PUBLIC - REDACTS MATERIALS FROM CONDITIONALLY SEALED RECORD

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-000117-26 Civil Action

BRIEF ON BEHALF OF PLAINTIFF CAPRICOR THERAPEUTICS IN SUPPORT OF ITS APPLICATION FOR A PRELIMINARY INJUNCTION

Andrew Muscato (NJ Bar ID 18661978)
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
(A Delaware Limited Liability Partnership)
One Manhattan West
New York, New York 10001
Telephone: (212) 735-3000
Facsimile: (212) 735-2000

Quyen L. Ta*
Emily Haffner*
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
525 University Avenue
Palo Alto, California 94301
Telephone: (650) 470-4500
Facsimile: (650) 470-4570

William K. Wray Jr.*
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
500 Boylston Ave.
Boston, MA 02116
Telephone: (617) 573-4889
Facsimile: (650) 470-4570
Attorneys for Plaintiff Capricor Therapeutics, Inc.

*Pro hac vice motion to be submitted

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Statutes

Regulations

Other Authorities

Plaintiff Capricor Therapeutics, Inc. ("Capricor") respectfully submits this brief in support of its application for an Order to Show Cause that seeks the entry of a Preliminary Injunction.

PRELIMINARY STATEMENT

This case concerns a potentially life-extending medicine for boys and young men dying from Duchenne muscular dystrophy ("Duchenne" or "DMD"), a flawed contract whose pricing structure makes distribution of that medicine economically impossible, and a distributor that has repudiated the contract and stands to obstruct alternative distribution. Given what is at stake, Capricor respectfully requests that the Court enter a preliminary injunction that recognizes the likelihood that the contract is subject to rescission, preserves the status quo, and permits Capricor to distribute Deramiocel on its own with partners other than Defendants Nippon Shinyaku Co. Ltd. and NS Pharma, Inc. (collectively, the "Distributor"). The injunction would also restrain the Distributor from interfering with Capricor's distribution activities.

- **The potentially life-extending medicine is Deramiocel.** Deramiocel is a first-in-class cell therapy for Duchenne muscular dystrophy—a progressive, irreversible, and invariably fatal genetic disorder that affects approximately 15,000 boys and young men in the United States. Most Duchenne patients lose mobility as young children, with most dying in their 20s or early 30s. In a recent Phase 3 trial, Deramiocel slowed patients' skeletal muscle deterioration by 54% and cardiac decline by 91%, both with statistical significance. The U.S. Food and Drug Administration ("FDA") has set a target action date of August 22, 2026. Approval may come sooner.
- **The flawed contract is the Distribution Agreement (the "Agreement").** Its [redacted]. In other words, the contract that sets forth the

exclusive means of distributing Deramiocel provides that doing so will be unprofitable for both parties.

- **The Distributor is Defendant Nippon Shinyaku and its wholly owned U.S. subsidiary, NS Pharma, Inc**. The Distributor has failed to prepare to distribute Deramiocel. It then repudiated the Distribution Agreement and attempted to bully Capricor into an arrangement that would benefit only the Distributor. An injunction is necessary to prevent the Distributor from obstructing Capricor's alternative distribution efforts.

The four elements necessary to issue a preliminary injunction set forth in Crowe v. De Gioia, 90 N.J. 126, 132-34 (1982), are satisfied here.

First, if the Court does not grant injunctive relief, Capricor and Duchenne patients will suffer irreparable harm. Deramiocel is an innovative medicine of great economic value that Capricor has spent decades and hundreds of millions of dollars to develop. Unless the roadblocks to its distribution are removed, Capricor will suffer harm that cannot be adequately remedied by money damages. Moreover, the Duchenne patients who are the prospective users of the medicine are suffering muscular and other physical degradation on a daily basis. No other therapy can slow down the progressive deterioration Duchenne patients experience as effectively as Deramiocel can. Any delayed or reduced access to Deramiocel will cause irreparable loss in their muscle mass, cardiac function, and remaining mobility. For many patients, lack of access to Deramiocel may lead to a much earlier death.

Second, Capricor is likely to succeed on the merits.

- The Distribution Agreement is subject to rescission based on, among other grounds, a mutual mistake: the parties mistakenly agreed to a pricing formula that does not work for either party and that leads to economic loss for both.
- The Distributor repudiated the Distribution Agreement and thus cannot rely on its protections.
- Furthermore, the Distributor has materially breached its obligations under the Distribution Agreement by failing to undertake commercially reasonable efforts to prepare for the launch and distribution of Deramiocel.

Third, the balance of hardships favors Capricor. On Capricor's side: Capricor has devoted years of its corporate existence and hundreds of millions of dollars to the development of Deramiocel and the rigors of obtaining FDA approval and is now on the eve of potentially recouping its investment. Moreover, thousands of Duchenne patients face the prospect of losing irreplaceable muscle and cardiac function each day distribution of Deramiocel is delayed. On Defendants' side, they stand to lose only the speculative profits of an Agreement they now acknowledge is unprofitable and unworkable. Indeed, that is why Nippon Shinyaku repudiated the Distribution Agreement. The Distributor cannot credibly claim hardship under an Agreement that is not economically viable and that it has repudiated.

Fourth**,** the public interest favors the injunctive relief sought. Access to Deramiocel implicates serious public health concerns. Again, the Distributor repudiated the Distribution Agreement on March 27, 2026 and confirmed the repudiation in writing five days later. Thus, the status quo, given the repudiation, is that the Distributor is not acting as the exclusive distributor. Injunctive relief will preserve the status quo by permitting Capricor to arrange alternative distribution of Deramiocel without Defendants' interference. An injunction will ensure that the

therapy can reach thousands of Duchenne patients who need it as soon as possible after approval while the parties resolve any issues relating to unwinding the Distribution Agreement.

Capricor respectfully requests that the Court enter the Order to Show Cause and on its return date, grant the requested Preliminary Injunction.

BACKGROUND AND STATEMENT OF FACTS

I. BACKGROUND

Capricor commenced this action on May 7, 2026 by filing its Verified Complaint for Equitable Relief by way of an Order to Show Cause seeking a Preliminary Injunction.

This Court has jurisdiction over this matter because Defendant NS Pharma, Inc. maintains its principal place of business in the Borough of Paramus, Bergen County, New Jersey, and conducts continuous and systematic business activities within New Jersey, including acting as a subdistributor for Deramiocel. Defendant Nippon Shinyaku is a Japanese corporation that has purposefully availed itself of the privilege of conducting business in New Jersey by, among other things, entering into the Distribution Agreement and establishing and maintaining a wholly owned U.S. subsidiary, NS Pharma, Inc., through which it directs its corporate activities concerning Deramiocel. Further, Nippon Shinyaku agreed in the Distribution Agreement that it could be sued through NS Pharma, Inc. Agreement § 4.2.

The Verified Complaint asserts eight claims:

- Count One: Rescission based on mutual mistake;
- Count Two: Rescission based on unilateral mistake (in the alternative);
- Count Three: Rescission based on frustration of purpose;
- Count Four: Declaratory judgment establishing Capricor's right to distribute Deramiocel outside the Distributor's exclusivity;
- Count Five: Breach of contract for failure to perform;

- Count Six: Breach of contract for anticipatory repudiation;
- Count Seven: Breach of the implied covenant of good faith and fair dealing; and
- Count Eight: Unjust enrichment.

The present application for a Preliminary Injunction is further supported by

1) the Certification of Dr. Linda Marbán, Chief Executive Officer of Capricor ("Marbán Cert."");
2) the expert Certification of Richard Rieger of Berkeley Research Group, LLC ("Rieger Cert."), who provides opinions on the Distributor's commercial launch readiness and the Medicare Part B reimbursement framework as applied to the Agreement's pricing;
3) the Certification of Aravindhan Veerapandiyan, M.D. ("Veerapandiyan Cert."), a treating Duchenne clinician;
4) the Certification of Jonathan Soslow, M.D. ("Soslow Cert."), a treating Duchenne clinician; and
5) Certifications from three individuals whose lives have been deeply affected by Duchenne: Aidan Leffler ("Leffler Cert."), Elijah Stacy ("Stacy Cert."), and Heather Hay ("Hay Cert.").

II. STATEMENT OF FACTS

A. The Parties

Capricor is a Delaware biotechnology company based in San Diego, California. (Verified Compl. ¶¶ 23; Marbán Cert. ¶ 5.) Capricor is publicly traded on Nasdaq Global Select Market. It is the developer and manufacturer of Deramiocel, an allogeneic cell therapy for the treatment of Duchenne muscular dystrophy. (Verified Compl. ¶¶ 23, 32-33.) Capricor manufactures Deramiocel at facilities at Cedars-Sinai Medical Center in Los Angeles and in San Diego, where

it has invested approximately $30 million for expanded manufacturing capacity in anticipation of commercial launch. (Verified Compl. ¶ 32.)

Nippon Shinyaku is a Japanese pharmaceutical corporation headquartered in Kyoto, Japan. (Verified Compl. ¶ 25.) NS Pharma, a Delaware corporation with its principal place of business in Paramus, New Jersey, is its wholly-owned U.S. subsidiary. (Verified Compl. ¶ 24.) Nippon Shinyaku is a direct party to the Distribution Agreement and has agreed that it "at all times [is] fully liable for the acts or omissions of [NS Pharma] as if such act or omission was undertaken directly by" Nippon Shinyaku, and that "any action or claim by Capricor in respect of any breach, act, error or omission" by Nippon Shinyaku "may be brought against" NS Pharma. (Agreement § 4.2.) NS Pharma markets Viltepso, an exon-skipping therapy for a genetically defined subset of Duchenne patients. Upon information and belief, Viltepso is the only product NS Pharma currently distributes in the United States. (Marbán Cert. ¶ 6.)

B. Duchenne Muscular Dystrophy and the Deramiocel treatment.

Duchenne is a progressive, irreversible, and invariably fatal genetic disorder that attacks every muscle in the body—including the heart. (Verified Compl. ¶ 2; Veerapandiyan Cert. ¶¶ 4-9; Soslow Cert. ¶¶ 4-6.) It is caused by the absence of dystrophin, a protein that stabilizes muscle cell membranes. (Verified Compl. ¶ 48.) Without dystrophin, muscle fibers are damaged with every use and progressively replaced by scar tissue and fat. The destruction is irreversible. Approximately 15,000 individuals in the United States are living with Duchenne, overwhelmingly boys and young men. (Verified Compl. ¶ 2; Veerapandiyan Cert. ¶ 5.)

Boys with Duchenne develop normally for their first few years, then begin to lose ground—first affecting the ability to run, then to climb stairs, then to walk. (Verified Compl. ¶ 2.) Aidan Leffler, for example, was diagnosed with Duchenne at age three; as a young child, he did not jump or run as fast as other kids, and by age twelve, after breaking his leg, he could no longer run and

struggled to participate in other physical activities. (Leffler Cert. ¶¶ 2-3.) Most of the boys are wheelchair-dependent by early adolescence. (Verified Compl. ¶ 2.) Elijah Stacy, now twenty-four, lost the ability to walk at age eleven and has been completely dependent on a power-wheelchair ever since. (Stacy Cert. ¶¶ 1, 3.)

As the teenage years progress, those with Duchenne lose the use of their arms and hands. Basic comforts that people take for granted every day, like sleeping comfortably, tend to become incredibly difficult, and only get harder with time. (See Stacy Cert. ¶ 3.) Their hearts progressively scar and weaken. Most die of heart failure or respiratory collapse in their twenties or early thirties. (Verified Compl. ¶ 2.) Elijah's heart health is now in decline; his left ventricular ejection fraction has dropped, and he understands that once it further drops, the effects of Duchenne tend to worsen fast. (Stacy Cert. ¶¶ 3, 8.) There is no cure to Duchenne. (Verified Compl. ¶ 2.) At present, no approved therapy addresses both the skeletal and cardiac dimensions of the disease. (Verified Compl. ¶ 49; Veerapandiyan Cert. ¶¶ 10, 21; Soslow Cert. ¶¶ 9-10.) Aidan has spent years of his life away from school and family participating in clinical trials, desperately searching for something which could arrest his inevitable decline, including one trial that turned out to be a placebo and two others that were unable to effectively slow his decline. (Leffler Cert. ¶¶ 4-5.) Elijah, too, has been a part of other clinical trials that were not successful. (Stacy Cert. ¶ 5.)

Deramiocel is composed of cardiosphere-derived cells isolated from donated human heart tissue. (Verified Compl. ¶ 49.) It works by shifting the immune response in affected muscle from one promoting inflammation and scarring to one promoting preservation. 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. (Verified Compl. ¶ 49.) Deramiocel has received Orphan Drug, Regenerative Medicine Advanced Therapy, and Rare Pediatric Disease designations

from the FDA. (Verified Compl. ¶ 49.) These designations reflect that Deramiocel addresses a serious, life-threatening condition with significant unmet medical need. (Veerapandiyan Cert. ¶ 12; Soslow Cert. ¶¶ 11-12.)

C. The FDA Approval Process.

In November 2017, the FDA cleared Capricor's Investigational New Drug application for Deramiocel (a/k/a, CAP-1002) on its initial submission, authorizing the randomized, double-blind, placebo-controlled HOPE-2 Phase 2 trial in Duchenne patients. (Marbán Cert. ¶ 22.) HOPE-2 met its primary efficacy endpoint, demonstrating a statistically significant benefit on the Performance of the Upper Limb (PUL 2.0) scale, and the trial results were published in The Lancet.[1] (Verified Compl. ¶ 77; Marbán Cert. ¶ 22.) Data from the HOPE-2 trial reported in June 2022 and extended through four years of follow-up, reinforced those findings and demonstrated preservation of both skeletal-muscle and cardiac function over time. (Marbán Cert. ¶¶ 24-25.) On the strength of the HOPE-2 record, and with the designations referenced above in hand, Capricor initiated the pivotal Phase 3 HOPE-3 Trial — a randomized, double-blind, placebo-controlled study of 106 Duchenne patients. (Marbán Cert. ¶ 25.)

In December 2025, Capricor announced the results of the HOPE-3 trial—a randomized, double-blind, placebo-controlled study of 106 Duchenne patients. (Verified Compl. ¶¶ 77-78.) The data showed that Deramiocel slowed skeletal muscle deterioration by approximately 54% and slowed cardiac decline by approximately 91%, both with statistical significance. (Verified Compl. ¶¶ 5, 77; Veerapandiyan Cert. ¶¶ 14-15; Soslow Cert. ¶ 14.) After reviewing these results, on March 10, 2026, the FDA set a target action "PDUFA" date of August 22, 2026 for Capricor's application for full approval for Deramiocel. (Marbán Cert. ¶ 72.)

[1] The Lancet is one of the world's most prestigious general medical journals focused on groundbreaking clinical research.

D. The Distribution Agreement is a fatally flawed contract that requires Capricor and the Distributor to sell Deramiocel at a loss.

The most consequential feature of the Distribution Agreement is that its pricing structure renders distribution of Deramiocel economically irrational for both parties—and for the healthcare providers who would administer the therapy. (Verified Compl. ¶¶ 9, 51, 56-58.) The broader background and terms of the Distribution Agreement are described below. (See infra §§ II.B.5-II.B.6.)

In summary, and as more fully described below, the Distribution Agreement's pricing mechanics guarantee that, shortly after launch, Medicare would only reimburse Deramiocel at approximately [redacted], not at the commercially determined market price. That is so because under the Distribution Agreement, [redacted], and because Medicare's Average Sales Price ("ASP") benchmark would be calculated from the manufacturer's own reported sales. As written, the Distributor's downstream price to providers is not captured in the ASP calculation. Medicaid and commercial payors, which benchmark to Medicare, follow that same trajectory. The pricing structure, in the words of Capricor's expert, "produces an economically unworkable result" that "is not consistent with the economic requirements of a provider-administered product reimbursed under Medicare Part B." Rieger Cert. § V.B. The mechanics that produce that result are set forth below.

That outcome is not what the parties intended, nor what they understood. At the time of contracting, both parties believed the Distribution Agreement's pricing terms would permit Capricor, the Distributor, and healthcare providers to distribute Deramiocel without economic loss. (Verified Compl. ¶¶ 9, 36, 62.) That was a fundamental assumption of the bargain. (Verified

Compl. ¶¶ 9, 61-62.) The Distributor's projections are consistent only with a pricing model that permits each participant in the distribution chain to earn a return.

The Distribution Agreement, however, does not permit the parties to economically make or distribute Deramiocel. The parties were fundamentally mistaken about how the contract would interact with the reimbursement mechanics of Medicare Part B. Medicare is the federal health-insurance program that covers Americans age 65 and older and persons under 65 with qualifying disabilities. Because Duchenne causes progressive and total disability, the overwhelming majority of Duchenne patients who live twenty years or more qualify for Medicare through the Social Security Disability Insurance entitlement after the 24-month waiting period. (Verified Compl. ¶ 58.) See 42 U.S.C. § 426(b); Rieger Cert. § II.

Medicare Part B reimburses physician-administered drugs—including cell therapies like Deramiocel, once approved—at 106% of the **manufacturer's** ASP. 42 U.S.C. § 1395w-3a(b)(1)(B); 42 C.F.R. § 414.904(a)(2); Rieger Cert. § III.B. The ASP is calculated from a drug manufacturer's own sales data, which it reports quarterly to CMS. 42 U.S.C. § 1395w-3a(c)(1); 42 C.F.R. §§ 447.500-447.522; Rieger Cert. § III.B.

How this plays out with the Distribution Agreement is as follows:

1. [redacted]
(See Agreement at Exhibit A.)

2. [redacted]

3. Articles 6.3 and 6.4 of the Distribution Agreement designate Capricor as the manufacturer, labeler, and NDC owner.[2] (Agreement §§ 6.3, 6.4.)

[2] An NDC is a National Drug Code—the FDA-assigned identifier that designates the manufacturer for regulatory and reimbursement purposes.

4. Because the contract purports to make the Distributor the exclusive US distributor for Deramiocel, the Distributor is Capricor's sole U.S. purchaser.

5. Accordingly, [redacted] (Rieger Cert. § V.B)

6. Because the Distributor is not the manufacturer, any sales the Distributor would make to a hospital, health care provider, or other buyer do not count for ASP calculations. (Rieger Cert. § V.B.)

The arithmetic that follows is straightforward and devastating. For the first two quarters of distribution, there is no ASP because there have been no reportable sales to CMS. Reimbursement during this brief interlude is calculated based on the Distributor's sales price from wholesale acquisition cost rather than ASP. See 42 U.S.C. § 1395w-3a(c)(4)(A)(ii)(I). But after CMS starts to calculate ASP, [redacted] Rieger Cert. § V.B. At that point, [redacted], ensuring a net loss after overhead and research and development. The Distributor would also lose money on distribution expenses (personnel, ultra-cold-chain logistics, specialty-pharmacy coordination, site-of-care infusion support, and state-level distribution licensing). No rational distributor will distribute Deramiocel on these terms. No rational manufacturer would make it.

The spiral propagates beyond Medicare patients. The majority of state Medicaid programs benchmark reimbursement for physician-administered drugs to Medicare's ASP-based formula, typically at an ASP plus a specified percentage. (Rieger Cert. § V.C. (describing how private insurers that reference Medicare pricing follow the same path.)) Within a short period after launch, every major payor class in the United States would effectively refuse to cover Deramiocel at a price above a fraction [redacted]. For a rare pediatric disease in which the vast majority of adult patients are Medicare beneficiaries due to Social Security

Disability Insurance entitlement after the 24-month waiting period, see 42 U.S.C. § 426(b), the effect is a comprehensive foreclosure: no rational provider will administer Deramiocel to the patients who need it. (Rieger Cert. §§ V.C-V.D.)

Neither party understood this dynamic at the time of contracting. (Marbán Cert. ¶ 34.) The Distributor's subsequent repudiation of the Distribution Agreement and demand for a revised [redacted] agreement, described below, confirms that they have since come to understand the flaw—and understand that the Distribution Agreement is not a viable path forward for anyone. (Marbán Cert. ¶ 34.)

E. Nippon Shinyaku, the Distributor, has breached and repudiated the Distribution Agreement.

By 2021, Capricor had been developing Deramiocel for well over a decade. (Marbán Cert. ¶ 28.) It had advanced the therapy through multiple clinical trials and had secured Orphan Drug, Regenerative Medicine Advanced Therapy, and Rare Pediatric Disease designations from the FDA. Marbán Cert. ¶ 21. Capricor sought a U.S. distribution partner with the infrastructure, personnel, and expertise to bring Deramiocel to market upon FDA approval. (Marbán Cert. ¶ 21, 28.)

In December 2021, Nippon Shinyaku delivered to Capricor a detailed capability presentation titled "[redacted]" (the "Capability Presentation"). (Verified Compl. ¶ 35; Marbán Cert. ¶ 29.) In the Capability Presentation, the Distributor represented that it had the commercial infrastructure, personnel, and expertise necessary to distribute a complex therapy like Deramiocel in the United States. (Verified Compl. ¶ 35.) The Distributor touted "u[redacted]" and highlighted [redacted]). The Distributor asserted that it had

specialty-distribution capabilities (without noting that, upon information and belief, its products did not require the ultra-cold-chain logistics, site-of-care coordination, or infusion infrastructure that a cell therapy like Deramiocel requires). The Distributor represented that it had the capability to "[redacted]," [redacted]" in required states, and manage third-party logistics providers, specialty pharmacies, and specialty distribution partners pre- and post-launch. (Marbán Cert. ¶ 29.)

The Capability Presentation also included the Distributor's financial projections for Deramiocel. Those projections reflected what Capricor and the Distributor both understood in 2022: that Deramiocel could be priced and sold at levels generating commercially viable margins for manufacture, distribution, and administration.

In January 2022, Capricor and Nippon Shinyaku executed the Distribution Agreement, granting Nippon Shinyaku the exclusive right to "promote, market, sell and distribute" Deramiocel in the United States, including Puerto Rico, through [redacted]. (Agreement §§ 2.1, 15.1.) The Agreement is governed by New York law. (Id. § 18.4.) Because Nippon Shinyaku has utilized NS Pharma as its agent and sub-distributor, 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 NS Pharma may be sued in Nippon Shinyaku's stead. (Id. § 4.2.)

F. After securing the exclusive right to distribute Deramiocel, the Distributor failed to prepare to do so.

In exchange for the exclusive right to distribute Deramiocel, the Distributor assumed extensive obligations to prepare for and execute a successful commercial launch. (Verified Compl. ¶ 39.) The Distributor must use "Commercially Reasonable Efforts" to promote, market, sell, and distribute Deramiocel, and must "vigorously promote the sale" of Deramiocel. (Agreement § 5.4.) The Distributor's specific obligations include developing and maintaining a commercial team with

sufficient experience and resources (id. § 5.5.5); establishing distribution infrastructure, including warehousing and logistics (id. § 5.5.6); and ensuring compliance with all applicable laws, including state distribution licensing (id. § 5.18). The Agreement requires the Distributor to obtain Capricor's prior written consent before appointing any subdistributors, except its own wholly-owned subsidiary. (Id. § 4.2.) It requires the parties' Joint Steering Committee to establish Minimum Sales Requirements within ninety days before anticipated BLA approval. (Id. § 5.2.1.)

The Agreement also contemplates the situation where the Distributor has shown it is unable or unwilling to perform. Article 4.1.2 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 . . . ; 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.

(Id. § 4.1.2.)

The Agreement provides for tiered dispute resolution: escalation to senior executives, followed by ICC arbitration with three arbitrators in New York or Los Angeles. (Agreement §§ 18.1-18.3.) Article 18.3.3 expressly preserves each party's right to seek injunctive relief in court: "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." (Id. § 18.3.3.)

Preparing for distribution of a medicine like Deramiocel requires extensive and continuous work. The Distributor has not done that work. Initially, the FDA set a PDUFA date for Deramiocel of August 31, 2025. (Verified Compl. ¶ 65.) Then, in July 2025, the FDA issued a Complete Response Letter ("CRL") identifying further steps Capricor needed to take to secure final approval. (Verified Compl. ¶ 66.) The Distributor treated the CRL as a license to disengage. (Verified

Compl. ¶ 67.) On July 15, 2025, an employee of the Distributor told Capricor's Director of Commercial that "[redacted]" on Deramiocel. (Verified Compl. ¶ 68; Marbán Cert. ¶¶ 55-58.) The [redacted]" were being [redacted]." (Id. ¶¶ 68, 71.)

Capricor objected and repeatedly sought assurances of performance and updates on the Distributor's preparations for distribution. On November 6, 2025, NS Pharma's General Counsel, [redacted], doubled down in writing. He asserted that [redacted]. (Verified Compl. ¶ 73; Marban Cert. ¶ 61.)

As noted above, in December 2025, Capricor announced the results of the HOPE-3 trial—a randomized, double-blind, placebo-controlled study of 106 Duchenne patients. Deramiocel slowed skeletal muscle deterioration by approximately 54% and slowed cardiac decline by approximately 91%, both with statistical significance. (Veerapandiyan Cert. ¶¶ 14-15; Soslow Cert. ¶ 14.)[3]

The FDA reacted positively to the HOPE-3 results. On March 10, 2026, the FDA indicated that it was resuming review of Capricor's application for full approval, and set a new PDUFA target action date of August 22, 2026. (Marbán Cert. ¶ 72.) FDA approval —which for most of 2025 had been a contingent future event that the Distributor treated as an excuse to stand down—is now a possibility. (Rieger Cert. § II.)

[3] On March 12, 2026, Capricor announced further positive results from the HOPE-3 trial. MRI scans showed Deramiocel significantly slowed heart muscle scarring—and for patients with existing heart damage, it reversed the expected decline in heart function. Functionally, it slowed the loss of basic abilities like feeding oneself by roughly 83%.

G. The Distributor repudiated the Distribution Agreement when it stated—then confirmed in writing—that a new Agreement was the only path forward.

On March 27, 2026—seventeen days after the FDA lifted the CRL—Nippon Shinyaku's Chief Executive Officer, Toru Nakai, traveled from Japan to meet in person with Capricor's Chief Executive Officer. (Verified Compl. ¶¶ 84.) At that meeting, the Distributor told Capricor that a "[redacted]" ("PLD") was "the only path forward" for the Distributor's distribution of Deramiocel in the United States. (Marbán Cert. ¶ 77.) Under that arrangement, [redacted]. (Verified Compl. ¶¶ 16, 87.)

On April 1, 2026, Dr. Marbán wrote to the Distributor to confirm her understanding of that position in writing: "[redacted]." [redacted], VP of Business Development at NS Pharma responded the same day: "[redacted]" (Id. ¶¶ 78-79.)

On April 10, 2026, the Distributor sent a formal draft amendment—the "Proposed Amendment"—to Capricor. (Verified Compl. ¶ 87; Marbán Cert. ¶ 81.) The Proposed Amendment confirmed in writing what the Distributor had communicated verbally. Under its terms, [redacted]

[redacted]

[redacted]” for purposes of federal reimbursement calculations. (Verified Compl. ¶ 88.) And Capricor would [redacted]. This was not the Distribution Agreement the parties had bargained for—it represented a total revision of the Distribution Agreement’s material terms. (Verified Compl. ¶ 87.)

Capricor, which now had confirmation that its distributor could not and would not properly distribute Deramiocel, invested substantial additional financial and personnel resources to prepare for the launch of Deramiocel upon FDA approval. Its efforts included initiating over [redacted]

[redacted], and pressing other projects forward to prepare for distribution. (Marbán Cert. ¶ 80.)

H. The Distributor stands to frustrate Capricor’s efforts to establish other distribution networks by claiming exclusive distribution rights.

Capricor rejected the Proposed Amendment in writing on May 6, 2026, informing Defendants that the proposal was unacceptable and that Capricor accepted Defendants’ repudiation of the Distribution Agreement. (Verified Compl. ¶¶ 88-89; Marbán Cert. ¶ 84.) Based on the Distributor’s conduct and communications, Capricor expects that the Distributor will interfere with Capricor’s attempts to establish alternative distribution channels.

Further, the Distributor is in no position to perform. More than four years after the Distribution Agreement was signed, and with potential FDA approval just a few months away, NS Pharma’s own Head of Commercial confirmed at the [redacted] that core launch-readiness tools remain unbuilt: [redacted]

[redacted]. (Verified Compl. ¶¶ 12, 63, 80(A); Marbán Cert. ¶ 75; Rieger Cert. § VI.B.) [redacted]. (Marbán Cert. ¶ 76.)

The Distributor's distribution infrastructure is likewise deficient. Defendants assert that [redacted]—without obtaining Capricor's prior written consent. To the extent those arrangement constitute subdistributor relationships, the Distributor was obligated to seek Capricor's written consent under Article 4.2. (Verified Compl. ¶¶ 42, 80(C); Marbán Cert. ¶ 75; Agreement § 4.2.) The Distributor has given Capricor inconsistent representations about state-level distribution licensing: at times representing that [redacted] and at other times—including most recently—acknowledging that they will [redacted] that Defendants never sought Capricor's consent to and have refused to document despite repeated requests. (Verified Complaint ¶ 81(C).) [redacted]. (Verified Compl. ¶ 80(C)) And no Minimum Sales Requirements were established 90 days before the original PDUFA target date of August 31, 2025, despite the Distribution Agreement's requirement that they be set within ninety days of anticipated BLA approval. (Verified Compl. ¶ 46; Agreement § 5.2.1.)

These [redacted]—unauthorized under Article 4.2 and made before the Distributor's March 2026 repudiation—do not negate the repudiation. Rather, they constitute further breaches: the Distributor unilaterally [redacted] Capricor never approved, while simultaneously failing to build the integrated launch apparatus the Distribution Agreement required. That the Distributor went partway down a distribution path before abandoning the Agreement, in an attempt to thrust a Private Label Distribution structure upon Capricor, confirms the Distributor has no intent to perform the bargain as written.

Although the Distributor is not prepared to perform, Capricor expects that the Distributor is prepared to obstruct Capricor's distribution of Deramiocel. Absent an injunction, the Distributor will impair Capricor's right to establish alternative distribution channels. The Distributor's position is heavy-handed and straightforward: agree to the Proposed Amendment, or no distribution will occur.

ARGUMENT

THE COURT SHOULD GRANT THE REQUESTED PRELIMINARY INJUNCTIVE RELIEF.

A party seeking a preliminary injunction must demonstrate: (1) a reasonable probability of success on the merits; (2) irreparable harm if the injunction is not granted; (3) the balance of hardships favors the moving party; and (4) the injunction will not harm the public interest. Crowe v. De Gioia, 90 N.J. 126, 132-34 (1982); McNeil v. Legis. Apportionment Comm'n, 176 N.J. 484, 484, (2003) ("[T]he standards informing the grant of a stay when an issue of significant public importance is raised must include not only the traditional factors applicable to disputes between private parties but also, and most paramount, considerations of the public interest . . . ."). Capricor satisfies each Crowe factor.

"[A] court may take a less rigid view in its consideration of these factors when the interlocutory injunction sought is designed to merely preserve the status quo." McKenzie v. Corzine, 396 N.J. Super. 405, 414 (App. Div. 2007).

Here, Capricor's requested relief preserves the status quo: the Distributor has repudiated the Distribution Agreement, and the parties also entered into the Agreement based on a mutual mistaken understanding of how pricing would work. Both support termination or rescission of the Distribution Agreement. Under the present circumstances, Capricor is or should be free to distribute Deramiocel on its own or establish alternative distribution channels and the parties should be free to resolve how the Distribution Agreement should be unwound. Any other view would give effect to an agreement both parties have concluded is unworkable. Moreover, no product is in the distribution channel today—Deramiocel has not yet received FDA approval, and no doses have reached any patient through any channel other than through participation in Capricor's clinical trials. The requested injunction disturbs no ongoing commercial relationship: no customer of the Distributor loses anything, no provider must change acquisition practices, and no reimbursement framework must be rebuilt. The injunction simply permits Capricor to proceed with alternative distribution avenues so that, if and when FDA approval issues, a viable path to patients is in place.

A. Capricor—and, more importantly, Duchenne patients—will suffer irreparable harm absent injunctive relief.

Irreparable harm exists where the injury cannot be adequately compensated by monetary damages. Crowe, 90 N.J. at 132-33. The harm here is not merely financial. It is physical, progressive, and irreversible for the thousands of Duchenne patients who stand to potentially benefit from Deramiocel.

The harm is ripe and requires action now, not after FDA approval. A rare-disease therapy's commercial viability is determined in the weeks and months surrounding launch, and launch preparation begins well in advance of the PDUFA action date. (Rieger Cert. § III.C.) Commercial readiness of the type Deramiocel requires—cold-chain logistics, site-of-care coordination, specialty-pharmacy relationships, payor engagement, hub services, and state-level distribution licensing—"requires extended lead times to address manufacturing, site-of-care, and market access readiness prior to the anticipated approval date." (Id.) The first several months following launch establish "prescribing patterns, provider confidence, and payor positioning, with effects that can persist over the product's lifecycle." (Id.) With a PDUFA action date of August 22, 2026, the commercial partnerships Capricor must assemble should be established as soon as possible. Judicial relief entered after FDA approval—and after the Distributor has communicated to payors and providers under a pricing structure that cannot sustain the distribution chain—would arrive too late. The harm the injunction would prevent is accruing now.

The causal chain between the injunction Capricor seeks and the harm it prevents is direct. The Distributor has informed Capricor in writing that it will not distribute Deramiocel under the existing Agreement; at the same time, the Distributor is poised to obstruct Capricor's alternative distribution efforts by asserting its claimed exclusivity. (See supra § II.B.8.) Without this Court's intervention, Deramiocel will not reach Aidan Leffler, Elijah Stacy, Heather Hay's sons, or the approximately 15,000 Duchenne patients in the United States who might benefit from it—because the only party with putative contractual rights to distribute refuses to do so, and the manufacturer with the product, the capacity, and the clinical data is blocked by the Distributor's own abandoned contract. (Rieger Cert. § II.)

If the Court does not grant the injunction sought, then it is likely that Deramiocel will not reach Duchenne patients in the first instance:

- The Distributor is both unprepared and unwilling to distribute Deramiocel. The Agreement providing for its distribution is fundamentally flawed in a manner that discourages both parties from investing in Deramiocel's distribution. The Distributor itself agrees, which is why it repudiated it in favor of a different "path." (See supra § II.B.7; infra § III.A.2.b.) Thus, Capricor is neither required to, nor inclined to, distribute Deramiocel through or with the Distributor.
- But distribution through means other than the Distributor is also impracticable without an injunction. Capricor expects the Distributor to conclude that it still has contractual exclusivity over U.S. distribution of Deramiocel; and the Distributor is poised to interfere with Capricor's attempts to establish the commercial partnerships needed to distribute Deramiocel. Although the Distribution Agreement is no longer binding, the Distributor may use the Distribution Agreement—which on its face provides the Distributor with the exclusive right to distribute Deramiocel—to interfere with Capricor's relations with third parties.

Capricor and Duchenne patients will be irreparably harmed even if it were possible to distribute Deramiocel to some patients for some amount of time. The Agreement's pricing structure guarantees that even if product were somehow to be sold under the Distribution Agreement, clinical administration would cease within quarters. Once the ASP is established, after two quarters of sales, Medicare reimbursement drops to 106% of [redacted] (Rieger Cert. § V.B; supra § II.B.4.) At that reimbursement level, both Capricor and the Distributor lose money from selling Deramiocel. This concrete projection about

the future discourages investments that must be made *today*. If Capricor cannot establish alternative means of distribution now, there will be no adequate and substantial system for making, distributing, and administering Deramiocel, resulting in fewer doses to fewer patients.

Duchenne is a disease of irreversible destruction. Deramiocel does not cure it and does not necessarily reverse existing damage. Rather, it preserves function that, once lost, is lost forever. (Veerapandiyan Cert. ¶¶ 18-19; Soslow Cert. ¶¶ 18-19.)

Aidan Leffler's experience illustrates the benefits of treatment: when he began treatment, he was still capable of getting out of bed, getting dressed, taking a shower, and could live mostly independently, but his family "did not expect any of this to last." (Leffler Cert. ¶ 6.) Four years after his treatment with Deramiocel, Aidan had not lost arm function, his ejection fraction was completely stable, and he was able to live almost completely independently. (Id. ¶ 7.) Deramiocel did not reverse Aidan's condition, but it prevented a likely decline in his health.

On the other hand, every month of delay in making Deramiocel available is a month of permanent harm to patients who would otherwise benefit. For Heather Hay, the mother of two boys with Duchenne (eight and eleven years old), "with each passing day, my sons lose muscle function that they will never recover." (Hay Cert. ¶ 2.) For Elijah, who is 24 years old and whose heart is beginning to fail, the need is immediate and concrete; his left ventricular ejection fraction is dropping to a level where Deramiocel may not be able to fully stabilize him (only slow his decline). For him, "those months [of delay] are not abstract—they are cardiac cells dying and eligibility slipping away." (Stacy Cert. ¶¶ 1, 8.)

In the HOPE-3 trial, untreated patients experienced measurable declines in both upper-limb and cardiac function over twelve months. Treated patients experienced significantly less decline—but neither group gained function. (Veerapandiyan Cert. ¶ 19; Soslow Cert. ¶ 21.) Muscle tissue

destroyed during a period of delay will never regenerate. Cardiac scar tissue formed during untreated progression will remain for the remainder of the patient's life.

In concrete terms, a fifteen-year-old boy who can currently lift a cup to his mouth may, in months without treatment, lose the ability to do so. That ability will not come back. A seventeen-year-old whose cardiac ejection fraction is at 40% may, without treatment, decline past the threshold at which heart failure symptoms manifest, with cardiac tissue permanently scarred. For non-ambulatory teenagers whose upper limbs are their last remaining tool for eating, communication, and any degree of independence, every percentage point of preserved function is the difference between self-sufficiency and total dependence. (Veerapandiyan Cert. ¶¶ 7, 20; Leffler Cert. ¶ 7; Hay Cert. ¶¶ 2, 4.)

There is no substitute for Deramiocel. No currently-approved therapy addresses both the skeletal and cardiac manifestations of Duchenne. (Veerapandiyan Cert. ¶ 21; Soslow Cert. ¶ 22.) If, following FDA approval, Deramiocel is not distributed to patients in a timely manner following FDA approval, Duchenne patients will have nowhere else to turn.

New Jersey courts have repeatedly recognized that threats to medical care and public health constitute irreparable harm warranting injunctive relief. See, e.g., Somerset Air Serv., Inc. v. Township of Bedminster, No. SOM-L-419-06, 2006 WL 861498, at *4 (N.J. Super. Ct. Law Div. Apr. 4, 2006), (finding irreparable harm based on termination of emergency medical transportation services for potential users), aff'd per curiam, No. A-5311-05T2, 2007 WL 1774058 (N.J. Super. Ct. App. Div. June 21, 2007); Horizon Health Ctr. v. Felicissimo, 263 N.J. Super. 200, 219 (App. Div. 1993) (affirming injunction to enjoin demonstrators in front of an abortion clinic because these demonstrations interfered with plaintiff's clients' rightful access to health care and abortion services), aff'd as modified, 135 N.J. 126 (1994); Monmouth Cnty. Corr. Inst. Inmates v. Lanzaro,

643 F. Supp. 1217, 1227-28 (D.N.J. 1986) (finding irreparable harm where substantial delays to abortion services may cause substantial injury to plaintiffs and that "[m]oney damages are obviously not an adequate remedy in such situations"), aff'd in part, modified in part on other grounds, 834 F.2d 326 (3d Cir. 1987); Suenram v. Soc'y of Valley Hosp., 155 N.J. Super. 593, 597 (Law. Div. 1977) (finding irreparable harm to temporarily enjoin defendant hospital from interfering with medical treatment of a terminally ill plaintiff where plaintiff "is in danger of suffering irreparable injury if relief is postponed for the shortest period of time or denied").

In Somerset Air Service, the plaintiff was an airport operator for emergency medical service helicopters and sought injunctive relief to enjoin the township from interfering with its medical service operations at the airport pending final resolution. 2006 WL 861498, at *7. The court found that the "abrupt termination" of this emergency medical service helicopter unit constituted irreparable harm because the public health and safety would suffer through "the danger of increased mortality to potential users of the service" who needed to be transported for medical emergencies. Id. at *4.

In Suenram, the plaintiff was a terminally ill woman whose prognosis showed that she would not survive another month based on the current medical treatment, and requested taking an unproven drug treatment whose use was not sanctioned by defendant hospital. Suenram, 155 N.J. Super. at 597. As plaintiff requested a temporary restraining order to allow for treatment, the court found plaintiff would suffer irreparable injury with even the shortest of delays in receiving this alternative treatment, and relief would "likely be of only academic value if secured at sometime in the future." Id.; see also id. ("For the terminally ill, the phrase 'justice delayed is justice denied' is especially significant." (citation omitted)). The same logic applies here: the patients at issue are

children with a fatal disease, and the harm is concrete and imminent. (See Veerapandiyan Cert. ¶¶ 17, 20, 23.)

Capricor, too, will suffer irreparable harm. It has invested nearly two decades and hundreds of millions of dollars bringing Deramiocel to market. It has built manufacturing capacity, hired personnel, and is preparing for commercial launch. (Marbán Cert. ¶ 27.) Specifically, Capricor's San Diego manufacturing facility is currently producing commercial-grade doses of Deramiocel and has capacity to supply an estimated 250 to 500 patients per year, with six new cleanrooms targeted for early 2027 that would scale capacity to 2,500 to 4,000 patients per year, and further expansion underway to support up to 10,000 patients per year by 2030. (Marbán Cert. ¶¶ 85-86.) Commercial-supply manufacturing has begun, and Capricor's patient-support call center is expected to be operational approximately one month before the PDUFA date. (Marbán Cert. ¶¶ 87-88.) The harm to Capricor's relationships with the clinical and patient communities, and to the credibility on which its ability to develop future therapies depends, cannot be reduced to money damages. See Russell v. Russell, 127 N.J. Eq. 555, 560, (Chan. 1940) (noting that the "difficulty of satisfactorily estimating damages to business is frequently recognized" and supportive of injunctive relief (citation omitted)); City of Orange Twp. Bd. of Educ. v. City of Orange Twp., 451 N.J. Super. 310, 320 (Ch. Div. 2017) ("Harm may be considered irreparable if it cannot be remedied by monetary damages."); J.I. Kislak, Inc., v. Artof, 13 N.J. Misc. 129, 132 (Chan. 1934) (holding there was irreparable harm where impairment of business and diversion of clients was "not calculable or readily ascertainable"). Moreover, the market launch of a rare-disease therapy is a one-time event. The commercial trajectory of Deramiocel will be largely determined by the success of its initial six to twelve

months on the market. (Rieger Cert. § III.C.) A disrupted or failed launch—caused by a distributor that cannot distribute—cannot be re-created later. The harm is permanent.

The company-level harm compounds the patient-level harm and cannot be disentangled from it. Capricor is a publicly traded, single-product company at the moment of its commercial launch. A rare-disease therapy has one opportunity to establish physician adoption, payor coverage postures, patient-advocacy relationships, and investor confidence. Once physicians form an impression that the therapy is unavailable or uneconomic, and once payors build coverage frameworks around a Distributor-led structure that cannot hold, those impressions and frameworks persist across product lifetimes. (Rieger Cert. § III.C.) The damage is not the loss of quarterly sales, which can, in principle, be quantified, but the loss of the conditions under which any future sales of Deramiocel or of Capricor's pipeline of cardiosphere-derived therapies are possible. See Waste Mgmt. of N.J., Inc. v. Union Cnty. Utilities Auth., 399 N.J. Super. 508, 534 (App. Div. 2008) ("A court may issue an interlocutory injunction on a less than exacting showing if necessary to prevent the subject matter of the litigation from being 'destroyed or substantially impaired.'" (citation omitted)); see also Christiansen v. Loc. 680 of Milk Drivers & Dairy Emps. of N. J., 127 N.J. Eq. 215, 220 (N.J. 1940) (holding an injunction to enjoin contractual enforcement was warranted if the "defendant Local is permitted to enforce its contract with the employer, to the extent of terminating the services of the individual complainants, the status will have been substantially impaired, if not destroyed"); Naylor v. Harkins, 11 N.J. 435, 446-47 (1953) (affirming an injunction to restrain defendants from "taking affirmative action which might destroy plaintiffs' status [quo] [as members of a union chapter] and the subject of the litigation"). That loss is not reducible to money.

The harm is further compounded by the distortion the Distributor is positioned to inflict on the reimbursement landscape itself. Payors form their initial coverage and reimbursement assumptions for a new therapy in the weeks surrounding launch, based on communications from the product's distributor, and once those assumptions are embedded in coverage policies and internal reimbursement models, they are extraordinarily difficult to revise. (Rieger Cert. § III.C.) If the Distributor communicates with payors as the purported exclusive U.S. distributor on the basis of a pricing structure that cannot generate viable margins, those early assumptions will calcify around that structure—and because Medicare's ASP sets the reimbursement ceiling for Medicaid and the commercial payors that benchmark to Medicare, a low initial ASP remains the ceiling indefinitely. Even if Capricor at a later time obtains relief to distribute through alternative channels, it would face a market in which payors have already formed relationships, expectations, and coverage frameworks around the Distributor that Capricor cannot replicate or unwind. A reimbursement framework corrupted at launch cannot be rebuilt by any later award of damages.

The harm is also actively inflicted, not merely passively permitted. Capricor expects that the Distributor will obstruct Capricor's efforts to distribute on its own or establish alternative distribution channels by asserting the disclaimed exclusivity rights against third-party logistics providers, specialty pharmacies, and specialty distributors that Capricor would otherwise engage. (see supra § II.B.8.) Those threats, which are based on an exclusivity clause Defendants have themselves abjured, deter the very counterparties Capricor needs to mitigate patient harm. If the Distributor interferes with Capricor's efforts, fewer commercial partners will be willing to transact with Capricor at all—and that erosion, once set, cannot be reconstituted by any later damages award.

B. Capricor is reasonably likely to succeed on the merits.[4]

Capricor has a reasonable probability of success on multiple, independently sufficient grounds. Courts routinely find that "mere doubt as to the validity of the claim" is not an adequate basis for denial of a preliminary injunction. Crowe, 90 N.J. at 133.

1. Capricor is likely to succeed on its claim for rescission due to mutual mistake.

Under both New Jersey and New York law, rescission is available where both parties labored under a mutual mistake of fact going to a basic assumption on which the contract was made, and the mistake has a material effect on the agreed exchange of performances. See Restatement (Second) of Contracts § 152 (A.L.I. 1981); Gould v. Board of Educ., 81 N.Y.2d 446, 453, 616 N.E.2d 142, 145-46, 599 N.Y.S.2d 787, 790-91 (1993); Da Silva v. Musso, 53 N.Y.2d 543, 550-52, 428 N.E.2d 382, 386-87, 444 N.Y.S.2d 50, 54-55 (1981); Beachcomber Coins, Inc. v. Boskett, 166 N.J. Super. 442, 445-46 (App. Div. 1979).

The New York Court of Appeals' decision in Gould v. Board of Education, 81 N.Y.2d 446, 616 N.E.2d 142, 599 N.Y.S.2d 787 (1993), illustrates the doctrine. Susan Gould, an elementary school teacher, acquired tenured status without her knowledge or that of the school board. When the school board later moved to deny tenure, Gould resigned in exchange for a clean personnel file, all parties believing she was relinquishing only a probationary position. After her resignation was accepted, her counsel discovered she had in fact been tenured. See id. at 449-50, 616 N.E.2d at 143-44, 599 N.Y.S.2d at 788-89. The Court of Appeals held the resignation a nullity and ordered her reinstated, reasoning that "a contract entered into under a mutual mistake of fact is voidable and subject to rescission" where the mistake existed at the time of contracting, is substantial, and

[4] New York law governs the Agreement's substantive terms. (Agreement Art. 18.4.) Because the Agreement has been repudiated and is voidable, Capricor also asserts that New Jersey law supports the requested outcome.

prevents a true "meeting of the minds." Id. at 453, 616 N.E.2d at 145-46, 599 N.Y.S.2d at 790-91. The Board's good-faith ignorance of its own employee's status did not save the transaction, because "a misconception concerning a critical aspect of [the contracting party's] employment pervade[d] the entire transaction." Id. at 453, 616 N.E.2d at 146, 599 N.Y.S.2d at 791.

The New York Appellate Division has applied Gould to commercial contracts on facts more analogous to those before this Court. In Lakshmi Grocery & Gas, Inc. v. GRJH, Inc., 138 A.D.3d 1290, 30 N.Y.S.3d 743 (3d Dep't 2016), the prospective lessee of a gas station and convenience store repeatedly asked the lessor for the store's "inside sales" figures—a critical metric for the store's profitability. The lessor's president provided figures purporting to represent August 2010 sales, but those figures actually represented August 2009 sales—an error she later admitted at trial. The actual August 2010 figures were roughly thirty percent lower and "too low to permit successful operation of the store." Id. at 1291-92, 30 N.Y.S.3d at 745. The court affirmed the rescission of the lease and the dismissal of the lessor's breach-of-contract counterclaim, id. at 1291-93, 30 N.Y.S.3d at 744-46, holding that the parties' shared misapprehension as to "the basis for the store's profitability" constituted mutual mistake warranting rescission. Id. at 1292, 30 N.Y.S.3d at 745-46 (citing Gould, 81 N.Y.2d at 453, 616 N.E.2d at 145-46, 599 N.Y.S.2d at 790-91).

Here, both parties entered the Distribution Agreement on the shared assumption that its pricing formula would yield commercially viable margins for every participant in the distribution chain. The Distributor's own Capability Presentation confirmed the assumption. (Marbán Cert. ¶ 29.)

That fundamental assumption was wrong. Under the interaction between Articles 6.3 and 6.4 of the Distribution Agreement (locking Capricor, the manufacturer, as the labeler and NDC

owner), the [redacted] (Capricor's only reportable sale), and 42 U.S.C. § 1395w-3a(c)(1) (anchoring ASP to the manufacturer's own sales), [redacted]. Rieger Cert. § V.B. To the contrary, distribution of Deramiocel will be uneconomical. As in Lakshmi, the parties' shared misapprehension goes to "the basis for [the venture's] profitability," 138 A.D.3d at 1292, 30 N.Y.S.3d at 745-46; and as in Gould, the misconception "pervade[s] the entire transaction." 81 N.Y.2d at 453, 616 N.E.2d at 146, 599 N.Y.S.2d at 791. The mistake is mutual, it goes to a basic assumption on which the parties contracted, and it materially defeats the agreed exchange. Capricor is therefore reasonably likely to prevail on its claim that the Distribution Agreement should be rescinded due to mutual mistake.

2. The Distributor repudiated the Distribution Agreement.

Under New York law, anticipatory repudiation occurs when a party communicates an "unequivocal" manifestation of intent not to perform its contractual obligations. Tenavision, Inc. v. Neuman, 45 N.Y.2d 145, 150, 379 N.E.2d 1166, 1168, 408 N.Y.S.2d 36, 38 (1978); Norcon Power Partners, L.P. v. Niagara Mohawk Power Corp., 92 N.Y.2d 458, 463, 705 N.E.2d 656, 659, 682 N.Y.S.2d 664, 667 (1998). The party's words or conduct must be "sufficiently positive to be reasonably interpreted to mean that the party will not or cannot perform." Restatement (Second) of Contracts § 250 cmt. B (A.L.I. 1981).

The Distributor's actions effected an anticipatory repudiation. On March 27, 2026, the Distributor told Capricor that a [redacted]" was "the only path forward" for the Distributor's continued distribution of Deramiocel. (Marbán Cert. ¶ 77.) On April 1, 2026, [redacted] of NS Pharma confirmed that position in writing. (Id. ¶ 78.) The Distributor's April 10 Proposed Amendment was consistent with its repudiation. The Proposed Amendment [redacted]

[redacted]. The Distributor unmistakably asserted that the only path forward was one to which the parties had never agreed. Its words and actions constitute repudiation as a matter of law. Cf. DiFolco v. MSNBC Cable L.L.C., 622 F.3d 104, 112 (2d Cir. 2010) ("[W]here the repudiation is in writing, . . .the court may resolve the issue of repudiation 'as a matter of law.'" (citation omitted)).

Capricor materially changed its position in reliance on the repudiation. It has committed financial and personnel resources to building alternative distribution, including initiating over [redacted], and pressing other projects forward to prepare for distribution. (Marbán Cert. ¶ 80.) Capricor then accepted the repudiation by rejecting the Proposed Amendment in writing. (Marbán Cert. ¶ 82.) Once accepted, a repudiation cannot be retracted. Restatement (Second) of Contracts § 256.

Once a repudiation has been accepted and relied upon by the non-repudiating party, it cannot be withdrawn. See Restatement (Second) of Contracts § 256 (A.L.I. 1981). Capricor accepted the repudiation in writing, and changed position in reliance on it by committing substantial financial and personnel resources to alternative distribution. (See supra § II.B.8.) A party that has repudiated and had its repudiation accepted cannot re-enter the contract it walked away from by changing its mind after the fact. Defendants have no exclusivity rights left to assert.

Capricor is reasonably likely to prevail on its repudiation claim.

3. Defendants have materially breached the Distribution Agreement.

A material breach by one party excuses further performance by the other. Frank Felix Assocs., Ltd. v. Austin Drugs, Inc., 111 F.3d 284, 289 (2d Cir. 1997) (applying New York law). A breach is material when it "go[es] to the root" of the agreement and "defeats the object of the parties in making the contract." Id.; see also Hadden v. Consol. Edison Co. of N.Y., Inc., 34 N.Y.2d 88, 96, 312 N.E.2d 445, 449, 356 N.Y.S.2d 249, 254-55 (1974).

The Agreement's principal object was the successful commercialization of Deramiocel. (Agreement § 5.4.) The Distributor has failed in the obligations that give effect to that object. It has failed to perform the obligations it assumed under the Distribution Agreement that are necessary to ensure a successful launch once FDA approval is received. Among other things, [redacted]. It has [redacted] without obtaining Capricor's prior written consent under Article 4.2 [redacted] that Capricor never agreed to. It [redacted] after the July 2025 CRL was received and did not adequately reprovision. And in writing, Defendants' General Counsel disclaimed Defendants' obligations, asserting that Defendants are [redacted]. (Marbán Cert. ¶ 61.) When asked about its commercial readiness, [redacted], told Capricor's CEO that it was [redacted] (Id. ¶ 70.)

These failures are not technical. They describe a distributor that has comprehensively abandoned the preparations that were its consideration for exclusivity, at the very moment when

those preparations were most needed. (Rieger Cert. § VI.B.) Defendants' own admissions at the [redacted] that core launch-readiness tools remain unfinished establish the breach. A breach this comprehensive is material as a matter of law. See Frank Felix Assocs., 111 F.3d at 289; Hadden, 34 N.Y.2d at 96, 312 N.E.2d 445, 449, 356 N.Y.S.2d 249, 254-55. Capricor is reasonably likely to prevail on its breach claim.

C. The balance of hardships favors Capricor

The balance of hardships decisively favors Capricor. On Capricor's side: a potentially life-extending therapy, the result of nearly two decades of research, is locked behind an exclusive distributor that has told Capricor in writing that it demands a fundamentally restructured arrangement that Capricor has repeatedly rejected. Patients with a fatal disease are suffering irreversible harm with every day of delay. (Veerapandiyan Cert. ¶¶ 18-22; Soslow Cert. ¶¶ 19-22; Stacy Cert. ¶¶ 8-9; Hay Cert. ¶¶ 2-5.)

On Defendants' side: the injunction Capricor seeks would suspend the Distribution Agreement's exclusivity provisions pending final judgment. Defendants would lose no right they have told Capricor they are prepared to exercise; Defendants have said the opposite, in writing, through their General Counsel, their CEO, and their April 10 draft amendment. (Marbán Cert. ¶ 81.)

Enforcing exclusivity under these circumstances would reward Defendants' non-performance, perpetuate harm to Duchenne patients, and prevent Capricor from distributing a therapy it has spent decades developing. The equities favor Capricor.

D. The public interest favors injunctive relief.

The public interest overwhelmingly supports the limited equitable relief Capricor seeks.

Where, as here, public-interest considerations predominate, courts "may, and frequently do, go much farther both to give and withhold relief in furtherance of the public interest than they

are accustomed to go when only private interests are involved." Waste Mgmt. of N.J., Inc. v. Morris Cnty. Mun. Utils. Auth., 433 N.J. Super. 445, 454 (App. Div. 2013) (citation omitted). In such cases, a court may grant an injunction based on a full and fair weighing of the Crowe factors, including "the impact the injunction would have on the public interest," even where a plaintiff has not fully demonstrated reasonable probability of success. Waste Mgmt. of N.J., Inc. v. Union Cnty. Utils. Auth., 399 N.J. Super. 508, 521 (App. Div. 2008).

First, the public interest supports securing treatment for Duchenne patients. Approximately 15,000 individuals are living with Duchenne in the United States. (Veerapandiyan Cert. ¶ 5.) Their families have waited decades for a therapy that can meaningfully change the trajectory of this disease. (Veerapandiyan Cert. ¶¶ 22-23; Soslow Cert. ¶¶ 22-23; Stacy Cert. ¶¶ 5, 10; Hay Cert. ¶¶ 3, 5.) Deramiocel is that therapy.

The FDA's Priority Review, Orphan Drug, Regenerative Medicine Advanced Therapy, and Rare Pediatric Disease designations reflect formal agency judgments that Deramiocel addresses a serious, life-threatening condition affecting a small population with significant unmet medical need. (Rieger Cert. at § II.) The public interest in ensuring timely access to a potentially life-saving therapy for children with a fatal disease is as powerful as any interest this Court could weigh.

New Jersey courts have repeatedly granted injunctive relief where public health and medical access are at stake. See, e.g., Somerset Air Serv., 2006 WL 861498, at *1 (emergency medical helicopter service); Morris Cnty. Transfer Station, Inc. v. Frank's Sanitation Serv., Inc., 260 N.J. Super. 570, 576, 578 (App. Div. 1992) (granting an injunction to enjoin defendant from diverting solid waste from plaintiff's transfer stations: "the interest of the general public and the protection of the environment is under constant threat so long as defendants operate their garage as an illegal transfer station and continue to divert waste from lawfully designated facilities");

Monmouth Cnty. Corr. Inst. Inmates, 643 F. Supp. at 1228 (noting that issuance of an injunction against defendant's policies and practices on abortions was in the public interest, addressing a denial of "financial and moral assistance to those in need of essential medical services"). This case presents a more direct public-health interest: the availability of what could potentially be the only approved therapy that addresses both dimensions of a fatal childhood disease.

Defendants cannot credibly claim a competing public interest. Capricor expects Defendants not to ask this Court to permit them to distribute Deramiocel; to ask this Court to prevent Capricor from distributing Deramiocel while Defendants themselves decline to do so. There is no public interest in preventing a therapy from reaching children with a fatal disease.

Second, the public interest supports preserving the status quo. Brown v. City of Paterson, 424 N.J. Super. 176, 188 (App. Div. 2012) (" [T]he public interest strongly favors preserving the status quo . . . pending resolution of the litigation."). Here, the status quo is that the parties are not bound by the repudiated Agreement, Capricor is entitled to distribute through alternative means, and the parties to the contract may unwind the Distribution Agreement with or without the assistance of arbitration.

Independent of the doctrines of mutual mistake, repudiation, and breach, the Distribution Agreement itself contemplates the relief Capricor seeks. Article 4.1.2 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; . . . 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." (Agreement § 4.1.2.)

Both conditions are satisfied. Defendants are unable to distribute Deramiocel: they lack the launch infrastructure, the pricing, the demand forecast, and the state-level regulatory authorization. (Rieger Cert. § VI.B; Marbán Cert. ¶ 75.) And the Distribution Agreement's pricing structure, as applied to the Medicare reimbursement framework, ensures that Defendants are "unable to sell and/or distribute" Deramiocel to Medicare beneficiaries, Medicaid recipients, and private-insurer patients whose payors benchmark to Medicare—categories that encompass the overwhelming majority of the Duchenne patient population. (Rieger Cert. §§ III.B, V.C-V.D.) Article 4.1.2, by its own terms, authorizes alternative distribution under present circumstances.

CONCLUSION

For the foregoing reasons, Plaintiff Capricor Therapeutics, Inc. respectfully requests that this Court enter a preliminary injunction directing that:

(a) Defendants NS Pharma, Inc. and Nippon Shinyaku Co., Ltd., and their agents, are preliminarily enjoined from holding themselves out as the exclusive distributor of Deramiocel in the United States and from taking any action to interfere with Capricor's efforts to commercialize and distribute Deramiocel, either directly or through a third party, pending the final judgment in this action; and

(b) Capricor Therapeutics, Inc. is authorized to distribute Deramiocel on its own or through alternative distribution channels pending final judgment in this action.

Respectfully submitted,

SKADDEN, ARPS, SLATE, MEAGHER &FLOM LLP

Attorneys for Plaintiff Capricor Therapeutics, Inc.

Dated: May 7, 2026

By: */s/ Andrew Muscato*
Andrew Muscato

Quyen L. Ta*
Emily Haffner*
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
525 University Avenue
Palo Alto, California 94301
Telephone: (650) 470-4500
Facsimile: (650) 470-4570

William K. Wray Jr.*
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP
500 Boylston Ave.
Boston, MA 02116
Telephone: (617) 573-4889
Facsimile: (650) 470-4570

Attorneys for Plaintiff Capricor Therapeutics, Inc.

*Pro hac vice motion to be submitted