March 15, 2023

Capricor Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

-Enrollment Continues to Progress in HOPE-3, the Phase 3 Clinical Trial of CAP-1002 in Duchenne Muscular Dystrophy (DMD); Plan to Report on Interim Analysis in Q4 2023-

-Held Type-B CMC Meeting with U.S. Food and Drug Administration (FDA) Regarding Pathway Towards Biologics License Application (BLA) for CAP-1002 in DMD-

-Expanded Partnership with Nippon Shinyaku to Japan to Leverage Commercial DMD Franchise with $12 Million Upfront and Additional Potential Milestone Payments of up to $89 Million-

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

SAN DIEGO, March 15, 2023 (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 muscular and other select diseases, announced today its financial results for the fourth quarter and full year ended December 31, 2022 and provided a corporate update.

“In 2022, we continued to advance our clinical development program for CAP-1002 in patients with Duchenne Muscular Dystrophy (DMD), highlighted by the initiation of our HOPE-3 Phase 3 trial and are well positioned to deliver on multiple value-driving milestones throughout 2023,” said Linda Marbán, Ph.D., Capricor’s chief executive officer. “As CAP-1002 continues to advance towards potential commercialization, we recently met with the FDA in a Type-B CMC meeting and discussed our manufacturing plans in anticipation of a Biologics License Application (BLA). We are pleased that the FDA continues to work with us under our RMAT designation and we will provide further updates on our plans as they become available. Furthermore, enrollment for HOPE-3 continues to progress and with patient dosing underway, we plan to report the results of our interim analysis in the fourth quarter of 2023. This trial builds on the recently presented statistically significant 18-month results from our ongoing HOPE-2 open label extension study (OLE), which further positions CAP-1002 as a potential anchor therapy for DMD. These results suggest that patients accumulate benefit over time with steady preservation of skeletal muscle functions, highlighting the potential disease modifying effect and long-term benefit of CAP-1002. They also contribute to the safety profile of the therapy. Further, we continue to explore opportunities for additional strategic partnerships outside of the United States and Japan to maximize the value of our asset and ensure rapid therapy availability to the global patient community.”

Dr. Marbán continued, “In parallel, we are pleased with the steady progress across our exosome program, designed to support the advancement of next generation vaccines and innovative therapeutics. We recently published preclinical data from our proprietary StealthX™ platform, which generated two vaccine candidates that induced a strong, long-lasting immune response against two SARS-CoV-2 proteins, spike and nucleocapsid. We look forward to exploring the potential therapeutic utility of these vaccine candidates, and more broadly, expanding our pipeline and partnership opportunities with this platform.”

Fourth Quarter 2022 and Recent Operational Developments

- HOPE-3, our Phase 3 clinical trial of CAP-1002 in DMD continues to progress well. The multi-center, randomized, double-blind, placebo-controlled study (NCT05126758) is designed to treat up to 68 subjects in the United States. At this time, we have treated over 30% of the patients in the currently designed study with 11 active sites.
- Met with the FDA in a Type-B CMC meeting to discuss our commercial planning in anticipation of a potential BLA submission. The meeting was very constructive and provides us with increased visibility on the expectations the FDA has for the HOPE-3 trial and commercial scale manufacturing of CAP-1002 in support of a future BLA.
- Entered into second agreement with Nippon Shinyaku Co., Ltd., for the exclusive commercialization and distribution in Japan of CAP-1002 for the treatment of DMD. This expands the exclusive Commercialization and Distribution Agreement entered into with Nippon Shinyaku in the United States in January 2022.
    - Under the terms of the agreement, Capricor will receive an upfront payment of $12 million and will potentially receive additional development and sales-based milestone payments of up to approximately $89 million and a meaningful, double-digit share of net product revenue.
- Reported positive 18-month and one-year results from ongoing HOPE-2 OLE study. 18-month data from the OLE study continue to suggest potential disease modification with statistically significant differences in the PUL v2.0 in the CAP-1002 original treatment group when compared to the original placebo group from HOPE-2 (p=0.02).
    - 18-month results were presented on a webinar hosted in conjunction with Parent Project Muscular Dystrophy (PPMD).
    - One-year results were featured in a poster presentation at the 2022 World Muscle Society Congress.
- The HOPE-2 study was named as a recipient of Clinical Research Forum’s 2023 Top Ten Clinical Research Achievement Award. The study was published in *The Lancet* in March 2022.
    - Clinical Research Forum’s Top Ten Clinical Research Achievement Awards honor outstanding accomplishments that exemplify significant advancements and impactful work being conducted by investigators from around the world.
- Published new preclinical data highlighting the therapeutic potential of Capricor’s proprietary StealthX™ exosome platform, which generated two vaccine candidates, that independently, and in combination induced a strong immune response against two SARS-CoV-2 proteins, spike and nucleocapsid.
    - The data from this study suggests that StealthX™ could potentially deliver a more potent vaccine with broader immunity by combining the advantages of both

mRNA and recombinant protein vaccines into a potentially superior, rapidly generated, low-dose vaccine.

Anticipated Milestones and Events

The Company has set forth the following guidance for pipeline progression:

- Continue discussions with FDA regarding pathway towards BLA for CAP-1002 in DMD
- Present 18-month HOPE-2 OLE results in a late-breaking session at the 2023 Muscular Dystrophy Association (MDA) Clinical and Scientific Conference being held in Dallas, Texas from March 19-22, 2023
- Plan to present 24-month follow-up data from HOPE-2 OLE in second quarter of 2023
- Plan to report interim analysis of HOPE-3 in fourth quarter of 2023

Fourth Quarter and Full Year 2022 Financial Results

Revenues: Capricor's primary source of revenue was from the ratable recognition of the $30.0 million upfront payment received from Nippon Shinyaku. Revenues for the fourth quarter of 2022 were approximately $1.0 million compared with zero for the fourth quarter of 2021.

Operating expenses: Total operating expenses for the fourth quarter of 2022 were approximately $9.0 million compared with approximately $6.4 million for the fourth quarter of 2021.

The Company reported a net loss of approximately $7.7 million, or $0.31 per share, for the fourth quarter of 2022, compared to a net loss of approximately $6.2 million, or $0.26 per share, for the fourth quarter of 2021. For the year ended December 31, 2022, the Company reported a net loss of approximately $29.0 million, or $1.18 per share, compared to a net loss of approximately $20.0 million, or $0.87 per share, for the year ended December 31, 2021.

The Company's cash, cash equivalents and marketable securities totaled approximately $41.4 million as of December 31, 2022 compared to approximately $34.9 million on December 31, 2021. Additionally, in the fourth quarter of 2022, Capricor raised approximately $3.0 million in gross proceeds through issuances of common stock at an average price of approximately $6.16 per share under its at-the-market offering program. Subsequent to December 31, 2022, no additional shares have been sold under the June 2021 ATM Program to date.

Financial Outlook

Capricor believes that based on the current operating plan and financial resources, its available cash, cash equivalents and marketable securities will be sufficient to cover anticipated expenses and capital requirements into the fourth quarter of 2024. This expectation includes the upfront payment of $12 million pursuant to our Japan distribution agreement which we expect to receive in the first quarter of 2023 and excludes any additional potential milestone payments under its exclusive commercialization and distribution agreements with Nippon Shinyaku as well as any strategic use of capital not

currently in the Company's base-case planning assumptions.

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: 13736398. To participate via a webcast, please click here. A replay of the webcast will be available following the conclusion of the live broadcast and will be accessible on the Company's website.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a biotechnology company focused on the development of transformative cell and exosome-based therapeutics for the treatment and prevention of muscular and other select diseases. Capricor's lead candidate, CAP-1002, is an allogeneic cardiac-derived cell therapy that is currently in late-stage clinical development for treating Duchenne muscular dystrophy. Capricor is also developing its exosome technology as a next-generation therapeutic platform. Capricor's 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 capricor.com, and follow Capricor 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; manufacturing capabilities; 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 and 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 and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 as filed with the Securities and Exchange Commission on November 10, 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 December 31,		Year ended December 31,	
	2022	2021	2022	2021
REVENUE				
Revenue	$ 959,903	$ -	$ 2,551,469	$ 244,898
TOTAL REVENUE	959,903	-	2,551,469	244,898
OPERATING EXPENSES				
Research and development	6,231,806	4,263,533	21,816,949	13,571,045
General and administrative	2,794,442	2,116,109	10,431,903	7,612,295
TOTAL OPERATING EXPENSES	9,026,248	6,379,642	32,248,852	21,183,340

LOSS FROM OPERATIONS	(8,066,345)	(6,379,642)	(29,697,383)	(20,938,442)
OTHER INCOME (EXPENSE)				
Other income	-	181,039	190,582	548,207
Investment income	379,699	15,984	521,535	57,460
Forgiveness of debt	-	-	-	318,160
Loss on disposal of fixed assets	(34,266)	(7,905)	(34,266)	(7,905)
TOTAL OTHER INCOME (EXPENSE)	345,433	189,118	677,851	915,922
NET LOSS	(7,720,912)	(6,190,524)	(29,019,532)	(20,022,520)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	(17,223)	-	105,244	-
COMPREHENSIVE LOSS	$ (7,738,135)	$ (6,190,524)	$(28,914,288)	$(20,022,520)
Net loss per share, basic and diluted	$ (0.31)	$ (0.26)	$ (1.18)	$ (0.87)
Weighted average number of shares, basic and diluted	25,163,711	24,150,714	24,552,688	23,089,323

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	December 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 41,421,262	$ 34,885,274
Total assets	$ 50,094,910	$ 41,330,323
Total liabilities	$ 38,308,816	$ 9,962,357
Total stockholders' equity - 25,241,402 and 24,185,001 common shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	11,786,094	31,367,966

Total liabilities and stockholders' equity	$ 50,094,910	$ 41,330,323

Source: Capricor Therapeutics