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)

October 5, 2016

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 October 5, 2016, 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.

Also on October 5, 2016, the Company issued a press release announcing completion of the enrollment of its ALLSTAR Phase II clinical trial. A copy of the press release is attached hereto as Exhibit 99.2 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 (including Exhibits 99.1 and 99.2 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 October 5, 2016.

99.2 Press Release, dated October 5, 2016, announcing completion of enrollment of the ALLSTAR Phase II Clinical Trial.

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.

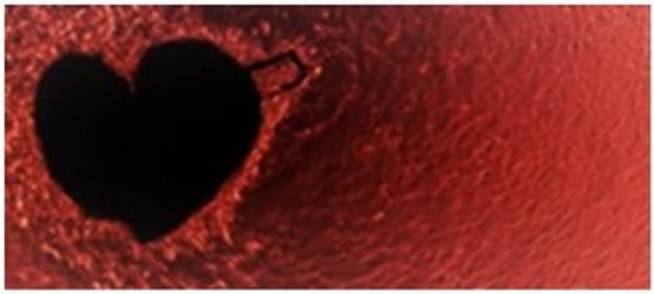
Date: October 5, 2016

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

Exhibit 99.1

Capricor Therapeutics

A Translational Medicine Company



NASDAQ: CAPR

www.capricor.com

Investor Presentation

October 2016

Forward-Looking Statements

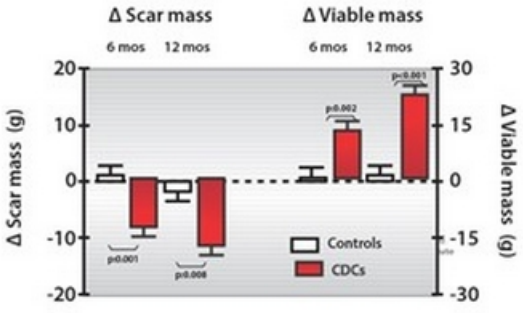
This presentation contains forward-looking statements and information that are based on the beliefs of the management of Capricor Therapeutics, Inc. (Capricor) as well as assumptions made by and information currently available to Capricor. All statements other than statements of historical fact included 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, 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 June 30, 2016 as filed with the Securities and Exchange Commission on August 15, 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.

Pipeline Summary

Product Candidate	Indication	Preclinical	Phase 1/2	Phase 2	Phase 3	Status & Upcoming Milestones
	Duchenne Muscular Dystrophy			HOPE		▪ Enrollment completed ▪ To report top-line six-month HOPE results in Q1:17
CAP-1002	Advanced Heart Failure			DYNAMIC		▪ To present 12-month DYNAMIC results at TCT annual meeting in Q4:16
	Post Myocardial Infarction				ALLSTAR	▪ Enrollment completed ▪ Expect decision on Janssen license option in mid-2017
CAP-2003	Ocular GVHD					▪ To submit IND in H1:17 ▪ To initiate clinical development in 2017
Cenderitide	Heart Failure					▪ Evaluating out-license opportunities

Capricor Therapeutics

Clinical Validation Provided by the CADUCEUS Trial



THE LANCET

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

Raj P Makkar, Rachel R Smith, Ke Cheng, Konstantinos Malliaras, Louise E J Thomson, Daniel Berman, Lawrence S C Czer, Linda Marbán, Adam Mendizabal, Peter V Johnston, Stuart D Russell, Karl N Schuleri, Albert C Lardo, Gary Gerstenblith, Eduardo Marbán

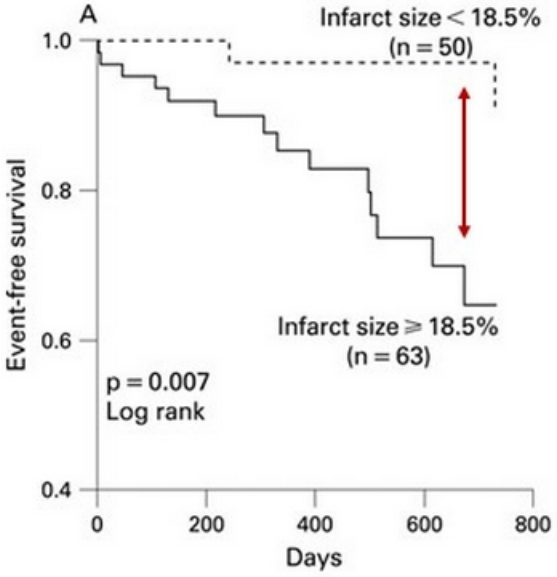
Lancet, 2012, 21(6): 1121-1135.

Showed for the <u>first time</u> that heart regeneration is therapeutically possible
Provides hope for a curative approach vs. stabilization, palliation

- <u>Randomized</u> trial in 25 patients with reduced ejection fraction following heart attack
- One-time intracoronary delivery of 25M autologous cardiosphere-derived cells (CDCs)
- Sponsored by Cedars-Sinai Medical Center with Johns Hopkins University

Capricor Therapeutics

Infarct (Scar) Size Significantly Impacts Survival



Kaplan-Meier curve for Major Adverse Cardiac Events (MACE) following acute ST-segment elevation MI, as stratified by infarct size.

MACE = death
myocardial infarction
heart failure admission

Capricor Therapeutics

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

Janssen has Option to License CAP-1002

- **CADUCEUS data attracted the interest of big pharma**
- **Capricor granted Janssen Biotech an exclusive option to enter into exclusive license agreement for worldwide rights to CAP-1002 for certain CV indications**
- **Expect Janssen's decision on license option by mid-2017**

  License fee and additional milestone payments totaling up to $325 million

  Low double-digit royalties on product sales

- **Collaboration with Janssen on manufacturing development since 2014**
- **Capricor received $12.5 million option fee**

Capricor Therapeutics

Heart Cells for Heart Disease

Capricor's core technology is the cardiosphere-derived cell (CDC):

- Does not act by 'stemness' – does not engraft into myocardium
- Exerts favorable and durable effects on target cells via exosome signalling
  - cardiomyogenic, anti-apoptotic, angiogenic, anti-fibrotic

CAP-1002 (allogeneic CDCs) is an "off the shelf" product

- One donor heart can provide thousands of doses of CAP-1002
- Product is packaged in Cryostor™, has 3-year frozen shelf life
- Clinical material currently produced at Capricor facility via proprietary process
- Commercial-scale process being developed in collaboration with Janssen

Record of immunological safety per cumulative clinical experience

IP licensed from Cedars-Sinai Medical Center, Johns Hopkins, U. of Rome

Capricor – Portfolio at a Glance

	PROGRAM	STAGE
CAP-1002	**Adult Cardiac Conditions**	Phase II
	Duchenne Muscular Dystrophy	Phase I / II
CAP-2003	Diseases of Inflammation and Fibrosis	Preclinical
Natriuretic Peptides	Outpatient Management of Heart Failure	Phase II

Capricor Therapeutics

Enrollment in Phase II ALLSTAR Trial has Completed

- **Similar patient population as CADUCEUS, but using allogeneic cells**
- **Phase II: randomized, double-blind, placebo-controlled**
  Patients enrolled at 30 centers in U.S. & Canada

  134 subjects with recent (30 – 90 d) or chronic (91 – 365 d) STEMI or NSTEMI

  25 million CDCs or placebo infused one time into infarct-associated coronary artery

  Primary efficacy analysis based on scar size at 12 month follow-up

  Expect decision on Janssen license option by mid-2017, following 6-month data

- **Phase I results support safety with evidence of:** **scar size reduction**
  ejection fraction improvement

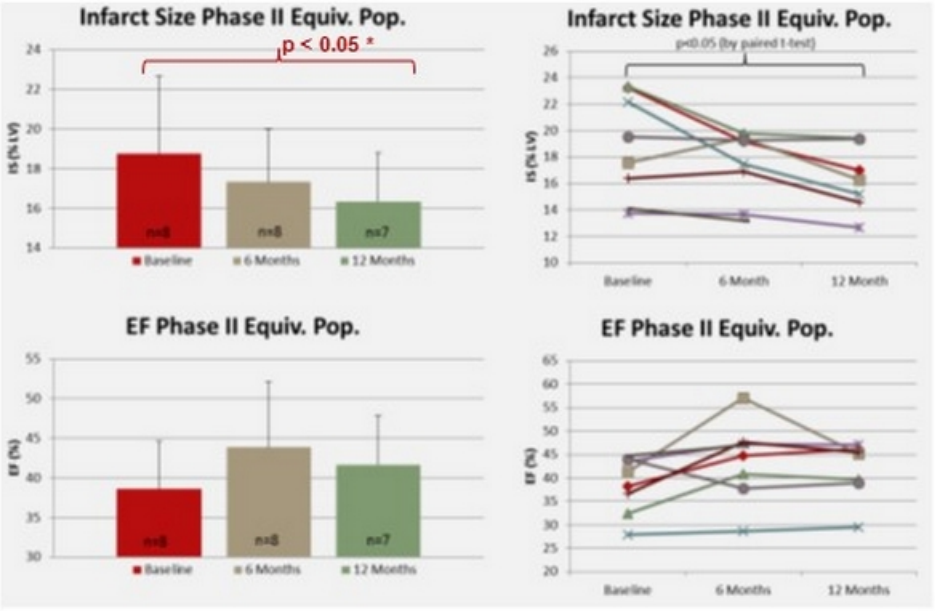
Capricor Therapeutics

ALLSTAR Phase I Efficacy (Phase II-Equivalent Population)

Received high dose CAP-1002 and lacked donor-specific antibodies (DSAs)

15% reduction in scar size at one year →

4 percentage-point improvement in ejection fraction at one year →



Capricor Therapeutics

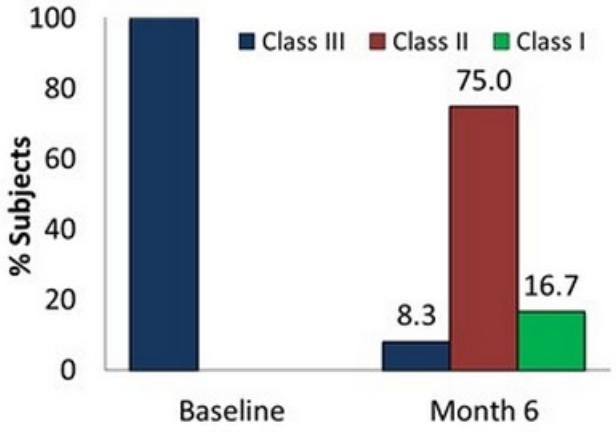
DYNAMIC Clinical Trial of CAP-1002 in Advanced HF

- **Phase IIa, open-label, dose-escalation clinical trial in heart failure patients**
  Conducted at Cedars-Sinai Medical Center
- **Enrollment was open to subjects with dilated cardiomyopathy**
  NYHA Class III or ambulatory Class IV
  Ischemic or non-ischemic origin
- **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 twelve-month follow-up**

Capricor Therapeutics

Six-Month DYNAMIC Results on CAP-1002 For Advanced HF

*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)

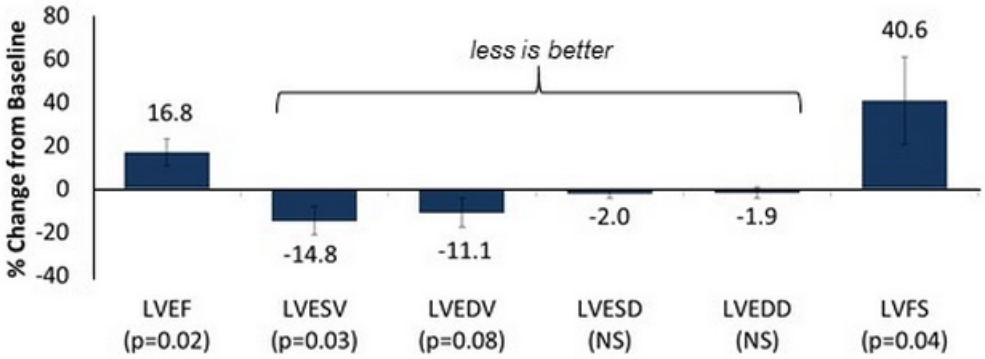
Capricor Therapeutics

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

Six-Month DYNAMIC Results on CAP-1002 For Advanced HF

*Presented at the American Heart Association Annual Meeting, November 2015**

Left Ventricular Dynamics & Dimensions



* N=14; two subjects lost to follow-up; measurements assessed by echocardiography.

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

Capricor Therapeutics

Capricor – Portfolio at a Glance

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CAP-1002	Adult Cardiac Conditions	Phase II
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Natriuretic Peptides	Outpatient Management of Heart Failure	Phase II

Capricor Therapeutics

Cardiomyopathy is #1 Cause of Death in DMD

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

Pediatric Cardiol. (2014) 35: 1279-1285

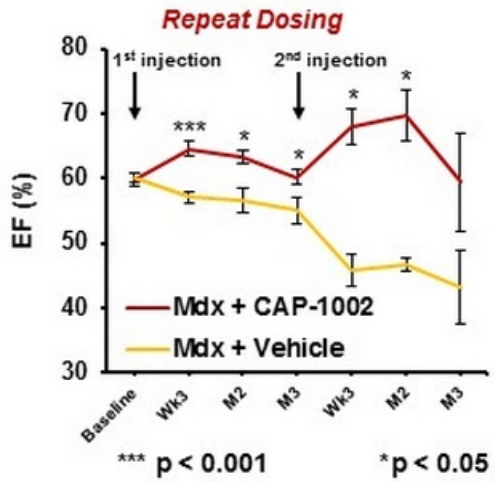
"As a result of respiratory support and glucocorticoid use, patients with DMD are living longer, bringing the associated cardiomyopathy to the forefront of management for Duchenne patients as they age"

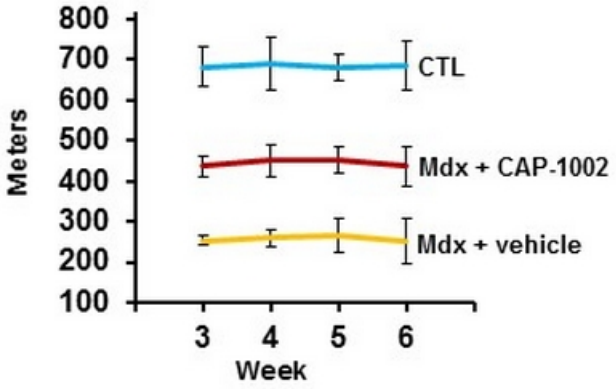
Circulation. 2015;131:1590-1598.

- **DMD results from mutation in dystrophin gene**
  - 1 per 3,600 male births
- **Lack of functional dystrophin in heart leads to:** inflammation
  cardiomyocyte death
  progressive cardiac fibrosis
- **Hearts become dilated and non-compliant, and eventually fail**
- **No approved therapies for heart disease associated with DMD**

Capricor Therapeutics

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





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

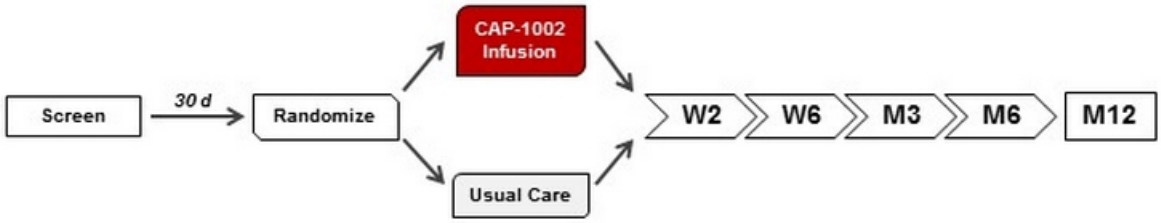
Capricor Therapeutics

ISEV, April 2015; AHA, November 2014

Cedars-Sinai Heart Institute

Enrollment in HOPE-Duchenne Trial Has Completed

- **Randomized Phase I/II trial at three U.S. centers**
  25 boys with DMD-associated cardiomyopathy
  13 in active arm – CAP-1002 triple-coronary infusion (single procedure)
  12 in comparator arm – usual care only



- **Successfully completed two interim DSMB safety reviews**
- **Expect to report top-line six-month data in Q1 2017**
  Structural (cardiac MRI)*, functional, quality-of-life endpoints
- **Results may enable Capricor to discuss product registration with FDA**

Capricor Therapeutics

* FDA Draft Guidance, June 2015.

Capricor – Portfolio at a Glance

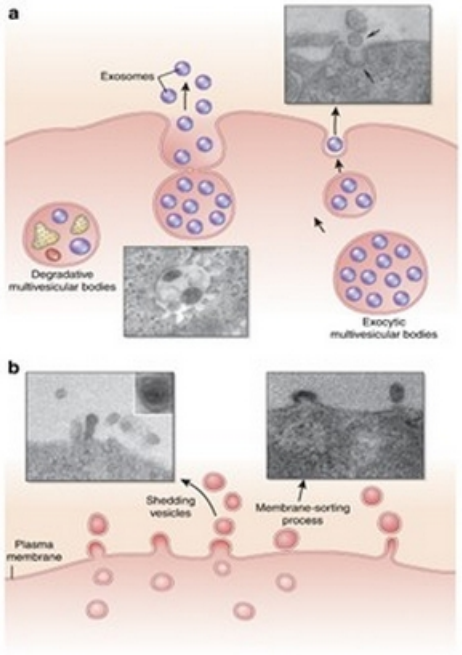
	PROGRAM	STAGE
CAP-1002	Adult Cardiac Conditions	Phase II
	Duchenne Muscular Dystrophy	Phase I / II
CAP-2003	**Diseases of Inflammation and Fibrosis**	Preclinical
Natriuretic Peptides	Outpatient Management of Heart Failure	Phase II

Capricor Therapeutics

Exosomes: Cell Free Regenerative Medicine Platform

- **CDC Exosomes are virus-sized vesicles that can reduce inflammation and regenerate damaged tissue**
- **CAP-2003 (CDC Exosomes) may be used in applications for which CDCs may not be well-suited**
- **Exclusive WW license from Cedars-Sinai Medical Center to CDC Exosomes technology**
- **Ocular graft-vs-host disease (oGVHD)** is first clinical indication for CAP-2003

Capricor Therapeutics



Camussi et al, Kidney Int 2010;78:838–848.

Ocular GVHD – First Clinical Development Opportunity

- **Graft-vs-host disease (GVHD)**
  - A common complication of bone marrow transplantation (BMT)
  - Chronic rejection of new cells
- **Ocular GVHD is a common, debilitating form of chronic GVHD and is an unmet medical need**
  - Burning, irritation, photophobia, pain, dryness
  - No approved therapies

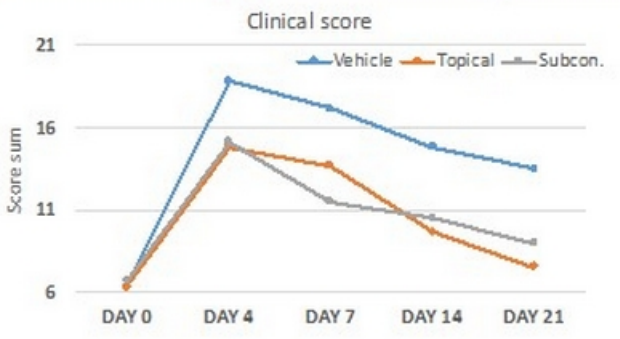
Orphan disease: **8,500** BMT are performed in the U.S. annually
40% of BMT recipients suffer from oGVHD

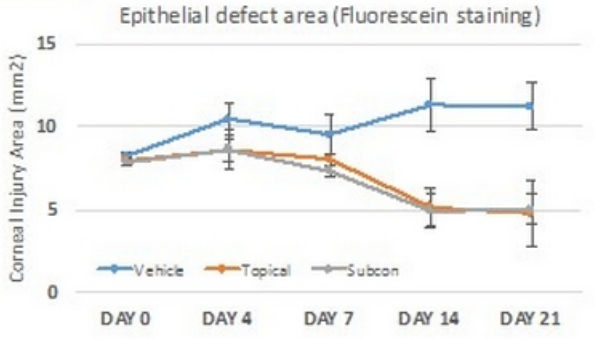
~3,400 new cases per year

- **Capricor attended a pre-IND meeting with FDA in July 2016**
  - Expect to submit IND application for CAP-2003 in oGVHD in H1:17
  - Alkali burn model sufficient for preclinical POC

http://bloodcell.transplant.hrsa.gov/about/general_faqs/index.html
Shikari et al, Surv Ophthalmol. 2013 May-Jun;58(3):233-51.

CAP-2003 Demonstrated Significant Improvement in Alkali Burn Injury Model





- **Clinical Score was calculated as the average of the sum of scores of six parameters (0-20):**

Conjunctival Injection (0-3)	Corneal Area Affected (0-4)	Aqueous Flare (0-4)
Corneal Opacification (0-3)	Corneal Neovascularization (0-2)	Aqueous Cell (0-4)

- **Epithelial defect area was evaluated using fluorescein staining**

Capricor Therapeutics

Cash Runway Through Key 2017 Milestones

Cash, cash equivalents, and marketable securities reported at June 30, 2016	**$11.4 million**
Net cash used in operations in H1:16	**$9.1 million**
Shares outstanding	**21.4 million***

* Includes approx. 3.4 million shares sold in September 2016 offering

– ***Raised approx. $10 million in net proceeds in September 2016 from sale of common stock***

Recent and Upcoming Milestones

CAP-1002 in Duchenne Heart Disease

✓ Announced completion of HOPE enrollment in September 2016

❑ Expect to report six-month top-line results of HOPE in Q1:17

CAP-1002 in Adult Heart Disease

✓ Announced completion of ALLSTAR enrollment in October 2016

❑ To present 12-month DYNAMIC data at TCT in Q4:16

❑ Expect Janssen decision on license option by mid-2017

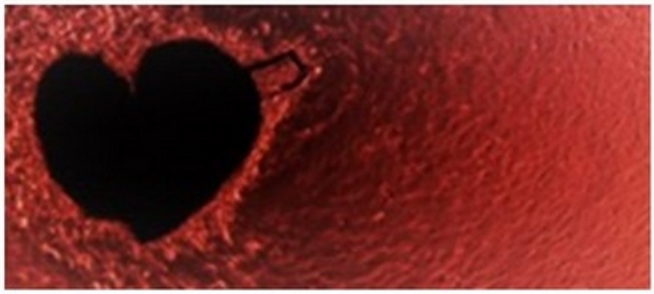
CAP-2003

✓ Demonstrated evidence of activity in several pre-clinical disease models

❑ Expect to submit IND application for oGVHD in H1:17

Capricor Therapeutics

A Translational Medicine Company



NASDAQ: CAPR

www.capricor.com

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Beverly Hills, CA 90211
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Exhibit 99.2

Capricor Therapeutics Completes Enrollment in Phase II ALLSTAR Clinical Trial

LOS ANGELES, October 5, 2016 – Capricor Therapeutics, Inc. (NASDAQ: CAPR), a clinical-stage biotechnology company developing biological therapies for cardiac and other serious medical conditions, today announced that its Phase II ALLSTAR clinical trial has completed patient enrollment. ALLSTAR (**ALL**ogeneic Heart **ST**em Cells to **A**chieve Myocardial **R**egeneration) is evaluating CAP-1002 (allogeneic cardiosphere-derived cells, or CDCs) in adults with cardiac dysfunction following a large heart attack (myocardial infarction, or MI).

"As we and others have shown, CAP-1002 possesses the ability to promote therapeutic regeneration in the injured heart, a powerful concept for the treatment of heart disease. In the CADUCEUS clinical trial, CDCs decreased scar size and increased viable tissue in the hearts of patients who had suffered a large heart attack. In ALLSTAR, not only are we studying a population similar to the one that delivered such astounding results in CADUCEUS (30 – 90 days post-MI), but we have also included patients that were 91– 365 days post-MI to see if we could extend the indication window. We have also moved to an allogeneic platform from autologous cells. With the last patient in ALLSTAR having been dosed on September 30th, we expect to report top-line 12-month primary efficacy outcome results in the fourth quarter of 2017," said Linda Marbán, Ph.D., president and chief executive officer of Capricor. "In the nearer-term, based on our current projections, we expect to learn of Janssen's decision on its exclusive license option by next summer. We are very much looking forward to seeing the results of the ALLSTAR trial because they may show, for the first time in a Phase II clinical trial, that cells can reduce scar and potentially improve outcomes."

"We recently reported 12-month results from our DYNAMIC clinical trial in patients with advanced heart failure, a condition that affects over five million people in the U.S. alone. Patients who received CAP-1002 had consistent and durable improvements in overall functional status, cardiac function and dimensions, as well as quality-of-life. We believe these patients represent a large share of the adult cardiology market, and our results appear to validate the bioactivity of the cells in improving heart function," added Dr. Marbán.

The randomized, double-blind, placebo-controlled Phase II ALLSTAR trial enrolled adults with a history of MI within the prior 12 months that resulted in scar tissue replacing at least 15 percent of total left ventricular mass and that was accompanied by cardiac dysfunction as evidenced by left ventricular ejection fraction (LVEF) no greater than 0.45. One hundred forty-two subjects were randomized to the active or control treatment groups in a 2:1 ratio, respectively, of whom 134 received a single infusion of either CAP-1002 or placebo into the infarct-associated coronary artery. Patients were stratified according to time between infarct event and study medication infusion (Recent MI = 30 – 90 days; Chronic MI = 91 – 365 days). Following infusion, patients are to be followed for periodic evaluations over the course of one year. Patients in the trial were enrolled at 30 centers in the U.S. and Canada.

For the pre-specified primary efficacy analysis, ALLSTAR is powered to detect a reduction in infarct size in the CAP-1002 group, relative to the placebo group, at 12 months post-infusion. Infarct size will be assessed by magnetic resonance imaging (MRI). ALLSTAR will also explore additional efficacy parameters, such as ejection fraction and cardiac volumes, as well as evaluate the safety and tolerability of CAP-1002.

ALLSTAR generally follows the design of the randomized CADUCEUS trial, which demonstrated a statistically significant reduction in infarct size as well as a statistically significant increase in viable heart muscle tissue, as measured at six and 12 months, in patients treated with a single intracoronary infusion of CAP-1001 (autologous CDCs) as compared to standard-of-care controls (Makkar et al, Lancet 2012;379:895–904). In contrast to CAP-1001, which was used in CADUCEUS and which had been prepared on an individual basis from each patient's own heart tissue, CAP-1002, which is being used in ALLSTAR, was prepared in advance from donor heart tissue and was stored under controlled conditions.

Under the terms of Capricor's Collaboration Agreement and Exclusive License Option with Janssen Biotech, at any time until 60 days following delivery to Janssen of six-month interim data from the Phase II ALLSTAR trial, Janssen has the right to enter into an exclusive, worldwide license agreement for the development and commercialization of CAP-1002. If Janssen exercises its option rights, Capricor will be eligible to receive an upfront license fee and milestone-based payments totaling up to $325 million, as well as royalties on any commercial product sales.

The Phase II portion of ALLSTAR clinical trial is funded in part through the support of the California Institute For Regenerative Medicine. The Phase I portion of the trial was funded in part by the National Institutes of Health.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a clinical-stage biotechnology company focused on the discovery, development and commercialization of biological therapies for the treatment of cardiac and other serious medical conditions. Capricor's lead candidate, CAP-1002, is a cardiac cell therapy that is currently being evaluated for the treatment of heart disease associated with Duchenne muscular dystrophy and myocardial infarction (heart attack). Capricor is advancing its proprietary exosome product candidate, CAP-2003, for the treatment of ophthalmic disorders and is exploring other therapeutic areas. Capricor's portfolio also features Cenderitide, a dual natriuretic peptide receptor agonist, which may have application for the outpatient treatment of advanced heart failure and other potential indications.

Cautionary Note Regarding 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; 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, expectations with respect to the expected use of proceeds from the recently completed offering 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 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 quarter ended June 30, 2016, as filed with the Securities and Exchange Commission on August 15, 2016. 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 and Cenderitide are Investigational New Drugs and are not approved for any indications. Capricor's exosomes technology has not yet been investigated in any clinical trial.

For more information, please contact:

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