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)

February 5, 2018

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 7.01 Regulation FD Disclosure.

On February 5, 2018 Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing that the FDA has granted the Company's request for the Regenerative Medicine Advanced Therapy (RMAT) designation for CAP-1002 being developed for the treatment of Duchenne muscular dystrophy. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference into this Item 7.01 of this Current Report on Form 8-K.

The information contained in this Form 8-K (including Exhibit 99.1 attached hereto) is being furnished and shall not be deemed to be "filed" for the 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 and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Capricor Therapeutics, Inc. Press Release, dated February 5, 2018.

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: February 5, 2018

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

Exhibit 99.1

Capricor Receives FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for Duchenne Muscular Dystrophy Therapy

CAP-1002 to Benefit from Expedited Review Program for Drugs for Unmet Needs

LOS ANGELES, Feb. 5, 2018 – Capricor Therapeutics (NASDAQ: CAPR) today announced that the U.S. Food and Drug Administration (FDA) has granted CAP-1002, its lead investigational cell therapy for the treatment of Duchenne muscular dystrophy, the Regenerative Medicine Advanced Therapy (RMAT) designation.

In notifying Capricor, the FDA Office of Tissues and Advanced Therapies, stated that the FDA will "work closely" with Capricor "to provide guidance on the subsequent development of CAP-1002" for the treatment of Duchenne muscular dystrophy, "including providing advice on generating the evidence needed to support approval of the drug in an efficient manner."

The FDA grants the RMAT designation to regenerative medicine therapies intended to treat a serious condition and for which preliminary clinical evidence indicates a potential to address unmet medical needs for that condition. The RMAT designation makes therapies eligible for the same actions to expedite the development and review of a marketing application that are available to drugs that receive breakthrough therapy designation – including increased meeting opportunities, early interactions to discuss any potential surrogate or intermediate endpoints and the potential to support accelerated approval.

"The RMAT designation is recognition by the FDA of the potential of CAP-1002 and the importance of bringing this therapy to market to serve the unmet needs of boys and young men who have lost the ability to walk because of Duchenne muscular dystrophy," said Linda Marbán, Ph.D., Capricor president and chief executive officer. "CAP-1002 is one of the few therapies currently in development to help non-ambulant patients with Duchenne muscular dystrophy, and it's important that we move forward into the next phase of clinical development to potentially help them maintain what function they have in their arms and hands."

To receive the RMAT designation, Capricor submitted data from an earlier trial, the HOPE-Duchenne Trial, which reported significant and sustained improvements in skeletal muscle function and cardiac structure in boys and young men in advanced stages of Duchenne muscular dystrophy following a single dose of intracoronary CAP-1002.

Capricor is launching a potential registration trial, the HOPE-2 Trial, to test the potential benefit of CAP-1002 as a multi-dose therapy delivered intravenously. HOPE-2 is a randomized, double-blind, placebo-controlled clinical trial that is planning to enroll approximately 84 participants in advanced stages of DMD.

Capricor already secured an Orphan Drug Designation for CAP-1002 which gives the company seven-year market exclusivity upon approval. In addition, Capricor has obtained a Rare Pediatric Disease Designation for CAP-1002, which means that if CAP-1002 is approved first for use in Duchenne muscular dystrophy, the company can secure a priority review voucher to fast-track a potential future therapy.

The RMAT designation is expected to further facilitate CAP-1002's path to potential registration. As an initial step in the RMAT process, Capricor intends to submit a meeting request to the FDA for a comprehensive discussion of the CAP-1002 development program for treatment of Duchenne muscular dystrophy and to specifically discuss the HOPE-2 Trial. For more information on the RMAT designation, please visit:

https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm537670.htm).

About Duchenne Muscular Dystrophy

Duchenne muscular dystrophy is a devastating genetic disorder that causes muscle degeneration and leads to death, generally before the age of 30, most commonly from heart failure. It occurs in one in every 3,600 live male births across all races, cultures and countries. Duchenne muscular dystrophy afflicts approximately 200,000 boys and young men around the world. Treatment options are limited, and there is no cure.

About CAP-1002

CAP-1002 consists of allogeneic cardiosphere-derived cells, or CDCs, a unique population of cells that contains cardiac progenitor cells. CAP-1002 has been shown to exert potent immunomodulatory activity and stimulate cellular regeneration. CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to approximately 140 human subjects across several clinical trials.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ:CAPR) is a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class biological therapeutics for the treatment of rare disorders. Capricor's lead candidate, CAP-1002, is an allogeneic cell therapy that is currently in clinical development for the treatment of Duchenne muscular dystrophy. Capricor has also established itself as one of the leading companies investigating the field of extracellular vesicles and is 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.

The HOPE-Duchenne trial was funded in part by the California Institute for Regenerative Medicine.

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; regulatory developments involving products, including the ability to obtain regulatory approvals or otherwise bring products to market; 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 the prospectus included therein and prospectus supplements thereto, and in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, as filed with the Securities and Exchange Commission on November 14, 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. CAP-2003 has not yet been approved for clinical investigation.

For more information, please contact:

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