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 11, 2025

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 July 11, 2025, Capricor Therapeutics, Inc. (the "Company" or "Capricor") issued a press release announcing that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its Biologics License Application (BLA) for Deramiocel, the Company's lead cell therapy candidate for the treatment of cardiomyopathy associated with Duchenne muscular dystrophy (DMD).

In the CRL, the FDA stated that it had completed its review of the application but was unable to approve the BLA in its current form, citing the BLA does not meet the statutory requirement for substantial evidence of effectiveness and the need for additional clinical data. The CRL also referenced certain outstanding items in the Chemistry, Manufacturing, and Controls (CMC) section of the application, most of which the Company believes it has addressed in communications to the FDA in response to prior comments before receipt of the letter, but which were not reviewed by the FDA due to the timing of the CRL issuance. The FDA confirmed that it will restart the review clock upon resubmission. In addition, the agency offered the Company the opportunity to request a Type A meeting to discuss the path forward. Capricor plans to engage further with the FDA to determine the appropriate next steps and intends to resubmit its BLA to include data from the ongoing Phase 3 HOPE-3 trial in the third quarter of 2025 in support of its pursuit of an indication for the treatment of cardiomyopathy associated with Duchenne muscular dystrophy.

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

The information under Item 7.01 of this Current Report on Form 8-K, Exhibit 99.1 attached hereto is 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 it be incorporated by reference into any of the Company's filings under 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 Provides Regulatory Update on Deramiocel BLA for Duchenne Muscular Dystrophy", dated July 11, 2025.
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: July 11, 2025

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

Exhibit 99.1

Capricor Therapeutics Provides Regulatory Update on Deramiocel BLA for Duchenne Muscular Dystrophy

- *FDA issued Complete Response Letter*
- *Capricor plans to resubmit its BLA to include data from the ongoing Phase 3 HOPE-3 trial in Q3 2025 to continue pursuing the indication for the treatment of cardiomyopathy associated with Duchenne muscular dystrophy*
- *FDA advised Capricor to request a meeting to determine next steps toward potential approval*
- *Conference call and webcast scheduled for today at 8:30 a.m. ET*

SAN DIEGO, July 11, 2025 (GLOBE NEWSWIRE) --Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for rare diseases, today announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its Biologics License Application (BLA) for Deramiocel, the Company's lead cell therapy candidate for the treatment of cardiomyopathy associated with Duchenne muscular dystrophy (DMD).

In the CRL, the FDA stated that it had completed its review of the application but is unable to approve the BLA in its current form, specifically citing that the BLA does not meet the statutory requirement for substantial evidence of effectiveness and the need for additional clinical data. The CRL also referenced certain outstanding items in the Chemistry, Manufacturing, and Controls (CMC) section of the application, most of which Capricor believes it has addressed in prior communications to the FDA. However, these materials were not reviewed by the FDA due to the timing of the CRL issuance. The FDA confirmed that it will restart the review clock upon resubmission. In addition, the agency offered the company the opportunity to request a Type A meeting to discuss the path forward. Capricor plans to engage further with the FDA to determine the appropriate next steps.

Capricor's BLA for Deramiocel was granted Priority Review in March 2025 and was supported by data from the HOPE-2 trial, its open-label extension (OLE), and natural history comparisons from FDA-funded datasets.

"We are surprised by this decision by the FDA. We have followed their guidance throughout the process. Prior to the CRL, the review had advanced without major issues, including a successful pre-licensure inspection and completion of the mid-cycle review," said Linda Marbán, Ph.D., CEO of Capricor. "Capricor plans to submit data from the Phase 3 HOPE-3 clinical trial to provide additional evidence of effectiveness from an adequate and well-controlled study. The HOPE-3 trial is a randomized, double-blind, placebo-controlled clinical trial of 104 patients, with topline results expected in the third quarter of 2025. We believe these data, if positive, along with our existing long-term clinical results showing cardiac stabilization, preservation of skeletal muscle function, and a consistent safety profile, could support efforts to resolve the questions raised by the FDA for the treatment of cardiomyopathy associated with DMD. While this was an unexpected decision by the FDA, we remain committed to the DMD community to get Deramiocel through the approval process."

Conference Call and Webcast

To participate in the conference call, please dial 1-800-717-1738 (Domestic) or 1-646-307-1865 (International) and reference the conference ID: 30613. Participants may dial in using the numbers above to speak with an operator or click the Call me™ link for instant access. To participate via webcast, click here to access the live stream 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 the HOPE-3, Phase 3 Trial

HOPE-3 is a Phase 3, multi-center, randomized, double-blind, placebo-controlled clinical trial consisting of two cohorts evaluating the safety and efficacy of Deramiocel in participants with DMD. Non-ambulatory and ambulatory boys who meet eligibility criteria are randomly assigned to receive either Deramiocel or placebo every 3 months for a total of 4 doses during the first 12 months of the study. Approximately 104 eligible study subjects have been enrolled in the dual-cohort study. For more information on this study, please visit (NCT05126758).

About Duchenne Muscular Dystrophy

Duchenne Muscular Dystrophy (DMD) is a severe, X-linked genetic disorder characterized by progressive muscle degeneration affecting the skeletal, respiratory, and cardiac muscles. It is caused by the absence of functional dystrophin, a key structural protein in muscle cells. DMD affects approximately 15,000 individuals in the United States and primarily impacts boys. Over time, deterioration of the heart muscle leads to cardiomyopathy and heart failure, which is the leading cause of death in DMD. There is no cure, and treatment options remain limited.

About Deramiocel

Deramiocel (CAP-1002) consists of allogeneic cardiosphere-derived cells (CDCs), a rare population of cardiac cells that have been shown in preclinical and clinical studies to exert potent immunomodulatory and anti-fibrotic actions in the preservation of cardiac and skeletal muscle function in dystrophiopathies such as DMD. CDCs act by secreting extracellular vesicles known as exosomes, which target macrophages and alter their expression profile to adopt a healing, rather than a pro-inflammatory phenotype. CDCs have been investigated in more than 250 peer-reviewed scientific publications and administered to over 250 human subjects across multiple clinical trials.

Deramiocel has received Orphan Drug Designation for the treatment of Duchenne Muscular Dystrophy (DMD) from both the U.S. FDA and the European Medicines Agency (EMA). In addition, it has been granted Regenerative Medicine Advanced Therapy (RMAT) designation in the U.S., Advanced Therapy Medicinal Product (ATMP) designation in Europe, and Rare Pediatric Disease Designation from the FDA, which may qualify Capricor for a Priority Review Voucher upon approval.

About Capricor Therapeutics

Capricor Therapeutics (NASDAQ: CAPR) is a biotechnology company dedicated to advancing transformative cell and exosome-based therapeutics to redefine the treatment landscape for rare diseases. At the forefront of our innovation is our lead product candidate, Deramiocel, an allogeneic cardiac-derived cell therapy. Extensive preclinical and clinical studies have shown Deramiocel to exert potent immunomodulatory and anti-fibrotic actions in the preservation of cardiac and skeletal muscle function in muscular dystrophies such as DMD. Deramiocel is currently in late-stage development for the treatment of Duchenne Muscular Dystrophy. Capricor is also harnessing the power of its exosome technology, using its proprietary StealthX™ platform in preclinical development focused on the areas of vaccinology, targeted delivery of oligonucleotides, proteins and small molecule therapeutics to potentially treat and prevent a diverse array of diseases. At Capricor, we stand committed to pushing the boundaries of possibility and forging a path toward transformative treatments for those in need. 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; dates for regulatory meetings; statements about our financial outlook; the potential that required regulatory inspections may be delayed or not be successful which would delay or prevent product approval; 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; potential future agreements; scope, duration, validity and enforceability of intellectual property rights; future

revenue streams and 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, 2024, as filed with the Securities and Exchange Commission on March 26, 2025, and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, as filed with the Securities and Exchange Commission on May 14, 2025. 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.

Capricor has entered into an agreement for the exclusive commercialization and distribution of Deramiocel for DMD in the United States and Japan with Nippon Shinyaku Co., Ltd. (U.S. subsidiary: NS Pharma, Inc.), subject to regulatory approval. Deramiocel is an Investigational New Drug (IND) and is not yet approved for any indications. Neither BMD nor any of Capricor's exosome-based candidates have been approved for clinical use.

For more information, please contact:

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