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)

February 14, 2017

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))

Item 7.01 Regulation FD Disclosure.

On February 14, 2017, 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 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. Corporate Presentation, dated February 14, 2017.

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: February 15, 2017

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

Capricor Therapeutics™

A Translational Medicine Company

Corporate Overview

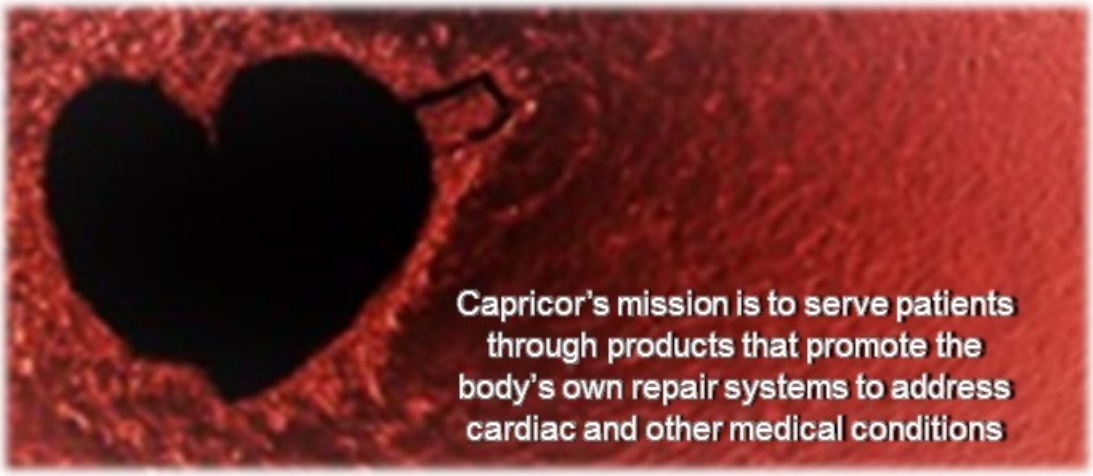
NASDAQ: CAPR

February 2017

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, 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 period ended September 30, 2016 as filed with the Securities and Exchange Commission on November 14, 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.

Transformative Therapies from Bench to Bedside



Capricor Therapeutics

Investment Highlights

Innovative, Proprietary Therapeutic Platforms	• First-in-class biologics with potential to reverse "irreversible" damage to the heart and other organs • Product candidates based on cells and exosomes
Technical and Strategic Execution	• Developing commercial manufacturing process • Janssen collaboration and license option
Strong Scientific Foundation & Leadership Team	• Translational approach to product development based on the research of leading academic scientists and institutions • Management has deep domain expertise
Capital Efficiency	• Successful record of securing non-dilutive capital
Potentially Transformative Newsflow in 2017	• Multiple clinical readouts expected • Decision on Janssen license option expected

Capricor Therapeutics

Capricor's Innovative Product Pipeline

Product Candidate	Indication/ Population	Development Phase	Status
		Preclinical / I / II / III	
CAP-1002 (allogeneic CDCs)	**Duchenne Muscular Dystrophy**		▪ To report top-line six-month results from Phase I/II HOPE clinical trial in early 2Q 2017
	Post-Myocardial Infarction		▪ To report top-line 12-month results from Phase II ALLSTAR clinical trial in 4Q 2017
	Advanced Heart Failure		▪ Presented positive 12-month DYNAMIC results at TCT
CAP-2003 (CDC exosomes)	**Ocular GVHD**		▪ Plan to submit IND in 2H 2017

Capricor Therapeutics

Estimated Global Patient Populations for CAP-1002

Duchenne Muscular Dystrophy

Population	
US	15 K
Europe	20 K

WW incidence ~ 1 per 3,600 male births

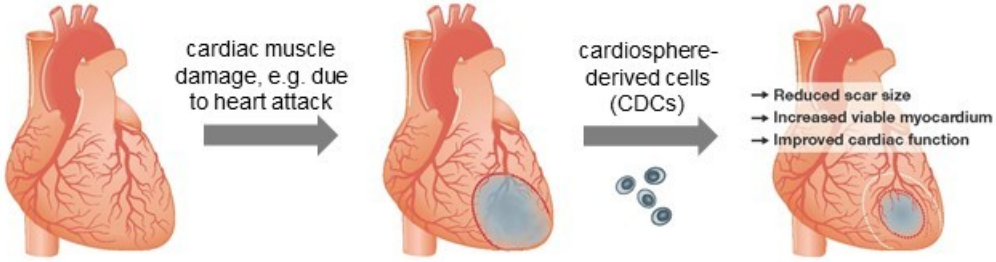
CAP-1002 has FDA orphan drug designation for the treatment of DMD.

Heart Failure

Population	
US	6 M
Europe	15 M
Japan	1 M

Capricor Therapeutics

The Power of Capricor's Technology



Scar formation results from heart muscle death, and the amount of scar correlates with outcomes.

Neither time nor current treatment options will lead to the replacement of scar tissue with muscle.

Capricor's technology offers transformative treatment potential through therapeutic regeneration.

Supported by results from clinical trials in heart attack and advanced heart failure populations.

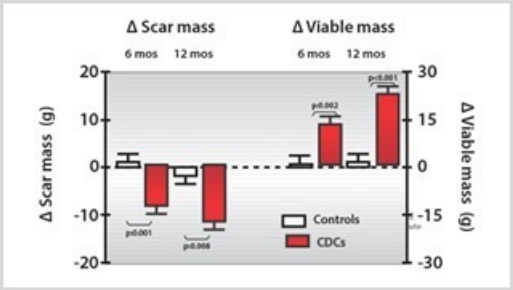
Capricor Therapeutics

Clinical Validation Provided by the CADUCEUS Trial

First in-human evidence for therapeutic heart regeneration

Treatment with CDCs

- **significant decrease** in scar mass
- **significant increase** in healthy muscle



THE LANCET

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

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

CADUCEUS was sponsored by Cedars-Sinai Medical Center, with Johns Hopkins University

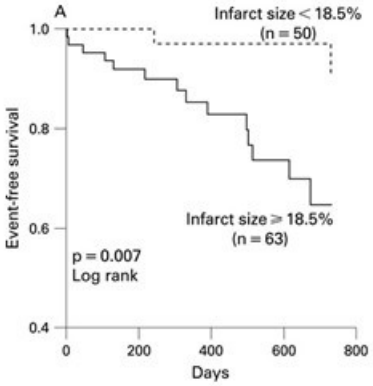
- Randomized trial in patients who had experienced a large heart attack (N=25; two centers)
- One-time intracoronary delivery of autologous CDCs vs. usual care controls

Capricor Therapeutics

Scar Size Predicts Outcomes Following MI

The size of the infarct or residual scar following MI is a predictor of outcomes, e.g.:

- re-infarction
- heart failure requiring hospitalization
- cardiac death

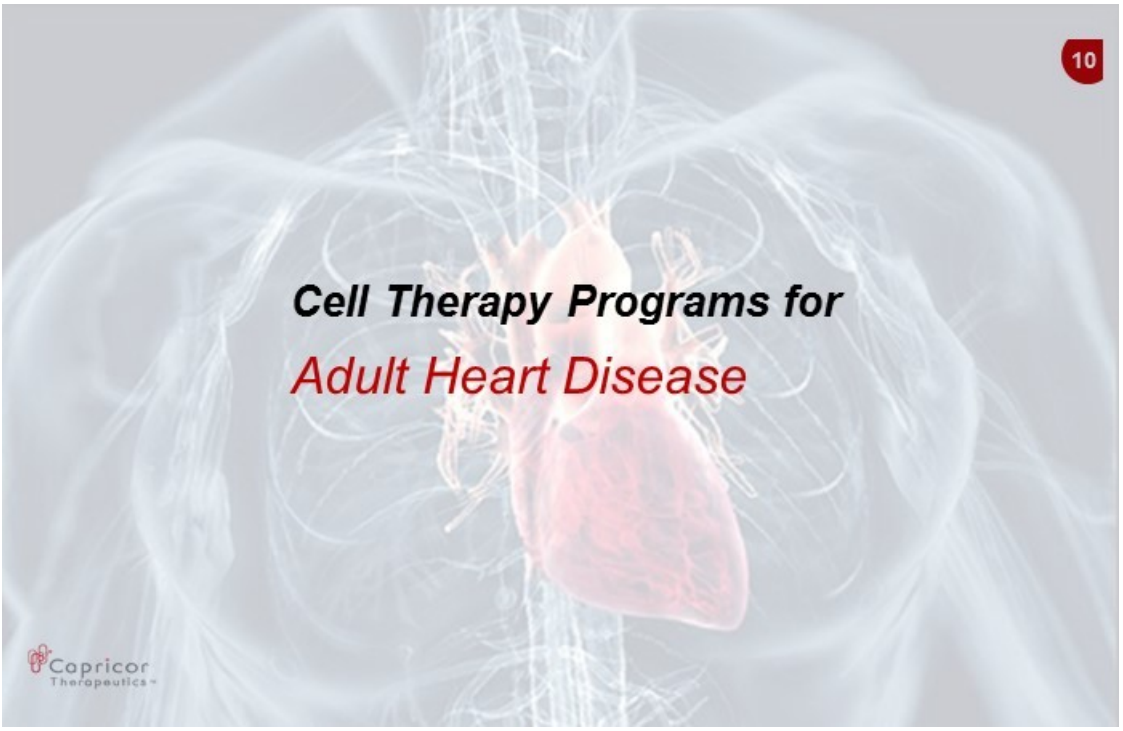


Wu et al, Heart **2008**;*94*:730-6.

CADUCEUS Trial Results	Scar Size (as mean percent of LV) (SD)	
	CDCs	Control
Baseline	23.8% (9.9)	22.4% (7.9)
12 Months	12.9% (6.1)	20.3% (7.5)

Malliaras et al, J Am Coll Cardiol **2014**;*63*:110-22.

Capricor Therapeutics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Cell Therapy Programs for
Adult Heart Disease
Capricor
Therapeutics

ALLSTAR & DYNAMIC Trials with "Off-the-Shelf" CAP-1002

Clinical trials of CAP-1002 in prevalent cardiovascular disorders:

Phase I/II
ALLSTAR trial

in post-myocardial infarction

Phase I portion – completed & results reported
Phase II portion – enrollment completed

Phase I
DYNAMIC trial

in advanced heart failure

Completed & results reported

- Well-tolerated in completed studies; no immune-related safety observations
- Positive and concordant efficacy results reported, with support for dose-response

Capricor Therapeutics

Enrollment in Phase II ALLSTAR Trial has Completed

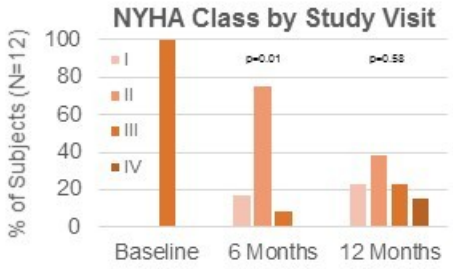
- **Similar to CADUCEUS trial, but using CAP-1002 (allogeneic)**
- **Randomized, double-blind, placebo-controlled Phase II trial of CAP-1002**
  134 patients who had experienced a large heart attack were enrolled
  Each received a one-time infusion of CAP-1002 (25M cells) or placebo
  Trial being conducted at 30 centers in U.S. & Canada

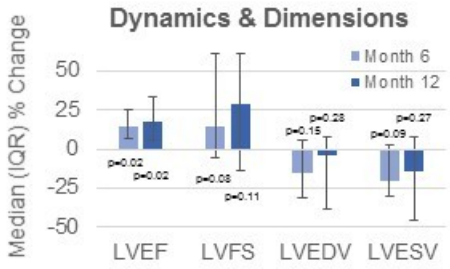
  Expect to report top-line 12-month data in 4Q 2017
  → primary efficacy analysis based on scar size at 12-month follow-up

- **Phase I results support safety, with evidence of scar size reduction**

Supported in part by loan award from CIRM

Positive Results with CAP-1002 in Advanced Heart Failure





- DYNAMIC demonstrated an efficacy signal despite its small sample size (N=14).
- Concordant improvements from baseline in functional status and ventricular function were observed, and were especially evident at six months,
- A dose effect was also seen, with the highest dose (75M cells) yielding the greatest benefit to NYHA Class.

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DYNAMIC was an open-label, dose-escalation clinical trial in patients with dilated cardiomyopathy.
NYHA Class III or ambulatory Class IV HF of ischemic or non-ischemic origin and baseline LV ejection fraction ≤ 35%.
One-time triple coronary infusion at one of four doses (37.5, 50, 62.5, or 75 million cells); six and 12-month follow-up.

Janssen Holds a License Option on CAP-1002

- In 2014, Capricor granted Janssen Biotech an exclusive option to enter into an exclusive license agreement for worldwide rights to CAP-1002 for certain CV indications
- Option period to end 60 days following Capricor's delivery of interim six-month ALLSTAR data to Janssen
- Under a potential license agreement for CAP-1002:

Janssen	Capricor	
Development and registration	License fee	*up to $325 million*
Product manufacture	Milestone payments	
Global commercialization	Sales royalties	*— low double-digit percent*

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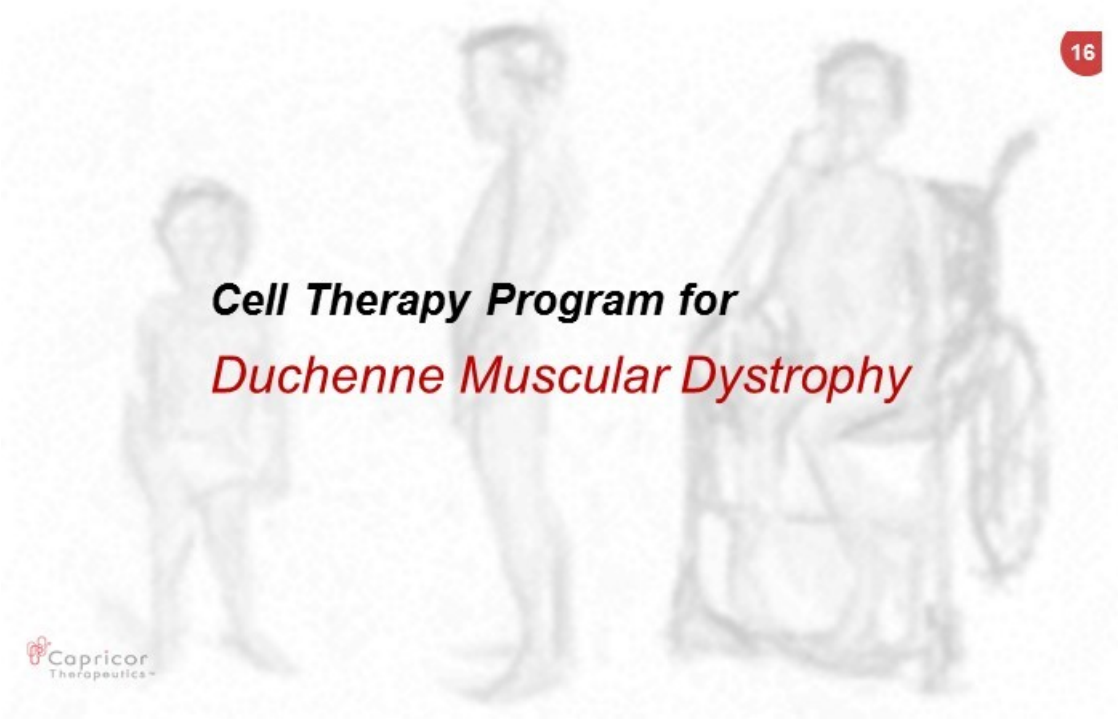
Manufacturing Process Development with Janssen

We expect to be able to generate thousands of doses of CAP-1002 from each donor heart via commercial process in development

CSps	CDCs	Wash	Formulate	Fill	CAP-1002
					

CSps	CDCs	Wash	Formulate	Fill	CAP-1002
					

Capricor Therapeutics



Cell Therapy Program for

Duchenne Muscular Dystrophy

Capricor Therapeutics

Heart Failure is #1 Cause of Death in DMD

"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.

- **DMD results from mutation in dystrophin gene**
- **By early adulthood, nearly all people with DMD have clinical manifestations of cardiac disease**
- **No approved therapies for the heart disease associated with DMD**

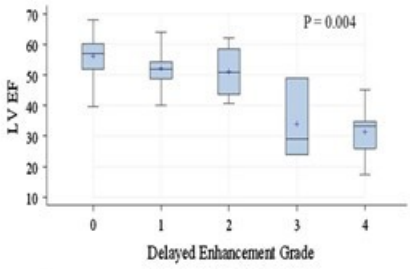
Capricor Therapeutics

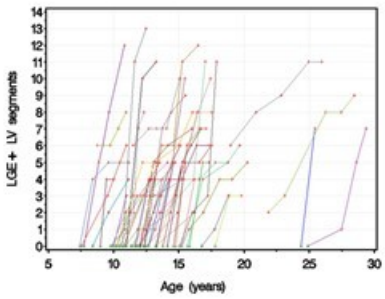
Heart Failure is the End Result of Progressive Scarring in DMD

may be clinically silent due to functional compensation until sufficient to cause HF

← **scarring in heart muscle** →

increases linearly with age and strongly correlates with LV ejection fraction





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Menon et al, Pediatr Cardiol **2014**;*35*:1279-85; Tandon et al, J Am Heart Assoc **2015**;*4*:e001338.

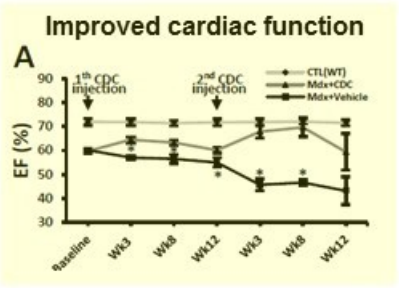
Concept of Using CAP-1002 to Treat DMD Heart Disease

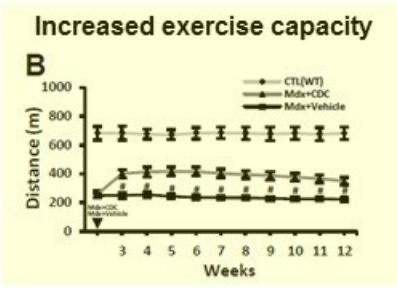
Diverse effects of CDCs support their potential to retard or reverse the multiple pathological processes that occur in DMD

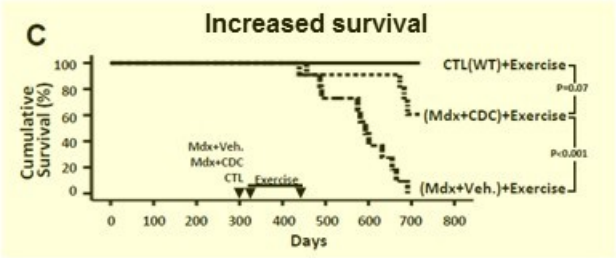
What happens in DMD	CDCs' Actions
Oxidative/nitrosative stress	⟵ Anti-oxidative
Inflammation	⟵ Anti-inflammatory
Apoptosis	⟵ Anti-apoptotic
Remodeling	⟵ Anti-remodeling
Loss of myocytes	⟵ Regenerative

Capricor Therapeutics

CDCs Improve Function and Increase Survival in Mdx Mice







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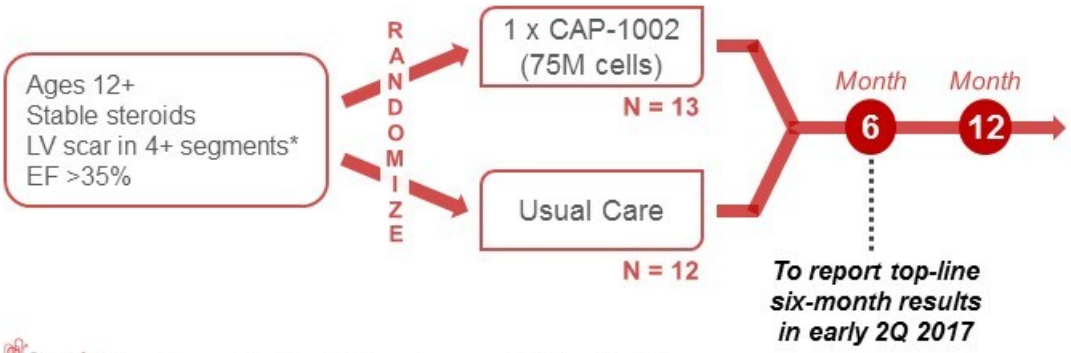
Randomized Phase I / II HOPE-Duchenne Trial of CAP-1002

Being conducted in 25 boys and young men with DMD-associated cardiomyopathy
Ambulatory and non-ambulatory patients are eligible
Single infusion of CAP-1002 or usual care only
Exploratory efficacy assessments to be conducted at six and 12 months



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* Assessed by late gadolinium enhancement (LGE) cardiac MRI.

HOPE Features a Variety of Exploratory Efficacy Analyses

	Week 6	Month 3	Month 6	Month 12
Imaging				
Cardiac magnetic resonance (cMRI)			•	•
Functional Tests				
Performance of the Upper Limb (PUL)	•	•	•	•
6-Minute Walk Test	•	•	•	•
Spirometry	•	•	•	•
Quality of Life				
Pediatric QL Inventory	•	•	•	•
PODCI Adolescent Questionnaire	•	•	•	•
Biomarkers				
Osteopontin, ST2, IL-10, Galectin-3, other	•	•	•	•

Cardiac MRI to Assess Several Parameters

Left Ventricular	Month 6	Month 12
Myocardial composition		
Scar (late gadolinium enhancement)	•	•
Viable mass	•	•
Dynamics		
Ejection fraction	•	•
Regional wall motion	•	•
Circumferential strain	•	•
Dimensions		
End-diastolic volume	•	•
End-systolic volume	•	•
Stroke volume	•	•

Capricor Therapeutics

Initial HOPE Data to be Reported in Early 2Q 2017

- Expected to be reported:
  - **Safety and tolerability**
  - **Exploratory efficacy measures** *(no powering for statistical significance)*

- Independent Data Safety Monitoring Board (DSMB) has met four times during study per a predefined schedule
  - Trial was recommended to continue following each review


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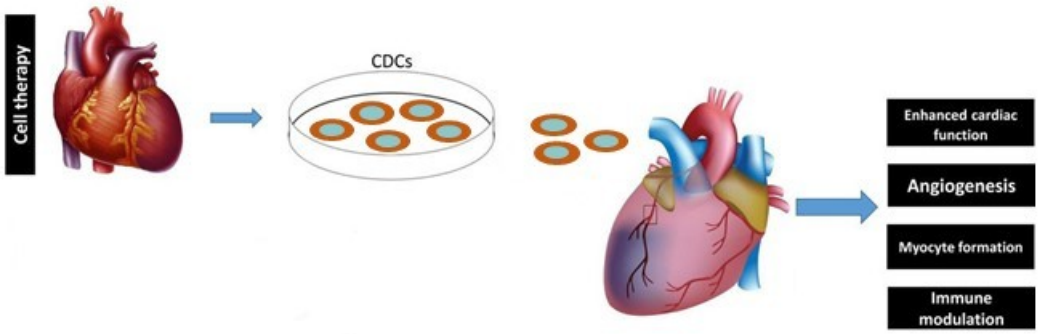
Exosome Program
"Next-Generation" Class of Biological Therapies
Capricor Therapeutics

Exosomes – a Cell-Free Regenerative Medicine Platform



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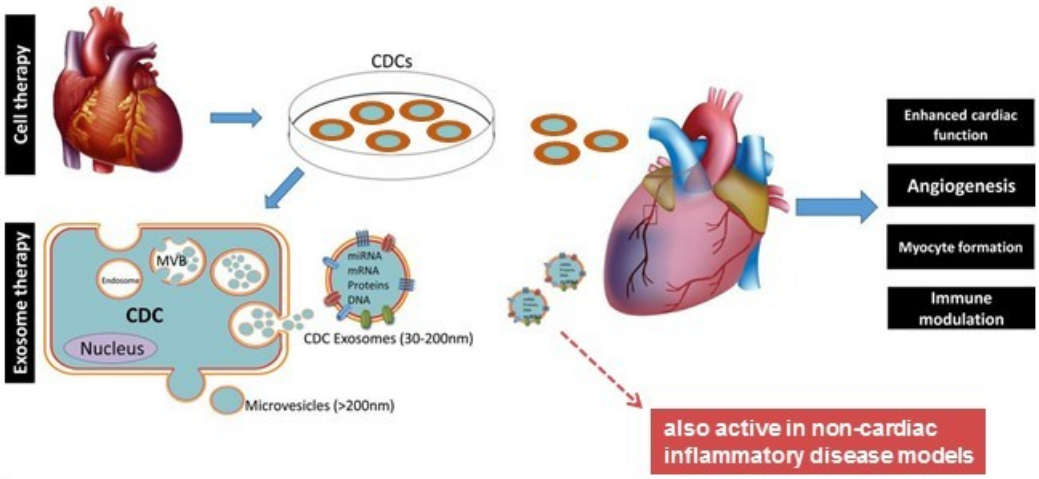
Gallet et al, Eur Heart J 2016;38:201-211.

Exosomes – a Cell-Free Regenerative Medicine Platform



Capricor Therapeutics

Gallet et al, Eur Heart J 2016;38:201-211.

Cash Runway Through Key 2017 Events

Cash and cash equivalents	$20.5 million (as of 9/30/16)
Net cash used in operations	$11.6 million (nine months ended 9/30/16)
Shares outstanding	21.4 million (February 13, 2017)

Capricor has received over $30 million in competitive grant and loan awards

Capricor Therapeutics

Cash Runway Through Key 2017 Events

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Capricor Therapeutics

Recent and Upcoming Milestones

Clinical Programs

CAP-1002 in Duchenne Heart Disease

- ✓ **3Q 2016:** Announced completion of enrollment in HOPE trial
- **Early 2Q 2017:** To report six-month top-line results of HOPE trial

CAP-1002 in Adult Heart Disease

- ✓ **4Q 2016:** Announced completion of ALLSTAR enrollment
- ✓ **4Q 2016:** Presented positive 12-month DYNAMIC results at TCT conference
- **Mid-2017:** Expect Janssen decision on license option

Preclinical

CAP-2003

- ✓ **3Q 2016:** Reported positive effects in oGVHD-relevant model
- **2H 2017:** Expect to submit IND application for oGVHD

A Translational Medicine Company