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)

August 6, 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 August 6, 2020, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended June 30, 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 Second Quarter 2020 Financial Results and Provides Corporate Update", dated August 6, 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: August 6, 2020

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

Exhibit 99.1

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

Exosome Platform for COVID-19
-Novel Multivalent Exosome mRNA and VLP Vaccine Candidates Underway in Animal Studies-
-Preclinical Data Shows Positive Antibody Response-

CAP-1002 for COVID-19
-Expanded Access Emergency Use Series Published in Peer Reviewed Journal-
-Randomized, Double-Blind, Placebo-Controlled, Phase II IND Submitted to FDA-
-Plan to Initiate Study in Third Quarter, Subject to FDA Approval-

Duchenne Muscular Dystrophy Program
-Reported Positive Top-Line 12-month Results from HOPE-2 Study-
-In Discussions with FDA on Next Steps in Pathway Forward-

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

LOS ANGELES, Calif. August 6, 2020 -- Capricor Therapeutics ("Capricor") (NASDAQ: CAPR), a clinical-stage biotechnology company focused on the development of first-in-class cell and exosome-based therapeutics for the treatment and prevention of diseases, announced today its financial results for the second quarter ending June 30, 2020 and provided a corporate update.

"We had a very successful first half of 2020, marked by continued achievements in our expanding cell and exosome programs. We are now well underway in animal studies and have seen promising results showing the mRNA vaccine is capable of generating an antibody response to multiple antigens expressed by COVID-19. Two distinct vaccines are now in development, one using the exosomes as virus-like particles and the other using exosomes loaded with viral protein mRNAs. We are moving forward as quickly as possible with the goal of bringing a vaccine into the clinic."

"Additionally, we have submitted a new investigational new drug application (IND) to the FDA for a randomized, placebo-controlled, double-blind, Phase II clinical trial to treat up to 60 patients in severe or critical condition with COVID-19 with CAP-1002. Furthermore, we continue to discuss next steps in our DMD program with the FDA" said Linda Marbán, Ph.D., Capricor's president and chief executive officer.

Dr. Marbán continued, "We are enthusiastic and encouraged to be engaged in the development of the next generation of potential vaccines using our proprietary exosome platform. Exosomes are intercellular communicators and are uniquely suited and have the potential to change how we treat, immunomodulate, and mediate serious life-threatening illnesses, correct genetic disorders, engineer vaccines to prevent diseases, and modify enzymes. A key advantage of exosomes beyond the ability to modify cells is the ability to deliver therapeutic payloads, without degradation into specific locations."

Capricor remains diligently focused on the treatment of DMD using CAP-1002. The FDA has continued to encourage us to conduct a Phase III study, however at this time, we are still discussing the pathway forward for this program with the FDA. Once the regulatory pathway is finalized we expect to expand our efforts to seek partnerships for this program. We also recently participated in the Parent Project Muscular Dystrophy (PPMD) Virtual Annual Conference to help better inform families and caregivers around the treatment of DMD.

"We are proud to deliver an update of those accomplishments today focused on our exosome platform, COVID-19 and DMD programs and our anticipated milestones in 2020," added Dr. Marbán.

Second Quarter Highlights and Recent Developments

Exosome Platform for COVID-19

- Generated mRNA loaded exosomes with 4 viral proteins expressed by SARS-CoV-2
- Generated exosome-based VLPs (virus like particles) with 4 viral antigens expressed on the surface of SARS-CoV-2
- Advanced exosome-based vaccine candidates into animal studies

CAP-1002 for COVID-19

- Peer Reviewed Publication: CAP-1002 in Critically Ill Patients – Compassionate Use Case Series
- Provided CAP-1002 for Expanded Access Emergency Use for Severe COVID-19 Patients
- Filed IND with FDA for randomized, double-blind, placebo-controlled Phase II study in severe or critical COVID-19 patients

Duchenne Muscular Dystrophy Program

- Presented positive 12-month results from the randomized, double-blind, Phase II HOPE-2 clinical trial of CAP-1002 in boys and young men with DMD
- In discussions with FDA to determine next steps and pathway forward

Featured Panelist Spotlight

- Featured Panelist - Capricor's CEO, Linda Marbán, "Cell therapy for ARDS - When Remdesivir is not enough" hosted by Maxim Group - Virtual Conference Series (May 2020)
- Featured Panelist – Capricor's CEO, Linda Marbán and Executive Consultant, Stephen Gould, Ph.D. "Exosomes, A New Therapeutic Approach" hosted by LifeSci Advisors, LLC (July 2020)

Anticipated Events and Targeted Milestones for Second Half of 2020

- Plan to initiate Phase II, randomized, double-blind, placebo-controlled study in patients in severe or critical condition with COVID-19, subject to FDA approval
- Plan to announce preliminary results from animal studies with exosome-based vaccine candidates
- Continue discussions with FDA on DMD program
- Plan to present HOPE-2 final 12-month results at medical conference

- Continue to pursue partnership opportunities for pipeline products
- Continue to pursue grant funding opportunities for pipeline products

Second Quarter Financial Results

The Company reported a net loss of approximately $3.5 million, or $0.23 per share, for the second quarter of 2020, compared to a net loss of approximately $2.0 million, or $0.59 per share, for the second quarter of 2019.

As of June 30, 2020, the Company's cash, cash equivalents and marketable securities totaled approximately $36.3 million, compared to approximately $13.2 million on March 31, 2020.

During the first half of 2020, Capricor has raised approximately $29.4 million in net proceeds from the sale of common stock and exercise of common warrants comprised of approximately $19.5 million in net proceeds at an average price of approximately $6.59 per share under its at-the-market offering program and approximately $9.9 million from the exercise of common warrants.

Conference Call and Webcast Details

To participate in the conference call, please dial 800-909-4164 (Domestic/Toll-Free) or
303-223-0117 (International) and reference the conference ID: 21967167

To participate via a webcast and view the slides,
please visit: http://public.viavid.com/index.php?id=141092.

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 cell and exosome-based 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 and COVID-19. 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 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 200 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 and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 as filed with the Securities and Exchange Commission on May 15, 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
310.358.3201

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

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
REVENUE				
Revenue	$ 49,864	$ 410,353	$ 235,557	$ 640,857
TOTAL REVENUE	49,864	410,353	235,557	640,857
OPERATING EXPENSES				
Research and development	1,927,473	1,644,110	3,082,629	3,455,292
General and administrative	1,610,237	831,933	2,748,282	1,808,423
TOTAL OPERATING EXPENSES	3,537,710	2,476,043	5,830,911	5,263,715
LOSS FROM OPERATIONS	(3,487,846)	(2,065,690)	(5,595,354)	(4,622,858)
OTHER INCOME (EXPENSE)				
Investment income	3,692	21,956	26,382	59,779
Loss on disposal of fixed asset	-	(2,720)	-	(2,720)
TOTAL OTHER INCOME (EXPENSE)	3,692	19,236	26,382	57,059
NET LOSS	(3,484,154)	(2,046,454)	(5,568,972)	(4,565,799)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	-	-	757	(12,393)
COMPREHENSIVE LOSS	$ (3,484,154)	$ (2,046,454)	$ (5,568,215)	$ (4,578,192)
Net loss per share, basic and diluted	$ (0.23)	$ (0.59)	$ (0.51)	$ (1.35)
Weighted average number of shares, basic and diluted	15,130,685	3,457,833	11,004,733	3,374,557

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	June 30, 2020 (unaudited)	December 31, 2019
Cash, cash equivalents and marketable securities	$ 36,252,623	$ 9,885,378
Total assets	$ 37,125,954	$ 11,113,637
Total liabilities	$ 5,472,000	$ 4,274,251
Total stockholders' equity - 19,697,576 and 5,227,398 common shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	31,653,954	6,839,386
Total liabilities and stockholders' equity	$ 37,125,954	$ 11,113,637