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 13, 2024

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 13, 2024, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended September 30, 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 Third Quarter 2024 Financial Results and Provides Corporate Update", dated November 13, 2024.
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 13, 2024

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

Exhibit 99.1

Capricor Therapeutics Reports Third Quarter 2024 Financial Results and Provides Corporate Update

- *Announced intent to file a biologics license application (BLA) for deramiocel to treat all patients with DMD-cardiomyopathy*
- *Rolling BLA submission initiated in October 2024 with full submission expected by year-end 2024*
- *Company anticipates potential PDUFA date in second half of 2025*
- *Announced signing of binding term sheet with Nippon Shinyaku for European expansion and commercialization of deramiocel; potential milestones from combined agreements would total approximately $1.5 billion payable to Capricor*
- *Reported positive long-term data from HOPE-2 OLE trial at 2024 World Muscle Society Congress*
- *StealthX™ exosome platform expanded to include PMO loading and targeting for the treatment of DMD presented at AAEV Annual Meeting*
- *Completed public offering of common stock for gross proceeds of approximately $86 million; cash runway is expected to support current planned operations into 2027*
- *Capricor to host conference call and webcast today at 4:30 p.m. ET*

SAN DIEGO, November 13, 2024 (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, 2024 and provided a corporate update.

"This has been a transformational quarter for Capricor as we move towards potential commercialization of deramiocel for the treatment of DMD. We have commenced the submission of our BLA which we expect to be complete by year end and we have significantly strengthened our balance sheet in order to scale up manufacturing as we anticipate a strong launch, pending FDA approval," said Linda Marbán, Ph.D., Capricor's chief executive officer. "In addition, we continue to advance our proprietary StealthX™ platform technology as part of our long-term strategy to leverage exosomes as vehicles for targeted delivery of payloads for therapeutic development. We continue to explore partnership opportunities and other non-dilutive sources of funding to advance this program."

Recent Updates and Upcoming Milestones

Deramiocel DMD Program: Deramiocel is an investigational cell therapy in late-stage development for the treatment of DMD. Deramiocel for the treatment of DMD has received Orphan Drug Designation and Regenerative Medicine Advanced Therapy Designation (RMAT) from the FDA in the U.S. In addition, if deramiocel is approved, Capricor would be eligible to receive a Priority Review Voucher (PRV) based on our previous receipt of a rare pediatric disease designation.

- Based on FDA feedback and following Capricor's recent pre-BLA meeting in August, Capricor initiated the rolling BLA submission in October of 2024 seeking full approval of deramiocel for the treatment of DMD-cardiomyopathy with full submission expected to be complete by year end 2024.
    - The BLA submission will be based on existing cardiac data from the Phase 2 HOPE-2 and HOPE-2 open label extension (OLE) trials compared to patient-level natural history data.
- To support potential label expansion to treat DMD, Capricor plans to provide clinical data on skeletal muscle myopathy by combining Cohorts A and B of the Phase 3 HOPE-3 clinical trial to serve as a post-approval study and does not intend to unblind Cohort A at this time, which was originally planned to occur in the fourth quarter of 2024.
    - Furthermore, if required, the HOPE 3 study may also potentially support ex-U.S. marketing authorizations. Currently, Capricor has initiated regulatory activities in Europe and Japan and will be working with the various regional health authorities to develop the most efficient path forward for regulatory approval of deramiocel in these regions.
- Capricor is actively working towards expansion of our commercial manufacturing capacity and throughput.
    - In addition, Capricor is exploring expansion opportunities for its GMP production for additional capacity that may be necessary to meet product demand in the U.S. and other regions.

- Capricor signed a binding term sheet with Nippon Shinyaku for European expansion and commercialization of deramiocel for the treatment of DMD. The potential transaction covered by the term sheet would be similar to the existing Commercialization and Distribution Agreements with Nippon Shinyaku in the U.S. and Japan with an opportunity for increased global product reach.
    - Subject to finalization of the Definitive Agreement, Capricor will receive an upfront payment of $20 million along with potential additional development and sales-based milestone payments to Capricor of up to $715 million and a double-digit share of product revenue.
- In September 2024, Nippon Shinyaku purchased approximately $15 million of Capricor common stock at a 20% premium to the 60-day volume weighted average price of Capricor's common stock.
- Capricor presented positive 3-year safety and efficacy results from its ongoing HOPE-2 OLE in a late-breaking poster presentation at the 29th Annual Congress of the World Muscle Society.
    - The 3-year data from HOPE-2 OLE demonstrated improvements in multiple measures of cardiac function, including left ventricular ejection fraction (LVEF%), as well as indexed volumes, which are considered highly relevant in terms of predicting long-term cardiac outcomes.
    - In addition to the cardiac data, patients demonstrated a statistically and clinically relevant benefit (+3.7 points, $p< 0.001$) in the PUL v2.0 total score when compared to an external comparator dataset of similar DMD patients.

StealthX™ Exosome Platform: Exosomes are membrane-bound extracellular vesicles and contain lipids, proteins, and nucleic acids. They act as messengers to regulate the functions of neighboring or distant cells. Capricor is developing our engineered exosome technology using our proprietary StealthX™ platform focused on the areas of targeted therapeutics and vaccines to potentially treat and prevent a diverse array of diseases.

- The Company's proprietary StealthX™ exosome-based vaccine (StealthX™ vaccine) for the prevention of SARS-CoV-2 was selected to be part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines.
    - Under the terms of the initiative, Capricor will supply its vaccine candidate for clinical use and NIAID's Division of Microbiology and Infectious Diseases will conduct the trial.
    - Currently, manufacturing is underway for our StealthX™ vaccine with current plans to deliver it to NIAID in the first quarter of 2025.
    - NIAID plans to initiate the trial in the first quarter of 2025, and Capricor expects that it will have preliminary data available in the second quarter of 2025, subject to FDA approval of the NIAID's IND.
    - If NIAID finds that our StealthX™ vaccine meets its criteria for safety and efficacy, they may consider funding our program for a Phase 2 study.
- Capricor presented preclinical data at the 2024 American Association of Extracellular Vesicles (AAEV) Annual Meeting highlighting a potential exosome-based approach by delivering phosphorodiamidate morpholino oligomers (PMOs) for the treatment of DMD.

Third Quarter 2024 Financial Results

Cash position: Cash, cash equivalents and marketable securities totaled approximately $85.0 million as of September 30, 2024 compared to $39.5 million as of December 31, 2023. In the third quarter of 2024, Capricor raised approximately $52.2 million in net proceeds through issuances of common stock at an average price of approximately $9.84 per share under its at-the-market (ATM) Program. Effective October 1, 2024, the ATM Program was closed and terminated. Additionally, on October 18, 2024, the Company completed a public offering of 5,073,800 shares of common stock and received gross proceeds of approximately $86.3 million before deducting underwriting discounts, commissions and offering expenses of approximately $5.5 million, for net proceeds of approximately $80.8 million.

Revenues: Revenues for the third quarter of 2024 were approximately $2.3 million compared to $6.2 million for the third quarter of 2023. Additionally, revenues for the nine months ended September 30, 2024 and 2023 were approximately $11.1 million and $13.1 million, respectively. Capricor's primary source of revenue was from the ratable recognition of the $40.0

million (upfront and milestone payments) in accordance with its U.S. Commercialization and Distribution Agreement with Nippon Shinyaku.

Expenses: Total operating expenses for the third quarter of 2024 were approximately $15.3 million compared to $13.1 million for the third quarter of 2023. Total operating expenses for the nine months ended September 30, 2024 and 2023 were approximately $46.0 million and $35.9 million, respectively.

Net loss: The Company reported a net loss of approximately $12.6 million, or $0.38 per share, for the third quarter of 2024, compared to a net loss of $6.4 million, or $0.25 per share, for the third quarter of 2024. Capricor reported a net loss of approximately $33.4 million, or $1.04 per share, and $21.5 million, or $0.85 per share, for the nine months ended September 30, 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:

- B. Riley Securities NextGen Tissue Delivery Modalities Summit, November 14, 2024, Virtual
- Piper Sandler 36th Annual Healthcare Conference, December 3-5, 2024, New York, NY
- Oppenheimer Movers in Rare Disease Summit, December 12, 2024, New York, NY

Conference Call and Webcast

To participate in the conference call, please dial 1-800-717-1738 (Domestic/Toll-Free) or 1-646-307-1865 (International) and reference the conference ID: 68076. 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 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 (CAP-1002), an allogeneic cardiac-derived cell therapy. Extensive preclinical and clinical studies have shown deramiocel to demonstrate immunomodulatory, antifibrotic, and regenerative actions specifically tailored for dystrophinopathies and heart disease. Deramiocel is currently advancing through Phase 3 clinical 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 June 30, 2024, as filed with the Securities and Exchange Commission on August 8, 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 (CAP-1002) 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
REVENUE				
Revenue	$ 2,261,642	$ 6,185,814	$ 11,139,956	$ 13,089,977
TOTAL REVENUE	2,261,642	6,185,814	11,139,956	13,089,977
OPERATING EXPENSES				
Research and development	11,807,867	10,028,964	35,413,649	26,507,872
General and administrative	3,463,655	3,021,450	10,593,308	9,378,672
TOTAL OPERATING EXPENSES	15,271,522	13,050,414	46,006,957	35,886,544
LOSS FROM OPERATIONS	(13,009,880)	(6,864,600)	(34,867,001)	(22,796,567)
OTHER INCOME (EXPENSE)				
Investment income	453,152	479,380	1,516,418	1,276,502
Loss on disposal of fixed assets	—	(5,388)	—	(5,388)
TOTAL OTHER INCOME (EXPENSE)	453,152	473,992	1,516,418	1,271,114
NET LOSS	(12,556,728)	(6,390,608)	(33,350,583)	(21,525,453)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	(58,766)	(66,485)	(139,592)	7,964
COMPREHENSIVE LOSS	$ (12,615,494)	$ (6,457,093)	$ (33,490,175)	$ (21,517,489)
Net loss per share, basic and diluted	$ (0.38)	$ (0.25)	$ (1.04)	$ (0.85)
Weighted average number of shares, basic and diluted	33,090,063	25,817,676	32,099,181	25,468,880

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	September 30, 2024 (unaudited)	December 31, 2023
Cash, cash equivalents and marketable securities	$ 85,028,624	$ 39,487,703
Total assets	$ 92,951,613	$ 58,734,327
Total liabilities	$ 24,686,654	$ 36,132,860
Total stockholders' equity - 40,332,392 and 31,148,320 common shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	68,264,959	22,601,467
Total liabilities and stockholders' equity	$ 92,951,613	$ 58,734,327