May 10, 2022

Capricor Therapeutics Reports First Quarter 2022 Financial Results and Provides Corporate Update

-Executed Partnership with Nippon Shinyaku for the Commercialization and Distribution of CAP-1002 for Duchenne Muscular Dystrophy in the United States-

-Upfront Payment of $30 Million Received in 1st Quarter Strengthens Cash Position and Extends Cash Runway-

-Positive Phase 2 Results Published in The Lancet Evaluating CAP-1002 in Late-Stage Duchenne Muscular Dystrophy-

-Pivotal Phase 3 Trial Expecting to Begin Enrolling Patients this Quarter-

-Pipeline Expansion Underway Using Engineered Exosomes-

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

SAN DIEGO, May 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 first quarter ended March 31, 2022 and provided a corporate update.

“I am proud of Capricor’s achievements this quarter as we delivered on our goal to secure a distribution and commercial partner for our Duchenne muscular dystrophy (DMD) program. This partnership with Nippon Shinyaku brought with it an upfront payment of $30 million and potentially includes up to $705 million additional milestone payments. We have now completed two successful clinical trials in DMD as we enter our Phase 3 pivotal study, HOPE-3. Publishing the results of HOPE-2 in The Lancet provides validation of the use of CAP-1002 to treat DMD. The published results showed statistically significant and clinically relevant evidence of CAP-1002’s ability to improve both skeletal and cardiac muscle function in patients in the latter stages of the disease. We have active sites that are currently screening patients for our Phase 3, HOPE-3 clinical trial and expect to enroll our first patient this quarter,” said Linda Marbán, Ph.D., Capricor’s chief executive officer.

Dr. Marbán continued, “We have assembled a world-class team in product development, manufacturing and clinical operations. This team, supported by our strong balance sheet, will enable us to deliver on our milestones while we continue to remain capital efficient as we drive CAP-1002 towards potential commercialization. Additionally, we continue to make progress with our engineered exosomes platform as we have invested internally in

developing a scaled-up manufacturing paradigm that we believe will support clinical development as well as future potential partnering opportunities. We look forward to sharing further updates later this year."

First Quarter Highlights and Recent Operational Developments

- Announced additional funding for our Phase 3, HOPE-3 trial ($30M upfront payment with potential for additional milestone payments of up to $705M) secured through a partnership for the exclusive commercialization and distribution of CAP-1002 in the United States, with Nippon Shinyaku Co., Ltd. – a Japanese pharmaceutical company with expertise in DMD and orphan diseases
- *The Lancet* published positive results from our Phase 2, HOPE-2 trial evaluating CAP-1002 in late-stage Duchenne muscular dystrophy (Publication Link Here)
    - Publication highlighted one-year final data for safety and efficacy in slowing upper limb and cardiac function deterioration
- Phase 3, HOPE-3 trial preparations ongoing and plan to enroll approximately 70 patients in a randomized, double-blind, placebo-controlled study across approximately 20-30 sites in the United States
- Appointed Dr. Daniel Paulson as Vice President of Clinical Development to lead Capricor's clinical programs

Anticipated Milestones and Events

- First patient dosed in pivotal Phase 3 HOPE-3 trial expected in Q2 2022
- Presentation at the PPMD Annual Conference, June 23-26 (Scottsdale, Arizona)
- Publication of additional preclinical work related to our engineered exosomes platform

Financial Results for First Quarter 2022

The Company reported a net loss of approximately $7.8 million, or $0.32 per share, for the first quarter of 2022, compared to a net loss of approximately $5.2 million, or $0.23 per share, for the first quarter of 2021.

As of March 31, 2022, the Company's cash and cash equivalents totaled approximately $58.3 million, compared to approximately $34.9 million on December 31, 2021. No shares were sold under the Company's at-the-market program in the first quarter of 2022.

Financial Outlook

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

Conference Call and Webcast

To participate in the conference call, please dial 888-256-1007 (Domestic/Toll-Free) or 929-477-0448 (International) and reference the conference ID: 3332017. 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. 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, 2021, as filed with the Securities and Exchange Commission on March 11, 2022. 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:

Capricor Media Contact:
Raquel Cona
KCSA Strategic Communications
rcona@kcsa.com
212.896.1204

Capricor Investor Contact:
Joyce Allaire
LifeSci Advisors, LLC

jallaire@lifesciadvisors.com
617.435.6602

Capricor Company Contact:
AJ Bergmann, Chief Financial Officer
abergmann@capricor.com
310.358.3200

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

	Three months ended March 31,	
	2022	2021
REVENUE		
Revenue	$ —	$ 40,816
TOTAL REVENUE	—	40,816
OPERATING EXPENSES		
Research and development	5,115,699	3,296,322
General and administrative	2,715,835	1,905,582
TOTAL OPERATING EXPENSES	7,831,534	5,201,904
LOSS FROM OPERATIONS	(7,831,534)	(5,161,088)
OTHER INCOME (EXPENSE)		
Investment income	13,440	9,165
TOTAL OTHER INCOME (EXPENSE)	13,440	9,165
NET LOSS	$ (7,818,094)	$ (5,151,923)
Net loss per share, basic and diluted	$ (0.32)	$ (0.23)
Weighted average number of shares, basic and diluted	24,282,743	22,228,723

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	March 31, 2022 (unaudited)	December 31, 2021
Cash and cash equivalents	$ 58,333,945	$ 34,885,274
Total assets	$ 64,921,918	$ 41,330,323
Total liabilities	$ 40,279,252	$ 9,962,357
Total stockholders' equity - 24,324,156 and 24,185,001 common shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	24,642,666	31,367,966
Total liabilities and stockholders' equity	$ 64,921,918	$ 41,330,323

Source: Capricor Therapeutics