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 9, 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 November 9, 2020, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing, among other things, its financial results for the quarter ended September 30, 2020. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K, and the section of the press release entitled "Financial Update for the Third Quarter of 2020" is the section including the Company's financial results.

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 8.01 Other Events.

Additionally, on November 9, 2020, the Company announced that positive data from a preclinical study for a multivalent exosome-based mRNA vaccine for COVID-19 has been posted on the bioRxiv preprint server and will be submitted for publication. A copy of the press release including this announcement is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release, titled "Capricor Therapeutics Announces Positive Preclinical Data for Multivalent Exosome-mRNA Vaccine For COVID-19", dated November 9, 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 9, 2020

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

Exhibit 99.1

Capricor Therapeutics Announces Positive Preclinical Data for Multivalent Exosome-mRNA Vaccine For COVID-19

Potential Vaccine Candidate Employs Novel Exosome-Based mRNA Delivery Platform that Induces Long-Lasting Immunity to Multiple SARS-CoV-2 Proteins

Capricor Scheduling Pre-IND Meeting with FDA to Discuss Clinical Strategy

LOS ANGELES, CALIF., Nov. 9, 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, in collaboration with researchers at Johns Hopkins University, announced today that positive data from a preclinical study for a multivalent exosome-based mRNA vaccine for COVID-19 has been posted on the bioRxiv preprint server and will be submitted for publication.

"Capricor's unique exosome-based mRNA delivery platform is a novel type of SARS-CoV-2 potential vaccine being developed to aid in the worldwide fight against this virus, which continues to plague the world," said Dr. Linda Marbán, Ph.D., CEO of Capricor. "Exosomes are the body's own drug delivery vehicle, produced by all cells, abundant in all biofluids, and demonstrated to be safe by decades of transfusion and transplantation medicine. This study represents a major step forward for our joint effort to develop exosome-based therapeutics. Furthermore, it highlights the ability of our exosome-based RNA delivery platform to deliver multiple mRNAs, induce long-lasting immune responses to multiple SARS-CoV-2 proteins, and potentially elicit a broad-based, cellular immunity that extends beyond the Spike protein alone, which is the sole target of leading vaccine candidates."

Key findings of the pre-clinical study in mice include:

- 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.
- Validation that an exosome mRNA vaccine can induce:
    - Persistent cellular immune responses to the SARS-CoV-2 N and S proteins.
    - Moderate but sustained antibody responses to the SARS-CoV-2 N and S proteins.

Exosomes represent a natural drug delivery vehicle. Their small size, biological origin, minimal immunogenicity and normal role in delivering signals and RNAs to human cells indicates that they have the potential to expand the range of therapeutics that can be deployed in the fight against human disease. As a cell-free substance, exosomes can be stored, handled, reconstituted and administered in a similar fashion to common biopharmaceutical products, such as antibodies and other recombinant protein drugs.

Dr. Marbán continued, "Over the last few years, Capricor has worked diligently to build our exosome platform to deliver biologics, primarily nucleic acids. The work reported reflects our commitment to translating our know-how in the area of exosomes to deliver biologic payloads. We are excited to continue the expansion of this platform of RNA-delivery using exosomes into other therapeutic indications where delivery has proved challenging. We are planning to meet with the FDA to discuss next steps for a clinical development strategy and look forward to sharing additional updates as they become available."

Study Design

The pre-clinical study was designed to interrogate the utility of Capricor's exosome-based mRNA delivery system, to test this system's ability to express multiple combinations of the SARS-CoV-2 virus spike (S), nucleocapsid (N), membrane (M) and envelope (E) proteins, and to assess immune responses to this vaccine in a standard mouse model. The value of this multiplexed, multivalent vaccination approach is highlighted by the fact that immunodominant epitopes in the T-cell response to SARS-CoV-2 infection extend well beyond the Spike protein and are particularly focused on the nucleocapsid (N) protein. Following a low-dose immunization protocol, we show that vaccinated animals generate persistent, long-lasting cellular and humoral immune responses, with no evidence of vaccine-induced adverse 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.

Financial Update for the Third Quarter of 2020

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. As of November 6, 2020, the Company has 20,251,602 shares issued and outstanding. The Company will report more detailed results later this week in its quarterly earnings report.

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.

None of Capricor's exosome-based candidates have been approved for clinical investigation.

For more information, please contact:

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