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 13, 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 May 13, 2025, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended March 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 First Quarter 2025 Financial Results and Provides Corporate Update" dated May 13, 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: May 13, 2025

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

Exhibit 99.1

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

- *Biologics License Application (BLA) for deramiocel in the treatment of Duchenne muscular dystrophy (DMD) remains under priority review by the U.S. FDA, with a target Prescription Drug User Fee Act (PDUFA) date slated for August 31, 2025*
- *Recently completed mid-cycle review meeting with FDA with no significant deficiencies identified; late cycle meeting scheduled for June*
- *FDA has indicated intent to convene advisory committee meeting*
- *Appointed Dr. Michael Binks as Chief Medical Officer, bringing deep experience in neuromuscular and rare diseases*
- *The National Institute of Allergy and Infectious Diseases (NIAID) plans to initiate phase 1 clinical trial of Capricor's StealthX™ exosome vaccine in the third quarter of 2025, subject to NIAID's regulatory approval*
- *Cash balance of approximately $145 million expected to support planned operations into 2027*
- *Capricor will host conference call and webcast today at 4:30 p.m. ET*

SAN DIEGO, May 13, 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 first quarter ended March 31, 2025, and provided a corporate update.

"We continue to make strong progress in 2025 as we advance toward our goal of delivering the first approved therapy for Duchenne cardiomyopathy—a condition with no approved treatments," said Linda Marbán, Ph.D., Capricor's Chief Executive Officer. "We continue to have active dialogue with the FDA as they review our BLA and we remain on track with our PDUFA target action date of August 31, 2025. Preparations are progressing for our upcoming FDA advisory committee meeting, pre-approval inspection, and potential commercial launch. In parallel, our StealthX™ vaccine program is on track for a Phase 1 clinical trial initiation in the third quarter of 2025, led by NIAID under Project NextGen, pending NIAID's regulatory clearance. Financially, we ended the first quarter with a strong cash position of approximately $145 million, enabling us to continue executing strategically as we approach key value-driving milestones."

First Quarter 2025 and Recent Developments

- ***In March 2025, the FDA accepted for review Capricor's BLA seeking full approval of deramiocel for the treatment of individuals with DMD-cardiomyopathy.*** The application was granted priority review, with a PDUFA action date set for August 31, 2025. In May 2025, we completed a mid-cycle review meeting with the FDA, during which no significant deficiencies were identified by the review committee. The FDA also confirmed its intent to convene an advisory committee meeting. The BLA is supported by data from Capricor's randomized double-blind and placebo-controlled Phase 2 HOPE-2 trial and the HOPE-2 open-label extension (OLE) trial, compared to an external comparator using propensity matched patient-level data from an FDA-funded and published dataset of DMD-cardiomyopathy and associated biomarkers of disease progression. Results from these studies demonstrated statistically significant and clinically meaningful improvements in cardiac function for up to three years post-treatment, along with a consistent safety profile. Notably, FDA has acknowledged that the ongoing HOPE-3 Phase 3 trial, which is assessing skeletal muscle function, is not a part of Capricor's BLA for full approval of deramiocel.

- ***Expansion of internal manufacturing capacity:*** In the first quarter of 2025, Capricor amended its current lease to secure additional GMP manufacturing space at its San Diego, California headquarters. This expansion to support increased commercial manufacturing capacity and throughput.

- ***Advancement of StealthX™ vaccine platform:*** Capricor announced that the National Institute of Allergy and Infectious Diseases (NIAID) plans to initiate a Phase 1 clinical study of its StealthX™ exosome-based vaccine in the third quarter of 2025, pending NIAID's regulatory approval. The vaccine was selected to participate in Project NextGen, a U.S. Department of Health and Human Services initiative aimed at advancing innovative vaccines to address future pandemics.

- ***Appointment of Michael Binks, M.D., as Chief Medical Officer:*** Dr. Binks brings more than 25 years of experience in global clinical development and translational research across the pharmaceutical and biotechnology sectors. He previously held senior leadership roles at Pfizer and GlaxoSmithKline, with expertise spanning immunology, neurology, cardiology, nephrology, and hematology.

First Quarter 2025 Financial Results

Cash position: Cash, cash equivalents and marketable securities totaled approximately $144.8 million as of March 31, 2025 compared to approximately $151.5 million as of December 31, 2024. In January 2025, the Company received $10.0 million from the second development milestone payment under our U.S. Commercialization and Distribution Agreement with Nippon Shinyaku (the "U.S. Distribution Agreement").

Revenues: Revenues for the first quarter of 2025 were $0 compared to $4.9 million for the first quarter of 2024. Capricor's primary source of revenue was from the ratable recognition of the $40.0 million (upfront and first development milestone payments) and the recognition of the $10.0 million second development milestone payment in accordance with our U.S. Distribution Agreement, both of which were fully recognized as of December 31, 2024.

Costs and Expenses: Total operating expenses for the first quarter of 2025 were approximately $25.0 million compared to $15.2 million for the first quarter of 2024.

Net loss: The Company reported a net loss of approximately $24.4 million, or $0.53 per share, for the first quarter of 2025, compared to a net loss of $9.8 million, or $0.31 per share, for the first quarter of 2024.

Financial Outlook: The Company believes that based on the current operating plan and financial resources, Capricor believes its available cash, cash equivalents and marketable securities will be sufficient to cover anticipated expenses and capital requirements into 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 events:

- H.C. Wainwright 3rd Annual BioConnect Investor Conference, May 20, 2025, New York, NY
- BIO International Convention, June 16-19, 2025, Boston, MA
- Parent Project Muscular Dystrophy (PPMD) 2025 Annual Conference, June 19-21, 2025, Las Vegas, NV

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: 73741. 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

DMD is a devastating genetic disorder characterized by progressive weakness and chronic inflammation of the skeletal, heart and respiratory muscles with mortality at a median age of approximately 30 years. It is estimated that DMD occurs in approximately one in every 3,500 male births and that the patient population is estimated to be approximately 15,000-20,000 in the United States. DMD pathophysiology is driven by the impaired production of functional dystrophin, which normally functions as a structural protein in muscle. The reduction of functional dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. In DMD patients, heart muscle cells progressively

die and are replaced with scar tissue. This cardiomyopathy eventually leads to heart failure which is currently the leading cause of death among those with DMD. Treatment options are limited and there is no cure.

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 preservation of cardiac and skeletal muscle function in dystrophiopathies 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 a 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 for the treatment of DMD has received Orphan Drug Designation from the FDA and European Medicines Agency (EMA). The regulatory pathway for deramiocel is supported by RMAT (Regenerative Medicine Advanced Therapy Designation) in the U.S. and the Advanced Therapy Medicinal Product (ATMP) Designation in the European region. In addition, if Capricor were to receive FDA marketing approval for deramiocel regarding the treatment of DMD, Capricor would be eligible to receive a Priority Review Voucher (PRV) based on its previous receipt of a rare pediatric disease designation.

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. Extensive preclinical and clinical studies have shown deramiocel to exert potent immunomodulatory and anti-fibrotic actions in preservation of cardiac and skeletal muscle function in dystrophiopathies such as DMD. Deramiocel is currently in late-stage development for the treatment of Duchenne muscular dystrophy. Capricor is also harnessing the power of its exosome technology, using its proprietary StealthX™ platform in preclinical development focused on the areas of vaccinology, targeted delivery of oligonucleotides, proteins and small molecule therapeutics to potentially treat and prevent a diverse array of diseases. At Capricor, we stand 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 Twitter.

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 discovery efforts and clinical trials; the pace of enrollment of clinical trials; plans regarding regulatory filings, future research and clinical trials; regulatory developments involving products, including the ability to obtain regulatory approvals or otherwise bring products to market; manufacturing capabilities; dates for regulatory meetings; statements about our financial outlook; 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; plans regarding current and future collaborative activities and the ownership of commercial rights; potential future agreements; scope, duration, validity and enforceability of intellectual property rights; future revenue streams and projections; expectations with respect to the expected use of proceeds from the recently completed offerings and the anticipated effects of the offerings; 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. 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 is an Investigational New Drug (IND) and is not yet approved for any indications. None of Capricor's exosome-based candidates have been approved for clinical investigation.

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

	Three Months Ended March 31,	
	2025	**2024**
REVENUE		
Revenue	$ —	$ 4,906,877
TOTAL REVENUE	—	4,906,877
OPERATING EXPENSES		
Research and development	18,915,572	11,101,013
General and administrative	6,067,376	4,071,766
TOTAL OPERATING EXPENSES	24,982,948	15,172,779
LOSS FROM OPERATIONS	(24,982,948)	(10,265,902)
OTHER INCOME (EXPENSE)		
Other income	12,485	—
Investment income	729,542	471,829
Loss on disposal of fixed assets	(150,673)	—
TOTAL OTHER INCOME (EXPENSE)	591,354	471,829
NET LOSS	(24,391,594)	(9,794,073)
OTHER COMPREHENSIVE INCOME		
Net unrealized gain on marketable securities	784,972	71,888
COMPREHENSIVE LOSS	$ (23,606,622)	$ (9,722,185)
Net loss per share, basic and diluted	$ (0.53)	$ (0.31)
Weighted average number of shares, basic and diluted	45,636,633	31,354,629

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	March 31, 2025 (unaudited)	**December 31, 2024**
Cash, cash equivalents and marketable securities	$ 144,777,396	$ 151,515,877
Total assets	$ 153,765,973	$ 170,481,086
Total liabilities	$ 26,120,506	$ 25,018,750
Total stockholders' equity - 45,676,887 and 45,582,288 common shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	127,645,467	145,462,336
Total liabilities and stockholders' equity	$ 153,765,973	$ 170,481,086