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)

April 25, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On April 25, 2017, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing positive six-month results from the randomized Phase I/II HOPE clinical trial in Duchenne muscular dystrophy. A copy of the press release 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.

The information contained in this Form 8-K (including Exhibit 99.1 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 Press Release, titled "Capricor Therapeutics Announces Positive Six-Month Results from the Randomized Phase I/II HOPE Clinical Trial in Duchenne Muscular Dystrophy", dated April 25, 2017.

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: April 25, 2017

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

Exhibit 99.1

Capricor Therapeutics Announces Positive Six-Month Results from the Randomized Phase I/II HOPE Clinical Trial in Duchenne Muscular Dystrophy

Statistically-Significant Improvements in Measures of Cardiac and Upper Limb Function in Patients Treated with CAP-1002

Capricor to Seek Breakthrough Therapy or Regenerative Medicine Advanced Therapy Designation

Conference Call and Webcast to be Held Today at 8:00 a.m. Eastern Time

LOS ANGELES, April 25, 2017 – Capricor Therapeutics, Inc. (NASDAQ: CAPR), a clinical-stage biotechnology company developing first-in-class biological therapies for cardiac and other medical conditions, today announced positive top-line results from a safety and exploratory efficacy analysis of six-month data from the randomized 12-month Phase I/II HOPE Clinical Trial of CAP-1002 (allogeneic cardiosphere-derived cells), an investigational candidate for the treatment of patients with Duchenne muscular dystrophy, or DMD. Duchenne muscular dystrophy is a rare, life-threatening genetic disorder for which treatment options are limited.

Highlights from the Phase I/II HOPE Clinical Trial six-month results:

- In a 25-patient, randomized, single-dose, three-center clinical trial being conducted in a DMD population with advanced cardiac disease, patients treated with CAP-1002 demonstrated statistically-significant ($p<0.05$) improvement compared to usual care controls in certain measures of cardiac and upper limb function.
- CAP-1002 was generally safe and well-tolerated over the initial six-month follow-up period.
- Clinical results corroborate a large body of preclinical data from studies in DMD models.
- Capricor has submitted a meeting request to the U.S. Food and Drug Administration, or FDA, to discuss potential product registration strategies for CAP-1002 in the DMD indication.
- Capricor intends to submit HOPE-Duchenne data to FDA and to request Breakthrough Therapy or Regenerative Medicine Advanced Technology, or RMAT, designations for CAP-1002. The RMAT designation, intended to expedite the approval of safe and effective cell therapies, was created by the U.S. Congress as part of the recently-enacted 21st Century Cures Act.

John L. Jefferies, M.D., Professor of Pediatric Cardiology and Adult Cardiovascular Diseases at the University of Cincinnati and Director, Advanced Heart Failure and Cardiomyopathy, and Principal Investigator of the HOPE Trial, said, “In HOPE, we saw potential effects in both the heart and skeletal muscle that appear quite compelling in an exploratory trial. These results clearly support the conduct of a confirmatory clinical trial in DMD to further evaluate the potential of CAP-1002. We look forward to an effective medication becoming available for people with this progressive and fatal disease, one that is poorly met by current options.”

Joao A. C. Lima, M.D., Professor of Medicine and Director of the Magnetic Resonance Imaging, or MRI, Core Lab at The Johns Hopkins University School of Medicine, said, “The observed signal in global cardiac scar reduction and the increase in the thickening of the left ventricle during contraction are very encouraging. The population treated in HOPE had very advanced cardiac involvement, and to see such positive results following just a single dose of CAP-1002 is remarkable. Cardiac disease is the most common cause of mortality among those with DMD.”

Pat Furlong, Founding President and CEO of Parent Project Muscular Dystrophy, the largest nonprofit organization in the U.S. solely focused on DMD, said, “I’m excited to see these data, especially given the advanced nature of the patients in the HOPE trial. It is also gratifying to see the field of cell therapy making progress after more than two decades in development. It is our hope that CAP-1002 will have broad potential to improve the lives of patients with Duchenne muscular dystrophy.”

The randomized HOPE (Halt cardiomyOPathy progrEssion in Duchenne) Clinical Trial was designed to evaluate the safety and exploratory efficacy of CAP-1002 in patients 12 years and older with DMD who had cardiomyopathy, or heart disease, secondary to DMD as evidenced by scar in four or more left ventricular segments as detected by late gadolinium-enhancement MRI. Twenty-five patients were randomized to receive either a single dose of CAP-1002 (13 patients) or usual care (12 patients). CAP-1002 was infused into each of the three main coronary arteries at a total dose of 75 million cells.

All cardiac assessments were performed by MRI. A validated test of upper limb function, the Performance of the Upper Limb test, or PUL, was used to assess skeletal muscle performance. The PUL was designed specifically for use in the DMD setting, and evaluates a variety of manual tasks, such as lifting cans, tearing paper, and removing a container lid, which simulate activities of daily living. Boys and young men with advanced DMD have difficulty with such common activities as feeding themselves and brushing their teeth.

CAP-1002 has been well-tolerated in the HOPE trial. During and immediately following CAP-1002 infusion, no treated subjects experienced a pre-specified composite safety endpoint, which included the major adverse cardiac events of death, myocardial infarction, or hospitalization for a cardiovascular event. There were no early study discontinuations due to adverse events.

In exploratory efficacy analyses, statistically-significant improvements in systolic thickening of the inferior wall of the heart ($p=0.030$), and in the function of the middle and distal upper limb according to a PUL responder analysis ($p=0.045$), were observed in patients treated with CAP-1002 as compared to usual care control patients. In addition, differences observed in several other cardiac and skeletal muscle measures, including cardiac scar ($p=0.09$), are consistent with a treatment effect. At three months, a statistically-significant difference in quality-of-life ($p=0.03$), according to the PODCI Adolescent Questionnaire, that favored the CAP-1002 arm was also observed. A more comprehensive summary of the top-line data will be provided in slides to be presented during today’s webcast.

“These initial positive clinical results build upon a large body of preclinical data which illustrate CAP-1002’s potential to broadly improve the condition of those afflicted by DMD, as they show that cardiosphere-derived cells exert salutary effects on cardiac and skeletal muscle,” said Linda Marbán, Ph.D., Capricor’s president and chief executive officer.

“We have submitted an FDA meeting request to discuss these results as well as next steps in our development of CAP-1002 for Duchenne muscular dystrophy, which includes our plan to begin a clinical trial of intravenously-administered CAP-1002 in the latter half of this year. We believe the interim HOPE results may enable us to pursue one of the FDA’s Expedited Programs for Serious Conditions, and we will apply for either or both of the Breakthrough Therapy and Regenerative Medicine Advanced Therapy (RMAT) designations for CAP-1002,” added Dr. Marbán.

Capricor expects to report top-line 12-month results from the HOPE-Duchenne Trial in the fourth quarter of 2017.

A pre-publication manuscript reporting on academic studies of cardiosphere-derived cells in animal models of DMD may be accessed at http://biorxiv.org/content/early/2017/04/20/128900.

The HOPE-Duchenne trial is funded in part by the California Institute for Regenerative Medicine.

Conference Call and Webcast Information

Capricor will host a conference call and webcast with slides today, April 25, 2017, at 8:00 a.m. Eastern Time to discuss the top-line six-month HOPE-Duchenne clinical trial results. Capricor's executive management team will be joined on the call by Dr. Lima. The conference call can be accessed by dialing (866) 901-2585 for participants in the U.S. and Canada and (404) 835-7099 for international callers (reference passcode 44797929). The conference call will be webcast live and can be accessed at Capricor's website or by clicking this link (www.wsw.com/webcast/cc/capr). The webcast will be archived on the Capricor website for approximately 90 days.

About Duchenne Muscular Dystrophy

DMD is a genetic disorder characterized by progressive muscle degeneration and weakness. It is caused by an abnormality in the dystrophin complex, a structural element that plays a critical role in muscle fiber integrity, which leads to chronic skeletal and cardiac muscle damage. Patients with DMD typically die in their twenties, most commonly due to heart disease. The incidence of DMD is estimated to be one in every 3,600 live male births, and DMD is believed to afflict approximately 15,000 to 20,000 boys and young men in the U.S.

About CAP-1002

CAP-1002 consists of allogeneic cardiosphere-derived cells, or CDCs, a type of cardiac progenitor cell. CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to approximately 140 human subjects across several clinical trials. CAP-1002 is currently being evaluated in the randomized, double-blind, placebo-controlled Phase II ALLSTAR Clinical Trial in adults who have suffered a large heart attack and in the Phase I/II HOPE Clinical Trial in boys and young men with DMD.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) isa clinical-stage biotechnology company developing first-in-class biological therapies for cardiac and other medical conditions. Capricor's lead candidate, CAP-1002, is a cell-based candidate currently in clinical development for the treatment of Duchenne muscular dystrophy, myocardial infarction (heart attack), and heart failure. Capricor is exploring the potential of CAP-2003, a cell-free, exosome-based candidate, to treat a variety of disorders. For more 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 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 offerings 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 is set forth in Capricor's Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the Securities and Exchange Commission on March 16, 2017, and in its Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on September 28, 2015, together with prospectus supplements thereto. 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 is an Investigational New Drug and is not approved for any indications. Capricor's exosomes technology, including CAP-2003, has not yet been approved for clinical investigation.

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