McCarter & English

Daniel M. Silver
Wilmington Office Managing Partner

T. 302-984-6331
F. 302-691-1260

dsilver@mccarter.com

McCarter & English, LLP

Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801-3717

www.mccarter.com

December 2, 2022

VIA CM/ECF AND HAND DELIVERY

The Honorable Gregory B. Williams
U.S. District Court for the District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street
Wilmington, DE 19801-3555

Re: *Jazz Pharms., Inc., et al. v. Avadel CNS Pharms., LLC*, C.A. No. 21-691-GBW

Dear Judge Williams:

We write regarding Jazz's Reply Brief in Support of its Motion to Stay (D.I. 253) to address three discrete points raised for the first time on reply.

First, Jazz asserts that "the FDA confirmed that, notwithstanding the injunction, Avadel is unlikely to obtain final approval in the next 60 days." Jazz Reply at 1. Avadel understands that it is eligible for approval sooner than Jazz's counsel asserts.

Second, Jazz states that "Avadel agreed to a Federal Circuit argument in February 2023 (Ex. B), which provides time to decide the appeal before expiration." Jazz Reply at 9. But that does not guarantee a decision in February or even an argument. The Federal Circuit adopted Jazz's expedited briefing schedule, but explicitly did not adopt Jazz's proposal for oral argument in the February session (February 6-10, 2023). See ECF No. 11 at 2 ("Oral argument will be addressed by separate order."); ECF No. 6 at 10. Even following the appeal, there would be an additional delay before the FDA actually de-lists the patent. Thus, the harm to Avadel and the public is indeterminate in duration.

Third, Jazz contends that "Avadel told its investors FT218 will not launch until the third quarter of 2023." Jazz Reply at 10. However, the cited statement presumes "a final approval decision in June." Jazz Reply, Ex. G at 5. With the '963 patent delisted, Avadel could receive final approval months earlier than that and thus be in a position to launch earlier. Indeed, Avadel has recently represented to the public that a final approval by the beginning of 2023 would put Avadel in position "to have commercial supply and potentially in a place to begin to serve patients as early as the backend of Q1" 2023. Exhibit 1, November 29, 2022, Piper Sandler 34th Annual Healthcare Conference Transcript at 8-9.

Counsel for Avadel is available should the Court require any further information.

Respectfully submitted,

/s/ *Daniel M. Silver*

Daniel M. Silver (#4758)

cc: All counsel of record (via CM/ECF and E-Mail)

EXHIBIT 1

Company Name: Avadel Pharmaceuticals PLC
Company Ticker: AVDL US Equity
Date: 2022-11-29

FINAL

Bloomberg Transcript

Piper Sandler 34th Annual Healthcare Conference

Company Participants

- David Amsellem, Pharmaceuticals Managing Director and Senior Research Analyst
- Gregory Divis, Chief Executive Officer
- Richard Kim, Chief Commercial Officer

Presentation

Gregory Divis {BIO 16183530 <GO>}

Hope you don't mind me behind the podium.

David Amsellem {BIO 15145021 <GO>}

Okay. That wasn't--

Gregory Divis {BIO 16183530 <GO>}

I can sit out there. Are we live?

David Amsellem {BIO 15145021 <GO>}

Oh, okay. Yeah, we're on. We're okay. We were just playing a little musical chairs here before we get started. But we're all set now.

Well, thanks everyone for joining us. This is David Amsellem from the Piper Sandler's specialty pharma team. Welcome again to the 34th Annual Piper Sandler Healthcare conference. We have Avadel with us, we have senior leadership Greg Divis, CEO. Richard Kim, Chief Commercial Officer. And Tom McHugh, Chief Financial Officer. Thanks gentlemen for joining us.

So I know there's legal stuff to talk about but I prepared an orderly list of questions. I wanted to mix in some questions on the commercial landscape and the value proposition for LUMRYZ. So I think that would be a good place to start before we go in to the all the legal developments surrounding the litigation with Jazz.

So with that in mind, just a high level discussion as a starting point regarding the product here and how you see the role of a once nightly oxybate product that albeit has high sodium in the context of a space that has migrated to some extent to a low sodium but twice nightly product. Still lot of patients on legacy Xyrem. But the broader question is how do you see the product sliding in to this evolving oxybate landscape?

FINAL

Bloomberg Transcript

Questions And Answers

A - Gregory Divis {BIO 16183530 <GO>}

Well, first, David thank you for the opportunity to be here and to share the status updates on where we are and how excited we are about being very close to a potential final approval decision and a subsequent launch to be able to effectively serve this narcolepsy community with some real innovation.

I'll let Richard maybe take the first answer, the first answers to your comment on the market. But needless to say, we're really excited about the prospects of a pending potential approval and launch as we enter into 2023.

A - Richard Kim {BIO 19285146 <GO>}

Yeah. And David, first, it's nice to be able to use the word LUMRYZ, so thank you for doing that as well.

A - David Amsellem {BIO 15145021 <GO>}

Yeah. As soon as I said LUMRYZ, I said LUMRYZ.

A - Richard Kim {BIO 19285146 <GO>}

It was pretty darn close.

A - David Amsellem {BIO 15145021 <GO>}

Okay.

A - Richard Kim {BIO 19285146 <GO>}

So we do thank you for that.

But if we think about LUMRYZ, in the field of narcolepsy, there is still a huge amount of unmet need. What we know is oxybates are seen as highly effective therapy. But today, the twice nightlies sort of don't address a lot of the current use in the marketplace.

So despite the fact that there is now a lower sodium version in the market, mixed salt version in the marketplace we seen sort of oxybate use sort of flatten out at about 16,000 persistent patients on therapy. We know from our market research, what we've done for once a bedtime option, that market could be 30,000 to 35,000 patients when you include recently discontinued patients and the de novo patients as well.

So we really see a tremendous opportunity for LUMRYZ and the simple innovation of a once a bedtime therapy is really quite transformative when you think about what a narcolepsy patient goes through. Two-thirds of them have this disrupted nighttime sleep to begin with as well. So this simple innovation is something that could really be quite transformative to many patients going forward.

FINAL

A - David Amsellem {BIO 15145021 <GO>}

And before we get into the launch, a follow-up to that is you have these two subgroups in narcolepsy patients. One with a lot of sleep fragmentation and another with lesser sleep fragmentation. So do you think a once nightly product is better suited to the group with less sleep fragmentation or do you think it's suited well for equally for both groups?

A - Richard Kim {BIO 19285146 <GO>}

Well we'd say it's equally suited for both.

And maybe the one thing, I've been in this field now for about two years and maybe the one thing I struggled with when I first joined the company, it was the fact that with people with narcolepsy who are often suffering from a lot of challenges of obviously affecting sleepiness or sleeping during the night, being forced to wake up during the middle of the night. So I guess we and most of the people we speak to don't really see that as natural or normal.

A - David Amsellem {BIO 15145021 <GO>}

Uh-hmm.

A - Richard Kim {BIO 19285146 <GO>}

So if you have fragmented or unfragmented sleep, the option of not having to do that, the option to have uninterrupted night's sleep, we see as something that both segments of patients would really welcome going forward.

A - David Amsellem {BIO 15145021 <GO>}

Okay, got it. So let's move and talk about the litigation. So you recently won in Federal District Court on your motion to delist Jazz's 963 patent surrounding its REMs program.

So I know there's some developments on the appellate process. But before we get into that, walk us through your view on why a delisting made sense here.

A - Richard Kim {BIO 19285146 <GO>}

Well, I think what the court decided a couple of weeks ago or nearly two weeks ago now which is something we've been of the perspective and position of for the last couple of years is that this 963 patent as the court ruled is a system patent. It's a computer-implemented system patent, not a drug or formulation patent or a method of using a drug or formulation patent.

So as such, we've always believed it should never have been in the Orange Book and we're pleased that the court has ruled in alignment with our views on that and has ordered that delisting to occur 14 days which would be Friday of this week. So December 2nd will be the day that that delisting is required to occur subject to any other rulings in other courts or jurisdictions. But that is the timeframe.

Bloomberg Transcript

FINAL

And it's important because in the receipt of our tentative approval that we received this past summer, what the FDA clearly noted that the only thing preventing them from moving to a final approval decision is the 963 REMs patent.

A - David Amsellem {BIO 15145021 <GO>}

Right.

A - Richard Kim {BIO 19285146 <GO>}

So having that potentially be ruled on and be delisted in a matter of days, potentially, certainly accelerates the potential timeframe to move to a final approval decision which leads to the opportunity to potentially come to the market much sooner than what we would have otherwise.

A - David Amsellem {BIO 15145021 <GO>}

Okay. So let's talk about the appellate process here. And I know that there has been some movement. So just wanted to first clarify, so the delisting has to happen on December 2nd in the absence of any developments in the courts?

A - Richard Kim {BIO 19285146 <GO>}

Yeah. The order the court issued on the requirement to delist was in alignment with the law which says that the delisting notification to FDA must occur within 14 days.

A - David Amsellem {BIO 15145021 <GO>}

Fourteen days.

A - Richard Kim {BIO 19285146 <GO>}

And day 14 is December 2nd.

A - David Amsellem {BIO 15145021 <GO>}

Okay. And what is Jazz doing now on the appeals front?

A - Richard Kim {BIO 19285146 <GO>}

So there's been a couple of actions that began last week around the holiday in the Delaware Court initially where they requested from the Delaware Court to stay the order to allow them to potentially pursue an appeal at the Federal Circuit Court of Appeals.

They've filed a couple of different stays in the Delaware Court. On Monday, the Delaware Court ruled that their seven-day administrative stay that they requested was denied and asked us to have our brief in response to their request for the first stay they issued in by tonight. And, again, noting that the decision on a stay in the Delaware courts or anywhere needs to be determined by Friday.

Bloomberg Transcript

FINAL

A - David Amsellem {BIO 15145021 <GO>}

Right.

A - Richard Kim {BIO 19285146 <GO>}

Because that's when the order goes into effect. So upon the court's decision yesterday, last night, Jazz filed an emergency stay and appeal in the Federal Circuit Court of Appeals.

A - David Amsellem {BIO 15145021 <GO>}

Okay.

A - Richard Kim {BIO 19285146 <GO>}

So not waiting for a decision from the Delaware Court but went to the Federal Court of Appeals last night seeking an expedited briefing schedule and requesting a stay and that's now pending at the Federal Court which we will reply to in due course.

A - David Amsellem {BIO 15145021 <GO>}

Okay. So all of this essentially has to be resolved by Friday or ahead of that?

A - Richard Kim {BIO 19285146 <GO>}

As it relates to staying the order…

A - David Amsellem {BIO 15145021 <GO>}

Staying the order.

A - Richard Kim {BIO 19285146 <GO>}

…that's been ordered by the Delaware Court. Correct.

A - David Amsellem {BIO 15145021 <GO>}

Okay. So if the stay happens, then what would happen going forward? Let's just sort of game it all out.

A - Richard Kim {BIO 19285146 <GO>}

Yeah. Well the answer to that is, how long of a stay? If a stay is granted, how long of a stay is granted? If a seven-day administrative stay is granted, then the order is halted for seven days.

A - David Amsellem {BIO 15145021 <GO>}

Sure.

A - Richard Kim {BIO 19285146 <GO>}

Bloomberg Transcript

Right? So whatever time bound gets placed on the stay would be placed on when that order goes into effect.

A - David Amsellem {BIO 15145021 <GO>}

Okay. And then assuming there would be a hearing to then consider the appeal if the stay is granted? Or I'm just trying to understand what happens during the process, during the stay process.

A - Richard Kim {BIO 19285146 <GO>}

Yeah. The stay process will run on its own course which will then lead to whenever the delisting can occur. If the stay order expires before the appeal occurs, then the order goes into effect.

A - David Amsellem {BIO 15145021 <GO>}

Okay.

A - Richard Kim {BIO 19285146 <GO>}

So whenever the appeal is heard it is heard.

A - David Amsellem {BIO 15145021 <GO>}

Right. Okay. Okay, that's helpful. I mean, it was out and, again, this is all pretty new. So I have seen any new court documents yet, but what essentially is Jazz asserting here? Because you've seen the arguments, we saw the amicus brief on the FTC, the court obviously reads that. So is Jazz asserting here that a REMs patent is indeed a method of use patent?

A - Richard Kim {BIO 19285146 <GO>}

I think the short answer to that question is they continue to assert the same arguments they made during the motion to delist arguments around the reason why they shouldn't be required to delist.

And, again, we're pleased that not only the FTC weighed in on it but that the Delaware Court agreed with us in our view that the system patent should not be listed in the Orange Book.

A - David Amsellem {BIO 15145021 <GO>}

Got it. Okay. So what happens next? And in terms of going from a tentative approval to a final approval, what has to happen?

A - Richard Kim {BIO 19285146 <GO>}

Yeah. It's pretty straightforward, it's very administrative and procedural in nature for which we're ready to go. So upon the expiry of the 14-day period or when the actual motion to delist requirement goes into effect, which right now we're planning to be this Friday, we

FINAL
Bloomberg Transcript

will file an amendment to our NDA. And it's a fairly simple amendment that seeks a transition from the tentative approval state to a final approval decision. There's a few things we have to provide along with that, a safety update, things like that, all that's done and ready to go.

So it really for us is upon notification that the request to delist has occurred because the order has gone into effect, we will immediately thereafter file our requisite documentation to move from a tentative approval to a final approval.

FINAL

A - David Amsellem {BIO 15145021 <GO>}

Okay, got it. And so let's switch gears and talk about the REMs. So help us understand where you are regarding buildout and then how much time you need to implement it?

A - Gregory Divis {BIO 16183530 <GO>}

I'll take that one. So along with the final approval that we received in December, what was important is we received the final documentation for the blueprint for the REMs. So that was a really important trigger for us and the team to start building out the final elements of the REMs. So we anticipate by the end of this year all of our programming for REMs is done.

A - David Amsellem {BIO 15145021 <GO>}

Yup.

Bloomberg Transcript

A - Gregory Divis {BIO 16183530 <GO>}

So, really all we need to do is with our partner have them staff up and we really don't see REMs as a regulating factor even from an accelerated approval.

A - David Amsellem {BIO 15145021 <GO>}

Got it. And then commercial inventory, where are you regarding that?

A - Gregory Divis {BIO 16183530 <GO>}

That's another great thing that the tentative approval helped us with, is we got our final artwork for our packaging.

A - David Amsellem {BIO 15145021 <GO>}

Uh-hmm.

A - Gregory Divis {BIO 16183530 <GO>}

So our team has already begun to put the beads into primary packaging, the six packs, the daily six packs.

A - David Amsellem {BIO 15145021 <GO>}

Uh-hmm.

A - Gregory Divis {BIO 16183530 <GO>}

So that's already being done right now with sort of then we figure out how much to put into seven or thirty-day carton. It's a relatively quick process.

And so we're really aiming to have our initial commercial inventory ready towards end of the first quarter.

A - David Amsellem {BIO 15145021 <GO>}

Okay. And then remind us how large of a salesforce you're planning to deploy and how long it will take to build out the sales organization initially?

A - Gregory Divis {BIO 16183530 <GO>}

David, I'd like that we're getting closer to the patient now, so that's great.

So all of our work has been based off of really deep market research and data analytics. And what the data tells us is there's about 5,000 prescribers of oxybates, 1,600 would make up 80% of the volume and 500 to make 50% of the volume. So we're gearing to cover off that entire segment of physicians and that will allow us to sort of staff up to about 50 representatives to also have the capacity to add in new prescribers to come into the mix as well.

So as far as time is concerned, if you would have asked me a couple weeks ago, maybe I would have given you slightly different answer. But our plans have always been geared toward June approval. That's clean now, been accelerated. So we have really solid plans and the way I think about it is sort of we are doing a lot of things subsequentially. Now we're going to be doing a lot more work in parallel to sort of pull those timelines forward. So I'm not going to give you an exact answer, but I can say is no one is more motivated to bring LUMRYZ to the marketplace than we are right now.

A - David Amsellem {BIO 15145021 <GO>}

So I guess you kind of know where I'm going with all these questions, REMs, inventory, salesforce, we're talking about steps to be in a position to launch. So with all that you've said, do you think you could be in a position to launch by the end of 1Q?

A - Gregory Divis {BIO 16183530 <GO>}

Well I think as we think about launch and timing, a big influence of that is when does the actual approval occur over the period of post the request to move from tentative approval to final approval.

But we certainly have great visibility in terms of timing, in terms of when. If an approval occurs, sometime within the first half of Q1 as an example that we should be in a position,

FINAL
Bloomberg Transcript

as Richard noted, to have commercial supply and potentially in a place to begin to serve patients as early as the backend of Q1.

A - David Amsellem {BIO 15145021 <GO>}

Okay. All right. That's helpful.

A - Gregory Divis {BIO 16183530 <GO>}

And we'll provide more color and clarity on that as timing evolves and whatnot around the regulatory process.

A - David Amsellem {BIO 15145021 <GO>}

Yeah. Obviously in the next few weeks.

A - Gregory Divis {BIO 16183530 <GO>}

It's coming to a head pretty soon.

A - David Amsellem {BIO 15145021 <GO>}

Yeah. Exactly. Okay. So let's talk about commercial dynamics. And one of the things that's sort of an obvious question is pricing. So how should we think about LUMRYZ pricing relative to where Xywav is and given that a Xyrem AG will for sure be on the market by the time we launch?

A - Gregory Divis {BIO 16183530 <GO>}

Yeah, sure. I mean, really simply our overall strategy with LUMRYZ is to win with patients, to win with providers and to sort of draw with the payers. Our strategy is really to see sort of parity with the branded oxybates as far as sort of general pricing and coverage is concerned.

And so we've been talking to the payers for well over a year to take them on this journey with us here as well. So we feel like we're in a really good position as far as our discussion. We've been in deep conversations with the three major GPOs that the PBMs that make up 85% of the coverage for commercial lives. And in many ways it's maybe a little more straightforward for us to deal with an AG before we have to sign those on the contract than after we do as well. And our general perception of the AG is it's going to be treated from the feedback that we received from the payers is it's going to be treated more like a brand extension.

A - David Amsellem {BIO 15145021 <GO>}

Yeah.

A - Gregory Divis {BIO 16183530 <GO>}

And generally likely to be more in the higher cost range (inaudible) are. And just a reminder, currently, Xyrem is about 8.5% more expensive than Xywav so there's also a

FINAL
Bloomberg Transcript

FINAL

Bloomberg Transcript

little bit of that spread to play with as well.

So what I can say David is our plans are fully accounted for in AGB in the marketplace so this is nothing new to us.

A - David Amsellem {BIO 15145021 <GO>}

So is it fair to say that you're probably pricing more in line with the Xywav than a brand Xyrem on a net basis?

A - Gregory Divis {BIO 16183530 <GO>}

Well I think what we can sort of say is we have that range to work with and those are probably the two bookends for us to work within.

A - David Amsellem {BIO 15145021 <GO>}

Okay. All right, that's helpful.

And then what about payer contract? I mean, Jazz's talked a lot about contracts on Xywav, right? They've been more aggressive here and they have to be. I mean it's a switch strategy. But how do you think about contracting for LUMRYZ? Or maybe I'll ask the question differently, are you essentially going to do from a payer perspective what Jazz has been doing with Xywav just to sort of get on the same playing field?

A - Gregory Divis {BIO 16183530 <GO>}

Well I can't really speak for what they've done.

A - David Amsellem {BIO 15145021 <GO>}

Sure.

A - Gregory Divis {BIO 16183530 <GO>}

Our goal is like with all of our constituents is we want to bring them on the journey with us. We want to help them and work with them, not against them.

Payers are a very important part of the mix in getting medications to patients as well. So our general strategy once again is we are seeking more of the parity. We want to make sure there's enough sort of natural sort of edit sort of steps that patients go through more clinically for patients to get to oxybates. We don't really need to disrupt that. So we're really seeking more to be on a parity, once again, pricing and sort of coverage as where the branded oxybates are.

And the feedback that we received so far is the payers really do understand our clinical value proposition. They generally see it as very different. Now they're going to haggle with us as they should do from their side. But because we brought them on the journey

with us, we feel like we're sort of right in the right place for where we need to be even with the potential for an accelerated approval.

A - David Amsellem {BIO 15145021 <GO>}

So talking about the presence of this AG which will be an expensive AG, I mean I totally agree, this is not really a genericized market in any way that we understand it. I guess with that in mind, do you think that there's going to be cases where patients will have to step through a Xyrem AG in order to get access to LUMRYZ?

A - Gregory Divis {BIO 16183530 <GO>}

It's a great question that we get asked quite a bit.

But the way we sort of think about the marketplace for patients is there's really three types of segments to patients, those currently on oxybates, those who've discontinued the last few years, and those who are de novo to oxybates. So if you think about this purchase segment, there's a larger segment, 16,000 and 10,000 to 15,000, almost 30,000 patients in those two segments, they've all been on oxybate and what we hear generally from providers is the reason why they would switch is they either can't, won't, or are failing taking a second middle of the night time dose.

So from a payer proposition, we see it very difficult for them to deny those patients when they already have been exposed to the oxybate. The one segment that maybe we can get in to a little bit is the patients are naive to oxybates. And what we know already is 30% of those today discontinue after 30 days. But our overall pricing strategy is to make sure that we have parity coverage for all segments. So even though we can play some different things, our goal is to make sure every patient in our initial launch can get access to LUMRYZ as fast as possible for oxybates.

A - David Amsellem {BIO 15145021 <GO>}

Yeah. And one thing that Jazz has pointed out and I wanted to pick your brain on this is that they've commented pretty clearly that the vast majority of narcolepsy patients who are oxybate naive are getting Xywav. So would that be a, in a way good thing as you think about LUMRYZ and your ability to access oxybate naive patients?

A - Gregory Divis {BIO 16183530 <GO>}

The more you say it the easier it is to pronounce, right? So you're spot on David.

So absolutely. So the conversion purpose clearly slowed down from Xyrem to Xywav. But what we know from our research that we've done with patients is patients who go on to Xywav generally have been diagnosed for a shorter period of time, they're generally younger and they're earlier adopters of new therapy as well.

So our research sort of shows out of all the segments, they are some of the most motivated to learn about LUMRYZ and potentially switch on to LUMRYZ as well.

FINAL
Bloomberg Transcript

FINAL

Bloomberg Transcript

A - David Amsellem {BIO 15145021 <GO>}

Okay. So let's look longer term at how the oxybate market will evolve. At some point we might see other agents like orexin agonists, for instance, and look, there might be other kinds of agents. I guess the question here is how do you see the overall oxybate footprint in narcolepsy trending amid the potential presence of new kinds of agents?

A - Gregory Divis {BIO 16183530 <GO>}

Yeah. Well, first, it's super exciting to sort of see the high level of interest in the field of narcolepsy. When we go to Congress' patient advocacy organization meetings, it's just great to hear the dialogue going on, the excitement.

So overall, I mean we sort of see a lot more attention and growth potential. When we think about oxybate market prices, I mentioned, there's only been about 16,000 persistent patients on oxybates. For us, once again, we see that's potentially a 30,000 to 35,000 patients who are eligible. So a much bigger opportunity, twice the size for (inaudible). And what we do know is we have opportunities to grow within current users, of prescribers, low volume user and non-users is where we see potential large potential in the future.

And patients across all the segments around on therapy discontinued or naive have all expressed high level of interest. So for oxybates, we see a really good opportunity to grow. And David, as far as your question around sort of future therapies, it's also really cool to sort of see just the innovation that's coming in to the research field in narcolepsy. When it comes to orexin agonists, we've had a chance to speak with Emmanuel Manel [ph] and others who have helped to discover pathway.

But it's really exciting but they're still relatively early, they're probably several years off until they can initiate phase three studies and the corresponding packages for an NDA. But what we know about the marketplace today it's probably going to be consistent in the future which is a lot of patients are on polypharmacy. There's not a one size fits all one therapy.

So we see that see that still playing forward going forward and keep in mind orexin agonists are really targeted to the etiology of NT1 not NT2 or even IH. And also two-thirds of people with narcolepsy also have underlying disturbances in their sleep. So we're definitely excited about new therapies but we see the opportunity for oxybates to still be a key player going forward as well.

A - David Amsellem {BIO 15145021 <GO>}

And what do you think the market's going to look like? And this is more of a pricing question. But once we see multiple generics of Xyrem by 2026, how do you see net realized price playing out, do yoou envision pressure on brand products?

A - Gregory Divis {BIO 16183530 <GO>}

FINAL

Yeah. I mean, first and foremost, I always have to remind myself that generics in that period of time would be for the twice nightly oxybates. And clearly, payers will use any opportunity they have to sort of leverage pricing. But I guess a couple of quick things, one, we don't really don't really sort of see payers forcing patients to do anything unusual if they're doing well on a one slightly oxybate.

The smallest segment will be the de novo patients. So we're going to work with the payers. So will there be some pressures? The answer is yes. But we're going to keep working with the payers in anticipation of that when that does occur.

A - David Amsellem {BIO 15145021 <GO>}

Okay. And then in the less than a minute we have left, wanted to get your thoughts on potential expansion opportunities, idiopathic hypersomnia is an obvious one. Xywav has had some early success. What is the likelihood that eventually you'll do a study in IH?

A - Gregory Divis {BIO 16183530 <GO>}

Well, based upon the demand from the scientific community in the narcolepsy field which is very high and a lot of interest to want to study LUMRYZ in IH, I think it's fair to say that as we clear the regulatory hurdles and come to market that's on our planning horizon as part of our lifecycle management strategy.

A - David Amsellem {BIO 15145021 <GO>}

Got it.

Okay. Well we're just about out of time. Thanks so much guys for joining us and thanks for you in the audience.

A - Gregory Divis {BIO 16183530 <GO>}

Thank you.

A - David Amsellem {BIO 15145021 <GO>}

All right.

Bloomberg Transcript

This transcript may not be 100 percent accurate and may contain misspellings and other inaccuracies. This transcript is provided "as is", without express or implied warranties of any kind. Bloomberg retains all rights to this transcript and provides it solely for your personal, non-commercial use. Bloomberg, its suppliers and third-party agents shall have no liability for errors in this transcript or for lost profits, losses, or direct, indirect, incidental, consequential, special or punitive damages in connection with the furnishing, performance or use of such transcript. Neither the information nor any opinion expressed in this transcript constitutes a solicitation of the purchase or sale of securities or commodities. Any opinion expressed in the transcript does not necessarily

reflect the views of Bloomberg LP. © COPYRIGHT 2022, BLOOMBERG LP. All rights reserved. Any reproduction, redistribution or retransmission is expressly prohibited.

FINAL

Bloomberg Transcript