

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

CAPRICOR THERAPEUTICS, INC.

Form: 8-K

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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 13, 2017

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))
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Item 1.02. Termination of a Material Definitive Agreement.

On November 14, 2013, Nile Therapeutics, Inc. (now known as Capricor Therapeutics, Inc.), (“Capricor”), entered into that certain Amended and Restated Technology License Agreement (the “Amended Mayo Agreement”) with the Mayo Foundation for Medical Education and Research (“Mayo”) with respect to the licensing of rights to Cenderitide (“CD-NP”), and a synthetic natriuretic peptide known as CU-NP. The Amended Mayo Agreement was filed as Exhibit 10.35 to Capricor’s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2014.

On February 13, 2017, Capricor provided Mayo with a notice of termination of the Amended Mayo Agreement pursuant to Section 7.03 of the Amended Mayo Agreement, thereby relinquishing all rights previously licensed by Mayo to Capricor with respect to CD-NP and CU-NP. Capricor has provided 90 days’ notice of the effectiveness of termination, but Mayo has indicated to Capricor that it considers the Amended Mayo Agreement to be terminated as of February 14, 2017 due to an ongoing dispute with Mayo regarding the payment of certain fees incurred in the prosecution of the intellectual property rights licensed by Mayo to Capricor, which fees Capricor does not deem to be material in amount. Capricor elected to terminate the Amended Mayo Agreement so that it may focus its resources and efforts on its cell therapy (CAP-1002) and exosomes (CAP-2003) programs which are advancing clinically in various disease indications.

On February 16, 2017, Capricor issued a press release announcing the termination of the Amended Mayo Agreement and discussing related matters. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 Press Release, dated February 16, 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: February 16, 2017

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



Capricor Therapeutics Provides Update on Natriuretic Peptide Program

To focus efforts on advancing cardiac cell and exosome-based therapeutic candidates

LOS ANGELES, February 16, 2017 – Capricor Therapeutics, Inc. (NASDAQ: CAPR), a clinical-stage biotechnology company developing first-in-class biological therapies for cardiac and other medical conditions, today announced that it has elected to terminate its license agreement with the Mayo Clinic relating to natriuretic peptide receptor agonists, including Cenderitide.

“Our decision to return these rights is a strategic move as we prioritize our efforts to advance our core cell and exosome-based therapeutic development programs,” said Dr. Linda Marbán, Ph.D., president and chief executive officer.

“We enter 2017 with the anticipation of several key events to occur this year. These include our expected announcement early next quarter of top-line results of our randomized Phase I/II HOPE clinical trial of CAP-1002 (allogeneic cardiosphere-derived cells) in people with Duchenne muscular dystrophy (DMD)-associated heart disease, as well our expectation to clinically evaluate CAP-1002 for its ability to improve peripheral and respiratory muscle in DMD in a trial that is currently being planned. We are also committing increased attention to our exosomes program, and we expect to file an Investigation New Drug application for CAP-2003 (cardiosphere-derived cell exosomes) in the second half of this year,” added Dr. Marbán.

Capricor Therapeutics (formerly Nile Therapeutics, Inc.) entered into an Amended and Restated Technology License Agreement in 2013 around the time of the corporate merger. Since that time, Capricor has completed two small Phase II studies of Cenderitide, also known as CD-NP, in subjects with chronic, stable heart failure.

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 therapies for the treatment of cardiac and other medical conditions. Capricor's lead candidate, CAP-1002, is a cardiac cell therapy that is currently being evaluated for the treatment of heart disease associated with Duchenne muscular dystrophy and myocardial infarction (heart attack). Capricor is exploring the use of CAP-2003, its exosome product candidate in various therapeutic areas including the treatment of ophthalmic disorders. For additional 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 offering 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 are set forth in Capricor's Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission on March 30, 2016, in its Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on September 28, 2015, and in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, as filed with the Securities and Exchange Commission on November 14, 2016. 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:

Corporate

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