

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

---

**FORM 8-K**

**CURRENT REPORT**  
**Pursuant to Section 13 or 15(d) of**  
**The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported)

November 12, 2014

---

**CAPRICOR THERAPEUTICS, INC.**

(Exact name of Registrant as Specified in its Charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-34058**  
(Commission  
File Number)

**88-0363465**  
(I.R.S. Employer  
Identification No.)

**8840 Wilshire Blvd., 2nd Floor, Beverly Hills, CA**  
(Address of principal executive offices)

**90211**  
(Zip Code)

**(310) 358-3200**  
(Registrant's telephone number, including area code)

**Not Applicable**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

**Item 2.02 Results of Operations and Financial Condition.**

On November 12, 2014, Capricor Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the quarter ended September 30, 2014. A copy of the press release is being furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information under Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto are being furnished and shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, unless expressly set forth as being incorporated by reference into such filing.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

99.1 Press Release, titled “Capricor Therapeutics Reports Third Quarter 2014 Financial & Business Highlights”, dated November 12, 2014.

---

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**CAPRICOR THERAPEUTICS, INC.**

Date: November 12, 2014

By: /s/ Linda Marbán, Ph.D.

Name: Linda Marbán, Ph.D.

Title: President and Chief Executive Officer

---



**Capricor Therapeutics Reports Third Quarter 2014  
Financial & Business Highlights**

*Announced Plans for Cenderitide Clinical Program and Clinical Program for  
Duchenne Muscular Dystrophy*

*Conference call scheduled for Wednesday, November 12, 2014 (4:30 p.m. EST)*

LOS ANGELES, November 12, 2014 (GLOBE NEWSWIRE) -- Capricor Therapeutics, Inc. (CAPR), a biotechnology company focused on developing novel therapeutics for the treatment of cardiovascular diseases, today provided a business and financial update for the third quarter ended September 30, 2014.

Recent Operational Highlights:

- Announced plans to pursue a Cenderitide clinical program for the treatment of post-acute heart failure;
- Entered into a Research Support Agreement with Insulet Corporation (NASDAQ: PODD);
- Announced acquisition of intellectual property rights to natriuretic peptides from Medtronic, Inc. (NYSE: MDT); and
- Announced plans to pursue a clinical program using CAP-1002 for the treatment of Duchenne Muscular Dystrophy.

Recently, Capricor announced that it plans to develop a clinical program using Cenderitide for the treatment of post-acute heart failure using Insulet's drug delivery system based on the OmniPod<sup>®</sup> insulin management system. Pursuant to the Research Support Agreement with Insulet, Insulet will support Capricor's research by engaging in certain product development, project management and design control activities, in addition to supplying products for the planned clinical trial. Additionally, Capricor recently announced it has entered into an intellectual property Transfer Agreement with Medtronic, Inc., pursuant to which Medtronic has assigned to Capricor all of its right, title and interest in all natriuretic peptide patents and patent applications previously owned by Medtronic or co-owned by each of the companies as part of their collaborative natriuretic peptide delivery program.

Furthermore, Capricor announced that it plans to develop a clinical program for Duchenne Muscular Dystrophy (DMD) using CAP-1002, Capricor's lead product candidate. CAP-1002 is an allogeneic, off-the-shelf, investigational cell therapy derived from donor heart tissue and is infused directly into a patient's coronary arteries during a catheterization procedure. CAP-1002 is currently in Phase II clinical testing for adults with ischemic heart disease.

Capricor plans to seek approval for its DMD clinical program based, in part, on data findings from the laboratory of Eduardo Marbán, M.D., Ph.D., Scientific Advisory Board Chairman of Capricor, Inc., and the Director of the Cedars-Sinai Heart Institute. The data will be presented at the Late Breaking Basic Science Posters and Reception during the American Heart Association's Scientific Sessions in Chicago on November 17<sup>th</sup>, 2014. Capricor plans to hold a conference call on November 18, 2014 at 9:30 a.m. EST to discuss the data findings.

---

Dr. Linda Marbán, Chief Executive Officer of Capricor, said, “Recently, we announced plans for two new clinical programs; Cenderitide for post-acute heart failure and CAP-1002 for Duchenne Muscular Dystrophy. We are planning clinical trials to commence for both of these programs in 2015. Additionally, we are progressing with Phase II of our ALLSTAR clinical trial and look forward to reporting on our next milestone. With our initiatives to advance our lead candidates, CAP-1002 and Cenderitide, we are positioning Capricor strategically to be a leader in the cardiovascular therapy space.”

Dr. Marbán further stated, “We continue to gain recognition in the industry and have presented findings at notable symposiums and forums over the past few months. Most notably, in September, we presented the six month Phase I safety results with an oral presentation by Dr. Raj R. Makker, M.D., of Cedars-Sinai Medical Center, at the Transcatheter Cardiovascular Therapeutics (TCT) conference in Washington, D.C. Additionally, we are scheduled to present the one-year Phase I results of the ALLSTAR trial at the Late Breaking Basic Science Posters and Reception at the American Heart Association’s Scientific Sessions 2014. The presentation will be held between 4:00–6:00 PM on Monday, November 17th, in South Hall A2 of McCormick Place, Chicago, IL.”

### **Three Months Ended September 30, 2014 Financial Results**

As of September 30, 2014, the Company had cash, cash equivalents and marketable securities totaling approximately \$10.1 million, plus approximately \$3.7 million restricted cash from the Company’s California Institute for Regenerative Medicine (CIRM) loan award, totaling approximately \$13.8 million. These amounts represent increases from the approximate \$2.1 million in cash, cash equivalents and marketable securities and the approximate \$1.4 million restricted cash from the CIRM loan award, each as of December 31, 2013. This increase in the first nine months of 2014 was primarily attributable to the \$12.5 million upfront payment received related to the Company’s previously announced Collaboration Agreement and Exclusive License Option with Janssen Biotech, Inc.

G&A expenses for the three months ended September 30, 2014 and 2013 were approximately \$0.8 million and \$0.6 million, respectively. The increase in the third quarter of 2014 of approximately \$0.2 million compared to the same period of 2013 is primarily attributable to professional fees related to legal, recruiting and increased headcount, as well as additional expenses related to relevant public company compliance.

R&D expenses for the three months ended September 30, 2014 and 2013 were approximately \$2.0 million and \$1.0 million, respectively. The increase of approximately \$1.0 million in the third quarter of 2014 over the same period of 2013 is primarily due to increased clinical development activities of the Phase I/II ALLSTAR trial and the Company’s planned DYNAMIC trial.

### **Conference Call**

Capricor will hold a conference call on Wednesday, November 12, 2014, at 4:30 p.m. Eastern Standard Time. During the call, Dr. Linda Marbán 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.

Participants can register for the call and webcast via the following link: <https://prismdigitalmedia.cwebcast.com/ses/5b1RxAY9rhdWBimYPOBW9A~~>. Once registered for the call, interested parties will receive the conference call dial-in information. An archived version of the webcast will remain on the Company’s Investors page at <http://www.capricor.com>.

### **About Capricor Therapeutics**

Capricor Therapeutics, Inc. (CAPR), a publicly traded biotechnology company, is focused on the development of novel therapeutics to prevent and treat heart disease. The Company has two leading product candidates: CAP-1002 and Cenderitide. The Company 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. For additional information, visit [www.capricor.com](http://www.capricor.com).

---

**About Cenderitide**

Cenderitide belongs to a class of drugs called natriuretic peptides. Preclinical and clinical data have shown that the natriuretic peptide class can act on multiple disease processes that play a role in negative outcomes associated with heart failure. Cenderitide is designed as an outpatient therapy to be delivered continuously using a validated subcutaneous infusion pump for up to 90 days (the “post-acute” period) following a hospital admission for Acute Decompensated Heart Failure. Cenderitide was designed by scientists at the Mayo Clinic and is the only dual natriuretic peptide receptor agonist.

Cenderitide is currently not an approved product and is strictly for investigational purposes.

**About CAP-1002**

CAP-1002, Capricor Therapeutics’ 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; scope, duration, validity and enforceability of intellectual property rights; 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 Annual Report on Form 10-K for the year ended December 31, 2013, as filed with the Securities and Exchange Commission on March 31, 2014, in our Amendment No. 1 to Registration Statement on Form S-1, as filed with the Securities and Exchange Commission on May 23, 2014, and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, as filed with the Securities and Exchange Commission on August 14, 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.

###

---

For more information, please contact:

**Capricor Therapeutics, Inc.**

AJ Bergmann, Vice President of Finance

+1-310-358-3200

[abergmann@capricor.com](mailto:abergmann@capricor.com)

**ProActive Capital Group**

Kirin Smith, COO

+1-646-863-6519

[ksmith@ProActiveCapital.com](mailto:ksmith@ProActiveCapital.com)

[www.ProActiveCapital.com](http://www.ProActiveCapital.com)

---