UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)

May 7, 2026

CAPRICOR THERAPEUTICS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware	**001-34058**	**88-0363465**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

10865 Road to the Cure, Suite 150, San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

(858) 727-1755
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	CAPR	The Nasdaq Global Select Market

Item 7.01 Regulation FD Disclosure.

On May 7, 2026, Capricor Therapeutics, Inc. (the "Company" or "Capricor") announced that it has filed a Complaint for Equitable Relief (the "Complaint") and Application for Preliminary Injunction (collectively, the "Lawsuit") in the Superior Court of New Jersey, Chancery Division, Bergen County.

A copy of the press release has been attached as Exhibit 99.1 hereto and is incorporated herein by reference. A copy of the Complaint has been attached as Exhibit 99.2 hereto and is incorporated by reference.

The information under Item 7.01 of this Current Report on Form 8-K, Exhibit 99.1 attached hereto is being furnished and shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be incorporated by reference into any of the Company's filings under the Exchange Act, unless expressly set forth as being incorporated by reference into such filing.

Item 8.01 Other Events.

On May 7, 2026, Capricor announced that it has filed a Complaint for Equitable Relief and Application for Preliminary Injunction in the Superior Court of New Jersey, Chancery Division, Bergen County (the "Lawsuit"). The Lawsuit alleges a fundamental pricing flaw in the Commercialization and Distribution Agreement dated January 24, 2022, between the Company and Nippon Shinyaku Co., Ltd. (the "U.S. Distribution Agreement"). The Lawsuit also seeks relief from Nippon Shinyaku Co. Ltd.'s U.S. subsidiary, NS Pharma (collectively "**NS**"). The Lawsuit alleges that NS have failed to adequately prepare for the commercial launch of the Company's product Deramiocel in the United States and have otherwise materially breached the terms of the U.S. Distribution Agreement. The Company seeks rescission of the U.S. Distribution Agreement, declaratory judgment that the Company has the right to distribute Deramiocel directly or through distributors other than NS, preliminary injunctive relief, and other equitable remedies.

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The Company intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act. All statements contained in this Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, any statements relating to the Complaint or the potential outcome thereof. Forward-looking statements are based on management's current expectations, beliefs and assumptions and on information currently available to the Company. Such statements are neither promises nor guarantees, and involve a number of known and unknown risks, uncertainties and assumptions. Actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, without limitation, risks and uncertainties associated with the Complaint and other risks identified from time to time in the reports the Company files with the Securities and Exchange Commission (the "SEC"), including the Annual Report on Form 10-K for the fiscal year ended December 31, 2025, as such factors may be updated from time to time in its other filings with the SEC, accessible on the SEC's website at www.sec.gov. The forward-looking statements in this Current Report on Form 8-K speak only as of the date of this Current Report on Form 8-K, and the Company undertakes no obligation to update or revise any of the statements. The Company's business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release, titled "Capricor Therapeutics Takes Legal Action to Protect Patient Access to Deramiocel for Duchenne Muscular Dystrophy", dated May 7, 2026.
99.2	Complaint for Equitable Relief, filed May 7, 2026.
104	Cover Page Interactive Data File (formatted as inline XBRL).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

CAPRICOR THERAPEUTICS, INC.

Date: May 7, 2026

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

Exhibit 99.1

Capricor Therapeutics Takes Legal Action to Protect Patient Access to Deramiocel for Duchenne Muscular Dystrophy

-Complaint outlines its distribution partner's failure to prepare for launch of DMD therapy; Capricor seeks to rescind the agreement while advancing plans to ensure treatment reaches patients-

SAN DIEGO, May 7, 2026 -- Capricor Therapeutics, Inc. (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for rare diseases, today announced that it has filed a lawsuit against Nippon Shinyaku Co., Ltd. and its U.S. subsidiary, NS Pharma, Inc., over the parties' U.S. distribution agreement for Deramiocel, Capricor's investigational cell therapy for the treatment of Duchenne muscular dystrophy (DMD).

DMD is a fatal genetic disorder affecting approximately 15,000 people in the United States, most of them boys and young men. Deramiocel represents one of the most significant therapeutic advances for DMD, addressing both its skeletal and cardiac manifestations. NS Pharma's inaction may now jeopardize patients' access to this life-changing treatment.

Capricor's complaint details how a fundamental pricing flaw in the Commercialization and Distribution Agreement with NS Pharma will prevent patients covered by Medicare, Medicaid, or private insurance from accessing the therapy. Capricor has sought to work in good faith to fix this pricing mechanism with NS Pharma, but NS Pharma has refused to compromise. NS Pharma also has failed to adequately prepare for commercial launch of Deramiocel, and Capricor is now taking legal action to ensure there is a path for Deramiocel to reach the patients who urgently need it.

"I have spent nearly two decades building Capricor with one goal in mind: making Deramiocel available to treat these boys," said Dr. Linda Marbán, CEO of Capricor. "I know what every additional month of delay costs them, because I know what is happening inside their muscles when they cannot be treated. There is no version of this case in which I am willing to watch NS Pharma's inaction take that away from them."

DMD is a progressive disease. For the thousands of families of children with DMD, every month of delay in receiving Deramiocel means irreversible loss—muscle destroyed, cardiac function permanently diminished, independence taken that may never be returned. Capricor's complaint, and corresponding motion for preliminary injunction, seeks to preserve the ability of Capricor to distribute Deramiocel to patients who need it, pending FDA approval.

Capricor is building commercial readiness in support of a responsible and effective launch of Deramiocel, if approved by the FDA. The Company anticipates a distribution timeline guided by established industry practices and scaled to align with manufacturing capacity, patient needs, and provider and payer processes.

The U.S. Food and Drug Administration has granted Deramiocel Priority Review, with a target PDUFA action date of August 22, 2026. The FDA review process and expected timing remain unchanged.

About Duchenne Muscular Dystrophy

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

About Deramiocel

Deramiocel (CAP-1002) consists of allogeneic cardiosphere-derived cells (CDCs), a rare population of cardiac cells that have been shown in preclinical and clinical studies to exert potent immunomodulatory and anti-fibrotic actions in the preservation of cardiac and skeletal muscle function in muscular dystrophies such as DMD. CDCs act by secreting extracellular vesicles known as exosomes, which target macrophages and alter their expression profile to adopt a healing rather than pro-inflammatory phenotype. CDCs have been investigated in more than 250 peer-reviewed scientific publications and administered to over 250 human subjects across multiple clinical trials.

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

About Capricor Therapeutics

Capricor Therapeutics (Nasdaq: CAPR) is a biotechnology company dedicated to advancing transformative cell and exosome-based therapeutics to redefine the treatment landscape for rare diseases. At the forefront of our innovation is our lead product candidate, Deramiocel, an allogeneic cardiac-derived cell therapy that is currently in late-stage development for the treatment of Duchenne muscular dystrophy (DMD). Extensive preclinical and clinical data have demonstrated Deramiocel's potent immunomodulatory and anti-fibrotic effects in helping to preserve cardiac and skeletal muscle function in DMD. Capricor is also leveraging the power of its exosome technology, using its proprietary StealthX™ platform in preclinical development focused on vaccinology and the targeted delivery of oligonucleotides, proteins, and small-molecule therapeutics, with the potential to treat and prevent a wide range of diseases. At Capricor, we are committed to pushing the boundaries of possibility and forging a path toward transformative treatments for those in need. For more information, visit capricor.com, and follow Capricor on Facebook, Instagram and X.

Cautionary Note Regarding Forward-Looking Statements

Statements in this press release regarding the efficacy, safety, and intended utilization of Capricor's product candidates; the initiation, conduct, size, timing and results of clinical trials; the pace of enrollment of clinical trials; plans regarding regulatory filings, future research and clinical trials; regulatory developments involving products, including future interactions with regulatory authorities and the ability to obtain regulatory approvals or otherwise bring products to market; manufacturing capabilities; dates for regulatory meetings; the potential that required regulatory inspections may be delayed or not be successful which would delay or prevent product approval; the ability to achieve product milestones and to receive milestone payments from commercial partners; and any other statements about Capricor's management team's future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements that are not statements of historical fact (including statements containing the words "believes," "plans," "could," "anticipates," "expects," "estimates," "should," "target," "will," "would" and similar expressions) should also be considered to be forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those indicated by such forward-looking statements. More information about these and other risks that may impact Capricor's business is set forth in Capricor's Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the Securities and Exchange Commission on March 17, 2026. All forward-looking statements in this press release are based on information available to Capricor as of the date hereof, and Capricor assumes no obligation to update these forward-looking statements.

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

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PUBLIC – REDACTS MATERIALS FROM CONDITIONALLY SEALED RECORD

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CAPRICOR THERAPEUTICS, INC., Plaintiff, v. NS PHARMA, INC., and NIPPON SHINYAKU CO., LTD., Defendants.	SUPERIOR COURT OF NEW JERSEY CHANCERY DIVISION: BERGEN COUNTY Docket No. BER-C- Civil Action **VERIFIED COMPLAINT FOR EQUITABLE RELIEF**

Plaintiff, Capricor Therapeutics, Inc. ("Capricor" or "Plaintiff"), by and through its attorneys, Skadden, Arps, Slate, Meagher & Flom LLP, by way of Complaint against Defendants NS Pharma, Inc. ("NS Pharma") and Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku" and, together with NS Pharma, "Distributor" or "Defendants"), says:

I. SUMMARY OF THE ACTION

1. This is a case about a potentially life-extending medicine for thousands of boys and young men suffering from a fatal genetic disorder, the flawed Commercialization and Distribution Agreement ("Distribution Agreement") that may prevent it from reaching those patients, and the recalcitrant distributor—Defendant Nippon Shinyaku—that has chosen to hold the medicine hostage rather than fulfill its promise to deliver it. Capricor respectfully invokes this Court's equitable jurisdiction to ensure that this medicine reaches the patients who urgently need it.

2. Duchenne muscular dystrophy ("DMD") is a cruel disease. It is a progressive, irreversible, and invariably fatal genetic disorder that attacks all voluntary muscles in the body, as well as the heart and respiratory muscles. It overwhelmingly strikes boys. A child with DMD will typically develop normally for the first two or three years of his life. Then the disease begins to take its crippling effect: First on the ability to run. Then to climb stairs. Then to walk. By early adolescence, most boys with DMD are confined to wheelchairs. As the teenage years progress, they lose the use of their arms, legs and hands. Their hearts progressively scar and weaken. Most die of heart failure or respiratory collapse in their twenties or early thirties. There are approximately 15,000 individuals living with DMD in the United States. There is no cure.

3. Leading Capricor's nearly two-decade fight against DMD is Dr. Linda Marbán, its Chief Executive Officer. Dr. Marbán came to science drawn by a desire to learn more about

medicine and to find a way to make people's lives better and longer. She earned her Ph.D. in physiology from Case Western Reserve University, then went to Johns Hopkins University as a postdoctoral fellow in cardiovascular physiology, where she studied what causes heart disease and how it might be better treated.

4. While at Johns Hopkins, Dr. Marbán was recruited to a gene therapy startup where she learned how to build a biotech company from the ground up. That experience laid the foundation for what would become Capricor. In 2005, Dr. Marbán co-founded Capricor. Dr. Marbán and her colleagues set out with a mission to develop biological therapeutics with an aim to change the trajectory of diseases like DMD.

5. Capricor has spent two decades developing Deramiocel, a first-in-class cell therapy that represents one of the most significant therapeutic advances for DMD. In a rigorous Phase 3 clinical trial, Deramiocel slowed the progression of skeletal muscle deterioration by approximately 54% and slowed cardiac decline by approximately 91% compared to placebo—both with statistical significance. Deramiocel does not cure DMD; no therapy does. But it slows the relentless destruction that defines the disease, preserving function that, once lost, is gone forever. To put it simply, Deramiocel aims to give DMD patients a longer lifespan and better quality of life.

6. The patients are waiting: The FDA has granted Deramiocel Priority Review, with a target action date of August 22, 2026 (the "PDUFA Date"[1]). The FDA grants Priority Review to applications for medicines that, if approved, provide significant improvements in the safety or

[1] PDUFA stands for the Prescription Drug User Fee Act. It is a U.S. law that requires pharmaceutical companies to pay fees to the FDA when submitting drug applications, which funds the FDA's drug review process. In practice, it establishes a target deadline (called a "PDUFA Date") by which the FDA aims to complete its review and make an approval decision on a new drug. The FDA can and sometimes does approve a drug before its PDUFA date, particularly if the review is straightforward, the drug received "Priority Review" or "Breakthrough Therapy" designation, or the agency simply completes its work early.

effectiveness of the treatment of a serious condition. **So, approval for Deramiocel could come even sooner than the target PDUFA Date.**

7. Capricor brings this action because, absent intervention by the Court, the Deramiocel launch will be delayed and disrupted by Defendants NS Pharma and Nippon Shinyaku. And Deramiocel will likely become unavailable to help desperate patients in need due to the Distribution Agreement's pricing structure which renders commercialization nonviable.

8. In January 2022, Capricor entered into the Distribution Agreement with Nippon Shinyaku (the "Distribution Agreement"), granting it and its U.S. subsidiary, NS Pharma, the exclusive right to distribute Deramiocel in the United States [redacted]. Nippon Shinyaku also agreed that NS Pharma, which upon information and belief it has appointed as Subdistributor, is responsible for Nippon Shinyaku's acts or omissions and vice versa. Distribution Agreement § 4.2. Thus, unless otherwise stated, all subsequent references to "Distributor" refer to both NS Pharma and Nippon Shinyaku.

9. The Distribution Agreement contains a fatal flaw. The parties agreed on a pricing structure for distributing Deramiocel in Exhibit A to the Distribution Agreement, but upon information and belief, neither party understood at the time that the agreed-upon structure was not viable. Upon information and belief, the parties' mutual mistake was that the interaction between the Distribution Agreement's pricing formula and the federal Medicare reimbursement framework ensures that, in a very short time, neither party can afford to manufacture, distribute, sell, or administer Deramiocel to patients covered by Medicare, and healthcare providers will not be able to afford Deramiocel for administration to their patients in need.

10. Because the federal Medicare program has a strong influence in setting prices that state Medicaid programs and private insurers pay for drugs, this flawed pricing structure will

also make it economically impracticable to distribute Deramiocel to patients covered by Medicaid or private insurance.

11. Simply put, neither Capricor nor the Distributor can afford to sell the medicine at a price much lower than the costs of making and distributing it.

12. Upon information and belief, [redacted]. The Distributor neglected the key elements for a successful launch: it did not complete an acceptable gross-to-net revenue model based on the Distribution Agreement, and to this day, still has not shared one with Capricor. It has not established a realistic wholesale price. To Capricor's knowledge, the Distributor has not conducted a single mock launch exercise. It has also arranged to enter into subdistribution agreements with third parties—essentially farming out contractual duties—without Capricor's written consent as agreed upon.

13. The Distributor has even declined to [redacted]. Upon information and belief, public records suggest that the Distributor [redacted].

14. Over a period of roughly one year, through a series of detailed written requests and meetings, including direct engagement with NS Pharma's and Nippon Shinyaku's most senior leadership, Capricor has asked the Distributor to show that it could fulfill its distribution obligations for Deramiocel. But the Distributor's sporadic and incomplete answers only confirmed Capricor's concerns. The Distributor was not adequately preparing for commercial launch, and was not being transparent with Capricor. The Distributor's actions and omissions constitute breaches of its obligations under the Distribution Agreement, under which the

Distributor assumed certain contractual obligations to prepare for and execute a successful Deramiocel launch and commercialization in exchange for exclusivity over this transformative cell therapy.

15. On March 10, 2026, the FDA established a new PDUFA target action date of August 22, 2026. With commercial approval now potentially within reach, Capricor's need for a competent, responsive, and motivated distributor became urgent.

16. Meanwhile, the Distributor proposed a possible alternative to the Distribution Agreement. But it did not negotiate a workable solution in good faith; it attempted to seize control of Deramiocel. It demanded that [redacted]. The Distributor's unreasonable demand, coupled with its failure to prepare for Deramiocel's launch, confirmed that the Distributor cannot be a responsible steward for Deramiocel. The Distributor improperly attempted to turn its *own* lack of readiness to distribute Deramiocel into leverage over Capricor.

17. On March 27, 2026, the Distributor drew a red line. Nippon Shinyaku's CEO, Mr. Toru Nakai, met with Capricor's CEO, Dr. Linda Marbán. At that meeting, [redacted]. It told Capricor that a "[redacted]" (the "PLD structure") was "[redacted]" for the Distributor's distribution of Deramiocel in the United States. Under the PLD structure, [redacted].

18. On April 1, 2026, Dr. Marbán wrote to NS Pharma's Vice President of Business Development, [redacted], confirming her understanding of the Distributor's position:

“[redacted].” Mr. Kimura responded the same day, confirming that Dr. Marbán had “[redacted]” and that the Distributor was [redacted].

19. The Distributor confirmed its position: [redacted].

20. NS Pharma followed up with a written PLD amendment to the Distribution Agreement on April 10, 2026. The amendment required complete surrender of Deramiocel to the Distributor. On May 6, 2026, Capricor notified the Distributor that it rejected the PLD amendment and accepted the Distributor's repudiation of the Distribution Agreement.

21. Distribution of a potentially life-saving therapy is tied to an exclusive distribution agreement that does not work for either party. Equity must intervene.

22. For the thousands of families of children with DMD, every month of delay means irreversible loss—muscle destroyed, cardiac function permanently diminished, independence taken that may never be returned. This Court should not permit a flawed contract and an obstructive distributor to stand between those families and the medicine that could change their lives.

II. THE PARTIES

23. Capricor is a biotechnology company incorporated under the laws of the State of Delaware, with principal offices located at 10865 Road to the Cure, Suite 150, San Diego,

California 92121. Capricor is a publicly-traded company listed on the Nasdaq Global Select Market. Capricor is the developer and manufacturer of Deramiocel (CAP-1002), an investigational allogeneic cell therapy for the treatment of DMD.

24. Defendant NS Pharma is a Delaware corporation with its principal place of business at 140 East Ridgewood Avenue, Suite 280S, Borough of Paramus, New Jersey 07652. NS Pharma is a wholly-owned subsidiary of Nippon Shinyaku. Upon information and belief, Nippon Shinyaku has appointed NS Pharma as its subdistributor for Deramiocel in the United States under Article 4.2 of the Distribution Agreement.

25. Defendant Nippon Shinyaku is a Japanese corporation with its principal office in Kyoto, Japan. Nippon Shinyaku is the parent company of NS Pharma and party to the Distribution Agreement at issue in this action. Under the Distribution Agreement, Nippon Shinyaku is "at all times [] fully liable for the acts or omissions of [NS Pharma] as if such act or omission was undertaken directly by" Nippon Shinyaku, and "any action or claim by Capricor in respect of any breach, act, error or omission by" Nippon Shinyaku "may be brought against" NS Pharma.

III. JURISDICTION AND VENUE

26. This Court has jurisdiction over this action under N.J.S.A. 2A:16-50 *et seq.* (Declaratory Judgments Act) and the inherent equitable jurisdiction of the Chancery Division.

27. This Court has personal jurisdiction over NS Pharma because NS Pharma maintains its principal place of business in Paramus, Bergen County, New Jersey, and conducts continuous and systematic business activities within the State of New Jersey sufficient to confer general jurisdiction.

28. This Court has personal jurisdiction over Nippon Shinyaku. Nippon Shinyaku has purposefully availed itself of the privilege of conducting business in New Jersey by, among other things, establishing and maintaining a wholly owned U.S. subsidiary, NS Pharma, with its principal place of business in Paramus, Bergen County, New Jersey; directing the commercial activities of NS Pharma in New Jersey, including activities relating to the distribution of pharmaceutical products, including Deramiocel, in the United States; entering into the Distribution Agreement that contemplated performance in New Jersey through NS Pharma; and dispatching its CEO, Mr. Toru Nakai, to participate directly in negotiations concerning the Distribution Agreement and the distribution of Deramiocel in the United States. Further, upon information and belief Nippon Shinyaku has appointed NS Pharma as Subdistributor. Nippon Shinyaku has therefore further agreed, under Article 4.2 of the Distribution Agreement, that it is fully liable for NS Pharma's acts and omissions in New Jersey, and that any breach-related claim by Capricor may be brought against NS Pharma. Nippon Shinyaku has thus affirmatively subjected itself to the adjudicative authority of New Jersey courts for disputes arising from the Distribution Agreement.

29. Venue is proper in Bergen County under R. 4:3-2 because NS Pharma maintains its principal place of business in the Borough of Paramus, Bergen County, and a substantial part of the events and omissions giving rise to this action occurred in Bergen County.

30. Capricor brings this action in the Chancery Division, General Equity Part, because it seeks equitable relief—including injunctive relief and rescission—that is within the traditional jurisdiction of equity courts. The Distribution Agreement between the parties contains an arbitration clause (Article 18), but expressly preserves each party's right to seek injunctive or other equitable relief in a court of competent jurisdiction where such relief is necessary to

prevent serious and irreparable injury. Id. §18.3.3 ("Nothing contained in this Article 18 shall prevent either Party from resorting to judicial process if injunctive **or other equitable relief** from a court is necessary to prevent serious and irreparable injury to one Party or to others.") (emphasis supplied). Capricor's claims fall squarely within this contractual carve-out.

31. Absent immediate equitable intervention, Capricor and the patients it serves will suffer irreparable harm for which no adequate remedy at law exists. The existing disruption and further expected disruption to the commercialization and distribution of Deramiocel caused by the Distributor will deprive these patients of access to a treatment they cannot obtain from any other source, causing suffering and disease progression that no amount of money damages can undo.

IV. FACTUAL BACKGROUND

A. The Parties, Their Relationship, and the Distribution Agreement

32. Capricor is a clinical-stage biotechnology company that, together with its subsidiary, Capricor, Inc., develops a cell therapy for DMD. Over the course of nearly two decades, Capricor has devoted hundreds of millions of dollars to developing Deramiocel, shepherding it through preclinical research, Phase 1 studies, Phase 2 and Phase 3 clinical trials, and the FDA regulatory process. Capricor manufactures Deramiocel at two facilities: one at Cedars-Sinai Medical Center in Los Angeles, California, and a second in San Diego, California, where it has invested approximately $35 - $40 million for expanded manufacturing capacity in anticipation of commercial launch.

33. Reaching this stage has required extraordinary scientific, clinical, regulatory, manufacturing, financial and operational execution in one of the most technically complex areas of drug development. Unlike traditional small molecules, biologics (such as cell therapies)

involve living biological material and require the development of highly specialized manufacturing processes, rigorous quality control systems, careful product characterization, validated potency assays and close regulatory coordination to support consistency, safety, scalability and reproducibility. In a rare, fatal pediatric disease such as DMD, these challenges are compounded by small patient populations, progressive and heterogeneous disease biology, long development timelines, and the need to generate meaningful clinical evidence in a vulnerable population with limited therapeutic options. Simply put, reaching this point required Capricor to do far more than develop a drug—it required building the scientific, clinical, manufacturing and regulatory foundation necessary to advance a living cell therapy in one of the most devastating pediatric diseases.

34. NS Pharma markets Viltepso (viltolarsen), an exon-skipping therapy for a genetically defined subset of DMD patients. As of November 2024, NS Pharma represented that Viltepso is the only product NS Pharma currently distributes in the United States.

35. Capricor and Nippon Shinyaku began discussing a potential distribution relationship in 2021. In December 2021, Nippon Shinyaku delivered a detailed capability presentation to Capricor titled "[redacted]" (the "Capability Presentation"). In that presentation, the Distributor represented [redacted]. The Distributor touted that it had "[redacted]" and highlighted [redacted]. The Distributor also [redacted]

[redacted]. The Distributor presented [redacted]. The Distributor also represented that it had the capability to [redacted]. These representations were material to Capricor's decision to enter into the Distribution Agreement. As set forth below, they proved to be false.

36. The Capability Presentation also included the Distributor's financial projections for Deramiocel. These projections reflected both parties' shared understanding at the time: that Deramiocel could be priced and sold at levels that would generate commercially viable margins for manufacture, distribution, and administration. As more fully described below, this shared assumption was fundamentally mistaken, because neither party understood at the time how the Distribution Agreement's pricing formula would interact with the federal Medicare reimbursement framework to make the distribution of Deramiocel economically unviable.

37. In January 2022, Capricor and Nippon Shinyaku entered into the Distribution Agreement granting Nippon Shinyaku the exclusive right to distribute Deramiocel in the United States through NS Pharma. As set forth above, because Nippon Shinyaku appointed NS Pharma as Subdistributor, Article 4.2 of the Distribution Agreement makes Nippon Shinyaku fully liable for NS Pharma's acts and omissions and authorizes Capricor to bring any breach-related claim against NS Pharma directly.

38. The Distribution Agreement grants the Distributor the exclusive right to "promote, market, sell and distribute" Deramiocel in the United States, including Puerto Rico, through [redacted]. Distribution Agreement §§ 2.1, 15.1.

39. In exchange for that exclusivity, the Distributor assumed extensive obligations to prepare for and execute a successful commercial launch. Among other things, the Distributor is required to use "Commercially Reasonable Efforts," as defined in the Distribution Agreement, to promote, market, sell, and distribute Deramiocel in the Territory. Distribution Agreement § 5.4. The Distributor's specific obligations include developing and maintaining a commercial team with sufficient experience and resources to fulfill its obligations (§ 5.5.5); establishing distribution infrastructure, including warehousing and logistics (§ 5.5.6); and ensuring compliance with all applicable laws, including state distribution licensing requirements (§ 5.18). The parties left no doubt about the Distributor's obligations: the Distributor must "vigorously promote the sale" of Deramiocel, with no reservations (§ 5.4). The Distributor has violated each of these contractual obligations. Taken together, its failures amount to a wholesale refusal to perform its core function under the Distribution Agreement: bringing Deramiocel to market.

40. The successful commercialization and distribution of a complex cell therapy like Deramiocel requires, among other things, mapping the patient journey, developing and testing the target product profile, creating the marketing strategy, establishing pricing, market access and reimbursement strategies, building trained sales and medical affairs teams, implementing HUB and patient support services and establishing the required distribution infrastructure. For a complex therapy, this work also includes federal and state reimbursement planning, securing state-level distribution licenses, and conducting mock-launch exercises to test commercial readiness. These activities are standard and well understood in the pharmaceutical industry, were

known to both parties at the time of contracting, and typically begin several years before launch based on the clinical, regulatory, manufacturing, market access and distribution work required to support a successful launch.

41. The Distribution Agreement also requires Nippon Shinyaku to obtain Capricor's prior written consent before appointing any sub-distributors or agents to distribute Deramiocel. Distribution Agreement § 4.2. The sole exception to this requirement is for NS Pharma itself, which, upon information and belief, Nippon Shinyaku has designated as a permitted subdistributor. No exception exists for any third-party logistics provider, specialty pharmacy, or distribution entity.

42. Upon information and belief, the Distributor has [redacted] —entities that will interact directly with providers, patients, and caregivers in the distribution chain—without first obtaining Capricor's prior written consent, in direct violation of Article 4.2 of the Distribution Agreement. To the extent that other arrangements with [redacted] likewise constitute subdistribution within the meaning of Article 4.2 rather than purely third-party logistics, those arrangements too were entered into without the required written consent. The Distributor disclosed the existence of [redacted] at joint committee meetings when it reported that [redacted]) but the Distributor never sought Capricor's Article 4.2 consent for any of those candidates. Indeed, Capricor expressly rejected the Distributor's proposal to [redacted] .

43. The pricing structure is set forth in Exhibit A to the Distribution Agreement. As more fully described below, per Exhibit A, [redacted]. Distribution Agreement Ex. A.

44. The Distribution Agreement provides for a tiered dispute resolution process (Distribution Agreement §§ 18.1–18.3), but expressly preserves each party's right to seek injunctive or other equitable relief from court "if injunctive or other equitable relief from a court is necessary to prevent serious and irreparable injury to one Party or to others." (*Id.* § 18.3.3.)

45. The Distribution Agreement provides that Capricor may distribute Deramiocel through or with others "if and to the extent Distributor is unable to so distribute the Products due to (a) regulatory requirements; (b) Distributor's failure to meet its Minimum Sales Requirements, subject to Article 5.2; or (c) Distributor being otherwise prohibited or prevented from selling and/or distributing the Products or refusing or being unable to sell and/or distribute the Products to any Customer or class of Customers other than by Customer decision." Distribution Agreement § 4.1.2(a).

46. The Joint Steering Committee was required to establish Minimum Sales Requirements within ninety days before anticipated BLA approval. (*Id.* § 5.2.1.) No Minimum Sales Requirements were established ninety days before the original PDUFA date of August 31, 2025.

B. Deramiocel, the HOPE-3 Clinical Trial, and the DMD Patient Population

47. DMD is caused by the absence of dystrophin, a protein that stabilizes muscle cell membranes. Without it, muscle fibers are damaged with every use and progressively replaced by scar tissue and fat.

48. Cardiomyopathy, the progressive scarring and weakening of the heart muscle, is the leading cause of death in DMD patients. No approved therapy addresses both the skeletal and cardiac dimensions of the disease.

49. Deramiocel is an investigational cell therapy developed by Capricor over nearly two decades of research and development. It comprises cardiosphere-derived cells, a population of cardiac-derived stromal cells isolated from qualified donated human hearts. Deramiocel is designed to slow disease progression through the immunomodulatory, anti-inflammatory and anti-fibrotic activities of cardiosphere-derived cells. These effects are mediated in part by exosomes secreted by these cells that contain bioactive molecules, including microRNAs and other signaling factors, which may influence gene expression and cellular pathways involved in inflammation, fibrosis, and tissue repair. It is administered intravenously every three months and does not require genetic matching; it is an off-the-shelf therapy that can be given to any eligible patient. Deramiocel has received Orphan Drug, Regenerative Medicine Advanced Therapy, and Rare Pediatric Disease designations from the FDA. These designations reflect the FDA's recognition that Deramiocel addresses a serious, life-threatening condition affecting a small patient population with significant unmet medical need; that it employs a novel cell-based therapeutic approach with the potential to address that need; and that it targets a disease affecting fewer than 200,000 individuals in the United States.

C. The Distribution Agreement's Broken Price Structure

50. Deramiocel faces a fundamental commercial barrier. The Distributor realized as much in or around March 2025. This is not a problem of execution. It is a problem of contract design, and one that neither party foresaw.

51. The pricing structure, at a high level, provides that:

A. [redacted]

B. Next, the Distributor will sell to doctors or hospitals ("Customers," as defined in Article 1.7 of the Distribution Agreement) at some higher price. The Distributor would [redacted]

C. Providers then administer Deramiocel, and payors (often Medicare, Medicaid, or the patient's insurance) reimburse the providers for Deramiocel's price, plus a small margin.

52. The value chain the parties believed they were agreeing to contemplated that both parties would profit from the sale of Deramiocel, or at least potentially recover the enormous investment made to develop Deramiocel. They contemplated that it would cost Capricor some amount to manufacture a dose of Deramiocel. Capricor would then [redacted]

[redacted] Both parties would make money on the transaction that they could use to defray their expenses (e.g., Capricor's hundreds of millions of dollars in research and development and its ongoing expenses, and the Distributor's costs to distribute Deramiocel). The health care provider would be reimbursed by the payor (Medicare, Medicaid, private insurance, or similar) for the price at which it acquired Deramiocel plus, typically, a small margin to cover the provider's costs.

53. A distributor can set prices high enough to cover its costs and earn a profit. So in the abstract, the general pricing model in the Distribution Agreement works. But in reality, it does not. For physician-administered therapies like Deramiocel, federal law dictates a Medicare reimbursement ceiling that neither the manufacturer nor the distributor can exceed. That Medicare ceiling, in turn, cascades through the rest of the healthcare system: state Medicaid programs and private insurers routinely tie their own reimbursement rates to Medicare's. This means that one federal formula effectively guides what every payor in the country will pay for Deramiocel.

54. Under federal law, Medicare Part B reimburses physician-administered drugs and biologicals—including Deramiocel, once it is approved—at 106% of the "manufacturer's average sales price" ("ASP"). 42 U.S.C. § 1395w-3a(b)(1)(B); 42 C.F.R. § 414.904(a)(2).

55. The ASP for Part B drugs is calculated by taking a manufacturer's total sales revenue for a drug divided by the total units sold, minus certain price concessions like discounts and rebates. It is based **only** on sales data reported by the manufacturers themselves, not third-party sources. The manufacturer reports this data quarterly to Centers for Medicare and Medicaid Services ("CMS"), which then uses it to set the reimbursement rate (typically ASP + 6%, as mentioned above).

56. Here, Medicare's ASP formula produces a devastating result. Because the Distributor is Capricor's sole U.S. purchaser, Capricor's only sales are to the Distributor. And [redacted]. The reimbursement ceiling that flows from that calculation leaves no room for either party to earn a viable return. [redacted]

57. No one in this value chain, as structured in the Distribution Agreement, has an economic incentive to produce, distribute, or sell Deramiocel where Medicare is the payor. Each unit sold (a "dose") is an economic loss. Returning to the example above, [redacted] But the Distributor cannot sell that dose to a provider at [redacted] because, per federal law, the provider cannot be reimbursed at more than cost plus 6%. [redacted]. Consequently, each dose sold is at a loss.

58. Upon information and belief, the vast majority of individuals with DMD who live to be 20 years old are Medicare beneficiaries. Because of the severity of the disease, most DMD patients qualify for Supplemental Security Income and Medicaid as children. Upon reaching adulthood, these individuals—who may become unable to work due to their disability—become entitled to Social Security Disability Insurance benefits as disabled adult children under a parent's Social Security record. After a mandatory 24-month waiting period, *see* 42 U.S.C. §

426(b), these individuals become entitled to Medicare benefits. As a result, Medicare is the primary payor for medical care for most adult DMD patients in the United States.

59. Unfortunately, this problem is not confined to Medicare patients. Upon information and belief, the Medicare reimbursement rate, in turn, directly influences what state Medicaid programs pay for the same drugs. The majority of states have adopted fee schedules that expressly benchmark to Medicare's ASP-based pricing, typically reimbursing at ASP plus a specified percentage. What is more, private insurers often reference Medicare pricing and similarly adjust their reimbursement rates downward. The pricing spiral therefore progressively renders the sale of Deramiocel uneconomical for all patient populations except those paying out of pocket. Over a short period after launch, several quarters at most, no provider in the United States would have an economic incentive to administer Deramiocel to the vast majority of the patient population.

60. There is a brief window before the ceiling closes. When a drug first enters the market, there is no sales history from which to calculate an ASP, so Medicare reimburses based on the wholesale acquisition cost for the first two quarters. During that initial period, the Distributor could potentially price Deramiocel at a level that generates a return. But beginning in the third quarter, once the ASP is calculated from Capricor's actual sales to the Distributor [redacted], the reimbursement ceiling drops to 106% of that cost and remains there permanently. The pricing structure does not merely fail over time. By the third quarter, providers face a choice: continue administering Deramiocel at a loss, or stop prescribing it altogether. The Distribution Agreement's pricing structure thus guarantees a cliff: two quarters of apparent viability followed by an indefinite period in which no party can economically make, distribute, or administer Deramiocel. Even before that cliff arrives, the certainty of imminent failure

depresses present-day investment in the launch: no rational party will commit the substantial pre-launch capital, personnel, and infrastructure that a successful launch requires when those investments are known to be stranded once the ASP-based reimbursement ceiling takes effect. The harm is therefore occurring now, not at some indeterminate future point.

61. At the time they entered into the Distribution Agreement, the parties *erroneously* believed that their pricing arrangement would permit them to distribute and sell Deramiocel at a price that generated adequate margins for manufacture, distribution, and administration, and that it would be economically rational for healthcare providers to administer Deramiocel, including to patients covered by Medicare. They were wrong.

62. Because the only patients for whom the distribution arrangement remains theoretically economically viable are those wealthy enough to pay out-of-pocket—a population that, for a rare pediatric disease like DMD, is vanishingly small, the Distribution Agreement's broken pricing structure at best limits access to a potentially life-saving therapy based upon wealth, with the sickest and poorest patients locked out first.

63. The Distributor's own failure to finalize an acceptable gross-to-net model based on the Distribution Agreement, establish a realistic wholesale price, or complete a demand forecast—all foundational to launch economics—evidences a wholesale failure to prepare for the commercial launch of Deramiocel.

64. The harm to Capricor and to patients is real. The unavoidable consequences of the Distribution Agreement's pricing structure will be fully realized on a schedule dictated by federal reimbursement law: Medicare patients lose access after the first two quarters, as the ASP calculation takes effect. Medicaid follows Medicare. Private insurers follow Medicaid and

Medicare. The circle tightens until the only patients who can access Deramiocel are those wealthy enough to pay the full cost themselves.

D. The Distributor Institutes an Indefinite "Pencils Down" Period on Launch Preparations

65. Capricor had submitted a formal application for FDA approval (called a Biologics License Application, or "BLA") that was completed by January 2025. In March 2025, the FDA accepted Capricor's application for review, granted it Priority Review (a designation that shortens the FDA's review timeline for therapies that offer significant advances over existing treatments), and set a target decision PDUFA date of August 31, 2025. At the mid-cycle review in May 2025 (a scheduled checkpoint where the FDA evaluates whether the application is progressing without major issues) the agency reported no significant deficiencies and confirmed the review was on track.

66. In May 2025, the FDA conducted and successfully completed a pre-approval inspection of Capricor's San Diego manufacturing facility, a step the FDA takes to verify that a company can reliably produce its product to the required standards before granting approval. As part of that inspection, the FDA issued a 483 notification, identifying 5 areas of concern. Capricor addressed those concerns and later received a letter from FDA confirming that all such matters had been reviewed and found acceptable. 483 notifications are quite common in PLI inspections and if corrected, as Capricor did, are not a roadblock to FDA approval. In July 2025, the FDA changed course, issuing a Complete Response Letter ("CRL") stating it could not approve the application without additional clinical data—notwithstanding its earlier guidance to the contrary, the absence of deficiencies at mid-cycle review, and more than 50 information requests the FDA had issued and Capricor had answered during the review. Notably, the CRL was issued amid significant leadership changes at the FDA and a widely reported shift toward

stricter requirements for rare-disease therapies that resulted in at least 22 Complete Response Letters issued to other companies relating to rare-disease treatments.

67. The Distributor, having already been lagging in its launch preparations, took the CRL as an invalid excuse to go "pencils down" (indefinitely). Initial launch planning that had been underway, however inadequate and incomplete, was paused. Upon information and belief, the Distributor's work on market access, pricing, distribution infrastructure, and payor engagement completely stopped.

68. The Distributor's directive was sweeping. On July 15, 2025, an employee of the Distributor reported to Capricor's Director of Commercial, Mr. Matt Stange, that "[redacted]"—confirming that the instruction had come from the top of the organization. [redacted]. The directive extended beyond the Distributor's own organization: Capricor personnel learned from [redacted].

69. On July 28, 2025, Capricor's CEO, Dr. Linda Marbán, sent an email to the Distributor objecting to the pause in the Distributor's commercial preparation activity. As she explained in that email, Capricor was not slowing down. Dr. Marbán offered to meet with the Distributor immediately to discuss this concerning situation.

70. On July 29, 2025, the Distributor confirmed it "[redacted]".

71. The Distributor treated the CRL as a license to defer the preparation obligations it had already been neglecting. [redacted] The Distributor's own July 29, 2025 email acknowledged as much, stating that "[redacted]" were being utilized [redacted]." Any progress made on distribution infrastructure was lost.

72. In October 2025, Capricor's CEO, Dr. Linda Marbán, sent a detailed email to the Distributor requesting information on the Distributor's progress on [redacted]—including the status of its state distribution licenses. The Distributor refused to provide a substantive response.

73. On November 6, 2025, the Distributor's General Counsel, [redacted], responded to Capricor's inquiries by email, asserting that the Distributor is [redacted]. That statement is inconsistent with the Distributor's obligations under Article 5.4 of the Distribution Agreement which requires the Distributor to use Commercially Reasonable Efforts to prepare for the commercial launch of Deramiocel.

74. On January 5, 2026, Dr. Marbán again wrote to the Distributor, requesting a current launch plan, an updated organizational chart with named personnel, market access

details, and market research updates. She reiterated the unanswered October 2025 requests and asked that the parties' joint planning meeting be moved up from February 2026. On January 23, 2026, the Distributor's Vice President of Business Development, [redacted], responded by deflecting—claiming that the Distributor's launch planning [redacted], and referring back to Mr. Dunham's November email.

75. In late January 2026, Dr. Marbán responded, again noting the Distributor's lack of a meaningful response about its pre-launch activities. She noted that the Distributor had not confirmed that it had been issued state distribution licenses; had not provided a Deramiocel-specific launch plan (only a generic template); had not finalized a Target Product Profile;[2] and had refused when asked to share a populated organizational chart demonstrating that the Distributor had established a marketing team as required by Article 5.5.5 of the Distribution Agreement. She rejected the Distributor's continued insistence on a private-label distributor model that Capricor had repeatedly refused. She expressed "great concern" about the Distributor's readiness to distribute Deramiocel.

76. Although it was evident that the Distributor had written off Deramiocel, Capricor had not lost hope. In December 2025, Capricor announced the results of its Phase 3 HOPE-3 clinical trial. A Phase 3 trial is a large-scale clinical study intended to test whether a drug is actually safe and effective compared to existing treatments or a placebo.

77. The Phase 3 HOPE-3 trial was a randomized, double-blind, placebo-controlled clinical study of 106 DMD patients conducted in the United States. The results were striking:

[2] A TPP is the document that defines the drug's key commercial attributes: indication, dosing, administration route, target patient population, efficacy/safety profile, and positioning relative to competing therapies. The TPP is a foundational document for pricing strategy, payer value messaging, the AMCP dossier, sales training materials, and reimbursement coding.

Deramiocel slowed skeletal muscle deterioration by approximately 54% and slowed cardiac decline by approximately 91%, both with statistical significance. Deramiocel also significantly reduced the progression of myocardial scarring. Additionally, the study showed statistical significance in all type 1 error controlled secondary endpoints. Furthermore, Deramiocel maintained a safety and tolerability profile consistent with prior clinical experience. These results built on years of prior clinical data, including a Phase 2 trial published in The Lancet and an open-label extension demonstrating durable benefits sustained up to four years.

78. Following the positive HOPE-3 results, Capricor submitted data to the FDA. On March 10, 2026, the FDA lifted the Complete Response Letter and resumed its review of the BLA, establishing a new "PDUFA" target action date of August 22, 2026. Capricor expects that FDA approval may issue by or before that date. Upon information and belief, the Distributor's launch preparations have not caught up and are seriously and irremediably delinquent, destroying the prospects of a successful launch. The months lost to inaction cannot be recovered, especially because the Distributor *still* has not devoted sufficient attention to Deramiocel, and will not do so until and unless Capricor agrees to its demand to cede control of Deramiocel to the Distributor.

E. The Distributor's Failures to Perform for the Deramiocel Launch

79. The Distributor's failures to prepare for the commercial launch of Deramiocel are extensive, well-documented, and span virtually every critical dimension of its contractual obligations. Capricor has repeatedly raised these deficiencies with the Distributor, beginning no later than March 2025 and continuing through the present. The Distributor has either failed to respond satisfactorily or has affirmatively disclaimed its obligations.

80. At the [redacted], the state and scope of the Distributor's unreadiness became fully apparent. Upon information and belief,

[redacted] revealed, among other things, the following deficiencies:

A. **Launch Planning:** The Distributor has no comprehensive plan to launch Deramiocel. It has not developed an integrated launch playbook. To Capricor's knowledge, the Distributor has not conducted a single mock launch exercise. Its gross-to-net revenue model is not acceptable and, by NS Pharma's own Head of Commercial's admission, "[redacted]." The[redacted], is stale and has no timeline for revision. And there is no non-branded disease education website to build awareness among patients, caregivers, or clinicians. All of these tasks are commercially reasonable tasks that are required for a successful launch.

B. **Target Product Profile ("TPP"):** The TPP is the single document on which pricing strategy, payer engagement, value messaging, and the AMCP dossier all depend. It is also used for sales forecasting, because projected adoption rates are multiplied by price to generate sales projections. It can also be used by patient advocacy and for a variety of other purposes. The TPP has not been finalized, more than four years after the Distribution Agreement was signed. NS Pharma's own Head of Commercial called it "[redacted]," yet it remains incomplete. [redacted]

[redacted]. The consequences of the TPP's ongoing incompleteness fall on the commercial launch, and the commercial launch is the Distributor's obligation.

C. **Distribution Infrastructure:** The Distributor purports to have entered into arrangements with [redacted], but without obtaining Capricor's prior written consent. To the extent those arrangements establish a subdistributor relationship, the Distributor should have obtained Capricor's prior written consent pursuant to Article 4.2 of the Distribution Agreement. The Distributor has also given Capricor inconsistent representations about its state-level distribution licensing: at times representing [redacted]. The Distributor never disclosed that [redacted] to Capricor during contracting, never sought Capricor's written consent under Article 4.2, and, despite Capricor's repeated requests, has refused to produce any documentation identifying the state licenses on which the Distributor proposes to rely or the terms of its arrangement with Cardinal.

D. **Market Access and Pricing**: [redacted]. The [redacted] need to be

updated. And [redacted] even though the Distribution Agreement mandates that they be established within ninety days of anticipated BLA approval—a deadline the Distributor did not meet ninety days ahead of the original PDUFA date of August 31, 2025.

81. The Distributor's persistent pattern of nonperformance spans launch planning, pricing, distribution infrastructure, personnel, subdistributor consent, and minimum sales requirements.

82. It also demonstrates that the Distributor's breaches are not isolated lapses but, upon information and belief, an intentional, systematic failure to discharge the obligations in exchange for which the Distribution Agreement afforded exclusive distribution rights.

F. The Distributor's Repudiation

83. Upon information and belief, the Distributor chose to disregard its launch obligations rather than adequately invest in a commercial infrastructure. It then waited until Capricor had no time left (with potential FDA approval foreseeable and no alternative distributor in place) to press for a complete restructuring of the deal.

84. On March 27, 2026, Nippon Shinyaku's CEO, Mr. Toru Nakai, met with Capricor's CEO, Dr. Linda Marbán. At that meeting, Mr. Nakai informed Capricor that a [redacted] was [redacted] for Deramiocel in the United States. Under the proposed PLD model, the [redacted]. This was not the bargain the parties had struck.

85. On April 1, 2026, Dr. Marbán wrote to Mr. Kimura of NS Pharma, confirming her understanding of the Distributor's repudiation: "[redacted]."

86. Kimura responded the same day: "[redacted]."

87. [redacted]. The PLD Proposal would make the Distributor—not Capricor—the "[redacted]" for purposes of federal reimbursement calculations.

88. The Distributor's proposal was unacceptable. The proposal required Capricor to [redacted]

[redacted]. It contemplated transferring that control to a distributor that had failed to meet its existing contractual obligations.

89. On May 6, 2026, Capricor informed the Distributor that it would not agree to the PLD arrangement, and that it accepted the repudiation.

G. Irreparable Harm to DMD Patients and Capricor

90. DMD is a disease of irreversible, progressive destruction. Deramiocel does not cure DMD and does not reverse existing damage. What it does is slow the rate at which damage accumulates—preserving muscle function, cardiac function, and independence that, once lost, can never be restored. This distinction is critical: because Deramiocel has been clinically shown to preserve existing function but not to measurably restore lost function, every month of delay in making the therapy available to patients can result in permanent, quantifiable harm that cannot be undone even if Deramiocel is eventually administered. And if the distribution of Deramiocel fails to launch or is halted because of the flawed, repudiated Distribution Agreement, every month the therapy is unavailable is another month during which disease progression continues unchecked—adding to the already irreversible toll.

91. In concrete terms, a fifteen-year-old boy with DMD who can currently lift a cup to his mouth may, within months and without effective treatment, lose the ability to do so. Once lost, that function will not return. Similarly, a seventeen-year-old whose cardiac ejection fraction—a measure of how strongly the heart pumps blood—is 40% may, without treatment, decline further toward heart failure. The underlying cardiac muscle may continue to scar and weaken, and that damage is irreversible. For non-ambulatory teenagers with DMD, upper-limb function is often the last remaining source of independence—the ability to eat, use the bathroom, communicate, operate a wheelchair or device, and participate in daily life with some measure of

control. For these patients, every percentage point of preserved function can mean the difference between retaining self-sufficiency and becoming entirely dependent on others. There is no substitute for Deramiocel. No other approved therapy addresses both the skeletal and cardiac manifestations of DMD. No other therapy has demonstrated the Phase 3 clinical efficacy described above. If Deramiocel is not distributed to patients in a timely manner following FDA approval, there is no alternative therapy patients can turn to. Every day of delay is a day of irreversible disease progression.

92. Without equitable relief, Capricor also suffers irreparable harm. It has invested hundreds of millions of dollars and devoted nearly two decades to the research necessary to bring Deramiocel to market. It has built its own manufacturing capacity, hired personnel, and retained numerous experts to assist it in preparing for commercial launch, all at great cost to Capricor. The inaction and failures of the Distributor left Capricor with no viable alternative. It cannot risk failure. Capricor cannot fulfill its mission to help patients in need—or recoup its investment—if its exclusive distributor is unable or unwilling to distribute.

93. The substantial harm to Capricor's business, reputation, and relationships with the clinical and patient communities cannot be adequately remedied through an award of money damages. An approved therapy that never reaches patients not only damages Capricor's commercial prospects; it undermines the credibility that is essential to Capricor's ability to attract future research partnerships, clinical trial participation, and investor confidence. These are harms that continue to compound over time, cannot be readily quantified, and cannot be reversed.

94. Capricor has unsuccessfully spent months attempting to find a way to move forward productively and to address with the Distributor its failure to perform as agreed, at all

times stressing the desire and hope for a successful collaboration. Only when those efforts had been exhausted and FDA approval had become a near-term possibility did the Distributor's inaction turn a problem into a matter of urgency.

95. The public interest strongly favors ensuring that Deramiocel reaches patients without further delay. Approximately 15,000 individuals are living with DMD in the United States. The families of these patients—parents who have watched their sons lose the ability to walk, to use their arms, to breathe independently—have waited decades for a therapy that can meaningfully change the trajectory of this disease and to provide these patients the quality of life they so deserve. Deramiocel is that therapy.

96. This Court should not permit a flawed contract and a recalcitrant distributor to stand between those families and the medicine that could preserve their children's remaining function and extend their lives.

COUNT ONE
(Rescission Based on Mutual Mistake)

97. Plaintiff repeats and incorporates by reference the allegations contained in the preceding paragraphs as if set forth fully herein.

98. At the time the parties entered the Distribution Agreement, both Capricor and Nippon Shinyaku shared a mistaken assumption that the pricing structure set forth in Exhibit A would generate commercially viable margins for the manufacture, distribution, and administration of Deramiocel. Both parties entered into the Distribution Agreement with the understanding that it would permit them to price and sell Deramiocel at commercially viable profit levels. They were wrong.

99. This mutual mistake goes to a basic assumption on which the Distribution Agreement was made. Its purpose—the successful commercialization and distribution of

Deramiocel to DMD patients—cannot be achieved under its terms and the failure of that purpose cannot be avoided even under a fair and reasonable interpretation of its terms. The mistake has a material effect on the agreed exchange of performances that is adverse to both parties.

100. Accordingly, Capricor is entitled to rescission of the Distribution Agreement based upon mutual mistake and the parties should be restored to the positions they occupied before its execution.

COUNT TWO
(Alternatively, Rescission Based on Unilateral Mistake)

101. Plaintiff repeats and realleges the allegations contained in the preceding paragraphs as if set forth fully herein. In the alternative to Count One, Capricor alleges that the mistake regarding the Distribution Agreement's pricing structure was Capricor's alone.

102. In the alternative to its mutual mistake claim, Capricor alleges that when the Distribution Agreement was executed in January 2022, Capricor mistakenly believed that the pricing structure set forth in Exhibit A would generate commercially viable margins for the manufacture, distribution, and administration of Deramiocel. This belief was reinforced by the Distributor's own December 2021 Capability Presentation. Capricor did not understand at the time of contracting that the interaction between the Distribution Agreement's pricing formula and the Medicare Part B ASP-based reimbursement framework would render the distribution of Deramiocel economically unviable.

103. Upon information and belief, the Distributor knew or should have known of the mistake at the time the Distribution Agreement was executed. Nippon Shinyaku's U.S. subsidiary, NS Pharma, already distributed Viltepso in the United States and had direct experience with payor reimbursement structures, including the Medicare Part B ASP framework. NS Pharma was therefore in a position to understand—or, with the exercise of reasonable

diligence, to have understood—that the Distribution Agreement's pricing formula would produce an ASP so low as to render provider reimbursement inadequate.

104. In the alternative, even if the Distributor did not know of the mistake, enforcement of the Distribution Agreement against Capricor under its current pricing terms would be unconscionable. Demand will be nonexistent given the flaw in reimbursement. And even if there were demand, the Distribution Agreement's pricing structure ensures that Capricor receives, at most, the marginal cost of manufacturing each dose of Deramiocel—generating no return on nearly two decades and hundreds of millions of dollars of research and development—while simultaneously preventing Capricor from distributing Deramiocel through any alternative channel that could yield viable economics. No reasonable party would have agreed to such terms had the consequences been understood.

105. Capricor is entitled to rescission of the Distribution Agreement based on its unilateral mistake.

COUNT THREE
(Rescission Based on Frustration of Purpose)

106. Plaintiff repeats and incorporates by reference the allegations contained in the preceding paragraphs as though set forth in full herein.

107. The principal purpose of the Distribution Agreement was the successful commercialization and distribution of Deramiocel to patients with DMD in the United States. Both parties understood this at the time of contracting, and the Distribution Agreement's structure—exclusivity, milestone payments, launch preparation obligations, and sales-based payments—was designed to achieve that purpose.

108. That purpose has been substantially frustrated. The Distribution Agreement's pricing structure, as applied to a cell therapy reimbursed primarily through Medicare Part B,

makes it commercially impossible to sustain a viable distribution of Deramiocel. The Distributor lacks both the economic incentive and the demonstrated capability to launch the product. The frustration of purpose was not reasonably foreseeable at the time of contracting and is not attributable to the fault of either party.

109. As a result of the frustration of the principal purpose of the Distribution Agreement, Capricor is entitled to rescission.

COUNT FOUR
(Declaratory Judgment — Right to Distribute Deramiocel)

110. Plaintiff repeats and incorporates by reference the allegations contained in the preceding paragraphs as if set forth fully herein.

111. An actual and justiciable controversy exists between the parties regarding whether, given the commercially impracticable pricing structure, the Distributor's material breaches, and the Distributor's anticipatory repudiation of the Distribution Agreement, the Distribution Agreement's exclusivity provisions bar Capricor from distributing Deramiocel to DMD patients through channels other than the Distributor.

112. Capricor is entitled to a declaratory judgment under N.J.S.A. 2A:16-50 et seq. declaring that Capricor has the right to distribute Deramiocel, directly or through distributors other than the Distributor, and the Distribution Agreement's exclusivity provisions do not bar such distribution. The Distribution Agreement itself authorizes Capricor to distribute Deramiocel if the Distributor cannot.

COUNT FIVE
(Breach of Contract — Failure to Perform Against Defendants)

113. Plaintiff repeats and incorporates by reference the allegations contained in the preceding paragraphs as if set forth fully herein.

114. The Distribution Agreement required the Distributor to prepare for and execute the commercial launch of Deramiocel, including obligations related to launch planning and commercial readiness (§ 5.4), personnel and field deployment (§ 5.5.5), distribution infrastructure (§ 5.5.6), market access and pricing (§§ 5.4, 5.8), state distribution licensing (§ 5.18), subdistributor consent (§ 4.2), establishment of Minimum Sales Requirements (§ 5.2.1), and fulfillment of all other Commercially Reasonable Efforts.

115. The Distributor has materially breached the Distribution Agreement by, among other things: failing to develop an integrated launch plan for Deramiocel; failing to finalize an acceptable gross-to-net revenue model or establish a realistic wholesale price; failing, to Capricor's knowledge, to conduct mock launch exercises; [redacted], without Capricor's prior written consent as required by Article 4.2; entering into an undisclosed [redacted], without obtaining Capricor's written consent, and refusing despite repeated requests to produce documentation identifying the licenses on which the Distributor proposes to rely; redirecting its commercial personnel to market and sell its Viltepso product rather than maintaining a dedicated Deramiocel team; and failing to establish Minimum Sales Requirements.

116. The Distributor's breaches are material.

117. As a direct and proximate result of the Distributor's breaches, Capricor has suffered and continues to suffer harm, including impairment of its ability to commercialize Deramiocel and delay in the launch of a potentially life-saving therapy.

COUNT SIX
(Breach of Contract — Anticipatory Repudiation Against Defendants)

118. Plaintiff repeats and incorporates by reference the allegations contained in the preceding paragraphs as if set forth fully herein.

119. The Distributor has repudiated its obligations under the Distribution Agreement through its words and conduct. NS Pharma's General Counsel affirmatively disclaimed the company's pre-launch obligations, asserting that the Distributor is [redacted].

120. The Distributor's repudiation was expressed again on March 27, 2026, when its parent company's CEO informed Capricor in a face-to-face meeting that a [redacted]" was "[redacted]" for the Distributor's distribution of Deramiocel in the United States. On April 1, 2026, the Distributor confirmed this position in writing. The Distributor's statement that a new agreement is "[redacted]" is a definite and unequivocal manifestation of its intention not to perform under the existing Distribution Agreement. The Distributor did not say that performance under the Distribution Agreement would be difficult, or that the parties should discuss modifications. It said [redacted]. That constitutes repudiation.

121. Capricor treated the Distributor's repudiation as such. After considering the Distributor's PLD proposal, Capricor informed the Distributor that the proposal was unacceptable.

122. As a direct and proximate result of the Distributor's anticipatory repudiation, Capricor has suffered and continues to suffer harm, including but not limited to the inability to commercialize Deramiocel through alternative distribution channels, ongoing expenditures to

maintain manufacturing readiness without corresponding revenue, and the continued deterioration of the DMD patient community's access to Deramiocel.

COUNT SEVEN
(Breach of the Implied Covenant of Good Faith and Fair Dealing Against Defendants)

123. Plaintiff repeats and incorporates by reference the allegations contained in the preceding paragraphs as if set forth fully herein.

124. Under the implied covenant of good faith and fair dealing, a party to an agreement cannot do anything that will have the effect of destroying or injuring the right of the other party to receive the fruits of the contract.

125. The Distributor has breached the implied covenant of good faith and fair dealing by, among other things: failing to adequately communicate with Capricor concerning its readiness and distribution preparations; disclaiming its pre-launch preparation obligations while simultaneously asserting its exclusive rights; and treating the CRL as license to abandon launch preparations while maintaining its contractual control over Deramiocel's U.S. distribution.

126. The Distributor's conduct has had the effect of destroying Capricor's right to receive the intended benefit of the Distribution Agreement—the successful distribution of Deramiocel to patients with DMD.

127. As a direct and proximate result of the Distributor's breach of the implied covenant of good faith and fair dealing, Capricor has suffered and continues to suffer harm, including Capricor's inability to distribute Deramiocel through alternative channels while the Distributor clings to exclusive rights it will not exercise.

COUNT EIGHT
(Unjust Enrichment Against Defendants)

128. Plaintiff repeats and incorporates by reference the allegations contained in the preceding paragraphs as if set forth fully herein.

129. In the alternative, and to the extent the Distribution Agreement is rescinded or held unenforceable, the Distributor has been unjustly enriched at Capricor's expense. The Distributor has received substantial benefits under the Distribution Agreement, including exclusive distribution rights over a potentially transformative cellular therapy, access to Capricor's proprietary data, and the reputational and commercial benefits of being the named U.S. distributor of Deramiocel.

130. The Distributor has failed to provide the consideration for which those benefits were exchanged—namely, a commercially ready distribution infrastructure capable of bringing Deramiocel to patients upon FDA approval. It would be unjust and inequitable to permit the Distributor to retain these benefits without performing its obligations.

131. Capricor is entitled to restitution and disgorgement of the benefits conferred upon the Distributor.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Capricor demands judgment against Defendants Nippon Shinyaku and NS Pharma as follows:

A. Rescinding the Distribution Agreement and restoring the parties to their pre-Distribution Agreement positions;

B. Entering a preliminary and permanent injunction enjoining the Distributor from interfering with Capricor's efforts to distribute Deramiocel, and from holding itself out as the exclusive distributor of Deramiocel in the United States;

C. In the alternative, declaring that Capricor has the right to distribute Deramiocel, directly or through distributors other than the Distributor, to DMD patients, and that the Distribution Agreement's exclusivity provisions do not bar such distribution;

D. Declaring that the Distributor has materially breached, and anticipatorily repudiated, the Distribution Agreement;

E. Awarding Capricor restitution and disgorgement of benefits unjustly conferred upon the Distributor;

F. Awarding Capricor its costs of suit and reasonable attorneys' fees to the extent permitted by law or contract; and

G. Awarding such other and further relief as this Court deems just and equitable.

SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP

Attorneys for Plaintiff Capricor Therapeutics, Inc.

By: */s/Andrew Muscato*
Andrew Muscato

Dated: May 7, 2026

R. 4:5-1 CERTIFICATION

To the best of my knowledge, information and belief, the matter in controversy is not presently the subject of any other court proceeding or arbitration, pending or contemplated, and no other parties need to be joined at this time.

SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP

Attorneys for Plaintiff Capricor Therapeutics, Inc.

By: */s/Andrew Muscato*
Andrew Muscato

Dated: May 7, 2026

R. 1:38-7(b) CERTIFICATION

I certify that confidential personal identifiers have been redacted from the documents now submitted to the Court and will be redacted from all documents submitted to the Court in the future in accordance with R. 1:38-7(b).

SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP

Attorneys for Plaintiff Capricor Therapeutics, Inc.

By: */s/Andrew Muscato*
Andrew Muscato

Dated: May 7, 2026

VERIFICATION

A.J. Bergmann, being of full age hereby verifies as follows:

1. I am the Chief Financial Officer of Capricor Therapeutics, Inc., the Plaintiff in the foregoing Verified Complaint.

2. I have read the Verified Complaint and verify that the allegations contained therein are true to the best of my knowledge, unless indicated, as set forth therein, as based upon information and belief, or unless they set forth statements about future events. To the extent any allegation is based upon information not within my personal knowledge, I have made reasonable inquiry of Capricor's officers, employees, advisors, and counsel and believe such allegations to be true.

I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: 5/6/26