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, 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 August 7, 2023, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended June 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 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 2023 Financial Results and Provides Corporate Update", dated August 7, 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: August 7, 2023

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

Exhibit 99.1

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

-Presented Statistically Significant 24-Month HOPE-2 Open Label Extension Data at the PPMD Annual Conference-

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

-Held Type-B Clinical Meeting with the FDA to Discuss CAP-1002's Pathway Towards Potential Biologics License Application Submission-

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

SAN DIEGO, Calif., August 7, 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 second quarter ended June 30, 2023 and provided a corporate update.

"In the second quarter of 2023 we presented positive two-year data from our ongoing HOPE-2 open label extension (OLE) study, which we believe further supports our rapidly advancing late-stage clinical development program for CAP-1002 in patients with Duchenne Muscular Dystrophy (DMD)," said Linda Marbán, Ph.D., Capricor's chief executive officer. "The robust and consistent results seen after two years of treatment with CAP-1002 are tremendously impactful for DMD patients, showing evidence of skeletal and cardiac functional improvements, which underscores the potential long-term benefit of CAP-1002 treatment. We recently held a clinical meeting with the U.S. Food and Drug Administration (FDA) to discuss these results, together with key features of our ongoing Phase 3 HOPE-3 trial. The objective was to outline the proposed path towards submission of a potential Biologics License Application (BLA) in the most expeditious way possible, and we look forward to sharing the outcome of this meeting once we receive final meeting minutes from the FDA. Additionally, with progress of HOPE-3 accelerating, we expect to complete enrollment and report the outcome from the interim analysis in the fourth quarter of 2023."

Dr. Marbán continued, "Further, as we remain committed to driving shareholder value as well as maximizing the value of CAP-1002, we continue to explore opportunities for additional partnerships for DMD as well as new potential indications for which CAP-1002 can provide benefits to patients in need. We look forward to building on the strength of the Company with the additions of Drs. Gotwals and Auwaerter to Capricor's Board of Directors and we are entering the second half of the year in a strong position. Their deep industry experience and forward-looking vision will be invaluable as we continue to deliver on important clinical and regulatory milestones for CAP-1002 and as we continue efforts to advance our exosome platform technology, StealthX™."

Second 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 currently designed to treat up to 68 subjects in the United States. To date, 48 patients have been randomized across 17 active sites. Capricor plans to complete enrollment and report the outcome from the interim analysis in the fourth quarter of 2023.
- Discussions continued with the FDA including a Type-B clinical meeting held in the third quarter of 2023. During the meeting with the FDA, Capricor outlined its proposed path towards submission of a potential BLA and further discussed the ongoing HOPE-3 clinical trial with the agency. We plan to share the outcome from this meeting once final minutes are available.
- Presented positive statistically significant 24-month results from ongoing HOPE-2 OLE study at the 2023 Parent Project Muscular Dystrophy (PPMD) Annual Conference.

- The HOPE-2-OLE study previously met its primary endpoint at the one-year timepoint on the PUL v2.0 scale (p=0.02). At the 24-month timepoint, data showed statistically significant differences in the PUL v2.0 in the OLE treatment group when compared to the original rate of decline of the placebo group from HOPE-2 after one-year (p=0.021). LVEF was measured using cardiac magnetic resonance imaging (cMRI) and six of nine patients showed improvements in heart function with CAP-1002 treatment compared to their final assessment at the end of the HOPE-2 study. Furthermore, the OLE study continues to show a favorable safety profile for long-term treatment of CAP-1002.
- Completed construction of our San Diego GMP manufacturing facility in the first quarter of 2023 and plan to have commercial-scale GMP CAP-1002 clinical doses available in the third quarter of 2023.
- Featured in a poster session at the ISCT 2023 Annual Meeting highlighting the latest advancements related to Capricor's potency assay development for CAP-1002.

Exosome Platform Technology

- Growing data from ongoing 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 targeted delivery tool for oligonucleotide, protein and small molecule therapeutics.
    - Published preclinical data in the peer-reviewed journal, Microbiology Spectrum highlighting data on the prospect of combining multiple targets in one vaccine and support exosomes as a potential suitable delivery vehicle for a variety of therapeutic cargo.
    - Published preclinical data in bioRxiv highlighting data on the prospect of creating a dual-antigen vaccine with efficacy against SARS-CoV-2 and the influenza virus.
    - 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

- Strengthened Capricor's leadership team with two appointments to our Board of Directors and two appointments to our leadership team.
    - Appointed Philip J. Gotwals, Ph.D., to the Capricor Board of Directors. Dr. Gotwals has experience in drug development, research, corporate strategy and business development with a career spanning nearly 30 years in the biotechnology industry. Dr. Gotwals most recently served as the Global Head, Vice President of Business Development and Licensing at Novartis Institutes for Biomedical Research (NIBR).
    - Appointed Paul Auwaerter, M.D., to the Capricor Board of Directors. Dr. Auwaerter brings over 30 years of internal medicine and infectious disease experience as the Sherrilyn and Ken Fisher Professor of Medicine at the Johns Hopkins University School of Medicine, serving as the Clinical Director for the Division of Infectious Diseases and Director of the Sherrilyn and Ken Fisher Center for Environmental Infectious Diseases.
    - Appointed Yushi Feng, Ph.D. as Vice President of Regulatory Affairs. Dr. Feng oversees all global regulatory strategy for our DMD program as well as our exosome platform. Dr. Feng brings over 17 years of regulatory experience from both industry and the FDA, with an expansive career focusing on oncology, neurology, rare and infectious diseases as well as CMC (Chemistry Manufacturing and Controls) experience spanning multiple disciplines with extensive experience in manufacturing and quality systems.
    - Appointed Jonathan Tayco as Vice President of Program Management and Business Operations. Mr. Tayco oversees our program strategic planning, management and executional leadership in relation to CMC, quality and regulatory filings and submissions. Prior experience for Mr. Tayco included Kite Pharma, a Gilead Company, where he played an integral role in the BLA approval of YESCARTA®, one of the first approved cell therapy treatments for large B-cell lymphoma.

Anticipated Milestones and Events

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

- Continue discussions with FDA regarding our pathway towards BLA for CAP-1002 in DMD
    - Plan to share FDA feedback on the HOPE-3 clinical trial once final minutes are available
- Plan to submit data from the ongoing HOPE-2-OLE study at a medical meeting in the fourth quarter of 2023
- Plan to complete enrollment of the currently designed HOPE-3 trial in the fourth quarter of 2023
- Plan to report outcome from interim analysis of HOPE-3 in fourth quarter of 2023
- Continue to explore opportunities for additional partnerships outside of the U.S. and Japan to support the potential commercialization of CAP-1002 in DMD

Second Quarter 2023 Financial Results

Cash position: The Company's cash, cash equivalents and marketable securities totaled approximately $37.8 million as of June 30, 2023 compared to approximately $41.4 million on December 31, 2022. Additionally, in the second quarter of 2023, Capricor raised approximately $2.1 million in net proceeds through issuances of common stock at an average price of approximately $4.87 per share under its 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 second quarter of 2023 were approximately $3.9 million compared with zero for the second quarter of 2022. Additionally, revenues for the first half of 2023 were approximately $6.9 million compared with zero for the first half of 2022.

Operating expenses: Total operating expenses for the second quarter of 2023 were approximately $11.7 million compared with approximately $7.3 million for the second quarter of 2022. Total operating expenses for the first half of 2023 were approximately $22.8 million compared with approximately $15.2 million for the first half of 2022.

Net loss: The Company reported a net loss of approximately $7.4 million, or $0.29 per share, for the second quarter of 2023, compared to a net loss of approximately $7.1 million, or $0.29 per share, for the second quarter of 2022. The Company reported a net loss of approximately $15.1 million, or $0.60 per share, for the first half of 2023, compared to a net loss of approximately $14.9 million, or $0.61 per share, for the first half 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 through the third 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 888-886-7786 (Domestic/Toll-Free) or 416-764-8658 (International) and reference the conference ID: 02236204. 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 March 31, 2023, as filed with the Securities and Exchange Commission on May 12, 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 June 30,		Six months ended June 30,	
	2023	2022	2023	2022
REVENUE				
Revenue	$ 3,917,467	$ —	$ 6,904,163	$ —
TOTAL REVENUE	3,917,467	—	6,904,163	—
OPERATING EXPENSES				
Research and development	8,817,389	4,965,088	16,478,908	10,080,787
General and administrative	2,847,337	2,356,666	6,357,222	5,072,501
TOTAL OPERATING EXPENSES	11,664,726	7,321,754	22,836,130	15,153,288
LOSS FROM OPERATIONS	(7,747,259)	(7,321,754)	(15,931,967)	(15,153,288)
OTHER INCOME (EXPENSE)				
Other income	—	190,582	—	190,582
Investment income	380,680	21,761	797,122	35,201
TOTAL OTHER INCOME (EXPENSE)	380,680	212,343	797,122	225,783
NET LOSS	(7,366,579)	(7,109,411)	(15,134,845)	(14,927,505)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain on marketable securities	84,707	22,830	74,449	22,830
COMPREHENSIVE LOSS	$ (7,281,872)	$ (7,086,581)	$ (15,060,396)	$ (14,904,675)
Net loss per share, basic and diluted	$ (0.29)	$ (0.29)	$ (0.60)	$ (0.61)
Weighted average number of shares, basic and diluted	25,335,342	24,324,156	25,291,591	24,303,564

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	June 30, 2023 (unaudited)	December 31, 2022
Cash, cash equivalents and marketable securities	$ 37,793,458	$ 41,421,262
Total assets	$ 46,011,198	$ 50,094,910
Total liabilities	$ 43,280,035	$ 38,308,816
Total stockholders' equity - 25,764,312 and 25,241,402 common shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	2,731,163	11,786,094
Total liabilities and stockholders' equity	$ 46,011,198	$ 50,094,910