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)

September 29, 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 7.01 Regulation FD Disclosure.

On September 29, 2023, the Company announced a positive outcome from a Type-B clinical meeting with the U.S. Food and Drug Administration (the "FDA") on the design and execution of HOPE-3, the Phase 3 pivotal trial of CAP-1002 in Duchenne Muscular Dystrophy ("DMD"). Feedback from the FDA on the proposed key clinical and regulatory requirements confirms CAP-1002's path towards Biologics License Application ("BLA") submission.

A copy of the press release has been filed as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 8.01 Other Events.

As disclosed above under Item 7.01, on September 29, 2023, the Company announced a positive outcome from a Type-B clinical meeting with the FDA on the design and execution of HOPE-3, the Phase 3 pivotal trial of CAP-1002 in DMD. Because the Company plans to submit a BLA for CAP-1002 in 2025 supported by results using product manufactured from the Los Angeles site, and not from the Company's San Diego manufacturing site, the Company intends to focus significant time and resources on additional work needed at the Los Angeles site (which is leased under a facilities lease previously disclosed by the Company) to support the BLA submission. The Company will also continue work on its San Diego site with a view toward supporting potential increased commercial demand, subject to the FDA's approval of the CAP-1002 product for treatment of DMD and its approval of the San Diego site.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, titled "Capricor Therapeutics Announces Positive Type-B Meeting with the FDA to Discuss Pathway to BLA for CAP-1002 in Duchenne Muscular Dystrophy" dated September 29, 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: September 29, 2023

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

Exhibit 99.1

Capricor Therapeutics Announces Positive Type-B Meeting with the FDA to Discuss Pathway to BLA for CAP-1002 in Duchenne Muscular Dystrophy

-FDA Feedback on the Proposed Key Clinical and Regulatory Requirements Confirms CAP-1002's Path Towards a Biologics License Application (BLA)-

-Company On Track to Complete HOPE-3 Enrollment and Report Outcome from Interim Analysis in Q4 2023-

-Conference Call and Webcast Today at 8:30 a.m. ET-

SAN DIEGO, Calif., September 29, 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 an update on the Company's positive Type-B clinical meeting with the U.S. Food and Drug Administration ("FDA") on the design and execution of HOPE-3, Capricor's pivotal Phase 3 trial with lead asset CAP-1002 in treating Duchenne muscular dystrophy ("DMD"). Feedback from the FDA on trial design and timeline confirms CAP-1002's path towards a future Biologics License Application ("BLA") submission.

"We are pleased to have reached an important regulatory milestone that further defines the path towards registration of CAP-1002 for DMD and brings us potentially one step closer to addressing the great unmet medical need for these patients," said Linda Marbán, Ph.D., Capricor's chief executive officer. "During recent meetings with the FDA, we aligned on key features of HOPE-3, which as currently designed, and if successful, is expected to provide sufficient evidence of effectiveness to support our BLA submission and significantly expedites our path towards potential approval of CAP-1002. In addition, although product from our San Diego site would not be required to support registration of CAP-1002, we do plan to enroll a separate cohort with product manufactured from our San Diego site, with a view toward meeting potential increased commercial demand following initial registration."

Dr. Marbán continued, "Looking ahead, we remain on track to complete HOPE-3 enrollment and expect to report the outcome of an interim analysis in the fourth quarter of 2023. We look forward to continuing to deliver important clinical and regulatory milestones, including the submission of a BLA for CAP-1002 for the treatment of DMD."

The FDA has affirmed alignment on the Phase 3 clinical trial's design and timeline. Key details for HOPE-3 are as follows:

- Primary endpoints remain unchanged. HOPE-3 will aim to enroll approximately 58 patients and enrollment is estimated to be completed in the fourth quarter of 2023.
    - As of today, Capricor has treated 52 patients.
- Topline data for HOPE-3 is expected in the fourth quarter of 2024.
- Capricor plans to submit a BLA for CAP-1002 in 2025, which will be supported by results using product manufactured at the Los Angeles site.
- Capricor and the FDA discussed the potential for alternative approval pathways and Capricor plans to further discuss these options with the FDA following the completion of enrollment.

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. Capricor retains full rights to the PRV, if received.

Conference Call and Webcast

Capricor will host a conference call and webcast with slides today September 29, 2023, at 8:30 a.m. ET. To participate in the conference call, please dial 877-451-6152 (domestic/toll-free) or 201-389-0879 (international) and reference the conference

ID: 13740749. To participate via a webcast, please click here to view the slides. A replay of the webcast will be available following the conclusion of the live broadcast and will be accessible on the Company's website.

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.

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 June 30, 2023, as filed with the Securities and Exchange Commission on August 8, 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.

For more information, please contact:

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