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)

November 18, 2014

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 8.01. Other Events.

Announcement of Data

Pre-clinical Data on Duchenne Muscular Dystrophy

On November 18, 2014, Capricor Therapeutics, Inc. (the "Company") issued a press release announcing positive pre-clinical data for cardiosphere-derived cells (CDCs) on Duchenne Muscular Dystrophy cardiomyopathy. The abstract was presented at the Late Breaking Basic Science Posters and Reception at the American Heart Association's Scientific Sessions 2014 on November 17, 2014. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

Announces Safety and Preliminary Efficacy Data on ALLSTAR Phase I

On November 18, 2014, the Company issued a press release announcing favorable safety results from the ALLSTAR Phase I clinical study and preliminary efficacy results. The data was announced at the American Heart Association's Annual Scientific Sessions 2014 on November 17, 2014. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release, dated November 18, 2014, announcing positive pre-clinical data for cardiosphere-derived cells (CDCs) on Duchenne Muscular Dystrophy cardiomyopathy.

99.2 Press Release, dated November 18, 2014, announcing favorable ALLSTAR Phase I safety results and encouraging preliminary efficacy results.

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: November 19, 2014

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

Exhibit 99.1

Capricor Therapeutics Announces Positive Pre-Clinical Data for Cardiosphere-Derived Cells (CDCs) on Duchenne Muscular Dystrophy Cardiomyopathy

Capricor Intends to File for Approval to Conduct Clinical Trial of CAP-1002 in Duchenne Cardiomyopathy

LOS ANGELES, November 18, 2014 – Capricor Therapeutics, Inc. (OTCBB: CAPR), a biotechnology company focused on developing novel therapeutics for the treatment of cardiovascular diseases, today announced positive data from the laboratory of Eduardo Marbán, M.D., Ph.D., Capricor's Scientific Advisory Board Chairman and the Director of the Cedars-Sinai Heart Institute. The abstract was presented at the Late Breaking Basic Science Posters and Reception at the American Heart Association's Scientific Sessions 2014 on November 17, 2014.

Capricor's Cardiosphere-derived cells (CDCs), also known as CAP-1002, promote cardiomyogenesis and angiogenesis, while inhibiting oxidative stress, inflammation and fibrosis. Dr. Marbán tested the hypothesis that CDC transplantation may be beneficial in mice with muscular dystrophy (mdx mice), which progressively develop cardiomyopathy due to dystrophin deficiency and the resultant intense oxidative stress, inflammation and apoptosis.

Methods and Results: A total of 56 mice were studied at a point when global cardiac dysfunction was already evident by echocardiography. Wild-type syngeneic mouse CDCs (10^5 cells total) or control were injected intra-myocardium in 5 left ventricular (LV) sites in 10-month old mdx mice.

- LV ejection fraction markedly improved 3 weeks after treatment in CDC-treated mice compared to vehicle-treated mice (60.4±1.6 vs 48.1±2.2; $p<0.005$).
- CDC-treated mdx mice exhibited higher maximal exercise capacity compared to vehicle-treated mice over 3 months of follow up ($p<0.05$).
- The functional improvement was associated with enhanced Nrf2 activation, up-regulation of Nrf2 downstream gene products, increased expression of mitochondrial transcription factor A and cellular mitochondrial content, restored expression of mitochondrial respiratory complex proteins, reduced collagen I and III deposition, and attenuated infiltration of inflammatory cells [$CD68^+$ macrophages and $CD3^+$ T cells] in the CDC-treated mouse hearts.

The data demonstrated that cardiac function and exercise capacity improved in CDC-treated mdx mice, accompanied by enhanced activation of the antioxidative Nrf2 pathway, attenuation of inflammation, reduction in collagen content and fibrosis, and augmented cardiomyogenesis in CDC-treated mdx hearts. The findings raise the possibility that CDCs may be useful therapeutically to treat heart failure in patients with Duchenne muscular dystrophy.

Dr. Linda Marbán, Chief Executive Officer of Capricor, said, "Data presented yesterday forms the basis for a clinical development plan that we intend to submit to FDA. Duchenne cardiomyopathy is a devastating complication of the disease that affects virtually all those affected by the disease and is the leading cause of death in patients with Duchenne Muscular Dystrophy. Notwithstanding the advances being made for the skeletal muscle symptoms of Duchenne, Capricor is addressing the devastating cardiac complications for which there is no specific treatment."

About Duchenne Muscular Dystrophy (DMD)
DMD afflicts approximately 25,000 boys and young men in the USA. The central cause is a genetic abnormality in the dystrophin complex, leading to membrane fragility with secondary damage to skeletal and cardiac muscle. No treatment has been proven effective for DMD; patients usually die in young adulthood. Various clinical trials are ongoing, but almost all target the skeletal myopathy. Much of the death and disability in the later years of DMD is due to heart disease rather than to skeletal muscle disease. Virtually all DMD patients aged >15 years develop heart failure, and mortality is high (10-20% per year) despite optimal medical therapy. Heart transplantation is not typically an option for DMD patients.

About Capricor Therapeutics
Capricor Therapeutics, Inc. (CAPR), a publicly traded biotechnology company, is focused on the development of novel therapeutics to prevent and treat heart disease. The Company has two leading product candidates: CAP-1002 and Cenderitide. The Company was formed through the November 2013 merger between Capricor, Inc., a privately held company whose mission is to improve the treatment of heart disease by commercializing cardiac stem cell therapies for patients, and Nile Therapeutics, Inc., a clinical-stage biopharmaceutical company developing innovative products for the treatment of cardiovascular diseases. For additional information visit www.capricor.com.

Cautionary Note Regarding Forward-Looking Statements
Statements in this press release regarding the efficacy, safety, and intended utilization of Capricor's product candidates; the conduct, size, timing and results of discovery efforts and clinical trials; 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 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 Form 10-Q for the quarter ended September 30, 2014, as filed with the Securities and Exchange Commission on November 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.

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For more information, please contact:

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Exhibit 99.2

Capricor Therapeutics Announces Favorable ALLSTAR Phase I Safety Results

Preliminary Efficacy Data Shows Encouraging Results

LOS ANGELES, November 18, 2014 – Capricor Therapeutics, Inc. (OTCBB:CAPR), a biotechnology company focused on developing novel therapeutics for the treatment of cardiovascular diseases, announced yesterday at the American Heart Association's Annual Scientific Sessions 2014, the one-year results of the Phase I **ALLSTAR** (**All**ogeneic Heart **St**em Cells to **A**chieve Myocardial **R**egeneration) clinical trial, which indicate that intracoronary injection of allogeneic cardiosphere-derived stem cells (CAP-1002) to achieve myocardial regeneration in patients with left-ventricular dysfunction who have had an anterior myocardial infarction appears to be safe, with no deaths, no acute myocarditis and no major adverse cardiac events.

The safety endpoints of the trial, including no acute myocarditis attributable to CAP-1002, no deaths due to ventricular tachycardia or ventricular fibrillation, no sudden death and no major adverse cardiac events, were achieved with no endpoint events in the 14 enrolled subjects at 1 month and at 12 months. The results showed that none of the pre-specified safety endpoints occurred. In addition, exploratory efficacy data in this Phase I trial have shown improvements in ejection fraction and reduction in scar size, most notably in the Phase II equivalent population.

This study prospectively enrolled 14 adults from 40 to 66 years old with a recent (within 28 to 90 days) or chronic (within 91 to 365 days) anterior myocardial infarction, left-ventricular dysfunction and an infarct size >15 percent of left-ventricular mass and infused them with CAP-1002 at a dose of either 12.5M or 25M using stop-flow intracoronary infusion. At baseline, the participants had left-ventricular function impairment with a mean ejection fraction of 42 percent with a range of 26.7 percent to 55.1 percent. Phase I was funded in large part by a grant received from the NIH.

In addition, exploratory efficacy data in this Phase I trial have shown improvements in ejection fraction and reduction in scar size, most notably in those participants who would be included in the Phase II clinical study by virtue of dose and tissue type compatibility. With respect to those participants, the data showed a relative reduction at one year of 15 percent of infarct scar size and a nearly 4 percent absolute improvement in ejection fraction. The Company suggests that these data be interpreted with caution as the sample size was small and there was no contemporaneous control group.

The Phase II portion of the trial, currently underway, began enrollment in January 2014, and is expected to enroll approximately 300 patients who have had an anterior myocardial infarction within 30 days to one year prior to enrollment, left-ventricular function and an infarct size >15 percent of left-ventricular mass. The participants will be randomized to receive either CAP-1002 or placebo in a 2:1 ratio favoring CAP-1002.

In addition, the Phase II portion of the ALLSTAR trial will aim to further establish the safety and determine the efficacy of this therapy in reducing the scar size and improving the ejection fraction in these subjects with moderate to large anterior myocardial infarction who are at significant risk of deterioration into heart failure and early death. Phase II of the ALLSTAR trial has been funded with the support of the California Institute for Regenerative Medicine.

“We are extremely pleased with the clinical results from our Phase I ALLSTAR trial, and look forward to completion of the ALLSTAR Phase II study, where in addition to safety, we will assess efficacy in a larger patient population” said Capricor CEO, Linda Marbán, Ph.D.” Dr. Marbán added, “Coupled with the positive pre-clinical results in the mdx mouse model which were presented on Monday afternoon at AHA, we intend to present a clinical plan for Duchenne cardiomyopathy to FDA with our lead product, CAP-1002.”

About Capricor Therapeutics
Capricor Therapeutics, Inc. (CAPR), a publicly traded biotechnology company, is focused on the development of novel therapeutics to prevent and treat heart disease. The Company has two leading product candidates: CAP-1002 and Cenderitide. The Company was formed through the November 2013 merger between Capricor, Inc., a privately held company whose mission is to improve the treatment of heart disease by commercializing cardiac stem cell therapies for patients, and Nile Therapeutics, Inc., a clinical-stage biopharmaceutical company developing innovative products for the treatment of cardiovascular diseases. For additional information visit www.capricor.com.

About CAP-1002
CAP-1002, Capricor’s lead product candidate, is a proprietary allogeneic adult stem cell therapy for the treatment of heart disease. The product is derived from donor heart tissue. The cells are expanded in the laboratory using a specialized process and then introduced directly into a patient’s heart via infusion into a coronary artery using standard cardiac catheterization techniques.

CAP-1002 is currently not an approved product and is strictly for investigational purposes.

Cautionary Note Regarding Forward-Looking Statements
Statements in this press release regarding the efficacy, safety, and intended utilization of Capricor’s product candidates; the conduct, size, timing and results of discovery efforts and clinical trials; 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 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 Form 10-Q for the quarter ended September 30, 2014, as filed with the Securities and Exchange Commission on November 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.

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