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)

May 11, 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 8.01 Other Events.

On May 12, 2017, Capricor Therapeutics, Inc. (the "Company") announced that a pre-specified administrative interim analysis performed on six-month follow-up data from its ALLSTAR Trial has demonstrated a low probability (futility) of achieving a statistically-significant difference in the 12 month primary efficacy endpoint of percent change from baseline infarct size as a percentage of left ventricular mass, measured by cardiac magnetic resonance imaging (MRI). The ALLSTAR Trial is an ongoing randomized, double-blind, placebo-controlled, 142-patient Phase II clinical trial of CAP-1002 in adults who have experienced a large heart attack with residual cardiac dysfunction. Capricor will continue to perform analyses of the cumulative ALLSTAR data to better understand the basis for this outcome.

In response to the ALLSTAR results, the Company plans to reduce the scope of its operations, including the size of its workforce, in order to focus its financial resources primarily on its Duchenne muscular dystrophy (DMD) program.

Item 9.01. Financial Statements and Exhibits.

(d) ***Exhibits.***

Exhibit Number	Description
99.1	Press Release issued by Capricor Therapeutics, Inc. on May 12, 2017, providing update on ALLSTAR trial.

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: May 12, 2017

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

Exhibit 99.1

Capricor Therapeutics Provides Update on ALLSTAR Trial

Unlikely to Achieve Primary Efficacy Endpoint of Change in Infarct Size in Patients Following Heart Attack

Capricor to Focus on Potential Registration Program in Duchenne Muscular Dystrophy

Company to Hold Conference Call Today at 5:00 AM PDT / 8:00 AM EDT

LOS ANGELES, May 12, 2017 – Capricor Therapeutics, Inc. (NASDAQ: CAPR) today announced that a pre-specified administrative interim analysis performed on six-month follow-up data from the ALLSTAR Trial, an ongoing randomized, double-blind, placebo-controlled, 142-patient Phase II clinical trial of CAP-1002 (allogeneic cardiosphere-derived cells) in adults who have experienced a large heart attack with residual cardiac dysfunction, has demonstrated a low probability (futility) of achieving a statistically-significant difference in the 12-month primary efficacy endpoint of percent change from baseline infarct size as a percent of left ventricular mass, measured by cardiac magnetic resonance imaging (MRI). Capricor will continue to perform analyses of the cumulative ALLSTAR data to better understand the basis for this outcome. At six months, a near-statistically-significant (p=0.05) reduction of mean end-diastolic volume, as well as a trend of reduction of mean end-systolic volume, were seen in the CAP-1002 treatment group. There was no notable difference between treatment groups with respect to the change in ejection fraction. There were no safety signals in the CAP-1002 treatment cohort.

Raj Makkar, M.D., Associate Director, Interventional Technologies in the Heart Institute at Cedars-Sinai Medical Center and Co-Principal Investigator of the ALLSTAR Trial, said, “We are disappointed that the ALLSTAR six-month data did not demonstrate evidence of scar size improvement with CAP-1002, given the robust findings demonstrated on this measure in the randomized Phase I CADUCEUS clinical trial of cardiosphere-derived cells in a similar patient population. We believe it is important to note that the observed improvements in scar size in the placebo group are markedly inconsistent with the well-established natural history of this disease process. It is certainly possible that, for a variety of reasons, the greater number of sites involved in the conduct of ALLSTAR contributed to an increase in variability seen in the scar measurements as determined by MRI.”

Tim Henry, M.D., Director, Division of Cardiology in the Heart Institute at Cedars-Sinai Medical Center and Co-Principal Investigator of the ALLSTAR Trial, added, “We are encouraged to see reductions in left ventricular volume measures in the CAP-1002 treated patients, an important indicator of reverse remodeling of the heart. These findings support the biological activity of CAP-1002.”

Following Capricor’s recent report of positive six-month data on clinical measures of skeletal muscle performance and cardiac biomarkers in the ongoing randomized 25-patient Phase I/II HOPE Trial of CAP-1002 in boys and young men with Duchenne muscular dystrophy (DMD), the Company plans to initiate enrollment into a randomized, double-blind, placebo-controlled, repeat-dose clinical trial of intravenous CAP-1002 in DMD in the second half of 2017, subject to regulatory approval. This anticipated trial will primarily evaluate skeletal (non-cardiac) muscle function.

“The lack of a clear difference in the change in scar size from baseline to six months between the active and control groups in the interim observations from ALLSTAR was unexpected. These results diverge from the consistent and extensive record of activity observed with our cell technology in the setting of cardiac fibrosis as demonstrated by both preclinical and clinical studies, and we hope to gain an understanding of the factors that led to these observations through the conduct of further analyses,” said Linda Marbán, president and CEO of Capricor.

“Although we are disappointed, the favorable safety profile demonstrated by CAP-1002 in ALLSTAR supports the prospect of its chronic, repeat administration in patients with Duchenne muscular dystrophy. Also, the potent anti-inflammatory properties of CAP-1002 may be well-suited to mitigate DMD progression, for which chronic inflammation is believed to play a causative role,” added Dr. Marbán.

Capricor plans to reduce the scope of its operations, including the size of its workforce, in order to focus its financial resources primarily on its DMD program.

Conference Call and Webcast

Capricor management will hold a conference call at 5:00 a.m. PDT / 8:00 a.m. EDT today. The live call may be accessed by dialing (866) 868-1282 (domestic) or (847) 413-2405 (international) and by using the passcode 7330466. Access to the live webcast as well as the link to the replay of the call can be found at http://wsw.com/webcast/cc/capr2. The webcast will be archived for approximately 30 days.

As previously announced, on May 15, 2017, Capricor will report its financial results for the first quarter of 2017.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a 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 also 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.

The ALLSTAR Trial is funded in part by the California Institute for Regenerative Medicine.

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.

For more information, please contact:

Corporate
Capricor Therapeutics, Inc.
AJ Bergmann, Vice President of Finance
+1-310-358-3200
abergmann@Capricor.com

Investor Relations
Argot Partners
Kimberly Minarovich
+1-212-600-1902
kimberly@argotpartners.com

Media
Argot Partners
Eliza Schleifstein
+1-917-763-8106
eliza@argotpartners.com