

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

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**FORM 8-K/A**  
(Amendment No. 1)

**CURRENT REPORT**  
Pursuant to Section 13 or 15(d) of  
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)

November 12, 2014

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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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## EXPLANATORY NOTE

On November 12, 2014, Capricor Therapeutics, Inc. (the “Company”) filed a Current Report on Form 8-K (the “Initial Report”) to report the issuance of a press release announcing its financial results for the quarter ended September 30, 2014. A copy of the press release was furnished as Exhibit 99.1 to the Initial Report. This Amendment No. 1 to Current Report on Form 8-K/A, which amends the Initial Report, is being filed solely to amend Item 9.01 of the Initial Report to include a copy of the presentation slides that will be presented during the Company’s earnings conference call, to be held on Wednesday, November 12, 2014, at 4:30 p.m. Eastern Standard Time. A copy of the earnings presentation is furnished herewith as Exhibit 99.2 to this Amendment No. 1 to Current Report on Form 8-K/A, and will be available on the “Investors” section of the Company’s website and will remain archived there for at least 30 days from the date posted. Except as described in this Explanatory Note, no other changes have been made to the Initial Report, and this Amendment No. 1 to Current Report on Form 8-K/A does not amend or update any other information set forth in the Initial Report.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

99.1\* Press Release, titled “Capricor Therapeutics Reports Third Quarter 2014 Financial & Business Highlights”, dated November 12, 2014.

99.2 Capricor Therapeutics, Inc. Earnings Presentation Slides, dated November 12, 2014

\* Previously filed.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**CAPRICOR THERAPEUTICS, INC.**

Date: November 12, 2014

By: /s/ Linda Marbán, Ph.D.  
Name: Linda Marbán, Ph.D.  
Title: President and Chief Executive Officer

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# QUARTERLY CONFERENCE CALL

**3<sup>rd</sup> Quarter, 2014**

**November 12, 2014**

**4:30p.m. EST / 1:30p.m. PST**



# 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. Statements in this presentation regarding the efficacy, safety, and intended utilization of Capricor's product candidates; the conduct, size, timing and results of discovery efforts and clinical trials; scope, duration, validity and enforceability of intellectual property rights; plans regarding regulatory filings, future research and clinical trials; plans regarding current and future collaborative activities and the ownership of commercial rights; future royalty streams, 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 our business are set forth in our Annual Report on Form 10-K for the year ended December 31, 2013, as filed with the Securities and Exchange Commission on March 31, 2014, in our Amendment No. 1 to Registration Statement on Form S-1, as filed with the Securities and Exchange Commission on May 23, 2014, and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, as filed with the Securities and Exchange Commission on August 14, 2014. All forward-looking statements in this press release are based on information available to us as of the date hereof, and we assume no obligation to update these forward-looking statements.

# Capricor Therapeutics Overview

**Clinical-stage biotechnology company with a diversified pipeline and near-term focus on cardiovascular diseases including orphan indications**



**Cardiac-derived stem cells (CDCs)**



**Peptide therapy for heart failure (Cenderitide)**



**Micro-RNA Platform (Exosomes)**

# Quarterly Financial Highlights

<b>Balance Sheet Highlights</b> (approximate)	<b>9.30.14</b>	<b>12.31.13</b>
<b>Cash</b> (Includes restricted cash and marketable securities)	<b>\$13.8M</b>	<b>\$3.5M</b>
<b>Outstanding Common Shares</b>	<b>11,703,774</b>	<b>11,687,747</b>
<b>P&amp;L Highlights</b> (approximate)	<b>Three months ended 9.30.14</b>	<b>Three months Ended 9.30.13</b>
<b>Income</b>	<b>\$1.3M</b>	<b>\$0.1M</b>
<b>R&amp;D Expenses</b>	<b>\$2.0M</b>	<b>\$1.0M</b>
<b>G&amp;A Expenses</b>	<b>\$0.8M</b>	<b>\$0.6M</b>
<b>Net Loss</b>	<b>\$(1.5M)</b>	<b>\$(1.5M)</b>
<b>Net Loss per share</b> (basic and diluted)	<b>\$(0.13)</b>	<b>\$(0.15)</b>

# Notable AHA Presentations

## American Heart Association Scientific Sessions Chicago, IL (November 15-19)

Mon. 11/17	4:00pm – 6:00pm	South Hall-A2	ALLogeneic Heart Stem Cells to Achieve Myocardial Regeneration (ALLSTAR): the One Year Phase I Results
Mon. 11/17	4:00pm – 6:00pm	South Hall-A2	Heart-derived Cell Therapy for Duchenne Cardiomyopathy: Cardiosphere-derived Cells and their Exosomes Improve Function, Restore Mitochondrial Integrity and Reverse Degenerative Changes in the Hearts of Mdx Mice
Tues. 11/18	3:00pm - 4:30pm	South Hall-A2	Regenerative Effects of Exosomes Secreted by Cardiospheres in a Rat Model of Chronic Myocardial Infarction Are Mimicked by Exosome-primed Fibroblasts
Wed. 11/19	9:00am – 10:15am	S404bc d	Intracoronary Delivery of Exosomes Secreted by Cardiosphere-Derived Cells Confers Cardioprotection with Delayed Administration After Ischemia-Reperfusion Injury in Rats
Wed. 11/19	9:00 am - 12:00	South Hall A2 - Core 5	Dose-Escalation Study Using Novel Continuous Flow Intracoronary Delivery of Allogeneic Cardiosphere-Derived Stem Cells: Is There a Threshold for Cell Therapy?





# **Clinical Update**

# CDCs: Clinical Development

<b>ALLSTAR Clinical Trial</b>	<b>DYNAMIC Clinical Trial</b>	<b>Duchenne Muscular Dystrophy</b>
<b>Post Myocardial Infarction (30 days – 1 year after MI)</b>	<b>NYHA Class III or ambulatory Class IV heart failure</b>	<b>DMD-related cardiomyopathy</b>
<b>Phase I – 14 patients Phase II – 300 patients</b>	<b>Phase Ia – 14 patients Phase Ib – 28 patients</b>	<b>Planned Phase I (~10 patients)</b>
<b>IND granted, Phase II currently enrolling</b>	<b>IND granted, Phase I plan to commence in 2014</b>	<b>Potential Orphan Designation by FDA</b>

# ALLSTAR Phase I – 12 month MRI Analysis

- **ALLSTAR Phase I**
  - Met safety endpoint (1 month)
  - No control group
- Preliminary 12 month MRI analysis on Phase II equivalent population (defined by tissue type compatibility)
  - **Ejection fraction improved by 5.2%**
  - **Relative reduction in scar size of 20.7%**
  - Measurements of viable mass and regional function also showed quantifiable improvements
  - Additional data on Phase I to be presented at AHA (November 17, 2014)

# ALLSTAR: Phase II Clinical Trial

## **ALL**logeneic heart **ST**em cells to **A**chieve myocardial **R**egeneration

- Ejection Fraction  $\leq$  45% and Infarct Size  $\geq$  15% (MRI)
- Primary Endpoint – Infarct Size by MRI at 1 year
- Secondary Endpoints – multiple; EF, volumes, quality of life, etc.
- Phase II: Est. 300 patients – currently enrolling
  - 23 sites activated

# New Indication: Duchenne Muscular Dystrophy



# Duchenne Muscular Dystrophy

- Affects 1 in 3,500 male births worldwide
  - ~20,000 male children affected in the US (~275,000 worldwide)
  - The disease is usually fatal; **a majority of deaths occur due to cardiomyopathy**
- Compelling pre-clinical data to be presented at AHA in November 2014
  - Targeting IND in early 2015
  - Phase I planned for 2015

# Upcoming Conference Call

- Tuesday – November 18, 2014
  - 9:30AM (EST)
- Hosted by Dr. Linda and Eduardo Marbán
- Topic: Cardiosphere-derived Cells and their Exosomes Improve Function, Restore Mitochondrial Integrity and Reverse Degenerative Changes in the Hearts of Mdx Mice
- Data to be presented at AHA on November 17, 2014
- Call-in number: 1-866-652-5200
- *Webcast Link:*  
<http://services.choruscall.com/links/capr141112.html>

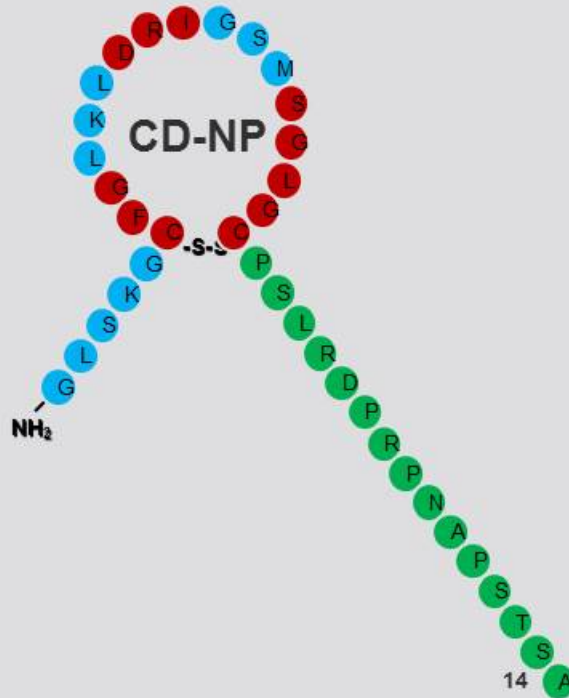


# **Cenderitide Update**



# Cenderitide: A Unique Protein Drug

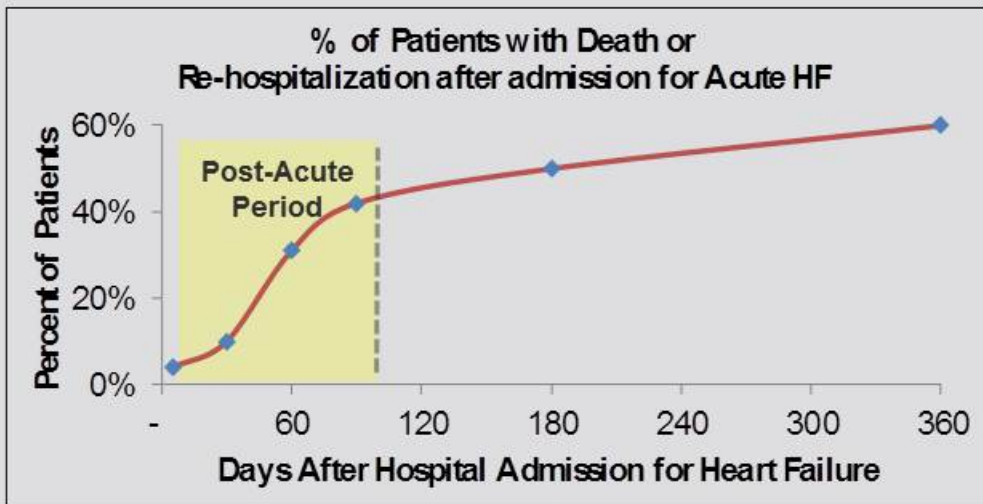
- Developed by scientists at the Mayo Clinic and derived from the venom of the green mamba snake
- **Cenderitide:**
  - Cardiac unloading
  - Renal function preserved
  - Aldosterone suppressing
  - Anti-fibrotic, apoptotic, and hypertrophic
- 270 patients with acute decompensated heart failure have been treated



# Annual U.S. Cenderitide Market Opportunity

- Heart failure - leading cause of hospitalizations among adults older than 65 years of age in the US
  - Costs \$17 billion annually
- Responsible for over 1 million hospital admissions annually
- No new class of heart failure drug approved for more than a decade
- Medicare has implemented financial penalties for re-hospitalizations within 30 days
- Complementary with LCZ696 (Novartis)
- **Cenderitide's treatment goal is to prevent readmission to hospital within 90 days due to cardiac events**

# 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

*Reference: estimate from analysis of DOSE, PROTECT, ASCEND, OPTIMIZE, & ADHERE*

# Continuous Subcutaneous Infusion Using the Insulet Omnipod® Technology

- Entered into a Research Support Agreement with Insulet Corporation (NASDAQ: [PODD](#))
- Insulet will supply Omnipod® for planned clinical trial:
  - Engage in product development
  - Project management
  - Design control activities

*Sample shown: Omnipod®*



*Fill the Pod*

*Apply the Pod*

*Press Start*

# Acquisition of Medtronic IP

- Entered into an agreement to acquire patent rights from Medtronic, Inc. (NYSE: MDT)
  - Related to the formulation and pump delivery of natriuretic peptides.
  - Assigned to Capricor all of its right, title and interest in all natriuretic peptide patents and patent applications previously owned by Medtronic or co-owned by each of the companies as part of their collaborative natriuretic peptide delivery program

# Cenderitide as a Potential Treatment for Post-Acute Heart Failure

<b>Target Indication</b>	Prevention of re-hospitalization in heart failure patients in the post-acute hospitalization period
<b>Treatment Duration</b>	90 days of out-patient treatment after hospital discharge for acute decompensated heart failure
<b>Drug Delivery</b>	Subcutaneous infusion using the Insulet Omnipod® validated technology
<b>Clinical Progress</b>	Planned Phase I 1H 2015
<b>FDA Status</b>	Fast Track designation granted

# Anticipated Milestones

- **2014**
  - Report additional ALLSTAR Phase I results (AHA)
  - Initiate DYNAMIC clinical trial
- **2015**
  - Initiate Duchenne Muscular Dystrophy trial
  - Initiate Cenderitide trial
  - Report initial Cenderitide results
  - Report initial DYNAMIC results



**Thank you**