase	Status
EC-XO (expanded culture XOs)	Inflammatory diseases		Target IND submission in 2020
Engineered XOs Small RNA Loading (siRNAs, miRs, sgRNAs)	Evaluating		Target IND submission
Engineered XOs (Membrane modifications)	Inflammatory diseases		Target IND submission
Engineered XOs (mRNA for gene editing)	Monogenic diseases		Target IND submission

Development Phase: Discovery Preclinical Phase I

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


EC-XOs:
Mechanism
of Action
Immunomodulatory
Anti-inflammatory
Anti-fibrotic
Anti-apoptotic
Angiogenic
Regenerative
10

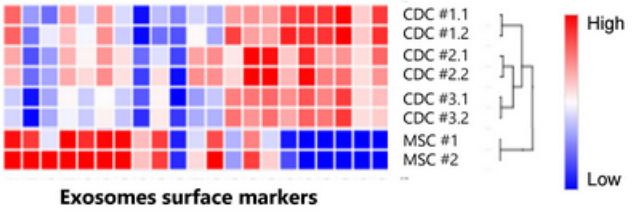
CDC-XOs Immunogenicity



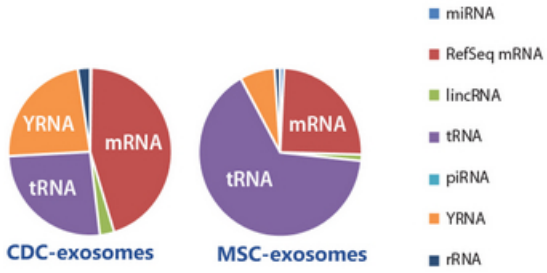
- Allogeneic CDCs have a low immunogenicity (20 times lower than xeno-transplant)
- In pre-clinical studies, CDC-XOs show a reduced immunogenicity when compared to CDCs, allowing multiple administration without significant immune response

Comparison of CDC-XO vs MSC-XOs Reveal Different Cargo

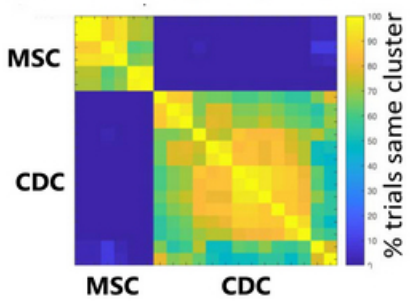
Exosomes surface expression profile (MACSplex)



Exosomes RNA-Seq Read counts (type)



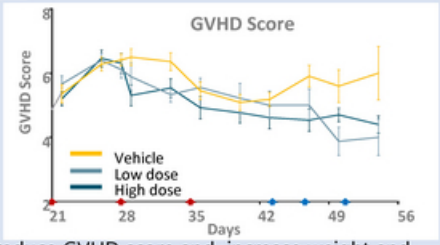
miRNA clustering analysis (RNA-Seq)



- CDC-XOs and MSC-XOs have a different expression phenotype in their surface, different RNA cargo and different miRNA profile

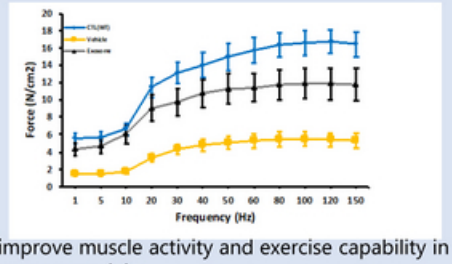
Exosomes: POC Established in Multiple Indications

GVHD



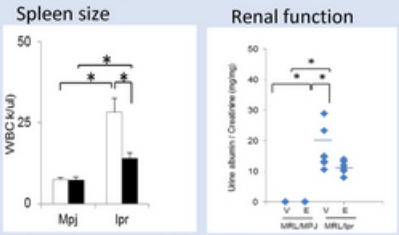
XOs reduce GVHD score and increase weight and survival in mouse model

DUCHENNE MUSCULAR DYSTROPHY*



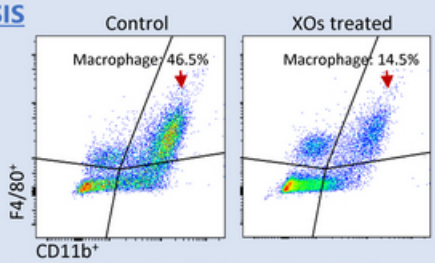
XOs improve muscle activity and exercise capability in mdx-mouse model

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

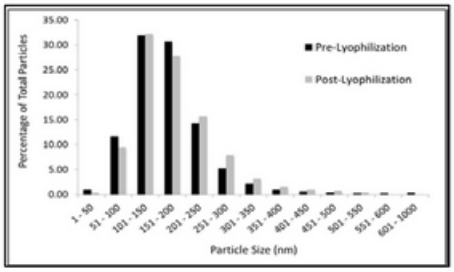
Capricor

Unpublished results

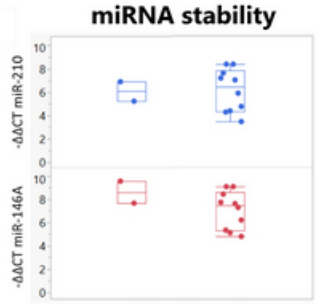
*Aminzadeh et al, Stem Cell Reports 2018.

Exosomes Lyophilization

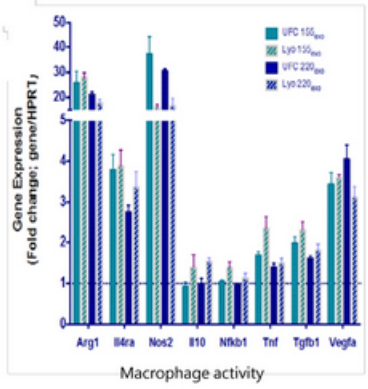
Particle size



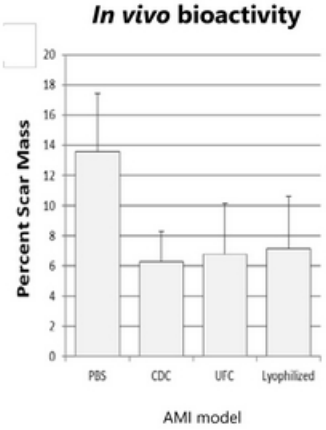
miRNA stability



***In vitro* bioactivity**



***In vivo* bioactivity**



Lyophilized CDC-XO show :

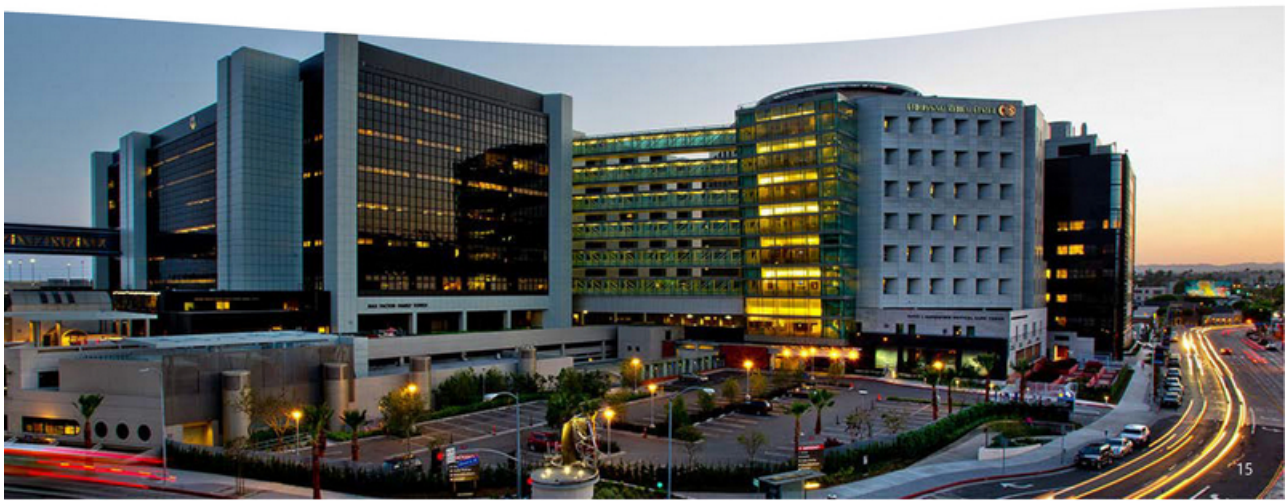
- Good conservation of miRs 146a and 210
- Similar particle size and concentration post lyophilization
- Similar results in-vitro and in-vivo to UFC product

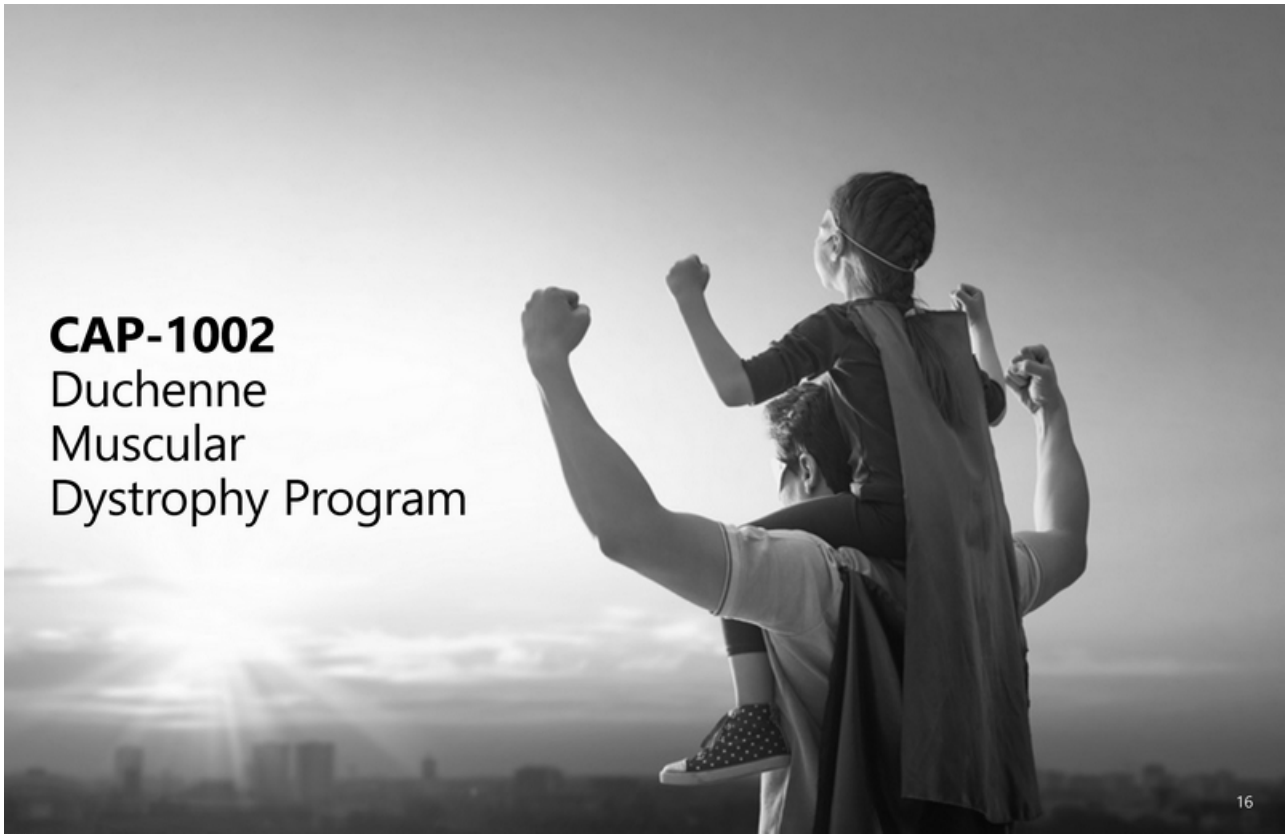
Capricor Therapeutics

Unpublished results

World-Class Facilities and Infrastructure

- Capricor's Research, Development and Manufacturing facilities are located in the Cedars-Sinai Medical Center in Los Angeles, CA
- Capricor has access to core research facilities




CAP-1002
Duchenne
Muscular
Dystrophy Program
16

Conclusions and Future Direction – CAP-1002 for DMD

Conclusions

- 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 pre-FDA planning stages (est. 70 pts.)
- 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
- Pursue partnership opportunities

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 Excigen, 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 muscle. 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

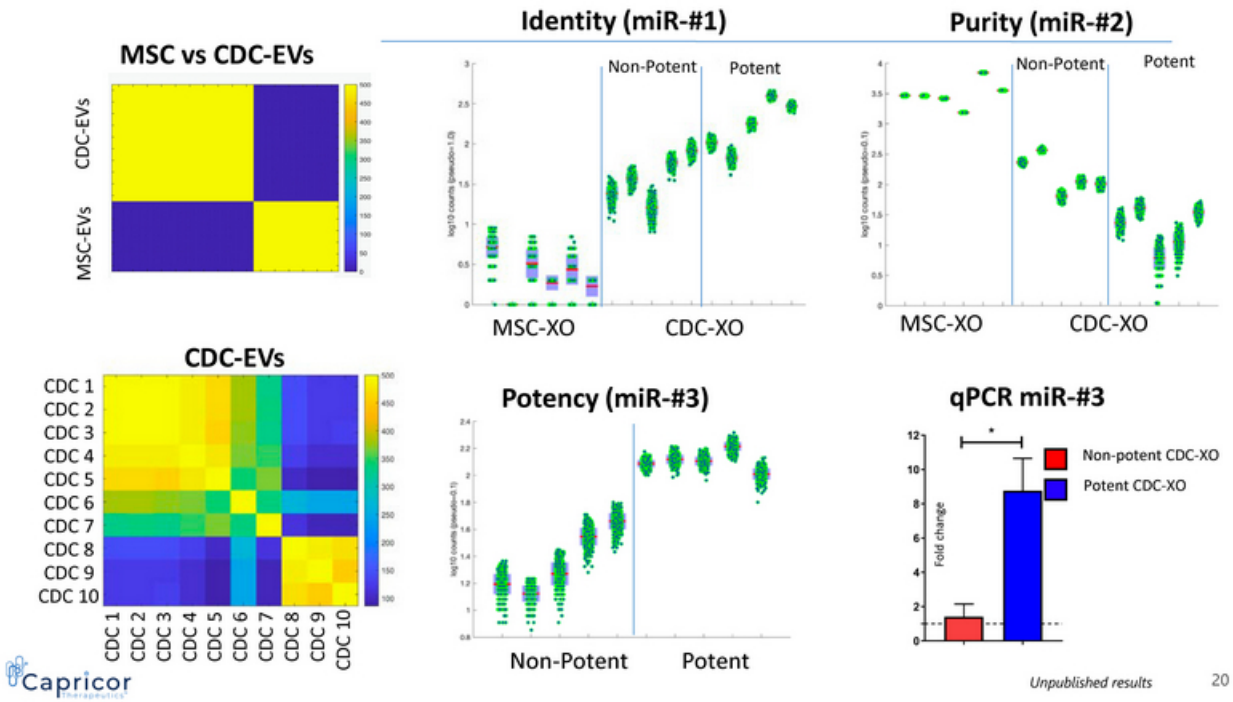
Ms. Krasney's career spans over 40 years and has been focused on domestic and international corporate and business law, as well as litigation. Ms. Krasney served as legal counsel of Biosensors International Group Ltd., a multinational medical device company that develops, manufactures and sells medical 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

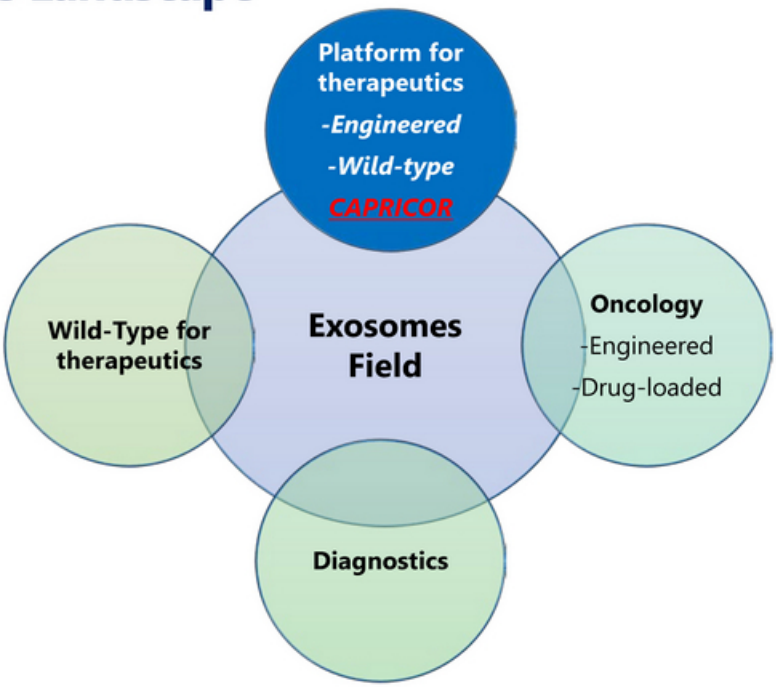
Dr. Rogy has over 25 years of clinical operations and development experience at companies including Baxter Bioscience, The Medicines Company and Maxim Pharmaceuticals. He led the clinical operations team for hemophilia products at Baxter Bioscience and in this role contributed to the US and EU marketing 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.

Appendices

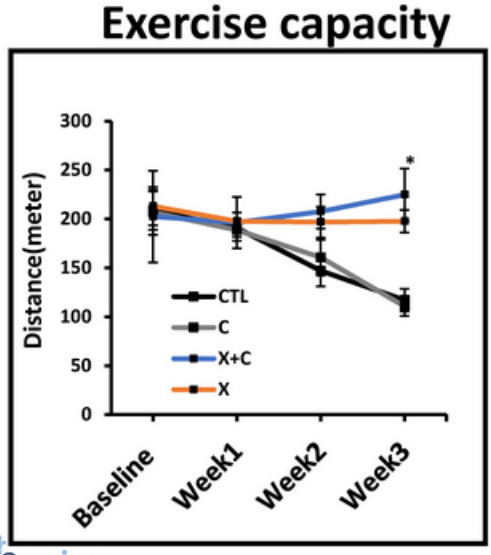
CDC-XOs miR Profile: Identity, Purity & Potency

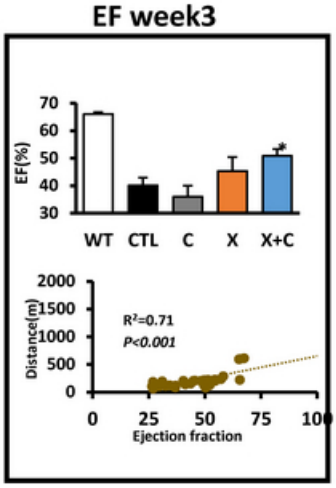


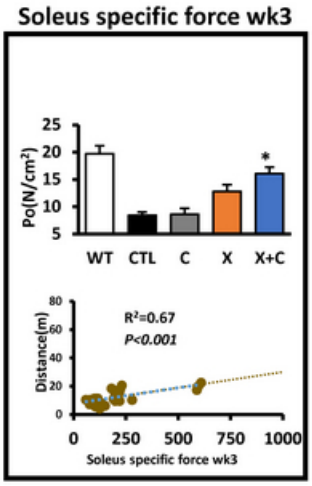
Exosomes Landscape



Functional capacity after every-other-day oral exosome delivery in MDX mice*



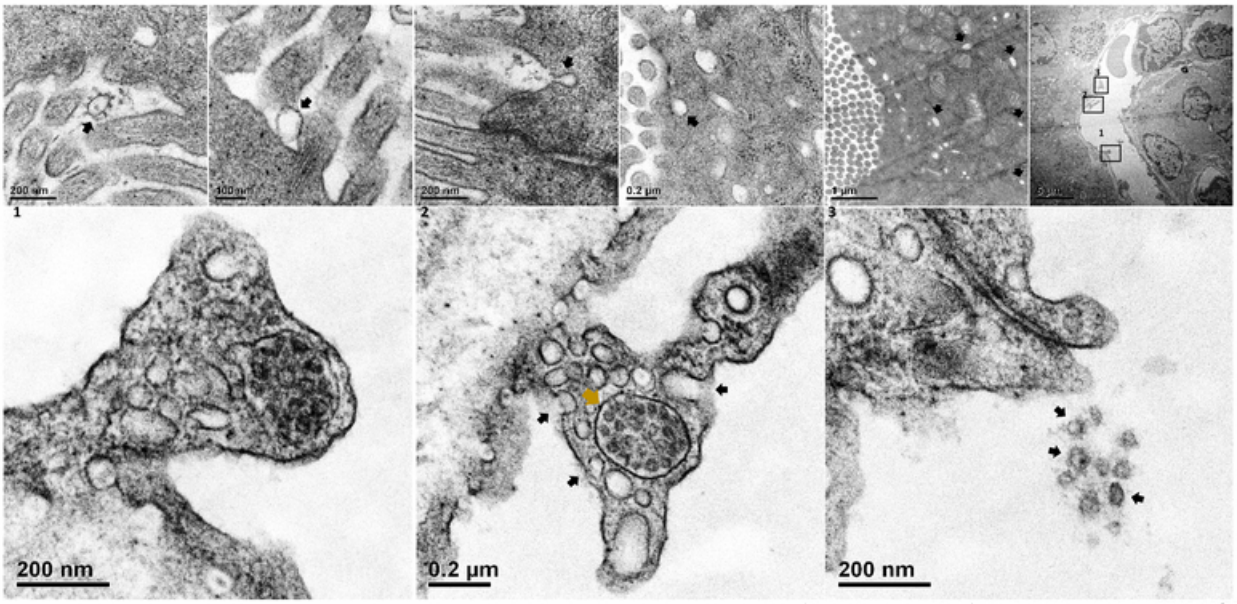




Capricor Therapeutics

*Unpublished data, Marbán lab, Smidt Heart Institute, CSMC, 12/2019

CDC-exosomes are taken up via endocytosis in duodenal epithelial cells and released into blood after fusion of their membrane or MVB membrane*



*Unpublished data, Marbán lab, Smidt Heart Institute, CSMC, 12/2019

Capricor