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)

May 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 Global Select Market

Item 2.02 Results of Operations and Financial Condition.

On May 12, 2026, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended March 31, 2026. 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 First Quarter 2026 Financial Results and Provides Corporate Update", dated May 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: May 12, 2026

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

Exhibit 99.1

Capricor Therapeutics Reports First Quarter 2026 Financial Results and Provides Corporate Update

- Deramiocel BLA under active FDA review; PDUFA target action date of August 22, 2026; labeling discussions expected to commence soon
- HOPE-3 Phase 3 trial met its primary endpoint (PUL v2.0; upper limb function) and all Type I error-controlled secondary endpoints
- GMP manufacturing facility fully operational; second-floor expansion well underway
- Chief Commercial Officer with direct DMD commercial experience expected to join the Company in the coming weeks
- Filed suit against Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. seeking rescission of U.S. distribution agreement and preliminary injunction; FDA review and PDUFA date unaffected
- Cash balance of approximately $279 million expected to support operations into Q4 2027
- Eligible for a Priority Review Voucher upon approval; PRV is transferable and monetizable, offering potential non-dilutive capital
- Conference call and webcast today at 4:30 p.m. ET

SAN DIEGO, May 12, 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 its financial results for the first quarter ended March 31, 2026, and provided a corporate update.

"Capricor enters this pivotal moment with important regulatory and clinical momentum as we work toward potential approval of Deramiocel for the treatment of Duchenne muscular dystrophy," 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: working closely with the Agency, preparing for potential launch, and continuing to build the capabilities of a commercial-stage company. We remain focused on ensuring that Deramiocel reaches every eligible patient as quickly as possible, which is why we took necessary legal action against NS Pharma to remove a structural barrier to patient access created by a flawed pricing arrangement and to address our distributor's failure to fulfill its commercial obligations."

“Our thesis is straightforward: a potential first-in-class approval in a defined rare disease population, proprietary in-house manufacturing, a growing pipeline, and a leadership team with the conviction and the capital to execute,” said Dr. Marbán. “We are building something that will create meaningful and durable value for patients, for this company, and for the shareholders who have believed in this mission.”

First Quarter 2026 and Recent Highlights

- **Deramiocel BLA Under FDA Review:** Capricor's Biologics License Application (BLA) seeking approval of Deramiocel for the treatment of DMD is currently under review by the U.S. Food and Drug Administration. The FDA accepted the Company's Class 2 resubmission as complete, resuming its full review of the BLA, with a PDUFA target action date of August 22, 2026. There has been a significant number of information requests from FDA to Capricor, all of which the Company has been able to address. The Company looks forward to continuing an active dialogue with the FDA and expects labeling discussions to commence soon.
- **Additional HOPE-3 Late-Breaking Data Presented at MDA, AAN, and ASGCT (2026):** HOPE-3 data were selected as one of only four late-breaking oral presentations at the 2026 MDA Clinical & Scientific Conference. Data were also presented at the 2026 AAN Annual Meeting and the 2026 ASGCT Annual Meeting. Cardiac MRI analyses showed a significant reduction in myocardial fibrosis by late gadolinium enhancement (LGE) versus placebo, a clinically meaningful finding given that fibrosis is cumulative and irreversible. The Duchenne Video Assessment (DVA) "eat 10 bites" measure, a home-based, caregiver-captured assessment of upper limb function and daily living activities, demonstrated statistically significant improvement versus placebo, directly correlated with patient independence and quality of life. The full HOPE-3 dataset has been submitted for publication to a peer-reviewed journal.
- **Commercial Launch Preparations Underway:** The Company's GMP manufacturing facility in San Diego successfully completed an FDA Pre-License Inspection, with all Form 483 observations addressed. The facility is

operational and positioned to support initial commercial launch. Second-floor expansion adding additional cleanrooms is well underway, scaling to approximately 2,000–2,500 patients per year, roughly 10,000 doses annually, at full capacity, with full facility validation and FDA approval targeted for the first half of 2027. The Company will begin stockpiling commercial doses once guidance on the label is received. Planning is underway across all critical launch functions, including patient support, market access, reimbursement planning, medical affairs and physician education.

- **Chief Commercial Officer Selected:** Capricor has secured a Chief Commercial Officer (CCO) with direct DMD commercial experience who will be joining the Company in the coming weeks. The Company looks forward to introducing the new CCO to the investment and DMD community shortly.
- **Legal Action Filed Against NS Pharma:** On May 7, 2026, Capricor filed suit against Nippon Shinyaku Co., Ltd. and its U.S. subsidiary, NS Pharma, Inc., seeking rescission of its U.S. Commercialization and Distribution Agreement and a preliminary injunction to preserve Capricor's ability to distribute Deramiocel to patients pending FDA approval. The Company determined that the pricing structure embedded in the agreement contains a fundamental flaw that, if unaddressed, would make it unfeasible to deliver Deramiocel to patients covered by Medicare, Medicaid, or private insurance — creating a structural barrier to patient access. Capricor engaged with NS Pharma extensively and in good faith to resolve this issue; NS Pharma refused to address it and instead demanded that Capricor cede control of its regulatory relationships and commercial identity as a condition of resolution. NS Pharma also failed to complete foundational commercial launch requirements. The FDA review and PDUFA date are unaffected by Capricor's lawsuit against NS Pharma.
- **Long-Term Safety and Open-Label Extension:** Approximately 90 patients are currently enrolled across Capricor's collective open-label extension studies, with several patients receiving continuous intravenous infusions of Deramiocel for up to five years. Deramiocel has maintained a consistent, well-tolerated safety profile across more than 800 infusions.
- **Priority Review Voucher:** Upon potential approval, Capricor expects to be eligible to receive a Rare Pediatric Disease Priority Review Voucher (PRV). PRVs are transferable and can be monetized through sale, representing a meaningful potential source of non-dilutive capital. Capricor retains all rights to sell or transfer any PRV it may receive.
- **Pipeline Development:** The StealthX™ platform is advancing several therapeutic programs, with a focus on muscle-targeted delivery of siRNA, proteins, and small molecules. The Company is also laying the groundwork for expansion of Deramiocel into Becker muscular dystrophy and engaging regulatory authorities in Europe and Japan.

First Quarter 2026 Financial Results

- **Cash position:** Cash, cash equivalents and marketable securities totaled approximately $278.6 million as of March 31, 2026, compared to approximately $318.1 million as of December 31, 2025.
- **Revenues:** There was no revenue recognized for the first quarter of 2026 or 2025.
- **Costs and Expenses:** Total operating expenses for the first quarter of 2026 were approximately $36.8 million, compared to approximately $25.0 million for the first quarter of 2025.
- **Net loss:** The Company reported a net loss of approximately $33.9 million, or $0.59 per share, for the first quarter of 2026, compared to a net loss of approximately $24.4 million, or $0.53 per share, for the first quarter of 2025.
- **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 Q4 2027. This outlook excludes any potential revenue from product sales, the potential monetization of a PRV, if received, or other non-operating sources of capital.

Upcoming Events

- American Society of Gene & Cell Therapy (ASGCT) 2026 Annual Meeting, May 11-15, 2026, Boston, MA
- H.C. Wainwright 4th Annual BioConnect Investor Conference, May 19, 2026, New York, NY
- CureDuchenne 2026 FUTURES National Conference, May 21-24, 2026, Orlando, FL
- PPMD's 2026 Annual Conference, June 25-27, 2026, Orlando, FL
- Goldman Sachs 47th Annual Global Healthcare Conference 2026, June 8-10, 2026, Miami, FL
- B. Riley Securities' Mind, Muscle & Vision Summit, July 16, 2026, Boston, MA

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: 60968. 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.

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

	Three Months Ended March 31,	
	2026	**2025**
REVENUE		
Revenue	$ —	$ —
TOTAL REVENUE	—	—
OPERATING EXPENSES		
Research and development	27,376,912	18,915,572
General and administrative	9,395,941	6,067,376
TOTAL OPERATING EXPENSES	36,772,853	24,982,948
LOSS FROM OPERATIONS	(36,772,853)	(24,982,948)
OTHER INCOME (EXPENSE)		
Other income	8,145	12,485
Investment income	2,904,506	729,542
Loss on disposal of fixed assets	(81,143)	(150,673)
TOTAL OTHER INCOME (EXPENSE)	2,831,508	591,354
LOSS BEFORE INCOME TAXES	(33,941,345)	(24,391,594)
(Provision for) benefit from income taxes	—	—
NET LOSS	$ (33,941,345)	$ (24,391,594)
OTHER COMPREHENSIVE INCOME (LOSS)		
Net unrealized gain (loss) on marketable securities	(536,881)	784,972
COMPREHENSIVE LOSS	$ (34,478,226)	$ (23,606,622)
Net loss per share, basic and diluted	$ (0.59)	$ (0.53)
Weighted average number of shares, basic and diluted	57,434,267	45,636,633

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	March 31, 2026 (unaudited)	December 31, 2025
Cash, cash equivalents and marketable securities	$ 278,609,914	$ 318,128,915
Total assets	$ 326,283,517	$ 355,949,294
Total liabilities	$ 47,580,884	$ 50,157,149
Total stockholders' equity - 57,664,673 and 57,370,909 common shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	278,702,633	305,792,145
Total liabilities and stockholders' equity	$ 326,283,517	$ 355,949,294