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)

March 18, 2020

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 March 18, 2020, 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, 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 Fourth Quarter and Full Year 2019 Financial Results and Provides Corporate Update", dated March 18, 2020.

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 18, 2020

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

Exhibit 99.1

Capricor Therapeutics Reports Fourth Quarter and Full Year 2019 Financial Results and Provides Corporate Update

-To Report Final 12-month HOPE-2 Data in the Second Quarter-

-Exosomes Platform Technology Expanded to Potentially Combat the Novel Coronavirus-

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

LOS ANGELES, March 18, 2020 – 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 fourth quarter and full year 2019 and provided a corporate update.

"We continue to make progress toward the goal of bringing CAP-1002 to patients with DMD with our final 12-month data expected in the second quarter. Importantly, we continue to expand our exosomes technology where we are aiming to develop a platform of exosomal-based vaccines that could potentially be beneficial in many indications, including infectious diseases such as the novel coronavirus (SARS-CoV-2). Further, we have strengthened our program with the appointment of Dr. Stephen Gould from Johns Hopkins University as an Executive Consultant to oversee our exosomes program. With our recent financing completed at the end of last year, we now have extended our runway through the second quarter of 2021 to deliver on our milestones and we continue to pursue potential strategic partnerships for our technologies. Over the next few months, we look forward to making more announcements focusing on our late-stage clinical program and our expanding exosomes program" said Linda Marbán, Ph.D., Capricor's president and chief executive officer.

Dr. Marbán further noted, "The fourth quarter and 2019 have been encouraging on multiple levels and we will be providing an overview on pipeline and regulatory developments, Key Opinion Leader support and increased financial discipline."

The 24th International Congress of the World Muscle Society provided an exciting venue for the Company's "late breaking" presentation unveiling our 6-month interim results in the Phase II HOPE-2 clinical trial of CAP-1002. This was a significant milestone not only for 2019 but also for the clinical pathway of CAP-1002 for DMD.

Ongoing and active communications with the FDA have been productive for Capricor, as we have the unique advantage for more frequent collaborations with the agency due to our RMAT Designation. The FDA has granted Capricor Orphan Drug Designation and a Rare Pediatric Disease Designation to CAP-1002 for the treatment of DMD. If Capricor were to receive market approval for CAP-1002 by the FDA, Capricor would be eligible to receive a Priority Review Voucher.

Capricor expects 2020 to be a transformative year with clarity on next steps in its DMD program and the planned expansion of our exosome platform technology that potentially may be used for vaccine development, vesicle-mediated protein therapies and treatment of inherited diseases, among other things.

"Building on the success and clinical evidence of our core cardiosphere-derived cells technology, we are enthusiastic to expand our knowledge of exosomes by building out a platform and utilizing our experience to engineer exosomes as drug delivery vehicles" Dr. Marbán said.

Fourth Quarter & FY Highlights and Recent Operational Developments

Pipeline Development

- Announced strategic plan for exosomes platform technology expansion *(March 2020)*
- Announced appointment of Stephen Gould, Ph.D. of Johns Hopkins University as Executive Consultant to oversee exosomes program *(March 2020)*
- Capricor's exosomes technology highlighted in *Nature Biomedical Engineering* *(January 2020)*
- Reported positive data from ongoing HOPE-2 Study of CAP-1002 in DMD at World Muscle Society: Data demonstrated improved PUL 2.0 performance at 6 Months. *(October 2019)*
- Reported that our independent Data and Safety Monitoring Board (DSMB) completed their safety assessment and futility analysis review of the HOPE-2 study and recommended that the trial continue. *(July 2019)*
- Reported interim analysis performed on 6-month data from the HOPE-2 trial showed meaningful results across several independent clinical measures. *(July 2019)*
- Hosted a webinar with Parent Project Muscular Dystrophy to discuss updates on the HOPE-2 clinical program. *(July 2019)*
- HOPE-Duchenne (Phase I/II) clinical data was published in the Journal of Neurology *(February 2019)*

Regulatory Advancement

- Plan to meet with the FDA after receipt of the final 12-month data from HOPE-2 to discuss next steps for the program
- Met with FDA under a Type B End-of-Phase 2 meeting to discuss pre-specified interim analysis for the HOPE-2 trial. *(October 2019)*

Key Opinion Leader Support

- Updated results from the interim analysis presented at the 24th International Annual Congress of the World Muscle Society
  - A study of CAP-1002 in ambulatory and non-ambulatory patients with Duchenne muscular dystrophy, HOPE-2. *(October 2019)*
- Hosted a presentation 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

- Completed approximate $5.1 Million offering priced at-the-market. *(December 2019)*
- As of December 31, 2019 – Capricor had approximately $9.9 million of cash, cash equivalents and marketable securities and utilizing conservative cash deployment has extended the company's runway through at least the second quarter of 2021.

Anticipated Events and Targeted Milestones for 2020

- Plan to host a KOL call on exosomal-based vaccines featuring Dr. Stephen Gould
- Plan to host a KOL call on cardiac complications of DMD on April 1, 2020 featuring Michael Taylor, M.D., Ph.D. (Cincinnati Children's Hospital)
- Plan to submit IND for DMD using CDC-exosomes
- Plan to announce final 12-month data for HOPE-2 in Q2-2020
- Plan to meet with the FDA to discuss next steps for the DMD program after receipt of the final 12-month data
- Plan to present HOPE-2 final results at medical conference
- Continue to pursue partnership opportunities for DMD program
- Continue to pursue grant funding opportunities for our product candidates
- Continue to advance exosome platform opportunities including additional product and indications expansion

Fourth Quarter and Full Year Financial Results

The Company reported a net loss of approximately $1.5 million, or $0.34 per share, for the fourth quarter of 2019, compared to a net loss of approximately $3.3 million, or $1.05 per share, for the fourth quarter of 2018.

As of December 31, 2019, the Company's cash, cash equivalents and marketable securities totaled approximately $9.9 million, compared to approximately $7.3 million on December 31, 2018. Additionally, in 2019, Capricor raised approximately $4.8 million in net proceeds at an average price of approximately $4.48 per share under its at-the-market offering programs.

Capricor believes that based on the current operating plan and financial resources, the Company expects that the cash, cash equivalents and marketable securities at December 31 will be sufficient to cover expenses and capital requirements through at least the second quarter of 2021.

Conference Call and Webcast

To participate in the conference call, please dial 877-451-6152 (Domestic/Toll-Free) or 201-389-0879 (International) and reference the conference ID: 13699780

To participate via a webcast, please visit: http://public.viavid.com/index.php?id=138327

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 Duchenne muscular dystrophy. Capricor has also established itself as one of the companies investigating the field of extracellular vesicles and is exploring the potential of exosome-based candidates 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 September 30, 2019, as filed with the Securities and Exchange Commission on November 8, 2019, and in its Registration Statement on Form S-1 as filed with the Securities and Exchange Commission on December 5, 2019 and the prospectus contained therein, together with any amendments and 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. None of Capricor's exosome-based candidates have been approved for clinical investigation.

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

	Three months ended December 31,		Years ended December 31,	
	2019	2018	2019	2018
REVENUE				
Revenue	$ 222,100	$ 648,082	$ 1,005,028	$ 1,671,356
TOTAL REVENUE	222,100	648,082	1,005,028	1,671,356
OPERATING EXPENSES				
Research and development	828,749	2,849,377	5,141,805	12,066,800
General and administrative	876,720	1,104,670	3,597,111	4,931,642
TOTAL OPERATING EXPENSES	1,705,469	3,954,047	8,738,916	16,998,442
LOSS FROM OPERATIONS	(1,483,369)	(3,305,965)	(7,733,888)	(15,327,086)
OTHER INCOME (EXPENSE)				
Investment income	13,951	46,086	94,791	135,991
Loss on disposal of fixed asset	-	-	(2,720)	-
TOTAL OTHER INCOME (EXPENSE)	13,951	46,086	92,071	135,991
NET LOSS	(1,469,418)	(3,259,879)	(7,641,817)	(15,191,095)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	(757)	(7,814)	(13,150)	773
COMPREHENSIVE LOSS	$ (1,470,175)	$ (3,267,693)	$ (7,654,967)	$ (15,190,322)
Net loss per share, basic and diluted	$ (0.34)	$ (1.05)	$ (2.06)	$ (5.17)
Weighted average number of shares, basic and diluted	4,338,434	3,103,781	3,711,333	2,941,084

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	December 31, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$ 9,885,378	$ 7,256,416
Total assets	$ 11,113,637	$ 9,247,065
Total liabilities	$ 4,274,251	$ 4,631,478
Total stockholders' equity - 5,227,398 and 3,138,748 common shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	6,839,386	4,615,587
Total liabilities and stockholders' equity	$ 11,113,637	$ 9,247,065