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 10, 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 2.02 Results of Operations and Financial Condition.

On May 10, 2018, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended March 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 are 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 2018 Financial Results and Provides Corporate Update", dated May 10, 2018.

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 10, 2018

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

Exhibit 99.1

Capricor Therapeutics Reports First Quarter 2018 Financial Results and Provides Corporate Update

HOPE-2 Clinical Trial is Currently Enrolling Patients

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

LOS ANGELES, May 10, 2018 – 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, which ended March 31, 2018, and provided a corporate update.

"We are excited by the recent initiation of the HOPE-2 clinical trial of CAP-1002, our lead cell therapy product, to treat Duchenne muscular dystrophy," said Linda Marbán, Ph.D., Capricor president and chief executive officer. "CAP-1002 is one of the very few clinical initiatives to focus on helping boys and young men who are in later stages of the disease process and whose ability to walk has been seriously impaired by the loss of muscle function as a result of the disease. We have seen the potential for improvements in muscle function in both pre-clinical studies and in our earlier HOPE-Duchenne trial, and we have been granted the RMAT and orphan disease designations by the U.S. Food and Drug Administration (FDA) for CAP-1002 for Duchenne muscular dystrophy."

These designations enable Capricor to work closely with the FDA in finalizing the regulatory approval pathway for CAP-1002 and to receive expedited FDA reviews.

"We are hopeful that HOPE-2 may potentially be a registration trial," said Dr. Marbán. "We see CAP-1002 as an important tool in the toolbox to treat Duchenne muscular dystrophy because it may work synergistically with the emerging disease-modifying therapies. While gene and other therapies have the potential to restore dystrophin expression and sustain muscle function, there will still be significant inflammation and fibrosis, which can offset the restorative effects. CAP-1002's primary mechanism of action is immunomodulatory, meaning it can help balance inflammation in this chronic inflammatory disease."

First Quarter 2018 Highlights and Recent Clinical and Operational Developments

- In April, Capricor initiated the HOPE-2 clinical trial at UC Davis Medical Center. Up to 84 boys and young men with Duchenne muscular dystrophy will be enrolled in HOPE-2, a Phase II, randomized, double-blind, placebo-controlled trial that will test CAP-1002 in participants with advanced stages of Duchenne muscular dystrophy. Approximately 12-15 investigative sites are expected to participate in the trial. Craig McDonald, M.D., UC Davis professor and chair of its Department of Physical Medicine and Rehabilitation, is the national principal investigator for HOPE-2. More information is available at www.HOPE2trial.com

- In an abstract presentation at the 11th Annual Neuromuscular Translational Research Conference in Cambridge, England in April, Capricor announced results of a new study that found that repeat dosing of CAP-1002 yields an increase in exercise performance in a mouse model of Duchenne muscular dystrophy.
- A newly published study in "Stem Cell Reports" from Cedars-Sinai Medical Center reported that cardiosphere-derived cells (CDCs) improved skeletal, diaphragm and cardiac muscle function in a mouse model of Duchenne muscular dystrophy.
- Capricor secured the Regenerative Medicine Advanced Therapy (RMAT) designation for CAP-1002 for Duchenne muscular dystrophy, which makes therapies eligible for expedited review.
- Capricor added seven new patent applications to its existing Exclusive License Agreements with Cedars-Sinai Medical Center, giving Capricor worldwide, exclusive rights to inventions related to cardiosphere-derived cells (CDCs and CAP-1002) and CDC-derived extracellular vesicles, including exosomes.
- Capricor hosted a Key Opinion Leaders Lunch in New York City on March 9 which included four distinguished speakers discussing the emerging paradigms in gene and cellular therapies to treat Duchenne muscular dystrophy. The speakers included Craig McDonald, M.D., professor and chair of the Department of Physical Medicine and Rehabilitation and Director of the Neuromuscular Disease Clinics at the University of California, Davis. Other speakers were Jeffrey Chamberlain, Ph.D., professor in the departments of Neurology, Medicine and Biochemistry and director of the Seattle Wellstone Muscular Dystrophy Center, and Michelle Eagle, Ph.D., the managing director of ATOM International LTD and one of the creators of, and who has published extensively on, the Performance of the Upper Limb (PUL) test, a validated test for skeletal muscle function in Duchenne muscular dystrophy. The fourth speaker was Pat Furlong**,** the founding president and CEO of the Parent Project Muscular Dystrophy (PPMD), the largest non-profit organization in the U.S. focused solely on Duchenne.

Anticipated Milestones in 2018

- Continue to add additional sites and enroll patients in the HOPE-2 clinical trial.
- Continue to conduct pre-clinical research for Capricor's investigational exosome-based therapy, CAP-2003, to treat various diseases of inflammation and fibrosis.
- Continue preparations for manufacturing scale-up and technology transfer of CAP-1002.
- Plan to meet with the FDA to discuss Capricor's Duchenne program through the RMAT process.

First Quarter 2018 Financial Results

The Company reported a net loss of approximately $3.7 million, or $0.14 per share, for the first quarter of 2018, compared to a net loss of approximately $3.7 million, or $0.17 per share, for the first quarter of 2017.

As of March 31, 2018, the Company's cash, cash equivalents and marketable securities totaled approximately $13.2 million, compared to approximately $14.1 million on December 31, 2017. Additionally, in the first quarter of 2018, Capricor raised approximately $2.4 million in net proceeds at an average price of approximately $1.88 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 first 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 5795736.

To participate via a webcast, please visit https://edge.media-server.com/m6/p/qz4u7wox. 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. 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, and 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. 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.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

	Three months ended March 31,	
	2018	2017
INCOME		
Collaboration income	$ -	$ 683,594
Grant income	306,750	197,214
Other income	93,316	-
TOTAL INCOME	400,066	880,808
OPERATING EXPENSES		
Research and development	2,696,517	3,257,149
General and administrative	1,389,732	1,189,238
TOTAL OPERATING EXPENSES	4,086,249	4,446,387
LOSS FROM OPERATIONS	(3,686,183)	(3,565,579)
OTHER INCOME (EXPENSE)		
Investment income	14,653	4,282
Interest expense	-	(105,320)
TOTAL OTHER INCOME (EXPENSE)	14,653	(101,038)
NET LOSS	(3,671,530)	(3,666,617)
OTHER COMPREHENSIVE INCOME (LOSS)		
Net unrealized gain on marketable securities	8,709	6,187
COMPREHENSIVE LOSS	$ (3,662,821)	$ (3,660,430)
Net loss per share, basic and diluted	$ (0.14)	$ (0.17)
Weighted average number of shares, basic and diluted	26,905,331	21,399,019

CAPRICOR THEAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	March 31, 2018 (unaudited)	December 31, 2017
Cash, cash equivalents and marketable securities	$ 13,164,642	$ 14,124,935
Total assets	$ 15,388,422	$ 16,273,789
Total liabilities	$ 4,854,158	$ 5,046,934
Total stockholders' equity - 27,970,879 and 26,270,491 common shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	10,534,264	11,226,855
Total liabilities and stockholders' equity	$ 15,388,422	$ 16,273,789

For more information, please contact:

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