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)

April 29, 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 8.01 Other Events.

On May 4, 2020, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), filed a new prospectus supplement (the "Prospectus Supplement") with the U.S. Securities and Exchange Commission (the "SEC") with respect to the offer and sale of shares of its common stock, par value $0.001 per share (the "Shares"), with an aggregate offering price of up to $40,000,000 (the "Offering") under the Company's existing at-the-market equity offering program pursuant to a Common Stock Sales Agreement with H.C. Wainwright & Co., LLC, as sales agent. Any Shares offered and sold in the Offering will be issued pursuant to the Company's Registration Statement on Form S-3 originally filed with the Securities and Exchange Commission on October 24, 2018 and subsequently amended on July 17, 2019 and declared effective on July 18, 2019 (the "Registration Statement") and the Prospectus Supplement, which forms a part of the Registration Statement.

The Company currently intends to use the net proceeds from the Offering, if any, for research and development related to the Company's product candidates, manufacturing of the Company's products, working capital and general corporate purposes. The Company reserves the right, at the discretion of its Board of Directors, to reallocate the proceeds of the Offering in response to developments in the Company's business and other factors. At this time, the Company cannot specify with certainty all of the particular uses for the net proceeds to the Company from the Offering, if any.

This Current Report on Form 8-K shall not constitute an offer to sell or the solicitation of an offer to buy the Shares, nor shall there be any offer, solicitation or sale of the Shares in any state or country in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or country.

The opinion of the Company's counsel regarding the validity of the Shares is filed as Exhibit 5.1 to this Current Report on Form 8-K. This opinion is also filed with reference to, and is hereby incorporated by reference into, the Registration Statement.

Additionally, on April 29, 2020, the Company issued a press release announcing new data regarding COVID-19 patients who were treated with the Company's lead asset, off-the-shelf ("allogeneic") cardiac cell therapy CAP-1002, at Cedars-Sinai Medical Center as part of six compassionate care cases. The press release is included as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

5.1	Opinion of Sidley Austin LLP.
23.1	Consent of Sidley Austin LLP (included in Exhibit 5.1).
99.1	Press Release issued by Capricor Therapeutics on April 29, 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 4, 2020

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

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May 4, 2020

Capricor Therapeutics, Inc.
8840 Wilshire Blvd., 2nd Floor
Beverly Hills, California 90211

Re: Registration Statement on Form S-3

Ladies and Gentlemen:

We refer to the Registration Statement on Form S-3, File No. 333-227955, as amended by Amendment No. 1 thereto (the "Registration Statement"), filed by Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"), which Registration Statement was declared effective on July 18, 2019. Pursuant to the Registration Statement, the Company is issuing shares (the "Shares") of its Common Stock, $0.001 par value per share (the "Common Stock") for an aggregate sales price of up to $40,000,000. The Shares are to be sold by the Company pursuant to a Common Stock Sales Agreement dated July 22, 2019 between the Company and H.C. Wainwright & Co., LLC (the "Sales Agreement").

This opinion letter is being delivered in accordance with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act.

We have examined the Registration Statement, the Company's base prospectus dated July 18, 2019, as supplemented by the Company's prospectus supplement dated May 4, 2020, relating to the Shares in the forms filed with the Commission pursuant to Rule 424(b) under the Securities Act (the "Prospectus"), the Sales Agreement, the Company's certificate of incorporation (as amended, the "Certificate of Incorporation") and the resolutions adopted by the board of directors of the Company and the finance committee thereof established by such board relating to the Registration Statement and the issuance of the Shares by the Company. We have also examined originals, or copies of originals certified to our satisfaction, of such agreements, documents, certificates and statements of the Company and other corporate documents and instruments, and have examined such questions of law, as we have considered relevant and necessary as a basis for this opinion letter. We have assumed the authenticity of all documents submitted to us as originals, the genuineness of all signatures, the legal capacity of all persons and the conformity with the original documents of any copies thereof submitted to us for examination. As to facts relevant to the opinions expressed herein, we have relied without independent investigation or verification upon, and assumed the accuracy and completeness of, certificates, letters and oral and written statements and representations of public officials and officers and other representatives of the Company.

Based on and subject to the foregoing and the other limitations, qualifications and assumptions set forth herein, we are of the opinion that the issuance and sale of the Shares pursuant to the Sales Agreement have been duly authorized by the Company, and such Shares will be validly issued, fully paid and non-assessable when certificates representing such Shares shall have been duly executed, countersigned and registered and duly delivered to the purchasers thereof against payment of the agreed consideration therefor in an amount not less than the par value thereof or, if any such Shares are to be issued in uncertificated form, the Company's books shall reflect the issuance of such Shares to the purchasers thereof against payment of the agreed consideration therefor in an amount not less than the par value thereof, in accordance with the Sales Agreement.

For the purposes of this opinion letter, we have assumed that, at the time of the issuance, sale and delivery of Shares: (i) the authorization thereof by the Company will not have been modified or rescinded, and there will not have occurred any change in law affecting the validity thereof; (ii) the Certificate of Incorporation and bylaws of the Company, as currently in effect, will not have been modified or amended and will be in full force and effect; and (iii) the Company will have authorized and unissued shares of Common Stock to issue as the Shares.

This opinion letter is limited to the General Corporation Law of the State of Delaware. We express no opinion as to the laws, rules or regulations of any other jurisdiction, including, without limitation, the federal laws of the United States of America or any state securities or blue sky laws.

We hereby consent to the filing of this opinion letter as an Exhibit to a Current Report on Form 8-K and to all references to our Firm included in or made a part of the Registration Statement, including the Prospectus. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act.

Very truly yours,

/s/ Sidley Austin LLP

Exhibit 99.1

New Capricor Data Reports 100 Percent Survival in Critical COVID-19 Patients Treated with CAP-1002

-U.S. FDA Approves Company's Expanded Access Protocol to Treat Additional Patients-

LOS ANGELES, Calif. April 29, 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 new data reporting 100 percent survival in critical COVID-19 patients who were treated with Capricor's lead asset, off-the-shelf ("allogeneic") cardiac cell therapy CAP-1002, at Cedars-Sinai Medical Center as part of six compassionate care cases.

Over the course of one month, six critically ill COVID-19 patients, all suffering from acute respiratory distress syndrome (ARDS) and five of whom were on mechanical ventilatory support, were safely treated with CAP-1002. Of the six patients treated, four of them have been discharged. Following a review of the available data, the U.S. Food and Drug Administration (FDA) approved the Company's expanded access protocol to treat up to 20 additional COVID-19 patients. There is also a randomized, placebo-controlled trial planned to treat patients with moderate and severe disease which is intended to be funded by non-equity capital.

In the compassionate care cases, five male patients and one female patient (between ages 19 and 75) suffering from COVID-19 received IV infusions of 150 million allogeneic cardiosphere-derived cells (CAP-1002). Of the five patients on ventilator support, four patients no longer required ventilator support within just one to four days following the infusion. The fifth patient remains on mechanical ventilation and the sixth patient is receiving supplemental oxygen and is currently clinically stable. Additionally, laboratory biomarkers correlated with poor outcomes were measured in all patients. Following infusion, several patients showed improvements in biomarkers, such as ferritin, absolute lymphocyte counts and CRP. No adverse events related to the administration of CAP-1002 were observed. This data has been submitted for publication.

CAP-1002 demonstrates immunomodulatory properties. Multiple published peer-reviewed studies of CDCs have demonstrated favorable modulation of various inflammatory cytokines and regulation of the immune response. The current understanding of COVID-19's later stages are thought to be due to overstimulation of the immune system, which triggers a cytokine storm in which the body is overwhelmed with pro-inflammatory molecules. This immune response may become excessive and pathologic, inducing pneumonia, organ failure and death. Therefore, it can be the body's overreaction to COVID-19, rather than the virus itself, that delivers the fatal blow.

"As the global medical community continues to come together in its battle against COVID-19, the results of our initial compassionate care cases are extremely promising and what we had anticipated. We look forward to continuing to treat additional patients under our recently approved expanded access program Investigational New Drug application," said Dr. Linda Marbán, Ph.D., CEO, Capricor. "CAP-1002 is an easy-to-deliver intravenous therapy that has been administered successfully to over 150 patients to date. Given its novel mechanism of action, it could be a potential game-changer in helping countless COVID-19 patients."

Capricor is also in late-stage clinical development of CAP-1002 for Duchenne muscular dystrophy (DMD). In DMD, the lack of dystrophin produces abnormal inflammatory responses, which are responsible for much of the damage to skeletal and cardiac muscle. The Company has previously announced that top-line results of HOPE-2, a randomized, placebo-controlled study, will be released by mid-May 2020.

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:

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