

**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)

May 13, 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:

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 May 13, 2021, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended March 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 Securities Act of 1933, as amended, or 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 First Quarter 2021 Financial Results and Provides Corporate Update", dated May 13 2021.](#)

---

**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: May 13, 2021

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

---

## Capricor Therapeutics Reports First Quarter 2021 Financial Results and Provides Corporate Update

--

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

-Data for Phase II INSPIRE Clinical Trial Expected in Third Quarter-

-Plan to File IND for Multivalent Exosome-mRNA Vaccine for SARS-CoV-2 in Third Quarter-

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

--

**LOS ANGELES, CA** May 13, 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 first quarter ended March 31, 2021, and provided an overview of its recent operational highlights. Management will host a webcast and conference call at 4:30 p.m. today after market.

“In the first quarter, we made significant progress across our clinical and preclinical programs. Most notably, we recently executed an exclusive, worldwide licensing agreement with Johns Hopkins University which allows Capricor to continue the expansion of our engineered exosome platform technology,” said Linda Marbán, Ph.D., CEO, Capricor Therapeutics. In parallel, we have several ongoing high-level discussions with potential collaborators as well as the FDA to evaluate all potential paths towards commercialization of our DMD program. While this evaluation is ongoing, we are encouraged by the continued interest and we look forward to updating investors in the quarter ahead. Lastly, we continue to make progress in enrollment of our INSPIRE clinical trial treating severe COVID-19 patients and look forward to sharing top-line data in the third quarter.”

Dr. Marbán continued, “Capricor has worked diligently to build our exosome platform to deliver biologics, primarily nucleic acids. We have launched our platform which will include vaccines, treatment of monogenic diseases, as well as other targets. We are excited to continue the expansion of our RNA-exosome platform into other therapeutic indications where delivery has proved challenging and look forward to sharing more updates as we move through 2021.”

### First Quarter 2021 Highlights and Recent Corporate Developments:

- Announced manufacturing collaboration with Lonza for the development of CAP-1002 for the treatment of Duchenne muscular dystrophy and other indications
- Signed an exclusive, worldwide licensing agreement with Johns Hopkins University (JHU) to include engineered exosomes for vaccines and therapeutics as part of the Company’s exosome technology portfolio
- Initiated IND-enabling studies for exosome-mRNA multivalent SARS-CoV-2 vaccine
- Published manuscript highlighting methods for enhanced potency of cardiosphere-derived exosomes
- Published manuscript highlighting new advances in exosome-mediated mRNA delivery platform
- Granted non-exclusive license from JHU to serology test to confirm activity of SARS-CoV-2 vaccines
- Presented at the American Society of Gene and Cell Therapy’s (ASGCT) 24<sup>th</sup> annual meeting

### Anticipated Milestones and Events

- Plan to present abstract on SARS-CoV-2 vaccination delivery at the International Society for Extracellular Vesicles (ISEV) 2021 Annual Meeting
- Plan to present at annual PPMD meeting in June 2021
- Requested to meet with FDA to discuss next steps on pathway to approval of CAP-1002 for DMD, plan to announce next steps in the third quarter 2021
- Plan to file an IND for exosome-mRNA vaccine product candidate for SARS-CoV-2, subject to regulatory approval in the third quarter 2021
- Plan to announce top-line data from INSPIRE study in the third quarter 2021
- Plan to publish additional preclinical data on cell and exosomes programs

### Financial Results for First Quarter 2021

The Company reported a net loss of approximately \$5.2 million, or \$0.23 per share, for the first quarter of 2021, compared to a net loss of approximately \$2.1 million, or \$0.30 per share, for the first quarter of 2020.

As of March 31, 2021, the Company’s cash and cash equivalents totaled approximately \$41.9 million, compared to approximately \$32.7 million on December 31, 2020. Additionally, in the first quarter of 2021, Capricor raised approximately \$12.6 million in net proceeds through issuances of common stock at an average price of approximately \$5.85 per share 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, cash equivalents and marketable securities will be sufficient to cover expenses and capital requirements through at least the second quarter of 2023.

### Conference Call and Webcast

To participate in the conference call, please dial 877-451-6152 (Domestic/Toll-Free) or 201-389-0879 (International) and reference the conference ID: 13719513. To participate via a webcast, please visit: <http://public.viavid.com/index.php?id=144798>

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 the development of transformative cell- and exosome-based therapeutics and vaccines for the treatment and prevention of 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 the treatment of Duchenne muscular dystrophy and the cytokine storm associated with COVID-19. Capricor is also developing our exosomes platform technology as a next-generation therapeutic platform. Our current focus is on the development of exosomes loaded with nucleic acids, including mRNA, to treat or prevent a variety of diseases. For more information, visit [www.capricor.com](http://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. 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:

#### Media Contact:

Caitlin Kasunich / Raquel Cona  
KCSA Strategic Communications  
[ckasunich@kcsa.com](mailto:ckasunich@kcsa.com) / [rcona@kcsa.com](mailto:rcona@kcsa.com)  
212.896.1241 / 212.896.1204

#### Investor Contact:

Joyce Allaire  
LifeSci Advisors, LLC  
[jallaire@lifesciadvisors.com](mailto:jallaire@lifesciadvisors.com)  
617.435.6602

#### Company Contact:

AJ Bergmann, Chief Financial Officer  
[abergmann@capricor.com](mailto:abergmann@capricor.com)  
310.358.3200

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

	Three months ended March 31,	
	2021	2020
<b>REVENUE</b>		
Revenue	\$ 40,816	\$ 185,693
<b>TOTAL REVENUE</b>	<b>40,816</b>	<b>185,693</b>
<b>OPERATING EXPENSES</b>		
Research and development	3,296,322	1,155,156
General and administrative	1,905,582	1,138,045
<b>TOTAL OPERATING EXPENSES</b>	<b>5,201,904</b>	<b>2,293,201</b>
<b>LOSS FROM OPERATIONS</b>	<b>(5,161,088)</b>	<b>(2,107,508)</b>
<b>OTHER INCOME (EXPENSE)</b>		
Investment income	9,165	22,690
<b>TOTAL OTHER INCOME (EXPENSE)</b>	<b>9,165</b>	<b>22,690</b>
<b>NET LOSS</b>	<b>(5,151,923)</b>	<b>(2,084,818)</b>
<b>OTHER COMPREHENSIVE INCOME (LOSS)</b>		
Net unrealized gain on marketable securities	—	757
<b>COMPREHENSIVE LOSS</b>	<b>\$ (5,151,923)</b>	<b>\$ (2,084,061)</b>
Net loss per share, basic and diluted	\$ (0.23)	\$ (0.30)
Weighted average number of shares, basic and diluted	22,228,723	6,878,782

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

	March 31, 2021 (unaudited)	December 31, 2020
Cash and cash equivalents	\$ 41,879,554	\$ 32,665,874
Total assets	<u>\$ 43,544,401</u>	<u>\$ 34,618,796</u>
Total liabilities	<u>\$ 7,163,616</u>	<u>\$ 6,419,012</u>
Total stockholders' equity - 22,797,930 and 20,577,123 common shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	36,380,785	28,199,784
Total liabilities and stockholders' equity	<u>\$ 43,544,401</u>	<u>\$ 34,618,796</u>

---