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EDITED TRANSCRIPT

HZNP.OQ - Horizon Therapeutics PLC To Discuss TEPEZZA Supply Disruption Call

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OVERVIEW:

Co. reported on 12/17/20 that it expects short-term disruption in the supply of TEPEZZA, its biologic medicine for the treatment of Thyroid Eye Disease (TED), due to government-mandated COVID-19 vaccine production orders related to recent Operation Warp Speed.

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CORPORATE PARTICIPANTS

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PRESENTATION

Operator

Good morning, and thank you for standing by. Welcome to the Horizon Therapeutics Conference Call. (Operator Instructions) As a reminder, today's conference call is being recorded.

I would now like to introduce Ms. Tina Ventura, Senior Vice President of Investor Relations.

Tina E. Ventura - *Horizon Therapeutics Public Limited Company - SVP of IR*

Thank you, Josh. Good morning, everyone, and thank you for joining us. On the call with me today are Tim Walbert, Chairman, President and Chief Executive Officer; Paul Hoelscher, Executive Vice President, Chief Financial Officer; and Andy Pasternak, Executive Vice President, Chief Strategy Officer. Tim will discuss the announcement we made this morning on TEPEZZA supply, after which, we'll take your questions.

As a reminder, during today's call, we'll be making certain forward-looking statements, including statements about product supply, financial projections, development activities and the expected timing and impact of future events. Our actual results could differ materially due to a number of factors, including the extent, duration and impact of supply disruption as well as other factors outlined in our latest Form 10-Q and the 8-K we filed this morning with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, and Horizon disclaims any obligation to update such statements.

In addition, on today's conference call, non-GAAP financial measures will be used. These non-GAAP financial measures are reconciled with the comparable GAAP financial measures in our latest earnings press release and other filings that are available on our investor website at www.horizontherapeutics.com.

I'll now turn the call over to Tim.

Timothy P. Walbert - *Horizon Therapeutics Public Limited Company - Chairman, President & CEO*

Thank you, Tina, and good morning, everyone. This morning, we announced that we expect a short-term disruption in the supply of TEPEZZA, which is our biologic medicine for the treatment of Thyroid Eye Disease, or TED. This is due to recent Operation Warp Speed government-mandated COVID-19 vaccine production orders. We currently anticipate that this drug supply shortage will begin at the end of December and could last through the first quarter.

Let me provide some additional context regarding what has taken place at Catalent, our contract manufacturer for drug product. Catalent fills and finishes vials for TEPEZZA as it does for any other injectable and infused medicines or vaccines. Operation Warp Speed per its authority provided by the Defense Production Act of 1950, recently ordered the prioritization of certain COVID-19 vaccine manufacturing, which resulted in the cancellation of previously guaranteed and contracted TEPEZZA drug product manufacturing lots in December. This was done so that manufacturing capacity could be instead used at Catalent for government-mandated orders to produce COVID-19 vaccine.

However, these manufacturing runs were required for us to maintain TEPEZZA supply for current demand as well as build inventory. After being informed of Operation Warp Speed mandate a few weeks ago, we quickly identified ways to potentially meet demand for existing patients. To offset the reduced slots allowed by Operation Warp Speed and Catalent, we accelerated our ongoing plan to increase the production scale of TEPEZZA drug product. In fact, as a result, Catalent was able to provide us one manufacturing slot this month, which began earlier this week.

With only one slot projected per month for the first quarter, we need increased scale manufacturing to meet patient demand versus the current several lots per month, which we have been producing at initial approved scale. As a result of this increased scale, we will need FDA approval of this lot, and we will be submitting analysis and data from this lot to the FDA in January for their review and approval.

The FDA has agreed to allow us to submit data on a rolling basis and indicated they will work with us to minimize drug shortage. Ultimately, the length of the TEPEZZA supply disruption will depend on whether this and future manufacturing slots are successfully completed at this increased scale as well as the decision by the FDA regarding this increased scale manufacturing process for TEPEZZA.

Additionally, we have been working with multiple government agencies to share the significant impact this drug shortage will have on patients and do everything in our power to mitigate this disruption. These organizations include the FDA Commissioner's Office; Senior Leadership of the FDA Center for drug Evaluation and Research or CDER; the Office of New Drugs within CDER; the Division of Ophthalmology within CDER; the FDA Drug Shortage Staff; the FDA Office of Pharmaceutical Quality; the FDA Office of Pharmaceutical Manufacturing Assessment; the Secretary of Health and Human Services Office; Operation Warp Speed; the HHS Assistant Secretary for Preparedness and response; BARDA; the Executive Office of the President; and the Office of the Vice President.

While working -- continuing to work closely with many of these organizations, particularly the FDA and Operation Warp Speed, to limit the length of the disruption and accelerate the availability of TEPEZZA supply, at this point, we needed to inform patients and physicians about the upcoming supply disruption. As things stand today, patients currently on TEPEZZA will be impacted and will need to temporarily stop their TEPEZZA treatment when the current supply runs out at the end of this month.

Treatment for new patients planning to start to TEPEZZA will be delayed. As we resume supply, our priority will be to enable patients who are already on treatment to resume therapy as quickly as possible. We're encouraging patients to reach out to their physicians to discuss how to manage their Thyroid Eye Disease during this time period, and we will be communicating with physicians and patients throughout this disruption via our patient services organization.

We launched TEPEZZA in January of this year. It's the first and importantly, the only approved treatment for Thyroid Eye Disease. This is why today's news is particularly disappointing. There are no other approved treatments available for these patients. Given the severity of this disease, the significant patient need and the dramatic efficacy profile of this medicine, the demand for TEPEZZA was substantially higher than our original expectations.

Before TRAPEZA received approval, we worked extensively to increase the production of TEPEZZA to meet demand levels significantly above our expectations. Securing significant additional batches of drug substance with our contract manufacturer, AGC Biologics and fill/finish slots with

Catalent for drug product. Up until these manufacturing slots at Catalent were canceled as a result of Operation Wrap Speed actions, we have sufficient drug product supply to meet current demand and continue to build inventory. We also understand that Catalent is setting up a new drug product manufacturing line, which it expects to have live in April to accommodate COVID-19 vaccine production that should further alleviate supply constraints.

We're also continuing to progress towards the planned addition of another product contract manufacturer in the second half of 2021. We initiated this process in the first quarter of this year. We are delaying the start of our TEPEZZA chronic TED trial as well as our TEPEZZA exploratory trial in diffuse cutaneous systemic sclerosis. We currently expect to begin these trials in the second quarter of 2021, assuming supply is back to normalized levels. If the chronic TED trial is initiated in the second quarter of 2021, we would continue to expect data readout in the first quarter of 2022.

As we noted in our release this morning, as a company, we're in extremely strong financial position with significant liquidity. We expect to have more than $2 billion in cash and cash equivalents at the end of this year. Given our current debt position of approximately $1 billion, this would result in a net cash position of more than $1 billion at year-end.

We do not expect the TEPEZZA supply disruption to impact the full year 2020 guidance we provided on our third quarter call, including our previously announced TEPEZZA full year net sales guidance of greater than $800 million. We do anticipate an impact to TEPEZZA net sales in 2021, given that we will not be able to supply TEPEZZA to the market at the start of the year.

As per our normal process, we plan to issue full year 2021 guidance when we report fourth quarter 2020 results and would at the time expect to have additional information regarding TEPEZZA supply. We certainly appreciate the efforts of Operation Warp Speed and the administration are taking to accelerate COVID-19 vaccine production to save lives and put an end to this pandemic.

At Horizon, we are committed to putting patients first and foremost. And in this respect, we are very pleased that COVID-19 vaccines will soon be available for the millions of people around the world who need them. At the same time, the impact of supply disruption will have on patients with TED is significant, particularly given the debilitating nature of this disease. We will do everything possible to provide support for TED patients and their physicians during the short-term disruption.

I will now open the call up for questions.

Tina E. Ventura - *Horizon Therapeutics Public Limited Company - SVP of IR*

Josh, please go ahead.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Chris Schott with JPMorgan.

Christopher Thomas Schott - *JPMorgan Chase & Co, Research Division - Senior Analyst*

Great. Just a little bit more color about the magnitude of the capacity impact only having the single slot would have on volumes of TEPEZZA in 1Q. I guess just trying to get a sense of how much product can you still make in this environment where you're not getting the capacity that you need?

And then maybe my follow-up to that is you mentioned that some patients are going to have to pause therapy. What does that do in terms of the progression of the treatment or the disease to the patient? So if somebody has to miss a few -- a month or 2 of therapy, do they have just start from

scratch? Or can they just pick up therapy and they won't see disease regression? I'm just trying to get a sense of what that actually practically means to the patients who are affected by this.

Timothy P. Walbert - *Horizon Therapeutics Public Limited Company - Chairman, President & CEO*

Thanks, Chris. So as far as impact to patients, we do not have data on stopping patients early in their treatment as this will happen here. So we're going to refer patients to their physicians. And certainly, if their physician feels appropriate to restart them on TEPEZZA that will be at their discretion, but we just don't have data on this, and it really depends where an individual patient is in their treatment course.

Relative to the situation, as I said, all of our lots were canceled for the month of December, and we have been doing a number of them every month to stay ahead of our supply and build inventory. We worked with Catalent and Operation Warp Speed to get the lot added, but one lot at the scale we have been doing many lots per month wouldn't meet supply needs. So we are increasing scale so that each lot would be essentially close to the equivalent of the many lots we typically produce in a month. And as a result of that increased scale, we need FDA approval. So we'll submit that data in January and hopefully have an expeditious review and be able to get to the market as soon as possible to end this disruption.

Operator

Our next question comes from Gary Nachman with BMO Capital Markets.

Rafay Sardar - *BMO Capital Markets Equity Research - Associate*

It's Rafay Sardar on for Gary. What kind of messaging will the sales force be communicating to physicians? Will physicians will be able to complete patient enrollment forms for new patients?

Timothy P. Walbert - *Horizon Therapeutics Public Limited Company - Chairman, President & CEO*

Thanks for the question. Our sales force will be communicating with them in the next hour or so. And because of the typical process that can take up to 60 to 90 days to get patients from patient enrollment form through to infusion. We will continue to build that database of patients who will be able to sequence on to TEPEZZA upon ending this drug shortage. So that process, we expect to continue.

Operator

Our next question comes from David Amsellem with Piper Sandler.

David A. Amsellem - *Piper Sandler & Co., Research Division - MD & Senior Research Analyst*

So I guess one question is, Tim, are you aware of this happening with any other biologic products? Is this something that you think is unique to TEPEZZA? And then specifically with patients with chronic TED, given the chronic nature of the condition, do you expect that the largest impact what we felt in terms of uptake in that population, again, given that there's there was sensibly less of a sense of urgency in terms of treating the inactive population? How should we think about that?

Timothy P. Walbert - *Horizon Therapeutics Public Limited Company - Chairman, President & CEO*

Thank you, David. As far as patients with chronic or acute disease, I don't know that this will impact any group differently. I think we will make sure to communicate with these patients and also awaiting treatment. And if a physician believes that they can benefit from TEPEZZA will work to help them get medicine as soon as we end this disruption.

To your other point, based on a variety of discussions we've had over the last few weeks, we do hear that there are other potential medicines impacted, but we don't have any specific details on that.

Operator

Our next question comes from David Risinger with Morgan Stanley.

David Reed Risinger - *Morgan Stanley, Research Division - MD in Equity Research and United States Pharmaceuticals Analyst*

So I have 2 questions. First, could you just discuss manufacturing slots in a little bit more detail, including -- as you work to address this situation, what will dictate whether an individual manufacturing slot is successfully completed? And then what your target might be for the number of slots, I don't know, in, let's call it, 3 to 6 months?

And then the second question is, does your contract with Catalent allow Horizon to receive financial restitution?

Timothy P. Walbert - *Horizon Therapeutics Public Limited Company - Chairman, President & CEO*

Sure, David. Thanks for your comments. As I said, with Operation Warp Speed, they're operating under the drug act of -- or the Defense Act of 1950, and we reviewed that and that does supersede our contract, at least based on a review. But obviously, we're all focused on helping patients get a COVID vaccine as fast as possible. So we're not really focused on recovering costs but getting medicine to patients first.

To your question around slots completed, we have been able to work with Catalent to get a slot underway now and be able to hopefully get at least one slot per month in the first quarter. And with the increased scale, we believe we'd be in a position to meet patient demand.

As we look at Q2 and beyond, we believe we'll be back to an acceptable level of manufacturing slots and overall vials produced to meet our expectations that we have for 2021. And as I said earlier, Catalent has been working on a second line, which they publicly disclosed, they expect to have done in April or by April. And that high-speed line would be dedicated to vaccine, COVID-19 vaccine production, which would alleviate some of the supply constraints that we're facing right now. So we feel comfortable that we will be able to get back to allowing for supply in that time period.

Operator

Next question comes from Jason Gerberry with Bank of America.

Jason Matthew Gerberry - *BofA Merrill Lynch, Research Division - MD in US Equity Research*

My question is specifically kind of 2Q plus the ability to realize a catch-up. Is it possible given the limited window to treat these patients with acute moderate to severe TED? Or would the capacity be a constraint coming out and time frame to "normalization?"

And what I'm wondering, too, is for those patients who would have been new starts in 1Q, is there a risk that they missed their window for treatment? I'm just curious if you can comment on those dynamics and the potential for catch up if the manufacturing situation resolves expediently.

Timothy P. Walbert - *Horizon Therapeutics Public Limited Company - Chairman, President & CEO*

Sure. Well, as we know, on average, these patients are in the acute phase for 2 years. So we don't believe that will -- a short delay like this will impact those dynamics. As far as catch up, we do believe we'll be able to catch up patients that are -- have been on therapy and the physician decides

they should restart therapy and sequence in new patients and meet demand based on the plans we have in place. So we do believe that we'll be able to catch up those patients' physicians determine are appropriate to restart treatment as well as meet the incremental demand based on the plans we have in place today.

Operator

Our next question comes from Ken Cacciatore with Cowen.

Kenneth Charles Cacciatore - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

Tim, some of the patients that you originally started clearly are coming off of treatment. So it sounds like even though you were having some roll off still couldn't manufacture enough. So I just want to talk about that kind of transition of some stopping and more starting back to your supply situation?

And then also on the second manufacturer, can you just clarify again and give us a little more detail on where they stand and timing and any disclosures around who this is? Or any nuance around when they could be up and running?

Timothy P. Walbert - *Horizon Therapeutics Public Limited Company - Chairman, President & CEO*

Sure. So for the second manufacturer, we started in the first quarter, working with them and got a contract in place and have been working to really map out that process. Typically, that takes a few years to get through. We believe that based on where we are at this point, we could have that second manufacturer on board by the second half of 2021. Obviously, we're working to see where we could accelerate those time lines. We've been working for about -- almost a full year through that process right now. So I don't know if that -- I just don't know that the contract of that specific company has been allowed us to disclose their name, but it's a major contract manufacturer. So that process has been underway.

I think on the -- what was the first question? Can you remind me? Or Ken, what was your first question?

Kenneth Charles Cacciatore - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

Yes. Sure, Tim. Patients are coming off, and there has been concern that the enrollments weren't that strong. So just trying to understand the push and pull of supply freeing up.

Timothy P. Walbert - *Horizon Therapeutics Public Limited Company - Chairman, President & CEO*

Well, our enrollments have been as strong as ever, and there's been significant new starts and significant demand for TEPEZZA continuing in the face of this second resurge of COVID-19. So as we said, we had a few thousand patients on drug as of last -- at the end of the third quarter. So there's under 2,000 patients that would be impacted by this drug shortage, all patients that are in the queue, which are a substantial number of patients, we will work with them, communicate with them and sequence them to begin treatment once we've resolved the supply situation.

Kenneth Charles Cacciatore - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

And Tim, you mentioned a lot of different organizations at least in the administration and the FDA that you're trying to communicate with. Has there been good communication back already? Is there good engagement on trying to help, specifically, you all solve this problem?

Timothy P. Walbert - *Horizon Therapeutics Public Limited Company - Chairman, President & CEO*

Absolutely. We've felt what pretty much every aspect of the government and administration. And I think people certainly understand the situation and FDA specifically, certainly understands the situation. I've had personal interactions with senior leadership, and they have indicated a strong willingness to work with us and have demonstrated that by agreeing to allow us to significantly increase scale and allow us to submit data on a rolling basis and then review this once it gets in on an expedited fashion.

So I think everyone here has been really favorable to in understanding and empathetic of the situation at hand. While understanding that we've got thousands of people dying every day from COVID-19. And the priority is to get the -- as you saw, the Vice President was at Catalent on Tuesday with the Moderna team and scaling up that vaccine production is a priority for the country in the world. And with that context, everyone certainly understands our situation and are going to work with us to ensure we get back to supply as soon as possible.

So I think everyone understands the situation and has been really empathetic in responding to us. I've been really impressed with the level of engagement across all the different constituents I mentioned in my comments.

Operator

Thank you. Our next question comes from Annabel Samimy with Stifel.

Annabel Eva Samimy - *Stifel, Nicolaus & Company, Incorporated, Research Division - MD*

Just really quickly, just wanted to understand if you're going to be reporting data on patients stopping treatment early? Or is this going to -- do you get a sense that this may cause a number of physicians to start experimenting with patients stopping treatment early, given the very strong effect that you have initially and going forward, right?

Timothy P. Walbert - *Horizon Therapeutics Public Limited Company - Chairman, President & CEO*

Sure. Thanks, Annabel. We don't expect physicians to routinely use the drug for a short period of time. The data demonstrated in Phase III and subsequent extension data clearly show patients continue to improve over a full 6 months of therapy. And as a result, we don't see that changing. That's the optimal course of treatment. That's what the treatment course is defined in our approval, and we expect physicians to continue to use that course of treatment.

Annabel Eva Samimy - *Stifel, Nicolaus & Company, Incorporated, Research Division - MD*

Will you be reporting on any of those patients that they did stop treatment early?

Timothy P. Walbert - *Horizon Therapeutics Public Limited Company - Chairman, President & CEO*

Again, we don't have access to those patients. They're being treated by their physicians. They're not in any particular protocol. So we would not, other than any spontaneous reporting that would come in through our safety organization or otherwise, we would not have access to that information. Certainly, we'll be working with all the prescribers and providing them support to their patients to communicate clearly with them to make sure that if they determine they should be restarted that we'll work through that process. But that's the information we have at this point in time.

Tina E. Ventura - *Horizon Therapeutics Public Limited Company - SVP of IR*

Thanks, Annabel. And Josh, it looks like we have time for one more question, please.

Operator

Our last question comes from Dana Flanders with Guggenheim.

Dana Carver Flanders - *Guggenheim Securities, LLC, Research Division - Senior Analyst*

Great. TIm, have you already brought on the additional sales reps? And maybe talk a little bit about your thoughts on marketing spend behind TEPEZZA into 1Q. Is there a potential for you to try to align that with when supply fully comes back on? Or given this is likely to be short-term in nature, that's not really part of the current thinking?

Timothy P. Walbert - *Horizon Therapeutics Public Limited Company - Chairman, President & CEO*

Dana, thanks. Really good question here. So I think most all of our -- if not all of our sales reps and expansion, patient support folks and reimbursement specialists are hired and are going through training and will be up and ready as we get into the first quarter.

As we said, this is a short-term supply situation. We will continue to aggressively market and make sure that patients are aware of thyroid eye disease. We have DTC up and running that committed spend. So that's not something as short term. We could pull back or would necessarily pull back. We see this resolving in the short term, and we'll look to get back to driving the significant growth we've been driving with TEPEZZA.

So our plans are to continue to drive the business forward. This is an unfortunate short term situation, obviously, driven for good reason with the COVID-19 vaccines being taking precedent. Obviously, it's very disappointing, but this is one of those few situations where something like this happens, it's unfortunate. We're going to be fine. Patients are going to hopefully have a minimal period of time as we work through this disruption. And the focus is on saving lives with the COVID-19 vaccine. We support that, and we will work through this situation aggressively to get patients back on to TEPEZZA.

Tina E. Ventura - *Horizon Therapeutics Public Limited Company - SVP of IR*

Thank you, Dana. And Josh, thank you. This concludes our call this morning. A replay of this call and webcast will be available in approximately 2 hours. Thanks for joining us.

Operator

Thank you. Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect.