IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	C.A. No. 21-691-GBW
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendants.	C.A. No. 21-1138-GBW
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendants.	C.A. No. 21-1594-GBW

MEMORANDUM ORDER

Pending before the Court is Defendant Avadel CNS Pharmaceuticals, LLC's ("Avadel") Emergency Motion to Stay (hereinafter, the "Motion to Stay," D.I. 670) the Court's August 27 Order (hereinafter, the "Order," D.I. 666), which granted-in-part Jazz Pharmaceuticals, Inc.'s ("Jazz") motion for limited permanent injunction. On August 28, 2024, Avadel appealed the Court's Order, and the Federal Circuit subsequently agreed to consider Avadel's appeal on an expedited schedule. D.I. 667; D.I. 677. Having reviewed Avadel's Motion and all related briefing, the Court **DENIES** Avadel's Motion to Stay.

I. LEGAL STANDARD[1]

In deciding whether to grant a motion to stay final judgment, courts consider four factors: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Standard Havens Prod., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990) (quoting *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)). A moving party "*must meet the threshold for the first two 'most critical' factors*: it must demonstrate that it can win on the merits (which requires a showing significantly better than negligible but not necessarily more likely than not) and that it is more likely than not to suffer irreparable harm in the absence of preliminary relief." *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 & n. 3 (3d Cir. 2017) (internal citations omitted & emphasis added). "If these gateway factors are met, a court then considers the remaining two factors and determines in its sound discretion if all four factors, taken together, balance in favor of granting the requested [] relief." *Id.*

[1] The Court writes for the benefit of the parties and assumes their familiarity with all pertinent facts.

II. DISCUSSION

A. The Order Exempts the Use of Lumryz for Narcolepsy and the Use of Lumryz in On-Going Clinical Trials.

As a preliminary matter, the Court finds it pertinent to discuss and clarify the scope of conduct enjoined by the Order. Avadel contends that Jazz now interprets the Court's Order as mandating that "Avadel 'withdraw' its long-pending request for pediatric narcolepsy." D.I. 671 at 4. Yet, in resolving Jazz's motion for permanent injunction, the Court explicitly declined to enjoin Avadel's conduct with respect to Lumryz for the treatment of narcolepsy. Indeed, as Avadel notes, "the Order contains an express exemption for "making, using, and selling [Lumryz]: (a) for the treatment of narcolepsy." D.I. 671 at 5 (citing D.I. 666 at 1). To the extent that Avadel believes that Jazz will seek to hold Avadel in contempt for such conduct, the Court emphasizes that the Order ***does not*** enjoin, in any way, Avadel's use of Lumryz for narcolepsy. Jazz concedes that "it will not argue that Avadel's application for FDA approval of Lumryz for pediatric patients with narcolepsy, and Avadel's maintenance of that request, is in contempt of the injunction." D.I. 679 at n. 1. Thus, there is no present danger that Avadel will be prevented from seeking FDA approval for Lumyrz to treat pediatric narcolepsy.

Similarly, under the explicit terms of the Order, Avadel is not enjoined from making, using, or selling Lumryz "in *currently on-going* clinical trials and studies." D.I. 666, ¶ 1.A.(c) (emphasis added). While the Court was not specifically aware that Avadel initiated its IH study prior to the issuance of the Order,[2] the Order and its exception for "currently on-going clinical trials" took effect on the date in which the Order was signed and entered by the Court. In excluding "currently on-going" trials, the Order exempted from its scope any clinical studies that were on-going (i.e.,

[2] Indeed, it appears that Avadel represented that it would not pursue IH trials if enjoined. *See* Hr. Tr. 64:15-21; 86:1-8.

initiated) before August 27, 2024, the effective date of the Order. Thus, to the extent that Avadel initiated the REVITALYZ clinical study on July 31, 2024, that study would constitute a "currently on-going clinical trial[]" exempt from the Court's injunction. As nothing in the Order prohibits or otherwise limits Avadel's ability to enroll subjects to an already ongoing study, the Order does not enjoin Avadel from enrolling approximately 150 adults to the REVITALYZ study. D.I. 671 at 2-3; *See also id.*, Exs. B-C. Finally, while the Order enjoins Avadel from seeking FDA approval for IH, the Order does not enjoin Avadel from *submitting information or results* from ongoing clinical studies to the FDA.

Avadel is, however, enjoined from: (1) offering open-label extensions to trial participants; (2) applying for FDA approval of Lumryz for IH; and (3) initiating *new* clinical trials or studies after the Order's effective date of August 27, 2024. *See generally* D.I. 666. Accordingly, in considering Avadel's Motion to Stay—and, particularly, in weighing the risk of irreparable harm—the Court must decide whether a stay is necessary pending appeal with respect to each of these three activities. For the following reasons, Avadel has not demonstrated a substantial risk of immediate and irreparable harm if it is not permitted to offer open-label extensions to trial participants, apply for FDA approval of Lumryz for IH, and/or initiate new clinical trials before the Federal Circuit resolves the pending appeal.

B. Avadel Has Not Demonstrated a Substantial Risk of Immediate and Irreparable Harm.

In support of its claim that a stay is necessary to prevent Avadel from suffering irreparable harm, Avadel submits the declaration of Jennifer Gudeman, the Senior Vice President, Medical and Clinical Affairs at Avadel Pharmaceuticals. D.I. 672 ("Gudeman Decl."), ¶ 2. Ms. Gudeman swears that Avadel intends to enroll approximately 150 subjects to the REVITALYZ trial "to ensure a minimum of 104 subjects complete the study." *Id.*, ¶ 4. According to Ms. Gudeman,

Avadel would suffer significant, irreparable harm if Avadel is enjoined from enrolling additional patients in the REVITALYZ trial. *Id.*, ¶ 6. For instance, Ms. Gudeman asserts that Avadel may be forced to terminate the trial altogether if it could not enroll a sufficient number of participants, "which would result in patients currently receiving Lumryz for IH losing access to their medication, as well as other clinical care that they are receiving as part of the study." *Id.* Ms. Gudeman adds that early termination would result in irreparable harm to "investigators participating in the REVITALYZ trial [who] have invested significant time and resources in enrolling patients, training for the study, and recording the necessary data . . . ." *Id.*, ¶ 7. Finally, Ms. Gudeman asserts that a freeze in enrollment would irreparably harm Avadel by "delay[ing] any potential application with FDA for approval of an idiopathic hypersomnia indication for Lumryz" and harming Avadel's reputation with "patients and investigators who become aware of a pause on enrollment . . . ." *Id.*, ¶ 8. As the Court noted *supra*, however, the Order does not enjoin Avadel from enrolling patients in the on-going REVITALYZ trial. Thus, given the REVITALYZ trial is ongoing and is not enjoined by the Order, there is not a substantial risk that, before the Federal Circuit decides the appeal, Avadel would suffer any of the harms which it alleges will result if it is forced to terminate or delay the REVITALYZ trial.

Ms. Gudeman asserts that Avadel will also suffer irreparable injury if it is "enjoined from conducting additional clinical studies or if the open label extension that is a part of REVITALYZ is halted." *Id.*, ¶ 9. With respect to new trials, however, Avadel has not demonstrated a risk of immediate harm because Avadel does not allege that it intends to initiate any new trial before the appeal is decided. Moreover, as Jazz notes, any harm stemming from Avadel's inability to initiate new trials is not immediate given that the Federal Circuit will decide the appeal on the parties' agreed-upon expedited schedule. D.I. 679 at 1.

As to its ability to use open-label extensions, Avadel contends that the open-label extensions "allow clinical-trial participants to continue using a trial drug following completion of the monitored phase of the clinical trial." D.I. 671 at 13. According to Avadel, the extensions "are part of the clinical trial itself and [are] a 'valuable recruiting tool' for boosting enrollment in clinical trials." *Id.* (internal citations omitted). Yet, Avadel does not show or claim that it would be unable to recruit participants to the REVITALYZ study without open-label extensions. *See* D.I. 679 at 15 (arguing that "open-label studies are merely '[d]ressing up marketing exercises as research'" (internal citations omitted)). Thus, the Court is not persuaded by Avadel's assertions alone that it would suffer *irreparable*, or even significant, harm if it was required to conduct its trial without allowing patients to continue using infringing forms of Lumryz through open-label extensions even after the clinical trial is complete. *Sunoco Partners Mktg. & Terminals L.P. v. Powder Springs Logistics, LLC*, No. 17-1390, 2018 WL 395750, at *14 (D. Del. Jan. 8, 2018) (finding that "conclusory and speculative allegations" are insufficient to "demonstrate irreparable harm.").

Lastly, Avadel cannot demonstrate imminent and irreparable harm stemming from the Order's injunction on seeking FDA approval of Lumryz for IH, since Avadel concedes that it will not seek FDA approval for IH until January 2026. D.I. 671 at 14. Because Avadel has not made the threshold showing of immediate and irreparable harm, the Court need not address the remaining factors.

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WHEREFORE, at Wilmington, this 24th day of September 2024, **IT IS HEREBY ORDERED** that Defendant Avadel's CNS Pharmaceuticals, LLC's Emergency Motion to Stay (D.I. 670) is **DENIED**.

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE