

May 15, 2014



# Capricor Therapeutics Reports First Quarter 2014 Business Highlights

*Signs Collaboration Agreement With Janssen Biotech;  
Initiates Phase II Clinical Study of CAP-1002*

*Conference Call Scheduled for Thursday May 15, 2014 at 4:30 p.m. Eastern Time*

LOS ANGELES, May 15, 2014 (GLOBE NEWSWIRE) -- Capricor Therapeutics, Inc. (OTCBB:CAPR), a biotechnology company focused on developing novel therapeutics to prevent and treat diseases, with a primary focus on heart disease, today provided a business and financial update for the first quarter ended March 31, 2014.

## **Recent Operational Highlights:**

- Announced the entry into a Collaboration Agreement and Exclusive License Option with Janssen Biotech, Inc. to partner on the development of Capricor's cell therapy program for cardiovascular applications, including its lead product candidate, CAP-1002, an allogeneic cardiosphere-derived stem cell (CDC) product being developed for patients who have suffered a myocardial infarction (MI);
- Received \$12.5M from Janssen Biotech, Inc. under the terms of the Collaboration Agreement and Exclusive License Option;
- Presented Phase I ALLSTAR data at American College of Cardiology annual meeting highlighting positive safety profile for its lead product candidate CAP-1002 in patients who suffered a myocardial infarction; and
- Initiated the Phase II ALLSTAR clinical trial which is actively enrolling patients.

Dr. Linda Marbán, Chief Executive Officer of Capricor, said, "During the quarter we made significant strides to position Capricor strategically as a leader in the cardiac therapy space with a series of strategic initiatives to advance our lead candidate, CAP-1002. We were particularly pleased to announce the Janssen collaboration in January, which provided an important validation of CAP-1002. Moreover, the opportunity to work with one of the largest, most respected companies in the healthcare industry is expected to benefit our team in aspects beyond the ongoing development of CAP-1002."

Dr. Marbán continued, "In March, we presented the positive data from the Phase I cohort of our ALLSTAR trial of CAP-1002 at ACC, demonstrating that it met its primary endpoint of safety. This data supports the continued development of our lead product candidate as a potential regenerative therapy for patients who have suffered a heart attack. Based on the safety profile established in the Phase I cohort, the National Institute of Health Data and Safety Monitoring Board approved the advancement to the double-blinded, randomized, placebo-controlled Phase II cohort of the trial, for which we are currently enrolling patients. We are looking forward to sharing details of the trial as continued clinical progress and new

milestones are achieved."

### **Three Months Ended March 31, 2014 Financial Results**

As of March 31, 2014, the Company had cash, cash equivalents and marketable securities totaling approximately \$13.3 million, up from \$2.1 million as of December 31, 2013. The increase in cash and cash equivalents in the first quarter of 2014 was primarily attributable to the \$12.5 million upfront payment related to the Company's recently announced collaboration with Janssen Biotech, Inc.

G&A expenses for the three months ended March 31, 2014 and 2013 were approximately \$0.9 million and \$0.5 million, respectively. The increase in the first quarter of 2014 of approximately \$0.4 million compared to the same period of 2013 is primarily attributable to an increase of approximately \$0.2 million in professional fees related to legal, consulting and accounting work related to the merger between Capricor and Nile, as well as additional expenses related to relevant public company compliance.

R&D expenses for three months ended March 31, 2014 and 2013 were approximately \$1.4 million and \$1.2 million, respectively. The increase of approximately \$0.2 million over the same period of 2013 is primarily due to the timing of clinical development activities of CAP-1002 in our Phase I/II trial throughout 2013 and 2014.

### **Conference Call**

Capricor Therapeutics, Inc. will hold a conference call Thursday, May 15, 2014, at 4:30 p.m. Eastern Time. During the call, Linda Marbán, Capricor's Chief Executive Officer, will review Capricor's recent accomplishments, provide an update on the clinical development program of the Company's lead product candidate, CAP-1002, and discuss other Company updates.

To access the call, please dial 1-877-407-4018 in the United States and 1-201-689-8471 internationally. The conference ID number for both is 13582990. A live webcast of the conference call, as well as a slide presentation to accompany the call, will be available on the Investors page of the Company's corporate website at <http://www.capricor.com>. Following the live webcast, an archive of the event will be available for at least 30 days from the date posted.

In addition, a telephonic replay of the call will be available until May 29, 2014. The replay dial-in numbers are 1-877-870-5176 for domestic callers and 1-858-384-5517 internationally. Please use event passcode 13582990.

### **About Capricor Therapeutics**

Capricor Therapeutics, Inc. (CAPR), a publicly-traded biotechnology company, is focused on the development of novel therapeutics to prevent and treat diseases, with a primary focus on heart disease. Capricor Therapeutics has two leading product candidates: CAP-1002 and Cenderitide. Capricor Therapeutics was formed through the November 2013 merger between Capricor, Inc., a privately-held company whose mission is to improve the treatment of heart disease by commercializing cardiac stem cell therapies for patients, and Nile Therapeutics, Inc., a clinical-stage biopharmaceutical company developing innovative products for the treatment of cardiovascular diseases. Capricor Therapeutics' stock began

trading under the symbol "CAPR" December 20, 2013. For additional information, please visit [www.capricor.com](http://www.capricor.com).

## **About CAP-1002**

CAP-1002, Capricor's lead product candidate, is a proprietary allogeneic adult stem cell therapy for the treatment of heart disease. The product is derived from donor heart tissue. The cells are expanded in the laboratory using a specialized process and then introduced directly into a patient's heart via infusion into a coronary artery using standard cardiac catheterization techniques.

CAP-1002 is currently not an approved product and is strictly for investigational purposes.

## **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; future royalty streams, 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 our business are set forth in our Form 10-K for the year ended December 31, 2013, as filed with the Securities and Exchange Commission on March 31, 2014, in our Registration Statement on Form S-1, as filed with the Securities and Exchange Commission on April 18, 2014, and in our Form 10-Q for the period ending March 31, 2014, as filed with the Securities and Exchange Commission on May 15, 2014. All forward-looking statements in this press release are based on information available to us as of the date hereof, and we assume no obligation to update these forward-looking statements.

CONTACT: Capricor Therapeutics, Inc.  
AJ Bergmann, VP of Finance  
+1-310-358-3200  
[abergmann@capricor.com](mailto:abergmann@capricor.com)

The Ruth Group  
Lee Roth (investors)  
[lroth@theruthgroup.com](mailto:lroth@theruthgroup.com)  
(646) 536-7012

Kirsten Thomas (media)  
[kthomas@theruthgroup.com](mailto:kthomas@theruthgroup.com)  
(646) 536-7014

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