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 13, 2020

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. ☐

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	CAPR	The Nasdaq Capital Market

Item 8.01 Other Events.

On May 13, 2020, Capricor Therapeutics, Inc. (the "Company") announced positive top-line results from the HOPE-2 trial. The one-year results demonstrated clinically meaningful benefits in multiple parameters of upper limb and cardiac function. HOPE-2 is a randomized, double-blind, placebo-controlled, Phase II clinical trial of CAP-1002 (allogeneic cardiosphere-derived cells) in steroid-treated boys and young men who are in advanced stages of Duchenne muscular dystrophy, or DMD. The Company has requested an End-of-Phase 2 meeting with the FDA to discuss the next steps and pathway to approval of a Biologics License Application for CAP-1002 in DMD.

A press release announcing the results is included as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, titled "Capricor Announces Positive Top-Line Results from HOPE-2 Study in Patients with Duchenne Muscular Dystrophy Treated with Lead Candidate CAP-1002", dated May 13, 2020.

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 13, 2020

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

Exhibit 99.1

Capricor Announces Positive Top-Line Final Results from HOPE-2 Study in Patients with Duchenne Muscular Dystrophy Treated with Lead Candidate CAP-1002

-One-Year Results from Randomized, Double-Blind, Placebo-Controlled Study Demonstrate Improved Performance of Upper Limb (PUL) 2.0 (p=0.05)-

-First Ever Study in DMD that Correlates Stabilization in Cardiac Function with a Reduction in a Biomarker of Cell Damage-

-Company Planning to Meet with FDA to Discuss Pathway to Approval-

-To Host Conference Call and Webcast Today at 8AM ET-

LOS ANGELES, Calif. May 13, 2020 -- Capricor Therapeutics ("Capricor") (NASDAQ: CAPR), a clinical-stage biotechnology company focused on the development of first-in-class biological therapeutics for the treatment and prevention of diseases, announced today positive top-line 12-month results of the HOPE-2 clinical trial using CAP-1002 to treat patients in advanced stages of Duchenne muscular dystrophy (DMD), a genetic disorder characterized by progressive weakness and chronic inflammation of the skeletal, heart, and respiratory muscles. Boys and young men typically lose their ability to walk in their teens and generally die of cardiac or respiratory complications by the 3rd decade of life. The data showed improvements in upper limb, cardiac and respiratory function with p-values less than p=0.05 in multiple measures.

The 12-month data from HOPE-2 showed statistically meaningful improvements in the PUL 2.0 in CAP-1002 treated patients (p=0.05) with a mean change of 2.4 points over placebo patients. With the exception of steroids, preservation of function in DMD is uncommon. The placebo patients declined consistent with natural history, but in the treated group, most patients were stable or improved throughout the one-year treatment period.

The performance of the upper limb (PUL) is a clinically validated measure that evaluates upper limb (shoulder, arm, hand) strength in patients who are generally non-ambulant. Retention of upper limb function is important for self-care and preservation of human dignity and has become a focus for physicians and advocates to find treatments to help these later stage patients. The FDA has suggested the use of the updated PUL 2.0 version as the primary efficacy endpoint in support of a Biologics License Application (BLA).

Craig McDonald, M.D., the national principal investigator for the HOPE-2 clinical trial and UC Davis professor and chair of the Department of Physical Medicine and Rehabilitation commented, "I am incredibly pleased with the outcome of the HOPE-2 trial which demonstrated clinically relevant benefits of CAP-1002 which resulted in measurable improvements in upper limb, cardiac and respiratory function. This is the first clinical trial which shows benefit to patients in advanced stages of DMD for which treatment options are limited."

The data also showed global improvements in cardiac function as measured by ejection fraction (p=0.004) and indexed volumes (LVESV, p=0.01, LVEDV p=0.07). These are surrogate measures of cardiac function and are considered the "gold standard" in terms of relevance to long term outcomes. Remarkably, there is also a reduction in the biomarker CK-MB, an enzyme that is only released when there is cardiac muscle cell damage. In normal human subjects, there is typically no CK-MB measurable in the blood. It is well accepted that continuous muscle cell damage in DMD leads to pathologically high enzyme levels associated with cardiac muscle cell loss. HOPE-2 demonstrated a reduction in CK-MB levels as compared to placebo (p=0.006). This is the first ever study in DMD that correlates cardiac functional stabilization with reduction of a biomarker of cell damage.

Linda Marbán, president and CEO of Capricor said, “To date, there are no therapies to treat the cardiomyopathy associated with DMD. Based on the statistically and clinically meaningful improvements in these and other measures of skeletal, cardiac and respiratory performance, we have requested an End-of-Phase 2 meeting with FDA to discuss next steps and a pathway to approval of a Biologics License Application for CAP-1002 in DMD.”

Phase II HOPE-2 Study Design

HOPE-2 is a randomized, double-blind, placebo-controlled, Phase II clinical trial of the Company’s lead investigational therapy, CAP-1002, in boys and young men who are in advanced stages of DMD. Study patients were treated via intravenous delivery with either CAP-1002 (150 million cells per infusion) or placebo every 3 months. Data from a total of 20 patients was analyzed (12 placebo and 8 treated) at the 12-month time-point in the intent to treat (ITT) population. Approximately 80% of the patients were non-ambulant and all patients were on a stable regimen of steroids. Demographic and baseline characteristics were similar between the two treatment groups.

Study Results

Top-Line Efficacy Data:

	12-month Time-point		
	CAP-1002 n=8	**Placebo n=12**	**p-value**
Upper Limb Function			
Mid-level PUL (version 1.2)	-2.1 (3.63)	-4.9 (2.57)	p=0.08
Shoulder + Mid + Distal PUL (version 1.2)	-2.3 (3.86)	-6.4 (3.84)	p=0.03
Shoulder + Mid + Distal PUL (version 2.0)	-1.3 (2.14)	-3.7 (1.50)	p=0.05
Cardiac			
LV Ejection Fraction %	-0.33 (2.01)	-1.89 (2.23)	p=0.004
LV End-Diastolic Volume, Indexed mL/m^2	-7.35 (6.10)	0.00 (7.34)	p=0.07
LV End-Systolic Volume, Indexed mL/m^2	-3.10 (1.68)	1.70 (5.02)	p=0.01
Creatine Kinase-MB (% of total CK)	-0.50 (0.55)	2.00 (1.00)	p=0.006

Mean Change from baseline to 12 months (standard deviation) shown.
ITT (intent to treat) population shown
P-values are nominal values unadjusted for multiple testing
Mixed model repeated measures analysis

Dr. Marban continued, “We are delighted with the final data from HOPE-2. It has met our expectations in terms of clinical meaningfulness in this population of patients where treatment options are extremely limited. In HOPE-2, CAP-1002 was delivered by intravenous infusions given quarterly. The data suggests that CAP-1002 could delay the progression of DMD. We are excited to share this data with FDA and discuss next steps towards commercialization. We have had tremendous support from the DMD advocacy community and we are grateful to the patients and families who participated in this study so that we could reveal the impact of CAP-1002 in treating DMD.”

Safety Update

CAP-1002 was generally safe and well tolerated throughout the study. With the exception of hypersensitivity reactions which were mitigated with a common pre-medication regimen, no safety signals were identified in the HOPE-2 trial.

The FDA has granted Capricor's CAP-1002 RMAT and Orphan Drug Designation, and the FDA has also granted a Rare Pediatric Disease Designation to CAP-1002 for DMD. The Rare Pediatric Disease Designation, as well as the Orphan Drug Designation previously granted, covers the broad treatment of DMD. If Capricor were to receive market approval for CAP-1002 by the FDA, Capricor would be eligible to receive a Priority Review Voucher. This is the second clinical trial investigating CAP-1002 showing similar results in DMD. Capricor completed the HOPE-Duchenne (Phase I/II) trial published in *Neurology*, the medical journal of the American Academy of Neurology in 2019.

The Company has initiated a technology transfer with a leading global CMO to prepare for commercial manufacturing of CAP-1002.

Conference Call and Webcast Details

Capricor will host a conference call and webcast with slides today, May 13, 2020, at 8:00 a.m. ET to discuss the top-line results of the HOPE-2 study. To participate in the conference call, please dial 855-327-6838 (domestic) or 604-235-2082 (international) and reference the access code: 10009621.

To participate via a webcast, please visit: http://public.viavid.com/index.php?id=139843 to view the slides. The webcast will be archived for approximately 30 days and will be available at http://capricor.com/news/events/.

Financial Update for the First Quarter of 2020

The Company reported a net loss of approximately $2.1 million, or $0.30 per share, for the first quarter of 2020, compared to a net loss of approximately $2.5 million, or $0.75 per share, for the first quarter of 2019.

As of March 31, 2020, the Company's cash, cash equivalents and marketable securities totaled approximately $13.2 million, compared to approximately $9.9 million on December 31, 2019. As of May 12, 2020, the Company has 12,464,006 shares issued and outstanding.

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 and prevention of diseases. 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 is also investigating the field of extracellular vesicles and exploring the potential of exosome-based candidates to treat or prevent a variety of disorders. The HOPE-Duchenne trial was funded in part by the California Institute for Regenerative Medicine. For more information, visit www.capricor.com and follow the Company on Facebook, Instagram and Twitter.

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 “off-the-shelf” cardiosphere-derived cells, or CDCs, a type of cardiac cell therapy that has been shown in pre-clinical and clinical studies to exert potent immunomodulatory activity. It is being investigated for its potential to modify the immune system’s activity to encourage cellular regeneration. The cells function by releasing exosomes that are taken up largely by macrophages and T-cells and begin a cycle of repair. CDCs have been the subject of over 100 peer-reviewed scientific publications and administered to approximately 150 human subjects across several clinical trials.

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, revenue projections; 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, 2019 as filed with the Securities and Exchange Commission on March 27, 2020. 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. None of Capricor’s exosome-based candidates have been approved for clinical investigation.

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