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, 2019

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. ☐

Securities registered pursuant to Section 12(b) of the 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 2.02 Results of Operations and Financial Condition.

On May 13, 2019 Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended March 31, 2019. A copy of the press release is being furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information under Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto is 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 Reports First Quarter 2019 Financial Results and Provides Corporate Update", dated May 13, 2019.

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, 2019

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

Exhibit 99.1

Capricor Therapeutics Reports First Quarter 2019 Financial Results and Provides Corporate Update

On Track to Report Interim Data from HOPE-2 Clinical Trial in Early Q3

To Host Conference Call and Webcast Today at 4:30 p.m. ET

LOS ANGELES, May 13, 2019 – Capricor Therapeutics (NASDAQ: CAPR), a clinical-stage biotechnology company focused on the development of first-in-class biological therapeutics for the treatment of Duchenne muscular dystrophy and other rare disorders, today announced its financial results for the first quarter 2019 and provided a corporate update.

"We continue with the clinical development of CAP-1002, our lead cell therapy product, to treat Duchenne muscular dystrophy," said Linda Marbán, Ph.D., Capricor president and chief executive officer. Our HOPE-2 clinical trial, which is testing the safety and efficacy of CAP-1002 in boys and young men in the advanced stages of Duchenne, has enrolled 20 patients to date. Previous pre-clinical and clinical studies have shown that CAP-1002 is generally safe, well-tolerated and demonstrated significant and sustained signals of improvement in cardiac and skeletal muscle function in patients with Duchenne muscular dystrophy. We will be conducting an interim analysis in early Q3 and look forward to sharing that data with the patient and investor community."

Capricor has been granted RMAT and Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for CAP-1002 for the treatment of Duchenne muscular dystrophy.

CAP-2003 is comprised of proprietary extracellular vesicles, including exosomes, which are derived from cardiosphere-derived cells. Exosomes are nano-sized, membrane-enclosed vesicles, that are secreted by cells and contain bioactive molecules, including proteins, RNAs and microRNAs. Exosomes act as messengers to regulate the functions of neighboring cells. Because of these unique capacities, researchers are increasingly viewing exosomes as both a potential therapeutic and a vehicle to deliver gene and other therapies to targeted tissues in the human body.

"We continue to be encouraged by exciting developments in the exosomes field and we continue to explore their use as a potential therapeutic and as a delivery vehicle for genes and other drugs to targeted tissues," said Dr. Marbán.

First Quarter Highlights and Recent Clinical and Operational Developments

- The Company resumed dosing of patients already enrolled in the HOPE-2 clinical trial of CAP-1002 in accordance with the study protocol. It is the Company's intention to conduct an interim analysis on available data in early Q3 2019. The HOPE-2 study is a Phase II, randomized, double-blind, placebo-controlled study in patients in the later stages of Duchenne muscular dystrophy, a fatal genetic disease with few treatment options. HOPE-2 will evaluate the safety and efficacy of repeat doses of CAP-1002, which consists of allogeneic cardiosphere-derived cells, or CDCs. CAP-1002 has been shown to exert potent immunomodulatory activity and stimulate cellular regrowth. Enrollment of new patients will depend on various factors but will not commence until additional funding is secured.

- The Journal of Neurology published the results of the HOPE-Duchenne clinical trial reporting significant improvements in Duchenne muscular dystrophy patients treated with Capricor's CAP-1002. The Phase I/II, randomized, controlled, open-label trial found that CAP-1002 demonstrated improvement in cardiac muscle function and reduction in cardiac scarring that were statistically-significant and sustained improvement of skeletal muscle functions in patients with Duchenne muscular dystrophy. The HOPE-Duchenne trial also found no serious safety issues, according to the study published in the January 23, 2019, online issue of *Neurology*, the medical journal of the American Academy of Neurology.

Anticipated Events and Milestones in 2019

- Plan to report interim data from the HOPE-2 clinical trial in early Q3 2019.
- Continue to conduct pre-clinical research for CAP-2003 to treat various diseases of inflammation and fibrosis.
- Continue to explore financing and other strategic alternatives with respect to the Company as well as one or more of our product candidates.

First Quarter Financial Results

The Company reported a net loss of approximately $2.5 million, or $0.08 per share, for the first quarter of 2019, compared to a net loss of approximately $3.7 million, or $0.14 per share, for the first quarter of 2018.

As of March 31, 2019, the Company's cash, cash equivalents and marketable securities totaled approximately $7.2 million compared to approximately $7.3 million on December 31, 2018. Additionally, in the first quarter of 2019, Capricor raised approximately $1.4 million in net proceeds at an average price of approximately $0.66 per share under its at-the-market offering program. The Company's at-the-market offering program expired on April 23, 2019.

Capricor believes that its current financial resources should be sufficient to fund its operations and meet its financial obligations into the fourth quarter of 2019 based on the Company's current projections.

Conference Call and Webcast

To participate in the conference call, please dial 866-717-4562 (domestic) or 210-874-7812 (international) and reference the access code: 4575759

To participate via a webcast, please visit**:** https://edge.media-server.com/m6/p/zxabvq2r. The webcast will be archived for approximately 30 days and will be available at http://capricor.com/news/events/.

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. The HOPE-Duchenne trial was funded in part by the California Institute for Regenerative Medicine. For more information, visit www.capricor.com.

Keep up with Capricor on social media:www.facebook.com/capricortherapeutics, www.instagram.com/capricortherapeutics/ and https://twitter.com/capricor

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, 2018 as filed with the Securities and Exchange Commission on March 29, 2019, and as amended by its Amendment No. 1 to Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on April 1, 2019. 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.

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

	Three months ended March 31,	
	2019	2018
REVENUE		
Revenue	$ 230,504	$ 400,066
OPERATING EXPENSES		
Research and development	1,811,182	2,696,517
General and administrative	976,490	1,389,732
TOTAL OPERATING EXPENSES	2,787,672	4,086,249
LOSS FROM OPERATIONS	(2,557,168)	(3,686,183)
OTHER INCOME (EXPENSE)		
Investment income	37,823	14,653
NET LOSS	(2,519,345)	(3,671,530)
OTHER COMPREHENSIVE INCOME (LOSS)		
Net unrealized gain (loss) on marketable securities	(12,393)	8,709
COMPREHENSIVE LOSS	$ (2,531,738)	$ (3,662,821)
Net loss per share, basic and diluted	$ (0.08)	$ (0.14)
Weighted average number of shares, basic and diluted	32,903,837	26,905,331

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	March 31, 2019 (unaudited)	December 31, 2018
Cash, cash equivalents and marketable securities	$ 7,170,220	$ 7,256,416
Total assets	$ 8,617,505	$ 9,247,065
Total liabilities	$ 4,877,203	$ 4,631,478
Total stockholders' equity - 33,661,346 and 31,387,729 common shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	3,740,302	4,615,587
Total liabilities and stockholders' equity	$ 8,617,505	$ 9,247,065

For more information, please contact:

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