UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

HAU XIANG LEONG, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

CAPRICOR THERAPEUTICS, INC. and LINDA MARBÁN,

Defendants.

Case No. '25CV1815 DMS AHG

CLASS ACTION

COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

Plaintiff Hau Xiang Leong ("Plaintiff"), individually and on behalf of all other persons similarly situated, by their undersigned attorneys, alleges in this Complaint for violations of the federal securities laws (the "Complaint") the following based upon knowledge with respect to their own acts, and upon facts obtained through an investigation conducted by her counsel, which included, *inter alia*: (a) review and analysis of relevant filings made by Capricor Therapeutics, Inc. ("Capricor" or the "Company") with the United States Securities and Exchange Commission (the "SEC"); (b) review and analysis of Capricor's public documents, conference calls, press releases, and stock chart; (c) review and analysis of securities analysts' reports and advisories concerning the Company; and (d) information readily obtainable on the internet.

Plaintiff believes that further substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. Most of the facts supporting the allegations contained herein are known only to the defendants or are exclusively within their control.

NATURE OF THE ACTION

1. This a federal securities class action on behalf of all investors who purchased or otherwise acquired Capricor securities between October 9, 2024 and July 10, 2025, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws (the "Class").

2. Defendants provided investors with material information concerning Capricor's lead cell therapy candidate drug deramiocel for the treatment of cardiomyopathy associated with Duchenne muscular dystrophy (DMD). Defendants' statements included, among other things, Capricor's ability to obtain a Biologics License Application (BLA) for deramiocel from the U.S. Food and Drug Administration (FDA).

3. Defendants provided these overwhelmingly positive statements to investors while, at the same time, disseminating false and misleading statements and/or concealing material adverse facts concerning its four-year safety and efficacy data from its Phase 2 HOPE-2 trial study of deramiocel. This caused Plaintiff and other shareholders to purchase Capricor's securities at artificially inflated prices.

4. The truth began to emerge on May 5, 2025 when Capricor issued a press release announcing it had completed its mid-cycle review meeting with the FDA on deramiocel for the treatment of DMD. In pertinent part, Defendants announced that no significant deficiencies were identified by the Review Committee and that the package is on track for a Prescription Drug User Fee Act (PDUFA) action date of August 31, 2025. Additionally, the FDA also confirmed its intent to hold an advisory committee meeting.

5. In response to this news, Capricor's stock price declined from $10.30 per share to $7.30 per share. However, Defendants materially misrepresented and/or created the false impression that they could obtain first approval for DMD

cardiomyopathy full approval, thereby causing Capricor's stock price to increase under false pretenses over the next few months.

6. Investors remained in the dark until *Stat News*[1] reported that Vinjay Prasad, the director of the FDA's Center for Biologics Evaluation and Research (CBER), canceled the advisory committee meeting regarding deramiocel due to being "skeptical of the treatment" and uncertain about the drug's efficacy and safety. On this news, the price of Capricor's common stock declined from $11.94 per share on June 18, 2025 to $8.26 per share on June 20, 2025.

7. Notwithstanding, Defendants continued to mislead investors with materially false statements as to the strength of its BLA submission for deramiocel and advancement toward eventual approval. These statements concealed the truth about the efficacy of Capricor's four-year data from its Phase 2 HOPE-2 trial until July 11, 2025, when Capricor issued another press release announcing it received a Complete Response Letter (CRL) from the FDA denying the BLA specifically citing it did not meet the statutory requirement for substantial evidence of effectiveness and the need for additional clinical data. Further, the CRL referenced outstanding items in the Chemistry, Manufacturing, and Controls (CMC) section of the application. As a result, the price of Capricor stock declined from $11.40 per share on July 10, 2025 to $7.64 per share on July 11, 2025.

[1] https://www.statnews.com/2025/06/20/fda-ouster-top-gene-therapy-official-nicole-verdun-placed-on-leave-after-review-committee-canceled/

8. Investors have sustained significant damages as a result of Defendants' fraudulent statements. Plaintiff seeks to recover those damages by way of this lawsuit.

JURISDICTION AND VENUE

9. Plaintiff brings this action, on behalf of herself and other similarly situated investors, to recover losses sustained in connection with Defendants' fraud.

10. The claims asserted herein arise under and pursuant to §§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).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. §78aa.

12. Venue is proper in this District pursuant to §27 of the Exchange Act and 28 U.S.C. §1391(b), as Defendant Capricor is headquartered in this District and a significant portion of its business, actions, and the subsequent damages to Plaintiff and the Class, took place within this District.

13. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

THE PARTIES

14. Plaintiff purchased Capricor common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the Defendants' fraud. Plaintiff's certification evidencing her transaction(s) in Capricor is attached hereto.

15. Capricor Therapeutics, Inc. is a Delaware corporation with its principal executive offices located at 10865 Road to the Cure, Suite 150, San Diego, CA 92121. During the Class Period, the Company's common stock traded on the NASDAQ Stock Market (the "NASDAQ") under the symbol "CAPR."

16. Defendant Linda Marbán ("Marbán") was, at all relevant times, the Chief Executive Officer and Director of Capricor.

17. Defendant Marbán is sometimes referred to herein as the "Individual Defendant." Capricor together with the Individual Defendant is referred to herein as the "Defendants."

18. The Individual Defendant, because of her position with the Company, possessed the power and authority to control the contents of Capricor's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant was 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 her

position and access to material non-public information available to her, the Individual Defendant 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 Defendant is liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendant.

19. Capricor is liable for the acts of the Individual Defendant, and its employees under the doctrine of respondeat superior and common law principles of agency as all the wrongful act complained of herein were carried out within the scope of their employment with authorization.

20. The scienter of the Individual Defendant, and other employees and agents of the Company are similarly imputed to Capricor under respondeat superior and agency principles.

SUBSTANTIVE ALLEGATIONS

A. Company Background

21. Capricor is a clinical-stage biotechnology company that engages in the development of transformative cell and exosome-based therapeutics for treating Duchenne muscular dystrophy (DMD) and other diseases with unmet medical needs in the United States. Its lead product candidate is deramiocel, an allogeneic cardiosphere-derived cells.

B. Defendants Materially Misled Investors Concerning the FDA Approval of its BLA for the Drug Deramiocel

October 9, 2024

22. On October 9, 2024, Capricor issued a press release announcing it initiated its rolling submission process with the FDA for a BLA seeking full approval for deramiocel to treat patients with DMD cardiomyopathy. The press release stated in pertinent part:

> Capricor plans to complete its rolling BLA submission by the end of 2024. The application may be eligible for priority review as deramiocel could potentially provide significant improvements in the safety and/or effectiveness of the treatment for the serious condition of DMD cardiomyopathy, where there are currently no approved treatment options available. Once the rolling BLA submission is completed, the FDA will notify the Company when it is formally accepted for review.

23. Defendant Marbán highlighting, in relevant part:

> ***This announcement marks an important step in the U.S. regulatory process towards a potential Biologics License Application approval of deramiocel for the treatment of DMD. An approval of deramiocel would allow us to expedite the delivery of this novel, first-in-class treatment to patients in need.*** We look forward to working with the FDA during this process.
>
> (Emphasis added.)

November 13, 2024

24. On November 13, 2024, Capricor issued a press release announcing third quarter 2024 financial results and provided an update as to its deramiocel DMD program. The press release stated in pertinent part:

> In addition, if deramiocel is approved, Capricor would be eligible to receive a Priority Review Voucher (PRV) based on our previous receipt of a rare pediatric disease designation.
>
> - ***Based on FDA feedback and following Capricor's recent pre-BLA meeting in August, Capricor initiated the rolling BLA submission in October of 2024 seeking full approval of deramiocel for the treatment of DMD-cardiomyopathy with full submission expected to be complete by year end 2024.***
>   - ***The BLA submission will be based on existing cardiac data from the Phase 2 HOPE-2 and HOPE-2 open label extension (OLE) trials compared to patient-level natural history data.***
>
> (Emphasis added.)

25. Marbán touted the Company's progress in obtaining a BLA for deramiocel, stating, in relevant part:

> This has been a transformational quarter for Capricor as we move towards potential commercialization of deramiocel for the treatment of DMD. ***We have commenced the submission of our BLA which we expect to be complete by year end and we have significantly strengthened our balance sheet in order to scale up manufacturing as we anticipate a strong launch, pending FDA approval.***
>
> (Emphasis added.)

26. During the same day earnings call, Defendant Marbán discussed the significant benefits of deramiocel after conducting multiple clinical trials, stating, in pertinent part:

> As you know, we have been working to develop deramiocel, formerly known as CAP-1002, for the treatment of DMD for the last 8 years. ***We have shown in multiple clinical trials the salutary benefits of deramiocel in attenuating the consequences of the skeletal muscle myopathy and improving the cardiomyopathy associated with this devastating disease. We have consistently presented the data as it has become available to the FDA, and the data has shown clinically meaningful as well as statistically significant improvements. Based***

> ***on the strength of the data as well as the large unmet medical need of the cardiac implications, we have decided after conferring with the FDA to file a BLA for full approval for the cardiomyopathy associated with DMD.***
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> * * *
>
> ***It is a clear strategy, which gives Capricor the opportunity to achieve potential approval for a first-in-class treatment for one of the most devastating consequences of DMD. I am pleased to report that the first module of the BLA was submitted, and we are on track to fully submit our BLA package by year-end 2024.*** I want to thank my team for their extraordinary efforts to this point and reiterate that we are focusing all of our efforts on this endeavor. This includes preparations for CMC inspection, pre-commercial activities and market access work with our distribution partner, NS Pharma. ***While we believe that an AdCom may not be necessary, we are preparing internally for that eventuality.***
>
> (Emphasis added.)

27. During a question-and-answer portion of the same earnings call, Defendant Marbán elaborated on the regulatory filing and the Company's agreement with Nippon Shinyaku for the marketing, sales and distribution of deramiocel in Europe, stating, in pertinent part:

> <Q: Edward Andrew Tenthoff – Piper Sandler – Analyst> Obviously, there's a lot to do behind the scenes here with the filings and with the regulatory approval that you're seeking with the FDA. What are you and Nippon Shinyaku doing to prepare this market and to get ready for launch?
>
> <A: Defendant Marbán > ***Now Capricor has joined in on the fact that we know CAP-1002 or deramiocel better than anybody else. So now we have put several of our people basically into the daily mix with Nippon Shinyaku to make sure that deramiocel is [breeded] and launched the way that it's supposed to. So the product is ready,***

> ***delivery is ready, the centers are ready, infusion centers are ready.*** All of the bells and whistles have been managed. Market access has been assessed. KOLs have been brought on board. Physicians are ready to prescribe it. ***It is all underway at this time in regular standard meetings and opportunities. So that's going great, and we have great opportunities ahead for launch.***
>
> In terms of your second question with manufacturing, we have been preparing for this day for a long time. ***So we started thinking about the commercialization of deramiocel, let's call it, a decade ago when we entered into the clinic. And so we knew what we had to do. The good thing is -- that we have done is we have kept manufacturing in-house all this time. So it's a derisked manufacturing procedure because nobody knows it better than we have.*** When we built the San Diego manufacturing facility, it's small, but it's commercial scale. So we know exactly how to do it. We've been preparing for PLI really for about 2 years since we designed and opened that facility. So that one is ready to go. We have high confidence that we should be able to pass inspection. And now because we are anticipating great adoption of deramiocel by Duchenne patients, we're also planning and executing a build-out of a new manufacturing facility.
>
> (Emphasis added.)

March 4, 2025

28. On March 4, 2025, Capricor issued a press release announcing that the FDA has accepted its BLA for review seeking full approval for deramiocel for patients with DMD cardiomyopathy. Notably, the release noted that the FDA did not identify any potential review issues and granted the BLA Priority Review with a PDUFA target date of August 31, 2025.

29. Marbán highlighting, in pertinent part:

> We are thrilled to announce the acceptance of our BLA bringing us one step closer to providing this first-in-class treatment for Duchenne-cardiomyopathy, a condition for which there are no approved therapies. If our application is successful, we expect deramiocel to be a lifelong

> treatment, administered quarterly, with the potential to be widely adopted across the DMD-cardiomyopathy treatment landscape. We want to extend our appreciation to the patients, their families and advocates who continue to work with Capricor and to the FDA for its commitment to accelerating treatments for DMD.

March 19, 2025

30. On March 19, 2025, Capricor issued a press release reporting fourth quarter and full year 2024 financial results and provided an update as to its BLA for deramiocel. The press release stated in pertinent part:

> **Fourth Quarter 2024 and Recent Developments**
>
> - **In March 2025, the FDA accepted Capricor's BLA seeking full approval of deramiocel for the treatment of individuals with Duchenne muscular dystrophy cardiomyopathy.** Our BLA has been granted Priority Review by the FDA, with a Prescription Drug User Fee Act (PDUFA) action date set for August 31, 2025. Deramiocel is a cellular therapy that 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 preservation of cardiac and skeletal muscle function in DMD. CDCs act by secreting exosomes, which reduce fibrosis in muscle resulting in a reduction in myocardial scarring and cardiac inflammation by targeting macrophages to adopt a healing, rather than a pro-inflammatory phenotype. ***The BLA submission for deramiocel included safety and efficacy data from Capricor's Phase 2 HOPE-2 placebo-controlled trial and the HOPE-2 open label extension (OLE) trial compared to natural history data from an FDA-funded and published dataset on the implications of DMD cardiomyopathy and potential biomarkers of disease progression. The results from these clinical studies demonstrated statistically significant and clinically relevant improvements in cardiac function up to three-years after treatment as well as a consistent safety profile.*** Capricor's ongoing HOPE-3 Phase 3 study which is assessing skeletal muscle function has not been requested for review by the FDA for this application.

> **Expanded internal manufacturing capacity for deramiocel production:** In February 2025, Capricor entered into an amendment to its current lease for additional GMP space in its headquarters located in San Diego, California to support additional commercial manufacturing capacity and throughput.
>
> (Emphasis added.)

31. Defendant Marbán reiterated the Company's goal in bringing the first cellular therapy to market to treat patients with DMD cardiomyopathy, stating, in relevant part:

> ***2024 was a transformational year for Capricor and the patients we serve as we move closer to our goal of bringing the first cellular therapy to market for the treatment of Duchenne-cardiomyopathy, a condition for which there are no approved therapies. We continue to work diligently towards our August 31, 2025 action date for our deramiocel Biologics License Application, directly engaging with the FDA, preparing for pre-approval licensure inspection and preparing for potential commercial launch with our partner Nippon Shinyaku Co. (U.S. subsidiary: NS Pharma Inc).*** Our BLA is the culmination of a body of work that has been focused on bringing this transformational therapy to those patients in need with the potential to alter the trajectory of this degenerative disease***. In addition to our operational achievements, we ended the year with over $150 million on our balance sheet allowing us to invest diligently in manufacturing expansion and commercial endeavors as we work to bring deramiocel to the Duchenne community in the United States and abroad.***

(Emphasis added.)

32. During the same day earnings call, Defendant Marbán remained confident in deramiocel's potential efficacy and noted the consistent positive data from the Phase 2 HOPE-2 trials, stating, in pertinent part:

> As we look ahead to our PDUFA date, set for August 31, 2025, we are working with the FDA as they are actively reviewing our application. At this time, the FDA has not indicated to us whether an AdCom will be necessary, but we are preparing for one should that be needed. And I'm pleased to inform you that we have officially scheduled our PLI, or pre-licensing inspection, of our manufacturing facility, which is set for the second quarter of this year.
>
> ***Our BLA is supported with data from 2 trials: our Phase II HOPE-2 placebo control trial and our HOPE-2 open-label extension trial compared to patient-level natural history data from the DMD Cardiac Consortium led by Dr. Jonathan Soslow at Vanderbilt University. Many factors have given us confidence in our BLA submission pathway.***
>
> ***First and foremost, it has a strong safety profile and has been administered to over 250 human subjects across several clinical trials over multiple years. Equally as important is that the data continues to show clinical and statistically significant efficacy in the treatment of DMD cardiomyopathy. This data is foundational to our BLA filing.***
>
> I would also like to point out that, it has become well-known that the cardiac and skeletal aspects of the disease do not decline at the same rate. ***So therefore, because we see an impact on both cardiac and skeletal muscle function, we are confident that we are seeing a treatment effect of deramiocel across multiple domains, further strengthening the opportunity to treat DMD with deramiocel.***
>
> (Emphasis added.)

33. During a question-and-answer portion of the same earnings call, Defendant Marbán commented on whether there will be an advisory committee with the FDA, stating in pertinent part:

> <Q: Joseph Pantginis – H.C. Wainwright & Co. – Analyst> And then I guess second question is, obviously, you have no indication that there's going to be an AdCom right now. When do you think you might hear an answer? And for example, if there were an AdCom, would that be a

place that they might want to not necessarily require but maybe force a discussion regarding HOPE-3?

<A: Defendant Marbán > Yes. So we're waiting every day to hear from them on whether they would want an AdCom. They will need some time to put it together. And even though we're actively prepping for one as we speak, they have to give us time to prepare as well. So we expect to hear soon.

I think part of the delay is just based on some of the turmoil that's going on in the government right now. And so I expect that things are moving at a different pace than they might have even just a few months ago. So stay tuned. When we know, we will let everybody else know. ***We see an AdCom neither as a benefit nor a risk. We believe very strongly in our application. We have clinically and statistically significant data. The data stands on its own. However, if we need to get up there and talk about it, we will absolutely do that.***

In terms of HOPE-3, what they have told us is that they are not considering HOPE-3 for this biologics license application that they understand that the primary efficacy endpoint of HOPE-3 is skeletal muscle that, that would be used for post-approval label expansion. We plan on taking HOPE-3 potentially outside the U.S. to order to expand our global footprint.

And the focus of this application as we and they understand it is the data that we've talked about, which is the HOPE-2 data, the HOPE-2 open-label extension data compared to the natural history data set from the Cardiac Consortium. And so I don't anticipate a discussion of HOPE-3 at an AdCom, but if it comes up, we'll be ready to take those questions as well.

(Emphasis added.)

34. The above statements in Paragraphs 23 to 33 were false and/or materially misleading. Specifically, Defendants created adverse facts concerning its four-year safety and efficacy data from its Phase 2 HOPE-2 trial study and gave the false impression that they could obtain first approval for DMD cardiomyopathy.

C. Capricor Announces FDA Request for Advisory Committee Meeting

May 5, 2025

35. May 5, 2025, Capricor issued a press release announcing it had completed its mid-cycle review meeting with the FDA on deramiocel for the treatment of DMD. Defendants also announced that no significant deficiencies were identified by the Review Committee and that the package is on track for a Prescription Drug User Fee Act (PDUFA) action date of August 31, 2025. Additionally, the FDA also confirmed its intent to hold an advisory committee meeting.

36. Defendant Marbán highlighting, in pertinent part:

> ***The successful completion of our mid-cycle review meeting along with the upcoming advisory committee meeting represents major milestones on the path towards approval of deramiocel.*** Deramiocel is a first-in-class cellular therapy with the potential to halt or slow the progression of DMD-cardiomyopathy, and we are pleased to have the opportunity to present the efficacy and safety data to the advisory committee. ***We have been actively preparing for an advisory committee meeting, and we look forward to providing the physician and patient perspectives to highlight the weight of evidence supporting the transformative potential of deramiocel in treating DMD-cardiomyopathy.***

(Emphasis added.)

37. Investors and analysts reacted immediately to Capricor's revelation. The price of Capricor's common stock declined from a closing market price of $10.30 per share on May 5, 2025 to $7.30 per share on May 6, 2025.

38. Although some information as to the Company's true conditions was revealed, Defendants continued to mislead investors. During an earnings call held on May 13, 2025, Defendant Marbán assured investors that participating in an Advisory Committee meeting is a positive step for deramiocel and touted the data supporting its BLA, stating in pertinent part:

> Our path with FDA to this point has been smooth, and FDA has not fallen behind in any way. Our objectives, deliverables and time lines remain on track. There has also been concern expressed over the announcement of an FDA advisory committee meeting for Capricor.
>
> ***I want to highlight that having the opportunity to participate in an AdCom is a positive step for Capricor, for deramiocel and for the program as a whole because it gives us the opportunity to showcase the strong scientific and clinical data that is the basis of our BLA. We do not believe nor has FDA signaled that the determination to hold an AdCom has anything to do with weaknesses in the application, but rather, we believe the nature of a first-in-class therapy for a new indication warrants additional feedback from subject matter experts in the field as well as giving the advocacy and patient community an opportunity to voice their opinion on deramiocel.***
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> The AdCom also affords us the opportunity to highlight that deramiocel has a strong safety record demonstrated in over 700 infusions, treating over 250 patients with some subjects receiving deramiocel infusions for almost 5 years. We are asking for approval for a therapy that has been shown to be generally safe and effective for the treatment of DMD cardiomyopathy for which there are no approved therapies.
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> * * *
>
> ***I would now like to discuss the data that supports our BLA. The filing is based on our blinded, randomized and placebo-controlled HOPE-2 study and also by the HOPE-2 open-label extension study compared to a robust FDA and NHLBI-funded natural history data set. While sample sizes are small, what is most relevant is not the size of the data set, but that the statistically and clinically significant differences are highly unlikely to be due to chance. We have worked with multiple***

> ***internal and external statisticians, presented the data at meetings and to KOLs.*** And what we have heard, seen and acted upon was that the likelihood is extremely low that the impact on the heart or for that matter, the skeletal muscle is due to chance.
>
> We have 3 clinical trials and approximately 4 years of open-label extension data that supports that premise. There has also been an emphasis and written guidance from FDA encouraging the use of real-world evidence to support clinical trial data, especially in rare diseases. Deramiocel is a perfect case for using this type of data to validate the efficacy of a drug product.

(Emphasis added.)

39. The aforementioned statements made in the press release on May 13, 2025 were false and/or misleading. Defendants misrepresented and/or failed to disclose material adverse facts concerning its four-year safety and efficacy data from its Phase 2 HOPE-2 trial study and gave the false impression that they could obtain first approval for DMD cardiomyopathy.

D. FDA Director of the Center for Biologics Evaluation and Research Cancels the Advisory Committee Meeting

June 20, 2025

40. On June 20, 2025, *Stat News*[2] reported that Vinjay Prasad, the director of the FDA's Center for Biologics Evaluation and Research (CBER), canceled the advisory committee meeting regarding deramiocel due to being "skeptical of the treatment" and uncertain about the drug's efficacy and safety.

[2] Id.

June 24, 2025

41. On June 24, 2025, Capricor issued a press release announcing that the FDA canceled the Advisory Committee meeting but still intends to conduct an in-person late-cycle review meeting in mid-July. Further, the release states that four-year data presented at the Parent Project Muscular Dystrophy Conference demonstrated sustained cardiac function and the BLA remains under Priority Review with a PDUFA target action date of August 31, 2025.

42. Defendant Marbán highlighted in pertinent part:

> We remain confident in the strength of our submission and continue to advance toward potential approval, with our next major step being the upcoming late-cycle review meeting. To date, all regulatory milestones have proceeded as expected, including a successful pre-license inspection and a mid-cycle review with no major issues. Our application remains under Priority Review, and we believe we are well positioned as we move toward our PDUFA date. We continue to work closely with the FDA and remain encouraged by the progress of our review.

43. The aforementioned news article, press release and statements made by the Individual Defendants were materially false and misleading. Defendants misrepresented and/or failed to disclose material adverse facts concerning its four-year safety and efficacy data from its Phase 2 HOPE-2 trial study and gave the false impression that they could obtain first approval for DMD cardiomyopathy.

E. The Truth Emerges

July 11, 2025

44. On July 11, 2025, Capricor issued a press release announcing it received a CRL from the FDA denying the BLA specifically citing it did not meet the statutory requirement for substantial evidence of effectiveness and the need for additional clinical data. Further, the CRL referenced outstanding items in the CMC section of the application. Defendant Marbán stated, in pertinent part:

> ***We are surprised by this decision by the FDA. We have followed their guidance throughout the process. Prior to the CRL, the review had advanced without major issues, including a successful pre-licensure inspection and completion of the mid-cycle review.*** Capricor plans to submit data from the Phase 3 HOPE-3 clinical trial to provide additional evidence of effectiveness from an adequate and well-controlled study. The HOPE-3 trial is a randomized, double-blind, placebo-controlled clinical trial of 104 patients, with topline results expected in the third quarter of 2025. We believe these data, if positive, along with our existing long-term clinical results showing cardiac stabilization, preservation of skeletal muscle function, and a consistent safety profile, could support efforts to resolve the questions raised by the FDA for the treatment of cardiomyopathy associated with DMD. ***While this was an unexpected decision by the FDA, we remain committed to the DMD community to get Deramiocel through the approval process.***

(Emphasis added.)

45. During a Special Call held the same day, Defendant Marbán was questioned about the Company's response to the CRL and the data obtained in the Phase 2 HOPE-2 clinical trial.

> <Q: Edward Andrew Tenthoff – Piper Sandler & Co. – Analyst> When it comes to the BLA, the response to the CRL, as you laid out, when do you think you might be able to respond to the CRL?

<Defendant Marbán> We are working directly with the agency now. So in the CRL, they open the door for an informal teleconference to discuss and quoting the letter, path to approval. They've also suggested a follow-up to that. We could actually request a Type A meeting in addition. So they're anxious to work with us. I think they could not include HOPE-3 opportunity in the CRL because it was not part of this initial application.

We're going to work closely with the agency to build HOPE-3 to be exactly what we need to get this BLA across the line. This BLA is for the cardiomyopathy. Therefore, the simplest path to approval is to see if they'll take HOPE-3 for the cardiomyopathy to treat DMD. And of course, there's a broader application in terms of skeletal muscle as well and we look forward to feedback from them.

<Q: Leland James Gershell – Oppenheimer & Co. – Analyst> I wanted to just clarify with respect to sort of dividing between the observations that have been made and the statistical analyses that have been applied.

<Defendant Marbán> This is the crux of the matter, right? So -- and this is where colloquially, the rubber meets the road. ***So obviously, FDA had raised concerns about the initial analysis of the HOPE-2 clinical data. That conversation has been back and forth with the agency literally for years.***

Let me just explain for a minute exactly how we get to the statistical significance and what we've been going back and forth with the agency on and, in fact, got over the hump in August of 2024 in our meetings with the agency. And that was that the original model that was designed for HOPE-2 was based on an 84-patient trial. Because of the early unblinding, there was an imbalance in the distribution. So a normally distributed curve was what the original model was based on. You have to meet the assumption of a normal distribution in order to do that analysis. Once the violation of a normal distribution occurs, you must use a nonparametric analysis, and our statisticians have talked to the agency about this in great detail.

When you apply the nonparametric analysis, you then have a very robust statistical significance of the performance of the upper limb, 1.2 mid in HOPE-2, which then leads to all of the other secondary endpoints, achieving statistical significance, most importantly being

> left ventricular ejection fraction. The agency had accepted that. ***That was one of the topics that was discussed in the meeting in August of 2024. And now they've gone back to a little bit more of their traditional dogma of the fact that it did not meet the original model assumptions.***
>
> <Q: Kristen Brianne Kluska – Cantor Fitzgerald & Co. – Analyst> First, was there anything that they said about the data itself being clinically or not clinically meaningful? Or is the sense here that it was just more on the magnitude, the way the study was statistically analyzed beyond what you just said for HOPE-2 and the number of patients?
>
> <A: Defendant Marbán > ***Yes, it seems mostly that the argument is around the statistical analysis. So in HOPE-2, the concept was, as I just explained, when Leland asked his question, was in the model assumptions and whether to use a parametric normal distribution or a nonparametric model, which was obviously acceptable to the statistical reviewers at the Lancet and to some of the previous reviewers at the Food and Drug Administration.***
>
> (Emphasis added.)

46. The aforementioned press release and statements made by the Individual Defendant was misleading and in direct contrast to statements made in her June 24, 2025 press release. In the press release, Defendant Marbán reiterated that all regulatory milestones were met with met including a successful pre-license inspection and mid-cycle review with no major issues. Further, the BLA for deramiocel remained under Priority Review with a PDUFA action date of August 31, 2025.

47. An analyst at Cantor Fitzgerald lowered its price target calling the CRL issuance a "disappointing setback" noting that "[i]t's unclear if a brand-new BLA will be required…or a major amendment."

48. Further, an analyst at Piper Sandler also lowered its price target noting the delay in FDA approval to 2026 stating that "[w]e anticipate FDA will deem this a Class II resubmission with a 6-month review period, and that deramiocel could gain FDA approval in mid'26."

49. As a result, investors and analysts reacted immediately to Capricor's revelation. The price of Capricor's common stock declined from a closing market price of $11.40 per share on July 10, 2025 to $7.64 per share on July 11, 2025, a decline of nearly 34% in the span of just a single day.

F. Loss Causation and Economic Loss

50. During the Class Period, as detailed herein, Capricor and Defendants made materially false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Capricor's common stock and operated as a fraud or deceit on Class Period purchasers of Capricor's common stock by materially misleading the investing public. Later, when Capricor and Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Capricor's common stock materially declined, as the prior artificial inflation came out of the price over time. As a result of their purchases of Capricor's common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages under federal securities laws.

51. Capricor's stock price fell in response to the corrective events, as alleged *supra*. On these dates, Defendants disclosed information that was directly related to their prior misrepresentations and material omissions concerning Capricor's four-year safety and efficacy data from its Phase 2 HOPE-2 trial study of deramiocel.

G. Presumption of Reliance; Fraud-On-The-Market

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

(a) Capricor's common stock met the requirements for listing and was listed and actively traded on the NASDAQ during the Class Period, a highly efficient and automated market;

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

(c) Capricor was followed by several securities analysts employed by major brokerage firms who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms during the Class Period. Each of these reports was publicly available and entered the public marketplace; and

(d) Unexpected material news about Capricor was reflected in and incorporated into the Company's stock price during the Class Period.

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

54. Alternatively, reliance need not be proven in this action because the action involves omissions and deficient disclosures. Positive proof of reliance is not a prerequisite to recovery pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

H. No Safe Harbor; Inapplicability of Bespeaks Caution Doctrine

55. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the material misrepresentations and omissions alleged in this Complaint. As alleged above, Defendants' liability stems from the fact that they provided investors with statements about regulatory

developments and prospects while at the same time omitting acute risks undermining the validity of their statements.

56. To the extent certain of the statements alleged to be misleading or inaccurate 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.

57. Defendants are also liable for any false or misleading "forward-looking statements" pleaded because, at the time each "forward-looking statement" was made, the speaker knew the "forward-looking statement" was false or misleading and the "forward-looking statement" was authorized and/or approved by an executive officer of Capricor who knew that the "forward-looking statement" was false. Alternatively, none of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by the defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

CLASS ACTION ALLEGATIONS

58. 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 those who purchased or otherwise acquired Capricor's common stock during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are defendants herein, 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.

59. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Capricor's common stock were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. 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. As of May 13, 2025, there were 45 million shares of the Company's common stock outstanding. Upon information and belief, these shares are held by thousands, if not millions, of individuals located throughout the country and possibly the world. Joinder would be highly impracticable.

60. 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.

61. 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. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

62. 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 misrepresented material facts about the business, operations and management of Capricor;

(c) whether the Individual Defendants caused Capricor to issue false and misleading financial statements during the Class Period;

(d) whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

(e) whether the prices of Capricor's common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

(f) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

63. 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 make 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.

COUNT I

Against All Defendants for Violations of Section 10(b) and Rule 10b-5 Promulgated Thereunder

64. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

65. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

66. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly

engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon. Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Capricor common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Capricor's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

67. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Capricor's securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company.

68. By virtue of their positions at the Company, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

69. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of the Company, the Individual Defendants had knowledge of the details of Capricor's internal affairs.

70. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of the Company. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Capricor's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the

aforementioned false and misleading reports, releases and public statements, the market price of Capricor's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning the Company which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Capricor's common stock at artificially inflated prices and relied upon the price of the common stock, the integrity of the market for the common stock and/or upon statements disseminated by Defendants, and were damaged thereby.

71. During the Class Period, Capricor's common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Capricor's common stock at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Capricor's common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Capricor's common stock declined sharply upon

public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

72. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

73. 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, acquisitions and sales of the Company's common stock during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

Against the Individual Defendants for Violations of Section 20(a) of the Exchange Act

74. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

75. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information about Capricor's misstatements.

76. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, and to correct promptly any public statements issued by Capricor which had become materially false or misleading.

77. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Capricor disseminated in the marketplace during the Class Period concerning the misrepresentations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Capricor to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Capricor's common stock.

78. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Capricor to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the

power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

79. By reason of the above conduct, the Individual Defendants and/or Capricor are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demand judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representatives;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: July 17, 2025