# 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)

May 5, 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 1.01. Entry into a Material Definitive Agreement.

#### **Exclusive License Agreement**

On May 5, 2014, Capricor, Inc. ("Capricor"), a privately-held company incorporated in Delaware and a wholly-owned subsidiary of Capricor Therapeutics, Inc., a Delaware corporation ("Capricor Therapeutics"), entered into an Exclusive License Agreement (the "License Agreement") with Cedars-Sinai Medical Center ("CSMC") for certain intellectual property rights related to exosomes technology. The License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor, with the right to sublicense, in order to conduct research using the patent rights and know-how and to develop and commercialize products in the field using the patent rights and know-how. In addition, Capricor has the exclusive right to negotiate for an exclusive license to any future rights arising from related work conducted by or under the direction of Dr. Eduardo Marbán on behalf of CSMC. In the event the parties fail to agree upon the terms of an exclusive license, Capricor will be granted a non-exclusive license to such future rights, subject to royalty obligations.

Pursuant to the License Agreement, CSMC was paid a license fee and Capricor reimbursed CSMC for certain fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor is required to meet certain non-monetary development milestones and is obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a single-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obliged to obtain a license from a third party for patent rights in connection with the royalty-bearing product.

The License Agreement will, unless sooner terminated, continue in effect on a country by country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the License Agreement, unless waived by CSMC, the License Agreement will automatically terminate: (i) if Capricor ceases, dissolves or winds up its business operations; (ii) in the event of the insolvency or bankruptcy of Capricor or if Capricor makes an assignment for the benefit of its creditors; (iii) if performance by either party jeopardizes the licensure, accreditation or tax-exempt status of CSMC or the agreement is deemed illegal by a governmental body; (iv) within 30 days for non-payment of royalties; (v) within 90 days if Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (vi) if a material breach has not been cured within 90 days; or (vii) if Capricor challenges any of the CSMC patent rights. Capricor may terminate the License Agreement if CSMC fails to cure any material breach within 90 days after notice.

Capricor Therapeutics is party to a lease agreement with CSMC, which holds more than 10% of the outstanding capital stock of Capricor Therapeutics. Additionally, Dr. Eduardo Marbán, who holds more than 10% of the outstanding capital stock of Capricor Therapeutics, is the Director of the Cedars-Sinai Heart Institute and the Co-founder and Scientific Advisory Board Chairman of Capricor.

Capricor Therapeutics expects to file the License Agreement as an exhibit to its next filing in which the License Agreement is required to be included, and intends to seek confidential treatment for certain terms and provisions of the License Agreement. The foregoing description is a summary of the material terms of the License Agreement, does not purport to be complete, and is qualified in its entirety by reference to the text of the License Agreement when filed.

On May 6, 2014, Capricor Therapeutics issued a press release announcing the entry into the License Agreement. A copy of the press release is filed herewith as Exhibit 99.1.

#### Item 9.01. Financial Statements and Exhibits.

## (d) Exhibits

99.1 Press Release, dated May 6, 2014, announcing the entry into an Exclusive License Agreement, dated May 5, 2014, by and between Capricor, Inc. and Cedars-Sinai Medical Center.



# SIGNATURES

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

# CAPRICOR THERAPEUTICS, INC.

Date: May 9, 2014

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



#### Capricor Therapeutics Enters into Exclusive License with Cedars-Sinai Medical Center for Exosome-related IP Portfolio

Provides Potential for Broad Regenerative Medicine Therapeutic Platform

LOS ANGELES, May 6, 2014 – Capricor Therapeutics, Inc. (OTCBB: CAPR), a biotechnology company focused on developing novel therapeutics for the treatment of cardiovascular diseases, today announced the execution of an Exclusive License Agreement with Cedars-Sinai Medical Center for intellectual property (IP) related to the development of exosomes. Exosome technology may have the potential to form the basis of a next generation therapeutic platform in regenerative medicine. Under the terms of the agreement, Capricor has been granted an exclusive world-wide license, with the right to sublicense, IP related to exosomes originating from cardiosphere-derived cells (CDCs).

Cedars-Sinai research about the development of exosomes is published in the May issue of *Stem Cell Reports*, the official journal of the International Society for Stem Cell Research (ISSCR).

The licensed technology is based upon preclinical research led by Eduardo Marbán, M.D., Ph.D, who is Director of the Cedars-Sinai Heart Institute and Co-founder and Scientific Advisory Board Chairman of Capricor. As reported in today's print issue of *Stem Cell Reports*, researchers showed that exosomes extracted from Capricor's CDCs prompted myocardial regeneration in pre-clinical models of ischemic heart disease. Further, the exosomes were shown to induce various structural and functional changes within the heart. These findings demonstrate for the first time that exosomes derived from CDCs possess regenerative capabilities and serve as proof of principle for their potential as therapeutic agents.

Released by nearly every cell type in the body and a vital mediator of cellular activities, exosomes are nano-sized, membrane-enclosed vesicles, or "bubbles," that are filled with select molecules, including proteins and microRNAs, which, when released, send messages to neighboring cells to regulate cellular functions. Exosomes act as the transport vehicle out of the cell for segments of genetic material and proteins that act as messengers between cells, ultimately providing regulatory function for many cell processes, including inflammation, angiogenesis, programmed cell death (apoptosis), and scarring. Research has shown that exogenous exosomes may be used as therapeutic agents aimed to direct or in some cases re-direct cellular activities. Their size, ease of crossing cell membranes, and ability to communicate in native cellular language makes them a class of exciting and novel therapeutic agents.

Linda Marbán, Ph.D., Chief Executive Officer of Capricor Therapeutics, said, "Licensing the exosome portfolio from Cedars-Sinai Medical Center is especially exciting because it allows Capricor to expand its regenerative medicine pipeline with a cell-free product platform that may have opportunities across various indications where inflammation, scarring, and cell death are part of the disease process. The unique properties of CDC-derived exosomes may allow us to develop novel cell-free therapeutics and expand our product portfolio. Though it is early in the development cycle, we are excited about this new platform technology. Capricor plans to explore development of the exosome technology as a next generative medicine platform in a variety of cardiovascular and non- cardiovascular areas."

## **About Capricor Therapeutics**

Capricor Therapeutics, Inc. (CAPR), a publicly-traded biotechnology company, is focused on the development of novel therapeutics to prevent and treat cardiovascular diseases. 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.

## **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," "plans," "should," "target," "will," "would" and similar expressions) should also be considered to be 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, and in our Registration Statement on Form S-1, as filed with the Securities and Exchange Commission to update these forward-looking statements.

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For more information or to schedule an interview with Dr. Linda Marbán, please contact:

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