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 12, 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 Capital Market

Item 2.02 Results of Operations and Financial Condition.

On March 12, 2026, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter and full year ended December 31, 2025. A copy of the press release is being furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information under Item 2.02 of this Current Report on Form 8-K and 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 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, titled "Capricor Therapeutics Reports Fourth Quarter and Full Year 2025 Results and Provides Corporate Update", dated March 12, 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 12, 2026

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

Exhibit 99.1

Capricor Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Corporate Update

- *Deramiocel BLA for Duchenne muscular dystrophy under U.S. FDA review with PDUFA target action date of August 22, 2026*
- *Pivotal HOPE-3 Phase 3 trial achieved primary endpoint (PUL v2.0) and key secondary cardiac endpoint (LVEF)*
- *Late-breaking HOPE-3 data presented at MDA 2026 demonstrated additional cardiac and functional benefits*
- *San Diego GMP manufacturing facility operational to support potential commercial launch*
- *Capricor uplisted to the Nasdaq Global Select Market*
- *Cash balance of approximately $318 million expected to support operations through 2027*
- *Conference call and webcast today at 4:30 p.m. ET*

SAN DIEGO, March 12, 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 its financial results for the fourth quarter and full year ended December 31, 2025, and provided a corporate update.

"Capricor enters 2026 with important regulatory and clinical momentum as we work toward potential approval of Deramiocel for the treatment of Duchenne muscular dystrophy (DMD)," said Linda Marbán, Ph.D., Chief Executive Officer of Capricor. "With the FDA review of our BLA underway and a PDUFA target action date of August 22, 2026, our highest priority is execution, including working closely with the Agency, preparing for potential launch, and continuing to build the capabilities for a commercial-stage company. Recent late-breaking data presented at the 2026 MDA Clinical & Scientific Conference further reinforced the strength of the program, highlighting Deramiocel's impact on both cardiac and skeletal muscle function in Duchenne. These findings build on the positive topline results from the Phase 3 HOPE-3 study and reinforce Deramiocel's potential to become a first-in-class therapy for Duchenne designed to address both the skeletal and cardiac manifestations of this devastating disease. At the same time, we remain focused on advancing our exosome platform and expanding the long-term potential of our pipeline. Supported by a strong balance sheet, we believe we are well positioned to execute on these priorities and deliver meaningful value for patients, families, and shareholders."

Fourth Quarter 2025 and Recent Highlights

- **Deramiocel BLA Under FDA Review:** Capricor's Biologics License Application (BLA) seeking full approval of Deramiocel for the treatment of DMD is currently under review by the U.S. Food and Drug Administration. The FDA informed the Company that its response to the previously issued Complete Response Letter was complete to support continued review and assigned a Prescription Drug User Fee Act (PDUFA) target action date of August 22, 2026. The FDA classified the submission as a Class 2 resubmission.
- **Positive Phase 3 HOPE-3 Trial Results:** Capricor reported positive topline results from the HOPE-3 Phase 3 trial, a multicenter, randomized, double-blind, placebo-controlled study which enrolled 106 patients with DMD. The trial met its primary endpoint of Performance of the Upper Limb (PUL v2.0) and the key secondary cardiac endpoint of left ventricular ejection fraction (LVEF), with both achieving statistical significance (p=0.03 and p=0.04, respectively). All Type I error-controlled secondary endpoints also achieved statistical significance. Deramiocel maintained a favorable safety and tolerability profile consistent with prior clinical studies.

- **Late-Breaking HOPE-3 Data Presented at MDA 2026:** Additional data from the HOPE-3 study were presented in a late-breaking oral presentation at the 2026 Muscular Dystrophy Association Clinical & Scientific Conference. Newly reported analyses further supported Deramiocel's potential impact on functional outcomes in Duchenne. Cardiac MRI analyses demonstrated a significant reduction in myocardial fibrosis as measured by late gadolinium enhancement (LGE), corresponding to a three-segment treatment difference versus placebo at 12 months (p=0.022). In patients with baseline cardiomyopathy, treatment resulted in a 3.3 percentage-point improvement in LVEF versus placebo, representing greater than 100% attenuation of expected cardiac decline (p=0.017). Additional functional outcomes were also presented. Data from the Duchenne Video Assessment (DVA), a measure of activities of daily living in individuals with Duchenne, showed the "eat 10 bites" task demonstrated approximately 83% slowing of disease progression versus placebo (p=0.018).
- **Commercial Launch Preparations Underway:** Capricor continues to advance commercial readiness in preparation for a potential launch. The Company's GMP manufacturing facility in San Diego successfully completed an FDA Pre-License Inspection (PLI) in connection with the BLA review process. All Form 483 observations have been addressed, and the facility is operational and positioned to support an initial commercial launch. Further manufacturing expansion is underway to increase capacity in anticipation of demand following potential approval.
- **Peer-Reviewed Publication on Deramiocel:** In October 2025, Capricor published a peer-reviewed paper in Biomedicines describing Deramiocel's anti-fibrotic and immunomodulatory mechanisms of action, including the release of exosomes and soluble factors that suppress fibrotic gene expression.
- **StealthX™ Platform Development:** The NIAID-sponsored Phase 1 clinical trial evaluating Capricor's StealthX™ exosome-based vaccine platform remains ongoing. Preliminary data indicate the vaccine has been well tolerated with a favorable safety profile across all doses tested. Final results are expected in the second quarter of 2026, subject to completion of the trial by NIAID.
- **Strengthened Balance Sheet:** During the fourth quarter of 2025, Capricor completed an underwritten public offering generating approximately $161.9 million in net proceeds, strengthening the Company's financial position and extending its expected cash runway through 2027.
- **Nasdaq Global Select Market Uplisting:** Capricor's common stock was approved for uplisting to the Nasdaq Global Select Market on March 9, 2026, representing Nasdaq's highest listing tier.

Fourth Quarter and Full Year 2025 Financial Results

Cash position: Cash, cash equivalents and marketable securities totaled approximately $318.1 million as of December 31, 2025, compared to approximately $151.5 million as of December 31, 2024. In December 2025, the Company completed a public offering for net proceeds of approximately $161.9 million and also raised approximately $75.1 million in net proceeds through issuances of common stock at an average price of approximately $28.88 per share under its at-the-market offering program.

Revenues: Revenues for the fourth quarter of 2025 were $0, compared to approximately $11.1 million for the fourth quarter of 2024. Additionally, revenues for the year ended December 31, 2025 were $0, compared to approximately $22.3 million for the year ended December 31, 2024. Capricor's primary source of revenue was from the ratable recognition of the $40.0 million in upfront and first development milestone payments from Nippon Shinyaku and the recognition of the $10.0 million second development milestone payment in accordance with the Company's U.S. Distribution Agreement with Nippon Shinyaku, all of which were fully recognized as of December 31, 2024.

Costs and Expenses: Total operating expenses for the fourth quarter of 2025 were approximately $29.2 million, compared to approximately $18.8 million for the fourth quarter of 2024. Total operating expenses for the year ended December 31, 2025 were approximately $108.1 million, compared to approximately $64.8 million for the year ended December 31, 2024.

Net loss: The Company reported a net loss of approximately $30.2 million, or $0.62 per share, for the fourth quarter of 2025, compared to a net loss of approximately $7.1 million, or $0.16 per share, for the fourth quarter of 2024. The Company reported a net loss of approximately $105.0 million, or $2.26 per share, for the year ended December 31, 2025, compared to a net loss of approximately $40.5 million, or $1.15 per share, for the year ended December 31, 2024.

Financial Outlook: The Company believes that, based on the current operating plan and financial resources, its available cash, cash equivalents and marketable securities will be sufficient to cover anticipated expenses and capital requirements through 2027. This expectation excludes any additional potential milestone payments under the Commercialization and Distribution Agreements with Nippon Shinyaku, as well as any strategic use of capital not currently in the Company's base case planning assumptions.

Upcoming Events

The Company plans to participate at the following upcoming investor events:

- 38th Annual Roth Conference, March 22-24, 2026, Dana Point, CA

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: 70035. Participants may dial in using the numbers above and ask to be joined to the call 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 shortly after the conclusion of the live event and will be accessible in the Investors section of the Company's website at www.capricor.com.

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.

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CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

	Three Months Ended December 31,		Year Ended December 31,	
	2025	**2024**	**2025**	**2024**
REVENUE				
Revenue	$ —	$ 11,130,509	$ —	$ 22,270,465
TOTAL REVENUE	—	11,130,509	—	22,270,465
OPERATING EXPENSES				
Research and development	23,132,671	14,554,936	84,454,595	49,968,585
General and administrative	6,024,937	4,273,414	23,687,535	14,865,122
TOTAL OPERATING EXPENSES	29,157,608	18,828,350	108,142,130	64,833,707
LOSS FROM OPERATIONS	(29,157,608)	(7,697,841)	(108,142,130)	(42,563,242)
OTHER INCOME (EXPENSE)				
Other income	11,205	7,471	45,421	7,471
Investment income	2,021,214	686,572	6,257,607	2,202,990
Interest expense	(3,045,725)	—	(3,045,725)	—
Loss on disposal of fixed assets	—	(112,805)	(157,519)	(112,805)
TOTAL OTHER INCOME (EXPENSE)	(1,013,306)	581,238	3,099,784	2,097,656
LOSS BEFORE INCOME TAXES	(30,170,914)	(7,116,603)	(105,042,346)	(40,465,586)
(Provision for) benefit from income taxes	—	—	(1,600)	(1,600)
NET LOSS	$ (30,170,914)	$ (7,116,603)	$ (105,043,946)	$ (40,467,186)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	(560,968)	930,734	(743,801)	791,142
COMPREHENSIVE LOSS	$ (30,731,882)	$ (6,185,869)	$ (105,787,747)	$ (39,676,044)
Net loss per share, basic and diluted	$ (0.62)	$ (0.16)	$ (2.26)	$ (1.15)
Weighted average number of shares, basic and diluted	48,850,452	44,509,154	46,478,416	35,218,628

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	December 31, 2025 (unaudited)	December 31, 2024
Cash, cash equivalents and marketable securities	$ 318,128,915	$ 151,515,877
Total assets	$ 355,949,294	$ 170,481,086
Total liabilities	$ 50,157,149	$ 25,018,750
Total stockholders' equity - 57,370,909 and 45,582,288 common shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	305,792,145	145,462,336
Total liabilities and stockholders' equity	$ 355,949,294	$ 170,481,086