# 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 11, 2025**

# 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.**

On August 11, 2025, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended June 30, 2025. 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 2025 Financial Results and Provides Corporate Update", dated August 11, 2025. |
| 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 11, 2025

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

**Exhibit 99.1**

# Capricor Therapeutics Reports Second Quarter 2025 Financial Results and Provides Corporate Update

- *Type A meeting with U.S. FDA scheduled to discuss Deramiocel BLA and path toward potential approval*
- *Capricor seeks to resubmit its BLA based on its existing dataset, with HOPE-3 data (expected in Q4 2025) potentially serving as supportive and confirmatory evidence, pending regulatory guidance*
- *All 483 observations noted in the Pre-License Inspection have been resolved and accepted by the FDA*
- *FDA clears IND for StealthX™ exosome-based vaccine; NIAID has initiated the Phase 1 clinical trial*
- *Cash balance of approximately $123 million expected to support planned operations into the fourth quarter of 2026*
- *Capricor will host a conference call and webcast today at 4:30 p.m. ET*

**SAN DIEGO,** August 11, 2025 (GLOBE NEWSWIRE) -- Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for rare diseases, today announced its financial results for the second quarter ended June 30, 2025, and provided a corporate update.

"We remain steadfast in our mission to deliver the first approved therapy for Duchenne cardiomyopathy—a serious and progressive complication of DMD with no approved treatments," said Linda Marbán, Ph.D., Chief Executive Officer of Capricor. "While the receipt of a CRL was a setback, we are working diligently to define a clear regulatory path forward, which has been delineated in our Type A briefing document. Our objective remains to gain approval based on our current Biologics License Application (BLA) submission as expeditiously as possible, with the primary evidence being the totality of data from our HOPE-2 trial and its open-label extension. These results provide a compelling foundation for our submission, and we are fully prepared to supplement the BLA with HOPE-3 data as needed, with topline results expected in the fourth quarter of 2025. Our upcoming Type A meeting with the FDA will be a critical step in outlining the approval pathway. Importantly, the FDA has now accepted all 483 observations noted in our Pre-License Inspection (PLI), marking a major milestone in our regulatory progress and commercial manufacturing readiness. We will share additional updates as they become available, including greater clarity on timelines for potential approval and overall commercial readiness."

Dr. Marbán continued, "Turning to our other programs, the FDA's clearance of the IND for StealthX™ marks the first clinical entry for our exosome platform and underscores its potential. While this vaccine trial is a meaningful starting point, our broader goal is to advance StealthX™ into therapeutic applications. Our collaboration with the National Institute of Allergy and Infectious Diseases (NIAID) under Project NextGen reflects our belief in the platform's potential and may lay the foundation for future strategic partnerships. As we continue to grow this platform, we remain focused on disciplined execution and building long-term value for both patients and shareholders alike."

***Second Quarter 2025 and Recent Highlights***

- **Upcoming Type A meeting with U.S. FDA:** Capricor will meet with the FDA in August 2025 to discuss next steps following receipt of a Complete Response Letter (CRL) for its BLA for Deramiocel. The Company seeks to resubmit the BLA based on its existing dataset and may include data from the ongoing HOPE-3 trial, pending regulatory guidance.
- **HOPE-3 Phase 3 clinical trial progressing:** A protocol amendment has been submitted to designate left ventricular ejection fraction (LVEF) as the primary efficacy endpoint. The study remains fully blinded. The 12-month treatment period in HOPE-3 was recently completed and topline data are expected to be available in the fourth quarter of 2025. Our hope is that these data would serve as supportive and confirmatory evidence for the BLA resubmission, if needed. HOPE-3 is a multi-center, 1:1 randomized, double-blind, placebo-controlled trial enrolling approximately 104 ambulatory and non-ambulatory DMD patients.
- **Pre-License Inspection successfully completed:** The FDA has recently accepted all of Capricor's responses to the 483 observations noted in the PLI, reinforcing Capricor's readiness for commercial manufacturing and supporting the broader regulatory submission.
- **Positive HOPE-2 OLE data presented at PPMD:** Four-year results from the study showed continued preservation of cardiac function (LVEF) and slowed skeletal muscle decline (PUL v2.0) in patients treated with Deramiocel. The therapy continues to show a favorable safety profile through four years of treatment.

- **Orphan Drug Designation granted for Becker muscular dystrophy:** The FDA granted Orphan Drug Designation for Deramiocel in Becker muscular dystrophy (BMD), aligning with Capricor's broader neuromuscular strategy. BMD is a related dystrophinopathy caused by mutations in the same gene as DMD. It typically presents later in life with a slower disease progression and affects an estimated 5,000 individuals in the United States. Despite its milder course, many BMD patients develop serious cardiac complications, including cardiomyopathy, which can significantly affect both quality of life and longevity.
- **StealthX™ platform enters the clinic:** The FDA cleared the IND for the StealthX™ exosome-based vaccine, selected for evaluation under Project NextGen—a U.S. Department of Health and Human Services initiative aimed at advancing next-generation vaccines. The Phase 1 clinical trial, conducted and funded by NIAID, was initiated in August 2025, with dosing of the first subject expected imminently. This trial marks the first-in-human use of Capricor's exosome platform and sets the stage for future therapeutic development.

***Second Quarter 2025 Financial Results***

**Cash position:** Cash, cash equivalents and marketable securities totaled approximately $122.8 million as of June 30, 2025, compared to approximately $151.5 million as of December 31, 2024.

**Revenues:** Revenues for the second quarter of 2025 were $0, compared to approximately $4.0 million for the second quarter of 2024. Additionally, revenues for the first half of 2025 were $0 compared to approximately $8.9 million for the first half of 2024. Capricor's primary source of revenue was from the ratable recognition of the $40.0 million (upfront and first development milestone payments from Nippon Shinyaku) and the recognition of the $10.0 million second development milestone payment in accordance with our U.S. Distribution Agreement, both of which were fully recognized as of December 31, 2024.

**Costs and Expenses:** Total operating expenses for the second quarter of 2025 were approximately $27.7 million compared to approximately $15.6 million for the second quarter of 2024. Total operating expenses for the first half of 2025 were approximately $52.7 million compared to approximately $30.7 million for the first half of 2024.

**Net Loss:** The Company reported a net loss of approximately $25.9 million, or $0.57 per share, for the second quarter of 2025, compared to a net loss of approximately $11.0 million, or $0.35 per share, for the second quarter of 2024. The Company reported a net loss of approximately $50.3 million, or $1.10 per share, for the first half of 2025, compared to a net loss of approximately $20.8 million, or $0.66 per share, for the first half of 2024.

**Financial Outlook:** The Company believes that based on the current operating plan and financial resources, its available cash, cash equivalents and marketable securities will be sufficient to cover anticipated expenses and capital requirements into the fourth quarter of 2026. This expectation excludes any additional potential milestone payments under the Commercialization and Distribution Agreements with Nippon Shinyaku, as well as any strategic use of capital not currently in the Company's base-case planning assumptions.

***Upcoming Events***

The Company plans to participate at the following upcoming investor events:

- Cantor Fitzgerald Global Healthcare Conference, September 3-5, 2025, New York, NY
- 2025 Wells Fargo Healthcare Conference, September 3-5, 2025, Boston, MA
- H.C. Wainwright Annual Global Investment Conference, September 8-10, 2025, New York, NY
- Cell & Gene Therapy Meeting on the Mesa 2025, October 6-8, 2025, Phoenix, AZ
- 4th Annual Roth Healthcare Opportunities Conference, October 9, 2025, New York, NY
- Maxim Growth Summit, October 22-23, 2025, 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: 90328. Participants can use guest dial-in numbers above and be answered by an operator 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 following the conclusion of the live broadcast and will be accessible on 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 dystrophiopathies 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 a 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 Duchenne Muscular Dystrophy (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. For Becker Muscular Dystrophy (BMD), Deramiocel has also received Orphan Drug Designation from the FDA.

***About Capricor Therapeutics***

Capricor Therapeutics (NASDAQ: CAPR) is a biotechnology company dedicated to advancing transformative cell and exosome-based therapeutics to redefine the treatment landscape for rare diseases. At the forefront of our innovation is our lead product candidate, Deramiocel, an allogeneic cardiac-derived cell therapy. Extensive preclinical and clinical studies have shown Deramiocel to exert potent immunomodulatory and anti-fibrotic actions in the preservation of cardiac and skeletal muscle function in muscular dystrophies such as DMD. Deramiocel is currently in late-stage development for the treatment of Duchenne Muscular Dystrophy. Capricor is also harnessing the power of its exosome technology, using its proprietary StealthX™ platform in preclinical development focused on the areas of vaccinology, targeted delivery of oligonucleotides, proteins and small molecule therapeutics to potentially treat and prevent a diverse array of diseases. At Capricor, we stand committed to pushing the boundaries of possibility and forging a path toward transformative treatments for those in need. For more information, visit capricor.com, and follow Capricor 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; manufacturing capabilities; dates for regulatory meetings; statements about our financial outlook; the potential that required regulatory inspections may be delayed or not be successful which would delay or prevent product approval; 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; potential future agreements; scope, duration, validity and enforceability of intellectual property rights; future revenue streams and 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, 2024, as filed with the Securities and Exchange Commission on March 26, 2025, and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, as filed with the Securities and Exchange Commission on May 14, 2025. 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.

*Capricor has entered into an agreement for the exclusive commercialization and distribution of Deramiocel for DMD in the United States and Japan with Nippon Shinyaku Co., Ltd. (U.S. subsidiary: NS Pharma, Inc.), subject to regulatory approval. 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, | |
|---|---|---|---|---|
| | 2025 | 2024 | 2025 | 2024 |
| REVENUE | | | | |
| Revenue | $ — | $ 3,971,438 | $ — | $ 8,878,315 |
| TOTAL REVENUE | — | 3,971,438 | — | 8,878,315 |
| OPERATING EXPENSES | | | | |
| Research and development | 22,047,254 | 12,504,769 | 40,962,826 | 23,605,782 |
| General and administrative | 5,671,880 | 3,057,888 | 11,739,256 | 7,129,654 |
| TOTAL OPERATING EXPENSES | 27,719,134 | 15,562,657 | 52,702,082 | 30,735,436 |
| LOSS FROM OPERATIONS | (27,719,134) | (11,591,219) | (52,702,082) | (21,857,121) |
| OTHER INCOME (EXPENSE) | | | | |
| Other income | 14,991 | — | 27,476 | — |
| Investment income | 1,793,352 | 591,437 | 2,522,894 | 1,063,266 |
| Loss on disposal of fixed assets | — | — | (150,673) | — |
| TOTAL OTHER INCOME (EXPENSE) | 1,808,343 | 591,437 | 2,399,697 | 1,063,266 |
| NET LOSS | (25,910,791) | (10,999,782) | (50,302,385) | (20,793,855) |
| OTHER COMPREHENSIVE INCOME (LOSS) | | | | |
| Net unrealized gain (loss) on marketable securities | (424,353) | (152,714) | 360,619 | (80,826) |
| COMPREHENSIVE LOSS | $ (26,335,144) | $ (11,152,496) | $ (49,941,766) | $ (20,874,681) |
| Net loss per share, basic and diluted | $ (0.57) | $ (0.35) | $ (1.10) | $ (0.66) |
| Weighted average number of shares, basic and diluted | 45,709,071 | 31,841,964 | 45,673,075 | 31,598,296 |

**CAPRICOR THERAPEUTICS, INC.**
**SUMMARY BALANCE SHEETS**

| | June 30, 2025 (unaudited) | December 31, 2024 |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 122,800,681 | $ 151,515,877 |
| Total assets | $ 133,569,011 | $ 170,481,086 |
| Total liabilities | $ 28,591,955 | $ 25,018,750 |
| Total stockholders' equity - 45,711,975 and 45,582,288 common shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively | 104,977,056 | 145,462,336 |
| Total liabilities and stockholders' equity | $ 133,569,011 | $ 170,481,086 |