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)

December 11, 2023

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)**

(858) 727-1755
(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 December 11, 2023, Capricor Therapeutics, Inc. (the "Company") announced a positive outcome of the interim futility analysis for HOPE-3, the pivotal Phase 3 trial evaluating CAP-1002 in patients with Duchenne muscular dystrophy ("DMD"). The results of the interim futility analysis, reviewed by the Data Safety Monitoring Board ("DSMB"), resulted in a favorable recommendation to continue the HOPE-3 trial as planned. This interim futility analysis triggers the first milestone payment under the Company's U.S. Commercialization and Distribution Agreement with Nippon Shinyaku Co., Ltd., which is due within 30 days of delivery of the results of the interim futility analysis. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, titled "Capricor Therapeutics Announces Continuation of Phase 3 HOPE-3 Trial of CAP-1002 in Duchenne Muscular Dystrophy Based on Completion of Interim Futility Analysis" dated December 11, 2023.
104	Cover Page Interactive Data File (formatted as inline XBRL).

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: December 11, 2023

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

Exhibit 99.1

Capricor Therapeutics Announces Continuation of Phase 3 HOPE-3 Trial of CAP-1002 in Duchenne Muscular Dystrophy Based on Completion of Interim Futility Analysis

--Favorable Interim Futility Analysis Results--

--Successful Completion Triggers First Milestone Payment Under U.S. Agreement with Nippon Shinyaku--

--HOPE-3 (Cohort A) Enrollment Complete; Topline Data Expected in the Fourth Quarter of 2024; Cohort B Enrollment Initiated--

--Company Plans to Request a Meeting with FDA in the First Quarter of 2024 to Further Discuss Opportunities for Expedited Approval Pathways--

SAN DIEGO, Calif., Dec. 11, 2023 (GLOBE NEWSWIRE) --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 a positive outcome of the interim futility analysis for HOPE-3, the pivotal Phase 3 trial evaluating CAP-1002 in patients with Duchenne muscular dystrophy (DMD). The results of the interim futility analysis, reviewed by the Data Safety Monitoring Board (DSMB), resulted in a favorable recommendation to continue the HOPE-3 trial as planned. This interim futility analysis triggers the first milestone payment under the Company's U.S. Commercialization and Distribution Agreement with Nippon Shinyaku Co., Ltd.

"We are pleased with the positive outcome of the DSMB review which supports the continued advancement of our HOPE-3 trial towards potential approval of CAP-1002 for the treatment of DMD," said Linda Marbán, Ph.D., Capricor's chief executive officer. "We believe CAP-1002 may address the high unmet medical need for these patients and we remain committed to its expeditious advancement towards approval. Based on this important milestone, we will be requesting a meeting with the U.S. Food and Drug Administration (FDA) to further discuss options for expedited review and approval. In addition, we believe we are well positioned to execute on additional value-driving clinical and regulatory milestones, including reporting topline data from HOPE-3 (Cohort A) in the fourth quarter of 2024."

About the HOPE-3, Phase 3 Trial

HOPE-3 is a Phase 3, multi-center, randomized, double-blind, placebo-controlled clinical trial comprised of two cohorts evaluating the safety and efficacy of CAP-1002 in participants with DMD and impaired skeletal muscle function. Non-ambulatory and ambulatory boys who meet eligibility criteria will be randomly assigned to receive either CAP-1002 or placebo every 3 months for a total of 4 doses during the first 12-months of the study. Approximately 102 eligible study subjects will participate in this dual-cohort study. Enrollment has been completed for Cohort A which is designed to enroll approximately 58 subjects randomized to either CAP-1002 or placebo in a 1:1 ratio and is intended to support a Biologics License Application submission. Enrollment has commenced for Cohort B which is designed to enroll approximately 44 participants randomized to either CAP-1002 or placebo in a 1:1 ratio. The aim of Cohort B is to support inclusion of our San Diego site following initial registration.

A primary analysis of efficacy and safety will be performed for each individual cohort at month 12 following 4 administrations of CAP-1002 or placebo. The primary outcome measure will be the Performance of the Upper Limb (PUL) v2.0, 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).

About Duchenne Muscular Dystrophy

Duchenne muscular dystrophy (DMD) is a devastating 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 approximately 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 CAP-1002

CAP-1002 consists of allogeneic cardiosphere-derived cells (CDCs), a population of stromal cells that have been shown in preclinical and clinical studies to exert potent immunomodulatory, antifibrotic and regenerative actions in dystrophinopathy and heart failure. CDCs act by secreting extracellular vesicles known as exosomes, which target macrophages and alter their expression profile so that they adopt a healing, rather than a pro-inflammatory, phenotype. CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to over 200 human subjects across several clinical trials.

CAP-1002 for the treatment of DMD has received Orphan Drug Designation and the regulatory pathway for CAP-1002 is supported RMAT (Regenerative Medicine Advanced Therapy Designation). In addition, if Capricor were to receive FDA marketing approval for CAP-1002 for the treatment of DMD, Capricor would be eligible to receive a Priority Review Voucher (PRV) based on its previous receipt of a rare pediatric disease designation.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is 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. Capricor's lead candidate, CAP-1002, is an allogeneic cardiac-derived cell therapy that is currently in late-stage clinical development for treating Duchenne muscular dystrophy. Further, Capricor has entered into a partnership for the exclusive commercialization and distribution of CAP-1002 for DMD in the United States and Japan with Nippon Shinyaku Co., Ltd. (U.S. subsidiary: NS Pharma, Inc.), subject to regulatory approval. Capricor is also developing its exosome technology as a next-generation therapeutic platform. Our proprietary StealthX™ exosome platform has potential for a broad range of new therapeutic applications in the field of vaccinology as well as targeted oligonucleotide, protein and small molecule therapeutics to treat or prevent a variety of diseases. For more information, visit capricor.com, and follow Capricor 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; manufacturing capabilities; 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 and 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, 2022, as filed with the Securities and Exchange Commission on March 17, 2023 and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, as filed with the Securities and Exchange Commission on November 14, 2023. 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.

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