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)

October 16, 2024

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.)**

10865 Road to the Cure, Suite 150, San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

(858) 727-1755
(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.

The information set below under "Recent Developments – Preliminary balance of cash, cash equivalents and short-term investments" in Item 8.01 is incorporated by reference herein.

Item 8.01 Other Events.

Recent Developments

Deramiocel for the treatment of Duchenne muscular dystrophy (DMD)

Following recent meetings with the U.S. Food and Drug Administration ("FDA"), Capricor Therapeutics, Inc. ("Capricor" or the "Company") announced its intent to file a Biologics License Application ("BLA") based on existing cardiac and natural history data for deramiocel to treat all patients diagnosed with Duchenne muscular dystrophy ("DMD") cardiomyopathy.

- Capricor commenced the filing of a BLA in October of 2024 seeking full approval of deramiocel for the treatment of DMD-cardiomyopathy with full submission expected by year-end 2024.
- The BLA filing will be based on existing cardiac data from the Phase 2 HOPE-2 and HOPE-2 Open Label Extension ("OLE") trials compared to natural history data provided by Vanderbilt University Medical Center and Cincinnati Children's Hospital Medical Center.
- In order to support potential label expansion to treat DMD skeletal muscle myopathy, Capricor plans to combine Cohorts A and B of the Phase 3 HOPE-3 clinical trial to serve as a post-approval study and does not intend to unblind Cohort A at this time, which was expected to occur in the fourth quarter of 2024.

StealthX™Exosome Platform

The Company's proprietary StealthX™ exosome-based multivalent vaccine (StealthX™ vaccine) for the prevention of SARS-CoV-2 was selected to be part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines. Under the terms of the collaboration, Capricor will supply the investigational product and NIAID's Division of Microbiology and Infectious Diseases will conduct the trial. Currently, our vaccine candidate is in the manufacturing phase with plans to deliver it to NIAID by the end of 2024.

Private Placement to Nippon Shinyaku

On September 16, 2024, the Company entered into a subscription agreement with Nippon Shinyaku pursuant to which on September 16, 2024, the Company issued and sold to Nippon Shinyaku in a private placement, an aggregate of 2,798,507 shares of the common stock of the Company, par value $0.001 per share, at a price per Share of $5.36, which was issued at a 20% premium to the 60-day volume-weighted average price, for an aggregate purchase price of approximately $15.0 million.

At-the-Market Program Sales

From June 30, 2024 through the date of this Current Report on Form 8-K (this "Current Report"), the Company sold an aggregate of 5,474,550 shares of common stock under its at-the-market program at an average price of $9.84 per share, resulting in gross proceeds of approximately $53.9 million, which represents all amounts that were available to be sold under that at-the-market program.

Preliminary balance of cash, cash equivalents and short-term investments

As of September 30, 2024, the Company estimates that it had approximately $85.0 million in cash and cash equivalents and short-term investments.

This estimate was prepared based on information available as of the date of this prospectus supplement and may vary from the Company's actual financial position as of September 30, 2024. The Company's financial closing procedures as of and for the nine months ended September 30, 2024 are not yet complete and, as a result, its final results upon completion of those

procedures may differ materially from its preliminary estimate. This preliminary estimate is subject to change, and any changes may be material. Further, this preliminary estimate does not present all information necessary for an understanding of the Company's financial condition and liquidity as of and for the nine months ended September 30, 2024. This preliminary estimate should not be viewed as a substitute for financial statements prepared in accordance with accounting principles generally accepted in the United States and they are not necessarily indicative of the results to be achieved in any future period. Accordingly, you should not draw any conclusions based on the foregoing estimate and should not place undue reliance on this preliminary estimate. The Company assumes no duty to update this preliminary estimate except as required by law.

The preliminary financial data included in the registration statement of which this prospectus supplement forms a part has been prepared by, and is the responsibility of, the Company's management. Rose, Snyder and Jacobs LLP has not audited, reviewed, examined, compiled, nor applied agreed-upon procedures with respect to this preliminary financial data. Accordingly, Rose, Snyder and Jacobs LLP does not express an opinion or any other form of assurance with respect thereto.

Forward-Looking Statements

This Current Report contains forward-looking statements, including within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the filing of a BLA for deramiocel, the design and conduct of our clinical trials, and the delivery of StealthX™ vaccine to NIAID.

These forward-looking statements are based on our current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Our actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including the factors referred to in the "Risk Factors" sections of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2024 and June 30, 2024. If one or more of these factors materialize, or if any underlying assumptions prove incorrect, our actual results, performance or achievements may vary materially from any future results, performance or achievements expressed or implied by these forward-looking statements.

You should consider these factors as being applicable to all related forward-looking statements wherever they appear in this Current Report. While we may elect to update forward-looking statements, we do not assume, and specifically disclaim, any obligation to do so, whether as a result of new information, future events or otherwise, except as required by law.

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: October 16, 2024

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