
**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)

March 10, 2022

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)

(310) 358-3200
(Registrant's telephone number, including area code)

8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211
(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 March 10, 2022, Capricor Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the quarter and full year ended December 31, 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 Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update”, dated March 10, 2022.](#)

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: March 10, 2022

CAPRICOR THERAPEUTICS, INC.

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

Capricor Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

CAP-1002 Cell Therapy Programs

- Pivotal Phase 3, HOPE-3 Trial Initiation Underway-
- Entered Exclusive Partnership with Nippon Shinyaku for Commercialization and Distribution of CAP-1002 for Duchenne Muscular Dystrophy in United States-
- Capricor to Receive Upfront Payment of \$30 Million with Additional Milestone Payments of up to \$705 Million-
- Phase 2 INSPIRE Top-Line Data Expected by End of First Quarter of 2022-

Engineered Exosomes Platform

- Pipeline Expansion Underway Using Engineered Exosomes-
- Expansion of Senior Leadership Team and Research Facilities in San Diego, California-

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

SAN DIEGO, Calif., March 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 a broad spectrum of diseases, announced today its financial results for the fourth quarter and full year 2021 and provided a corporate update.

"In 2021, Capricor made significant progress on our late-stage cell therapy program for Duchenne muscular dystrophy (DMD) and COVID-19 as well as the continued expansion of our exosomes platform. We recently announced an exclusive partnership with Nippon Shinyaku for the commercialization and distribution of CAP-1002 for DMD in the United States. HOPE-3, the Phase 3 clinical trial that will be supported by this partnership, will commence shortly and is expected to be the pivotal trial for CAP-1002 in DMD. In 2021, we completed our Phase 2, HOPE-2 clinical trial, achieving positive outcomes for critical study endpoints in a population that was in the late stages of the disease process and largely non-ambulant with few therapeutic options. Across the study population, the treatment reduced the rate at which upper limb function declined and also improved cardiac function. It is important to understand the real differences this treatment can potentially make in patients' lives. We are hopeful that CAP-1002 can improve the trajectory of DMD and will share further updates on this program as they become available," said Linda Marbán, Ph.D., Capricor's chief executive officer.

Dr. Marbán continued, "In another important development, we completed enrollment of our Phase 2, INSPIRE clinical study using CAP-1002 to treat severe COVID-19 patients and plan to have top-line data available by the end of this quarter."

"Turning to our exosomes program, at this time, based on the current availability of vaccines for COVID-19, we have decided to hold off on further development of our exosome-mRNA vaccine. However, the power of exosomes as nature's drug delivery system motivates us to becoming a leading exosomes company. To that end, we are currently focused on the expansion of our platform of exosome-based therapeutics and vaccines. Finally, we have completed the expansion of our corporate and research headquarters to San Diego where we are building a world-class management team to continue the development of CAP-1002 and our exosome platform," added Dr. Marbán.

Full Year 2021 Highlights and Recent Operational Developments

CAP-1002 Cell Therapy Programs

CAP-1002 for Duchenne Muscular Dystrophy

- Announced additional funding for our HOPE-3 trial (\$30M upfront payment with potential for additional milestone payments of up to \$705M) secured through a new partnership for the exclusive
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commercialization and distribution of CAP-1002, with Nippon Shinyaku Co., Ltd. – a Japanese pharmaceutical company with expertise in DMD and orphan diseases (January 2022)

- Announced FDA clearance for our HOPE-3 Phase 3 clinical trial, which is aiming to enroll approximately 70 patients in a randomized, double-blind, placebo-controlled study across approximately 20-30 sites in the United States (November 2021)
- Announced positive final data from our Phase 2 HOPE-2 clinical trial in patients with advanced stages of DMD (September 2021)

CAP-1002 for COVID-19

- Completed the enrollment for our Phase 2 INSPIRE clinical trial, a randomized, double-blind, placebo-controlled study with 63 patients randomized in the United States (November 2021)
- Top-line data from INSPIRE expected in the first quarter of 2022

Engineered Exosomes Platform

- Announced positive preclinical data describing Capricor's multivalent exosome mRNA vaccine for SARS-CoV-2's capacity to elicit a strong T-cell and antibody response with potential for long-term, multivariant protection (December 2021)
- Announced preclinical data demonstrating Capricor's cardiosphere-derived exosome product as an antishock therapeutic (August 2021)
- Signed exclusive, worldwide licensing agreement with Johns Hopkins University to include engineered exosomes for vaccines and therapeutics as part of the Capricor's exosome technology portfolio (April 2021)
- Announced new advances in exosome-mediated mRNA delivery platform (March 2021)

Corporate Developments

- Announced relocation of corporate and research headquarters to San Diego, California, focused on both our cell and exosome-based platform expansion in multiple disease areas
- Appointed Dr. Daniel Paulson as Vice President of Clinical Development to lead Capricor's clinical programs
- Appointed Yasmine Shad as Vice President of Quality to oversee quality for Capricor's product pipeline
- Appointed Dr. Kristi Elliott 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 bringing over 35 years of biopharma leadership, drug development, venture investing and transactional experience to Capricor's Board

Fourth Quarter and Full Year 2021 Financial Results

The Company reported a net loss of approximately \$6.2 million, or \$0.26 per share, for the fourth quarter of 2021, compared to a net loss of approximately \$4.2 million, or \$0.21 per share, for the fourth quarter of 2020. For the year ended December 31, 2021, the Company reported a net loss of approximately \$20.0 million, or \$0.87 per share, compared to a net loss of approximately \$13.7 million, or \$0.88 per share, for the year ended December 31, 2020.

Operating expenses: Total operating expenses for the fourth quarter of 2021, were approximately \$6.4 million compared with approximately \$4.2 million for the fourth quarter of 2020.

The Company's cash and cash equivalents totaled approximately \$34.9 million as of December 31, 2021, compared to approximately \$32.7 million on December 31, 2020. The Company's cash balance as of December 31, 2021 does not include the expected \$30.0 million upfront payment from Nippon Shinyaku. Additionally, in the fourth quarter of 2021, Capricor issued no shares of common stock under its at-the-market offering program.

Financial Outlook

Capricor believes that based on the current operating plan and financial resources, the Company expects that the cash and cash equivalents will be sufficient to cover expenses and capital requirements for at least two years.



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: 8000939. 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) 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 capable of delivering nucleic acids, including mRNA as well as proteins, 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; 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, 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 September 30, 2021 as filed with the Securities and Exchange Commission on November 12, 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.

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CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

	Three months ended December 31,		Year ended December 31,	
	2021	2020	2021	2020
REVENUE				
Revenue	\$ —	\$ 57,830	\$ 244,898	\$ 310,250
TOTAL REVENUE	—	57,830	244,898	310,250
OPERATING EXPENSES				
Research and development	4,263,533	2,745,104	13,571,045	8,457,000
General and administrative	2,116,109	1,493,266	7,612,295	5,543,221
TOTAL OPERATING EXPENSES	6,379,642	4,238,370	21,183,340	14,000,221
LOSS FROM OPERATIONS	(6,379,642)	(4,180,540)	(20,938,442)	(13,689,971)
OTHER INCOME (EXPENSE)				
Other income	181,039	—	548,207	—
Investment income	15,984	2,608	57,460	32,943
Forgiveness of debt	—	—	318,160	—
Loss on disposal of fixed assets	(7,905)	—	(7,905)	—
TOTAL OTHER INCOME (EXPENSE)	189,118	2,608	915,922	32,943
NET LOSS	(6,190,524)	(4,177,932)	(20,022,520)	(13,657,028)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain on marketable securities	—	—	—	757
COMPREHENSIVE LOSS	\$ (6,190,524)	\$ (4,177,932)	\$ (20,022,520)	\$ (13,656,271)
Net loss per share, basic and diluted	\$ (0.26)	\$ (0.21)	\$ (0.87)	\$ (0.88)
Weighted average number of shares, basic and diluted	24,150,714	20,373,647	23,089,323	15,571,056



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

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
Cash and cash equivalents	\$ 34,885,274	\$ 32,665,874
Total assets	<u>\$ 41,330,323</u>	<u>\$ 34,618,796</u>
Total liabilities	\$ 9,962,357	\$ 6,419,012
Total stockholders' equity - 24,185,001 and 20,577,123 common shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	31,367,966	28,199,784
Total liabilities and stockholders' equity	<u>\$ 41,330,323</u>	<u>\$ 34,618,796</u>
