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 4, 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 October 4, 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. Additionally, the Company made available on its website a poster from its presentation at the 22nd International Congress of the World Muscle Society.

The information contained in this Form 8-K (including Exhibit 99.1 and 99.2 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 Capricor Therapeutics, Inc. Press Release, dated October 4, 2017

99.2 Capricor Therapeutics, Inc. World Muscle Society Poster

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 4, 2017

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

Exhibit 99.1

Capricor Therapeutics Presents Positive Six-Month Results in Duchenne Muscular Dystrophy at World Muscle Society International Congress

Data Set the Stage for the Upcoming HOPE-2 Clinical Trial of CAP-1002

SAINT MALO, FRANCE – (Oct. 4, 2017) –Capricor Therapeutics, Inc. (NASDAQ: CAPR), in its presentation today at the 22nd Annual International Congress of the World Muscle Society, reported that teens and young men in the advanced stages of Duchenne muscular dystrophy (DMD) experienced meaningful improvements in cardiac and upper limb function after a single dose of Capricor's lead investigational product, CAP-1002. DMD is a rare, life-threatening genetic disorder for which treatment options are limited.

The late breaking abstract and results presented at the late breaking poster session describe the first six months of follow-up data from the randomized 12-month Phase I/II HOPE clinical trial of CAP-1002. CAP-1002 is a cell-based therapeutic candidate and consists of allogeneic cardiosphere-derived cells, whose mechanism of action is immunomodulatory and anti-fibrotic, and which have been shown to generate new muscle cells in preclinical models.

"These findings are especially significant because the patients in the HOPE trial were preteens or young men who were in advanced stages of Duchenne muscle disease," said Ron Victor, M.D., professor of medicine and Burns and Allen Chair in Cardiology Research at Cedars-Sinai Heart Institute and a principal investigator for the HOPE Trial. "Most other studies in DMD have focused on pediatric patients in earlier stages of the disease. To see such positive results in a clinical trial with just one dose of CAP-1002 sets the stage for the next step of evaluating multiple doses of this innovative cellular therapy in a larger trial."

The HOPE Trial was a randomized, open label trial of 25 males with DMD, of ages 12 to 25 years (mean 17.8). For 17 of them, the disease had progressed to the point of wheelchair dependence for mobility. Cardiomyopathy, or heart disease, secondary to DMD was an eligibility criterion and was evidenced by scar in four or more left ventricular segments. All participants had been receiving chronic corticosteroid therapy at entry. Thirteen received a single dose of CAP-1002, while the others received the standard of care, and all participants were to be followed for 12 months. CAP-1002 was administered by infusion into each of the three main coronary arteries for a total dose of 75 million cells.

In the trial, cardiac muscle was assessed by magnetic resonance imaging (MRI) studies performed at baseline, six months, and 12 months. All MRI interpretations were conducted in a manner blinded to treatment assignment and clinical outcomes.

Regional left ventricular (LV) function significantly differed between treatment groups following a single dose of CAP-1002, as determined by assessments of systolic thickening of LV wall segments. At six months, a statistically-significant increase in mean (standard deviation, or SD) change from baseline in inferior wall segments was observed with CAP-1002 (+31.2% (46.9)) compared to the usual care group (-8.8% (27.7)) (p=0.02). Six-month mean changes in anterior (+16.3 (46.5)) and lateral (+24.5 (51.2)) wall segments numerically favored CAP-1002 as compared to usual care ((-14.1 (24.9)) (p=0.11) and (-4.5 (35.0)) (p=0.24), respectively).

Differences observed in the change from baseline in cardiac scar size are consistent with a treatment effect on the heart. At six months, the mean (SD) percent change from baseline in observed scar size was -5.1 (8.5) in the CAP-1002 group (p=0.04) and -0.2 (11.5) in the usual care group (p=0.71) (p=0.09 for treatment group difference).

Skeletal muscle was assessed by the Performance of the Upper Limb test (PUL), a validated instrument for the assessment of upper limb motor function in individuals with DMD and consists of manual tasks that relate to activities of daily living. Scoring on the PUL was evaluated at baseline and at six weeks, and then at three, six, and 12 months.

Following a single dose of CAP-1002, the mean (SD) percent changes from baseline to six weeks and three months, respectively, in combined middle-plus-distal PUL dimension were +8.8 (15.0) and +8.9 (15.4) in the CAP-1002 group and -1.7 (3.7) and +0.8 (3.7) in the usual care group. By a post hoc responder analysis, mid-distal PUL score increased at six weeks by ≥ 10% (or maximum possible) in 42% of CAP-1002 participants compared to none of the usual-care participants (p=0.045). At three months, the group difference in response was 33% CAP-1002 vs. 10% usual care (p=0.32). Given the ages of the trial participants, shoulder function (upper PUL scoring) had been essentially lost prior to entry.

Treatment with CAP-1002 was generally safe and well-tolerated over the initial six-month follow-up period of the HOPE Trial. There was no significant difference in the incidence of treatment-emergent adverse events of either group.

“These exciting findings propel us into our next phase of development of CAP-1002 for the treatment of DMD,” said Linda Marbán, Ph.D., Capricor’s president and chief executive officer. “Subject to regulatory approvals, we expect to initiate the randomized, double-blind, placebo-controlled HOPE-2 clinical trial of intravenous (IV), repeat-dose CAP-1002 in the first quarter of 2018. The primary efficacy endpoint will be based on the PUL, and the HOPE-2 Trial may potentially serve as a registration study. We also look forward to presenting 12-month follow-up results from the HOPE Trial at a major medical conference later this quarter.”

The poster is available at the Events & Presentations section of Capricor’s website.

DMD is a devastating genetic disorder that causes muscle degeneration and leads to death generally before the age of 30, most commonly from heart failure. DMD occurs in one in every 3,600 live male births across all races, cultures and countries. DMD afflicts approximately 15,000 to 20,000 boys and young men in the U.S. Treatment options are limited and there is no cure.

The HOPE trial was funded in part by the California Institute for Regenerative Medicine.

About CAP-1002

CAP-1002 consists of allogeneic cardiosphere-derived cells, or CDCs, a unique population of cells that contains cardiac progenitor cells. CAP-1002 has been shown to exert potent immunomodulatory activity and alters the immune system’s activity to encourage cellular regeneration. 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.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a clinical-stage biotechnology company developing biological therapies for Duchenne muscular dystrophy (DMD) and other rare diseases. Capricor's lead candidate, CAP-1002, is a cell-based candidate currently in clinical development for the treatment of DMD. Capricor is also exploring the potential of CAP-2003, a cell-free, extracellular vesicle-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; regulatory developments involving products, including the ability to obtain regulatory approvals or otherwise bring products to market; the timing of regulatory approvals; 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, 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, and in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, as filed with the Securities and Exchange Commission on August 14, 2017. 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:

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Cardiosphere-derived cells for the treatment of Duchenne Cardiomyopathy: Six-Month Results of the Halt cardiomyopathy ProgrEssion [HOPE]-Duchenne Trial

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Introduction

- HOPE-Duchenne (Halt cardiomyopathy ProgrEssion in Duchenne, NCT02485938) is a randomized, open-label trial to test safety and explore efficacy of a single dose of intracoronary CAP-1002 in DMD cardiomyopathy.
- CAP-1002 is a cell-based therapeutic comprised of allogeneic cardiosphere-derived cells (CDCs) with immunomodulatory, anti-fibrotic, and regenerative properties.
- In the *mdx* mouse DMD model, intramyocardial CDCs improve cardiac function, but also act systemically via secretion of exosomes to increase exercise capacity, and ultimately improve long-term survival.

Methods

- Cardiac magnetic resonance imaging (MRI) and Performance of the Upper Limb (PUL) tests were used to assess efficacy in this population with advanced myopathy.

Patient Enrollment

- Twenty-five males who met all eligibility criteria (age ≥12; myocardial scar in ≥4 left ventricular segments by MRI and EF>35%; systemic corticosteroid regimen ≥6 months) were randomized 1:1 to either CAP-1002 (n=13) or control (n=12).
- Both groups received standard medical care.
- Mean age of enrolled subjects was 18 years, and 68% were wheelchair-dependent.

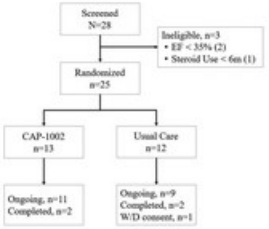

Fig. 1 Trial profile. Summary of patient disposition in the 6-month interim analysis

Demographics, Baseline Characteristics, and Safety

Table 1. Demographics and baseline characteristics

Table 2. Safety Outcome Measures

Table 3. Safety & Tolerability

Results

Cardiac Assessment

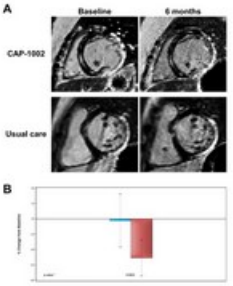

Fig. 2 Change in myocardial scar by LGE MRI. **A)** Short-axis images at end-diastole at baseline (left) and 6 months (right) from a patient treated with CAP-1002 (top row) and from a patient receiving usual care (bottom row). **B)** Relative change in myocardial scar (expressed as a percent of LV mass) from baseline to 6 months is shown for usual care (blue) and CAP-1002 treated (red) patients.

Table 4. Change in global myocardial scar by LGE MRI

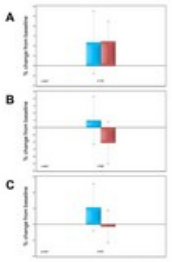

Fig. 3 Changes in LVEF and cardiac volumes by MRI. Relative change from baseline in **A)** LVEF, **B)** LVESV, and **C)** LVEDV is displayed for usual care (blue) and CAP-1002-treated (red) subjects.

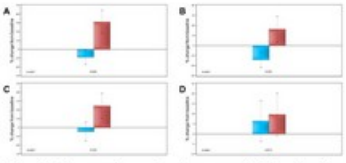

Fig. 4 Change in regional myocardial function by MRI. Relative change from baseline in LV systolic wall thickening in the **A)** inferior, **B)** anterior, **C)** lateral, and **D)** septal regions is displayed for usual care (blue) and CAP-1002-treated (red) subjects.

Assessments of Upper Limb Performance

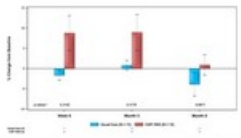

Fig. 5 Change in skeletal muscle function. Relative changes in PUL middle + distal dimensions from baseline to six weeks, three months, and six months is shown for usual care (blue) and CAP-1002-treated (red) patients in the mITT population.

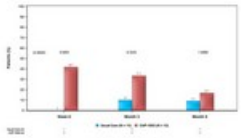

Fig. 6 Percent of subjects with improvements in skeletal muscle function. Percent responders (defined post hoc as patients with ≥10% or maximum possible improvement in middle-plus-distal PUL) from baseline to six weeks, three months, and six months for usual care (blue) and CAP-1002-treated (red) patients.

Table 5. Summary of PUL scores

Quality of Life

Table 6. Change in patient-reported PODCI parameters

Table 7. Change in patient-reported PedsQL parameters

Conclusions

- Data indicate that CAP-1002 is safe and well-tolerated;
- Clinical results consistent with preclinical data that illustrate bioactivity of CAP-1002 on both cardiac and skeletal muscle in DMD;
- Exploratory efficacy analyses support potential benefit of CAP-1002 for patients with advanced DMD;
- Repeat administration of CAP-1002 may lead to longer-lasting, potentially cumulative benefits