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, 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 2.02 Results of Operations and Financial Condition.

On November 10, 2025, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended September 30, 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 Third Quarter 2025 Financial Results and Provides Corporate Update", dated November 10, 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: November 10, 2025

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

Exhibit 99.1

Capricor Therapeutics Reports Third Quarter 2025 Financial Results and Provides Corporate Update

- *Topline results from pivotal HOPE-3 Phase 3 study (n=105) of Deramiocel for the treatment of Duchenne muscular dystrophy expected in the coming weeks (Q4 2025)*
- *Pending the results of the topline data from the HOPE-3 study, the Company expects to resubmit its BLA, leveraging the data in support of its application for approval*
- *Commercial launch preparations underway to support potential approval and market introduction of Deramiocel in 2026*
- *NIAID-sponsored Phase 1 clinical trial underway with StealthX™ exosome-based vaccine; initial topline data currently expected in the first quarter of 2026, subject to completion by NIAID*
- *Cash balance of approximately $99 million expected to support planned operations into the fourth quarter of 2026*
- *Conference call and webcast today at 4:30 p.m. ET*

SAN DIEGO, Nov. 10, 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 its financial results for the third quarter ended September 30, 2025, and provided a corporate update.

"We are entering one of the most pivotal periods in Capricor's history as we approach the topline readout from our HOPE-3 Phase 3 trial of Deramiocel for the treatment of Duchenne muscular dystrophy," said Linda Marbán, Ph.D., Chief Executive Officer of Capricor. "Deramiocel was developed to address the cardiomyopathy that ultimately claims the lives of nearly all patients with Duchenne, and our mission has never been clearer: to bring forward the first therapy specifically designed to target this life-limiting aspect of the disease. Over the past decade, we have generated compelling and statistically significant data showing durable improvements in both cardiac and skeletal muscle function. With our commercial-ready manufacturing facility in place and our Pre-License Inspection completed, we believe we are well positioned for potential approval and launch. We remain confident in the strength, consistency, and reproducibility of our science and fully focused on advancing Deramiocel toward approval and commercialization, with the broader goal of delivering meaningful and lasting value to patients, families, and shareholders."

Third Quarter 2025 and Recent Highlights

- **Topline results from HOPE-3 Phase 3 clinical trial imminent:** Capricor has completed the 12-month treatment phase of its pivotal HOPE-3 study (n=105), a multi-center, randomized, double-blind, placebo-controlled trial evaluating Deramiocel for the treatment of Duchenne muscular dystrophy (DMD). HOPE-3 is independently powered to measure both skeletal and cardiac function (PUL v2.0 and LVEF by cMRI). Topline results are expected in the coming weeks (Q4 2025).
- **Recent Type A meeting with FDA:** In August 2025, Capricor held a Type A meeting with FDA following receipt of a Complete Response Letter (CRL) for its Biologics License Application (BLA) for Deramiocel. During our Type A meeting in August, the FDA supported the submission of the HOPE-3 results in order to address the issues raised in the CRL. Capricor plans to submit the HOPE-3 results with a formal complete response while maintaining the existing indication for DMD-associated cardiomyopathy. The resubmission is expected to be reviewed under a Type 2 classification with an anticipated review period of up to six months.
- **Commercial manufacturing readiness:** Capricor's GMP facility in San Diego successfully completed its FDA Pre-License Inspection (PLI). All 483 observations were addressed and accepted by FDA, and the facility is now operational and capable of supporting initial commercial launch upon approval, with systems for product quality, scalability, and consistency.
- **Peer-reviewed publication reinforces Deramiocel's mechanism of action:** In October 2025, Capricor published a peer-reviewed paper in *Biomedicines* detailing Deramiocel's anti-fibrotic and immunomodulatory mechanisms through the release of exosomes and soluble factors that suppress fibrotic gene expression. These findings, reproduced across more than 100 manufacturing lots, confirm Deramiocel's biological consistency and potency. A scientific overview video illustrating this mechanism is available on Capricor's website.
- **StealthX™ exosome platform advancing under Project NextGen:** The NIAID-sponsored Phase 1 clinical trial evaluating Capricor's StealthX™ exosome-based vaccine is ongoing, assessing multiple dose levels with initial data

expected in the first quarter of 2026, subject to completion by NIAID. Positive results could further support StealthX™ as a versatile delivery platform for vaccinology and future therapeutic applications.

Third Quarter 2025 Financial Results

Cash position: Cash, cash equivalents and marketable securities totaled approximately $98.6 million as of September 30, 2025, compared to approximately $151.5 million as of December 31, 2024. As of November 10, 2025, no shares have been sold under the Company's ATM Program.

Revenues: Revenues for the third quarter of 2025 were $0, compared to approximately $2.3 million for the third quarter of 2024. Additionally, revenues for the first nine months of 2025 were $0 compared to approximately $11.1 million for the first nine months of 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 third quarter of 2025 were approximately $26.3 million, compared to approximately $15.3 million for the third quarter of 2024. Total operating expenses for the first nine months of 2025 were approximately $79.0 million, compared to approximately $46.0 million for the first nine months of 2024.

Net loss: The Company reported a net loss of approximately $24.6 million, or $0.54 per share, for the third quarter of 2025, compared to a net loss of approximately $12.6 million, or $0.38 per share, for the third quarter of 2024. The Company reported a net loss of approximately $74.9 million, or $1.64 per share, for the first nine months of 2025, compared to a net loss of approximately $33.4 million, or $1.04 per share, for the first nine months of 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 into the fourth quarter of 2026. 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:

- Piper Sandler 37th Annual Healthcare Conference, December 2-4, 2025 New York, NY
- Oppenheimer Movers in Rare Disease Summit, December 11, 2025, New York, NY

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: 13683. 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 105 eligible subjects have been enrolled 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 June 30, 2025, as filed with the Securities and Exchange Commission on August 11, 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
REVENUE				
Revenue	$ —	$ 2,261,642	$ —	$ 11,139,956
TOTAL REVENUE	—	2,261,642	—	11,139,956
OPERATING EXPENSES				
Research and development	20,359,098	11,807,867	61,321,924	35,413,649
General and administrative	5,924,942	3,463,655	17,664,198	10,593,308
TOTAL OPERATING EXPENSES	26,284,040	15,271,522	78,986,122	46,006,957
LOSS FROM OPERATIONS	(26,284,040)	(13,009,880)	(78,986,122)	(34,867,001)
OTHER INCOME (EXPENSE)				
Other income	6,740	—	34,216	—
Investment income	1,713,499	453,152	4,236,393	1,516,418
Loss on disposal of fixed assets	(6,846)	—	(157,519)	—
TOTAL OTHER INCOME (EXPENSE)	1,713,393	453,152	4,113,090	1,516,418
NET LOSS	(24,570,647)	(12,556,728)	(74,873,032)	(33,350,583)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized loss on marketable securities	(543,452)	(58,766)	(182,833)	(139,592)
COMPREHENSIVE LOSS	$ (25,114,099)	$ (12,615,494)	$ (75,055,865)	$ (33,490,175)
Net loss per share, basic and diluted	$ (0.54)	$ (0.38)	$ (1.64)	$ (1.04)
Weighted average number of shares, basic and diluted	45,716,151	33,090,063	45,687,630	32,099,181

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	September 30, 2025 (unaudited)	December 31, 2024
Cash, cash equivalents and marketable securities	$ 98,565,971	$ 151,515,877
Total assets	$ 126,438,207	$ 170,481,086
Total liabilities	$ 42,570,952	$ 25,018,750
Total stockholders' equity - 45,716,975 and 45,582,288 common shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	83,867,255	145,462,336
Total liabilities and stockholders' equity	$ 126,438,207	$ 170,481,086