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)

January 22, 2019

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 January 22, 2019 Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing an update on its HOPE-2 clinical program. A copy of the press release is being furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release, titled "Capricor Announces Positive Outcomes from Comprehensive Multidisciplinary Meeting with FDA", dated January 22, 2019.

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: January 22, 2019

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

Exhibit 99.1

Capricor Announces Positive Outcomes from Comprehensive Multidisciplinary Meeting with FDA

FDA Provides Positive Feedback on Design for HOPE-2 Clinical Trial

LOS ANGELES, January 22, 2019 – Capricor Therapeutics (NASDAQ: CAPR), a clinical-stage biotechnology company, today announced that it had positive outcomes in its comprehensive multidisciplinary meeting with the U.S. Food and Drug Administration (FDA) regarding development of the company's novel cell therapy candidate, CAP-1002, to treat Duchenne muscular dystrophy.

Capricor met with the FDA in December 2018, as part of the expedited review afforded under the Regenerative Medicine Advanced Therapy**(**RMAT**)** designation which the FDA granted to CAP-1002 in February 2018. The FDA grants the RMAT designation to investigational regenerative medicine therapies intended to treat a serious condition and for which preliminary clinical evidence indicates a potential to address unmet medical needs for that condition.

During the meeting discussion and in subsequent meeting minutes, Capricor asked whether the FDA would agree to its current clinical trial,HOPE-2, serving as the registration study, if HOPE-2 provides evidence that CAP-1002 is safe and effective in treating Duchenne muscular dystrophy. The FDA advised Capricor to request an end of phase meeting after completion of the trial to determine whether HOPE-2 could serve as the registration study.

The FDA also reiterated support for the use of the Performance of the Upper Limb (PUL) 2.0 mid-level test, which measures the ability to use arm and hand muscles, as the primary efficacy endpoint for HOPE-2. In addition, the agency stated that the trial would need to provide evidence of clinically meaningful changes in the PUL, as well as other evidence supportive of CAP-1002 efficacy for patients with advanced Duchenne muscular dystrophy, in order to serve as a registration trial.

"Our interactions with the FDA have been collaborative and supportive," said Linda Marbán, Ph.D., Capricor's chief executive officer. "Capricor's unique cellular therapy offers the opportunity to benefit skeletal and cardiac muscle, which, if supported by the HOPE-2 trial results, would provide meaningful benefits to patients with advanced Duchenne muscular dystrophy and important differentiation in a market that has very limited treatment options. We have designed HOPE-2 to be a registration trial, and it is reassuring that the FDA will consider that possibility, should the results be positive."

Duchenne muscular dystrophy is a fatal genetic disorder with few therapeutic options. The HOPE-2 trial is studying the safety and effectiveness of CAP-1002 in older Duchenne patients who are not currently eligible for gene therapy clinical trials. To date, 17 patients have been enrolled in the Phase II, randomized, double-blind, placebo-controlled trial.

“Originally, HOPE-2 was designed as an 84 patient clinical trial, but after the feedback from the FDA, Capricor is considering a sample size re-estimation that will likely lead to a significant reduction in the number of patients from 84 to approximately 40-50, which would be sufficient to determine clinical relevance and efficacy of CAP-1002,” said Dr. Marbán, “If we are able to achieve the goal of showing that CAP-1002 improves muscle function with fewer patients, we will be able to expedite product development and potential commercialization so that it can be available to the patients with Duchenne muscular dystrophy.”

Voluntary Dosing Hold has Been Lifted and HOPE-2 Enrollment Can Resume

After a patient in the HOPE-2 trial had a serious adverse event in the form of anaphylaxis, Capricor put a voluntary hold on dosing in December to develop a plan to manage potential allergic reactions. The investigation suggests that the patient may have been allergic to something contained in the investigational product, including an excipient, or inactive ingredient, in the formulation.

To prevent future events, Capricor has initiated a pre-medication strategy that is commonly used by doctors to prevent and treat allergic reactions. The Data and Safety Monitoring Board (DSMB) and HOPE-2 clinical trial steering committee support this approach, and the FDA and DSMB approved resuming enrollment in the study. The timing of the trial’s resumption depends upon various factors, including the availability of additional funding.

About Duchenne Muscular Dystrophy

Duchenne muscular dystrophy is a devastating genetic disorder that causes muscle degeneration and leads to death, generally before the age of 30, most commonly from heart failure. It occurs in one in every 3,600 live male births across all races, cultures and countries. Duchenne muscular dystrophy afflicts approximately 200,000 boys and young men around the world. Treatment options are limited, and there is no cure.

About CAP-1002

CAP-1002 consists of allogeneic cardiosphere-derived cells, or CDCs, a type of progenitor cell that has been shown in pre-clinical and clinical studies to exert potent immuno-modulatory activity, and is being investigated for its potential to modify 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 focused on the discovery, development and commercialization of first-in-class biological therapeutics for the treatment of rare disorders. Capricor’s lead candidate, CAP-1002, is an allogeneic cell therapy that is currently in clinical development for the treatment of Duchenne muscular dystrophy. Capricor has also established itself as one of the leading companies investigating the field of extracellular vesicles and 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.

Keep up with Capricor on social media:www.facebook.com/capricortherapeutics, www.instagram.com/capricortherapeutics/ and https://twitter.com/capricor

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; 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, 2017 as filed with the Securities and Exchange Commission on March 22, 2018, in its Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on September 28, 2015, together with the prospectus included therein and prospectus supplements thereto and in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, as filed with the Securities and Exchange Commission on November 14, 2018. 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. CAP-2003 has not yet been approved for clinical investigation.

For more information, please contact:

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