May 15, 2017

Capricor Therapeutics Reports First Quarter 2017 Financial Results and Provides Corporate Update

To Propose Registrational Strategy for Duchenne Muscular Dystrophy Indication to FDA

LOS ANGELES, May 15, 2017 /PRNewswire/ --Capricor Therapeutics, Inc. (NASDAQ: CAPR) today announced its financial results for the first quarter ended March 31, 2017 and provided an update on its business.

"Following our report in late April of positive results from our ongoing HOPE-Duchenne clinical trial of CAP-1002, we look forward to meeting with the FDA to propose a potential registrational strategy and clinical development plan for the Duchenne muscular dystrophy indication," said Linda Marbán, Ph.D., president and CEO of Capricor. "We are delighted to announce that Dr. Francesco Muntoni, Professor of Paediatric Neurology at University College London, and Head of the Dubowitz Neuromuscular Centre at Great Ormond Street Hospital, has agreed to serve as a key advisor for our upcoming clinical trial of intravenous CAP-1002 in DMD."

"Although we remain disappointed with last week's interim results from the ALLSTAR clinical trial of CAP-1002 in the heart attack setting, in which a signal on the parameter of change in cardiac scar size was not observed, the inconsistency of the placebo response with the well-established natural history of this disease process as well as the divergence from the extensive record observed with our cell technology together warrant the conduct of further analyses to understand the factors that led to these unexpected observations," added Dr. Marbán. "The observed reductions in left ventricular volume measures in the CAP-1002 treated patients, an important indicator of reverse remodeling of the heart, support the biological activity of CAP-1002."

CAP-1002 Program in Duchenne Muscular Dystrophy

- Capricor reported positive six-month data from the Phase I/II HOPE-Duchenne clinical trial of CAP-1002 (allogeneic cardiosphere-derived cells) in boys and young men with DMD on April 25, 2017. Following are top-line results from this interim analysis:
    - In exploratory efficacy analyses, statistically-significant improvements in systolic thickening of the inferior wall of the heart (p=0.030), and in the function of the middle and distal upper limb according to a 10% responder analysis of the Performance of the Upper Limb test (PUL) results (p=0.045), were observed in patients treated with CAP-1002 as compared to usual care control patients.
    - Differences observed in several other cardiac and skeletal muscle measures,

    - including cardiac scar (p=0.09), are consistent with a treatment effect.
    - CAP-1002 was generally safe and well-tolerated over the initial six-month follow-up period.
- A meeting with the U.S. Food and Drug Administration, or FDA, to discuss potential product registration strategies for CAP-1002 in the DMD indication is expected to occur this summer.
- Capricor believes the six-month results from HOPE will support Breakthrough Therapy or Regenerative Medicine Advanced Technology, or RMAT, designations for CAP-1002, for which applications are in preparation.

Other Recent Highlights

- On May 12, 2017, Capricor announced that a pre-specified administrative interim analysis performed on six-month follow-up data from the randomized, double-blind, placebo-controlled Phase II ALLSTAR clinical trial demonstrated a low probability (futility) of achieving a statistically-significant difference in the 12 month primary efficacy endpoint of percent change from baseline infarct size as a percentage of left ventricular mass, measured by cardiac magnetic resonance imaging (MRI).
- Following the ALLSTAR results, Capricor plans to reduce the scope of its operations, including the size of its workforce, in order to focus its financial resources primarily on its DMD program.
- Capricor recently closed on $3.7 million in gross proceeds from a private placement of common stock.

Anticipated Events and Milestones

- Decision by Janssen Biotech on its license option for CAP-1002 expected by the end of the third quarter of 2017.
- Randomized, double-blind, placebo-controlled, repeat-dose clinical trial of intravenous CAP-1002 in DMD expected to begin patient enrollment in the second half of 2017, subject to regulatory approval.
- Top-line 12-month data from the Phase I/II HOPE-Duchenne clinical trial expected to be reported in the fourth quarter of 2017.
- Investigational New Drug application (IND) for CAP-2003 (cardiosphere-derived cell exosomes) expected to be submitted in 2018.

First Quarter Financial Results

The Company reported a net loss of approximately $3.7 million, or $0.17 per share, for the first quarter of 2017, compared to a net loss of approximately $4.3 million, or $0.26 per share, for the first quarter of 2016.

As of March 31, 2017, the Company's cash, cash equivalents and marketable securities totaled approximately $11.7 million compared to approximately $16.2 million on December 31, 2016. Capricor believes that its current financial resources, including the proceeds from the recently-completed private placement, should be sufficient to fund its operations and meet its financial obligations through the first quarter of 2018 based on the Company's current projections.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a clinical-stage biotechnology company developing first-in-class biological therapies for cardiac and other medical conditions. Capricor's lead candidate, CAP-1002, is a cell-based candidate currently in clinical development for the treatment of Duchenne muscular dystrophy, myocardial infarction (heart attack), and heart failure. Capricor is exploring the potential of CAP-2003, a cell-free, exosome-based candidate, to treat a variety of disorders. For more information, visit www.capricor.com.

The ALLSTAR and HOPE-Duchenne clinical trials are funded in part by the California Institute for Regenerative Medicine.

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; 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, 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, 2016, as filed with the Securities and Exchange Commission on March 16, 2017, and in its Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on September 28, 2015, together with prospectus supplements thereto. 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. Capricor's exosomes technology, including CAP-2003, has not yet been approved for clinical investigation.

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

	Three months ended March 31,	
	2017	2016
INCOME		

Collaboration income	$ 683,594	$ 911,458
Grant income	197,214	303,631
TOTAL INCOME	880,808	1,215,089
OPERATING EXPENSES		
Research and development	3,257,149	4,341,119
General and administrative	1,189,238	1,084,696
TOTAL OPERATING EXPENSES	4,446,387	5,425,815
LOSS FROM OPERATIONS	(3,565,579)	(4,210,726)
OTHER INCOME (EXPENSE)		
Investment income	4,282	10,510
Interest expense	(105,320)	(66,125)
TOTAL OTHER INCOME (EXPENSE)	(101,038)	(55,615)
NET LOSS	(3,666,617)	(4,266,341)
OTHER COMPREHENSIVE GAIN (LOSS)		
Net unrealized gain (loss) on marketable securities	6,187	(6,157)
COMPREHENSIVE LOSS	$ (3,660,430)	$ (4,272,498)
Net loss per share, basic and diluted	$ (0.17)	$ (0.26)
Weighted average number of shares, basic and diluted	21,399,019	16,537,502

CAPRICOR THEAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	March 31, 2017 (unaudited)	December 31, 2016
Cash, cash equivalents and marketable securities	$ 11,743,453	$ 16,194,888
Total assets	$ 14,068,041	$ 18,747,355
Total deferred revenue	683,592	1,367,186
Total liabilities	$ 21,259,835	$ 22,750,509
Total stockholders' equity (deficit) - 21,399,019 common shares issued and outstanding at March 31, 2017 and December 31, 2016	(7,191,794)	(4,003,154)
Total liabilities and stockholders' equity	$ 14,068,041	$ 18,747,355

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/capricor-therapeutics-reports-first-quarter-2017-financial-results-and-provides-corporate-update-300457779.html

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