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)

July 19, 2022

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.)**

10865 Road to the Cure, Suite 150, San Diego, California	**92121**
(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. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	CAPR	The Nasdaq Capital Market

Item 8.01 Other Events.

On July 19, 2022, the Company announced the commencement of patient dosing in the HOPE-3 clinical trial, a Phase 3 study investigating CAP-1002 for treating Duchenne muscular dystrophy. HOPE-3 is a randomized, double-blind, placebo-controlled study designed to enroll approximately 70 patients in the United States. A copy of the press release including this announcement is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Capricor Therapeutics Announces First Patient Dosed in Pivotal Phase 3 Study of CAP-1002 for the Treatment of Duchenne Muscular Dystrophy.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).

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: July 19, 2022

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

Exhibit 99.1

Capricor Therapeutics Announces First Patient Dosed in Pivotal Phase 3 Study of CAP-1002 for the Treatment of Duchenne Muscular Dystrophy

-Double-Blind, Randomized, Placebo-Controlled HOPE-3 Clinical Trial Designed to Enroll approximately 70 Patients-

-HOPE-3 Builds on Positive Data Results from HOPE-2 Study Recently Published in The Lancet-

SAN DIEGO, Calif., July 19, 2022 -- Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company focused on the development of transformative cell and exosome-based therapeutics for the treatment and prevention of muscular and other select diseases, today announced commencement of dosing in HOPE-3, a Phase 3 clinical trial investigating CAP-1002, a cell therapy for treating late-stage Duchenne muscular dystrophy (DMD). HOPE-3 is a randomized, double-blind, placebo-controlled study designed to enroll approximately 70 patients in the United States. Capricor recently announced a partnership with Nippon Shinyaku Co., Ltd. which has commercialization and distribution rights in the U.S. This partnership provides funding for the support of HOPE-3 as well as other potential milestone-based payments to support the clinical development of CAP-1002 in DMD.

“We are delighted to begin dosing patients in HOPE-3. The data from our Phase 2 clinical trial suggest that CAP-1002 can slow loss of function by as much as 70% in terms of upper limb skeletal muscle function. Since there are very limited therapeutic options for these patients and CAP-1002 has been shown to be safe and effective, we are pleased to begin this pivotal trial with the goal of achieving regulatory approval as quickly as possible,” said Linda Marbán, Ph.D., CEO of Capricor. “Beginning this clinical trial is a significant milestone, not only for Capricor, but most importantly for those boys and young men with DMD.”

HOPE-3 participants will be randomized to either CAP-1002 or placebo in a 1:1 ratio. The active arm of participants in the trial will receive 150 million cardiosphere-derived cells (CAP-1002) via intravenous infusion every 3 months for a total of 4 doses. CAP-1002 is comprised of human allogeneic cardiosphere-derived cells, with a differentiated mechanism of action that is immunomodulatory and regenerative. Its broad applicability makes it suitable for patients regardless of genetic mutation. The Phase 3 study’s primary outcome measure will be the Performance of the Upper Limb (PUL) 2.0, a validated tool specifically designed for assessing high (shoulder), mid (elbow) and distal (wrist and hand) function, with a conceptual framework reflecting weakness progression in upper limb function. HOPE-3 will also measure various secondary endpoints including cardiac function assessments. For more information on this study, please visit (NCT05126758).

The regulatory pathway for CAP-1002 is supported by RMAT (Regenerative Medicine Advanced Therapy Designation) as well as Orphan Drug Designation. If Capricor were to receive market approval for CAP-1002 by the FDA, Capricor would be eligible to receive a Priority Review Voucher based on its designation as a rare pediatric disease. Capricor holds worldwide commercial rights to CAP-1002 outside of the United States.

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 immunomodulatory 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 over 200 human patients across several clinical studies.

About Duchenne Muscular Dystrophy

Duchenne muscular dystrophy is a genetic disorder characterized by progressive weakness and chronic inflammation of the skeletal, heart and respiratory muscles. Patients suffering from DMD typically lose their ability to walk in their teenage years and generally die of cardiac or respiratory complications by age 30. It occurs in one in every 3,600 live male births across all races, cultures and countries. DMD afflicts approximately 200,000 boys and young men around the world. Treatment options are limited, and there is no cure.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a biotechnology company focused on developing transformative cell and exosome-based therapeutics and vaccines for treating and preventing a broad spectrum of diseases. Capricor's lead candidate, CAP-1002, is an allogeneic cardiac-derived cell therapy that is currently in clinical development for treating Duchenne muscular dystrophy. Capricor is also developing its exosome technology as a next-generation therapeutic platform. The Company's current focus is on developing exosomes capable of delivering nucleic acids, including mRNA, as well as proteins to treat or prevent a variety of diseases. For more information, visit www.capricor.com, and follow the Company on Facebook, Instagram and Twitter.

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 ability to achieve product milestones and to receive milestone payments from commercial partners; 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, revenue projections; 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, 2021 as filed with the Securities and Exchange Commission on March 11, 2022 and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 as filed with the Securities and Exchange Commission on May 11, 2022. 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. None of Capricor's exosome-based candidates have been approved for clinical investigation.

For more information, please contact:

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