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)

August 7, 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 August 7, 2024, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended June 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 Second Quarter 2024 Financial Results and Provides Corporate Update", dated August 7, 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: August 7, 2024

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

Exhibit 99.1

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

-Recently Held Positive Pre-BLA Meeting with FDA with Aim to Accelerate Approval Pathway of Deramiocel for the Treatment of Duchenne Muscular Dystrophy-

-Phase 3, HOPE-3 Trial of Deramiocel in DMD Fully Enrolled; On Track to Report Top-Line Data from Cohort A in Q4 2024-

-Reported Positive 3-Year Skeletal and Cardiac Data from HOPE-2 Open-Label Extension Trial-

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

SAN DIEGO, August 7, 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 second quarter ended June 30, 2024 and provided a corporate update.

"We continue to make significant progress across our pipeline as we move closer to the filing of our Biologics License Application (BLA) of our lead asset, deramiocel (also referred to as CAP-1002), for the treatment of Duchenne muscular dystrophy (DMD)," said Linda Marbán, Ph.D., Capricor's chief executive officer. "We recently conducted a positive pre-BLA meeting with the U.S. Food and Drug Administration (FDA) and we will provide further updates on our plans as they become available. Furthermore, our recently announced 3-year HOPE-2 open label extension (OLE) data gives us confidence in the totality of safety and efficacy data we have seen year over year and the potential benefit that deramiocel can provide to patients with DMD. Lastly, on the corporate front, we remain focused on securing a partnership in Europe in order to support our balance sheet as we move towards major inflection points over the next several quarters."

Dr. Marbán continued, "In addition, we continue to progress our proprietary StealthX™ platform technology as part of our long-term strategy to leverage exosomes for therapeutic development. We continue to explore partnership opportunities and other non-dilutive sources of funding to advance this program."

Second Quarter 2024 and Recent Operational Highlights

Deramiocel DMD Program: Deramiocel is an investigational cell therapy in Phase 3 development for the treatment of DMD. Deramiocel 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. Deramiocel 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 deramiocel 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.

- Announced the completion of a positive pre-BLA meeting with FDA that occurred in Q3 2024, where we discussed our rolling BLA submission schedule, potential label expansion, plans for commercial manufacturing as well as other topics.
    - We plan to announce further details from this meeting once the final meeting minutes are made available.
- Announced positive results from our 36-month HOPE-2 OLE study at the Parent Project Muscular Dystrophy (PPMD) Annual Conference.
    - The 3-year results showed a statistically significant 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. Data also showed improvements in multiple cardiac measures, including left ventricular ejection fraction, as well as indexed volumes (left ventricular end systolic volume and left ventricular end diastolic volume).
- Announced enrollment has been completed for our HOPE-3 Phase 3 (Cohorts A and B) clinical trial which enrolled 105 subjects randomized to either deramiocel or placebo in a 1:1 ratio.
    - Next steps for Cohort A: plan to readout top-line data in the fourth quarter of 2024.
    - Next steps for Cohort B are under consideration.

- Announced positive results from a Type-B clinical FDA meeting held in Q2 2024 where FDA granted our request for a pre-BLA meeting.
- Announced positive results from a Type-B CMC FDA meeting held in Q1 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 allowed for the use of deramiocel drug product manufactured at our San Diego manufacturing facility upon potential product approval (subject to approval of the facility).
- Presented at the PPMD Cardiac Workshop III. Capricor was featured in a panel on industry perspectives on cardiac monitoring in DMD clinical trials.
- Presented at the Cure Duchenne 2024 Futures National Conference. Capricor presented the 24-month safety and efficacy results from the HOPE-2 OLE study.

StealthX™ Exosome Platform: Exosomes are membrane-bound extracellular vesicles which are secreted by most cells and contain characteristic lipids, proteins and nucleic acids. 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.

- 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.
    - Under the terms of the collaboration, Capricor will supply the investigational product and NIAID's Division of Microbiology and Infectious Diseases will conduct the trial.
    - Currently, our vaccine candidate is in the manufacturing phase with plans to deliver it to NIAID by the end of 2024.
- Presented data at the American Society of Gene and Cell Therapy 27th Annual Meeting. Highlights from the presentation included preclinical data showing 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.
- Presented data at the International Society of Extracellular Vesicles Annual Meeting 2024. Highlights from the abstract included preclinical data showing targeted cargo delivery to the lower limbs of mice by exosomes carrying a muscle targeting moiety by intravenous injection.
- Presented data at the International Society for Cell & Gene Therapy 2024 Meeting. Highlights from the abstract included preclinical data showing targeted delivery of ASOs using exosomes leads to exon skipping.

Corporate Updates

- Announced that the Company has been added to the Russell 2000 and 3000 Indexes.
- Presented at the Cantor Fitzgerald's Muscular Dystrophy Symposium.

Anticipated Upcoming Milestones

- Plan to announce the outcome from our pre-BLA meeting in the third quarter of 2024.
- Plan to present additional 3-year data from our HOPE-2 OLE study at a medical meeting in the fourth quarter of 2024.
- 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 approval and commercialization of deramiocel in DMD.
- Plan to provide updates on our NIAID collaboration for our StealthX™ vaccine as they become available.
- Continue to explore opportunities for partnerships and non-dilutive sources of funding to support advancement of our StealthX™ exosome platform technology.

Second Quarter 2024 Financial Results

Cash position: Cash, cash equivalents and marketable securities totaled approximately $29.5 million as of June 30, 2024 compared to approximately $39.5 million as of December 31, 2023. Additionally, in the second quarter of 2024, Capricor raised approximately $2.1 million in net proceeds through issuances of common stock at an average price of approximately $6.46 per share under its at-the-market offering program.

Revenues: Revenues for the second quarter of 2024 were approximately $4.0 million compared to approximately $3.9 million for the second quarter of 2023. Additionally, revenues for the first half of 2024 were approximately $8.9 million compared to approximately $6.9 million for the first half 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: Total operating expenses for the second quarter of 2024 were approximately $15.6 million compared to approximately $11.7 million for the second quarter of 2023. Total operating expenses for the first half of 2024 were approximately $30.7 million compared to approximately $22.8 million for the first half of 2023.

Net loss: The Company reported a net loss of approximately $11.0 million, or $0.35 per share, for the second quarter of 2024, compared to a net loss of approximately $7.4 million, or $0.29 per share, for the second quarter of 2023. The Company reported a net loss of approximately $20.8 million, or $0.66 per share, for the first half of 2024, compared to a net loss of approximately $15.1 million, or $0.60 per share, for the first half 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 our 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:

- H.C. Wainwright 26th Annual Global Investment Conference, September 9-11, 2024, New York, NY
- 6th Annual Exosome-Based Therapeutic Development Summit, September 17-19, 2024, Boston, MA
- 2024 Cantor Fitzgerald Global Healthcare Conference, September 17-19, 2024, New York, NY
- 2024 Cell & Gene Meeting on the Mesa, October 7-9, 2024, Phoenix, AZ
- 29th Annual Congress of the World Muscle Society, October 8-12, 2024, Prague, Czech Republic
- 2024 Maxim Healthcare Summit, October 15-17, 2024, Virtual

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: 30827. 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, 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 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, and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, as filed with the Securities and Exchange Commission on May 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 (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.

For more information, please contact:

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
REVENUE				
Revenue	$ 3,971,438	$ 3,917,467	$ 8,878,315	$ 6,904,163
TOTAL REVENUE	3,971,438	3,917,467	8,878,315	6,904,163
OPERATING EXPENSES				
Research and development	12,504,769	8,817,389	23,605,782	16,478,908
General and administrative	3,057,888	2,847,337	7,129,654	6,357,222
TOTAL OPERATING EXPENSES	15,562,657	11,664,726	30,735,436	22,836,130
LOSS FROM OPERATIONS	(11,591,219)	(7,747,259)	(21,857,121)	(15,931,967)
OTHER INCOME (EXPENSE)				
Investment income	591,437	380,680	1,063,266	797,122
TOTAL OTHER INCOME (EXPENSE)	591,437	380,680	1,063,266	797,122
NET LOSS	(10,999,782)	(7,366,579)	(20,793,855)	(15,134,845)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	(152,714)	84,707	(80,826)	74,449
COMPREHENSIVE LOSS	$ (11,152,496)	$ (7,281,872)	$ (20,874,681)	$ (15,060,396)
Net loss per share, basic and diluted	$ (0.35)	$ (0.29)	$ (0.66)	$ (0.60)
Weighted average number of shares, basic and diluted	31,841,964	25,335,342	31,598,296	25,291,591

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	June 30, 2024 (unaudited)	December 31, 2023
Cash, cash equivalents and marketable securities	$ 29,462,030	$ 39,487,703
Total assets	$ 38,277,453	$ 58,734,327
Total liabilities	$ 26,775,147	$ 36,132,860
Total stockholders' equity - 31,983,927 and 31,148,320 common shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	11,502,306	22,601,467
Total liabilities and stockholders' equity	$ 38,277,453	$ 58,734,327