# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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# 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)

**November 29, 2017**

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# 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 November 29, 2017, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing clearance from the FDA for its Investigational New Drug (IND) Application for CAP-1002 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 under Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto are being furnished and shall not be deemed to be filed for 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, nor shall they be incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, unless expressly set forth as being incorporated by reference into such filing.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

| | |
|---|---|
| 99.1 | Press Release, titled "Capricor Therapeutics Announces FDA Clearance of Investigational New Drug (IND) Application for CAP-1002", dated November 29, 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: November 29, 2017

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

**Exhibit 99.1**

**Capricor Therapeutics Announces FDA Clearance of Investigational New Drug (IND) Application for CAP-1002**

*Potential Registration Trial in Duchenne Muscular Dystrophy*
*on Track to Initiate in First Quarter of 2018*

*Company to Host Conference Call and Webcast at 4:30 p.m. ET Today*

LOS ANGELES, Nov. 29, 2017 – Capricor Therapeutics (NASDAQ: CAPR) today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application to conduct a new clinical trial of CAP-1002, its lead investigational therapy, in boys and young men in advanced stages of Duchenne muscular dystrophy, a fatal genetic disorder for which there are limited treatment options.

This randomized, double-blind, placebo-controlled clinical trial will be called the HOPE-2 Trial and is designed to evaluate the safety and efficacy of intravenous, repeat doses of CAP-1002 in boys and young men whose ability to walk has been seriously impaired by the loss of muscle function that occurs as Duchenne muscular dystrophy progresses. The primary efficacy endpoint will be the relative change in the mid-level dimension of the Performance of the Upper Limb test from baseline to Month 12. The HOPE-2 Trial is expected to enroll approximately 84 patients and be conducted at 10-12 U.S. sites.

Capricor believes that if the primary endpoint is reached, the HOPE-2 Trial could serve as a registration trial, meaning that its results could support the submission of a Biologics License Application (BLA) to obtain marketing approval of CAP-1002. Capricor expects to initiate the HOPE-2 Trial in the first quarter of 2018.

Capricor plans to apply for the Regenerative Medicine Advanced Therapy (RMAT) Designation for CAP-1002 based on updated guidance recently issued by the FDA. If granted, the RMAT Designation would be expected to facilitate CAP-1002's path to potential registration.

The national principal investigator for the HOPE-2 trial will be Craig M. McDonald, M.D., a distinguished thought leader in the clinical management of neuromuscular diseases, including muscular dystrophies, and the development of novel outcome measures for Duchenne muscular dystrophy clinical trials.

"The FDA's clearance of this IND upon its initial submission is a significant step forward in our development of CAP-1002," said Linda Marbán, Ph.D., president and chief executive officer. "While there are many clinical initiatives in Duchenne muscular dystrophy, this is one of the very few to focus on non-ambulant patients. These boys and young men are looking to maintain what function they have in their arms and hands and, based on our previous study, we think CAP-1002 may be able to do exactly that."

Capricor previously reported significant and sustained improvements in cardiac structure and function, as well as skeletal muscle function, following a single dose of intracoronary CAP-1002. The HOPE-2 Trial will test the potential benefit of CAP-1002 as a repeated therapy delivered intravenously, with the goal of providing long-term benefit in a format that is compatible with repeat dosing over time. Support for intravenous infusion, a common mode of drug delivery, is provided by studies which have shown therapeutic benefit in an animal model of Duchenne muscular dystrophy.

Capricor will hold a conference call and slide presentation at 4:30 p.m. ET today to discuss this development. To join: please dial 1-866-652-5200 (domestic) or 1-412-317-6060 (international). Access to the webcast and a replay of the call may be found at http://capricor.com/news/events/.

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

**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 unique population of cells that contains cardiac progenitor cells. CAP-1002 has been shown to exert potent immunomodulatory activity and stimulate 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.

**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, 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 the prospectus included therein and prospectus supplements thereto, and in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, as filed with the Securities and Exchange Commission on November 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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