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)

June 30, 2017

CAPRICOR THERAPEUTICS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware	**001-34058**	**88-0363465**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

8840 Wilshire Blvd., 2nd Floor, Beverly Hills, CA	**90211**
(Address of principal executive offices)	**(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.02. Termination of a Material Definitive Agreement.

Capricor, Inc. ("Capricor"), a wholly-owned subsidiary of Capricor Therapeutics, Inc. (the "Company") entered into a Collaboration Agreement and License Option on December 27, 2013 (the "Agreement") with Janssen Biotech, Inc. ("Janssen"), a wholly-owned subsidiary of Johnson & Johnson. Under the terms of the Agreement, Capricor and Janssen agreed to collaborate on a CMC Development Plan for the manufacturing of Capricor's CDC cells and CDC products for cardiovascular applications, including its lead product, CAP-1002.

On June 30, 2017, Capricor was informed by Janssen that it will not be exercising its exclusive option right to exploit CAP-1002 as well as certain allogeneic cardiospheres and cardiosphere-derived cells in the field of cardiology. Capricor will retain full rights to CAP-1002 in all indications as a result of this decision. Capricor will also have an irrevocable, fully paid-up non-exclusive license under patents controlled by Janssen utilized in the production of the clinical trial materials manufactured pursuant to the CMC development plan between Capricor and Janssen and a non-exclusive perpetual license to publish, disclose and use the information of Janssen that was utilized in the production of the clinical trial materials manufactured pursuant to the CMC development plan.

Item 7.01. Regulation FD Disclosure.

On July 6, 2017, the Company issued a press release regarding the termination of the Agreement and announcing that Capricor will retain full rights to CAP-1002 in all indications as a result of this termination. A copy of the press release is being furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 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 Retains Full Rights to CAP-1002 as Janssen Biotech, Inc. Decides Not to Exercise Option", dated July 6, 2017.

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: July 6, 2017

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

Exhibit 99.1

Capricor Therapeutics Retains Full Rights to CAP-1002 as Janssen Biotech, Inc. Decides Not to Exercise Option

LOS ANGELES, July 6, 2017 – Capricor Therapeutics, Inc. (NASDAQ: CAPR) today announced that Janssen Biotech, Inc. (Janssen) has decided not to exercise its option to exclusively license Capricor's lead candidate CAP-1002 (allogeneic cardiosphere-derived cells) for development and commercialization in the field of cardiology. In connection with this decision, the Collaboration Agreement and License Option entered into between Capricor and Janssen has been terminated. As a result, Capricor shall retain all rights to develop and commercialize CAP-1002 for any indication, either independently or in collaboration with third parties. Capricor will also have an irrevocable, fully paid-up non-exclusive license under patents controlled by Janssen utilized in the production of the clinical trial materials manufactured pursuant to the Chemistry, Manufacturing, and Controls (CMC) development plan between Capricor and Janssen and a non-exclusive perpetual license to publish, disclose and use the information of Janssen that was utilized in the production of the clinical trial materials manufactured pursuant to the CMC development plan. No payments between Capricor and Janssen are required to be made in relation to this decision.

"Over the last few years, and during the term of the Janssen option period, we believe that significant value for our CAP-1002 asset has been created through the demonstration of clinical proof-of-concept to treat Duchenne muscular dystrophy (DMD) and also from the progress that has been made towards the development of a commercial-scale manufacturing process for the cells," said Linda Marbán, Ph.D., Capricor's president and chief executive officer. "Although Janssen's decision removes a potential corporate partner for Capricor, this decision also resolves uncertainty concerning the scope of the license for CAP-1002 and provides Capricor the freedom to enter into new licensing and/or business development opportunities around this promising therapeutic candidate."

"Following our announcement of positive results from our Phase I/II HOPE clinical trial in April, we have focused our efforts toward the clinical development of CAP-1002 for DMD. We discussed potential product registration strategies for this indication at our recent meeting with the U.S. Food and Drug Administration, and we look forward to providing an update on our clinical development plans in DMD very shortly. We expect to commence a randomized, double-blind, placebo-controlled clinical trial of repeat administrations of intravenous CAP-1002 in boys and young men with DMD in the second half of this year, subject to regulatory approval" added Dr. Marbán.

Capricor previously announced that a six-month interim analysis of the Phase II ALLSTAR clinical trial in people who had suffered a myocardial infarction showed a low probability that CAP-1002 would achieve the primary endpoint of scar size reduction, as measured by late gadolinium-enhanced magnetic resonance imaging, at 12 months. However, non-significant group differences in certain pre-specified secondary endpoints, including changes in left ventricular end-systolic and end-diastolic volumes (LVESV and LVEDV), suggest a potential beneficial effect from CAP-1002 on remodeling, one of the major culprits in the development of chronic heart failure.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a clinical-stage biotechnology company developing first-in-class biological therapies. Capricor's lead candidate, CAP-1002, is a cell-based candidate currently in clinical development for the treatment of Duchenne muscular dystrophy. Capricor is also exploring the potential of CAP-2003, a cell-free, exosome-based candidate, to treat a variety of disorders. For more information, 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 initiation, conduct, size, timing and results of discovery efforts and clinical trials; the pace of enrollment of 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 offerings and the anticipated effects of the offerings, 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 Capricor's business is set forth in Capricor's Annual Report on Form 10-K for the year ended December 31, 2016 as filed with the Securities and Exchange Commission on March 16, 2017, in its Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on September 28, 2015, together with prospectus supplements thereto, and in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, as filed with the Securities and Exchange Commission on May 15, 2017. 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.

CAP-1002 is an Investigational New Drug and is not approved for any indications. Capricor's exosomes technology, including CAP-2003, has not yet been approved for clinical investigation.

For more information, please contact:

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