# 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)

**February 4, 2019**

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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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On February 4, 2019, the board of directors of Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), approved a reduction to the annual base salary for Dr. Linda Marbán, Chief Executive Officer from $232,909 to $150,000 per year, with the reduction being effective February 1, 2019. This reduction to annual base salary modifies that certain employment agreement dated September 1, 2010, by and between Capricor, Inc. and Dr. Marbán (the "Marbán Employment Agreement"). The description of the Marbán Employment Agreement provided in the Company's Definitive Proxy Statement for its 2018 Annual Meeting of Stockholders, filed with the Securities and Exchange Commission on April 26, 2018, under the heading "Employment Agreements and Post-Termination Benefits — Linda Marbán, Ph.D. — President and Chief Executive Officer" is incorporated herein by reference. All other terms and conditions of the Marbán Employment Agreement remain in effect.

**Item 8.01 Other Events**

On February 6, 2019, the Company issued a press release announcing an update on its HOPE-2 clinical program. Furthermore, to reduce expenses and better align resources and personnel on the Company's core lead programs, the Company has reduced its staff by 21 full-time employees. The reduction in operating expenses is expected to extend the Company's currently available cash, cash equivalents and marketable securities into late 2019. Additionally, the Company is exploring strategic alternatives, with respect to one or more of its product candidates.

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 Resumes Dosing of Enrolled Patients in HOPE-2 Clinical Trial for Duchenne Muscular Dystrophy", dated February 6, 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: February 6, 2019

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

**Exhibit 99.1**

**Capricor Resumes Dosing of Enrolled Patients in HOPE-2 Clinical Trial for Duchenne Muscular Dystrophy**

**LOS ANGELES**, February 6, 2019 – Capricor Therapeutics (NASDAQ: CAPR), a clinical-stage biotechnology company, today announced that it has resumed per protocol dosing of patients already enrolled in its HOPE-2 clinical trial of CAP-1002, the company's novel cell therapy candidate to treat Duchenne muscular dystrophy. Approximately 20 young men and boys in advanced stages of Duchenne muscular dystrophy have already been enrolled in the randomized, double-blind, placebo-controlled trial to date.

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

To reduce the risk of future events, Capricor initiated a pre-medication strategy commonly used by physicians to prevent and treat allergic reactions. The U.S. Food and Drug Administration (FDA) and the Data and Safety Monitoring Board (DSMB) have granted permission to resume enrollment in the HOPE-2 study.

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. Enrollment of new patients will depend on various factors but will not commence until additional funding is secured.

To reduce expenses and better align resources and personnel on the company's core lead programs, Capricor has reduced its staff by 21 full-time employees. The reduction in operating expenses is expected to extend the company's cash, cash equivalents and marketable securities into late 2019. Additionally, Capricor is exploring strategic alternatives, with respect to one or more of its product candidates.

**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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