
**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 12, 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 August 12, 2021, Capricor Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the quarter ended June 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 Second Quarter 2021 Financial Results and Provides Corporate Update”, dated August 12, 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.

Date: August 12, 2021

CAPRICOR THERAPEUTICS, INC.

By: /s/ Linda Marbán, Ph.D.

Linda Marbán, Ph.D.

Chief Executive Officer

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

CAP-1002 – Capricor’s Cell Therapy Program for Duchenne Muscular Dystrophy

- Phase III Trial Protocol Submitted to FDA Following FDA Guidance-
- Commencing Start-Up Activities for Pivotal Trial-
- Phase II, HOPE-2 Final Data Submitted for Publication-

CAP-1002 – Capricor’s Cell Therapy Program for COVID-19

- Phase II INSPIRE Trial Enrollment Nearing Completion-

Capricor’s Exosomes Platform Technology

- Positioning Multivalent Exosome-mRNA Vaccine as Booster to Currently Available Vaccines-
- Completing Non-Clinical Studies for IND Submission-

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

LOS ANGELES, CA Aug. 12, 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 second quarter ended June 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.

“This has been a productive quarter for Capricor and I am pleased to report our progress across the organization as we have a busy back half of 2021 planned. We now have a clear path forward with CAP-1002 for DMD as we prepare to initiate a pivotal study later this year. The final data has been submitted for publication which shows that CAP-1002 has a significant impact on skeletal and cardiac muscle function in late-stage DMD patients, which we believe will further support the clinical path to potential approval. The positive momentum of this program has continued to advance our partnering discussions. Additionally, we have made progress in our exosome program, by expanding our team with seasoned biotechnology leaders who bring a wealth of experience in engineering exosomes for therapeutic use. We are now moving our multivalent exosome-mRNA vaccine towards the clinic designed, to be a booster to currently available vaccines. We believe that this multiple protein approach could potentially confer greater immune protection against variants of SARS-CoV-2,” said Linda Marbán, Ph.D., Capricor’s chief executive officer. Lastly, we have seen enrollment of our INSPIRE clinical trial for treating severe COVID-

19 patients increase with the emerging prevalence of the Delta variant and we look forward to sharing top-line data in the near future.”

Second Quarter 2021 Highlights and Recent Corporate Developments:

- Completed an end-of-phase-II meeting with FDA and planning to move forward with start-up activities for a Phase III pivotal trial for CAP-1002 for the treatment of DMD.
- Completed GLP toxicology study and are nearing completion of IND-enabling studies for multivalent exosome-mRNA vaccine candidate.
- Presented preliminary findings from HOPE-2 open-label extension study in DMD at Parent Project Muscular Dystrophy (PPMD) 2021 Virtual Annual Conference.
 - Presented comparative video of clinical subject improvement in patient that received CAP-1002.
- Signed exclusive, worldwide licensing agreement with Johns Hopkins University to include engineered exosomes for vaccines and therapeutics as part of the Company’s exosome technology portfolio.
- Appointed Karimah Es Sabar to its 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 from biotech, specifically in the vaccine space as well as pharmaceuticals and the financial industry.
- Publication in conjunction with the US Army Institute of Surgical Research for Cardiosphere Derived Exosomes as a Potential Therapeutic for Shock.
 - The preclinical data demonstrates Capricor’s exosome product as an antishock therapeutic, if delivered early. This further supports Capricor’s exosome platform advancement.
- Presented preclinical data for multivalent exosome-mRNA vaccine for SARS-CoV-2 at the International Society for Extracellular Vesicles (ISEV) Annual Meeting.
 - The data demonstrated that Capricor’s exosome-based, multivalent mRNA vaccine elicited long-lasting cellular and humoral responses to both the N and S proteins. The data further supports new, tailored and targeted therapeutic approaches to a variety of diseases and disorders.
- Presented at the American Society of Gene and Cell Therapy’s (ASGCT) 24th annual meeting.

Financial Results for Second Quarter 2021

Revenues in conjunction with collaborations and grants: Capricor’s primary sources of revenues were from collaborative payments received from clinical trial arrangements and grant awards. For the three months ended June 30, 2021, the Company reported revenue of approximately \$200,000 compared with approximately \$50,000 for the three months ended June 30, 2020.

Operating expenses: Total operating expenses for the three months ended June 30, 2021, were approximately \$5.3 million compared with approximately \$3.5 million for the three months ended June 30, 2020.

The Company reported a net loss of approximately \$4.7 million, or \$0.21 per share, for the three months ended June 30, 2021, compared to a net loss of approximately \$3.5 million, or \$0.23 per share, for the three months ended June 30, 2020.

The Company’s cash and cash equivalents balance totaled approximately \$38.1 million as of June 30, 2021, compared to approximately \$32.7 million on December 31, 2020. Additionally, in the second quarter of 2021, Capricor raised approximately \$1.0 million in net proceeds through issuances of common stock at an average price of approximately \$5.41 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: Thursday, August 12, 2021 at 4:30 p.m. ET

Domestic: 866-269-4264
International: 929-477-0577
Conference ID: 1169561
Webcast: <http://public.viavid.com/index.php?id=146080>

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 March 31, 2021 as filed with the Securities and Exchange Commission on May 14, 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 June 30,		Six months ended June 30,	
	2021	2020	2021	2020
REVENUE				
Revenue	\$ 204,082	\$ 49,864	\$ 244,898	\$ 235,557
TOTAL REVENUE	204,082	49,864	244,898	235,557
OPERATING EXPENSES				
Research and development	3,497,275	1,927,473	6,793,597	3,082,629
General and administrative	1,789,974	1,610,237	3,695,556	2,748,282
TOTAL OPERATING EXPENSES	5,287,249	3,537,710	10,489,153	5,830,911
LOSS FROM OPERATIONS	(5,083,167)	(3,487,846)	(10,244,255)	(5,595,354)
OTHER INCOME (EXPENSE)				
Investment income	16,741	3,692	25,906	26,382
Forgiveness of debt	318,160	—	318,160	—
TOTAL OTHER INCOME (EXPENSE)	334,901	3,692	344,066	26,382
NET LOSS	(4,748,266)	(3,484,154)	(9,900,189)	(5,568,972)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain on marketable securities	—	—	—	757
COMPREHENSIVE LOSS	\$ (4,748,266)	\$ (3,484,154)	\$ (9,900,189)	\$ (5,568,215)
Net loss per share, basic and diluted	\$ (0.21)	\$ (0.23)	\$ (0.44)	\$ (0.51)
Weighted average number of shares, basic and diluted	22,861,051	15,130,685	22,546,634	11,004,733

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	June 30, 2021 (unaudited)	December 31, 2020
Cash and cash equivalents	\$ 38,077,964	\$ 32,665,874
Total assets	\$ 39,930,052	\$ 34,618,796
Total liabilities	\$ 6,549,922	\$ 6,419,012
Total stockholders' equity - 22,998,434 and 20,577,123 common shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	33,380,130	28,199,784
Total liabilities and stockholders' equity	\$ 39,930,052	\$ 34,618,796