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 11, 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 May 11, 2023, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended March 31, 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 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 2023 Financial Results and Provides Corporate Update", dated May 11, 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: May 11, 2023

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

Exhibit 99.1

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

-Enrollment Continues to Progress in HOPE-3, the Phase 3 Clinical Trial of CAP-1002 in Duchenne Muscular Dystrophy (DMD); On Track to Report Interim Analysis in Fourth Quarter of 2023-

-Plan to Present 24-Month HOPE-2 Open Label Extension Data in Second Quarter of 2023-

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

SAN DIEGO, Calif., May 11, 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 first quarter ended March 31, 2023 and provided a corporate update.

"We are pleased with the progress of our late-stage clinical development program for CAP-1002 in patients with DMD, and are well positioned to deliver on important clinical and regulatory milestones throughout 2023," said Linda Marbán, Ph.D., Capricor's chief executive officer. "We plan to present 24-month follow-up data from our ongoing HOPE-2 open label extension study (OLE) in the second quarter of 2023, and with enrollment for our Phase 3 HOPE-3 trial progressing, we remain on track to report the interim analysis in the fourth quarter of 2023. Furthermore, based on the positive data from our previous clinical trials, we are currently working with the FDA to determine the most expeditious path to registration for CAP-1002 in DMD. In parallel, we are exploring opportunities for additional partnerships outside of the United States and Japan to maximize the value of this asset."

First Quarter 2023 and Recent Operational Developments

CAP-1002 Duchenne Muscular Dystrophy Program

- HOPE-3, our Phase 3 clinical trial of CAP-1002 in DMD continues to progress well. The multi-center, randomized, double-blind, placebo-controlled study (NCT05126758) is designed to treat up to 68 subjects in the United States. At this time, we have 13 active sites and we expect to fully enroll the currently designed study by the second half of 2023.
- Continued discussions with FDA following our Type-B CMC meeting regarding commercial plans in anticipation of a potential BLA submission and we have now submitted a request for a Type-B clinical meeting.
- Completed construction of new San Diego GMP manufacturing facility and plan to have commercial-scale GMP CAP-1002 product available in the third quarter of 2023.
- In February 2023, entered into second agreement with Nippon Shinyaku Co., Ltd., for the exclusive commercialization and distribution in Japan of CAP-1002 for the treatment of DMD.
    - Under the terms of the agreement, Capricor received an upfront payment of $12 million and will potentially receive additional development and sales-based milestone payments of up to approximately $89 million and a meaningful, double-digit share of net product revenue.
- Presented positive 18-month results from ongoing HOPE-2 OLE study in a late-breaking session at the 2023 MDA Clinical and Scientific Conference.

- 18-month data from the OLE study continue to suggest potential disease modification with statistically significant differences in the PUL v2.0 in the CAP-1002 original treatment group when compared to the original placebo group from HOPE-2 (p=0.02).
- 18-month results were presented on a webinar hosted in conjunction with Parent Project Muscular Dystrophy (PPMD).

- The HOPE-2 study was named as a recipient of Clinical Research Forum's 2023 Top Ten Clinical Research Achievement Award.

Exosome Platform Technology

- Published preclinical data in the peer-reviewed journal, *Microbiology Spectrum* highlighting the therapeutic potential of Capricor's proprietary StealthX™ exosome platform.
  - These results established the prospect of combining multiple targets in one vaccine and support exosomes as a potential suitable delivery vehicle for a variety of therapeutic cargo.
- Featured in two poster presentations at the 2023 World Vaccine Congress highlighting the data from our StealthX™ exosome platform.

Anticipated Milestones and Events

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

- Continue discussions with FDA regarding pathway towards BLA for CAP-1002 in DMD
  - Plan to share additional feedback from FDA on the HOPE-3 clinical trial when available
- Plan to present 24-month follow-up data from HOPE-2 OLE in second quarter of 2023
- Expect to fully enroll the currently designed HOPE-3 trial by the second half of 2023
- Plan to report outcome from interim analysis of HOPE-3 in fourth quarter of 2023
- Explore opportunities for additional strategic partnerships outside of the United States and Japan to support the potential commercialization of CAP-1002 in DMD

First Quarter 2023 Financial Results

Cash position: The Company's cash, cash equivalents and marketable securities totaled approximately $45.2 million as of March 31, 2023 compared to approximately $41.4 million on December 31, 2022. In the first quarter of 2023, Capricor received an upfront payment of $12.0 million from Nippon Shinyaku in accordance with its Japan Exclusive Commercialization and Distribution Agreement. Subsequent to December 31, 2022 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 first quarter of 2023 were approximately $3.0 million compared with zero for the first quarter of 2022.

Operating expenses: Total operating expenses for the first quarter of 2023 were approximately $11.2 million compared with approximately $7.8 million for the first quarter of 2022.

Net loss: The Company reported a net loss of approximately $7.8 million, or $0.31 per share, for the first quarter of 2023, compared to a net loss of approximately $7.8 million, or $0.32 per share, for the first quarter 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 the fourth quarter of 2024. This expectation 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 855-327-6837 (Domestic/Toll-Free) or 631-891-4304 (International) and reference the conference ID: 10021769. 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. Capricor is also developing its exosome technology as a next-generation therapeutic platform. Capricor's focus is on developing exosomes capable of delivering nucleic acids, including mRNA, as well as proteins 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. 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 March 31,	
	2023	**2022**
REVENUE		
Revenue	$ 2,986,696	$ —
TOTAL REVENUE	2,986,696	—
OPERATING EXPENSES		
Research and development	7,661,519	5,115,699
General and administrative	3,509,885	2,715,835
TOTAL OPERATING EXPENSES	11,171,404	7,831,534
LOSS FROM OPERATIONS	(8,184,708)	(7,831,534)
OTHER INCOME (EXPENSE)		
Investment income	416,442	13,440
TOTAL OTHER INCOME (EXPENSE)	416,442	13,440
NET LOSS	(7,768,266)	(7,818,094)
OTHER COMPREHENSIVE INCOME (LOSS)		
Net unrealized loss on marketable securities	(10,258)	—
COMPREHENSIVE LOSS	$ (7,778,524)	$ (7,818,094)
Net loss per share, basic and diluted	$ (0.31)	$ (0.32)
Weighted average number of shares, basic and diluted	25,247,354	24,282,743

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	March 31, 2023 (unaudited)	**December 31, 2022**
Cash, cash equivalents and marketable securities	$ 45,171,870	$ 41,421,262
Total assets	$ 53,863,409	$ 50,094,910
Total liabilities	$ 47,657,160	$ 38,308,816
Total stockholders' equity - 25,255,154 and 25,241,402 common shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	6,206,249	11,786,094
Total liabilities and stockholders' equity	$ 53,863,409	$ 50,094,910