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 22, 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 8.01. Other Events.

On February 22, 2016, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing the continuing enrollment of, and treatment of the first patient in, the Company's HOPE-Duchenne Phase I/II clinical trial. 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release of Capricor Therapeutics, Inc., dated February 22, 2016.

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: February 22, 2016

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

Exhibit 99.1

Capricor Therapeutics Announces the First Patient with Duchenne Muscular Dystrophy-Related Cardiomyopathy Treated with CAP-1002 in the HOPE-Duchenne Phase I/II Clinical Trial

LOS ANGELES, February 22, 2016 – Capricor Therapeutics, Inc. (NASDAQ: CAPR), a biotechnology company focused on the discovery, development and commercialization of first-in-class therapeutics, today announced continuing enrollment of, and the treatment of the first patient with Duchenne Muscular Dystrophy (DMD)-related cardiomyopathy with CAP-1002 in the HOPE-Duchenne Phase I/II clinical trial (**H**alt cardiomy**OP**athy progr**E**ssion in Duchenne). CAP-1002 is Capricor's allogeneic, cardiosphere-derived stem cell (CDC) therapy. The patient was treated at the Cincinnati Children's Hospital Medical Center under the direction of Dr. John Jefferies, the national principal investigator for the HOPE-Duchenne trial. Enrollment is now ongoing at Cincinnati Children's Hospital Medical Center in Cincinnati, Ohio and at Cedars-Sinai Heart Institute in Los Angeles, California.

The HOPE-Duchenne trial is designed to enroll 24 patients in a randomized, multi-center study evaluating the safety and efficacy of CAP-1002. Patients randomized to receive the cells will receive CAP-1002 in all three coronary arteries which will enable delivery extensively across the myocardium. Improvement in cardiac function was recently reported using this approach in Capricor's DYNAMIC trial for adult patients with Class III Heart Failure. Cardiomyopathy is currently the leading cause of death in patients with DMD now that other treatments are available to mitigate other aspects of the disease process.

"DMD is a genetic disorder characterized by progressive muscle deterioration. Patients with DMD also develop cardiopulmonary dysfunction in their teen years with death often occurring in their twenties," said John L. Jefferies, M.D., MPH, FAAP, FACC, Professor, Pediatric Cardiology and Adult Cardiovascular Diseases, University of Cincinnati College of Medicine, and Director, Advanced Heart Failure and Cardiomyopathy, Cincinnati Children's Hospital Medical Center. "Based on Capricor's prior encouraging clinical experience with CDC cell therapy in adults who have either suffered a heart attack or have heart failure, supplemented by the positive data in the mouse pre-clinical model of DMD (*mdx*), we are pleased to be able to begin the HOPE trial in boys and young men with DMD. Scarring is the hallmark of DMD cardiomyopathy and as the patients get older, the scar quantity expands and cardiac function then deteriorates. CDCs have been shown clinically in both the CADUCEUS and ALLSTAR Phase I clinical trials to reduce scar in the heart which might also benefit boys with DMD cardiomyopathy. We are happy to report that our first patient in the trial tolerated the CAP-1002 infusion procedure extremely well."

"We are thrilled to have initiated the HOPE-Duchenne clinical trial." said Linda Marbán, Ph.D., Chief Executive Officer of Capricor. "CAP-1002 is to our knowledge the only clinical stage therapy intended to reduce fibrosis and scar in hearts affected by DMD. One of our goals with our CDCs is to target orphan diseases with cardiac implications, and DMD cardiomyopathy is our first target along these lines. We are hopeful that CAP-1002 may be a big step forward as a treatment option for DMD cardiomyopathy which at present is a progressive disease with poor therapeutic options."

For more information, please visit: http://capricor.com/hope/ or ClinicalTrials.gov (NCT02485938).

About Duchenne Muscular Dystrophy (DMD)

DMD afflicts approximately 20,000 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 despite optimal medical therapy. Heart transplantation is not typically an option for DMD patients.

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.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class therapeutics. The Company's lead programs target post myocardial infarction (heart attack), heart failure and Duchenne Muscular Dystrophy. The Company has two lead product candidates under investigation: CAP-1002, a cardiac cell therapy, and Cenderitide, a natriuretic peptide receptor agonist. CAP-1002 is in development for the treatment of post myocardial infarction, advanced heart failure and Duchenne muscular dystrophy-associated cardiomyopathy. Cenderitide is in development for the outpatient treatment of heart failure as well as potential other indications. In addition, the Company is conducting research and development on its exosomes platform technology for cardiac diseases and other potential indications. 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; scope, duration, validity and enforceability of intellectual property 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 Capricor's business are set forth in Capricor's Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the Securities and Exchange Commission on March 16, 2015, 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 September 30, 2015, as filed with the Securities and Exchange Commission on November 13, 2015. 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.

For more information, please contact:

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