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October 18, 2021

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

*VIA ELECTRONIC FILING*

PUBLIC VERSION

Confidential Version Filed: October 18, 2021

Public Version Filed: October 25, 2021

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

Dear Judge Noreika:

This firm, together with Quinn Emanuel, represents Plaintiff Jazz Pharmaceuticals, Inc. in this matter. We write pursuant to paragraph 2(c) of the Scheduling Order (D.I. 31) to provide the Court with a status report regarding whether preliminary injunction proceedings are necessary at this time.

On October 15, 2021, Defendants (“Avadel”) publicly announced that the FDA’s review of its NDA is still ongoing, that action will likely not be taken in October, and that a new target action date under the Prescription Drug User Fee Act (“PDUFA”) will be provided at a later date.<sup>1</sup>

<sup>1</sup> See <https://investors.avadel.com/news-releases/news-release-details/avadel-pharmaceuticals-announces-ongoing-fda-review-nda-ft218>.

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[REDACTED] preliminary injunction proceedings would not be appropriate at this time. Consequently, Jazz does not intend to file a motion for a preliminary injunction by October 22, 2021. Jazz will provide the Court with an update regarding whether preliminary injunction proceedings may be necessary shortly after receiving the FDA's updated PDUFA target action date from Avadel.<sup>3</sup>

We are available at the Court's convenience if Your Honor would like to discuss this matter.

Respectfully,

*/s/ Jeremy A. Tigan*

Jeremy A. Tigan (#5239)

cc: Clerk of the Court (via hand delivery)  
All Counsel of Record (via CM/ECF and email)

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<sup>3</sup> We have discussed this proposal with counsel for Avadel and understand Avadel's position to be that they are willing to discuss a new briefing schedule following the FDA's updated PDUFA date, but that they reserve all rights with respect to Your Honor's comments regarding preliminary injunction proceedings during the July 30, 2021 scheduling conference.