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)

March 10, 2026

CAPRICOR THERAPEUTICS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware (State or other jurisdiction of incorporation)	001-34058 (Commission File Number)	88-0363465 (I.R.S. Employer Identification No.)

10865 Road to the Cure, Suite 150, San Diego, California
(Address of principal executive offices)

92121
(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 March 10, 2026, Capricor Therapeutics, Inc. (the "Company" or "Caprcior") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has lifted the previously issued Complete Response Letter ("CRL") and resumed review of its Biologics License Application ("BLA") seeking full approval of Deramiocel, an investigational cell therapy, for the treatment of Duchenne muscular dystrophy ("DMD") cardiomyopathy.

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

Item 8.01 Other Events.

As disclosed above, the FDA has lifted the previously issued CRL and resumed review of the Company's BLA seeking full approval of Deramiocel, an investigational cell therapy, for the treatment of DMD cardiomyopathy. The submission has been classified as a Class 2 resubmission, with a Prescription Drug User Fee Act ("PDUFA") target action date of August 22, 2026.

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding review of the Company's BLA and potential eligibility to receive a PRV. The forward-looking statements included in this Current Report are subject to a number of risks, uncertainties and assumptions, including, without limitation known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the important factors discussed under the caption "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2024, and other filings with the Securities and Exchange Commission. These statements are based only on facts currently known by the Company and speak only as of the date of this Current Report on Form 8-K. As a result, you are cautioned not to rely on these forward-looking statements and the Company undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, titled "Capricor Therapeutics Announces Establishment of New PDUFA Date for Deramiocel BLA", dated March 10, 2026.
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: March 10, 2026

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

Exhibit 99.1

Capricor Therapeutics Announces Establishment of New PDUFA Date for Deramiocel BLA

- *Deramiocel has the potential to become the first therapy to address both skeletal and cardiac manifestations of Duchenne muscular dystrophy*
- *BLA supported by positive pivotal HOPE-3 Phase 3 results, including achievement of the primary endpoint and all Type I error-controlled secondary endpoints*
- *PDUFA target action date set for August 22, 2026; Company expects to be eligible for a Priority Review Voucher upon potential approval*

SAN DIEGO, March 10, 2026 (GLOBE NEWSWIRE) -- Capricor Therapeutics, Inc. (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for the treatment of rare diseases, today announced that the U.S. Food and Drug Administration ("FDA") has lifted the previously issued Complete Response Letter and resumed review of its Biologics License Application ("BLA") seeking full approval of Deramiocel, an investigational cell therapy, for the treatment of Duchenne muscular dystrophy ("DMD") cardiomyopathy. The submission has been classified as a Class 2 resubmission, with a Prescription Drug User Fee Act ("PDUFA") target action date of August 22, 2026.

"We are encouraged by the FDA's acknowledgment of our response to the Complete Response Letter and its continued review of our BLA for Deramiocel," said Linda Marbán, Ph.D., Chief Executive Officer of Capricor. "We believe the positive HOPE-3 results and broader clinical evidence reinforce Deramiocel's potential to become a first-in-class therapy for Duchenne muscular dystrophy, with the opportunity to address both skeletal and cardiac manifestations of the disease. We look forward to continuing to work closely with the FDA throughout the review process and remain focused on bringing this important therapy to patients as expeditiously as possible."

The Company received a Complete Response Letter ("CRL") from the FDA in July 2025. Following submission of data and supporting documentation from the HOPE-3 clinical trial, the FDA resumed review of the application and assigned a PDUFA target action date of August 22, 2026. At this time, the FDA has not identified any potential review issues in its response to the Company.

Capricor also expects to be eligible to receive a Priority Review Voucher ("PRV") upon potential approval of Deramiocel.

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 muscular dystrophies 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 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 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 that is currently in late-stage development for the treatment of Duchenne muscular dystrophy (DMD). Extensive preclinical and clinical data have demonstrated Deramiocel's potent immunomodulatory and anti-fibrotic effects in helping to preserve cardiac and skeletal muscle function in DMD. Capricor is also leveraging the power of its exosome technology, using its proprietary StealthX™ platform in preclinical development focused on vaccinology and the targeted delivery of oligonucleotides, proteins, and small-molecule therapeutics, with the potential to treat and prevent a wide range of diseases. At Capricor, we are 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 X.

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 clinical trials; the pace of enrollment of clinical trials; plans regarding regulatory filings, future research and clinical trials; regulatory developments involving products, including future interactions with regulatory authorities and the ability to obtain regulatory approvals or otherwise bring products to market; manufacturing capabilities; dates for regulatory meetings; 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; 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 September 30, 2025, as filed with the Securities and Exchange Commission on November 10, 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 and the StealthX™ vaccine are investigational candidates and have not been approved for commercial use in any indication.

For more information, please contact:

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