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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

_____, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. CAPRICOR THERAPEUTICS, INC., LINDA MARBAN, ANTHONY J. BERGMANN, Defendants.	Case No. **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**

Plaintiff _____ ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, his counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by Capricor Therapeutics, Inc. ("Capricor" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Capricor; and (c) review of other publicly available information concerning Capricor.

NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Capricor securities between December 17, 2025 and July 26, 2026, inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Capricor is a biotechnology company focused on the development of cell and exosome-based therapeutics for the treatment of Duchenne muscular dystrophy, a rare genetic disorder characterized by progressive muscle degeneration and premature death. Its lead product candidate is Deramiocel, a cell therapy to address cardiac and skeletal muscle complications associated with Duchenne muscular dystrophy.

3. In late 2024, Capricor submitted its Biologics License Application ("BLA") to the U.S. Food and Drug Administration for Deramiocel as a cell therapy for the treatment of Duchenne muscular dystrophy.

4. In July 2025, the FDA issued a Complete Response Letter because it could not approve the BLA in its current form. According to the Company, the CRL cited "that the BLA does not meet the statutory requirement for substantial evidence

of effectiveness and the need for additional clinical data." By March 2026, Capricor claimed it had addressed the issues identified in the CRL.

5. On July 27, 2026, before the market opened, the U.S. Food and Drug Administration ("FDA") released briefing documents ahead of its advisory committee ("AdCom") meeting for the BLA. According to the briefing documents, Capricor made changes to the pre-specified statistical analysis plan ("SAP") and that the final version "was not submitted to FDA for review prior to BLA submission and was not discussed and consequently not agreed upon." Critically, the final SAP was created one day before the data was unblinded. The FDA disagreed with the changes made to the SAP, stating that the **"**FDA does not consider the conversion of raw change to percent change and then back to raw change to have been scientifically justified, as it adds complexity and reduces accuracy." As a result, the FDA stated that it "considers [Capricor's] analyses based on the post-study SAP versions to be post-hoc and exploratory." According to the briefing documents, "***the benefit-risk assessment for deramiocel appears unfavorable in the absence of evidence of effectiveness.***"[1]

6. The same day, at 11:00 a.m. ET, the Company provided "an update" ahead of the AdCom meeting, stating that "Capricor has engaged fully and transparently with the FDA throughout the review process" and that "[i]t is critical to understand that the post-hoc analyses in the FDA's briefing materials rely on SAP version 1.1, an unsigned incomplete internal draft which became obsolete with the addition of cohort B and did not include content specifically requested by the FDA."

7. The same day, Cantor Fitzgerald published an investor note, stating the FDA's **"**briefing documents paint an ugly picture**"** and **"*raise several concerns and make allegations about the integrity of data collecting*."**

8. On this news, Capricor's stock fell $12.70, or 64%, to close at $7.00 per share on July 27, 2026, on unusually heavy trading volume.

[1] Unless otherwise stated, all emphasis in bold and italics hereinafter is added.

9. On July 29, 2026, the AdCom met to discuss the Deramiocel BLA. The next day, Medscape reported that the panel relied on SAP version 1.1 as the "prespecified plan" and, in a non-binding 9-3 vote, the panel "concluded that the available evidence does not support the efficacy of deramiocel for treating DMD-associated cardiomyopathy."

10. On this news, Capricor's stock fell $2.38, or 36%, to close at $4.19 per share on July 30, 2026, on unusually heavy trading volume.

11. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the Company had not reached an agreement with the FDA to permit the statistical analysis plan used to analyze data for Deramiocel's BLA; (2) that, as a result, there was a significant risk that the clinical results did not demonstrate that the benefits of Deramiocel outweighed the risks; (3) that, as a result of the foregoing, there was a substantial risk to regulatory approval of Deramiocel for the treatment of Duchenne muscular dystrophy; and (4) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

12. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

13. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

15. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company's principal executive offices are in this District.

16. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

17. Plaintiff _____, as set forth in the accompanying certification, incorporated by reference herein, purchased Capricor securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

18. Defendant Capricor is incorporated under the laws of Delaware with its principal executive offices located in San Diego, California. Capricor's common stock trades on the NASDAQ exchange under the symbol "CAPR."

19. Defendant Linda Marban ("Marban") was the Chief Executive Officer ("CEO") of Capricor at all relevant times.

20. Defendant Anthony J. Bergmann ("Bergmann") was the Chief Financial Officer ("CFO") at Capricor at all relevant times.

21. Defendants Marban and Bergmann (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and

institutional investors, i.e., the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

22. Capricor is a biotechnology company focused on the development of cell and exosome-based therapeutics for the treatment of Duchenne muscular dystrophy, a rare genetic disorder characterized by progressive muscle degeneration and premature death. Its lead product candidate is Deramiocel, a cell therapy to address cardiac and skeletal muscle complications associated with Duchenne muscular dystrophy.

23. In late 2024, Capricor submitted its Biologics License Application ("BLA") to the U.S. Food and Drug Administration for Deramiocel as a cell therapy for the treatment of Duchenne muscular dystrophy.

24. In July 2025, the FDA issued a Complete Response Letter because it could not approve the BLA in its current form. According to the Company, the CRL cited "that the BLA does not meet the statutory requirement for substantial evidence of effectiveness and the need for additional clinical data."

Materially False and Misleading Statements Issued During the Class Period

25. The Class Period begins on December 17, 2025. On that day, Capricor participated in a webinar with Parent Project Muscular Dystrophy to "discuss positive

topline results from Capricor's Phase 3 HOPE-3 trial evaluating Deramiocel" and "how the findings inform ongoing regulatory discussions." During the webinar, Defendant Marban stated, in relevant part:

> So what this is called is a fourth plot. And you guys probably have seen me present one similar to this from the HOPE-2 study before, but just to remind you that it basically shows the propensity of multiple endpoints either due to a treatment effect of the drug that you're giving or whether or not it's driving towards placebo or basically no clinical efficacy. And what we can see here in the performance of the upper limb 2.0, ***our primary efficacy endpoint, it's trending, in fact, statistically significant towards deramiocel being the effective in treating the skeletal muscle myopathy.***
>
> We saw the key secondary endpoint, a key secondary endpoint is very important nomenclature because it allows for labeling opportunities. We saw improvement and statistical significance in cardiac function in the patients that were treated with deramiocel compared to placebo. Digging down a little deeper, we saw that we had even more statistical significance in the mid-level dimension of the POL 2.0. Dr. McDonald did a great job of describing that, but I'll just remind you that's arm function, so might be correlated with the ability to feed yourself or take a drink of water or as Pat used to say, to hug your mother. The total global statistical test was also statistically significant in terms of field function and survived metrics, so skeletal muscle function, cardiac improvement of left ventricular ejection fraction. And finally, a patient-reported outcome measure called the PGI.
>
> And then finally, as John just talked about late gadolinium enhancement, which is the amount of scar in the heart, and we see that, that was statistically significant too. ***All of these are what statisticians call type 1 error controlled.*** That means that you put very, very tight regulation around them mathematically as to whether what you're seeing can be due to chance or whether, in fact, it is actually due to treatment by your therapeutic. So taken together, we are going to present this data to the FDA. ***We believe that this should answer all the questions raised in their complete response letter on the BLA that was submitted last December, and we're hoping to move rapidly towards an approval for deramiocel in DMD, not only now cardiomyopathy, but also skeletal muscle function.***

26. On January 20, 2026, Capricor issued a press release to provide a "Regulatory Update on Deramiocel BLA Following FDA Review of HOPE-3 Topline Data." It stated, in relevant part:

> As previously disclosed, the Company provided topline results from its Phase 3 HOPE-3 clinical study to the U.S. Food and Drug Administration (FDA) in late 2025. Following its review of these data, the FDA has formally requested the full HOPE-3 clinical study report (CSR) and supporting data to address the Complete Response Letter

(CRL). The FDA did not request any additional clinical studies or new patient data as part of this request.

Preparation of the HOPE-3 CSR is well underway, and the Company plans to submit the requested materials to the FDA in February 2026. ***The Company expects that this submission will address the items outlined in the CRL and support continued review of the BLA***, including the assignment of a new Prescription Drug User Fee Act (PDUFA) target action date.

"***We are actively engaging with the FDA in order to facilitate an efficient review of the HOPE-3 data that directly address the issues raised in the CRL we received in July 2025.*** We were pleased that the FDA requested the HOPE-3 clinical study report, as this is an expected and appropriate next step following their initial review of the topline data," said Linda Marbán, Ph.D., Chief Executive Officer of Capricor. "The HOPE-3 results demonstrated statistically significant and clinically meaningful improvements in both skeletal muscle and cardiac function—key drivers of disease progression and long-term outcomes in Duchenne. These findings build on more than a decade of consistent clinical evidence and reinforce our confidence in Deramiocel's potential. Our near-term priority is to address the FDA's request and continue working collaboratively so that patients with late-stage DMD, who currently have very limited treatment options, may gain access to Deramiocel as soon as possible."

27. On March 10, 2026, Capricor announced a PDUFA target action date of August 22, 2026. Specifically, the Company issued a press release that stated, in relevant part:

Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for the treatment of rare diseases, today announced that the U.S. Food and Drug Administration ("FDA") has lifted the previously issued Complete Response Letter and resumed review of its Biologics License Application ("BLA") seeking full approval of Deramiocel, an investigational cell therapy, for the treatment of Duchenne muscular dystrophy ("DMD") cardiomyopathy. The submission has been classified as a Class 2 resubmission, with a Prescription Drug User Fee Act ("PDUFA") target action date of August 22, 2026.

"We are encouraged by the FDA's acknowledgment of our response to the Complete Response Letter and its continued review of our BLA for Deramiocel," said Linda Marbán, Ph.D., Chief Executive Officer of Capricor. "We believe the positive HOPE-3 results and broader clinical evidence reinforce Deramiocel's potential to become a first-in-class therapy for Duchenne muscular dystrophy, with the opportunity to address both skeletal and cardiac manifestations of the disease. We look forward to continuing to work closely with the FDA throughout the review process and remain focused on bringing this important therapy to patients as expeditiously as possible."

> The Company received a Complete Response Letter ("CRL") from the FDA in July 2025. Following submission of data and supporting documentation from the HOPE-3 clinical trial, the FDA resumed review of the application and assigned a PDUFA target action date of August 22, 2026. At this time, the FDA has not identified any potential review issues in its response to the Company.
>
> Capricor also expects to be eligible to receive a Priority Review Voucher ("PRV") upon potential approval of Deramiocel.

28. On March 12, 2026, Capricor issued a press release to announce its fourth quarter and full year 2025 financial results and provide a corporate update. It stated, in relevant part:

> "Capricor enters 2026 with important regulatory and clinical momentum as we work toward potential approval of Deramiocel for the treatment of Duchenne muscular dystrophy (DMD)," said Linda Marbán, Ph.D., Chief Executive Officer of Capricor. "With the FDA review of our BLA underway and a PDUFA target action date of August 22, 2026, our highest priority is execution, including working closely with the Agency, preparing for potential launch, and continuing to build the capabilities for a commercial-stage company. ***Recent late-breaking data presented at the 2026 MDA Clinical & Scientific Conference further reinforced the strength of the program, highlighting Deramiocel's impact on both cardiac and skeletal muscle function in Duchenne.*** These findings build on the positive topline results from the Phase 3 HOPE-3 study and ***reinforce Deramiocel's potential to become a first-in-class therapy for Duchenne designed to address both the skeletal and cardiac manifestations of this devastating disease.*** At the same time, we remain focused on advancing our exosome platform and expanding the long-term potential of our pipeline. Supported by a strong balance sheet, we believe we are well positioned to execute on these priorities and deliver meaningful value for patients, families, and shareholders."
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> **Fourth Quarter 2025 and Recent Highlights**
>
> - **Deramiocel BLA Under FDA Review**: Capricor's Biologics License Application (BLA) seeking full approval of Deramiocel for the treatment of DMD is currently under review by the U.S. Food and Drug Administration. The FDA informed the Company that its response to the previously issued Complete Response Letter was complete to support continued review and assigned a Prescription Drug User Fee Act (PDUFA) target action date of August 22, 2026. The FDA classified the submission as a Class 2 resubmission.
>
> - **Positive Phase 3 HOPE-3 Trial Results**: Capricor reported positive topline results from the HOPE-3 Phase 3 trial, a multicenter, randomized, double-blind, placebo-controlled study which enrolled 106 patients with DMD. The trial met its primary endpoint of Performance of the Upper Limb (PUL v2.0) and the key secondary cardiac endpoint of left ventricular ejection fraction (LVEF), with both achieving statistical significance (p=0.03 and p=0.04, respectively). All Type I error-controlled secondary endpoints also achieved statistical significance.

Deramiocel maintained a favorable safety and tolerability profile consistent with prior clinical studies.

- **Late-Breaking HOPE-3 Data Presented at MDA 2026:** Additional data from the HOPE-3 study were presented in a late-breaking oral presentation at the 2026 Muscular Dystrophy Association Clinical & Scientific Conference. Newly reported analyses further supported Deramiocel's potential impact on functional outcomes in Duchenne. Cardiac MRI analyses demonstrated a significant reduction in myocardial fibrosis as measured by late gadolinium enhancement (LGE), corresponding to a three-segment treatment difference versus placebo at 12 months (p=0.022). In patients with baseline cardiomyopathy, treatment resulted in a 3.3 percentage-point improvement in LVEF versus placebo, representing greater than 100% attenuation of expected cardiac decline (p=0.017). Additional functional outcomes were also presented. Data from the Duchenne Video Assessment (DVA), a measure of activities of daily living in individuals with Duchenne, showed the "eat 10 bites" task demonstrated approximately 83% slowing of disease progression versus placebo (p=0.018).

- **Commercial Launch Preparations Underway**: Capricor continues to advance commercial readiness in preparation for a potential launch. The Company's GMP manufacturing facility in San Diego successfully completed an FDA Pre-License Inspection (PLI) in connection with the BLA review process. All Form 483 observations have been addressed, and the facility is operational and positioned to support an initial commercial launch. Further manufacturing expansion is underway to increase capacity in anticipation of demand following potential approval.

- **Peer-Reviewed Publication on Deramiocel**: In October 2025, Capricor published a peer-reviewed paper in *Biomedicines* describing Deramiocel's anti-fibrotic and immunomodulatory mechanisms of action, including the release of exosomes and soluble factors that suppress fibrotic gene expression.

29. On March 17, 2026, Capricor filed its annual report on Form 10-K for the period ended December 31, 2025. Therein, the Company stated, in relevant part:

> *Biologics License Application*: In late 2024, we completed our submission of a BLA to the FDA seeking approval of Deramiocel for the treatment of Duchenne muscular dystrophy. The FDA accepted the BLA for review, granted Priority Review, and assigned a PDUFA target action date of August 31, 2025. In July 2025, we received a Complete Response Letter ("CRL") from the FDA stating that the application did not meet the statutory requirement for substantial evidence of effectiveness and requesting additional clinical data.
>
> ***Following a Type A meeting with the FDA in August 2025, we aligned with the Agency on a regulatory path forward to address the CRL, including the submission of additional clinical data from the Phase 3 HOPE-3 trial.*** We subsequently submitted our response to the CRL, which the FDA accepted as a complete response and classified as a Class 2 resubmission, assigning a new Prescription Drug User Fee Act target action date of August 22, 2026. If approved, Deramiocel has the potential

to become the first therapy designed to address both skeletal and cardiac muscle manifestations of Duchenne muscular dystrophy.

30. On May 12, 2026, Capricor issued a press release to announce its first quarter 2026 financial results and provide a corporate update. It stated, in relevant part:

First Quarter 2026 and Recent Highlights

- **Deramiocel BLA Under FDA Review:** Capricor's Biologics License Application (BLA) seeking approval of Deramiocel for the treatment of DMD is currently under review by the U.S. Food and Drug Administration. The FDA accepted the Company's Class 2 resubmission as complete, resuming its full review of the BLA, with a PDUFA target action date of August 22, 2026. ***There has been a significant number of information requests from FDA to Capricor, all of which the Company has been able to address. The Company looks forward to continuing an active dialogue with the FDA and expects labeling discussions to commence soon.***

- **Additional HOPE-3 Late-Breaking Data Presented at MDA, AAN, and ASGCT (2026):** HOPE-3 data were selected as one of only four late-breaking oral presentations at the 2026 MDA Clinical & Scientific Conference. Data were also presented at the 2026 AAN Annual Meeting and the 2026 ASGCT Annual Meeting. Cardiac MRI analyses showed a significant reduction in myocardial fibrosis by late gadolinium enhancement (LGE) versus placebo, a clinically meaningful finding given that fibrosis is cumulative and irreversible. The Duchenne Video Assessment (DVA) "eat 10 bites" measure, a home-based, caregiver-captured assessment of upper limb function and daily living activities, demonstrated statistically significant improvement versus placebo, directly correlated with patient independence and quality of life. The full HOPE-3 dataset has been submitted for publication to a peer-reviewed journal.

- **Commercial Launch Preparations Underway:** The Company's GMP manufacturing facility in San Diego successfully completed an FDA Pre-License Inspection, with all Form 483 observations addressed. The facility is operational and positioned to support initial commercial launch. Second-floor expansion adding additional cleanrooms is well underway, scaling to approximately 2,000–2,500 patients per year, roughly 10,000 doses annually, at full capacity, with full facility validation and FDA approval targeted for the first half of 2027. The Company will begin stockpiling commercial doses once guidance on the label is received. Planning is underway across all critical launch functions, including patient support, market access, reimbursement planning, medical affairs and physician education.

31. The above statements identified in ¶¶25-30 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to

investors: (1) that the Company had not reached an agreement with the FDA to permit the statistical analysis plan used to analyze data for Deramiocel's BLA; (2) that, as a result, there was a significant risk that the clinical results did not demonstrate that the benefits of Deramiocel outweighed the risks; (3) that, as a result of the foregoing, there was a substantial risk to regulatory approval of Deramiocel for the treatment of Duchenne muscular dystrophy; and (4) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis

Disclosures at the End of the Class Period

32. On July 27, 2026, before the market opened, the FDA released briefing documents ahead of its AdCom meeting for the BLA. According to the briefing documents, Capricor made changes to the pre-specified statistical analysis plan ("SAP") and that the final version "was not submitted to FDA for review prior to BLA submission and was not discussed and consequently not agreed upon." In the overview of the issues, the briefing documents stated:

> Study HOPE-3 was a phase 3, randomized, double blind, placebo controlled, 12-month study of deramiocel compared to placebo in males with DMD who were predominantly non-ambulatory and had an average age of 15 years old. . . . The study did not meet its pre-specified primary and secondary efficacy endpoints showing no statistically significant difference between deramiocel and placebo at 12 months.
>
> After completion of the randomized, double blind part of Study HOPE-3 and during Study HOPE-3-OLE (where all patients were treated with deramiocel), changes were made to the pre-specified statistical analysis plan (SAP), generating at least 2 additional versions. ***Those changes included modifications to the primary and key secondary endpoint definitions; the analytical methods; and the data imputation strategy for certain intercurrent events. FDA noted that the Applicant's final analyses presented in the BLA submission included additional statistical changes without an associated, updated SAP. The final version of the SAP (v. 3.0), dated November 24, 2025 was not submitted to FDA for review prior to BLA submission and was not discussed and consequently not agreed upon. In addition, the process for SAP changes outlined in the study's pre-specified blinding plan was not followed and the final clinical study protocol (Protocol 9.0) deviated from the associated SAP (v. 3.0).*** Lastly, the distinctive adverse event profile observed between treatment groups —hypersensitivity reactions seen in 42% of deramioceltreated patients versus 15% of placebo-treated patients — raises the possibility that treatment assignment could be

> inferred even under formal blinding conditions. This risk of functional unblinding was further extended by the open-label period of HOPE-3, during which additional treatment-related data accumulated and may have made treatment assignment more apparent. Given the post-hoc nature of the SAP changes, FDA considers all analyses implemented following study completion.

33. The FDA disagreed with the changes made to the SAP, stating that the "FDA does not consider the conversion of raw change to percent change and then back to raw change to have been scientifically justified, as it adds complexity and reduces accuracy."

34. Critically, the final SAP was created one day before the data was unblinded. The briefing documents described the relevant history of regulatory milestones, in relevant part:

Date	Milestone	Topic
November 24, 2025	SAP 3.0* created by Applicant	Not submitted to FDA for review and comment, No FDA concurrence
November 25, 2025	Database lock and data unblinding for Study HOPE-3	
December 29, 2025	BLA resubmission	Study HOPE-3 (missing documents)
January 13, 2026	Incomplete Response Letter	The submission was deemed incomplete due to multiple missing documents, including a complete clinical study report, all versions of the clinical protocol and Statistical Analysis Plan, and narrative summaries.
February 20, 2026	BLA resubmission	Study HOPE-3 with requested additional data and information for a complete submission

35. As a result, the FDA stated that it "considers [Capricor's] analyses based on the post-study SAP versions to be post-hoc and exploratory." According to the briefing documents, "***the benefit-risk assessment for deramiocel appears unfavorable in the absence of evidence of effectiveness.***"[2]

36. The same day, at 11:00 a.m. ET, the Company provided "an update" ahead of the AdCom meeting, stating that "Capricor has engaged fully and transparently with the FDA throughout the review process" and that "[i]t is critical to understand that the post-hoc analyses in the FDA's briefing materials rely on SAP

[2] Unless otherwise stated, all emphasis in bold and italics hereinafter is added.

version 1.1, an unsigned incomplete internal draft which became obsolete with the addition of cohort B and did not include content specifically requested by the FDA."

37. The same day, Cantor Fitzgerald published an investor note, stating the FDA's **"**briefing documents paint an ugly picture**"** and **"*raise several concerns and make allegations about the integrity of data collecting*."**

38. On this news, Capricor's stock fell $12.70, or 64%, to close at $7.00 per share on July 27, 2026, on unusually heavy trading volume.

39. On July 29, 2026, the AdCom met to discuss the Deramiocel BLA. The next day, Medscape reported that the panel relied on SAP version 1.1 as the "prespecified plan" and, in a non-binding 9-3 vote, the panel "concluded that the available evidence does not support the efficacy of deramiocel for treating DMD-associated cardiomyopathy."

40. On this news, Capricor's stock fell $2.38, or 36%, to close at $4.19 per share on July 30, 2026, on unusually heavy trading volume.

CLASS ACTION ALLEGATIONS

41. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired Capricor securities between December 17, 2025 and July 26, 2026, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

42. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Capricor's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class.

Millions of Capricor shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Capricor or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

43. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

44. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

45. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Capricor; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

46. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

47. The market for Capricor's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Capricor's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Capricor's securities relying upon the integrity of the market price of the Company's securities and market information relating to Capricor, and have been damaged thereby.

48. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Capricor's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about Capricor's business, operations, and prospects as alleged herein.

49. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Capricor's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

50. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

51. During the Class Period, Plaintiff and the Class purchased Capricor's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

52. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Capricor, their control over, and/or receipt and/or modification of Capricor's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Capricor, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

53. The market for Capricor's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Capricor's securities traded at artificially inflated prices during the Class Period. On April 21, 2026, the Company's share price closed at a Class Period high of $35.34 per share. Plaintiff and other members of the

Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Capricor's securities and market information relating to Capricor, and have been damaged thereby.

54. During the Class Period, the artificial inflation of Capricor's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Capricor's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Capricor and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

55. At all relevant times, the market for Capricor's securities was an efficient market for the following reasons, among others:

(a) Capricor shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Capricor filed periodic public reports with the SEC and/or the NASDAQ;

(c) Capricor regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Capricor was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

56. As a result of the foregoing, the market for Capricor's securities promptly digested current information regarding Capricor from all publicly available sources and reflected such information in Capricor's share price. Under these circumstances, all purchasers of Capricor's securities during the Class Period suffered similar injury through their purchase of Capricor's securities at artificially inflated prices and a presumption of reliance applies.

57. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

58. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful

cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Capricor who knew that the statement was false when made.

FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

59. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

60. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Capricor's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

61. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Capricor's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-

5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

62. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Capricor's financial well-being and prospects, as specified herein.

63. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Capricor's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Capricor and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

64. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times;

and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

65. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Capricor's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

66. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Capricor's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Capricor's securities during the Class Period at artificially high prices and were damaged thereby.

67. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Capricor was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Capricor securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

68. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

69. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM

Violation of Section 20(a) of The Exchange Act

Against the Individual Defendants

70. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

71. Individual Defendants acted as controlling persons of Capricor within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had

unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

72. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

73. As set forth above, Capricor and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

DATED: _____, 2026

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