

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)

April 28, 2021

CAPRICOR THERAPEUTICS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-34058
(Commission
File Number)

88-0363465
(I.R.S. Employer
Identification No.)

8840 Wilshire Blvd., 2nd Floor, Beverly Hills, CA
(Address of principal executive offices)

90211
(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 1.01. Entry into a Material Definitive Agreement.

Exclusive License Agreement

On April 28, 2021, Capricor, Inc. ("Capricor"), a wholly-owned subsidiary of Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), entered into an Exclusive License Agreement (the "License Agreement") with Johns Hopkins University ("JHU") for its co-owned interest in certain intellectual property rights related to exosome-mRNA vaccines and therapeutics. The License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by JHU to Capricor, with the right to sublicense, in order to conduct research using the patent rights and know-how and to develop and commercialize products in the field using the patent rights and know-how.

Pursuant to the License Agreement, JHU was paid an upfront license fee of \$10,000 and Capricor has agreed to reimburse JHU for certain

fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor is required to meet certain development milestones for which a milestone payment fee shall be due and is obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a double-digit percentage of any non-royalty consideration received from any sublicenses. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to pay royalties on one or more third party patents as a requirement to make or sell a licensed product. In addition, Capricor will, beginning with the third year of the License Agreement, be obligated to pay JHU a minimum annual royalty which is non-refundable but will be credited against royalties incurred by Capricor for the year in which the minimum annual royalty becomes due.

The License Agreement will, unless sooner terminated, continue in each country until the date of expiration of the last to expire patent included within the patent rights in that country, or if no patents issue, then for 20 years. The License Agreement may be terminated by Capricor upon 90 days' written notice in its discretion and with 60 days' notice with respect to any particular patent or application or as to any particular licensed product. The License Agreement may also be terminated by either party if it fails to perform or otherwise breaches any of its obligations and fails to cure such breach within a 60-day cure period commencing upon notice. A material breach by Capricor may include (a) a delinquency with respect to payment or reporting; (b) the failure by Capricor to timely achieve a specified milestone or otherwise failing to diligently develop, commercialize, and sell licensed products throughout the term of the License Agreement; (c) non-compliance with record keeping or audit obligations; (d) voluntary bankruptcy or insolvency of Capricor; and (e) non-compliance with Capricor's insurance obligations.

The foregoing summary of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the License Agreement. A copy of the License Agreement will be filed with the Securities and Exchange Commission (the "SEC") as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2021 (the "Form 10-Q") or via an amendment to this Current Report on Form 8-K. Certain terms of the License Agreement have been omitted from this Current Report on Form 8-K and will be omitted from the version of the License Agreement to be filed as an exhibit to the Form 10-Q or via an amendment to this Current Report on Form 8-K pursuant to Item 601(b) (10) of Regulation S-K because such terms are both (i) not material and (ii) would likely cause competitive harm to the Company if publicly disclosed.

On April 29, 2021, Capricor Therapeutics issued a press release announcing the entry into the Exclusive License Agreement. A copy of the press release is filed herewith as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

[99.1 Press Release, dated April 29, 2021, announcing the entry into an Exclusive License Agreement, by and between Capricor, Inc. and Johns Hopkins University.](#)

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: April 30, 2021

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



Capricor Therapeutics Signs Exclusive Worldwide License Agreement with Johns Hopkins University to Expand its Exosome Platform Technology Portfolio

-Portfolio Will Now Include Exclusive Rights to Engineered Exosomes for Vaccines and Therapeutics-

LOS ANGELES, CALIF., April 29, 2021 – Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company focused on the development of transformative cell- and exosome-based therapeutics for the treatment and prevention of a broad spectrum of diseases, today announced that it has signed an exclusive, worldwide licensing agreement with Johns Hopkins University (JHU) to include engineered exosomes for vaccines and therapeutics as part of the Company's exosome technology portfolio.

"This exclusive license agreement with JHU allows Capricor to continue the expansion of our engineered exosome platform technology. We are focused on developing this platform to deliver nucleic acids or proteins effectively into cells and drive the expression of functional proteins," said Linda Marbán, Ph.D., CEO, Capricor Therapeutics. "This agreement marks a significant milestone in the development of our Company. We believe that this new platform technology has the ability to expand into disease areas of high unmet medical need."

Under the terms of the agreement, Capricor has been granted the exclusive, worldwide rights to JHU's co-owned interest in intellectual property described in the licensed patent applications, enabling Capricor to exclusively develop, manufacture and commercialize, with the right to sublicense, IP related to exosome technology for applications across both vaccine and therapeutic areas. Capricor is the co-owner of the intellectual property associated with the patent applications covered by the agreement.

The licensed technology is based on extensive preclinical research conducted by Capricor and Stephen Gould, Ph.D., who serves as Capricor's executive consultant. Dr. Gould, Professor of Biological Chemistry at JHU, is an internationally recognized exosome expert who brings an unparalleled understanding of exosome engineering to Capricor's exosome-based research and development programs. Capricor and JHU have collaborated over the last decade to accelerate several technologies at the forefront of biotechnology in areas that include chronic heart failure, as well as cardiovascular, genetic and muscular diseases.

Exosomes are the body's own drug delivery vehicle, produced by all cells, abundant in all biofluids, and demonstrated to be safe following decades of transfusion and transplantation medicine. Their small size, biological origin, minimal immunogenicity and normal role in delivering signals and RNAs to human cells indicates that exosomes have the potential to expand the range of therapeutics that can be deployed in the fight against a broad spectrum of diseases. Their ease of crossing cell membranes and the ability to communicate in native cellular language makes them a class of novel therapeutic agents.

"By harnessing the power of this unique platform, Capricor can potentially provide and develop therapeutics to treat a variety of diseases," added Dr. Marbán. "With our foundational data and through collaboration with Dr. Gould and his colleagues at JHU, we believe that exosomes can provide a new approach in drug development. Capricor plans to announce further pipeline opportunities and intends to move this technology into the clinic in the near future, subject to regulatory approval."

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a biotechnology company focused on the development of transformative cell- and exosome-based therapeutics and vaccines for the treatment and prevention of a broad spectrum of diseases. Capricor's lead candidate, CAP-1002, is an allogeneic cardiac-derived 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 developing our exosomes platform technology as a next-generation therapeutic platform. Our current focus is on the development of exosomes loaded with nucleic acids, including mRNA, to treat or prevent a variety of diseases. 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, 2020 as filed with the Securities and Exchange Commission on March 15, 2021. 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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