

**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 6, 2014

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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Item 8.01 Other Events.

New Planned Clinical Programs

Clinical Program for the Treatment of Duchenne Muscular Dystrophy

On October 6, 2014, Capricor Therapeutics, Inc. (the "Company") issued a press release announcing plans to pursue a clinical program for the treatment of Duchenne Muscular Dystrophy with cardiosphere-derived cells (CDCs). This press release announced the intention of the Company to pursue plans for a clinical program to treat patients affected by the disorder using the Company's lead product candidate, CAP-1002. 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.

Clinical Program for the Treatment of Post-Acute Heart Failure

On October 9, 2014, the Company issued a press release announcing plans to pursue a clinical program using Cenderitide for the treatment of post-acute heart failure using the Insulet Delivery Technology. This press release described the Investigator-Initiated Research Support Agreement with Insulet Corporation and additional plans associated with the planned clinical trial. 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 October 6, 2014, announcing plans to pursue a clinical program for Duchenne Muscular Dystrophy with cardiosphere-derived cells (CDCs).
 - 99.2 Press Release, dated October 9, 2014, announcing plans to pursue a Cenderitide clinical program and entry into Investigator-Initiated Research Support Agreement with Insulet Corporation.
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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 9, 2014

By: /s/ Linda Marbán, Ph.D.

Linda Marbán, Ph.D.

Chief Executive Officer



Capricor Announces Plans to Pursue Clinical Program for the Treatment of Duchenne Muscular Dystrophy with Cardiosphere-Derived Cells (CDCs)

LOS ANGELES, October 6, 2014 – Capricor Therapeutics, Inc. (OTCBB: CAPR), a biotechnology company focused on developing novel therapeutics for the treatment of cardiovascular diseases, today announced that it plans to develop a clinical program for Duchenne Muscular Dystrophy (DMD) using CAP-1002, Capricor's lead product candidate. CAP-1002 is an allogeneic, off-the-shelf, investigational cell therapy derived from donor heart tissue and is infused directly into a patient's coronary arteries during a catheterization procedure. CAP-1002 is currently in Phase II clinical testing for adults with ischemic heart disease.

The clinical program will move forward based, in part, on data findings from the laboratory of Eduardo Marbán, M.D., Ph.D., Scientific Advisory Board Chairman of Capricor and the Director of the Cedars-Sinai Heart Institute. The data will be presented at the Late Breaking Basic Science Posters and Reception during the American Heart Association's Scientific Sessions in Chicago on November 17th, 2014.

Duchenne Muscular Dystrophy (DMD) is a genetic disorder caused by a mutation of the dystrophin gene and is characterized by progressive muscle degeneration and weakness. Symptoms usually appear in male children before age six but may be visible in early infancy and the disorder is often fatal. Though characterized by progressive skeletal muscle weakness which often results in patients requiring the use of a wheelchair and having respiratory complications, DMD also results in cardiac dysfunction in most patients. Many deaths occur due to cardiomyopathy caused by a weakening of the cardiac muscle as a result of the gene mutation that is responsible for the disease. Many patients do not survive beyond their mid-twenties. Nearly 20,000 male children are living with the disease in the United States alone and approximately 275,000 are affected worldwide.

"We are extremely excited to develop a clinical program targeting DMD as a potential indication for our CDC platform technology," said Capricor CEO, Linda Marbán, Ph.D. "In early clinical trials, CDCs have shown to be safe and to reduce scar size in patients with ischemic heart disease. Treatment of DMD cardiomyopathy provides a unique opportunity to apply Capricor's CDC technology for the treatment of patients with a potentially fatal orphan disease. Although, there is no cure for DMD, we look forward to raising the overall scientific understanding of this disease, and hopefully to improving the lives of patients with DMD and their families."

About the Presentation

An abstract entitled, "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," will be presented at the Late Breaking Basic Science Posters and Reception at the American Heart Association's Scientific Sessions 2014. The presentation will be held between 4:00–6:00 PM on Monday, November 17th, in South Hall A2 of McCormick Place, Chicago, IL.

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 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.

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For more information, please contact:

Capricor Therapeutics, Inc.

AJ Bergmann, Vice President of Finance

+1-310-358-3200

abergmann@capricor.com

ProActive Capital Group

Kirin Smith, COO

+1-646-863-6519

ksmith@ProActiveCapital.com

www.ProActiveCapital.com



Capricor Therapeutics Announces Plans to Pursue a Cenderitide Clinical Program and Enters into Research Support Agreement with Insulet Corporation

Clinical Trial Expected to Commence in Early 2015 Using the Insulet Delivery Technology

LOS ANGELES, October 9, 2014 – Capricor Therapeutics, Inc. (OTCBB: CAPR), a biotechnology company focused on developing novel therapeutics for the treatment of cardiovascular diseases, today announced that it plans to develop a clinical program using Cenderitide for the treatment of post-acute heart failure using Insulet's drug delivery system based on the OmniPod[®] insulin management system.

Additionally, Capricor announced that it has entered into an Investigator-Initiated Research Support Agreement (the "Agreement") with Insulet Corporation (NASDAQ: PODD). Pursuant to the Agreement, Insulet will support Capricor's research by engaging in certain product development, project management and design control activities in addition to product supply for the planned clinical trial.

Dr. Linda Marbán, Chief Executive Officer of Capricor, said, "Recent positive results in Novartis' PARADIGM-HF trial have shown the mechanism of action of their ARNI (angiotensin receptor neprilysin inhibitor) can raise the level of endogenous natriuretic peptides by preventing their enzymatic breakdown in chronic heart failure patients. We believe this validates the mechanism of action of Cenderitide, which is a dual receptor natriuretic peptide agonist. We intend to develop Cenderitide as an outpatient therapy to be delivered continuously for up to 90 days after discharge from the hospital to patients who have been admitted for acute decompensated heart failure (ADHF). There are currently no treatments on the market that specifically target the stabilization and reduction of the early re-hospitalization rate of acute decompensated heart failure patients."

According to the American Heart Association, heart failure is the leading cause of hospitalization among adults older than 65 years of age in the United States and is responsible for over 1 million hospital admissions annually. Among those patients that have been admitted, approximately 24% are re-hospitalized in one month, and 50% are re-hospitalized in six months.

Dr. Linda Marbán, continued, "These staggering statistics, coupled with the prevalence and incidence of heart failure increasing around the world, leads us to believe this could be an extremely exciting market opportunity for Capricor. We are pleased to announce our pursuit of this key clinical program with Insulet's support as we continue to execute on our strategy to bring Cenderitide back into the clinic. We are planning a clinical trial to commence in early 2015. Of note, we have been granted Fast-Track designation by the FDA for the post-acute development program for Cenderitide."

Currently, there are no drugs on the market targeting the post-acute period, 90 days following a hospital admission for Acute Decompensated Heart Failure (ADHF). Cenderitide's treatment goal and target indication is prevention of re-hospitalization in heart failure patients during the post-acute hospitalization period.

About Cenderitide

Cenderitide belongs to a class of drugs called natriuretic peptides. Preclinical and clinical data have shown that the natriuretic peptide class can act on multiple disease processes that play a role in negative outcomes associated with heart failure. Cenderitide is designed as an outpatient therapy to be delivered continuously using a validated subcutaneous infusion pump for up to 90 days (the "post-acute" period) following a hospital admission for ADHF. Cenderitide was designed by scientists at the Mayo Clinic to be the only dual natriuretic peptide receptor agonist.

Cenderitide is currently not an approved product and is strictly for investigational purposes.

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About Insulet Corporation

Insulet Corporation (NASDAQ: PODD) is an innovative medical device company primarily focused on making it easier for people living with diabetes to manage their disease. Through its OmniPod Insulin Management System, Insulet seeks to expand the use of insulin pump therapy among people with insulin-dependent diabetes. The OmniPod is a revolutionary and easy-to-use tubeless pump that features just two parts and fully-automated cannula insertion. The OmniPod technology has also been adapted to deliver additional drugs in other disease states. Insulet has also developed variations of the OmniPod to allow for delivery of drugs to treat other medical conditions. Founded in 2000, Insulet Corporation is based in Billerica, Mass. For more information, please visit: <http://www.myomnipod.com>.

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Kirin Smith, COO
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ksmith@ProActiveCapital.com
www.ProActiveCapital.com
