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July 29, 2021

**VIA ELECTRONIC FILING**

**PUBLIC VERSION**

The Honorable Maryellen Noreika  
United States District Court  
for the District of Delaware  
844 North King Street  
Room 4324, Unit 19  
Wilmington, DE 19801

Re: *Jazz Pharmaceuticals, Inc. v. Avadel Pharmaceuticals plc, et al.*  
Civil Action No. 21-691 (MN)

Dear Judge Noreika:

This firm, together with Quinn Emanuel, represents Plaintiff Jazz Pharmaceuticals, Inc. (“Jazz”) in this matter. We write pursuant to Your Honor’s Order earlier today (D.I. 24) to submit a letter regarding the Scheduling Conference to take place before the Court tomorrow, July 30, 2021, in particular with respect to the parties’ proposals regarding potential preliminary injunction proceedings.

When the FDA accepted Defendants’ (“Avadel”) NDA that is the subject of this litigation, it assigned it a Prescription Drug User Fee Act (“PDUFA”) target action date of October 15, 2021, by which time the FDA may approve Avadel’s NDA or request additional information. In light of this, the parties have discussed the potential need for proceedings relating to a preliminary injunction in this matter, but were unable to reach agreement regarding how to address this potential need in the Proposed Scheduling Order (D.I. 23).<sup>1</sup>

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<sup>1</sup> Specifically, last month, it was Avadel that first contacted Jazz to discuss potential proceedings relating to a preliminary injunction in this matter. In order to have a productive discussion regarding that possibility, Jazz asked whether Avadel would agree to produce its NDA and related FDA correspondence on an outside counsels’ eyes only basis. Had Avadel already produced the NDA, the parties would likely be in a position to propose a plan to the Court in the Scheduling Order regarding how to proceed. Instead, Avadel has only agreed to produce its NDA at a later date, and conditioned on certain occurrences, which Jazz believes to be unreasonable and prejudicial, as discussed below.

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It is Jazz's position that, in order to have an informed discussion regarding whether preliminary injunction proceedings will be necessary, it will first need to review Avadel's NDA and related correspondence with the FDA. Without this, Jazz does not and cannot know when or if Avadel's NDA will receive FDA approval. Also, review of Avadel's NDA may reveal the need for additional discovery that goes beyond the contents of the NDA itself. In short, there may be no need for a preliminary injunction at all and, thus, setting a schedule for briefing relating to a preliminary injunction at this time would be premature. For at least this reason, Jazz proposed in Sections 2(b)-(d) of the Proposed Scheduling Order that, following Avadel's production of the NDA, the parties can meet and confer and update the Court regarding whether they believe preliminary injunction proceedings will be necessary at this time, and/or whether there will be a need for additional discovery. Moreover, during the parties' prior meet and confer regarding the Scheduling Order, Avadel's counsel stated that, even if approved, Avadel will not launch its NDA product until at least January 2022, so there is adequate time for the parties to work through Jazz's proposal. To ensure that the parties and the Court will have up-to-date information regarding the status of Avadel's NDA, Jazz also proposed that the scheduling order include a provision in Section 2(b) requiring Avadel to produce any FDA correspondence that occurs after Avadel's initial production of the NDA within seven days of such correspondence. Jazz respectfully submits that its proposal is fair and reasonable.

Avadel, on the other hand, proposes in Section 2(d) that the Court set a schedule for preliminary injunction proceedings now, prior to production of its NDA and related FDA correspondence. Jazz respectfully submits that it would be unfair and prejudicial to Jazz—and a waste of the Court's time—to set a specific date by which Jazz "shall" file a motion for a preliminary injunction when Jazz does not and cannot know whether a preliminary injunction will ever be necessary, let alone now, because Jazz does not and cannot know the contents of Avadel's NDA or whether Avadel is anywhere near approval until after Avadel produces the NDA and related correspondence. Further, under Avadel's proposal, it appears that Avadel seeks to preclude Jazz from seeking a preliminary injunction after Avadel's proposed date. Again, this is unfair and prejudicial to Jazz, which may not have a need for a preliminary injunction now or any time soon, but may need to seek such relief at an unknown future date. Avadel has not cited any authority supporting such a drastic measure, and Jazz is not aware of any. At a minimum, Avadel's proposal would likely violate Jazz's due process rights. Avadel also proposes in Section 2(c) that Avadel should be allowed to propound discovery requests on Jazz relating to preliminary injunction proceedings that Jazz must answer on an expedited basis. Again, this proposal is prejudicial and premature, at least because Jazz does not yet have access to Avadel's NDA or FDA correspondence and does not know whether preliminary injunction proceedings will ever be necessary, let alone in the near term.

In addition, Avadel proposes in Section 2(b) that, if the parties do not have a Protective Order entered by August 27, 2021, Avadel should not have to produce its NDA. This too is unreasonable given that the parties may have disagreements regarding the provisions of the Protective Order that may take time to resolve. Indeed, Avadel's proposal would incentivize Avadel to create disputes so that it can delay production of the NDA. Under Jazz's proposal, if there is no Protective Order entered by August 27, 2021, then Avadel would produce its NDA and related FDA correspondence on an outside counsel's eyes only basis pursuant to

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D. Del. LR 26.2, plus one expert who Jazz would identify to Avadel prior to any disclosure of Avadel's confidential information. Jazz's proposal ensures that the parties and the Court will have access to Avadel's NDA and related FDA communications by August 27, and the parties can thereafter determine whether preliminary injunction proceedings will be necessary in the near term. Further, if Avadel fails to produce its NDA and related FDA communications by August 27, then Avadel's proposed dates for preliminary injunction proceedings are all the more unreasonable.

In short, under Jazz's proposal, the parties and the Court will avoid unnecessary and premature preliminary injunction proceedings. Avadel's proposal, on the other hand, would force Jazz to bring a preliminary injunction motion by a date certain regardless of whether Avadel has obtained FDA approval or is likely to do so any time soon, and without any regard for Jazz's due process rights. Jazz therefore respectfully requests that the Court adopt Jazz's proposed language for the Scheduling Order in this case.

We appreciate Your Honor's attention to this matter.

Respectfully,

*/s/ Jeremy A. Tigan*

Jeremy A. Tigan (#5239)

JAT:rs

cc: Clerk of the Court (*via Hand Delivery*)  
All Counsel of Record (*via CM/ECF and email*)