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)

August 24, 2026

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 Global Select Market

Item 8.01 Other Events.

On August 24, 2026, Capricor Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has extended the Prescription Drug User Fee Act ("PDUFA") target action date for its Biologics License Application ("BLA") for Deramiocel, an investigational cell therapy for Duchenne muscular dystrophy ("DMD"), from August 22, 2026 to November 22, 2026. The FDA has classified the submission as a major amendment, which extends the review period by three months. The amendment includes 24-month open-label extension data from Capricor's pivotal Phase 3 HOPE-3 study, and additional analyses with a request for FDA's review of the existing and new data in support of a refined proposed indication focused on upper limb function, the primary endpoint of HOPE-3.

A copy of the press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, titled "Capricor Therapeutics Announces Extension of PDUFA Target Action Date as FDA Continues Review of Deramiocel BLA", dated August 24, 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: August 24, 2026

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

Exhibit 99.1

Capricor Therapeutics Announces Extension of PDUFA Target Action Date as FDA Continues Review of Deramiocel BLA

– New PDUFA target action date of November 22, 2026 follows submission of additional Phase 3 HOPE-3 data and analyses supporting a refined proposed indication –

SAN DIEGO, Aug. 24, 2026 (GLOBE NEWSWIRE) — Capricor Therapeutics (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 extended the Prescription Drug User Fee Act (PDUFA) target action date for its Biologics License Application (BLA) for Deramiocel, an investigational cell therapy for Duchenne muscular dystrophy (DMD), from August 22, 2026 to November 22, 2026.

As part of its ongoing discussions with the FDA following the July 2026 Advisory Committee meeting, Capricor submitted an amendment to the BLA that includes 24-month open-label extension data from its pivotal Phase 3 HOPE-3 study and additional robustness analyses, with a request that the FDA review the existing and new data in support of a refined proposed indication focused on upper limb function, the primary endpoint of HOPE-3. The FDA's Center for Biologics Evaluation and Research (CBER) accepted the amendment for review, citing the significant unmet medical need in DMD. The FDA has classified the submission as a major amendment and extended the PDUFA target action date by three months to allow additional time to review the information.

“With an additional year of follow-up from HOPE-3, we now have one of the most extensive clinical datasets evaluating upper limb function in Duchenne,” said Linda Marbán, Ph.D., Chief Executive Officer of Capricor. “HOPE-3 met its primary endpoint, demonstrating a statistically significant benefit in upper limb function, and we believe the additional open-label data and further analyses included in the amendment strengthen the evidence supporting a refined proposed indication. We appreciate the FDA’s continued engagement and look forward to working constructively with the agency as it completes its review.”

Marbán continued, “The powerful testimony shared by patients, families and clinicians at the July Advisory Committee meeting underscored the importance of preserving upper limb function and the independence it provides for people living with Duchenne. In a progressive disease where function, once lost, cannot be recovered, we believe preservation of upper limb function has the potential to translate into meaningful differences in patients' independence and daily lives. That impact reinforces the urgency of our work and our commitment to bringing Deramiocel to the Duchenne community as soon as possible.”

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 immunomodulatory and anti-fibrotic actions in the preservation of skeletal and cardiac 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. For the treatment of DMD, Deramiocel holds Orphan Drug, RMAT and Rare Pediatric Disease designations in the

U.S., and Orphan Drug and ATMP designations in Europe. The Rare Pediatric Disease Designation may qualify Capricor for a Priority Review Voucher upon approval.

About Capricor Therapeutics

Capricor Therapeutics (NASDAQ: CAPR) is a biotechnology company dedicated to advancing cell and exosome-based therapeutics for the treatment of rare diseases. Our lead product candidate, Deramiocel, is an allogeneic cardiac-derived cell therapy in late-stage development for Duchenne muscular dystrophy (DMD), evaluated in clinical studies for its potential to preserve skeletal and cardiac muscle function. Capricor is also advancing its proprietary StealthX™ exosome platform for the targeted delivery of oligonucleotides, proteins, and small-molecule therapeutics across a range of diseases. At Capricor, we are committed to delivering new therapies for patients with rare diseases. 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, revenue and reimbursement estimates, projected terms of definitive agreements, our financial position, our possible uses of existing cash and investment resources; results of securities litigation; and statements regarding our litigation with Nippon Shinyaku Co., Ltd. and NS Pharma, Inc., including the nature of the dispute, our expectations regarding any legal proceedings, and our ability to commercialize Deramiocel independent of our existing distribution agreement 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, 2025, as filed with the Securities and Exchange Commission on March 17, 2026 and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, as filed with the Securities and Exchange Commission on August 14, 2026. 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.

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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