

# Capricor Therapeutics Reports Fourth Quarter and Full Year 2015 Financial Results and Business Update

Awarded CIRM Grant of Approximately \$3.4 Million to Support the Phase I/II HOPE-Duchenne Clinical Trial

Six-Month Data from Phase II ALLSTAR Clinical Trial Expected to be Available in the First Quarter of 2017 Following Protocol Amendment

Company to Host Conference Call and Webcast at 4:30 p.m. EDT, Today, March 17, 2016

LOS ANGELES, March 17, 2016 /PRNewswire/ -- <u>Capricor Therapeutics, Inc.</u> (NASDAQ: CAPR), a biotechnology company focused on the discovery, development and commercialization of first-in-class therapeutics, today provided financial results for the fourth quarter and full year ended December 31, 2015 as well as a business update.

"In 2015 and through the early part of 2016, we expanded the scope of our clinical and preclinical programs as well as strengthened our management team with key hires," said Linda Marbán, Ph.D., president and chief executive officer of Capricor. "We believe these initiatives position us well as we look forward to a productive year in our therapeutics development programs."

"In addition, we have now completed statistical modelling of the design of ALLSTAR, our ongoing Phase II clinical trial of CAP-1002, Capricor's cardiosphere-derived cell therapy, in patients who have suffered a heart attack. This modelling incorporated the expanded dataset that has become available from our other clinical trials of CAP-1002. Based on its results, we have elected to decrease the enrollment goal of ALLSTAR to approximately 120 patients, a sample size that is expected to maintain sufficient statistical power to detect a reduction in infarct, or scar, size as measured by MRI at twelve months. This decision was made with the concurrence of the ALLSTAR Data Safety Monitoring Board, and is a strong positive for Capricor. Under the revised enrollment goal, we expect to have six-month data from ALLSTAR in the first quarter of 2017," added Dr. Marbán.

Phase II of the ALLSTAR study is being funded in part through the support of the California Institute for Regenerative Medicine (CIRM).

## **Fourth Quarter and Recent Operational Highlights**

• Completed \$4.1 million equity offering with new and existing investors.

- Received a grant award of approximately \$3.38 million from CIRM to support the Phase I/II HOPE-Duchenne clinical trial, which is evaluating CAP-1002 in Duchenne muscular dystrophy (DMD)-associated cardiomyopathy.
- Completed enrollment of the pre-specified first patient cohort in the HOPE-Duchenne clinical trial. Topline data from this trial are expected to be reported in the first quarter of 2017.
- Presented positive six-month DYNAMIC clinical trial results of CAP-1002 in advanced heart failure at the American Heart Association (AHA) annual meeting.
- Appointed Leland J. Gershell, M.D., Ph.D., as Chief Financial Officer.

#### Fourth Quarter and Full Year Financial Results

The Company reported a net loss of approximately \$3.3 million, or \$0.21 per share, for the fourth quarter of 2015, compared to a net loss of approximately \$1.9 million, or \$0.16 per share, for the fourth quarter of 2014. For the year ended December 31, 2015, the Company reported a net loss of approximately \$12.9 million, or \$0.81 per share, compared to a net loss of approximately \$6.2 million, or \$0.53 per share, for the year ended December 31, 2014. At December 31, 2015, the Company's cash, cash equivalents and marketable securities totaled approximately \$13.6 million compared to \$8.0 million at December 31, 2014.

#### **Conference Call and Slides**

Capricor management will hold a conference call at 4:30 p.m. EDT today. The live call may be accessed by dialing (866) 635-0172 for domestic callers and (785) 424-1629 for international callers, and by using "Capricor" as the conference ID. Access to the live webcast and slides as well as the link to the replay of the call can be found at <a href="http://capricor.com/news/events/">http://capricor.com/news/events/</a>. The webcast will be archived for approximately 90 days.

## **About Capricor Therapeutics**

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class therapeutics. Capricor's lead programs target post myocardial infarction (heart attack), heart failure and Duchenne muscular dystrophy. Capricor has two lead product candidates under investigation: CAP-1002, a cardiac cell therapy, and Cenderitide, a natriuretic peptide receptor agonist. CAP-1002 is in development for the treatment of post myocardial infarction, advanced heart failure and Duchenne muscular dystrophy-associated cardiomyopathy. Cenderitide is in development for the outpatient treatment of heart failure as well as potential other indications. In addition, Capricor is conducting research and development on its exosomes platform technology for cardiac diseases and other potential indications. For additional information, visit <a href="https://www.capricor.com">www.capricor.com</a>.

#### **Cautionary Note Regarding Forward-Looking Statements**

Statements in this press release regarding the efficacy, safety, and intended utilization of Capricor's product candidates; the conduct, size, timing and results of discovery efforts and 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 offering and the anticipated effects of the offering, 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 forwardlooking statements. More information about these and other risks that may impact Capricor's business are set forth in Capricor's Annual Report on Form 10-K for the year ended December 31, 2014, as filed with the Securities and Exchange Commission on March 16, 2015, in its Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on September 28, 2015, and in its Quarterly Report on Form 10-Q for the guarter ended September 30, 2015, as filed with the Securities and Exchange Commission on November 13, 2015. 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.

# CAPRICOR THERAPEUTICS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Years ended December 31,		
	2015	2014	
INCOME			
Collaboration income	\$ 3,776,041	\$ 4,166,667	
Grant income	1,741,607	620,033	
TOTAL INCOME	5,517,648	4,786,700	
OPERATING EXPENSES			
Research and development	13,757,279	7,787,384	
General and administrative	4,372,195	3,017,301	
TOTAL OPERATING EXPENSES	18,129,474	10,804,685	
LOSS FROM OPERATIONS	(12,611,826)	(6,017,985)	
OTHER INCOME (EXPENSE)			
Investment income	3,113	1,898	
Interest expense	(248,626)	(200,505)	
TOTAL OTHER INCOME (EXPENSE)	(245,513)	(198,607)	
NET LOSS	(12,857,339)	(6,216,592)	

#### OTHER COMPREHENSIVE GAIN

Net unrealized gain on marketable securities	9,385	980	
COMPREHENSIVE LOSS	\$ (12,847,954)	\$ (6,215,612)	
Net loss per share, basic and diluted	\$ (0.81)	\$ (0.53)	
Weighted average number of shares, basic and diluted	15,902,133	11,696,980	

# CAPRICOR THERAPEUTICS, INC. SUMMARY BALANCE SHEETS

	December 31, 2015		December 31, 2014	
Cash, cash equivalents and marketable securities	\$	13,567,316	\$	8,034,765
Total Assets	\$	16,069,572	\$	13,632,072
Total deferred revenue	4,557,292		8,333,333	
Total liabilities	\$	17,101,346	\$	19,880,795
Total stockholders' equity (deficit) - 16,254,985 and 11,707,051 common shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	(1,031,	774)	(6,248	,723)
Total liabilities and stockholders' equity	\$	16,069,572	\$	13,632,072

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To view the original version on PR Newswire, visit<a href="http://www.prnewswire.com/news-releases/capricor-therapeutics-reports-fourth-quarter-and-full-year-2015-financial-results-and-business-update-300237939.html">http://www.prnewswire.com/news-releases/capricor-therapeutics-reports-fourth-quarter-and-full-year-2015-financial-results-and-business-update-300237939.html</a>

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