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 14, 2023

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 14, 2023, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended September 30, 2023. 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 Securities Act of 1933, as amended, or 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 2023 Financial Results and Provides Corporate Update" dated November 14, 2023.
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 14, 2023

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

Exhibit 99.1

Capricor Therapeutics Reports Third Quarter 2023 Financial Results and Provides Corporate Update

-Completed Targeted Enrollment for HOPE-3, the Phase 3 Trial of CAP-1002 in Duchenne Muscular Dystrophy-

-On Track to Report Interim Futility Analysis in Fourth Quarter of 2023; Successful Outcome Would Trigger Milestone Payment to Capricor Under Commercialization and Distribution Deal with Nippon Shinyaku-

-Positive FDA Feedback on the Proposed Key Clinical and Regulatory Requirements Confirms CAP-1002's Path Towards a Biologics License Application Submission-

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

SAN DIEGO, Calif., Nov. 14, 2023 (GLOBE NEWSWIRE) -- Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company focused on the development of transformative cell and exosome-based therapeutics for the treatment and prevention of muscular and other select diseases, announced today its financial results for the third quarter ended September 30, 2023 and provided a corporate update.

"During our recent meeting with the U.S. Food and Drug Administration (FDA), we aligned on key features of our Phase 3 pivotal program and are pleased to have completed the targeted enrollment in this study, which marks a major milestone on our path towards potential approval of CAP-1002 for the treatment of Duchenne muscular dystrophy (DMD)," said Linda Marbán, Ph.D., Capricor's chief executive officer. "While there are limited treatment options currently available for patients with DMD, we believe the potential for slowing of disease progression, robust and consistent efficacy, together with the favorable safety/tolerability profile, positions CAP-1002 as a potential anchor therapy. Further, we will continue to discuss options for expedited approval pathways with the FDA and in parallel, are well-positioned to execute on important clinical and regulatory milestones including reporting the outcome of an interim futility analysis in the fourth quarter of 2023, followed by top-line data in late 2024."

Dr. Marbán, continued, "While our major focus is on commercializing CAP-1002, 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."

Third Quarter 2023 and Recent Operational Developments

CAP-1002 Duchenne Muscular Dystrophy Program

- Cohort A of our HOPE-3, Phase 3 clinical trial of CAP-1002 in DMD has completed its targeted enrollment. The multi-center, randomized, double-blind, placebo-controlled study is currently designed to treat approximately 58 subjects in the United States.
    - *Next steps for Cohort A:*
        - Plan to report the outcome from the interim futility analysis in the fourth quarter of 2023. A successful outcome from the analysis will trigger the first milestone payment under our U.S. Exclusive Distribution and Commercialization Agreement with Nippon Shinyaku.
        - Plan to report top-line data from Cohort A in the fourth quarter of 2024.
- Held a positive Type-B clinical meeting with FDA in the third quarter of 2023. The FDA affirmed alignment on the current HOPE-3 clinical trial design. Based on the feedback from FDA, we plan to submit a Biologics License Application (BLA), supported by results from Cohort A using product manufactured from our Los Angeles site.
- Cohort B of the HOPE-3 trial will enroll approximately 44 patients and support inclusion of our San Diego site following initial registration.
    - *Next steps for Cohort B:*
        - Expect to commence enrollment for Cohort B in the fourth quarter of 2023.
- Planning to request a meeting with the FDA in the first quarter of 2024 to discuss chemistry, manufacturing and controls (CMC) and explore the potential for expedited approval pathways.

- Hosted a webinar in conjunction with Parent Project Muscular Dystrophy (PPMD) where key updates on our DMD program were outlined.
- Presented a late-breaking poster at the 28th International Annual Congress of the World Muscle Society (WMS).
    - **WMS Poster #1:** Data from the HOPE-2 OLE study measured by the Performance of the Upper Limb (PUL 2.0) showed a delta change=4.9 points, p=0.021 after 24-months of treatment, compared with the placebo patient group.
        - The average rate of decline in CAP-1002 treated patients showed an attenuation of disease progression by approximately 64%.
        - CAP-1002 revealed clinically meaningful improvements in ameliorating cardiac function. Cardiac function, as measured by left ventricular ejection fraction (LVEF%) by MRI at the 24-month timepoint, improved in 67% of patients, compared to a steady decline in a comparable natural history population.

Exosome Platform Technology

- Growing data from preclinical studies continue to underscore the therapeutic potential of Capricor's proprietary StealthX™ exosome platform and potential for a broad range of new therapeutic applications in the field of vaccinology as well as a targeted delivery tool for oligonucleotide, protein and small molecule therapeutics.
- Presented a late-breaking poster at the 28th International Annual Congress of the WMS on the application of the StealthX™ exosome platform for the delivery of antisense oligonucleotides (ASO).
    - **WMS Poster #2:** One of the predominant strategies for treating DMD has been through the employment of ASOs to exclude exons resulting in DMD proteins with partially restored function. To overcome challenges associated with drug delivery, a muscle-targeting moiety was engineered on the surface of the exosomes using the StealthX™ technology.
        - Results showed the presence of exosomes loaded with a labeled ASO in the lower limbs of mice 24 hours post-intravenous (IV) injection. Notably, the exosomes carrying the muscle-targeting moiety were not detected in any other tissues except for the expected clearance pathways (kidney and liver) with a single dose.
- Featured in a poster session at the American Association of Extracellular Vesicles (AAEV) 2023 Annual Meeting showing exosomes loaded with siRNA targeting the RRM2 gene trigger apoptosis in the SKOV3 ovarian cancer cell-line.
- Featured in a poster session at the 5th Exosome Based Therapeutic Development Summit highlighting data on scalable production, purification and characterization methods for exosomes.
- Published preclinical data in the peer-reviewed publication PLOS ONE showing that nanograms of SARS-CoV-2 spike protein, delivered by exosomes induce neutralization of delta and omicron variants.
- Featured in a poster session at SelectBIO Extracellular Vesicles 2023 highlighting the latest advancements related to methods for loading nucleic acid cargo in exosomes.

Corporate Updates

- Announced completion of a registered direct offering with participation from Nippon Shinyaku, Co., Ltd. for gross proceeds of approximately $23.0 million.
- Strengthened Capricor's leadership team with the appointment of Michael Kelliher to the Board of Directors.
    - Mr. Kelliher is an experienced business development and finance professional with expertise in corporate strategy, mergers and acquisitions, strategic partnerships and licensing, with a career spanning more than 20 years with leading biotechnology and global pharmaceutical companies. Mr. Kelliher currently serves as Group Vice President of M&A and Business Development at Horizon Therapeutics (now Amgen).

Anticipated Milestones and Events

The Company has set forth the following guidance for pipeline progression:

- Plan to report outcome from interim futility analysis of HOPE-3 (Cohort A) in the fourth quarter of 2023.
- Plan to initiate HOPE-3 (Cohort B) enrollment in the fourth quarter of 2023.
- Capricor plans to request a meeting with FDA in the first quarter of 2024 to discuss our CAP-1002 program for DMD.
- 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.
- Continue to explore opportunities for partnerships and non-dilutive sources of funding to support advancement of our StealthX™ exosome platform technology.

Third Quarter 2023 Financial Results

Cash position: The Company's cash, cash equivalents and marketable securities totaled approximately $28.5 million as of September 30, 2023 compared to approximately $41.4 million on December 31, 2022. Subsequent to September 30, 2023, the Company completed a registered direct offering for approximately $23.0 million in gross proceeds. Additionally, in the third quarter of 2023, Capricor raised approximately $0.4 million in net proceeds through issuances of common stock at an average price of approximately $5.72 per share under its at-the-market offering program. Subsequent to September 30, 2023 and through the date of this filing, no shares were sold under the Company's at-the-market offering program.

Revenues: Capricor's primary source of revenue was from the ratable recognition of the $30.0 million upfront payment in accordance with its U.S. Exclusive Commercialization and Distribution Agreement received from Nippon Shinyaku in the first quarter of 2022. Revenues for the third quarter of 2023 were approximately $6.2 million compared with approximately $1.6 million for the third quarter of 2022. Additionally, revenues for the nine months ended September 30, 2023 were approximately $13.1 million compared with approximately $1.6 million for the same period of 2022.

Operating expenses: Total operating expenses for the third quarter of 2023 were approximately $13.1 million compared with approximately $8.1 million for the third quarter of 2022. Total operating expenses for the nine months ended September 30, 2023 were approximately $35.9 million compared with approximately $23.2 million for the same period of 2022.

Net loss: The Company reported a net loss of approximately $6.4 million, or $0.25 per share, for the third quarter of 2023, compared to a net loss of approximately $6.4 million, or $0.26 per share, for the third quarter of 2022. The Company reported a net loss of approximately $21.5 million, or $0.85 per share, for the nine months ended September 30, 2023, compared to a net loss of approximately $21.3 million, or $0.87 per share, for the same period of 2022.

Financial Outlook

Capricor believes that based on the current operating plan and financial resources, its available cash, cash equivalents and marketable securities will be sufficient to cover anticipated expenses and capital requirements into 2025. This expectation includes the recent registered direct offering which closed in October 2023 for approximately $23.0 million in gross proceeds and excludes any additional potential milestone payments under its exclusive 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.

Conference Call and Webcast

To participate in the conference call, please dial 888-886-7786 (Domestic/Toll-Free) or 416-764-8658 (International) and reference the conference ID: 46361431. 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 focused on the development of transformative cell and exosome-based therapeutics for the treatment and prevention of muscular and other select diseases. Capricor's lead candidate, CAP-1002, is an allogeneic cardiac-derived cell therapy that is currently in late-stage clinical development for treating Duchenne muscular dystrophy. Further, 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. Capricor is also developing its exosome technology as a next-generation therapeutic platform. Our proprietary StealthX™ exosome platform has potential for a broad range of new therapeutic applications in the field of vaccinology as well as targeted oligonucleotide, protein and small molecule therapeutics to treat or prevent a variety of diseases. 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; 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 royalty streams and revenue 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, 2022, as filed with the Securities and Exchange Commission on March 17, 2023 and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, as filed with the Securities and Exchange Commission on August 8, 2023. 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.

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.

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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,	
	2023	2022	2023	2022
REVENUE				
Revenue	$ 6,185,814	$ 1,591,566	$ 13,089,977	$ 1,591,566
TOTAL REVENUE	6,185,814	1,591,566	13,089,977	1,591,566
OPERATING EXPENSES				
Research and development	10,028,964	5,504,356	26,507,872	15,585,143
General and administrative	3,021,450	2,564,960	9,378,672	7,637,461
TOTAL OPERATING EXPENSES	13,050,414	8,069,316	35,886,544	23,222,604
LOSS FROM OPERATIONS	(6,864,600)	(6,477,750)	(22,796,567)	(21,631,038)
OTHER INCOME (EXPENSE)				
Other income	—	—	—	190,582
Investment income	479,380	106,635	1,276,502	141,836
Loss on disposal of fixed assets	(5,388)	—	(5,388)	—
TOTAL OTHER INCOME (EXPENSE)	473,992	106,635	1,271,114	332,418
NET LOSS	(6,390,608)	(6,371,115)	(21,525,453)	(21,298,620)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	(66,485)	99,637	7,964	122,467
COMPREHENSIVE LOSS	$ (6,457,093)	$ (6,271,478)	$ (21,517,489)	$ (21,176,153)
Net loss per share, basic and diluted	$ (0.25)	$ (0.26)	$ (0.85)	$ (0.87)
Weighted average number of shares, basic and diluted	25,817,676	24,431,787	25,468,880	24,346,775

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	September 30, 2023 (unaudited)	December 31, 2022
Cash, cash equivalents and marketable securities	$ 28,521,472	$ 41,421,262
Total assets	$ 37,152,330	$ 50,094,910
Total liabilities	$ 38,939,986	$ 38,308,816
Total stockholders' equity (deficit) - 25,855,070 and 25,241,402 common shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	(1,787,656)	11,786,094
Total liabilities and stockholders' equity (deficit)	$ 37,152,330	$ 50,094,910