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 10, 2022

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)**

(310) 358-3200
(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 10, 2022, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended June 30, 2022. 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 2022 Financial Results and Provides Corporate Update", dated August 10, 2022.
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).

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 10, 2022

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

Exhibit 99.1

Capricor Therapeutics Reports Second Quarter 2022 Financial Results and Provides Corporate Update

-First Patient Treated in HOPE-3, the Pivotal Phase 3 Clinical Trial of CAP-1002 in Duchenne Muscular Dystrophy-

-Positive One-Year Safety and Efficacy Results From HOPE-2 Open Label Extension Study of CAP-1002 in Non-Ambulant Duchenne Muscular Dystrophy Patients Presented at PPMD's 2022 Annual Conference-

-Requesting Meeting with FDA to Discuss Next Steps in Development of CAP-1002 for Duchenne Muscular Dystrophy-

-Pipeline Expansion Underway Using Engineered Exosomes-

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

SAN DIEGO, Calif., Aug. 10, 2022 (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, 2022 and provided a corporate update.

"The second quarter was marked by important progress across our ongoing development program for CAP-1002 in patients with late-stage Duchenne Muscular Dystrophy (DMD), highlighted by the initiation of our pivotal Phase 3 trial, HOPE-3, as well as the positive one-year results from our HOPE-2 open label extension (OLE) study," said Linda Marbán, Ph.D., Capricor's chief executive officer. "Positive data from the HOPE-2 OLE study were recently presented at this year's Parent Project Muscular Dystrophy (PPMD) Annual Conference and further validate the statistically significant and clinically relevant evidence of CAP-1002's ability to improve skeletal muscle function, with disease modification and long-term safety potential in patients with later stages of DMD. Together, with the data generated to date, we believe CAP-1002 is positioned to become an anchor therapy for non-ambulant DMD patients. Based on this recently announced data and our RMAT designation, we are requesting a meeting with FDA later this year to discuss the best path forward with the objective of getting CAP-1002 to approval as quickly as possible."

Dr. Marbán continued, "In parallel, our engineered exosome platform continues to advance in several areas. We are internally developing a streamlined manufacturing paradigm to support future development efforts. This foundational work will drive our platform strategy to leverage the development of external partnerships where companies have therapeutics that can benefit from a targeted delivery vehicle which can be obtained using engineered exosomes. We look forward to sharing further updates, including the expansion into new indications."

Second Quarter Highlights and Recent Operational Highlights

- Treated first patient in HOPE-3, our pivotal Phase 3 clinical trial of CAP-1002 in late-stage DMD. The randomized, double-blind, placebo-controlled study is designed to enroll approximately 70 patients across approximately 15 to 20 sites in the United States (NCT05126758).
    - Partnership with Nippon Shinyaku Co., Ltd., which has commercialization and distribution rights in the United States, provides funding for the support of HOPE-3 ($30M upfront payment with potential for additional milestone payments of up to $705M).
- Reported positive one-year results from our HOPE-2 open label extension study in patients with later-stage DMD. Treatment with CAP-1002 resulted in statistically significant clinical benefits in skeletal muscle function, demonstrated by improvements on the Performance of the Upper Limb (PUL version 2.0) scale (p=0.02). Additionally, results underscore the disease modifying and long-term safety potential of CAP-1002 in patients with DMD.

    - Results were presented at the PPMD Annual Conference on June 25, 2022 in Scottsdale, Arizona.
- Appointed Xavier Avat as Chief Business Officer, who brings deep industry knowledge, to oversee Capricor's strategic priorities, the development and potential commercialization of its pipeline products and business development activities.

Anticipated Milestones and Events

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

- Requesting meeting with FDA to discuss next steps in our CAP-1002 DMD program
- Publication of additional preclinical work related to our engineered exosomes platform
- Full enrollment of HOPE-3 expected by the third quarter of 2023

Upcoming Events

The Company plans to participate in the following events:

- H.C. Wainwright 24th Annual Global Investment Conference: September 12-14
- Cantor Fitzgerald Cell and Genetic Medicines Conference: September 15
- 4th Extracellular Vesicle Based Therapeutic Development: October 4-6

Financial Results for Second Quarter 2022

The Company reported a net loss of approximately $7.1 million, or $0.29 per share, for the second quarter of 2022, compared to a net loss of approximately $4.7 million, or $0.21 per share, for the second quarter of 2021.

As of June 30, 2022, the Company's cash, cash equivalents and marketable securities totaled approximately $51.4 million, compared to approximately $34.9 million on December 31, 2021. No shares were sold under the Company's at-the-market program in the second quarter of 2022.

Financial Outlook

Capricor believes that based on the current operating plan and financial resources, the Company expects that its available cash and cash equivalents will be sufficient to cover anticipated expenses and capital requirements into the second quarter of 2024. This expectation excludes 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 800-289-0571 (Domestic/Toll-Free) or 929-477-0324 (International) and reference the conference ID: 6015762. To participate via a webcast, please click here. The webcast will be archived for approximately 30 days and will be available at http://capricor.com/news/events/

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) 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. The Company's current 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, visitcapricor.com, and follow the Company 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; 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, 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, 2021, as filed with the Securities and Exchange Commission on March 11, 2022 and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 as filed with the Securities and Exchange Commission on May 11, 2022. 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.

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,	
	2022	2021	2022	2021
REVENUE				
Revenue	$ —	$ 204,082	$ —	$ 244,898
TOTAL REVENUE	—	204,082	—	244,898
OPERATING EXPENSES				
Research and development	4,965,088	3,497,275	10,080,787	6,793,597
General and administrative	2,356,666	1,789,974	5,072,501	3,695,556
TOTAL OPERATING EXPENSES	7,321,754	5,287,249	15,153,288	10,489,153
LOSS FROM OPERATIONS	(7,321,754)	(5,083,167)	(15,153,288)	(10,244,255)
OTHER INCOME (EXPENSE)				
Other income	190,582	—	190,582	—
Investment income	21,761	16,741	35,201	25,906
Forgiveness of debt	—	318,160	—	318,160
TOTAL OTHER INCOME (EXPENSE)	212,343	334,901	225,783	344,066
NET LOSS	(7,109,411)	(4,748,266)	$ (14,927,505)	$ (9,900,189)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain on marketable securities	22,830	—	22,830	—
COMPREHENSIVE LOSS	$ (7,086,581)	$ (4,748,266)	$ (14,904,675)	$ (9,900,189)
Net loss per share, basic and diluted	$ (0.29)	$ (0.21)	$ (0.61)	$ (0.44)
Weighted average number of shares, basic and diluted	24,324,156	22,861,051	24,303,564	22,546,634

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	June 30, 2022 (Unaudited)	December 31, 2021
Cash, cash equivalents and marketable securities	$ 51,416,950	$ 34,885,274
Total assets	$ 58,065,574	$ 41,330,323
Total liabilities	$ 39,336,579	$ 9,962,357
Total stockholders' equity - 24,334,952 and 24,185,001 common shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	18,728,995	31,367,966
Total liabilities and stockholders' equity	$ 58,065,574	$ 41,330,323