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

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

Exhibit 99.1

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

-Phase 3, HOPE-3 Trial (Cohort A) of CAP-1002 in Duchenne Muscular Dystrophy Fully Enrolled; On Track to Report Top-Line Data in Q4 2024-

-Positive Type-B CMC FDA Meeting held in Q1; Company Aligned with FDA on Demonstration of Non-Clinical Comparability, A Major Milestone on Path to CMC Clearance for BLA-

-Received First Milestone Payment of $10 Million under U.S. Distribution and Commercialization Agreement with Nippon Shinyaku in Q1-

-Recent FDA Feedback Supports Requests for a Pre-BLA Meeting and Subsequent Rolling BLA Submission at Upcoming Type-B Clinical FDA Meeting in May 2024-

-Plan to Report 3-Year Data from HOPE-2 Open-Label Extension (OLE) Trial in Q2 2024-

-Conference Call and Webcast Today at 4:30 p.m. ET-

SAN DIEGO, May 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 first quarter ended March 31, 2024 and provided a corporate update.

"Capricor continues to make tremendous progress across our pipeline marked by significant advancements in our CAP-1002 cell therapy program for the treatment of Duchenne muscular dystrophy (DMD)," said Linda Marbán, Ph.D., Capricor's chief executive officer. "With enrollment completed in Cohort A of our Phase 3 pivotal trial, we further aligned with the U.S. Food and Drug Administration (FDA) on key CMC (chemistry manufacturing and controls) deliverables necessary for the filing of a Biologics License Application (BLA) including the establishment of non-clinical comparability, a major milestone on the path to clearance for a BLA submission. We are appreciative of the FDA's continued guidance under our RMAT designation and we will provide further updates on our plans as they become available. Furthermore, we continue to work diligently with our partner, Nippon Shinyaku (U.S. subsidiary: NS Pharma, Inc.) as we prepare for the potential launch of CAP-1002. Looking ahead, later this quarter, we plan to meet with FDA to continue to discuss options for potential expedited approval pathways as well as announce the 3-year HOPE-2 OLE results."

Dr. Marbán, continued, "We continue our efforts to advance our proprietary StealthX™ exosome platform to leverage exosomes for our vaccine program as well as for therapeutic development. This quarter, we announced a collaboration for our exosome-based multivalent vaccine for the prevention of SARS-CoV-2 with the National Institute of Allergy and Infectious Diseases (NIAID) where they will conduct and fully fund a Phase 1 clinical trial, subject to regulatory approval. We continue to remain focused on advancing this program through partnerships and other non-dilutive sources of funding."

First Quarter 2024 and Recent Operational Highlights

CAP-1002 Duchenne Muscular Dystrophy Program: CAP-1002 is an investigational cell therapy in Phase 3 development for the treatment of DMD. CAP-1002 aims to slow disease progression through immunomodulatory, anti-inflammatory, and anti-fibrotic actions, with the goal of potentially improving skeletal and cardiac muscle function in patients with DMD. HOPE-3, our Phase 3 study, is a multi-center, randomized, double-blind, placebo-controlled clinical trial comprised of two cohorts evaluating the safety and efficacy of CAP-1002 in participants with DMD and impaired skeletal muscle function. The trial is being conducted in the United States. Approximately 102 eligible study subjects will participate in this dual-cohort study (Cohort A and B). CAP-1002 for the treatment of DMD has received Orphan Drug Designation and Regenerative Medicine Advanced Therapy Designation (RMAT). In addition, if Capricor receives FDA marketing approval for CAP-1002 for the treatment of DMD, Capricor would be eligible to receive a Priority Review Voucher (PRV) based on our previous receipt of a rare pediatric disease designation.

- Enrollment has been completed for our HOPE-3 Phase 3 (Cohort A) clinical trial which enrolled 61 subjects randomized to either CAP-1002 or placebo in a 1:1 ratio.
    - Reported a positive outcome from the interim futility analysis for Cohort A which triggered the first milestone payment of $10.0 million received in the first quarter of 2024 under our U.S. Distribution and Commercialization Agreement with Nippon Shinyaku.
- Announced a positive outcome from a Type-B CMC FDA meeting held in the first quarter of 2024. In the meeting, the FDA affirmed alignment on the following topics:
    - Comparability between drug product manufactured at our two different facilities (Los Angeles and San Diego) has been demonstrated using the provided analytical comparability data.
    - This will now allow for the use of CAP-1002 drug product manufactured at our San Diego manufacturing facility upon potential product approval (subject to approval of the facility).
- Granted a Type-B clinical FDA meeting scheduled to be held in May 2024 to continue discussing our pathway to BLA.
    - The FDA advised us to include discussion and a request for a pre-BLA meeting and rolling BLA schedule at this meeting.
    - We also plan to share with FDA our HOPE-2 OLE 3-year safety and efficacy data.
- Announced further specifics under our U.S. Distribution and Commercialization Agreement with Nippon Shinyaku.
    - Capricor will receive a meaningful mid-range double-digit share of product revenue. For clarity, mid-range falls in between 30-50%, which sum will be offset by the amounts paid to us as the transfer price for the purchase of the product.
    - As previously disclosed, there is an additional $90.0 million in potential milestone payments up to the time of approval which are triggered upon certain regulatory-based achievements. Following potential approval, there is an additional $605.0 million in potential milestones payments which may be payable to Capricor based on various sales-based targets being met.
- Announced we are on track to enroll 44 U.S. based patients by the end of second quarter in HOPE-3 (Cohort B) clinical trial, however at this time, we are evaluating various options, with one of such options being the opportunity for an expansion of Cohort B to include European patients.
- Announced the scale-up of manufacturing capacity of CAP-1002 in our new San Diego facility, intended for commercial use, subject to regulatory approval.
    - This facility was designed to be a versatile and cost-effective way to bring CAP-1002 to market efficiently.
    - Currently, our San Diego facility is fully operational, staffed and producing doses for clinical use. Along with BLA readiness activities, we are also actively preparing for commercial runs.
- Presented at H.C. Wainwright 2nd Annual Cell Therapy Conference.
- Presented at the Cantor Fitzgerald's Muscular Dystrophy Symposium.
- Presented at the 2024 Muscular Dystrophy Association (MDA) Clinical & Scientific Conference sharing the previously presented positive 24-month results from our HOPE-2 OLE study.
    - Key results included skeletal muscle function as measured by the Performance of the Upper Limb (PUL v2.0) showed a mean PUL v2.0 decline after 24-months of treatment with CAP-1002 was 2.8 points versus a 7.7 point decline on average observed over 24-months in the placebo patient group. Additionally, CAP-1002 revealed clinically meaningful improvements in ameliorating cardiac function.
- Presented at the Parent Project Muscular Dystrophy (PPMD) Cardiac Workshop III. Capricor was featured in a panel on industry perspectives on cardiac monitoring in DMD clinical trials.

StealthX™ Exosome Platform: Exosomes are membrane-bound extracellular vesicles which are secreted by most cells and contain characteristic lipids, proteins and nucleic acids such as mRNA and microRNAs. They act as messengers to regulate the functions of neighboring or distant cells and have been shown to regulate functions such as cell survival, proliferation, inflammation and tissue regeneration. We are developing our exosome technology, using our proprietary StealthX™ platform 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.

- Announced that our proprietary StealthX™ exosome-based multivalent 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.
    - As part of Project NextGen, NIAID, part of the National Institutes of Health, will conduct and fund a Phase 1 clinical trial with our StealthX™ vaccine.

- Under the terms of the collaboration, Capricor will supply the investigational product and NIAID's Division of Microbiology and Infectious Diseases (DMID) will conduct the trial.
- If NIAID finds that our StealthX™ vaccine meets its criteria for safety and efficacy, they may consider our program for a funded Phase 2.

- Currently, in collaboration with an undisclosed pharmaceutical company, we are also investigating the therapeutic application of our StealthX™ exosome platform.
- Presented data in an oral presentation at the American Society of Gene and Cell Therapy (ASGCT) 27th Annual Meeting The findings highlight a potential exosome-based approach for the treatment of arginase-1 deficiency (ARG1-D), a rare genetic metabolic disease characterized by complete or partial lack of the enzyme arginase in the liver and red blood cells. The data from this preclinical study further characterize our StealthX™ exosome platform.
- Presented data at the International Society of Extracellular Vesicles (ISEV) Annual Meeting 2024. Highlights from the abstract included data showing targeted cargo delivery to mouse lower limbs by exosomes carrying a muscle targeting moiety by intravenous injection.

Anticipated Upcoming Milestones

CAP-1002 DMD Program

- Plan to have a Type-B clinical FDA meeting in May 2024 to discuss requests for a pre-BLA meeting and rolling BLA schedule. Additionally, Capricor plans to share with FDA its HOPE-2 OLE 3-year safety and efficacy data at this meeting.
- Plan to report 3-year HOPE-2 OLE data in the second quarter of 2024.
- Plan to announce further updates with respect to next steps for HOPE-3 (Cohort B), when available.
- Plan to report topline data from HOPE-3 (Cohort A) in the fourth quarter of 2024.
- Continue to explore opportunities for additional partnerships outside of the U.S. and Japan to support the potential commercialization of CAP-1002 in DMD.

StealthX™ Exosome Platform

- Plan to provide updates on our NIAID collaboration for our StealthX™ vaccine as they become available. NIAID plans to initiate the Phase 1 clinical trial in late 2024, subject to regulatory approval.
- Continue to explore opportunities for partnerships and non-dilutive sources of funding to support advancement of our StealthX™ exosome platform technology.

First Quarter 2024 Financial Results

Cash position: Cash, cash equivalents and marketable securities totaled approximately $39.9 million as of March 31, 2024 compared to approximately $39.5 million as of December 31, 2023. In the first quarter of 2024, the Company received $10.0 million from the first milestone payment under our U.S. Distribution and Commercialization Agreement with Nippon Shinyaku and raised approximately $2.3 million in net proceeds through issuances of common stock at an average price of approximately $5.33 per share under its at-the-market offering program.

Revenues: Revenues for the first quarter of 2024 were approximately $4.9 million compared with approximately $3.0 million for the first quarter of 2023. 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: Operating expenses for the first quarter of 2024 were approximately $15.2 million compared with approximately $11.2 million for the first quarter of 2023.

Net loss: The Company reported a net loss of approximately $9.8 million, or $0.31 per share, for the first quarter of 2024, compared to a net loss of approximately $7.8 million, or $0.31 per share, for the first quarter of 2023.

Financial Outlook: We believe that based on the current operating plan and financial resources, Capricor's available cash, cash equivalents and marketable securities will be sufficient to cover anticipated expenses and capital requirements into the first

quarter of 2025. This expectation excludes any additional potential milestone payments under its 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 in the following upcoming events:

- CureDuchenne 2024 FUTURES National Conference, May 23-26, 2024, Orlando
- International Society for Cell & Gene Therapy (ISCT) 2024 Meeting May 29-June 1, 2024, Vancouver
- BIO International Convention 2024, June 3-6, 2024, San Diego
- Parent Project Muscular Dystrophy (PPMD) 30th Annual Conference, June 27-29, 2024, Orlando

Conference Call and Webcast

To participate in the conference call, please dial 1-888-886-7786 (Domestic/Toll-Free) or 1-416-764-8658 (International) and reference the conference ID: 01529679. 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 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, CAP-1002 - an allogeneic cardiac-derived cell therapy. Extensive preclinical and clinical studies have shown CAP-1002 to demonstrate immunomodulatory, antifibrotic, and regenerative actions specifically tailored for dystrophinopathies and heart disease. CAP-1002 is currently advancing through Phase 3 clinical development for the treatment of Duchenne muscular dystrophy (DMD). Capricor is also harnessing the power of our exosome technology, using our 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; 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. 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 a partnership for the exclusive commercialization and distribution of 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. CAP-1002 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.

For more information, please contact:

Capricor Company Contact:
AJ Bergmann, Chief Financial Officer
abergmann@capricor.com
858.727.1755

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

	Three months ended March 31,	
	2024	**2023**
REVENUE		
Revenue	$ 4,906,877	$ 2,986,696
TOTAL REVENUE	4,906,877	2,986,696
OPERATING EXPENSES		
Research and development	11,101,013	7,661,519
General and administrative	4,071,766	3,509,885
TOTAL OPERATING EXPENSES	15,172,779	11,171,404
LOSS FROM OPERATIONS	(10,265,902)	(8,184,708)
OTHER INCOME (EXPENSE)		
Investment income	471,829	416,442
TOTAL OTHER INCOME (EXPENSE)	471,829	416,442
NET LOSS	(9,794,073)	(7,768,266)
OTHER COMPREHENSIVE INCOME (LOSS)		
Net unrealized gain (loss) on marketable securities	71,888	(10,258)
COMPREHENSIVE LOSS	$ (9,722,185)	$ (7,778,524)
Net loss per share, basic and diluted	$ (0.31)	$ (0.31)
Weighted average number of shares, basic and diluted	31,354,629	25,247,354

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	March 31, 2024 (unaudited)	**December 31, 2023**
Cash, cash equivalents and marketable securities	$ 39,917,078	$ 39,487,703
Total assets	$ 49,444,442	$ 58,734,327
Total liabilities	$ 31,009,504	$ 36,132,860
Total stockholders' equity - 31,600,183 and 31,148,320 common shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	18,434,938	22,601,467
Total liabilities and stockholders' equity	$ 49,444,442	$ 58,734,327