
**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 9, 2021

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.)

8840 Wilshire Blvd., 2nd Floor, Beverly Hills, CA
(Address of principal executive offices)

90211
(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:

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, par value \$0.001 per share	CAPR	The Nasdaq Capital Market

Item 2.02 Results of Operations and Financial Condition.

On November 9, 2021, Capricor Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the quarter ended September 30, 2021. 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 2021 Financial Results and Provides Corporate Update”, dated November 9, 2021.](#)
- 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.

Date: November 9, 2021

CAPRICOR THERAPEUTICS, INC.

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

Capricor Therapeutics Reports Third Quarter 2021 Financial Results and Provides Corporate Update

CAP-1002 – Capricor’s Cell Therapy Program for Duchenne Muscular Dystrophy
-Phase 3 Pivotal Study Cleared to Proceed-
-Presented Positive Phase 2 HOPE-2 Final Data at Late-Breaking Oral Presentation at the 2021 World Muscle Society Virtual Congress-
-Met Primary Efficacy Endpoint of Mid Performance of Upper Limb (PUL) v1.2 (p=0.01)-

CAP-1002 – Capricor’s Cell Therapy Program for COVID-19
-Phase 2 INSPIRE Trial Enrollment Complete with 63 Patients Randomized-

Capricor’s Exosomes Platform Technology
-Completing Non-Clinical Studies for IND Submission-
-Pipeline Expansion Underway Using Engineered Exosomes-

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

SAN DIEGO, CA Nov. 9, 2021 (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 a broad spectrum of diseases, today reported its financial results for the third quarter ended September 30, 2021, and provided an overview of its recent operational highlights. Management will host a webcast and conference call at 4:30 p.m. Eastern Time today.

“The Company’s developments in the third quarter have been marked by important achievements in our expanding cell and exosome-based platforms. We continue to progress with the development of our late-stage clinical asset, CAP-1002, for the treatment of advanced stages of Duchenne muscular dystrophy (DMD). I am pleased to share that our planned Phase 3, pivotal study, known as HOPE-3, has been cleared by the FDA to proceed. Our recently announced final HOPE-2 data showed statistically significant evidence of CAP-1002’s ability to improve both skeletal and cardiac function in patients with DMD. We are initiating start-up activities in anticipation of beginning this pivotal study as we continue to evaluate the best path forward to bring this therapeutic to patients as quickly as possible,” said Linda Marbán, Ph.D., Capricor’s chief executive officer. “Additionally, now that we have completed enrollment in our INSPIRE Phase 2 trial, we look forward to sharing these data when available. This study is designed to assess the ability of CAP-1002 to modulate the cytokine storm and attenuate the sequelae associated with severe COVID-19.”

Dr. Marbán continued, “We have now completed the expansion of our research and development headquarters to San Diego and our exosomes platform team continues to cultivate new pipeline opportunities which we will present in greater detail next year. Our goal for this platform is focused on becoming a leading exosome-RNA company and our work in the development of a vaccine for SARS-CoV-2 lays the groundwork for the future development of exosome-based vaccines and therapeutics,

with the ultimate goal of generating formulations of targeted engineered exosomes to potentially prevent and treat human diseases.”

Third Quarter 2021 Highlights and Recent Corporate Developments:

- Cleared to proceed with our pivotal Phase 3 study, known as HOPE-3, a Phase 3 trial of approximately 70 later-stage DMD patients
 - The HOPE-3 trial is a randomized, double-blind, placebo-controlled study to be conducted at approximately 20 sites across the United States
 - The National Principal Investigator will be Dr. Craig McDonald, professor and chair of the Department of Physical Medicine and Rehabilitation at UC Davis
- Completed enrollment of INSPRIRE, a Phase 2 study randomizing 63 subjects from several clinical sites across the US
- Announced positive final data from the HOPE-2 trial in patients with Duchenne muscular dystrophy who were treated with CAP-1002. The trial met its primary efficacy endpoint of mid-PUL v1.2 as well as various skeletal and cardiac endpoints suggesting clinically relevant slowing of disease progression.
 - Primary efficacy endpoint of mid-level Performance of Upper Limb (PUL) v1.2 (p=0.01)
 - Additional positive endpoints of full PUL v2.0 (p=0.04) and cardiac endpoint of ejection fraction (p=0.002)
 - One-year results demonstrated CAP-1002 slowed decline by 71% (mid-level PUL v1.2)
- Opened new research and development headquarters in San Diego, California focused on both our cell and exosome-based platform expansion in multiple disease areas
- Published preclinical data in the Journal of Biological Chemistry demonstrating our potential vaccine candidate employs a novel exosome-based mRNA delivery platform that induces long-lasting immunity to multiple SARS-COV-2 proteins
- Announced a publication in conjunction with the US Army Institute of Surgical Research for cardiosphere-derived exosomes as a potential therapeutic for shock
- Appointed Dr. Kristi Elliot as Vice President of Research and Development to lead expansion efforts for our exosome-based platform
- Appointed Karimah Es Sabar to our Board of Directors
 - Ms. Es Sabar brings over 35 years of biopharma leadership, drug development, venture investing and transactional experience to Capricor’s Board. She has extensive work experience and knowledge in the biotech space, specifically in vaccine and pharmaceutical development as well as in the financial industry

Financial Results for Third Quarter 2021

The Company reported a net loss of approximately \$3.9 million, or \$0.17 per share, for the three months ended September 30, 2021, compared to a net loss of approximately \$3.9 million, or \$0.20 per share, for the three months ended September 30, 2020.

Operating expenses: Total operating expenses for the three months ended September 30, 2021, were approximately \$4.3 million compared with approximately \$3.9 million for the three months ended September 30, 2020.

The Company’s cash and cash equivalents balance totaled approximately \$40.8 million as of September 30, 2021, compared to approximately \$32.7 million on December 31, 2020. Additionally, in the third quarter of 2021, Capricor raised approximately \$6.6 million in net proceeds through issuances of common stock at an average price of approximately \$5.92 per share under its at-the-market offering program.

Based on our current pipeline and operating plan, the Company’s cash position is expected to be sufficient to support operations for at least two years.

Conference Call: Tuesday, November 9, 2021 at 4:30 p.m. ET

Domestic: 877-451-6152
International: 201-389-0879
Conference ID: 13724013
Webcast: <https://78449.themediaframe.com/dataconf/productusers/vvdb/mediaframe/46931/index1.html>

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) is a biotechnology company focused on developing transformative cell- and exosome-based therapeutics and vaccines for treating and preventing a broad spectrum of diseases. Capricor's lead candidate, CAP-1002, is an allogeneic cardiac-derived cell therapy that is currently in clinical development for treating Duchenne muscular dystrophy and the cytokine storm associated with COVID-19. Capricor is also developing its exosome technology as a next-generation therapeutic platform. The Company's current focus is on developing exosomes loaded with nucleic acids, including mRNA, to treat or prevent a variety of diseases.

For more information, visit www.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; 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, 2020, as filed with the Securities and Exchange Commission on March 15, 2021, and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 as filed with the Securities and Exchange Commission on August 13, 2021. 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 September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
REVENUE				
Revenue	\$ —	\$ 16,863	\$ 244,898	\$ 252,420
TOTAL REVENUE	—	16,863	244,898	252,420
OPERATING EXPENSES				
Research and development	2,513,915	2,629,267	9,307,512	5,711,896
General and administrative	1,800,630	1,301,673	5,496,186	4,049,955
TOTAL OPERATING EXPENSES	4,314,545	3,930,940	14,803,698	9,761,851
LOSS FROM OPERATIONS	(4,314,545)	(3,914,077)	(14,558,800)	(9,509,431)
OTHER INCOME (EXPENSE)				
Other income	367,168	—	367,168	—
Investment income	15,570	3,953	41,476	30,335
Forgiveness of debt	—	—	318,160	—
TOTAL OTHER INCOME (EXPENSE)	382,738	3,953	726,804	30,335
NET LOSS	(3,931,807)	(3,910,124)	(13,831,996)	(9,479,096)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain on marketable securities	—	—	—	757
COMPREHENSIVE LOSS	\$ (3,931,807)	\$ (3,910,124)	\$ (13,831,996)	\$ (9,478,339)
Net loss per share, basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.20)</u>	<u>\$ (0.61)</u>	<u>\$ (0.68)</u>
Weighted average number of shares, basic and diluted	<u>23,095,375</u>	<u>19,801,841</u>	<u>22,731,638</u>	<u>13,958,507</u>

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	September 30, 2021 (unaudited)	December 31, 2020
Cash and cash equivalents	\$ 40,839,158	\$ 32,665,874
Total assets	\$ 43,100,521	\$ 34,618,796
Total liabilities	\$ 6,364,551	\$ 6,419,012
Total stockholders' equity - 24,149,155 and 20,577,123 common shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	36,735,970	28,199,784
Total liabilities and stockholders' equity	<u>\$ 43,100,521</u>	<u>\$ 34,618,796</u>