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)

June 26, 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 June 26, 2026, Capricor Therapeutics, Inc. (the "Company" or "Capricor") issued a press release announcing that the Cellular, Tissue, and Gene Therapies Advisory Committee of the U.S. Food and Drug Administration ("FDA") is planning to convene an Advisory Committee meeting to discuss the Company's Biologics License Application ("BLA") seeking approval of Deramiocel, an investigational cell therapy for the treatment of Duchenne muscular dystrophy ("DMD"). The date for the Advisory Committee meeting is July 29, 2026, and the meeting will be available for live streaming. The Company's BLA remains on track for a target action date under the Prescription Drug User Fee Act ("PDUFA") of August 22, 2026.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, titled "Capricor Therapeutics Announces FDA Advisory Committee Meeting to Review BLA for Deramiocel for the Treatment of Duchenne Muscular Dystrophy", dated June 26, 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: June 26, 2026

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

Exhibit 99.1

Capricor Therapeutics Announces FDA Advisory Committee Meeting to Review BLA for Deramiocel for the Treatment of Duchenne Muscular Dystrophy

–Advisory Committee meeting scheduled for July 29, 2026–
–Company's Biologics License Application on track with PDUFA target action date of August 22, 2026–

SAN DIEGO, June 26, 2026 (GLOBE NEWSWIRE) — Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for rare diseases, today announced that the Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) of the U.S. Food and Drug Administration (FDA) is planning to convene an advisory committee meeting to discuss the Company's Biologics License Application (BLA) seeking approval of Deramiocel, an investigational cell therapy for the treatment of Duchenne muscular dystrophy (DMD). The BLA is supported by the Company's Phase 2 HOPE-2 trial and long-term outcomes from the HOPE-2-OLE trial, as well as positive results from the Phase 3 HOPE-3 trial, which achieved statistical significance on its primary endpoint (PUL v2.0), the key secondary cardiac endpoint (LVEF), and all other Type I error-controlled secondary endpoints. The date for the Advisory Committee meeting is July 29, 2026, and the meeting will be available for live streaming.

"We are encouraged by the opportunity to bring Deramiocel before the Advisory Committee and engage directly with the FDA, the DMD patient community, and the physicians who care for them," said Linda Marbán, Ph.D., CEO of Capricor. "We have confidence in the totality of evidence supporting Deramiocel, which has demonstrated clinically meaningful, statistically significant skeletal and cardiac benefits with a consistent safety profile, across multiple studies supporting its potential as a first-in-class therapy for Duchenne muscular dystrophy. Our focus remains on supporting the Agency's review and preparing for this meeting, with the urgent needs of the DMD community guiding every step, and we remain committed to bringing this therapy to the families who need it."

For additional information on the meeting, please visit the Federal Register or the Company's website.

About 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 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 DMD, shown in clinical studies to preserve cardiac and skeletal 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, 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 March 31, 2026, as filed with the Securities and Exchange Commission on May 13, 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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