

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**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 10, 2015**

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**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)

**90211**  
(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))
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**Item 7.01 Regulation FD Disclosure.**

On December 10, 2015, Capricor Therapeutics, Inc., a Delaware corporation (the “Company”), posted a Corporate Presentation to provide an update of the Company’s current business and products, which is located in the “Investors” section of the Company’s website at [www.capricor.com](http://www.capricor.com). 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 this Form 8-K (including Exhibit 99.1 attached hereto) 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. Corporate Presentation, dated December 2015.

**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 10, 2015

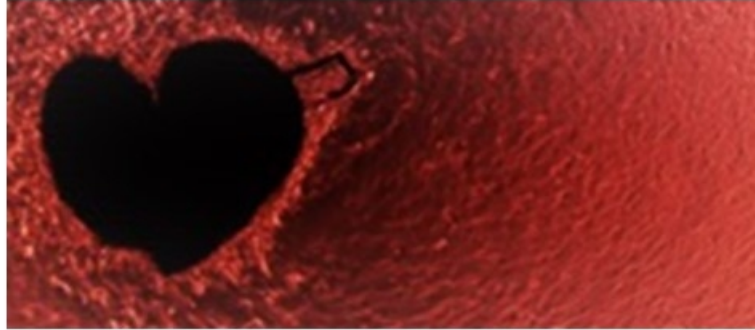
By: /s/ Linda Marbán, Ph.D.  
Linda Marbán, Ph.D.  
Chief Executive Officer

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Capricor  
Therapeutics™

*Transformative Therapies from Bench to Bedside*



December 2015

**NASDAQ: CAPR**

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# Forward-Looking Statements

This presentation contains forward-looking statements and information that are based on the beliefs of the management of Capricor Therapeutics, Inc. (Capricor) as well as assumptions made by and information currently available to Capricor. All statements other than statements of historical fact included in this presentation are forward-looking statements, including but not limited to statements identified by the words "anticipates," "believes," "estimates," and "expects" and similar expressions. Such forward-looking statements also include any expectation of or dates for commencement of clinical trials, IND filings, similar plans or projections and other matters that do not relate strictly to historical facts. These statements reflect Capricor's current views with respect to future events, based on what we believe are reasonable assumptions; however, the statements are subject to a number of risks, uncertainties and assumptions. 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 are set forth in Capricor's Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the Securities and Exchange Commission on March 16, 2015, in its Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on September 28, 2015, and in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, as filed with the Securities and Exchange Commission on November 13, 2015. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those in the forward-looking statements. Further, Capricor's management does not intend to update these forward-looking statements and information after the date of this presentation.



# Capricor **Financial** Highlights

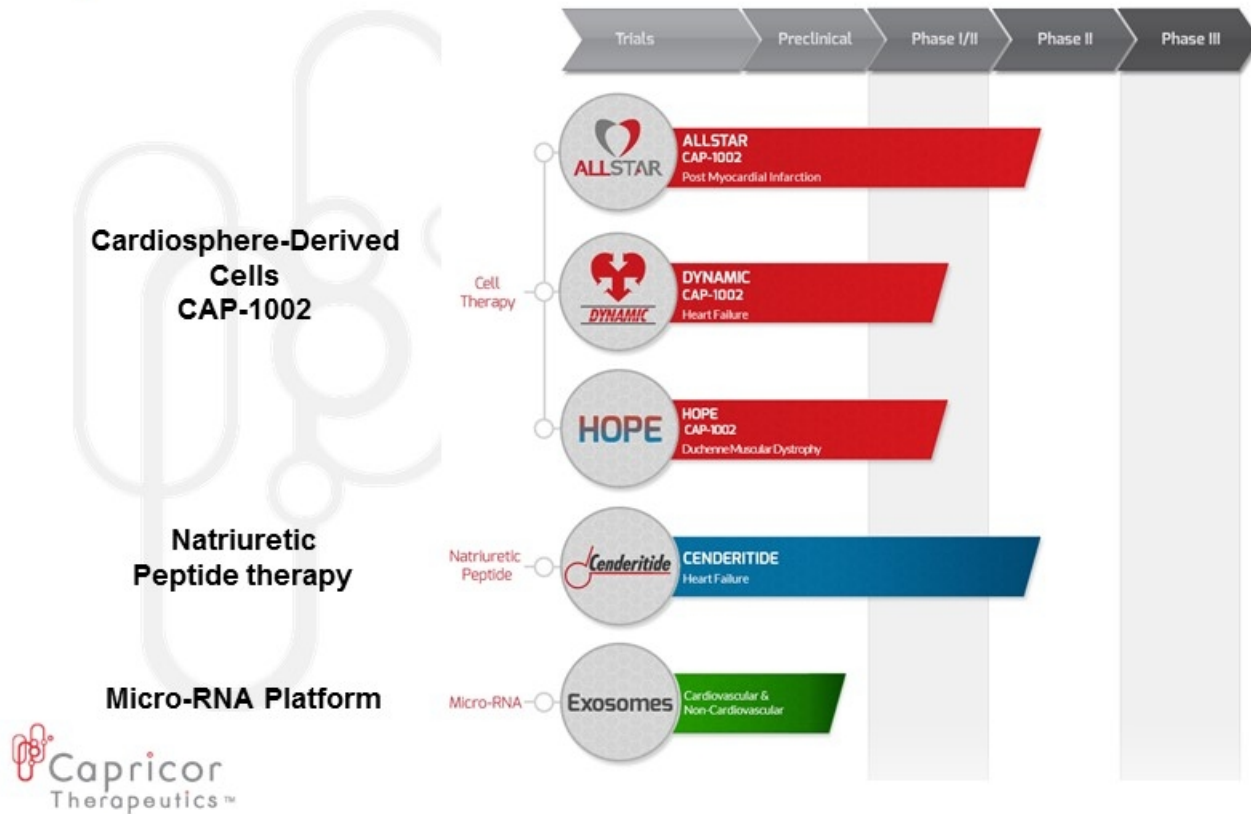
- Capricor, Inc. founded in 2005 (Baltimore, MD; JHU spinoff)
- Completed reverse merger with Nile Therapeutics in November 2013
- Uplisted to NASDAQ in March 2015
- Total Cash as of Sept. 30, 2015: \$17.2M (current cash out: ~Q3 2016)
- Non-dilutive capital funding to date: \$39.5M
- Shares Outstanding: 16.3M
- Headquarters: Los Angeles, CA



# Capricor Opportunity

- Pioneer in Cardiac-Derived Cell (CDC) Technology and CDC-Derived Exosomes
- Solid IP position in CDC and Exosome Technology
- Diversified platform and therapeutic pipeline
- Orphan indication: DMD-associated cardiomyopathy program
- Meaningful clinical milestones over the next 12 months
- License Option and Development Collaboration with Johnson and Johnson

# Capricor's Platform & Therapeutic Pipeline

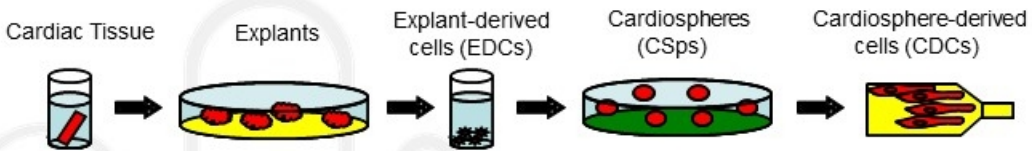




# Cardiosphere-Derived Cells (CDCs): Adult Heart disease



# Cell Therapy Platform: CDCs (CAP-1002)



Features	Cardiosphere-Derived Cells (CDCs)
Cell Type	Human cardiac derived cell
Characteristics	Unique panel of cellular markers and secreted factors
Mechanism of Action	<p>Cells Function as a Local Drug Delivery System (paracrine):</p> <ul style="list-style-type: none"> <li>- Prevent cardiomyocyte apoptosis (programmed cell death)</li> <li>- Promote cardiomyocyte proliferation and angiogenesis (cell growth and blood vessel formation)</li> <li>- Attract endogenous stem cells</li> <li>- Anti-fibrotic (anti-scarring)</li> </ul>
IP	CDCs are exclusively licensed from Johns Hopkins University, Cedars-Sinai Medical Center and The University of Rome

# CADUCEUS: Proof of Concept First-in-Man Data

## THE LANCET

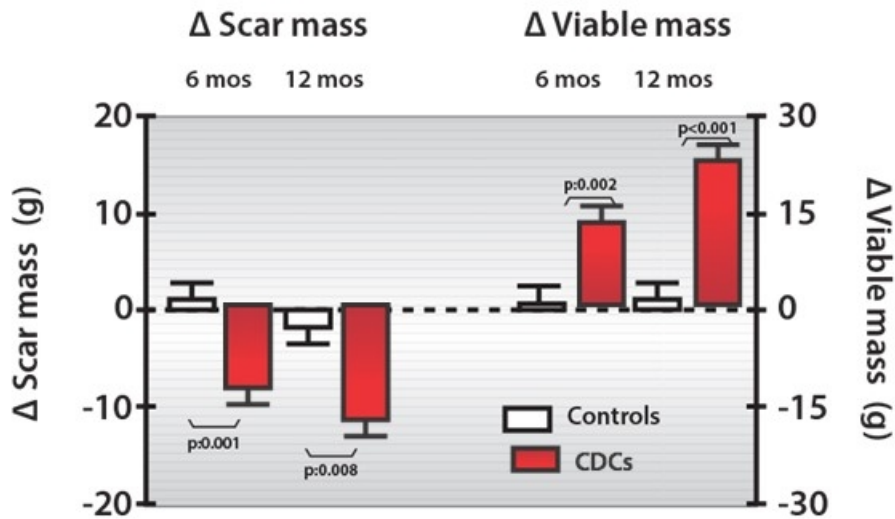
Intracoronary cardiosphere-derived cells for heart  
regeneration after myocardial infarction (CADUCEUS):  
a prospective, randomised phase 1 trial

Raj R Mulkar, Rachel R Smith, Ke Cheng, Konstantinos Malliaras, Louise E J Thomson, Daniel Berman, Lawrence S C Czei, Linda Marbán,  
Adam Mendizabal, Peter V Johnston, Stuart D Russell, Karl H Scholer, Albert C Landa, Gary Gerstenblith, Eduardo Marbán

Lancet, 2012, 21(6): 1121-1135.

- Intracoronary delivery of autologous CDCs - 25M cells
- Patients with reduced ejection fraction following MI
- 25 patients (17 CDCs, 8 Controls)
- Sponsored by Cedars-Sinai Medical Center
- **Results:** CDCs reduced the amount of scar in the heart caused by a heart attack; therefore, smaller scars may lead to better outcomes

# CADUCEUS: CDC Therapy Reduced Scar Size & Increased Healthy Heart Muscle

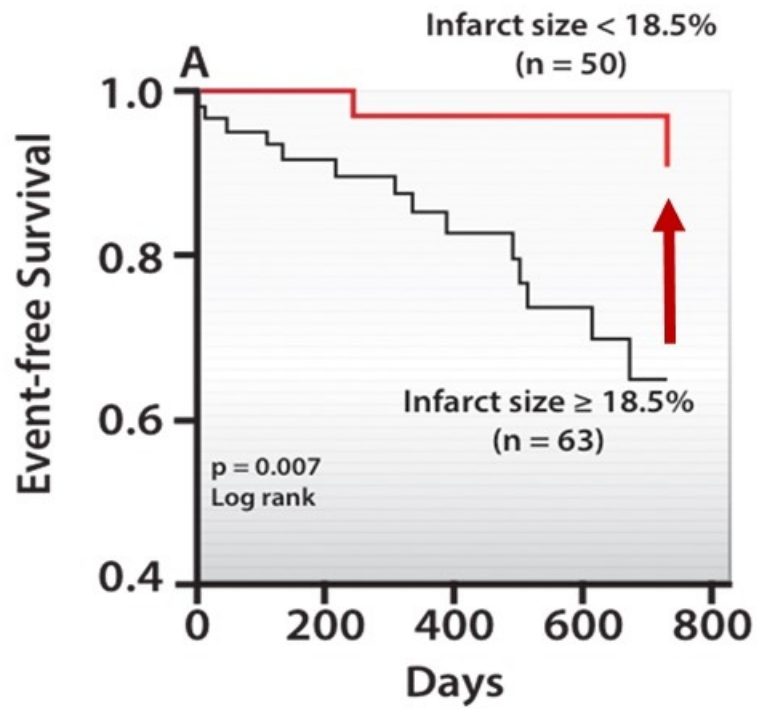


Makkar et al, Lancet, 2012.

**CDC patients had a significant reduction in infarct (scar) size and an increase in healthy heart muscle mass. We hypothesize improvement in clinical outcomes.**



# Effect of **Infarct** (Scar) Size on Events



## Conclusions from **CADUCEUS**

- CDCs reduced the amount of scar in the heart caused by a heart attack
- Smaller scars may lead to better outcomes
- CDCs increase healthy heart muscle mass
- Autologous manufacturing is not a viable business model in this indication
- Multiple clinical programs underway using allogeneic cells

## Janssen (J&J) Deal Highlights

### Collaboration Agreement and Exclusive License Option with Janssen Biotech for Cell Therapy Program for Cardiovascular Applications

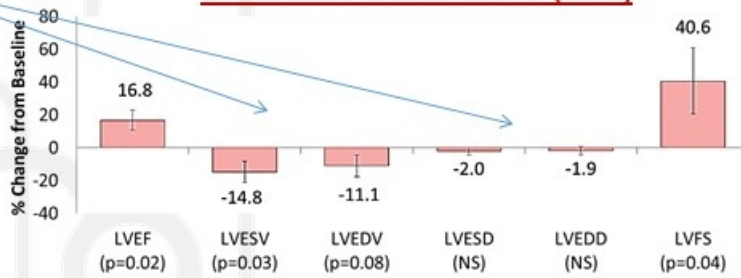
- Received upfront payment of \$12.5M
- Collaboration on elements of cell manufacturing
- Exclusive license agreement option for CAP-1002 up to 60 days after receipt of **six month ALLSTAR Phase II data**
  - If exercised, Capricor to receive an upfront license fee and additional milestone payments which may total up to \$325M
  - If exercised, Janssen to pay all future clinical trial and development costs of CAP-1002
  - Double-digit royalty to be paid to Capricor on commercial sales of licensed products



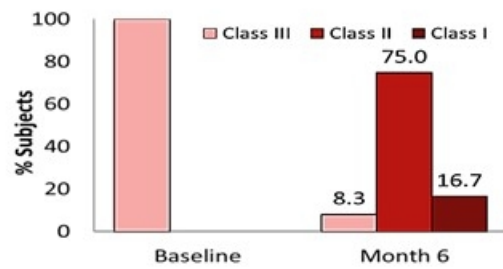
# DYNAMIC: Concordance of Data Suggest Improvement

Less is better

## LV Function & Dimensions (echo)



## NYHA class



AHA: November 2015  
6 month data for 2 subjects pending

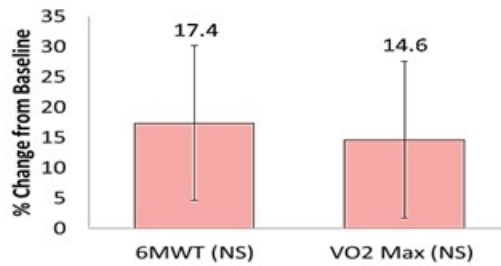


# DYNAMIC: Concordance of Data Suggest Improvement

Less is better



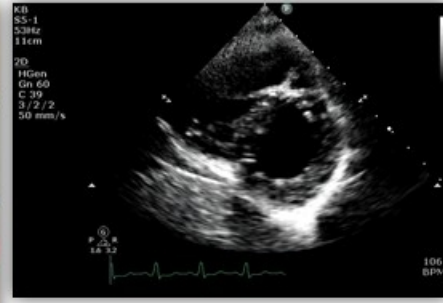
## 6MWT & VO<sub>2</sub> Max



# CDCs: Clinical Development

	<b>ALLSTAR Clinical Trial</b>	<b>DYNAMIC Clinical Trial</b>	<b>HOPE Clinical Trial</b>
Indication	Validate CADUCEUS data POC with ALLO cells	Adult Heart Failure Market (5M HF patients US \$32B/annual cost)	Orphan Disease Small market/ Big Upside
Clinical	Phase II	Phase I/II	Phase I/II
Development	Collaboration with Janssen Biotech (J&J) ~\$20M loan award from CIRM	\$3M funded by NIH	Orphan designation granted
Status	Enrolling Data anticipated: Q1 2017	Enrollment complete Data announced: AHA, Nov. 2015	Enrolling Data anticipated: Q1 2017

# Duchenne Muscular Dystrophy



Prevalence: 1 in 3,500 male births worldwide  
~20,000 male children affected in the US (~275,000 worldwide)  
**DMD is fatal with most deaths due to cardiomyopathy**

# Orphan Drug Designation Granted to CAPR

- **CAP-1002 can be used in CONJUNCTION with ANY other dystrophin-correcting therapies targeting skeletal muscle**
  - These therapies do not appear effective in cardiac muscle
  - Very few clinical trials to treat DMD cardiomyopathy
- Presents potential billion dollar market opportunity

"Cardiomyopathy is an almost universal finding in boys affected with DMD"

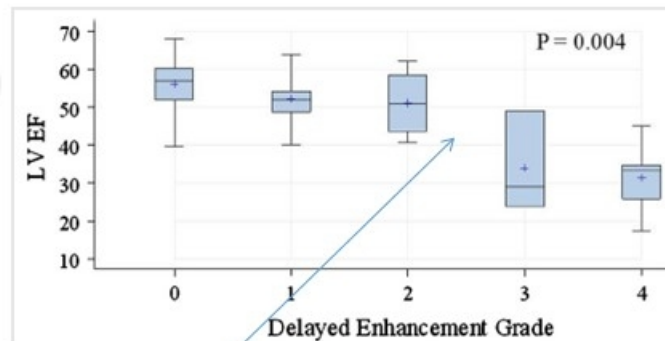
*Pediatric Cardiol. (2014) 35: 1279-1285*

"As a result of respiratory support and glucocorticoid use, patients with DMD are living longer, bringing the associated cardiomyopathy to the forefront of management for Duchenne patients as they age"

*Circulation. 2015;131:1590-1598.*

# Correlation between Scar and LVEF

- Advances in MRI technology have enabled accurate scar measurement
- Data shows the difference between “compensated” vs “decompensated” HF is defined by a small amount of muscle mass
- Reducing scar could potentially lead to a longer and more productive life

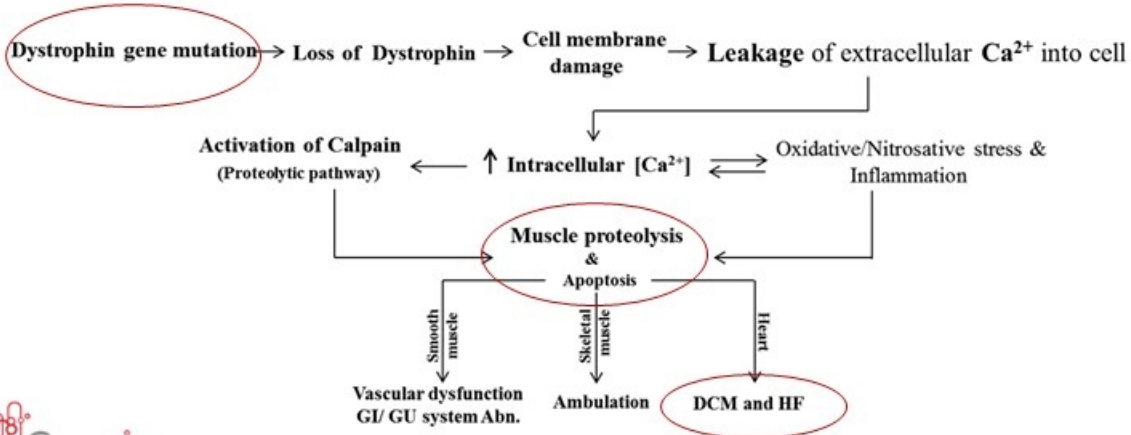


The “cliff”

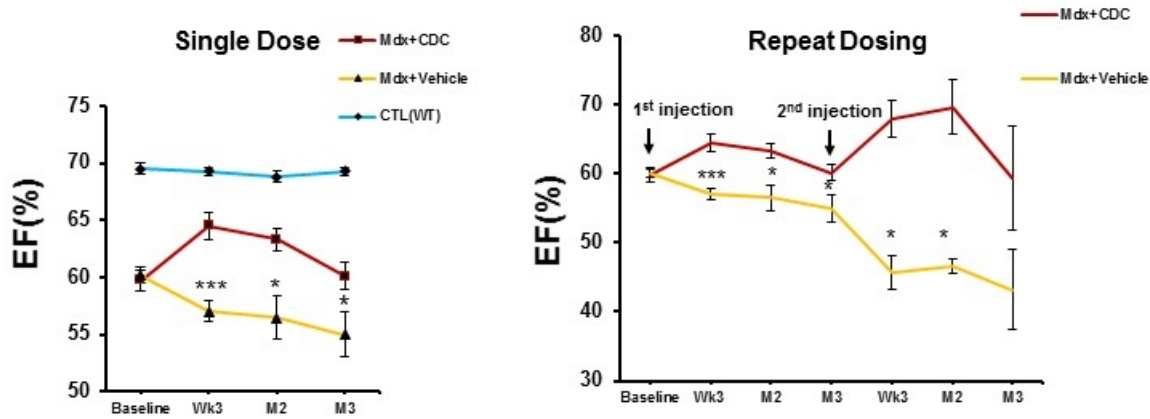
Imaging language = scar

# *mdx* Mouse Model of Duchenne Muscular Dystrophy

- Mimics the target indication, DMD
- Aged to the point at which cardiac dysfunction becomes evident:  $\geq 10$  months old



# Global **Cardiac** Function is improved in *mdx* Mice



\*\*\*  $p < 0.001$

\*  $p < 0.05$

$n = 12$  Mdx + CDC, Mdx + vehicle

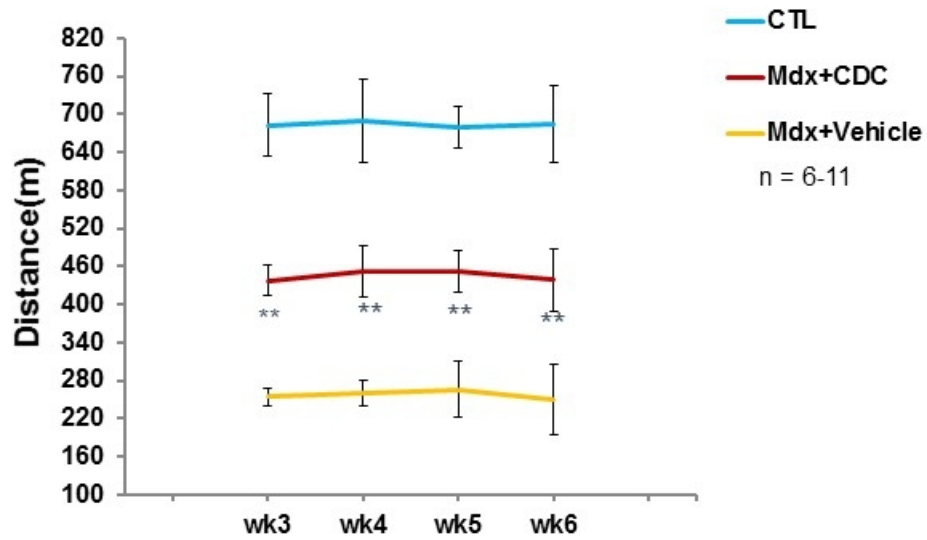
$n = 5$  CTL (WT)

Presented at AHA - November 2014, Chicago, IL

Reference: Cedars-Sinai Heart Institute

Presented at ISEV - April 2015, Washington DC

# CDCs Increased Maximal Exercise Capacity in mdx Mice





# Duchenne Cardiomyopathy and CDCs

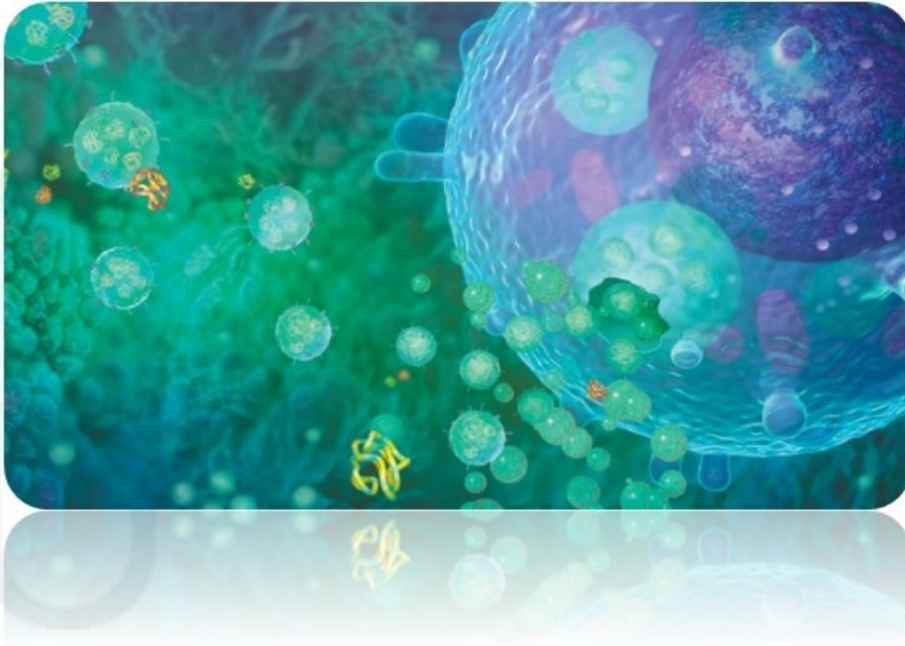
## Injection of CDCs into *mdx* mouse hearts

- Improves global function
- Decreases fibrosis
- Improves exercise capacity
- Exerts potent anti-oxidant effects
- Reverses abnormalities in mitochondrial abundance, structure and function
- Increases cardiomyocyte proliferation and activation/recruitment of endogenous repair

## Halt cardiomyOPathy progrESSION in Duchenne (HOPE)

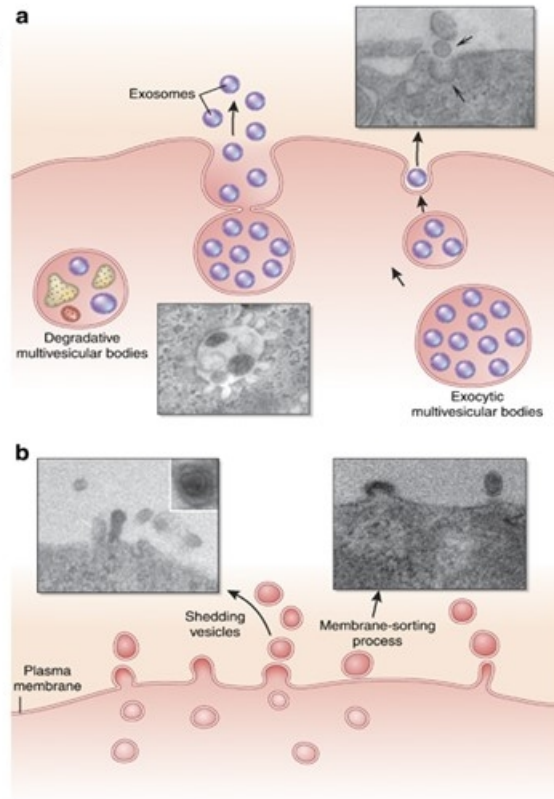
- FDA approved Phase I/II clinical trial (orphan designation)
- Randomized, open label multi-center study (~3-4 sites)
  - 12 boys randomized to CDC (CAP-1002) infusion
  - 12 boys randomized to 'usual care'
- Triple vessel intra-coronary infusion
- Preliminary efficacy assessed at 6 and 12 months
- Trial open for enrollment

# Exosomes: Next Generation Regenerative Medicine Therapeutic Platform



# Exosomes: Cell Free Regenerative Medicine

- 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)**

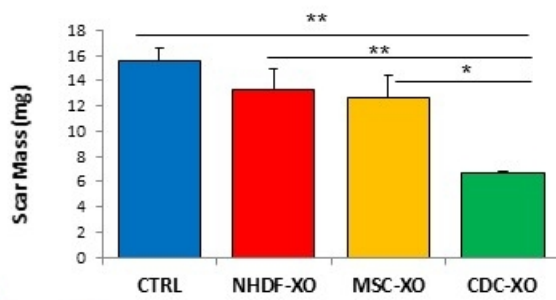
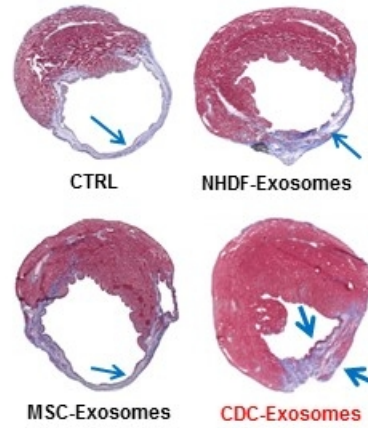
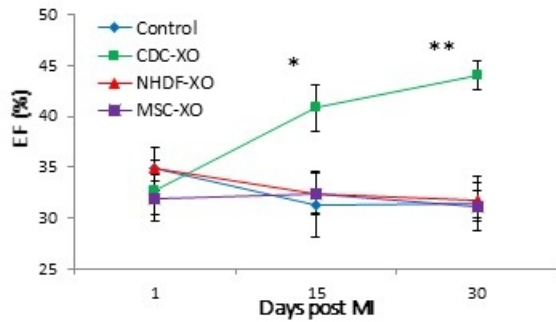


*Kidney International* (2010) 78, 838–848

## Exosomes: Paracrine Signals Suggest Cells MOA

- Autologous and allogeneic cells show a similar potency
- Delivered cells are cleared shortly after administration (< 1 month)
- The therapeutic benefit is maintained after delivered cells are gone
- Administered cells promote endogenous regenerative pathways
- Paracrine signals play an essential role in the effects mediated by these cells

# CDC Exosomes Improve Cardiac Function and Preserve Muscle Mass



## Exosomes: Targeted Milestones

- Targeting announcing First-in-Man clinical indication: Q1 2016
- Indications under consideration:
  - Eyes
  - Skin
  - Cancer
- Meet with FDA: Q1 2016
- Targeting IND submission: 2016

# NATRIURETIC PEPTIDE TECHNOLOGY

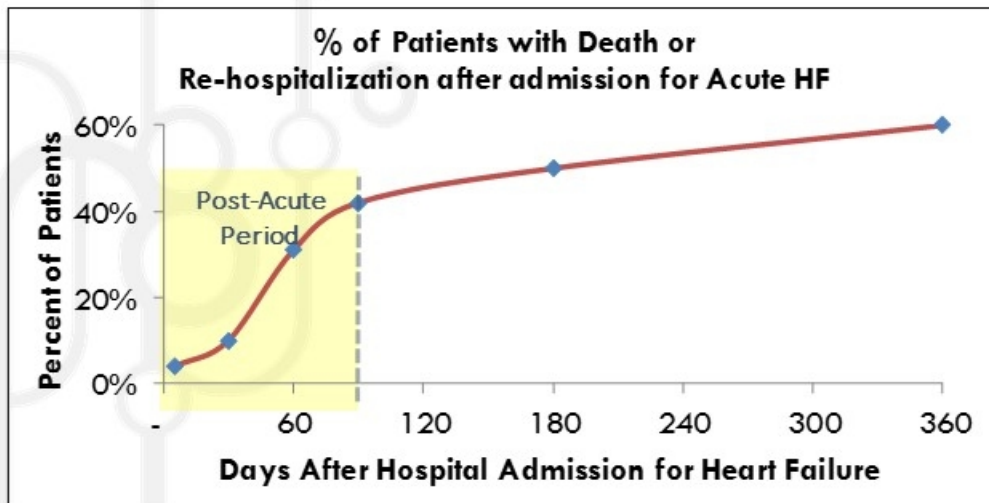


 **Capricor**  
Therapeutics™

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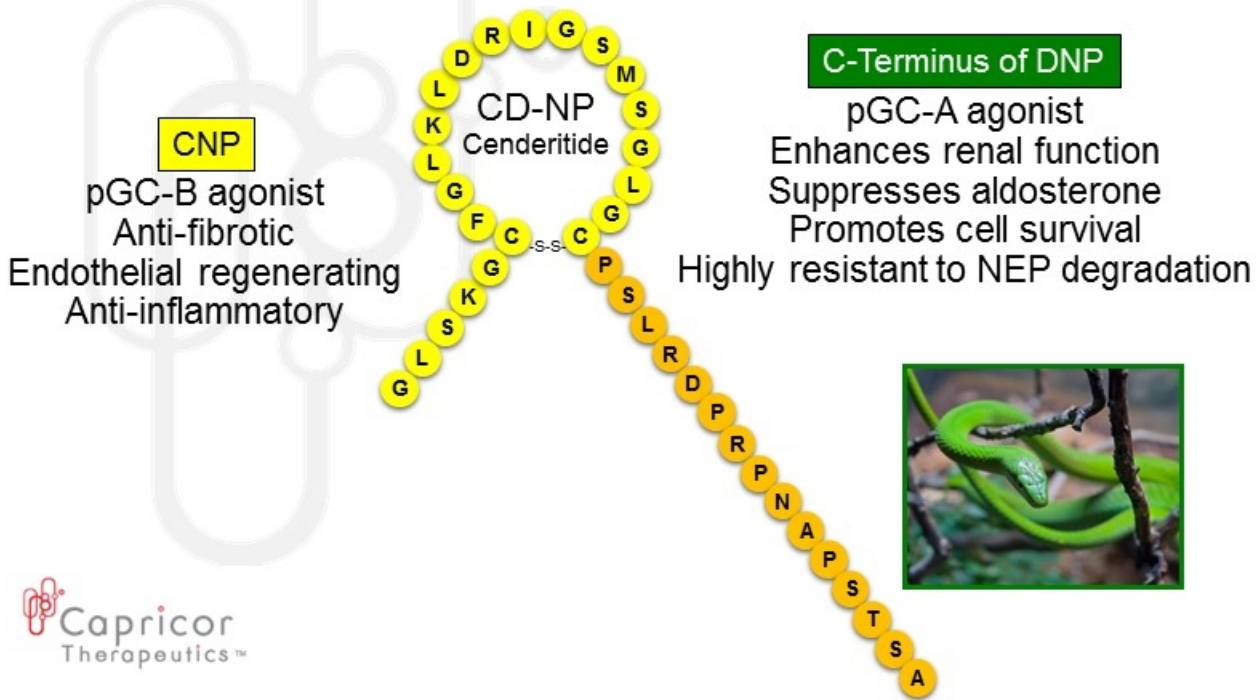


# The Post-Acute Hospitalization Period (90 days): When the Rate of Re-hospitalization and Death are Highest



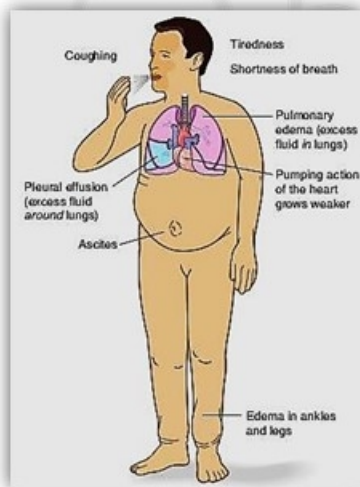
- As days in hospital have decreased, patient's physiology is unstable at discharge
- HF patients are frequently non-compliant with their chronic medications

# Mayo Designed CD-NP/Cenderitide: Only Dual NP Receptor Activator



# Cenderitide

## The Opportunity



+



1<sup>st</sup> arm of  
Phase II  
complete

# Cenderitide for Outpatient and Ambulatory Heart Failure

## Target Indication

Prevention of re-hospitalization in patients with a recent acute heart failure admission as well as other potential indications

- **Phase IIa PK/PD Trial**
  - 1<sup>st</sup> arm - 14 patients treated, enrollment complete
  - Patients with stable chronic heart failure
  - Trial assessed the safety and tolerability, pharmacokinetics profiles, and pharmacodynamic response to increasing dose levels of Cenderitide
  - No significant safety issues and Insulet pump proved effective
  - Early results suggest tolerability and physiologic effect
- Initiating a second study to further assess higher doses
- Announce further plans following results of second study

# Senior Management & Board of Directors

## Senior Management

- **Chief Executive Officer**  
Linda Marbán, Ph.D. (Founder, JHU, Cleveland Clinic)
- **Chief Medical Officer**  
Deborah Ascheim, M.D. (Mount-Sinai, Columbia University)
- **EVP & General Counsel**  
Karen Krasney, J.D.
- **Acting VP Clinical Operations:**  
Jeff Rudy, (Amgen, Celladon)
- **VP of New Therapies**  
Houman Hemmati, M.D., Ph.D. (Allergan)
- **VP of R&D for Regenerative Therapies**  
Luis Rodriguez-Borlado, Ph.D. (Coretherapix)
- **VP of Research and Development**  
Rachel Smith, Ph.D. (Johns Hopkins)
- **VP of Finance**  
AJ Bergmann, M.B.A.

## Board of Directors

- **Executive Chairman**  
Frank Litvack, M.D. (ConorMed)
- Linda Marbán, Ph.D.
- Dave Musket (ProMed Partners)
- Earl M. (Duke) Collier, Jr. (Genzyme)
- George W. Dunbar, Jr. (Aastrom)
- Joshua Kazam (Kite, Two-River)
- Gregory Schafer (Aduro, Onyx)
- Louis Manzo (Investor)
- Louis J. Grasmick (Investor)

## Scientific Advisory Board

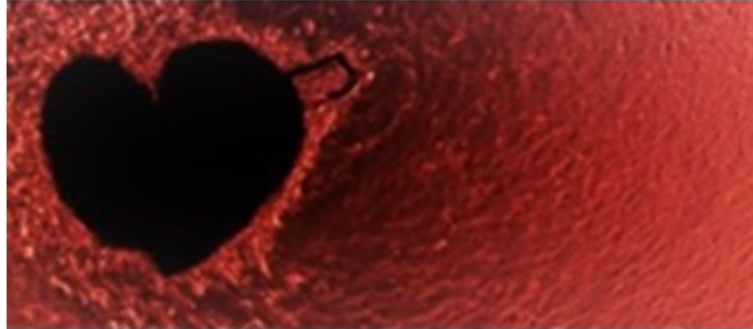
- **Chairman**  
Eduardo Marbán, M.D., Ph.D. (Founder, JHU, Cedars-Sinai)





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