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 12, 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. ☐

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 12, 2020, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended September 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 Third Quarter 2020 Financial Results and Provides Corporate Update", dated November 12, 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: November 12, 2020

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

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

Exosome Platform Technology

-Announced Positive Preclinical Data for Multivalent Exosome-mRNA Vaccine For COVID-19-
-Novel Vaccine Induced Long-Lasting Immunity to Multiple SARS-CoV-2 Proteins-
-Development of Safe, Non-toxic Exosome Formulation Capable of Delivering Functional mRNA in vitro and in vivo-
-Platform Expansion Underway Using Engineered Exosomes-

Duchenne Muscular Dystrophy Program

-In Discussions with FDA on Next Steps in Pathway Forward-

CAP-1002 for COVID-19

-Patient Screening Underway in Randomized, Double-Blind, Placebo-Controlled INSPIRE Study-

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

LOS ANGELES, CALIF., Nov. 12, 2020 – Capricor Therapeutics, Inc. (NASDAQ: CAPR), 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 a variety of diseases and disorders, announced today its financial results for the third quarter ending September 30, 2020 and provided a corporate update.

“The Company’s development and achievements in the third quarter have been encouraging on multiple levels. We have continued to build momentum with our exosome platform technology as well as with our CAP-1002 program. The pandemic has provided a unique opportunity for the development of a vaccine candidate but also for the use of CAP-1002 as a potential therapeutic,” said Linda Marbán, Ph.D., Capricor’s president and chief executive officer.

“We are advancing two separate and novel vaccine programs. Our strategy has evolved from our original plan to use exosomes from our cell as drug delivery vehicles to creating exosomes from multiple cell types that are readily available to build products that can be designed to address targets where delivery has proved to be challenging. We are now leveraging thought leaders and our own expertise to direct the development of exosome-based vaccines and exosome-based therapeutics. We expect significant pipeline expansion and will be seeking partnering opportunities in the months ahead to further cement our rebranding. I have never been more excited at the possibilities for Capricor,” Dr. Marbán added.

The Company continues the development of our late-stage clinical asset, CAP-1002, for the treatment of advanced stages of DMD, and is currently in discussions with potential partners for this program. The FDA has continued to encourage us to conduct a Phase III study, however at this time, Capricor continues to work with FDA to explore alternative pathways forward.

Capricor is currently screening patients for its INSPIRE Phase II study, which is designed to assess the ability of CAP-1002 to modulate the cytokine storm and attenuate the sequelae associated with severe COVID-19. While other therapeutics are in testing for early and much later stage COVID-19, there are very few options for those with severe disease at risk for ventilation. Based on our preclinical data, as well as the data from our emergency use authorization program, CAP-1002 is poised to potentially be an important tool in the toolbox to treat severe COVID-19.

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

Third Quarter Highlights and Recent Developments

Engineered Exosomes Platform

- Announced positive preclinical data for multivalent exosome-mRNA Vaccine for COVID-19
  - Development of safe, non-toxic exosome formulation capable of delivering functional mRNA *in vitro* and *in vivo*
  - Creation of a multiplexed exosome-RNA vaccine that expresses viral antigens engineered to induce cellular immunity and antibody responses to multiple proteins of SARS-CoV-2
    - Demonstrated persistent cellular immune responses to the SARS-CoV-2 N and S proteins
    - Demonstrated moderate but sustained antibody responses to the SARS-CoV-2 N and S proteins
- 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

Duchenne Muscular Dystrophy Program

- Presented positive final 12-month results from the HOPE-2 Phase II study at the International World Muscle Society Virtual Congress 2020
- In discussions with FDA and potential partners to determine next steps and pathway forward

CAP-1002 for COVID-19

- Initiated patient screening for INSPIRE study
- FDA Acceptance of Capricor's IND Application for Phase II INSPIRE study

Anticipated Events and Targeted Milestones Into 2021

- Plan to initiate patient enrollment of Phase II INSPIRE study in patients in severe or critical condition with COVID-19
- Plan to meet with FDA in PRE-IND meeting to discuss next steps in exosome mRNA vaccine clinical strategy
- Plan to publish additional preclinical data on exosomes platform
- Plan to announce continued pipeline expansion with exosome platform
- Plan to announce updates on INSPIRE study
- Continue discussions with FDA on DMD program
- Continue to pursue partnership opportunities for pipeline products
- Continue to pursue grant funding opportunities for pipeline products

Third Quarter Financial Results

The Company reported a net loss of approximately $3.9 million, or $0.20 per share, for the third quarter of 2020, compared to a net loss of approximately $1.6 million, or $0.43 per share, for the third quarter of 2019.

As of September 30, 2020, the Company's cash, cash equivalents and marketable securities totaled approximately $35.3 million, compared to approximately $9.9 million on December 31, 2019. Additionally, in the third quarter of 2020, Capricor raised approximately $2.0 million in net proceeds at an average price of approximately $5.87 per share under its at-the-market offering program.

Conference Call and Webcast Details

To participate in the conference call, please dial 877-451-6152 (Domestic/Toll-Free) or 201-389-0879 (International) and reference the conference ID: 13712434

To participate via a webcast, please visit: http://public.viavid.com/index.php?id=142179

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 the cytokine storm associated with 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. We are now developing two potential vaccines for COVID-19 as part of our exosome platform. For more information, visit www.capricor.com and follow the Company on Facebook, Instagram and Twitter.

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 June 30, 2020 as filed with the Securities and Exchange Commission on August 10, 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:

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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,	
	2020	2019	2020	2019
REVENUE				
Revenue	$ 16,863	$ 142,071	$ 252,420	$ 782,928
TOTAL REVENUE	16,863	142,071	252,420	782,928
OPERATING EXPENSES				
Research and development	2,629,267	857,764	5,711,896	4,313,056
General and administrative	1,301,673	911,968	4,049,955	2,720,391
TOTAL OPERATING EXPENSES	3,930,940	1,769,732	9,761,851	7,033,447
LOSS FROM OPERATIONS	(3,914,077)	(1,627,661)	(9,509,431)	(6,250,519)
OTHER INCOME (EXPENSE)				
Investment income	3,953	21,061	30,335	80,840
Loss on disposal of fixed asset	-	-	-	(2,720)
TOTAL OTHER INCOME (EXPENSE)	3,953	21,061	30,335	78,120
NET LOSS	(3,910,124)	(1,606,600)	(9,479,096)	(6,172,399)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	-	-	757	(12,393)
COMPREHENSIVE LOSS	$ (3,910,124)	$ (1,606,600)	$ (9,478,339)	$ (6,184,792)
Net loss per share, basic and diluted	$ (0.20)	$ (0.43)	$ (0.68)	$ (1.76)
Weighted average number of shares, basic and diluted	19,801,841	3,746,801	13,958,507	3,500,002

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	September 30, 2020 (unaudited)	December 31, 2019
Cash, cash equivalents and marketable securities	$ 35,300,340	$ 9,885,378
Total assets	$ 36,187,057	$ 11,113,637
Total liabilities	$ 5,779,138	$ 4,274,251
Total stockholders' equity - 20,211,602 and 5,227,398 common shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	30,407,919	6,839,386
Total liabilities and stockholders' equity	$ 36,187,057	$ 11,113,637