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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**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 10, 2022

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**CAPRICOR THERAPEUTICS, INC.**

(Exact name of Registrant as Specified in its Charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-34058**  
(Commission  
File Number)

**88-0363465**  
(I.R.S. Employer  
Identification No.)

**10865 Road to the Cure, Suite 150, San Diego, California**  
(Address of principal executive offices)

**92121**  
(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

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**Item 2.02 Results of Operations and Financial Condition.**

On November 10, 2022, Capricor Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the quarter ended September 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 Third Quarter 2022 Financial Results and Provides Corporate Update”, dated November 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.

Date: November 10, 2022

**CAPRICOR THERAPEUTICS, INC.**

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

## Capricor Therapeutics Reports Third Quarter 2022 Financial Results and Provides Corporate Update

*-Enrollment Continues to Progress in HOPE-3, the Pivotal Phase 3 Clinical Trial of CAP-1002 in Duchenne Muscular Dystrophy-*

*-Presented Positive One-Year Safety and Efficacy Results From HOPE-2 Open Label Extension Study of CAP-1002 in Duchenne Muscular Dystrophy Patients at World Muscle Society 2022-*

*-Presented New Advances in Engineered Exosome Platform at Exosome-Based Therapeutic Development Summit-*

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

**SAN DIEGO, Calif.**, Nov. 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 third quarter ended September 30, 2022 and provided a corporate update.

“In the third quarter we continued to advance our late-stage clinical development program for CAP-1002 in patients with Duchenne Muscular Dystrophy (DMD), and took important steps toward potential commercialization,” said Linda Marbán, Ph.D., Capricor’s chief executive officer. “We are encouraged by the growing dataset including the statistically significant and clinically relevant data from the HOPE-2 open label extension trial which we recently presented at this year’s World Muscle Society Congress. These and prior results further support CAP-1002’s ability to improve both skeletal and cardiac muscle functions, which suggest potential disease modification, as well as the long-term safety profile of the therapy. Our main priority now is to continue to advance the ongoing HOPE-3 pivotal Phase 3 clinical trial. Patient dosing is underway and as enrollment progresses, we will continue to work closely with the FDA to define next steps in the regulatory pathway for CAP-1002 and at the request of the FDA, we have submitted the results from our HOPE-2 open label extension for their review. In parallel, we are exploring opportunities for additional strategic partnerships outside of the United States to allow for rapid therapy availability to the global patient community, if approved, and to maximize the value of this asset.”

Dr. Marbán continued, “Turning to our exosomes program, earlier this quarter, we presented results from our most advanced application of our proprietary StealthX™ platform for the production of a multivalent exosome-based vaccine or booster for COVID-19. Based on this unique platform, we were able to rapidly develop a protein-based vaccine that elicited a potent immune response without the need for an adjuvant or lipid nanoparticle carrier. We also continue to make progress with the second modality of this platform and are developing exosomes as precision delivery vehicles to more effectively bring a payload to targeted cells or tissues. In summary, we see our StealthX™ platform technology having the potential to support the next generation of vaccines and supporting the development of innovative therapeutics. We look forward to sharing further updates, including a planned publication of this preclinical work in the coming months.”

### Third Quarter and Recent Operational Highlights

- HOPE-3, our pivotal, randomized, double-blind, placebo-controlled, Phase 3 clinical trial of CAP-1002 in DMD continues to progress well and enrollment remains on track ([NCT05126758](#)).
    - Capricor continues its efforts toward potential commercialization, including manufacturing scale-up.
  - Presented previously announced 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, observed by improvements in the Performance of the Upper Limb (PUL version 2.0) scale (p=0.02). Additionally, the results support potential disease modifying outcomes and reinforce the long-term safety potential of CAP-1002 in patients with DMD.
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- Results were presented at a poster session at the World Muscle Society Congress (WMS) in Halifax, Nova Scotia, Canada on October 14, 2022.
- Presented new preclinical data on Capricor's StealthX™ platform showing the rapid development of a recombinant protein-based vaccine for immunization and prevention against SARS-CoV-2, the virus causing COVID-19.
  - These data were featured in a presentation at the 4<sup>th</sup> Exosome Based Therapeutic Development Summit, held in Boston, MA from October 4-6, 2022.

#### **Anticipated Milestones and Events**

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

- Continue discussions with FDA regarding pathway towards a Biologics License Application or BLA for CAP-1002 in DMD
- Planned publication of preclinical work related to our StealthX™ engineered exosomes platform
- Planned interim analysis of HOPE-3 expected by mid-2023
- Full enrollment of HOPE-3 expected by the third quarter of 2023

#### **Financial Results for Third Quarter 2022**

*Revenues:* Capricor's primary source of revenue was from the ratable recognition of the \$30.0 million upfront payment received from Nippon Shinyaku. For the three months ended September 30, 2022, the Company reported revenue of approximately \$1.6 million compared with zero for the three months ended September 30, 2021.

*Operating expenses:* Total operating expenses for the three months ended September 30, 2022, were approximately \$8.1 million compared with approximately \$4.3 million for the three months ended September 30, 2021.

The Company reported a net loss of approximately \$6.4 million, or \$0.26 per share, for the third quarter of 2022, compared to a net loss of approximately \$3.9 million, or \$0.17 per share, for the third quarter of 2021.

As of September 30, 2022, the Company's cash, cash equivalents and marketable securities totaled approximately \$46.6 million, compared to approximately \$34.9 million on December 31, 2021. Additionally, in the third quarter of 2022, Capricor raised approximately \$1.9 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.

#### **Financial Outlook**

Capricor expects 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 second quarter of 2024. This expectation excludes any potential milestone payments under its commercialization and distribution agreement 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 888-204-4368 (Domestic/Toll-Free) or 929-477-0402 (International) and reference the conference ID: 5157311. 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

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well as proteins to treat or prevent a variety of diseases. For more information, visit [capricor.com](http://capricor.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 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, 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 June 30, 2022 as filed with the Securities and Exchange Commission on August 12, 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)**

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2022</b>	<b>2021</b>	<b>2022</b>	<b>2021</b>
<b>REVENUE</b>				
Revenue	\$ 1,591,566	\$ —	\$ 1,591,566	\$ 244,898
<b>TOTAL REVENUE</b>	<b>1,591,566</b>	<b>—</b>	<b>1,591,566</b>	<b>244,898</b>
<b>OPERATING EXPENSES</b>				
Research and development	5,504,356	2,513,915	15,585,143	9,307,512
General and administrative	2,564,960	1,800,630	7,637,461	5,496,186
<b>TOTAL OPERATING EXPENSES</b>	<b>8,069,316</b>	<b>4,314,545</b>	<b>23,222,604</b>	<b>14,803,698</b>
<b>LOSS FROM OPERATIONS</b>	<b>(6,477,750)</b>	<b>(4,314,545)</b>	<b>(21,631,038)</b>	<b>(14,558,800)</b>
<b>OTHER INCOME (EXPENSE)</b>				
Other income	—	367,168	190,582	367,168
Investment income	106,635	15,570	141,836	41,476
Forgiveness of debt	—	—	—	318,160
<b>TOTAL OTHER INCOME (EXPENSE)</b>	<b>106,635</b>	<b>382,738</b>	<b>332,418</b>	<b>726,804</b>
<b>NET LOSS</b>	<b>(6,371,115)</b>	<b>(3,931,807)</b>	<b>\$ (21,298,620)</b>	<b>\$ (13,831,996)</b>
<b>OTHER COMPREHENSIVE INCOME (LOSS)</b>				
Net unrealized gain on marketable securities	99,637	—	122,467	—
<b>COMPREHENSIVE LOSS</b>	<b>\$ (6,271,478)</b>	<b>\$ (3,931,807)</b>	<b>\$ (21,176,153)</b>	<b>\$ (13,831,996)</b>
Net loss per share, basic and diluted	\$ (0.26)	\$ (0.17)	\$ (0.87)	\$ (0.61)
Weighted average number of shares, basic and diluted	24,431,787	23,095,375	24,346,775	22,731,638

**CAPRICOR THERAPEUTICS, INC.**  
**SUMMARY BALANCE SHEETS**

	<b>September 30, 2022</b>	<b>December 31, 2021</b>
	<b>(Unaudited)</b>	
Cash, cash equivalents and marketable securities	\$ 46,613,512	\$ 34,885,274
Total assets	\$ 53,928,107	\$ 41,330,323
Total liabilities	\$ 38,501,615	\$ 9,962,357
Total stockholders' equity - 24,702,684 and 24,185,001 common shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	15,426,492	31,367,966
Total liabilities and stockholders' equity	\$ 53,928,107	\$ 41,330,323