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 29, 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.

Phase 3 Peer-Review Publication; Update to Statistical Model for LVEF

On July 29, 2026, Capricor Therapeutics, Inc. ("Capricor" or the "Company") issued a press release announcing the publication in *The Lancet* of the final one-year results from its HOPE-3, Phase 3 clinical trial evaluating Deramiocel, its investigational cell therapy for the treatment of Duchenne muscular dystrophy ("DMD"). The manuscript underwent independent peer review, providing external validation of the trial's statistical methodology and findings. The results, which have now been published, are based on the Company's prespecified Statistical Analysis Plan version 3.0 ("SAP 3.0").

As part of its ongoing dialogue with the FDA regarding the HOPE-3 data, and in connection with the peer review process with *The Lancet*, the Company identified an update to the statistical model used in its analysis of left ventricular ejection fraction ("LVEF"), the key secondary endpoint of the study. Under the revised model, LVEF yields a p=0.09 (1.8 percentage point treatment difference), compared to p=0.04 previously reported (2.4 percentage point treatment difference). In the pre-specified cardiomyopathy subgroup, the result is nominally significant at p=0.02 (2.8 percentage point treatment difference). The other additional type-1 error-controlled endpoints will be characterized as nominally significant under applicable hierarchical testing procedures. The primary efficacy endpoint result and all other trial data remain unchanged.

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

Bioresearch Monitoring (BIMO) Inspection

On July 4, 2026, the Company was notified by the FDA of a Bioresearch Monitoring (BIMO) inspection of the Company's clinical operations related to its Biologics License Application for Deramiocel for the treatment of DMD. The inspection commenced on July 6, 2026 and concluded on July 20, 2026.

At the conclusion of the inspection, the FDA issued a Form FDA 483, Notice of Inspectional Observations, citing one observation relating primarily to the Company's standard operating procedures, documentation practices, vendor oversight, and audit report timeliness in connection with the conduct of the HOPE-3 clinical trial. The Company does not believe the observation affects the integrity or reliability of the HOPE-3 data. The Company is preparing its formal response and intends to respond completely in a timely manner.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, titled "*The Lancet* Publishes HOPE-3 Data for Capricor Therapeutics' Deramiocel in Duchenne Muscular Dystrophy", dated July 29, 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: July 29, 2026

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

Exhibit 99.1

The Lancet Publishes HOPE-3 Data for Capricor Therapeutics' Deramiocel in Duchenne Muscular Dystrophy

--Independent Peer Review Provides External Validation of the Trial's Design, Statistical Methodology and Findings--

--Randomized, Double-Blind, Placebo-Controlled HOPE-3 Phase 3 Trial (n=106) Met Primary Endpoint, with Deramiocel Slowing Upper Limb Function Decline by 54 Percent versus Placebo (PUL 2.0, p=0.03) and Showing Clinically Meaningful Cardiac Benefit--

--Deramiocel BLA Remains Under Active FDA Review, with PDUFA Target Action Date of August 22, 2026--

SAN DIEGO, July 29, 2026 (GLOBE NEWSWIRE) — Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for rare diseases, today announced that *The Lancet*, one of the most selective and highly regarded peer-reviewed journals in medicine, has published results from the Company's pivotal Phase 3 HOPE-3 clinical trial evaluating Deramiocel, its investigational cell therapy for the treatment of Duchenne muscular dystrophy (DMD). The manuscript underwent independent expert peer review, providing external validation of the trial's design, statistical methodology and findings. The results are based on the Company's prespecified Statistical Analysis Plan version 3.0 (SAP 3.0). The paper, titled "Deramiocel heart-derived cellular therapy in advanced Duchenne muscular dystrophy (HOPE-3): a phase 3, randomised, double-blind, placebo-controlled trial" can be accessed here.

"The HOPE-3 results are a landmark moment for the Duchenne community, demonstrating a significant benefit on skeletal muscle function alongside compelling data shown in cardiac function," said Craig McDonald, M.D., Distinguished Professor of Physical Medicine & Rehabilitation and Pediatrics at UC Davis Health, National PI of the HOPE-2 and HOPE-3 trials and lead author of the publication. "A 54 percent slowing of upper limb disease progression (p=0.03) is a substantial, meaningful effect in a population where functional decline is typically relentless and irreversible. HOPE-3 is the first Phase 3 trial to demonstrate a significant benefit on function in a largely non-ambulatory DMD population, and the concurrent benefits in several cardiac measures lend biological support to a consistent treatment effect across skeletal and cardiac muscle. After many years of work, seeing a therapy deliver at this level has been a profound privilege."

"The totality of evidence for Deramiocel is strong, with clinically meaningful benefits now published in *The Lancet*, one of medicine's most highly regarded journals," said Linda Marbán, Ph.D., CEO of Capricor. "*The Lancet's* rigorous, independent peer review process further validates these results. This is the same body of evidence that forms the foundation of our BLA and will be discussed at our Advisory Committee meeting. The publication reinforces our confidence in the strength and durability of these results in advance of Deramiocel's PDUFA target action date of August 22. We have continued to work with the FDA throughout its review, and we firmly believe this evidence supports approval. Deramiocel can change the course of this disease, and we are focused on our goal of bringing it to patients as the first approved cell therapy for Duchenne."

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:

Capricor Media Contact:
Caitlin Kasunich
KCSA Strategic Communications
ckasunich@kcsa.com
212.896.1241

Capricor Company Contact:
AJ Bergmann, Chief Financial Officer
abergmann@capricor.com
858.727.1755