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 19, 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 March 19, 2025, 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, 2024. 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 2024 Financial Results and Provides Corporate Update", dated March 19, 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: March 19, 2025

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

Exhibit 99.1

Capricor Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Corporate Update

- *Announced the U.S. FDA has accepted our Biologics License Application (BLA) seeking full approval of deramiocel for the treatment of Duchenne muscular dystrophy (DMD) cardiomyopathy*
- *BLA granted priority review with a Prescription Drug User Fee Act (PDUFA) target action date set for August 31, 2025*
- *Reported positive data from HOPE-2 open label extension (OLE) trial at 2025 MDA Conference showing preservation of skeletal muscle function over 3 years resulting in 52% slowing of disease*
- *Received $10 million milestone payment from Nippon Shinyaku; cash balance of approximately $152 million at year-end 2024 expected to support current planned operations into 2027*
- *Capricor to host conference call and webcast today at 4:30 p.m. ET*

SAN DIEGO, March 19, 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 fourth quarter and full year ended December 31, 2024 and provided a corporate update.

“2024 was a transformational year for Capricor and the patients we serve as we move closer to our goal of bringing the first cellular therapy to market for the treatment of Duchenne-cardiomyopathy, a condition for which there are no approved therapies" said Linda Marbán, Ph.D., Chief Executive Officer of Capricor. “We continue to work diligently towards our August 31, 2025 action date for our deramiocel Biologics License Application, directly engaging with the FDA, preparing for pre-approval licensure inspection and preparing for potential commercial launch with our partner Nippon Shinyaku Co. (U.S. subsidiary: NS Pharma Inc). Our BLA is the culmination of a body of work that has been focused on bringing this transformational therapy to those patients in need with the potential to alter the trajectory of this degenerative disease. In addition to our operational achievements, we ended the year with over $150 million on our balance sheet allowing us to invest diligently in manufacturing expansion and commercial endeavors as we work to bring deramiocel to the Duchenne community in the United States and abroad.”

Fourth Quarter 2024 and Recent Developments

- ***In March 2025, the FDA accepted Capricor’s BLA seeking full approval of deramiocel for the treatment of individuals with Duchenne muscular dystrophy cardiomyopathy.*** Our BLA has been granted Priority Review by the FDA, with a Prescription Drug User Fee Act (PDUFA) action date set for August 31, 2025. Deramiocel is a cellular therapy that 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 DMD. CDCs act by secreting exosomes, which reduce fibrosis in muscle resulting in a reduction in myocardial scarring and cardiac inflammation by targeting macrophages to adopt a healing, rather than a pro-inflammatory phenotype. The BLA submission for deramiocel included safety and efficacy data from Capricor’s Phase 2 HOPE-2 placebo-controlled trial and the HOPE-2 open label extension (OLE) trial compared to natural history data from an FDA-funded and published dataset on the implications of DMD cardiomyopathy and potential biomarkers of disease progression. The results from these clinical studies demonstrated statistically significant and clinically relevant improvements in cardiac function up to three-years after treatment as well as a consistent safety profile. Capricor’s ongoing HOPE-3 Phase 3 study which is assessing skeletal muscle function has not been requested for review by the FDA for this application.

- ***Expanded internal manufacturing capacity for deramiocel production:*** In February 2025, Capricor entered into an amendment to its current lease for additional GMP space in its headquarters located in San Diego, California to support additional commercial manufacturing capacity and throughput.

- ***The European Medicines Agency (EMA) granted deramiocel both Orphan Drug and Advanced Therapy Medicinal Product (ATMP) designations for the treatment of DMD.*** The Orphan Drug designation provides Capricor with several benefits that support the development of deramiocel in Europe, including market exclusivity for 10 years if approval is granted and substantially reduced regulatory fees. The ATMP designation provides substantial regulatory

support to assist in the development of cell-based therapies. The additional support can potentially reduce time to market, streamline development, and open up access to critical resources. The ongoing HOPE-3 study may also support ex-U.S. marketing authorizations.

- ***Capricor presented new positive data at the 2025 Muscular Dystrophy Association (MDA) Annual Clinical and Scientific Conference.*** The late-breaking poster showed that patients treated with deramiocel over three years experienced an average decline in Performance of the Upper Limb (PUL v2.0) total score of 3.46 points, compared to a 7.19-point decline in the external comparator group (p=0.019). This equates to a 52 percent slowing of disease progression, reinforcing deramiocel's potential long-term therapeutic durability.

- ***Capricor presented preclinical data at the 2024 American Association of Extracellular Vesicles (AAEV) Annual Meeting.*** The data highlighted a potential exosome-based approach for delivering phosphorodiamidate morpholino oligomers (PMOs) to muscle for the treatment of DMD.

- ***The Company's StealthX™ exosome-based vaccine for the prevention of SARS-CoV-2 was selected to be part of Project NextGen.*** This initiative led by the U.S. Department of Health and Human Services is to advance a pipeline of new, innovative vaccines for future pandemics. Currently, manufacturing is underway for our StealthX™ vaccine and the National Institute of Allergy and Infectious Diseases (NIAID) is planning for regulatory approval in the second quarter of 2025 with the clinical study initiated soon thereafter.

Fourth Quarter and Full Year 2024 Financial Results

Cash position: Cash, cash equivalents and marketable securities totaled approximately $151.5 million as of December 31, 2024 compared to approximately $39.5 million as of December 31, 2023. In October 2024, the Company completed a public offering for net proceeds of approximately $80.8 million. Additionally, in January 2025, the Company received $10.0 million from the second development milestone payment under our U.S. Distribution and Commercialization Agreement with Nippon Shinyaku.

Revenues: Revenues for the fourth quarter of 2024 were approximately $11.1 million compared to $12.1 million for the fourth quarter of 2023. Additionally, revenues for the year ended December 31, 2024 and 2023 were approximately $22.3 million and $25.2 million, respectively. 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 its U.S. Commercialization and Distribution Agreement with Nippon Shinyaku.

Costs and Expenses: Total operating expenses for the fourth quarter of 2024 were approximately $18.8 million compared to $13.4 million for the fourth quarter of 2023. Total operating expenses for the year ended December 31, 2024 and 2023 were approximately $64.8 million and $49.3 million, respectively.

Net loss: The Company reported a net loss of approximately $7.1 million, or $0.16 per share, for the fourth quarter of 2024, compared to a net loss of $0.8 million, or $0.02 per share, for the fourth quarter of 2023. Capricor reported a net loss of approximately $40.5 million, or $1.15 per share, and $22.3 million, or $0.83 per share, for the year ended December 31, 2024 and 2023, respectively.

Financial Outlook: The Company believes that based on the current operating plan and financial resources, our 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 present at the following upcoming events:

- Piper Sandler & Co. Cardio Day, April 1-2, 2025, Virtual
- JonesTrading Technology and Innovation Conference, April 8-9, 2025, Las Vegas

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: 98172. 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 the subject of over 200 peer-reviewed scientific publications and have been administered to over 250 human subjects across several clinical trials.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (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 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, 2023, as filed with the Securities and Exchange Commission on March 11, 2024, and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, as filed with the Securities and Exchange Commission on November 14, 2024. 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 and is not 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 December 31,		Year Ended December 31,	
	2024	2023	2024	2023
REVENUE				
Revenue	$ 11,130,509	$ 12,088,089	$ 22,270,465	$ 25,178,066
TOTAL REVENUE	11,130,509	12,088,089	22,270,465	25,178,066
OPERATING EXPENSES				
Research and development	14,554,936	9,940,167	49,968,585	36,448,039
General and administrative	4,273,414	3,429,214	14,866,722	12,807,886
TOTAL OPERATING EXPENSES	18,828,350	13,369,381	64,835,307	49,255,925
LOSS FROM OPERATIONS	(7,697,841)	(1,281,292)	(42,564,842)	(24,077,859)
OTHER INCOME (EXPENSE)				
Other income	7,471	67,657	7,471	67,657
Investment income	686,572	452,199	2,202,990	1,728,701
Loss on disposal of fixed assets	(112,805)	(653)	(112,805)	(6,041)
TOTAL OTHER INCOME (EXPENSE)	581,238	519,203	2,097,656	1,790,317
NET LOSS	(7,116,603)	(762,089)	(40,467,186)	(22,287,542)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain on marketable securities	930,734	122,605	791,142	130,569
COMPREHENSIVE LOSS	$ (6,185,869)	$ (639,484)	$ (39,676,044)	$ (22,156,973)
Net loss per share, basic and diluted	$ (0.16)	$ (0.02)	$ (1.15)	$ (0.83)
Weighted average number of shares, basic and diluted	44,509,154	30,664,100	35,218,628	26,778,360

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	December 31, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 151,515,877	$ 39,487,703
Total assets	$ 170,481,086	$ 58,734,327
Total liabilities	$ 25,018,750	$ 36,132,860
Total stockholders' equity - 45,582,288 and 31,148,320 common shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	145,462,336	22,601,467
Total liabilities and stockholders' equity	$ 170,481,086	$ 58,734,327