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)

November 10, 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 November 10, 2026, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended September 30, 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 Third Quarter 2026 Financial Results and Provides Corporate Update", dated November 10, 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: November 10, 2026

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

Exhibit 99.1

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

- *Deramiocel Biologics License Application (BLA) for Duchenne muscular dystrophy (DMD) under FDA review; PDUFA target action date of November 22, 2026*
- *Major BLA amendment added two-year open-label extension (OLE) HOPE-3 data and proposed a refined indication focused on upper limb impairment in patients > 9 years old*
- *Two-year HOPE-3 OLE data presented at the World Muscle Society (WMS) Congress: 76% slower upper limb decline after patients switched from placebo to Deramiocel*
- *HOPE-3 cardiac results received the American Heart Association (AHA) Outstanding Research Award in Pediatric Cardiology*
- *Cash, cash equivalents, restricted cash and marketable securities of approximately $199 million as of September 30, 2026*
- *Conference call and webcast today at 4:30 p.m. ET*

SAN DIEGO, Nov. 10, 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 third quarter ended September 30, 2026, and provided a corporate update.

"This quarter, we took important steps forward on both our regulatory filing and our launch readiness, submitting two-year HOPE-3 OLE data in a major amendment to our BLA while advancing our manufacturing and commercial preparations. In the OLE phase, patients who switched from placebo to Deramiocel saw their upper limb decline slow by 76% compared with their year on placebo, and this past weekend our HOPE-3 cardiac results received the AHA Outstanding Research Award in Pediatric Cardiology. As Duchenne progresses, boys and young men lose the use of their arms and hands, and with it their independence, which is what Deramiocel is designed to slow. We appreciate the FDA's engagement throughout this review and are encouraged by the Agency's current focus on rare disease, including its recently launched Rare Disease Framework Initiative. As we approach our PDUFA date, we remain confident in the strength of our data. With our San Diego facility operational, we are prepared to move quickly to bring Deramiocel to patients, if approved," said Linda Marbán, Ph.D., Capricor's Chief Executive Officer.

Third Quarter 2026 and Recent Highlights

- **BLA Under Review; PDUFA November 22:** Capricor continues to work with the FDA on its review of the BLA for Deramiocel, the Company's investigational cell therapy for DMD. In August, the Company submitted two-year OLE data and additional robustness analyses from HOPE-3, its randomized, placebo-controlled Phase 3 trial, and an integrated summary of efficacy across HOPE-2 and HOPE-3. The submission also proposed a refined indication focused on upper limb impairment in patients > 9 years old – the population studied in HOPE-3 and the focus of its primary endpoint. The FDA classified the submission as a major amendment, extending the review by three months to November 22, 2026.
- **FDA Clinical Trial Inspection:** As part of the BLA review, the FDA conducted a Bioresearch Monitoring (BIMO) inspection in July 2026 and issued a Form 483 with one observation. The Company has submitted its response and is awaiting FDA feedback.
- **Two-Year HOPE-3 OLE Data Presented at WMS:** In October, Capricor presented the two-year HOPE-3 OLE data as a late-breaking poster at the 31st Annual WMS Congress. Patients who switched from placebo to Deramiocel after year one declined 1.56 points less on the Performance of the Upper Limb (PUL 2.0) scale, a validated assessment of arm and hand function, than they had in their year on placebo – a 76% slowing in this open-label, cross-phase comparison. Patients treated with Deramiocel maintained a slower rate of decline over two years, supporting the durability of the treatment effect.

- **HOPE-3 Cardiac Data Win AHA Outstanding Research Award:** On November 7, Jonathan Soslow, M.D., MSCI, of Vanderbilt University Medical Center presented results showing slower progression of myocardial fibrosis (heart muscle scarring) with Deramiocel versus placebo and, in patients with cardiomyopathy, left ventricular ejection fraction favoring Deramiocel. Results were generally consistent when compared with a matched natural history group. Additional details are available in the Company's press release issued November 9, 2026.
- **HOPE-3 Results Published in *The Lancet*:** The paper, published in July, reported a statistically significant slowing of upper limb disease progression with Deramiocel as measured by PUL 2.0 (p=0.029), with supportive results across additional functional and cardiac measures.
- **Manufacturing and Launch Readiness:** The Company's GMP facility in San Diego is positioned to support an initial commercial launch, if Deramiocel is approved. A second-floor cleanroom expansion is underway, with validation targeted for the first half of 2027. Launch preparations span distribution, patient support, market access, reimbursement, medical affairs and physician education.
- **Pipeline:** Capricor has initiated regulatory engagement in Europe and Japan for Deramiocel. Expansion into younger DMD patients and Becker muscular dystrophy remains an area of focus, with next steps to be informed by the U.S. regulatory outcome for Deramiocel. Programs not directly related to Deramiocel, including the Company's exosome-based platform, have been slowed to prioritize Deramiocel pending further regulatory clarity.
- **NS Pharma Dispute:** Capricor continues to pursue its contractual dispute with Nippon Shinyaku and its U.S. subsidiary, NS Pharma, regarding the Deramiocel distribution agreement. As previously disclosed, Capricor withdrew its motion for a preliminary injunction, without prejudice, to resolve the dispute in arbitration following the FDA's decision. The Company expects the arbitration hearing to commence in mid-2027.

Third Quarter 2026 Financial Results

- **Cash Position:** Cash, cash equivalents, restricted cash and marketable securities totaled approximately $198.5 million as of September 30, 2026, compared to approximately $318.1 million as of December 31, 2025. From January 1, 2026, through November 10, 2026, the Company has not sold any shares under its at-the-market (ATM) program.
- **Revenue:** There was no revenue recognized for the first three quarters of 2026 or 2025.
- **Costs and Expenses:** Total operating expenses for the third quarter of 2026 were approximately $44.7 million, compared to approximately $26.3 million for the third quarter of 2025. Total operating expenses for the first three quarters of 2026 were approximately $124.4 million, compared to approximately $79.0 million for the first three quarters of 2025. The increase was primarily driven by pre-commercial activities and manufacturing scale-up. Additionally, the Company implemented a workforce reduction in the third quarter affecting approximately 10% of its employees to reduce operating expenses and align resources with its priorities.
- **Net Loss:** The Company reported a net loss of approximately $42.7 million, or $0.73 per share, for the third quarter of 2026, compared to a net loss of approximately $24.6 million, or $0.54 per share, for the third quarter of 2025. The net loss for the first three quarters of 2026 was approximately $117.3 million, or $2.03 per share, compared to a net loss of approximately $74.9 million, or $1.64 per share, for the first three quarters of 2025.
- **Financial Outlook:** The Company believes that, based on its current operating plan and financial resources, its available cash, cash equivalents and marketable securities are sufficient to fund its operating capital requirements for at least the next twelve months. The Company expects to provide additional guidance on its longer-term financial outlook following greater regulatory clarity, which will inform future strategic and capital allocation decisions. This outlook excludes any potential revenue from product sales, the potential monetization of a Priority Review Voucher, if received, and other non-operating sources of capital.

Upcoming Investor Events

Information on upcoming investor events will be available on the Investors section of Capricor's website.

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: 13662. 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, primarily males. Over time, deterioration of the heart muscle leads to cardiomyopathy and heart failure, 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 immunomodulatory and anti-fibrotic actions in the preservation of skeletal and cardiac 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. For the treatment of DMD, Deramiocel holds Orphan Drug, RMAT and Rare Pediatric Disease designations in the U.S., and Orphan Drug and ATMP designations in Europe. The Rare Pediatric Disease designation 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 the treatment of Duchenne muscular dystrophy, evaluated in clinical studies for its potential to preserve skeletal and cardiac 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; results of securities litigation; 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 June 30, 2026, as filed with the Securities and Exchange Commission on August 14, 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 Capricor's StealthX™ exosome therapeutics are investigational 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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
REVENUE				
Revenue	$ —	$ —	$ —	$ —
TOTAL REVENUE	—	—	—	—
OPERATING EXPENSES				
Research and development	29,558,388	20,359,098	85,801,592	61,321,924
General and administrative	15,124,348	5,924,942	38,599,617	17,662,598
TOTAL OPERATING EXPENSES	44,682,736	26,284,040	124,401,209	78,984,522
LOSS FROM OPERATIONS	(44,682,736)	(26,284,040)	(124,401,209)	(78,984,522)
OTHER INCOME (EXPENSE)				
Other income	749	(106)	(69,978)	(123,303)
Investment income	2,025,886	1,713,499	7,141,687	4,236,393
TOTAL OTHER INCOME (EXPENSE)	2,026,635	1,713,393	7,071,709	4,113,090
LOSS BEFORE INCOME TAXES	(42,656,101)	(24,570,647)	(117,329,500)	(74,871,432)
(Provision for) benefit from income taxes	—	—	(1,600)	(1,600)
NET LOSS	$ (42,656,101)	$ (24,570,647)	$ (117,331,100)	$ (74,873,032)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	9,648	(543,452)	(437,047)	(182,833)
COMPREHENSIVE LOSS	$ (42,646,453)	$ (25,114,099)	$ (117,768,147)	$ (75,055,865)
Net loss per share, basic and diluted	$ (0.73)	$ (0.54)	$ (2.03)	$ (1.64)
Weighted average number of shares, basic and diluted	58,128,772	45,716,151	57,832,339	45,687,630

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	September 30, 2026 (unaudited)	December 31, 2025
Cash, cash equivalents, restricted cash and marketable securities	$ 198,538,594	$ 318,128,915
Total assets	$ 330,370,421	$ 355,949,294
Total liabilities	$ 120,605,812	$ 50,157,149
Total stockholders' equity - 58,138,989 and 57,370,909 common shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	209,764,609	305,792,145
Total liabilities and stockholders' equity	$ 330,370,421	$ 355,949,294