

**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)

June 22, 2016

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))
-

Item 7.01 Regulation FD Disclosure.

On June 22, 2016, 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. 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. Additionally, on June 22, 2016, the Company will be providing a corporate update at the JMP Life Sciences Conference at 9:00 am EDT in New York City, which update will include some or all of the content of the Corporate Presentation.

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 June 2016.

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.

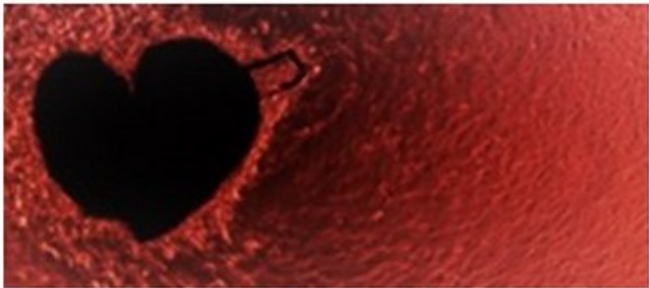
Date: June 22, 2016

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



Capricor
Therapeutics

A Translational Medicine Company



NASDAQ: CAPR

www.capricor.com

Investor Presentation

June 2016

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, 2015, as filed with the Securities and Exchange Commission on March 30, 2016, and in its Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on September 28, 2015 and in our Quarterly Report on Form 10-Q for the period ending March 31, 2016 as filed with the Securities and Exchange Commission on May 13, 2016. 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.

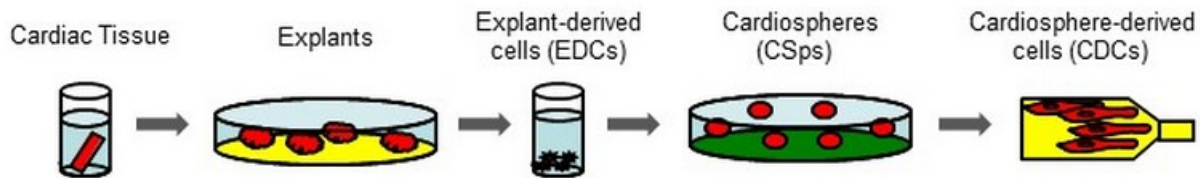
Capricor – Portfolio at a Glance

	PROGRAM	STAGE	STRATEGY
Cardiosphere-Derived Cells	Duchenne Muscular Dystrophy	Phase I / II	TBD
	Adult Cardiac Conditions	Phase II	Janssen Option
CDC Exosomes	Diseases of Inflammation and Fibrosis	Preclinical	Internal & External
Natriuretic Peptides	Outpatient Management of Heart Failure	Phase II	Potential Outlicense

Cardiosphere-Derived Cells (CDCs)

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- Derived from donor human hearts (allogeneic)
- Manufactured by Capricor via proprietary process
- Record of immunological safety per cumulative clinical experience
- Packaged in Cryostor™, three-year frozen shelf life
- IP licensed from Johns Hopkins, U. of Rome, Cedars-Sinai Medical Cntr



- Do not act by 'stemness' – do not engraft
- Act as local drug delivery vehicles
- Are epigenetic modulators of gene expression and cell function
- Release a wide variety of regulatory bio-molecules to effect their actions
 - RNAs
 - Proteins
- Secrete these bio-molecules within exosomes

– **A large body of reproducible data shows that CDCs:**

- Induce cardiac myogenesis
- Prevent cardiomyocyte apoptosis (programmed cell death)
- Promote new blood vessel formation
- Exert anti-scarring activity
- Attract endogenous progenitor cells

– **Clinical trials of CDCs have shown durable cardiac improvements:**

Post-myocardial infarction (MI) cardiac dysfunction

- | | |
|-----------------------|------------------------------|
| – ↓ Scar mass | – ↑ Regional contractility |
| – ↑ Viable heart mass | – ↑ Systolic wall thickening |

Advanced heart failure

- | | |
|----------------------------|-----------------------|
| – ↓ NYHA class | – ↑ Quality of life |
| – ↓ Ventricular dimensions | – ↑ Functional status |

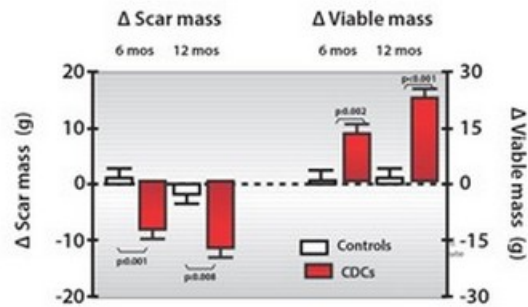
THE LANCET

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

Raj R Mulkaj, Rachel B Smith, Ke Cheng, Konstantinos Malliaris, Louise E J Thomson, David Bettsman, Lawrence S C Cret, Linda Marbán, Adam Mendizabal, Peter V Johnston, Stuart D Russell, Karl H Schaefer, Albert C Lanza, Gary Gerstenblith, Eduardo Marbán

Lancet, 2012, 21(8): 1121-1135.

- Patients with reduced ejection fraction (EF) following myocardial infarction (MI)
- N=25 (17 active, 8 control)
- One-time intracoronary delivery of *autologous* CDCs (25 million cells)
- Sponsored by Cedars-Sinai Medical Center, with Johns Hopkins University



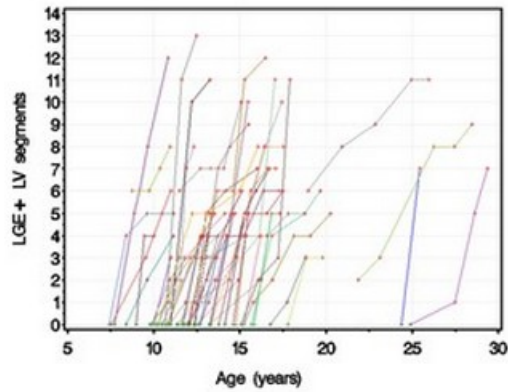
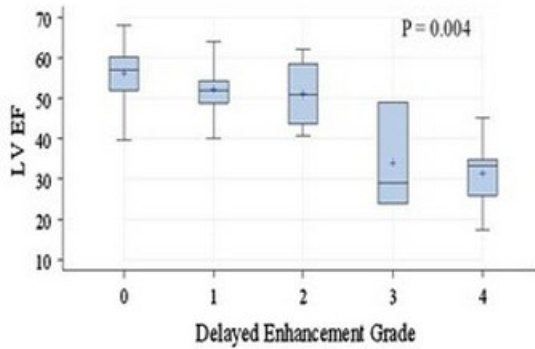
Capricor – Detail by Program

	PROGRAM	STAGE	STRATEGY
Cardiosphere-Derived Cells	Duchenne Muscular Dystrophy	Phase I / II	TBD
	Adult Cardiac Conditions	Phase II	Janssen Option
CDC Exosomes	Diseases of Inflammation and Fibrosis	Preclinical	Internal & External
Natriuretic Peptides	Outpatient Management of Heart Failure	Phase II	Potential Outlicense

- **DMD results from mutation of calcium-regulating dystrophin gene**
 - 1 per 3,500 male births
- **Induces profound, progressive dysfunction of all muscle types**
- **Cardiac involvement is universal and #1 cause of death**
- **DMD cardiomyopathy results in dilated, non-compliant failing hearts due to abnormal transmembrane calcium flux**
- **Consequence is inflammation, necrosis, cardiomyocyte death and progressive cardiac fibrosis**

- In DMD, myocardial fibrosis (scar):

- Independently predicts adverse cardiac remodeling, ventricular arrhythmia, death
- Increases linearly with age and strongly correlates with LV ejection fraction

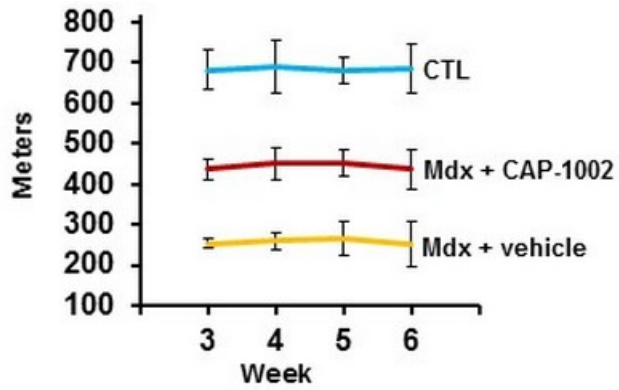
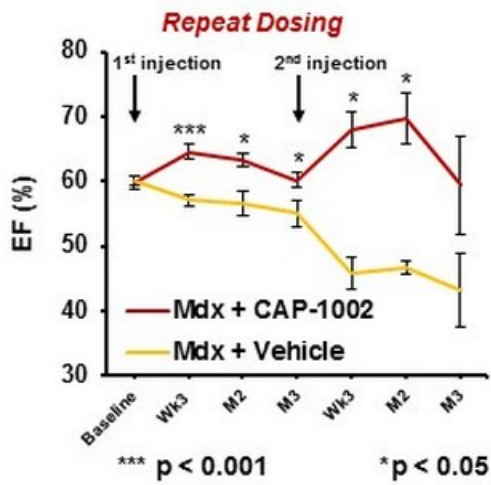


Menon et al, *Pediatr Cardiol* 2014;35:1279-85.

Tandon et al, *J Am Heart Assoc* 2015;4:e001338.

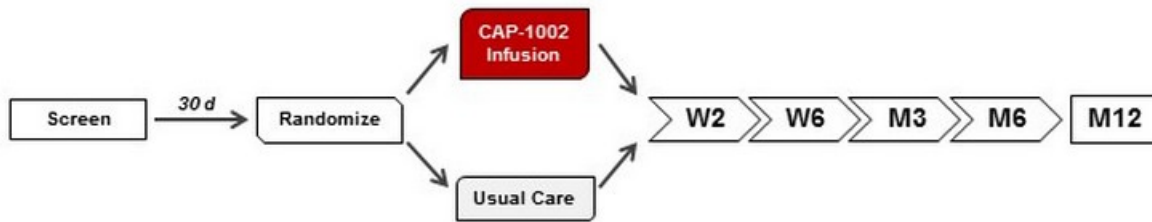


CAP-1002 Improves Cardiac Function and Exercise Capacity in DMD Mouse Model



Mdx mice + CAP, n=12 Mdx mice + vehicle, n=12 CTL (wild-type), n=5

- **Ongoing HOPE-Duchenne study designed to support registration**
- **CAP-1002 is distinct from the exon skipping therapies**
Apparent lack of mutation dependence supports use in any genotype
- **FDA Orphan Drug Designation for the treatment of DMD**



- Boys with cardiomyopathy secondary to DMD
- N=24, parallel-group study (3-4 sites)
 - 1:1 randomization to one-time CAP-1002 (75 million cells) or 'usual care'
- **Expect to report six-month top-line data in Q1 2017**
 - Structural (cardiac MRI)* and functional endpoints
 - Quality of Life endpoints

✓ Passed interim DSMB safety review

Success in HOPE may enable Capricor to discuss a BLA with FDA by late 2017.



* FDA Draft Guidance, June 2015.

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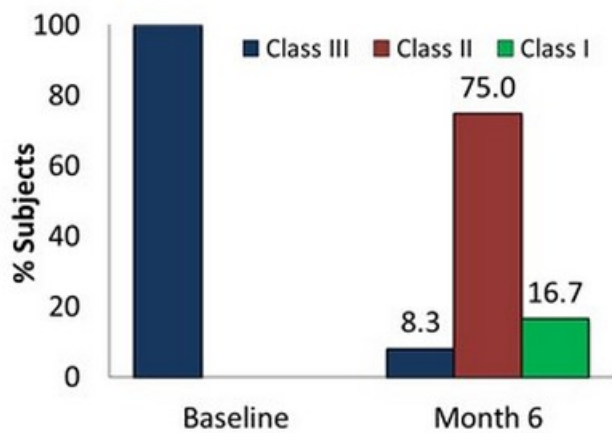


- **>5 million U.S. patients estimated to have heart failure**
Current treatments largely fail to address the progressive underlying disease
- **In a preclinical model of non-ischemic dilated cardiomyopathy, CDCs have been shown to:**
 - reverse abnormalities in cell signaling
 - prevent adverse remodelling
 - improve survival
- **DYNAMIC I study evaluated CAP-1002 in patients with advanced heart failure**
 - Open-label clinical trial conducted at Cedars-Sinai Medical Center
 - Subjects treated with a one-time, triple coronary infusion (37.5 – 75 million cells)
 - Six- and 12-month follow-up

→ *CAP-1002 demonstrated an efficacy signal with concordant improvements in functional status, quality-of-life, and left ventricular function and size*

DYNAMIC Results Support CAP-1002 For Advanced HF

Six-Month Data Presented at the American Heart Association Annual Meeting, November 2015*



NYHA Class	Physical Activity
I	No limitation
II	Slight limitation
III	Marked limitation
IV	Severe limitation

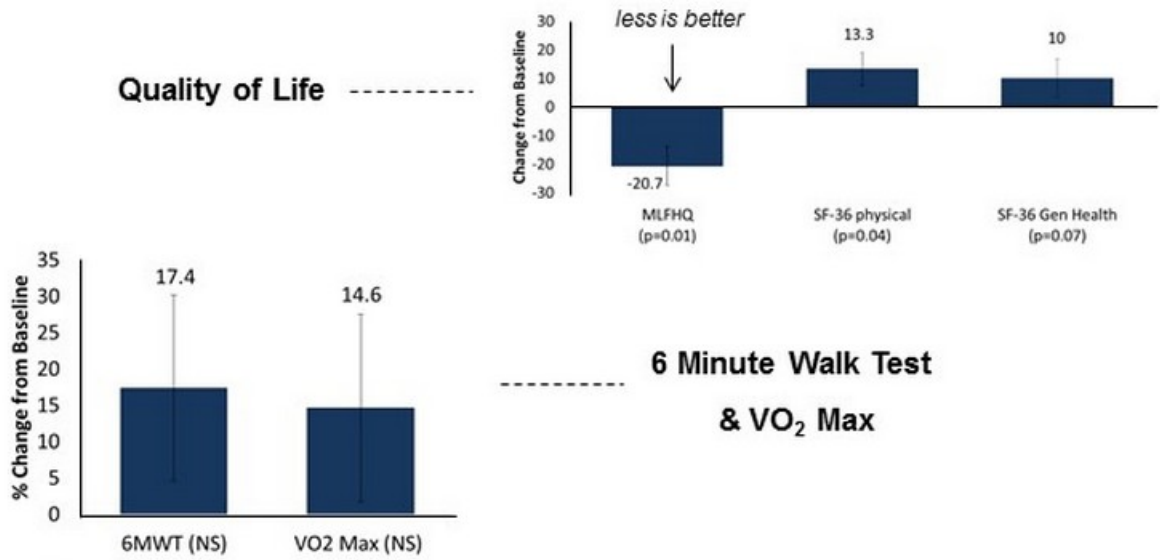
- Of the 12 evaluable Class III patients at six months, 11 (92%) improved by at least one class (p=0.006)



* N=14; two subjects lost to follow-up.

DYNAMIC Results Support CAP-1002 For Advanced HF

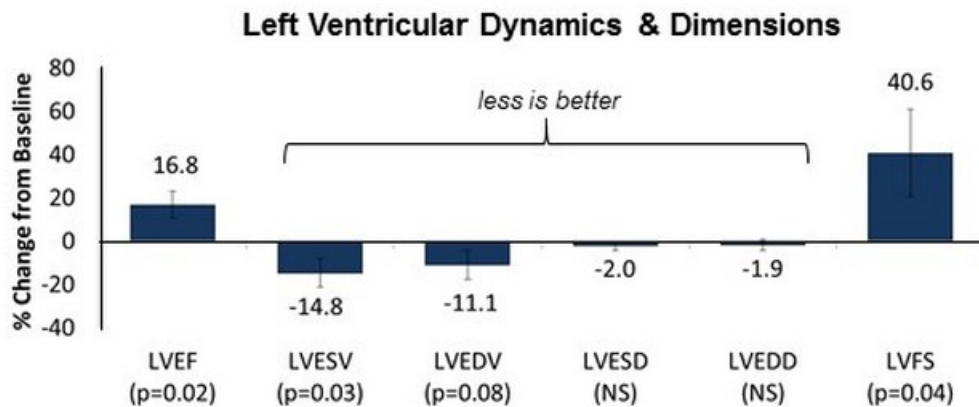
Six-Month Data Presented at the American Heart Association Annual Meeting, November 2015*



* N=14; two subjects lost to follow-up; AHA Annual Meeting, November 2015.

DYNAMIC Results Support CAP-1002 For Advanced HF

Six-Month Data Presented at the American Heart Association Annual Meeting, November 2015*



– Efficacy signal continued to be observed at 12 months
LVEF +17.5% (median) from baseline (p=0.02)

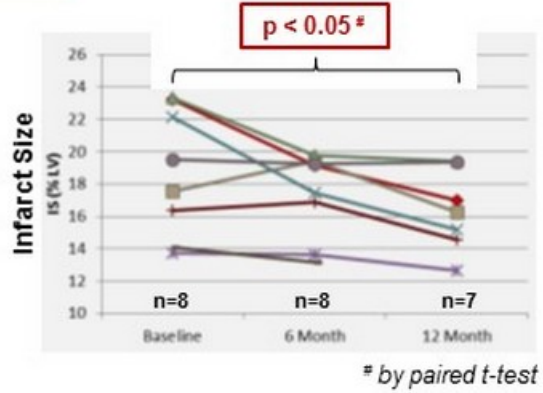
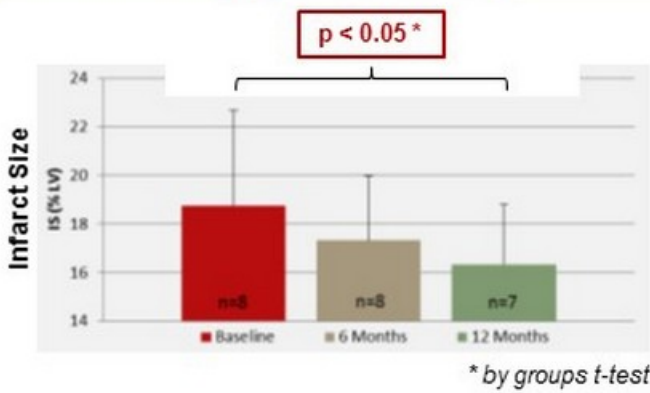


* N=14; two subjects lost to follow-up; measurements assessed by echocardiography; AHA Annual Meeting, November 2015.

- Janssen has exclusive option to enter into exclusive license agreement for worldwide rights to CAP-1002 for certain cardiovascular indications
- **If exercised, Janssen to fund all future development costs and Capricor eligible to receive:**
 - License fee and additional milestone payments totaling up to \$325 million
 - Low double-digit royalties on product sales
- **Actively collaborating with Janssen on manufacturing development**
- **\$12.5 million upfront payment received in early 2014**

- **Randomized, double-blind, placebo-controlled; 30-35 U.S. centers**
- **120 subjects with recent (30 – 90 d) or chronic (91 – 365 d) STEMI or NSTEMI**
 - Left ventricular scar size $\geq 15\%$ of LV mass
 - Left ventricular ejection fraction $\leq 45\%$
- **25 million CDCs or saline infused one time into infarct-associated coronary artery**
 - Followed for 12 months post-dosing
- **Efficacy evaluated by centrally-read cardiac MRI and other measures**
- **Six-month data to be available in Q1 2017**
 - Janssen has until 60 days following delivery of six-month data to exercise option

ALLSTAR Phase I Results: Showed Improvement in Scar Size



- Results shown are from the “Phase II Equivalent” population
Received high dose CAP-1002
Lacked donor-specific antibodies (DSAs)



DSA = donor-specific antibody

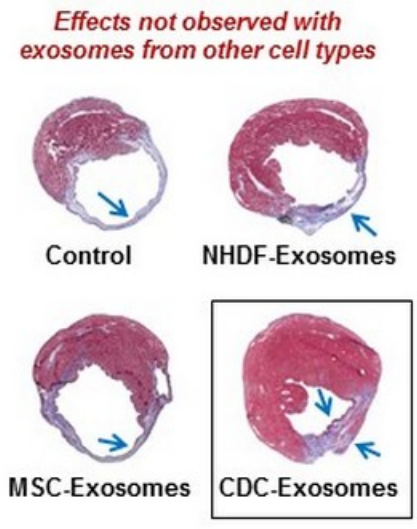
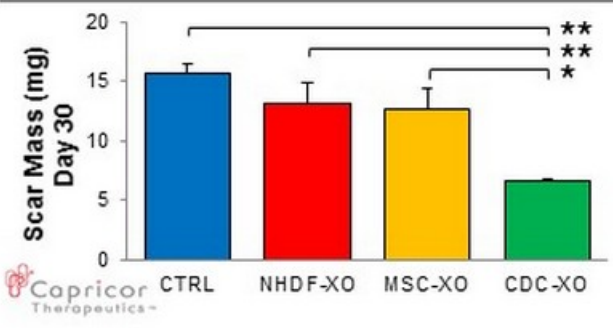
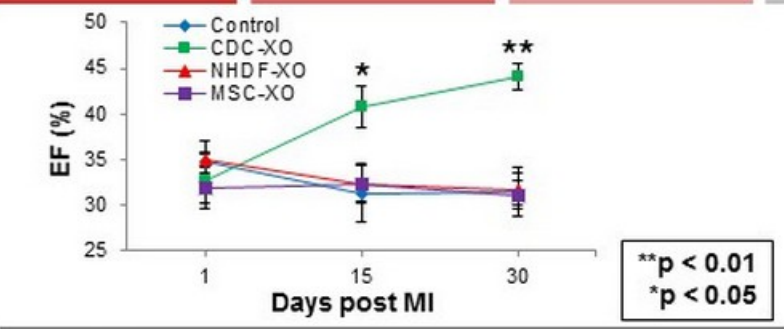
Capricor – Detail by Program

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CDC Exosomes	Diseases of Inflammation and Fibrosis	Preclinical	Internal & External
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- **Exosomes represent a potential next-generation, cell-free therapeutic platform**
- **Exosomes mediate the regenerative and cardioprotective effects of CDCs**
Were discovered in the course of elucidating CDCs' mechanism of action
- **Like exosomes from other cells, CDC Exosomes:** are rich in RNAs and proteins
readily cross cell membranes
function as a cell signaling modality
- **Have demonstrated striking activity in several inflammatory models**
(cardiac and non-cardiac)
- **Capricor has an exclusive WW license to CDC Exosomes technology from Cedars-Sinai Medical Center**

CDC Exosomes Significantly Improve Cardiac Structure and Function in Preclinical Studies



Ibrahim et al, Stem Cell Reports 2014;2:606-19.

CDC Exosomes Provide Rapid and Dose-Dependent Improvement in Ocular Inflammation Model

- Keratoconjunctivitis induced in rabbits (wound followed by LPS application)
- After development of severe inflammation, eyes were treated with a single administration of CAP-2003 or control, then followed for three days



- Day three data show that CAP-2003 can rapidly improve:
 - corneal wound injury
 - ocular surface inflammation
 - conjunctivitis
 - corneal edema



LPS = lipopolysaccharide

- CDC exosomes have regenerative and cell-modulating capabilities
- **Broad treatment potential in inflammatory and fibrotic conditions**
Supported by growing body of preclinical data
- **Capricor plans to announce the first indication for CAP-2003 in mid-2016**

Capricor – Detail by Program

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Cenderitide (CD-NP) – For Potential Outlicense

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Dual Natriuretic Peptide Receptor Activator for Cardio-Renal Disease States

- **Provides a first-in-class product licensing opportunity**
Positioned to address a large heart failure market segment lacking in therapeutic options
- **Proof-of-concept for chronic patch pump delivery**
Two Phase II PK/PD studies have been completed
Well-tolerated at pharmacologically-active levels
Flexible dosing for individual dose titration
- **Designed for outpatient management of heart failure**



OmniPod®
(Insulet)

Cash Runway Through Early 2017 Data Readouts

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Cash, cash equivalents, and marketable securities reported at March 31, 2016	\$14.3 million
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Net cash used in operations in 2015	\$10.8 million
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Shares outstanding (May 12, 2016)	18.0 million
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Upcoming Milestones

2016	2017	Anticipated Event
Mid		Announce first indication for CAP-2003
Q3		Complete enrollment in HOPE-Duchenne trial of CAP-1002 Complete enrollment in ALLSTAR trial of CAP-1002
H2		Report Phase II data (higher dose range) on Cenderitide
	Q1	Report six-month data from HOPE-Duchenne trial Six-month data from ALLSTAR trial to be available to Capricor*
	H1	Submit IND for CAP-2003



** Janssen has the right to exercise its option to CAP-1002 at any time until 60 days after the delivery by Capricor of the six-month follow-up results from the ALLSTAR clinical trial.*

Senior Management

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Linda Marbán, PhD
Chief Executive Officer



AJ Bergmann, MBA
VP of Finance



Leland Gershell, MD PhD
Chief Financial Officer



Rachel Smith, PhD
VP of Research & Development



Deborah Ascheim, MD
Chief Medical Officer



Houman Hemmati, MD PhD
VP of New Therapy Development



Karen Krasney, JD
EVP & General Counsel



Luis Rodriguez-Borlado, PhD
VP of Regenerative Therapies

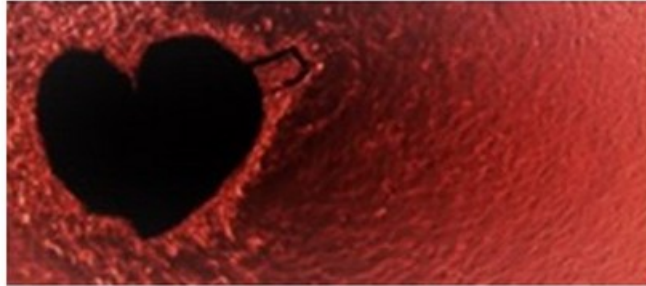


Frank Litvack, MD – Executive Chairman



Capricor Therapeutics

A Translational Medicine Company



NASDAQ: CAPR

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