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)

November 13, 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 November 13, 2018 Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the fiscal quarter ended September 30, 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 Third Quarter 2018 Financial Results and Provides Corporate Update", dated November 13, 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: November 13, 2018

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

Exhibit 99.1

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

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

LOS ANGELES, November 13, 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 third quarter of 2018, which ended September 30, 2018, and provided a corporate update.

"Capricor continues its progress in the clinical development of our novel cell therapy, CAP-1002, to treat Duchenne muscular dystrophy, and we are moving forward with our exosome-based therapy, CAP-2003," said Linda Marbán, Ph.D., Capricor CEO. "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, is well underway with 11 sites recruiting participants and more sites expected to begin enrollment before the end of the year. 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."

Capricor has been granted RMAT and Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for CAP-1002. The company's leaders and key opinion leaders in the Duchenne community are scheduled to meet with the FDA in December under Capricor's RMAT designation to discuss milestones for development and commercialization of CAP-1002.

Capricor has 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 pleased to see that the power of exosomes is beginning to be recognized by the academic and the biotech communities," said Dr. Marbán. "Pre-clinical studies indicate CAP-2003 has potential as a treatment for diseases of inflammation and fibrosis, which may mean it can potentially serve as both a therapy for those diseases and as a delivery vehicle for gene and other therapies to treat those diseases."

Third Quarter Highlights and Recent Clinical and Operational Developments

- Eleven study sites have opened and enrollment is underway in the HOPE-2 clinical trial. It 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. Current plans are to open up to 15 study sites and enroll approximately 84 patients. 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.
- Capricor announced it will be meeting with the FDA in December as part of the expedited review process CAP-1002 received under the 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.
- At the Gordon Research Conference on Extracellular Vesicles in Newry, Maine in August, Capricor presented a poster on the mechanism of action and the immunomodulatory capacities of CAP-2003. The poster provided additional evidence that exosomes may be the active pharmaceutical ingredient in CAP-1002. The pre-clinical studies further elucidated Capricor's progress in developing the exosomes which comprise CAP-2003 as an exciting new potential therapeutic for diseases of inflammation and fibrosis.
- In October, Capricor presented a poster at the 2018 Cell & Gene Meeting on the Mesa in La Jolla, CA. The poster reported on a pre-clinical study that assessed the biological mechanisms of action of paracrine factors and exosomes secreted by CDCs, the active component of CAP-1002. The poster showed that growth factors released by CDCs are able to activate survival signals in treated cells. Capricor also reported that the exosomes were responsible for CAP-1002's immunomodulatory effects.
- In November, Capricor presented a poster at the Action Duchenne International Conference in Birmingham, UK. The poster reported on a pre-clinical study that found exosomes secreted by CDCs were effective in increasing exercise capabilities and muscle activity in a mouse model of Duchenne muscular dystrophy. The poster also reported that the exosomes secreted by the CDCs reduced muscle fibrosis, which causes a loss of muscle function in Duchenne patients, and the proliferation of activated T cells, which help govern the body's immune response, in the Duchenne mouse model.
- Capricor provided corporate updates at the BTIG Fall Biotechnology Conference in New York and at the American Society of Exosomes and Microvesicles Annual Meeting in October. In November, Capricor provided an update on its research and development of cell and exosome-based therapies for Duchenne muscular dystrophy and other rare diseases during the BIO-Europe® 24th Annual International Partnering Conference in Copenhagen, Denmark.

Anticipated Events and Milestones in Fourth Quarter of 2018

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

Third Quarter Results

The Company reported a net loss of approximately $4.1 million, or $0.14 per share, for the third quarter of 2018, compared to a net loss of approximately $2.7 million, or $0.12 per share, for the third quarter of 2017.

As of September 30, 2018, the Company's cash, cash equivalents and marketable securities totaled approximately $10.4 million, compared to approximately $14.1 million on December 31, 2017. Additionally, in the third quarter of 2018, Capricor raised approximately $1.1 million in net proceeds at an average price of approximately $1.44 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 second 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: 4974294.

To participate via a webcast, please visit: https://edge.media-server.com/m6/p/msqxw8py. 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 June 30, 2018, as filed with the Securities and Exchange Commission on August 13, 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.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
INCOME				
Collaboration income	$ -	$ -	$ -	$ 1,367,186
Grant income	172,589	260,771	766,641	770,855
Other income	46,658	52,500	256,633	52,500
TOTAL INCOME	219,247	313,271	1,023,274	2,190,541
OPERATING EXPENSES				
Research and development	3,131,999	1,862,369	9,217,423	8,247,700
General and administrative	1,259,180	1,088,635	3,826,972	3,524,815
TOTAL OPERATING EXPENSES	4,391,179	2,951,004	13,044,395	11,772,515
LOSS FROM OPERATIONS	(4,171,932)	(2,637,733)	(12,021,121)	(9,581,974)
OTHER INCOME (EXPENSE)				
Investment income	35,792	10,393	89,905	26,726
Interest expense	-	(107,653)	-	(318,500)
TOTAL OTHER INCOME (EXPENSE)	35,792	(97,260)	89,905	(291,774)
NET LOSS	(4,136,140)	(2,734,993)	(11,931,216)	(9,873,748)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain on marketable securities	1,922	1,276	8,587	5,069
COMPREHENSIVE LOSS	$ (4,134,218)	$ (2,733,717)	$ (11,922,629)	$ (9,868,679)
Net loss per share, basic and diluted	$ (0.14)	$ (0.12)	$ (0.41)	$ (0.44)
Weighted average number of shares, basic and diluted	30,610,064	23,378,141	28,862,665	22,311,369

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	September 30, 2018 (unaudited)	December 31, 2017
Cash, cash equivalents and marketable securities	$ 10,371,917	$ 14,124,935
Total assets	$ 12,232,816	$ 16,273,789
Total liabilities	$ 5,252,394	$ 5,046,934
Total stockholders' equity - 30,748,872 and 26,270,491 common shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	6,980,422	11,226,855
Total liabilities and stockholders' equity	$ 12,232,816	$ 16,273,789

For more information, please contact:

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