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)

August 13, 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 2.02 Results of Operations and Financial Condition.

On August 13, 2026, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended June 30, 2026. A copy of the press release is being furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information under Item 2.02 of this Current Report on Form 8-K and 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 Reports Second Quarter 2026 Financial Results and Provides Corporate Update", dated August 13, 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: August 13, 2026

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

Exhibit 99.1

Capricor Therapeutics Reports Second Quarter 2026 Financial Results and Provides Corporate Update

- *Deramiocel Biologics License Application (BLA) under active FDA review*
- *HOPE-3 Phase 3 results published in The Lancet; primary endpoint of upper limb function achieved at p=0.029*
- *Cash, cash equivalents and marketable securities of approximately $238 million as of June 30, 2026*
- *Conference call and webcast today at 4:30 p.m. ET*

SAN DIEGO, Aug. 13, 2026 (GLOBE NEWSWIRE) — Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for the treatment of rare diseases, today announced its financial results for the second quarter ended June 30, 2026, and provided a corporate update.

"Our priority is, and always has been, to get Deramiocel to the patients and families living with Duchenne who need it most," said Linda Marbán, Ph.D., Chief Executive Officer of Capricor. "The Advisory Committee outcome was not the one we hoped for. The indication we requested in 2024 was the treatment of cardiomyopathy in DMD, and that is the question the Committee was asked to vote on, not the HOPE-3 primary endpoint. HOPE-3 was designed and powered to demonstrate efficacy in upper limb function; cardiac function was a key secondary endpoint, measured across all patients enrolled rather than only those with established cardiomyopathy. The full dataset has since been published in The Lancet following extensive and independent peer review, and we continue to believe there is a path to approval for Deramiocel."

Dr. Marbán continued, "The most powerful part of the Advisory Committee was the open public hearing, where patients, families and clinicians described what this therapy has meant, or could mean, to them. That testimony is on the public record, and it is a reminder of how urgent the unmet need in Duchenne remains. We are continuing to work with the Agency on a path forward."

Second Quarter 2026 and Recent Highlights

- **Deramiocel BLA Under FDA Review:** Capricor is continuing to work with the FDA on the review of its BLA. The Company plans to provide a regulatory update on its conference call today and will provide further updates as they become available.
- **FDA Advisory Committee Outcome:** On July 29, 2026, the Cellular, Tissue and Gene Therapies Advisory Committee voted 3 in favor and 9 against on whether available evidence provides substantial evidence of effectiveness of Deramiocel for the treatment of cardiomyopathy in patients with DMD. The Committee was not asked to vote on the HOPE-3 primary endpoint or on overall benefit-risk, and in a separate discussion of upper limb function its feedback was directionally supportive of the HOPE-3 clinical evidence. The recommendation is advisory and non-binding.
- **HOPE-3 Results Published in *The Lancet*:** The full HOPE-3 Phase 3 dataset was published in *The Lancet* in July following extensive and independent peer review. Deramiocel demonstrated a statistically significant slowing of upper limb disease progression as measured by PUL 2.0 (p=0.029), with supportive results across additional functional and cardiac measures, which are characterized as nominally significant under the applicable hierarchical testing procedures. In connection with the peer review, Capricor identified an issue with the statistical model in the clinical study report and reverted to the statistical analysis plan in place prior to unblinding. The only endpoint affected was left ventricular ejection fraction, which yields (p=0.09) and a 1.8 percentage point treatment difference, compared to (p=0.04) and a 2.4 percentage point difference reported as topline data. The pre-specified cardiomyopathy subgroup was unchanged at (p=0.02), nothing else changed in the data or its analysis, and the HOPE-3 primary endpoint was unaffected.
- **FDA Bioresearch Monitoring Inspection:** As part of the review process, the FDA conducted a BIMO inspection in July 2026 and issued a Form 483 citing one observation. The Company has submitted its responses and is currently awaiting feedback.
- **Commercial and Manufacturing Readiness:** The Company's GMP manufacturing facility in San Diego is operational and positioned to support an initial commercial launch, if Deramiocel is approved. The second-floor expansion is targeted for full validation and FDA inspection in 2027, as planned. Michael Maurer joined as Chief

Commercial Officer, bringing direct DMD and rare disease experience, and has been judiciously building out the launch organization. Capricor is advancing commercial readiness at a slower pace pending regulatory clarity.

- **NS Pharma Dispute:** The state court was scheduled to hear Capricor's motion for preliminary injunction on August 10, 2026, ahead of the PDUFA action date. Capricor withdrew the motion, without prejudice, having determined that resolving this contractual dispute in arbitration following the FDA's decision would give the parties a more complete regulatory record to work from. The Company estimates arbitration to begin this fall. Capricor's position on the underlying dispute has not changed: it continues to believe the pricing structure in the U.S. Distribution Agreement is fundamentally flawed in a way that would impede patient access, and continues to seek rescission.
- **Long-Term Safety and Efficacy Experience:** Capricor has administered approximately 1,300 intravenous infusions of Deramiocel to over 200 patients with DMD across three separate clinical trials. More than 80 patients are enrolled in the Company's collective open-label extension studies, with some receiving continuous infusions for more than five years, and the long-term safety profile is consistent and well characterized.
- **Pipeline and Lifecycle Management:** Capricor has initiated regulatory engagement in Europe and Japan for Deramiocel. Expansion into younger DMD patients and Becker muscular dystrophy remains a priority, with trial initiations stage-gated to the U.S. regulatory pathway for Deramiocel. Programs not directly related to Deramiocel, including the Company's exosome-based platform, are on hold pending further regulatory clarity.

Second Quarter 2026 Financial Results

- **Cash position:** Cash, cash equivalents and marketable securities totaled approximately $237.9 million as of June 30, 2026, compared to approximately $318.1 million as of December 31, 2025.
- **Revenues:** There was no revenue recognized for the first half of 2026 or 2025.
- **Costs and Expenses:** Total operating expenses for the second quarter of 2026 were approximately $42.9 million, compared to approximately $27.7 million for the second quarter of 2025. Total operating expenses for the first half of 2026 were approximately $79.7 million, compared to approximately $52.7 million for the first half of 2025.
- **Net loss:** The Company reported a net loss of approximately $40.7 million, or $0.70 per share, for the second quarter of 2026, compared to a net loss of approximately $25.9 million, or $0.57 per share, for the second quarter of 2025. The net loss for the first half of 2026 was approximately $74.7 million, or $1.29 per share, compared to a net loss of approximately $50.3 million, or $1.10 per share, for the first half of 2025.
- **Financial Outlook:** The Company believes that, based on its current operating plan and financial resources, its available cash, cash equivalents and marketable securities are sufficient to fund its operating capital requirements for at least the next twelve months. The Company expects to provide additional guidance on its longer-term financial outlook following greater regulatory clarity, which will inform future strategic and capital allocation decisions. This outlook excludes any potential revenue from product sales, the potential monetization of a Priority Review Voucher, if received, or other non-operating sources of capital.

Upcoming Investor Events

- 2026 Wells Fargo Healthcare Conference, September 8-10, 2026, Boston, MA
- Cantor Global Healthcare Conference 2026, September 9-11, 2026, New York, NY
- H.C. Wainwright 28th Annual Global Investment Conference, September 14-16, 2026, New York, NY

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: 91880. 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 and primarily impacts boys. Over time, deterioration of the heart muscle leads to cardiomyopathy and heart failure, which is 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 potent immunomodulatory and anti-fibrotic actions in the preservation of cardiac and skeletal 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. CDCs have been investigated in more than 250 peer-reviewed scientific publications and administered to over 250 human subjects across multiple clinical trials.

Deramiocel has received Orphan Drug Designation for the treatment of DMD from both the U.S. FDA and the European Medicines Agency (EMA). In addition, it has been granted Regenerative Medicine Advanced Therapy (RMAT) designation in the U.S., Advanced Therapy Medicinal Product (ATMP) designation in Europe, and Rare Pediatric Disease Designation from the FDA, which may qualify Capricor for a Priority Review Voucher upon approval.

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 Duchenne muscular dystrophy (DMD), 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; 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, 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 March 31, 2026, as filed with the Securities and Exchange Commission on May 13, 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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CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
REVENUE				
Revenue	$ —	$ —	$ —	$ —
TOTAL REVENUE	—	—	—	—
OPERATING EXPENSES				
Research and development	28,866,292	22,047,254	56,243,204	40,962,826
General and administrative	14,079,328	5,670,280	23,475,269	11,737,656
TOTAL OPERATING EXPENSES	42,945,620	27,717,534	79,718,473	52,700,482
LOSS FROM OPERATIONS	(42,945,620)	(27,717,534)	(79,718,473)	(52,700,482)
OTHER INCOME (EXPENSE)				
Other income	2,271	14,991	(70,727)	(123,197)
Investment income	2,211,295	1,793,352	5,115,801	2,522,894
TOTAL OTHER INCOME (EXPENSE)	2,213,566	1,808,343	5,045,074	2,399,697
LOSS BEFORE INCOME TAXES	(40,732,054)	(25,909,191)	(74,673,399)	(50,300,785)
(Provision for) benefit from income taxes	(1,600)	(1,600)	(1,600)	(1,600)
NET LOSS	$ (40,733,654)	$ (25,910,791)	$ (74,674,999)	$ (50,302,385)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	90,186	(424,353)	(446,695)	360,619
COMPREHENSIVE LOSS	$ (40,643,468)	$ (26,335,144)	$ (75,121,694)	$ (49,941,766)
Net loss per share, basic and diluted	$ (0.70)	$ (0.57)	$ (1.29)	$ (1.10)
Weighted average number of shares, basic and diluted	57,926,347	45,709,071	57,681,666	45,673,075

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	June 30, 2026 (unaudited)	December 31, 2025
Cash, cash equivalents and marketable securities	$ 237,934,782	$ 318,128,915
Total assets	$ 368,735,835	$ 355,949,294
Total liabilities	$ 122,516,945	$ 50,157,149
Total stockholders' equity - 58,108,989 and 57,370,909 common shares issued and outstanding at June 30, 2026 and December 31, 2025, respectively	246,218,890	305,792,145
Total liabilities and stockholders' equity	$ 368,735,835	$ 355,949,294