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)

January 24, 2022

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 1.01 Entry into a Material Definitive Agreement.

Commercialization and Distribution Agreement

On January 24, 2022, Capricor Therapeutics, Inc. (the "Company" or "Capricor") entered into an Exclusive Commercialization and Distribution Agreement (the "Agreement") with Nippon Shinyaku, Co., Ltd., a Japanese corporation, ("Nippon Shinyaku"). Under the terms of the Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in the United States, of CAP-1002, the Company's lead product candidate, for the treatment of Duchenne muscular dystrophy.

Under the terms of the agreement, Capricor will be responsible for the conduct of HOPE-3 as well as the manufacturing of CAP-1002. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in the United States. Capricor will sell commercial product to Nippon Shinyaku and in addition will receive a meaningful, double-digit share of product revenue and additional development and sales-based milestone payments. Capricor will receive an upfront payment of $30.0 million with potential additional milestone payments of up to $705.0 million.

The Company expects to file the Agreement as an exhibit to its Annual Report on Form 10-K for the year ended December 31, 2021 and intends to seek confidential treatment for certain terms and provisions of the Agreement. The foregoing description is a summary of the material terms of the Agreement, does not purport to be complete, and is qualified in its entirety by reference to the text of the Agreement when filed.

A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, titled "Capricor Therapeutics and Nippon Shinyaku Enter Partnership for Exclusive Commercialization and Distribution of CAP-1002 for the Treatment of Duchenne Muscular Dystrophy in the U.S.", dated January 25, 2022.
104	Cover Page Interactive Data File (formatted as Inline XBRL)

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: January 25, 2022

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

Exhibit 99.1

Capricor Therapeutics and Nippon Shinyaku Enter Partnership for Exclusive Commercialization and Distribution of CAP-1002 for the Treatment of Duchenne Muscular Dystrophy in the U.S.

-Partnership Leverages Nippon Shinyaku's Deep Experience in Drug Development for Rare Diseases and its Commercial DMD Franchise in the U.S.-

-Capricor to Receive an Upfront Payment of $30 Million, Additional Potential Milestone Payments of up to $705 Million-

-Capricor to Receive Meaningful Double-Digit Percentage of Revenue Based on Product Sales-

-Pivotal Phase 3, HOPE-3 Trial Cleared by FDA to Proceed, Initiation of Trial Underway-

SAN DIEGO, Calif., January 25, 2022 – Capricor Therapeutics (NASDAQ: CAPR) ("Capricor" or "the Company"), 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, announced today that it has entered into a partnership with Nippon Shinyaku Co., Ltd., a Japanese pharmaceutical company listed on the TYO (US subsidiary: NS Pharma), for the exclusive commercialization and distribution in the United States of Capricor's lead asset, CAP-1002, for the treatment of Duchenne muscular dystrophy (DMD), a rare neuromuscular disease with limited treatment options.

Capricor's proprietary cell therapy, CAP-1002, is comprised of human allogeneic cardiosphere-derived cells, which have demonstrated positive results in patients with DMD. CAP-1002's mechanism of action is immunomodulatory and regenerative and its broad applicability makes it suitable for patients regardless of genetic mutation. HOPE-Duchenne and HOPE-2, the Phase 1 and Phase 2 clinical trials using CAP-1002 to treat late-stage DMD patients, showed statistically significant improvements in upper limb and/or cardiac function in the treatment groups. HOPE-3, the Phase 3 clinical trial that will be supported by this partnership, will commence shortly and is expected to be the pivotal trial for CAP-1002 in DMD. The regulatory pathway for CAP-1002 is supported by RMAT (Regenerative Medicine Advanced Therapy Designation) as well as Orphan Drug Designation. If Capricor were to receive market approval for CAP-1002 by the FDA, Capricor would be eligible to receive a Priority Review Voucher based on its designation as a rare pediatric disease.

Under the terms of the agreement, Capricor will be responsible for the conduct of HOPE-3 as well as the manufacturing of CAP-1002. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in the United States. Capricor will sell commercial product to Nippon Shinyaku and in addition will receive a meaningful, double-digit share of product revenue and additional development and sales-based milestone payments. Capricor will receive an upfront payment of $30 million with potential additional milestone payments of up to $705 million.

"The partnership with Nippon Shinyaku aligns us with a larger, seasoned pharmaceutical company experienced in rare disease with specific expertise in DMD. Nippon Shinyaku recently launched Viltepso, an exon skipping agent for the treatment of DMD and has a fully assembled U.S. team to support a broad commercialization effort. The addition of non-equity capital from this transaction provides the requisite funding for the execution of HOPE-3 without dilution to Capricor shareholders. Further, the structure of the agreement allows us to leverage our expertise in manufacturing CAP-1002 and to have a very meaningful share of future product revenues. Our initial planned indication is for late-stage DMD patients with more advanced disease. Presently, this comprises approximately half of all DMD patients. Indication expansion to younger boys is something we hope to look at in the future as well as potential synergies with other developing therapies including gene therapy and oligonucleotides" said Dr. Linda Marbán, CEO of Capricor.

“At Nippon Shinyaku, we believe in the potential of CAP-1002 to address the severe unmet need for boys and young men with Duchenne muscular dystrophy,” said Toru Nakai, President of Nippon Shinyaku. “As we have an established commercial program for DMD in the USA, working with Capricor to bring CAP-1002 to patients presents the opportunity for a strong partnership for both companies. As CAP-1002 moves towards potential commercialization, the overarching goal of both companies is to develop novel, life changing therapies for DMD and, most importantly, give hope to patients in need.”

About Capricor Therapeutics
Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a biotechnology company focused on developing transformative cell and exosome-based therapeutics and vaccines for treating and preventing 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 treating Duchenne muscular dystrophy and the cytokine storm associated with COVID-19. Capricor is also developing its exosome technology as a next-generation therapeutic platform. The Company’s current focus is on developing exosomes capable of delivering nucleic acids, including mRNA as well as proteins, to treat or prevent a variety of diseases. For more information, visit www.capricor.com, and follow the Company on Facebook, Instagram and Twitter.

About Duchenne Muscular Dystrophy
Duchenne muscular dystrophy is a devastating genetic disorder characterized by progressive weakness and chronic inflammation of the skeletal, heart and respiratory muscles. Patients suffering from DMD typically lose their ability to walk in their teenage years and generally die of cardiac or respiratory complications by age 30. It occurs in one in every 3,600 live male births across all races, cultures and countries. DMD afflicts approximately 200,000 boys and young men around the world. Treatment options are limited, and there is no cure.

About CAP-1002
CAP-1002 consists of allogeneic cardiosphere-derived cells (CDCs), a type of progenitor cell that has been shown in pre-clinical and clinical studies to exert potent immuno-modulatory activity and is being investigated for its potential to modify the immune system’s activity to encourage cellular regeneration. CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to over 200 human subjects across several clinical trials.

About Nippon Shinyaku
Nippon Shinyaku’s mission is to help people lead healthier and happier lives. Through creating unique medicines that will bring hope to patients and families struggling with illness, it aims to be an organization trusted by the community. Please visit its website (https://www.nippon-shinyaku.co.jp/english/) for products or detailed information.

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; the ability to achieve product milestones and to receive milestone payments from commercial partners; 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, and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 as filed with the Securities and Exchange Commission on November 12, 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.

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