SECURITIES & EXCHANGE COMMISSION EDGAR FILING

CAPRICOR THERAPEUTICS, INC.

Form: 8-K

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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 7, 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 November 7, 2019, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended September 30, 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 Third Quarter 2019 Financial Results and Provides Recent Corporate Update", dated November 7, 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: November 7, 2019

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

Exhibit 99.1

Capricor Therapeutics Reports Third Quarter 2019 Financial Results and Provides Recent Corporate Update

Provides Update on End of Phase Type-B Meeting with FDA

Positive Data from the HOPE-2 Clinical Trial Presented at World Muscle Society

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

LOS ANGELES, November 7, 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 (DMD) and other rare disorders, today announced its financial results for the third quarter 2019 and provided a recent corporate update.

“The Company’s development and achievements in the third quarter have been encouraging on multiple levels and we will be providing updates on trial advancement, evidence development, KOL support, regulatory developments and increased financial discipline across the firm” said Linda Marbán, Ph.D., Capricor President and Chief Executive Officer.

The 24th International Congress of the World Muscle Society provided an exciting venue for the Company’s “late breaking” presentation unveiling our interim results in the Phase II HOPE-2 clinical trial of CAP-1002. This brought a significant amount of international attention to Capricor at the conference. This new data also opens the possibility for potential collaborations with other companies passionate about aiding patients with DMD.

A meeting with the FDA was recently held where data from the interim analysis of the HOPE-2 trial was presented. As the company disclosed previously, Capricor has been granted RMAT and Orphan Drug Designation by the FDA for CAP-1002 for the treatment of Duchenne muscular dystrophy.

“For the later stage DMD patients, which the HOPE-2 trial is focused on, we hope that our therapeutic may one day be an important treatment option. Capricor has been able to demonstrate meaningful benefit to non-ambulant patients where there are limited options in treating DMD. We are eager to enrich the lives of patients and their families who suffer from DMD due to limitations in the current treatment paradigm.” Dr. Marbán said.

Third Quarter Highlights and Recent Clinical and Operational Developments

Clinical Evidence Development

- Capricor reported positive data from its ongoing HOPE-2 Study of CAP-1002 in Duchenne Muscular Dystrophy at World Muscle Society: Data Demonstrates Improved PUL 2.0 Performance at 6 Months. *(October 2019)*
- Capricor reported that its independent Data and Safety Monitoring Board (DSMB) completed its safety assessment and futility analysis review of the Company’s ongoing Phase II HOPE-2 study and recommended that the trial continue. *(July 2019)*
- Capricor reported interim analysis performed on 6-month data from the HOPE-2 trial showed meaningful results across several independent clinical measures. *(July 2019)*
- Capricor and Parent Project Muscular Dystrophy hosted a webinar, to discuss updates on Capricor's HOPE-2 clinical program. *(July 2019)*

Regulatory Advancement

- Capricor was granted a Type B End-of-Phase 2 meeting with the FDA to discuss pre-specified interim analysis of the Company's HOPE-2 clinical trial. (September 2019)
- Capricor expects to announce further updates on its clinical development strategy for CAP-1002 in DMD later this year, including an update on guidance it receives from the FDA (*Estimated Q4-2019)

Key Opinion Leader Support

- A Study of CAP-1002 in Ambulatory and Non-Ambulatory Patients with Duchenne Muscular Dystrophy HOPE-2 (October 2019)
  - *Updated Results from the Interim Analysis Presented at the 24th International Annual Congress of the World Muscle Society*
- A presentation hosted by Capricor on Dystrophin Deficient Muscular Dystrophy: Diagnosis, Natural History and Current Therapies presented by Dr. Craig McDonald from UC Davis (October 2019)

Strategic Alignment and Financial Discipline

- Capricor continued to strengthen its financial position in the quarter by reducing its quarterly burn rate
- As of September 30, 2019 – the Company had approximately $6.8 million of cash and cash equivalents on hand and utilizing conservative cash deployment has extended its runway through at least the second quarter of 2020

Anticipated Q4 2019 Events and Upcoming Targeted Milestones

- Plans for further clinical development of CAP-1002 in DMD will be based on guidance received from the FDA as well as other factors and we are awaiting final minutes from the meeting with the FDA
- Continue to finalize the protocol for a potential Phase III trial
- Plan to discuss additional data with the FDA from the HOPE-2 study as it becomes available
- Plan to present 12-month data from the HOPE-2 study in the second quarter of 2020
- Continue to treat previously enrolled patients in the HOPE-2 study
- Continue to conduct pre-clinical research for CAP-2003 to treat various diseases of inflammation and fibrosis, including DMD

Third Quarter Financial Results

The Company reported a net loss of approximately $1.6 million, or $0.43 per share, for the third quarter of 2019, compared to a net loss of approximately $4.1 million, or $1.35 per share, for the third quarter of 2018.

As of September 30, 2019, the Company's cash, cash equivalents and marketable securities totaled approximately $6.8 million compared to approximately $7.3 million on December 31, 2018. Additionally, so far in the third quarter of 2019, Capricor has raised approximately $2.6 million in net proceeds at an average price of approximately $3.81 per share under its at-the-market offering programs.

Capricor believes that its current financial resources should be sufficient to fund its operations and meet its financial obligations through at least the second quarter of 2020 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: 9775366.
To participate via a webcast, please visit: https://edge.media-server.com/mmc/p/4uhn24bi. The webcast will be archived for approximately 30 days and will be available at http://capricor.com/news/events/.

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 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, and is being investigated for its potential to modify the immune system's activity to encourage cellular regeneration. CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to over 150 human subjects across several clinical trials.

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 DMD. Capricor is also 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, 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, 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, in its Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019, as filed with the Securities and Exchange Commission on August 8, 2019, and in its Registration Statement on Form S-3 as filed with the Securities and Exchange Commission on October 24, 2018, and as amended by its Amendment No. 1 to Form S-3 filed with the Securities and Exchange Commission on July 17, 2019, together with 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.

For more information, please contact:

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

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
REVENUE				
Revenue	$ 142,071	$ 219,249	$ 782,928	$ 1,023,274
OPERATING EXPENSES				
Research and development	857,764	3,131,999	4,313,056	9,217,423
General and administrative	911,968	1,259,180	2,720,391	3,826,972
TOTAL OPERATING EXPENSES	1,769,732	4,391,179	7,033,447	13,044,395
LOSS FROM OPERATIONS	(1,627,661)	(4,171,930)	(6,250,519)	(12,021,121)
OTHER INCOME (EXPENSE)				
Investment income	21,061	35,792	80,840	89,905
Loss on disposal of fixed asset	-	-	(2,720)	-
NET LOSS	(1,606,600)	(4,136,138)	(6,172,399)	(11,931,216)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	-	1,922	(12,393)	8,587
COMPREHENSIVE LOSS	$ (1,606,600)	$ (4,134,216)	$ (6,184,792)	$ (11,922,629)
Net loss per share, basic and diluted	$ (0.43)	$ (1.35)	$ (1.76)	$ (4.13)
Weighted average number of shares, basic and diluted	3,746,801	3,060,988	3,500,002	2,886,255

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	September 30, 2019 (unaudited)	December 31, 2018
Cash, cash equivalents and marketable securities	$ 6,827,570	$ 7,256,416
Total assets	$ 7,907,415	$ 9,247,065
Total liabilities	$ 4,336,981	$ 4,631,478
Total stockholders' equity - 4,174,856 and 3,138,748 common shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	3,570,434	4,615,587
Total liabilities and stockholders' equity	$ 7,907,415	$ 9,247,065