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)

March 28, 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. ☐

Item 2.02 Results of Operations and Financial Condition.

On March 28, 2019 Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter and full year ended December 31, 2018. 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 Fourth Quarter and Full Year 2018 Financial Results and Provides Corporate Update", dated March 28, 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: March 28, 2019

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

Exhibit 99.1

Capricor Therapeutics Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Corporate Update

Plan 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, March 28, 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 fourth quarter and full year 2018 and provided a corporate update.

"This has been a busy year for Capricor as 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. "We began our HOPE-2 trial, were granted RMAT designation and had a positive meeting with FDA late last year. To date, 20 young men and boys in advanced stages of Duchenne muscular dystrophy have been enrolled in the randomized, double-blind, placebo-controlled trial. We are now planning on conducting an interim analysis in early Q3 and look forward to sharing that data with the patient and investor community."

Additionally, in 2018, Capricor entered into a collaboration with the U.S. Army Institute of Surgical Research (USAISR), which is studying the potential for CAP-2003 to address trauma-related injuries and conditions. 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 are encouraged to see an increased interest in exosomes in the field as a potential therapeutic and as a delivery vehicle for genes and other drugs to targeted tissues," said Dr. Marbán. "This exciting collaboration with USAISR may allow us to further the clinical development of CAP-2003 and we continue to work with them and other branches of the US military on potential future opportunities for continued development."

Fourth Quarter Highlights and Recent Clinical and Operational Developments

- Resumed per protocol dosing of patients already enrolled in the HOPE-2 clinical trial of CAP-1002, the company's novel cell therapy candidate to treat Duchenne muscular dystrophy. It is our 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.
- Capricor put a voluntary hold on dosing in December to develop a plan to manage potential allergic reactions after a patient had a serious adverse event in the form of anaphylaxis. After an approximate one-month period, we lifted our voluntary dosing hold in the HOPE-2 trial. The investigation suggests that the patient may have been allergic to something contained in the investigational product, including an excipient, or inactive ingredient, in the formulation. To reduce the risk of future events, we initiated a pre-medication strategy that is commonly used by doctors to prevent and treat allergic reactions. The Data and Safety Monitoring Board (DSMB) and HOPE-2 clinical trial steering committee support this approach, and the FDA and DSMB approved resuming enrollment in the study.
- In December 2018, Capricor met with the FDA , as part of the expedited review afforded under the Regenerative Medicine Advanced Therapy (RMAT) designation which the FDA granted to CAP-1002 in February 2018. 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 Journal of Neurology published a study reporting significant improvements in Duchenne muscular dystrophy patients treated with Capricor's novel cell therapy, 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 strategic alternatives, with respect to one or more of our product candidates.

Fourth Quarter and Full Year Financial Results

For the fourth quarter of 2018, the company reported a net loss of approximately $(3.3) million, or $(0.11) per diluted share, compared to, after giving effect to the forgiveness of the California Institute of Regenerative Medicine (CIRM) loan payable, net income of approximately $12.3 million, or $0.42 per diluted share, for the fourth quarter of 2017.

For the year ended December 31, 2018, the company reported a net loss of approximately $(15.2) million, or $(0.52) per diluted share, compared to, after giving effect to the forgiveness of the CIRM loan payable, net income of approximately $2.4 million, or $0.09 per diluted share, for the year ended December 31, 2017. As of December 31, 2018, the company's cash, cash equivalents and marketable securities totaled approximately $7.3 million compared to approximately $14.1 million on December 31, 2017. Additionally, in 2018, Capricor raised approximately $6.7 million in net proceeds at an average price of approximately $1.48 per share under its at-the-market offering program.

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: 7167797.

To participate via a webcast, please visit: https://edge.media-server.com/m6/p/zkf3ocjd. 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, 2017 as filed with the Securities and Exchange Commission on March 22, 2018, 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, 2018, as filed with the Securities and Exchange Commission on November 14, 2018. 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 December 31,		Years ended December 31,	
	2018	2017	2018	2017
REVENUE				
Revenue	$ 648,082	$ 475,799	$ 1,671,356	$ 2,666,340
TOTAL REVENUE	648,082	475,799	1,671,356	2,666,340
OPERATING EXPENSES				
Research and development	2,849,377	2,518,395	12,066,800	10,766,095
General and administrative	1,104,670	1,237,827	4,931,642	4,762,642
TOTAL OPERATING EXPENSES	3,954,047	3,756,222	16,998,442	15,528,737
LOSS FROM OPERATIONS	(3,305,965)	(3,280,423)	(15,327,086)	(12,862,397)
OTHER INCOME (EXPENSE)				
Investment income	46,086	11,768	135,991	38,494
Interest expense	-	(80,307)	-	(398,807)
Forgiveness of loan payable	-	15,654,133	-	15,654,133
TOTAL OTHER INCOME (EXPENSE)	46,086	15,585,594	135,991	15,293,820
NET INCOME (LOSS)	(3,259,879)	12,305,171	(15,191,095)	2,431,423
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain on marketable securities	(7,814)	3,027	773	8,096
COMPREHENSIVE INCOME (LOSS)	$ (3,267,693)	$ 12,308,198	$ (15,190,322)	$ 2,439,519
Net income (loss) per share - basic	$ (0.11)	$ 0.48	$ (0.52)	$ 0.10
Weighted average number of shares - basic	31,038,018	25,810,249	29,410,973	23,193,278
Net income (loss) per share - diluted	$ (0.11)	$ 0.42	$ (0.52)	$ 0.09
Weighted average number of shares - diluted	31,038,018	29,471,009	29,410,973	26,788,076

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	December 31, 2018	December 31, 2017
Cash, cash equivalents and marketable securities	$ 7,256,416	$ 14,124,935
Total assets	$ 9,247,065	$ 16,273,789
Total liabilities	$ 4,631,478	$ 5,046,934
Total stockholders' equity - 31,387,729 and 26,270,491 common shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	4,615,587	11,226,855
Total liabilities and stockholders' equity	$ 9,247,065	$ 16,273,789

For more information, please contact:

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