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 20, 2026

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 Global Select Market

Item 7.01 Regulation FD Disclosure.

On November 20, 2026, the Company issued a press release announcing that it has received a Complete Response Letter ("CRL") from the U.S. Food and Drug Administration ("FDA") regarding its resubmitted Biologics License Application ("BLA") for Deramiocel, the Company's lead cellular therapy candidate for the treatment of Duchenne muscular dystrophy ("DMD").

The CRL states that the FDA does not consider the data sufficient to establish substantial evidence of effectiveness and cites certain other clinical deficiencies.

As of September 30, 2026, the Company had cash, cash equivalents, restricted cash and marketable securities of approximately $198.5 million, which it believes is sufficient to fund its planned operations for at least the next 12 months. The Company is reviewing its operating costs to further extend its cash runway.

A copy of the press release has been filed as Exhibit 99.1 hereto and is incorporated herein by reference.

The information under Item 7.01 of this Current Report on Form 8-K, 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 Exchange Act, unless expressly set forth as being incorporated by reference into such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, titled "Capricor Therapeutics Provides Regulatory Update on Deramiocel BLA for Duchenne Muscular Dystrophy", dated November 20, 2026.
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: November 20, 2026

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

Exhibit 99.1

Capricor Therapeutics Provides Regulatory Update on Deramiocel BLA for Duchenne Muscular Dystrophy

- Company receives Complete Response Letter from FDA for Deramiocel BLA
- Conference call and webcast Monday, November 23, at 8:30 a.m. ET

SAN DIEGO, Nov. 20, 2026 — Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for rare diseases, today announced that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its resubmitted Biologics License Application (BLA) for Deramiocel, its investigational cell therapy for Duchenne muscular dystrophy (DMD). The CRL states that the FDA does not consider the data sufficient to establish substantial evidence of effectiveness and cites certain other clinical deficiencies.

"We are deeply disappointed for the boys and young men living with Duchenne and their families," said Linda Marbán, Ph.D., Capricor's Chief Executive Officer. "Deramiocel has been studied in two randomized, double-blind, placebo-controlled trials, HOPE-2 and HOPE-3, both of which met their primary endpoints. We stand behind the rigor of our clinical program and the integrity of our data, and we believe the data support approval. We are reviewing the letter carefully and will share next steps once we have completed our evaluation."

As of September 30, 2026, the Company had cash, cash equivalents, restricted cash and marketable securities of approximately $198.5 million, which it believes is sufficient to fund its planned operations for at least the next 12 months. The Company is reviewing its operating costs to further extend its cash runway.

Conference Call and Webcast

To participate in the conference call, please dial 1-800-717-1738 (Domestic) or 1-646-307-1865 (International) and reference the conference ID: 27699. Participants may dial in using the numbers above and ask to be joined to the call or click the Call Me™ link for instant telephone access to the event. To participate via a webcast, please click here. A replay of the webcast will be available shortly after the conclusion of the live event and will be accessible in the Investors section of the Company's website.

About Duchenne Muscular Dystrophy

Duchenne muscular dystrophy (DMD) is a severe, X-linked genetic disorder characterized by progressive muscle degeneration affecting the skeletal, respiratory, and cardiac muscles. It is caused by the absence of functional dystrophin, a key structural protein in muscle cells. DMD affects approximately 15,000 individuals in the United States, primarily males. Over time, deterioration of the heart muscle leads to cardiomyopathy and heart failure, the leading cause of death in DMD. There is no cure, and treatment options remain limited.

About Deramiocel

Deramiocel (CAP-1002) consists of allogeneic cardiosphere-derived cells (CDCs), a rare population of cardiac cells that have been shown in preclinical and clinical studies to exert immunomodulatory and anti-fibrotic actions in the preservation of skeletal and cardiac muscle function in muscular dystrophies such as DMD. CDCs act by secreting extracellular vesicles known as exosomes, which target macrophages and alter their expression profile to adopt a healing rather than pro-inflammatory phenotype. For the treatment of DMD, Deramiocel holds Orphan Drug, RMAT and Rare Pediatric Disease designations in the U.S., and Orphan Drug and ATMP designations in Europe.

About Capricor Therapeutics

Capricor Therapeutics (NASDAQ: CAPR) is a biotechnology company dedicated to advancing cell and exosome-based therapeutics for the treatment of rare diseases. Our lead product candidate, Deramiocel, is an allogeneic cardiac-derived cell

therapy in late-stage development for the treatment of Duchenne muscular dystrophy, evaluated in clinical studies for its potential to preserve skeletal and cardiac muscle function. Capricor is also advancing its proprietary StealthX™ exosome platform for the targeted delivery of oligonucleotides, proteins, and small-molecule therapeutics across a range of diseases. At Capricor, we are committed to delivering new therapies for patients with rare diseases. For more information, visit capricor.com, and follow Capricor on Facebook, Instagram and X.

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 clinical trials; the pace of enrollment of clinical trials; plans regarding regulatory filings, future research and clinical trials; regulatory developments involving products, including future interactions with regulatory authorities and the ability to obtain regulatory approvals or otherwise bring products to market; the contents of, and our response to, the Complete Response Letter and the timing of any resubmission; manufacturing capabilities; dates for regulatory meetings; the potential that required regulatory inspections may be delayed or not be successful, which would delay or prevent product approval; revenue and reimbursement estimates; projected terms of definitive agreements, our financial position, cash runway and planned cost reductions, our possible uses of existing cash and investment resources; results of securities litigation; and statements regarding our litigation with Nippon Shinyaku Co., Ltd. and NS Pharma, Inc., including the nature of the dispute, our expectations regarding any legal proceedings, and our ability to commercialize Deramiocel independent of our existing distribution agreement; 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, 2025, as filed with the Securities and Exchange Commission on March 17, 2026, and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2026, as filed with the Securities and Exchange Commission on November 10, 2026. 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.

Deramiocel and the StealthX™ vaccine are investigational candidates and have not been approved for commercial use in any indication.

For more information, please contact:

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