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)

December 3, 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 December 3, 2025, Capricor Therapeutics, Inc. (the "Company") announced positive topline results from its pivotal Phase 3 HOPE-3 clinical trial. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference into this Item 7.01 of this Current Report on Form 8-K.

The information under Item 7.01 of this Current Report on Form 8-K, including 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 8.01 Other Events.

As disclosed above, the Company announced positive topline results from its pivotal Phase 3 HOPE-3 clinical trial. HOPE-3 is a randomized, double-blind, placebo-controlled Phase 3 clinical trial evaluating Deramiocel in boys and young men with Duchenne muscular dystrophy. The study randomized 106 participants across 20 leading U.S. clinical sites. Participants received intravenous Deramiocel at 150 million cells per infusion or placebo every three months for a 12-month period. The average age of participants was approximately 15 years and all were on a stable corticosteroid regimen throughout the study. Baseline demographics were well balanced between treatment arms, approximately 90 percent were receiving cardiac medications at baseline, and over 75 percent had diagnosed cardiomyopathy. Deramiocel maintained a favorable safety and tolerability profile consistent with prior clinical experience.

Topline Efficacy Results

Endpoint	% Slowing of Progression[3] (Deramiocel vs. Placebo)	p-value
Performance of Upper Limb (PUL v2.0) Total Score[1] (Primary, n=105)	54%	p=0.029
Left Ventricular Ejection Fraction (LVEF %)[2] (Key Secondary, n=83)	91%	p=0.041

[1] n reflects the number of patients in the ITT population with evaluable PUL v2.0 assessments at 12 months.
[2] n reflects the number of patients in the ITT population with centrally reviewed and evaluable cardiac MRI LVEF assessments at 12 months.
[3] Percent slowing is calculated as the treatment difference divided by the placebo change from baseline.

The Company expects that detailed HOPE-3 results will be submitted for presentation at a future scientific meeting and for publication in a peer-reviewed journal. Concurrently, the Company and its commercial partner, Nippon Shinyaku (U.S. subsidiary, NS Pharma, Inc.) are advancing launch readiness activities aimed to support timely patient access to Deramiocel, pending potential regulatory approval.

Forward-Looking Statements

Statements in this Current Report on Form 8-K regarding the efficacy, safety, and intended utilization of the Company'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 the Company'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 the Company's business is set forth in the Company'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 the Company's 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 the Company as of the date hereof, and the Company assumes no obligation to update these forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, titled "Capricor Therapeutics Announces Positive Topline Results from Pivotal Phase 3 HOPE-3 Study of Deramiocel in Duchenne Muscular Dystrophy", dated December 3, 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: December 3, 2025

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

Exhibit 99.1

Capricor Therapeutics Announces Positive Topline Results from Pivotal Phase 3 HOPE-3 Study of Deramiocel in Duchenne Muscular Dystrophy

- *Pivotal Phase 3 randomized, double-blind, placebo-controlled study (n=106) met the primary endpoint (PUL v2.0) and the key secondary cardiac endpoint (LVEF), both achieving statistical significance (p=0.03 and p=0.04, respectively)*
- *Statistical significance was achieved in all type 1 error controlled secondary endpoints*
- *Results demonstrate clinically meaningful and statistically significant skeletal and cardiac benefits, supporting Deramiocel as a potential first-in-class therapy designed to treat Duchenne cardiomyopathy, the leading cause of mortality in Duchenne*
- *Deramiocel maintained a favorable safety and tolerability profile consistent with prior clinical experience*
- *Company plans to submit its response to the Complete Response Letter incorporating HOPE-3 data, following prior alignment with FDA*
- *Conference call and webcast today at 8:00 a.m. ET*

SAN DIEGO, Dec. 3, 2025 (GLOBE NEWSWIRE) -- Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for the treatment of rare diseases, today announced positive topline results from its pivotal Phase 3 HOPE-3 trial evaluating Deramiocel, the Company's investigational cell therapy for the treatment of Duchenne muscular dystrophy (DMD).

"HOPE-3 delivered strong and definitive evidence that Deramiocel can meaningfully improve the course of Duchenne muscular dystrophy, demonstrating statistically significant improvements in both skeletal and cardiac function," said Linda Marbán, Ph.D., Chief Executive Officer of Capricor. "These results reinforce the durable benefits seen in HOPE-2 and its open-label extension, which has continued for over 48 months, and highlight the strength, consistency and reproducibility of Deramiocel's clinical profile after more than a decade of rigorous clinical development. We believe these pivotal study results, in addition to the evidence from the HOPE-2 and HOPE-2 OLE studies, position us to address the clinical issues in the Complete Response Letter received earlier this year, consistent with prior FDA guidance that HOPE-3 results should be sufficient to support regulatory approval."

HOPE-3 is a randomized, double-blind, placebo-controlled, Phase 3 clinical trial evaluating Deramiocel in boys and young men with Duchenne muscular dystrophy. The study randomized 106 participants across 20 leading U.S. clinical sites. Participants received intravenous Deramiocel at 150 million cells per infusion or placebo every three months for a 12-month period. The average age of participants was approximately 15 years, and all were on a stable corticosteroid regimen throughout the study. Baseline demographics were well balanced between treatment arms, approximately 90 percent were receiving cardiac medications at baseline, and over 75 percent had a clinical diagnosis of cardiomyopathy. Deramiocel maintained a favorable safety and tolerability profile consistent with prior clinical experience.

Topline Efficacy Results

Endpoint	% Slowing of Progression[3] (Deramiocel vs. Placebo)	p-value
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[2] n reflects the number of patients in the ITT population with centrally reviewed and evaluable cardiac MRI LVEF assessments at 12 months.
[3] Percent slowing is calculated as the treatment difference divided by the placebo change from baseline.

"We believe the HOPE-3 PUL results show statistically and clinically meaningful and significant treatment effects on both upper limb function and cardiomyopathy," said Craig McDonald, M.D., Distinguished Professor of Physical Medicine &

Rehabilitation and Pediatrics at UC Davis Health, and National PI of the HOPE-3 trial. “A nearly 54 percent slowing of skeletal muscle disease progression is extraordinary in Duchenne and directly linked to maintaining independence and quality of life in the most severely affected patients with greatest unmet need. The preservation of function reflected in PUL v2.0 translates into real, practical benefits for boys and young men living with this disease, and the effect of Deramiocel on cardiomyopathy will potentially translate to improved long-term survival. The HOPE-3 study is the first-ever Phase 3 trial in a largely non-ambulatory population with DMD to successfully meet its primary endpoint and to support the development of an innovative therapy over many years with this level of impact has been a profound privilege.”

“The cardiac findings from HOPE-3 represent a significant advance in the management of Duchenne muscular dystrophy cardiomyopathy,” said Jonathan Soslow, M.D., MSCI, Professor of Pediatrics (Cardiology) at Vanderbilt University Medical Center. “Cardiomyopathy is the leading cause of mortality in Duchenne, and stabilizing cardiac function has remained a major unmet need. The statistically and clinically significant preservation of left ventricular ejection fraction in patients treated with Deramiocel observed in HOPE-3 underscores the potential of Deramiocel to address one of the most critical aspects of the disease.”

Dr. Marbán continued, “For families living with Duchenne who are looking for therapies that preserve functional ability, protect the heart and maintain independence, today’s results provide real momentum and meaningful progress, offering renewed confidence as we work to advance Deramiocel toward potential regulatory approval.”

We expect that detailed HOPE-3 results will be submitted for presentation at a future scientific meeting and for publication in a peer-reviewed journal.

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: 52151. Participants can use guest dial-in numbers above and be answered by an operator or click the Call me™ link for instant telephone access to the event. To participate via a webcast, please click here. 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 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 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 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 four doses during the first 12 months of the trial. A total of 106 eligible subjects were randomized in the dual-cohort trial. For more information, please visit ClinicalTrials.gov (NCT05126758).

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 clinical 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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