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 14, 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 May 14, 2020, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended March 31, 2020. 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 First Quarter 2020 Financial Results and Provides Corporate Update", dated May 14, 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: May 14, 2020

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

Exhibit 99.1

Capricor Therapeutics Reports First Quarter 2020 Financial Results and Provides Corporate Update

Duchenne Muscular Dystrophy Program

-Final Top-Line 12-month Results from Phase II Randomized, Double-blind, Placebo-controlled HOPE-2- Study Demonstrated Improved Performance of Upper Limb (PUL) 2.0 (p=0.05)-

COVID-19 Program

-COVID-19 Compassionate Use Case Series Published in Peer Reviewed Journal-

-Reported 100 Percent Survival in Critical COVID-19 Patients Treated with CAP-1002 Under Compassionate Use Pathway-

-Expanded Access Protocol Approved by FDA to Treat Critical COVID-19 Patients-

-Appointed Stephen J. Gould, Ph.D. to lead Capricor's Exosome-Based Platform Vaccine Approach Against COVID-19-

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

LOS ANGELES, Calif. May 14, 2020 -- Capricor Therapeutics ("Capricor") (NASDAQ: CAPR), a clinical-stage biotechnology company focused on the development of first-in-class biological therapeutics for the treatment and prevention of diseases, announced today its financial results for the first quarter 2020 and provided a recent corporate update.

"The first quarter of 2020 has been incredibly productive on so many levels and I am pleased that we have been able to advance our pipeline during these challenging times. As we have described, CAP-1002, our lead product candidate, has strong immunomodulatory characteristics and has been shown preclinically to address some of the same pathology caused by COVID-19. We were very quick to institute a compassionate use program where CAP-1002 was used to treat six patients with COVID-19 which led to the publication of a peer-reviewed paper. Based on that encouraging data, we filed and now have an approved IND for an expanded access program to treat up to 20 additional patients," said Linda Marbán, Ph.D., Capricor's president and chief executive officer.

Capricor also remains diligently focused on the treatment of DMD using CAP-1002. Capricor continues to advance CAP-1002 for the treatment of DMD with the positive 12-month data announced earlier this week showing improvements in upper limb, cardiac and respiratory function. The 12-month data from the HOPE-2 trial showed statistically meaningful improvements in the PUL 2.0 in CAP-1002 treated patients (p=0.05) with a mean change of 2.4 points over placebo patients. The FDA has suggested the use of the updated PUL 2.0 version as the primary efficacy endpoint in support of a Biologics License Application (BLA). Capricor has requested an End-of-Phase 2 meeting with FDA to discuss next steps and a pathway to approval of a Biologics License Application for CAP-1002 in DMD. Additionally, this new positive data reengages our business development discussions with potential collaborators and other partnership opportunities.

Dr. Marbán continued, “Additionally, as we previously announced, we have appointed Stephen Gould, Ph.D. of Johns Hopkins University, as Executive Consultant to oversee our exosomes program and expand our exosome platform technology, the first products of which, will be two vaccine candidates for the potential prevention of COVID-19. The first candidate, often referred to as a VLP (virus-like particle) is similar in structure to an exosome. These VLPs are produced by the same process developed by Capricor in our studies of CAP-1002. The other is an exosome-mRNA vaccine formulation which is designed to elicit a protective, long-lasting immune response to SARS-CoV-2 by targeting all 4 structural proteins of the virus. We remain committed at Capricor to advancing our innovative therapeutics for the treatment and prevention of serious diseases.”

Capricor expects 2020 to be a transformative year with clarity on next steps in its DMD program, the results from our expanded access program in COVID-19 and the planned expansion of Capricor’s exosome platform technology for vaccine development.

“We are proud to deliver an update of those accomplishments today focused on our DMD and COVID-19 pipeline development and Key Opinion Leader support,” added Dr. Marbán.

First Quarter Highlights and Recent Developments

DMD Pipeline Development

- Final 12-month results from the randomized, double-blind, Phase II HOPE-2 clinical trial of CAP-1002 in boys and young men with DMD *(May 2020)*
  - Improvements in the PUL 2.0 in CAP-1002 treated patients (p=0.05) with a mean change of 2.4 points over placebo patients
  - Improvements in the mid-level PUL 1.2 in CAP-1002 treated patients (p=0.08) with a mean change of 2.8 points over placebo patients
  - Improvements in cardiac function as measured by ejection fraction (p=0.004)
  - Reduction in the biomarker CK-MB, an enzyme that is only released when there is cardiac muscle cell damage. Reduction in CK-MB levels as compared to placebo (p=0.006)
  - First ever study in DMD that correlates cardiac functional stabilization with reduction of a biomarker of cell damage
- IND filed to investigate CDC-exosomes in patients with DMD *(April 2020)*

COVID-19 Pipeline Development

- Peer Reviewed Publication: CAP-1002 in Critically Ill Patients – Compassionate Use Case Series *(May 2020)*
- FDA approves Capricor Expanded Access Program to treat up to 20 additional COVID-19 Patients *(April 2020)*
- CAP-1002 Data Reports 100 Percent Survival in Critical COVID-19 Patients *(April 2020)*
- Initiated Compassionate Use Program for Severe COVID-19 Patients using CAP-1002 *(April 2020)*
- Announced Strategic Expansion for Exosome Platform Technology *(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)*

Key Opinion Leader Support

- Featured KOL webcast & presentation by Michael Taylor, M.D., Ph.D. from Cincinnati Children's Hospital, Cardiac Complications of DMD *(April 2020)*
- Hosted KOL presentation by Stephen J. Gould, Ph.D., from Johns Hopkins University, Why Exosomes are Uniquely Suited for Vaccine Development *(March 2020)*

Anticipated Events and Targeted Milestones for 2020

- Continue development of ongoing vaccine program for COVID-19
- Plan to meet with FDA under an End-of-Phase 2 Meeting to discuss next steps and pathway to approval for CAP-1002 in DMD
- Plan to announce updates from the expanded access program in COVID-19
- Plan to present HOPE-2 final 12-month results at medical conference
- Continue to pursue partnership opportunities for DMD and COVID-19 programs
- Continue to pursue grant funding opportunities for pipeline products

First Quarter and Financial Results

The Company reported a net loss of approximately $2.1 million, or $0.30 per share, for the first quarter of 2020, compared to a net loss of approximately $2.5 million, or $0.75 per share, for the first quarter of 2019.

As of March 31, 2020, the Company's cash, cash equivalents and marketable securities totaled approximately $13.2 million, compared to approximately $9.9 million on December 31, 2019.

In the first quarter, Capricor completed a warrant inducement generating net proceeds of approximately $4.5 million. In addition, from January 1, 2020 through May 13, 2020, Capricor has raised approximately $12.8 million in net proceeds at an average price of approximately $7.34 per share under its at-the-market offering program. As of May 13, 2020, the Company has 14,264,006 shares issued and outstanding.

Conference Call and Webcast Details

To participate in the conference call, please dial 800-734-8507 (Domestic/Toll-Free) or 212-231-2932 (International) and reference the conference ID: 21962261. To participate via a webcast and view the slides, please visit: http://public.viavid.com/index.php?id=139834. 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 and prevention of diseases. 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 is also investigating the field of extracellular vesicles and exploring the potential of exosome-based candidates to treat or prevent a variety of disorders. For more information, visit www.capricor.com and follow the Company on Facebook, Instagram and Twitter.

About CAP-1002

CAP-1002 consists of allogeneic “off-the-shelf” 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. It is being investigated for its potential to modify the immune system’s activity to encourage cellular regeneration. The cells function by releasing exosomes that are taken up largely by macrophages and T-cells and begin a cycle of repair. CDCs have been the subject of over 100 peer-reviewed scientific publications and administered to approximately 150 human subjects across several clinical trials.

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, 2019 as filed with the Securities and Exchange Commission on March 27, 2020. 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.

For more information, please contact:

Media Contact:
Caitlin Kasunich
KCSA Strategic Communications
ckasunich@kcsa.com
212.896.1241

Investor Contact:
Joyce Allaire
LifeSci Advisors, LLC
jallaire@lifesciadvisors.com
617.435.6602

Company Contact:
AJ Bergmann, Chief Financial Officer
abergmann@capricor.com
310.358.3200

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

	Three months ended March 31,	
	2020	2019
REVENUE		
Revenue	$ 185,693	$ 230,504
TOTAL REVENUE	185,693	230,504
OPERATING EXPENSES		
Research and development	1,155,156	1,811,182
General and administrative	1,138,045	976,490
TOTAL OPERATING EXPENSES	2,293,201	2,787,672
LOSS FROM OPERATIONS	(2,107,508)	(2,557,168)
OTHER INCOME (EXPENSE)		
Investment income	22,690	37,823
TOTAL OTHER INCOME (EXPENSE)	22,690	37,823
NET LOSS	(2,084,818)	(2,519,345)
OTHER COMPREHENSIVE INCOME (LOSS)		
Net unrealized gain (loss) on marketable securities	757	(12,393)
COMPREHENSIVE LOSS	$ (2,084,061)	$ (2,531,738)
Net loss per share, basic and diluted	$ (0.30)	$ (0.75)
Weighted average number of shares, basic and diluted	6,878,782	3,347,427

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	March 31, 2020 (unaudited)	December 31, 2019
Cash, cash equivalents and marketable securities	$ 13,217,481	$ 9,885,378
Total assets	$ 14,293,789	$ 11,113,637
Total liabilities	$ 4,701,155	$ 4,274,251
Total stockholders' equity - 9,188,506 and 5,227,398 common shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	9,592,634	6,839,386
Total liabilities and stockholders' equity	$ 14,293,789	$ 11,113,637