

August 12, 2021



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, Aug. 12, 2021 (GLOBE NEWSWIRE) -- [Capricor Therapeutics](https://www.capricortherapeutics.com) (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.

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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	<u>1,789,974</u>	<u>1,610,237</u>	<u>3,695,556</u>	<u>2,748,282</u>
TOTAL OPERATING EXPENSES	<u>5,287,249</u>	<u>3,537,710</u>	<u>10,489,153</u>	<u>5,830,911</u>
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	<u>318,160</u>	<u>—</u>	<u>318,160</u>	<u>—</u>
TOTAL OTHER INCOME (EXPENSE)	<u>334,901</u>	<u>3,692</u>	<u>344,066</u>	<u>26,382</u>
NET LOSS	<u>(4,748,266)</u>	<u>(3,484,154)</u>	<u>(9,900,189)</u>	<u>(5,568,972)</u>
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain on marketable securities	<u>—</u>	<u>—</u>	<u>—</u>	<u>757</u>
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, cash equivalents	<u>\$ 38,077,964</u>	<u>\$ 32,665,874</u>
Total assets	<u>\$ 39,930,052</u>	<u>\$ 34,618,796</u>
	<u>\$ 6,549,922</u>	<u>\$ 6,419,012</u>
Total liabilities		

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	<u>\$ 39,930,052</u>	<u>\$ 34,618,796</u>



Source: Capricor Therapeutics