## 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)

August 13, 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)

8840 Wilshire Blvd., 2nd Floor, Beverly Hills, CA (Address of principal executive offices) 88-0363465 (I.R.S. Employer Identification No.)

> 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))

D 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 August 13, 2014, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended June 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 Second Quarter 2014 Financial & Business Highlights", dated August 13, 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: August 13, 2014

By: /s/ Linda Marbán, Ph.D. Linda Marbán, Ph.D. Chief Executive Officer



#### Capricor Therapeutics Reports Second Quarter 2014 Financial & Business Highlights

Reports Encouraging Results from Phase I of the ALLSTAR Clinical Trial and Signed Exclusive License with Cedars-Sinai Medical Center for Exosomes IP Portfolio

#### Conference call scheduled for Wednesday August 13, 2014 (4:30 p.m. Eastern Time)

LOS ANGELES, August 13, 2014 – 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 second quarter ended June 30, 2014.

#### **Recent Operational Highlights:**

- Company announced that MRI data collected on the patients in the Phase I open-label dose-escalation study of the allogeneic CDC product (CAP-1002) revealed that
  those patients who would be included in the Phase II clinical study by virtue of dose and tissue type compatibility, exhibited measurable improvements in ejection
  fraction, a global measure of the heart's pumping ability. In those patients, ejection fraction improved from an average of 38.9% at baseline to 44.1% at six-month
  follow-up. Measurements of infarct (scar) size, viable mass, and regional function also showed quantifiable improvements;
- CNN aired a story during Sanjay Gupta's program discussing Capricor's ALLSTAR clinical trial. For the full story click here:
- http://www.cnn.com/2014/07/11/health/stem-cells-heart-damage/index.html?hpt=he\_c1
- · Company entered into an Exclusive License with Cedars-Sinai Medical Center for its exosomes-related IP portfolio.

Dr. Linda Marbán, Chief Executive Officer of Capricor, said, "During this past quarter we continued to execute on our strategy as we announced encouraging analysis of the MRI data at the six-month time point from our Phase I ALLSTAR trial. We are pleased with the six-month data as there are indications of both myocardial regeneration as well as possible functional improvements. 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 candidate, CAP-1002, we are clearly positioning Capricor strategically to be a leader in the cardiac 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. In May, we presented findings from a preclinical study on exosomes, Capricor's newly licensed platform technology, at the 11th International Symposium on Stem Cell Therapy and Cardiovascular Innovations. The preclinical study sponsored by Cedars-Sinai Medical Center showed that exosomes were able to improve cardiac function and reduce the damage resulting from a heart attack. Dr. Rachel Ruckdeschel Smith, Ph.D., Vice President of Research and Development at Capricor, outlined the study findings, which were published in the May issue of *Stem Cell Reports*, the official journal of the International Society for Stem Cell Research (ISSCR)."

In June, the Company announced that Dr. Rachel Ruckdeschel Smith participated in a panel discussion on the regulation of therapeutic products derived from human stem cells at the Drug Information Association (DIA) 2014 50th Annual Meeting. The forum, titled "FDA Regulation of Therapeutic Products Derived from Human Stem Cells: Successfully Navigating the Regulatory Hurdles" (#135), addressed the basic regulatory requirements for therapeutic products derived from human stem cells as biological drugs, common hurdles that arise in research and development, and options for addressing those hurdles.

In late June, during the BIO International Convention, Dr. Marbán presented during a panel at the first, all-day Regenerative Medicine Forum organized by the California Institute for Regenerative Medicine (CIRM), in association with the Alliance for Regenerative Medicine (ARM) and the International Society for Stem Cell Research (ISSCR). The panel, titled "Commercializing a New Therapeutic Modality—Case Studies", was moderated by Randall Mills, President and CEO of CIRM. It focused on the importance of clinical data in bringing cell-based therapies to market, the role of clinical data at every step of the process, the importance of involving regulators early and often in the pathway to market, as well as how the players in reimbursement in this field are responding to these new approaches.

#### Three Months Ended June 30, 2014 Financial Results

As of June 30, 2014, the Company had cash, cash equivalents and marketable securities totaling approximately \$11.9 million, plus approximately \$4.4 million restricted cash from our CIRM loan award, totaling approximately \$16.3 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 our CIRM loan award as of December 31, 2013. This increase in the first six months of 2014 was primarily attributable to the \$12.5 million upfront payment received related to the Company's Collaboration Agreement and Exclusive License Option with Janssen Biotech, Inc.

G&A expenses for the three months ended June 30, 2014 and 2013 were approximately \$0.7 million and \$0.5 million, respectively. This increase of approximately \$0.2 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 expenses, as well as additional expenses related to relevant public company compliance.

R&D expenses for the three months ended June 30, 2014 and 2013 were approximately \$1.9 million and \$1.3 million, respectively. This increase of approximately \$0.6 million compared to the same period of 2013 is primarily due to increased clinical development activities of the Phase I/II ALLSTAR trial.

#### **Conference Call**

Capricor Therapeutics, Inc. will hold a conference call Wednesday, August 13, 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 CAP-1002, and discuss other Company updates.

Participants can register for the call and webcast via the following link: https://platform.cinchcast.com/ses/uNst-anWETWo3Syj4Ea81A~~. 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.

#### 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, our Form 10-Q for the quarter ended March 31, 2014, as filed with the Securities and Exchange Commission on May 23, 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.

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For more information, please contact:

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