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ONCO.ST - Q2 2021 Oncopeptides AB Earnings Call

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PRESENTATION

Operator

Welcome to the Oncopeptides Audiocast with teleconference Q2 2021. (Operator Instructions)

Today, I am pleased to present Marty Duvall, CEO. Please go ahead with your meeting.

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Good morning, and thanks for listening to the Oncopeptides Q2 webcast. It's been a pivotal quarter for us, and we're at an important inflection point for the company. In 2021, we've experienced some dramatic swings in our market price from a high of SEK 215 to the lows of the past week. But through it all, there's been one constant and that constant is confidence, our one Oncopeptides team confidence, confidence in our platform, confidence in our lead drug, confidence in our data, confidence in the hope that we bring to patients and confidence in one another. Following an encouraging launch of Pepaxto in the United States, the challenge in the second half of 2021 will be reaching common ground with regulatory bodies, the FDA, in particular, on the strength of our pivotal Phase III OCEAN trial.

Now, let's look at the specifics of our Q2 performance, if we can flip to Slide 2. So joining me on the call today are Dr. Klaas Bakker, our Chief Medical Officer; and Anders Martin- Löf, our Chief Financial Officer. On Slide 3, I remind that I will be making forward-looking statements and ask you to please consult some of our filings for appropriate balance.

Now switching to Slide 4. On Slide 4 are the key takeaway messages for this call. First of all, this is our first full quarter with revenue, and we're excited about the revenue that has been generated. There's extremely strong interest in Pepaxto among health care professionals and hundreds of patients have already received and are receiving our drug for the treatment of their refractory multiple myeloma. As you will see, when we look at the details, there is double-digit demand growth on a month-to-month basis. You see our Q2 net sales of $7.2 million or SEK 66.4 million, and year-to-date net sales, which includes those first 2 weeks of mid-March at around USD10.2 million and SEK 85.7 million.

Third major point here is our updated OCEAN data. So this was a big quarter for the OCEAN trial and data. And just a reminder, head-to-head versus pomalidomide, and here we see melflufen or melphalan flufenamide, demonstrating superiority on the primary endpoint of progression-free survival. And in the intent-to-treat population, we see consistent data on the strong activity of our drug with respect to objective response, depth of response and duration of response. But as a reminder, on the secondary endpoint of overall survival, there was a slight favor for pomalidomide in that intent-to-treat population. And we'll give -- provide a little bit more color around that, but also look forward to the IMW meeting in September, where our late-breaking abstract on the OCEAN data has been accepted for an oral presentation. And at that point, we'll be able to provide more of the data and more of the specifics behind our excitement on that data.

And finally, we are progressing on key work streams related to the partial clinical hold and the key here is establishing that common ground with the FDA on the interpretation of the OCEAN data and the impact that it will have on the development and commercialization going forward, and we're confident that this data points to patient population of high unmet needs that may benefit from Pepaxto therapy.

So now, I'll provide some more specifics on the commercialization, if you can flip through to Slide 6. So this is just a reminder on our accelerated approval, which occurred on February 26, patients of high unmet need of refractory, triple refractory patient population who have received at least 4 prior lines of therapy. We've talked about the high unmet need of this population and the fact that 41% in the subset from the HORIZON study at extramedullary disease and commercial drug was shipped to patients beginning on March 15. So this label remains unchanged as we continue our commercialization efforts in the U.S.

Next slide, please, Slide 7. So we outlined in previous calls, our strategy for the development and commercialization of Pepaxto. And I'm happy to say, and I think you'll see in the numbers that this strategy is playing out. We hope to become a foundational treatment in relapsed/refractory multiple myeloma. In the treatment of today, we see a lot of recycling of the old classes, those triple classes, the IMIDs, the PIs and the CD-38s. And our strategy is looking forward to a future where drugs with new mechanisms of action, such as our peptide drug conjugate, Pepaxto, gain increasing share, and we stopped the recycling of the old classes, which really was the premise behind the OCEAN study. So the 2-pronged strategic approach is on the right hand side of the slide. One is to become a treatment of choice for appropriate and indicated patients, looking at those that are specifically labeled in the triple-class refractory populate. While secondarily, expanding the market for the new mechanisms of action and minimize the recycling of failed drug classes.

Let's flip to Slide 8. So we are off to a strong start through the first full quarter of commercialization on some of the revenue metrics, top line numbers, $10.2 million in net sales from that mid-March to the end of June time frame, we had reported at our Q1 call, which stretched into April that we had about 100 accounts, we've doubled that in the following 2 months, so approximately 200 unique accounts that are using Pepaxto through Q2. And we shipped approximately 1,200 20 milligram vials during that time period. As it relates to our activity and field metrics, we continue to focus on top tier customers. Our reach is over 90%, and now we're improving on our frequency number in terms of calling on those most productive customers. Our customer awareness has exceeded the 90% mark, and our payer coverage continues to be at 97%, so very strong.

Let's flip to Slide 9. So on Slide 9, I thought I'd give a little bit more flavor to this double-digit growth and accelerating demand. And in this case, we've also chosen to provide more detail on July. So this represents in blue, the monthly pull-through into customer accounts on a monthly basis. And what you see through the March to April, May, June, July time frame, is double-digit growth on a month-to-month basis. And as indicated, the jump from June to July is particularly impressive with a 32% jump in demand with 456 vials of Pepaxto shift to our end users in the month of July. Now of course, with the FDA safety communication, it will be difficult for us to comment on what happens from here. But certainly, I think these early indicators suggest that there is an unmet need for the product that is growing, that the commercialization to date has been well received and that we are helping patients in the United States with our product.

Flipping to Slide 10. I want to take a look at this on a column by column basis. Overall headline here is that we are gaining market share on our key competitors and specifically where we're indicated after 4 lines of therapy or after 4 prior therapies, which is the fifth line plus multiple myeloma market. But on the left-hand side, we have quarterly revenue as it's been projected and announced by competitors in the triple class refractory population. And obviously, our entry in Q1 2021 with $2 million, we see the revenue for both XPOVIO and BLENREP. But stepping forward to Q2 of 2021, I'd point out 2 things here and relate back to the strategy. #1, here, we see that the quarterly net revenue for these 3 products that are indicated for triple-class refractory population is growing. So we have helped to fuel this growth of new mechanism of action use and the stopping of the recycling of classes. We also see that BLENREP is level from a quarter-to-quarter basis, and we see a slight drop from XPOVIO. So we are in the beginning, we believe to have an impact in being a leading product in that fifth line plus population.

So in the middle, let's keep in mind the key revenue drivers as it relates to each of these products. So in this case, Pepaxto, down at the bottom, is the lower on the pricing side from a comparison and that was done specifically as we priced in the U.S. market closer to pomalidomide, given our ambition relating to the OCEAN trial. And we are only approved in fifth line plus as a doublet or a single agent approval, whereas product BLENREP as an example, higher price, yes, it is labeled for fifth line plus, but it's also labeled in earlier lines of therapy. And as for XPOVIO, it not only has the fifth line plus indication, but an indication in earlier lines of therapy. It also has a triplet label in combination with bortezomib and also utilization outside of multiple myeloma that has been approved at a higher price.

So on the right-hand side of the slide, as we look specifically at new patient share among these key competitors in that fifth line plus population, we see Pepaxto becoming a leading product where indicated in this marketplace.

Let's flip forward to Slide 11. We believe Pepaxto is well positioned for community-based care and an important reminder here that it's about that doublet use that is critical here. We feel in the community setting and here, you see some of that data by line of therapy as we move from first line to second line to third line, fourth line, fifth line, we see an increasing use of doublet therapy, the place that we're going to play. So we have efficacy in later lines of therapy, we have a manageable safety profile given our current package insert and this convenient administration and better compliance play very well in the community-based setting. And on the right-hand side of the slide, continue to and pleased to report our continued update in both community and academic centers with 66% of those 200 -- approximately 200 accounts being in that important community setting, but also having the support and growing support in the academic marketplace.

Let's switch to Slide 12. In this slide, just highlighting for you some of the leading academic centers and community practices that make up those 200 unique accounts that have ordered Pepaxto through June. So we see the addition of many important and prestigious multiple myeloma centers and community practices across the United States who are now using Pepaxto.

So flipping to Slide 13. Also pleased to report that we now have a permanent J-code for Pepaxto that will be effective in the fourth quarter. So this replaces a miscellaneous J-code or hospital C-code that have been utilized to date. And this has great benefit to our customers, specifically now, it's reducing billing and coding errors, decreasing time to reimbursement, ensuring more accurate reimbursement from payers. And the net-net here is, increasing confidence amongst our providers that Pepaxto will be reimbursed, which is particularly important in the community oncology offices and centers.

On the next slide, Slide 14, just a brief comment here on Europe. We have the timeline that we have provided in prior calls, and I'd like to call out August 15th, and on that date, at the top of the slide we see that we have received the day 80 assessment report from the rapporteur. And I'm pleased to report, while there are a lot of questions and we, overall, feel that they are quite addressable and are pleased to report that we feel we are on track as it relates to the EMA review of the Pepaxto approval with a continued target of potential launch of Pepaxto in Europe. In the second quarter of 2022. On our end, we had started a build-up, as you recall, in March of 2021, with the addition of our commercial and medical leadership, and now we're focused on country of first launch in setting up a German legal entity in Germany and beginning our efforts to prepare for the launch of Pepaxto in Europe and Germany specifically.

Now let's turn to Slide 15. I just wanted to mention now the FDA safety notification that was proposed on July 28, this is in addition to the partial clinical hold that had been announced earlier in the month. So this is in the backdrop of that growing demand trend that we saw in the United States market. And just want to reiterate that we take seriously this FDA alert and just as a reminder, this is on the overall survival results in the intent-to-treat population. As you look at the details on the right-hand side of the panel. As a reminder, hazard ratio was 1.104, which is suggesting about a 10% detriment in the intent-to-treat population that actually favors pomalidomide. And I just want to convey a little bit more information here regarding this is early as it relates to the overall survival and is not statistically significant, but of course, patient safety is significant, and we take it seriously. From the standpoint of the trial overall, we believe the data that will come out at the IMW will support the fact that there are populations that can greatly benefit from Pepaxto and that the overall positive result in the progression-free survival primary endpoint pull-through into some patient subsets where we see a very strong result for our drug.

So with that, I'm going to turn it over to Dr. Klaas Bakker, to talk about our clinical studies and other activities on the medical affairs and clinical development side. Klaas?

Klaas Bakker - *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

Yes. Thank you, Marty, and good morning, good afternoon, everyone, on the call. And I would like to flip to Slide #17 for a quick recap of the OCEAN top line results, which we presented earlier. It's very important to state that this study met its primary endpoint as per IRC assessment. We had a superior progression-free survival under a spa, special protocol assistance with the FDA, which will be an important driver of ongoing communication with the agency.

As Marty already mentioned, overall response rate higher for melflufen when compared to pomalidomide. The secondary endpoint, the overall survival hazard ratio of 1.104 favoring pomalidomide in the intent-to-treat population, and I've put some emphasis on the intent-to-treat population because at IMW, we will be able to give some more flavor of that result. But I would like to repeat what Marty said, and that is that we have confidence that when people see the data, there will be a much better understanding of this overall survival hazard ratios and it is also important to understand that the FDA needs to take its responsibility when they see a certain hazard ratio above a threshold that that triggers certain actions. And that is what we see and that is before the agency has been able to do a rough review of all the data. And this is exactly what Marty mentioned, safety first, then you look at the data. Since we have strong belief in the data, we feel very confident that in the end, will play out, and in particular, for a very, very important sector of patients.

Now on the clinical hold, the partial clinical hold that the FDA issued and it's important to mention that this is a partial clinical hold, which means that patients who are on treatment already can stay on treatment provided that they have been reconsented. This goes through our complete clinical program on melflufen, and you'll see the studies mentioned. On top of that, we have a full clinical hold that we already put in place ourselves before the FDA asked us on our OPD5 program. No patients were enrolled yet, but we felt with the data in the OCEAN study that of course needs to be reconsidered. And that is something that we are considering and even already initiated before the FDA asked us to do so.

I'd also like to give you some flavor on the partial clinical hold and the implication so far. So of all the patients on clinical trials, all but 2 patients have reconsented to continue. And this is, of course, largely driven by their individual health care provider, but we feel very confident given that nearly all patients stayed on track that both patients and health care providers feel confident that the patient is deriving a positive effect from this drug with a positive benefit risk ratio. Important to note that these trials are among also earlier lines of treatment.

Regarding the interactions with the FDA on the clinical hold, we have key work streams ongoing, what that means is that we are providing a package to the agency in the coming months where we address the concerns and come forward with a part to reopening our clinical studies. And I'm very pleased to mention that we, from our side, are making nice progress on that work, but that is, of course, also dependent on the interaction with the agency. We appreciate that there is uncertainty and there is a range of outcomes with the full FDA review of OCEAN trial. Of note, the FDA has all the raw data set has all the materials, so the agency is also doing their own review alongside our review and the interaction that we have.

So first, there is a scenario that the OCEAN data review will result in an extended label that includes the third and fourth line, which is basically mirroring the foundational label, which would have been the case with a very clean and consistent study where the OS would have moved in the same direction. That's still a possibility, but that depends on how we interpret the data together with the FDA. The second scenario is that the OCEAN data is viewed as so-called hypothesis generating, which means there is a very positive signal that needs to be reconfirmed in our clinical development program, while we can continue to promote in our indications today. This is not an unlikely scenario, as you want to see a confirmation of a signal in a study. It's all about how strong is the signal, and this is where we feel very confident that we have a good path forward there. Of course, there also is a and we consider this a low likelihood, and I'd like to emphasize that, but it could be that the OCEAN data results in general in a level of concern around the overall survival that challenges the continued accelerated approval of Pepaxto. Now this is a worst-case scenario, where we, as I said earlier, feel confident that this, in the end, won't happen. But of course, we cannot exclude that scenario.

On top of that, the FDA may hold a future public meeting to discuss melflufen. We haven't and we cannot share any information on that as of today, but normally, the FDA gives notice to such a meeting approximately 30 days in advance of a meeting.

So taking a look at Slide #20, where we have the detailed timeline for the upcoming events. And this is the timeline around OCEAN, where the data releases on the very left, and we then move through 2021, where we released the final IRC results in July 8 and the FDA safety alert on July 28. I'm very pleased, as Marty also mentioned to report that we will present the data in Vienna during the IMW workshop, where we will shed a lot more light on the OCEAN study, and in particular, also the overall survival result because we really would like to share the overall survival data and what's believing. So stay tuned for that. In advance of the IMW meeting, there may be an abstract or there will be an abstract actually that will be made public on the 27th of August, but I would like to remind everyone that an abstract has only a limited number of characters that can be put into the abstract as such, don't expect too much details around the efficacy results in that abstract simply because there is no space for more information.

Let's go to the next slide, Slide #21. The IMW Oncopeptides is a platinum sponsor, we will have high visibility there, we will interact a lot, we have a lot of interactions planned around our clinical data, and we will discuss our data also at a symposium to make sure that we get the most inputs from a clinical perspective on our data. And as mentioned, stay tuned for that, we are very much looking forward there to share the data and following up, of course, with the investor community to talk in more depth about the data.

With that, I would like to turn it over to Anders Martin-Löf, our CFO.

Anders Martin-Löf - *Oncopeptides AB (publ) - Deputy CEO & CFO*

Thank you, Klaas. If we then turn to Slide #23, I'll go through the numbers for the period. As you see, the revenues for the first half of the year amounted to SEK 85.7 million or $10.2 million, as Marty already mentioned, and SEK 66.4 million for the second quarter. This presence of revenues means that our operating loss has now started to decrease slightly for the first half of the year to SEK 692 million, but quite significantly for the second quarter, going down to SEK 345 million from SEK 399 million in the last -- in 2020. And on the left-hand side, you see that we are seeing quite a shift in our cost base now. The R&D costs for the first half of the year went down from SEK 441 million last year to SEK 346 million in 2021 and on the other hand, the marketing and sales costs increased from SEK 149 million to SEK 383 million. So this is the first time when the marketing and sales costs are actually higher than R&D costs, and that's a trend that I think is likely to continue.

R&D costs went down quarter-by-quarter, it was SEK 179 million in the first quarter and SEK 167 million in the second quarter. This is mostly driven by the fact that our OCEAN study is now coming closer to the end. So last year, for the first half of the year, we spent roughly SEK 177 million on OCEAN, and this year was SEK 78 million, so SEK 100 million less on OCEAN in the first half of the year. The marketing and sales growth is, of course, coming from the fact that we have built in the entire U.S. organization and are also now starting to build a little bit in Europe as well. So that the majority of the increase comes from the U.S. organization, which almost tripled in size from the end of the second quarter last year to the end of the second quarter this year.

Cash flow was negative of SEK 733 million for the first half of the year and SEK 347 million for the second quarter. The quarterly negative cash flow actually decreased quite a bit from the first quarter, so we have a negative SEK 387 million for the first quarter and now it's down to SEK 347 million. So a positive trend there as well. At the end of June, the cash position was roughly SEK 1 billion. On top of that, we have a EUR40 million loan facility from the EIB that we have not utilized. I should also mention that due to the uncertainty with the FDA situation, we are, of course, being very prudent and are working with measures to implement -- we have implemented already measures to increase the cash runway. For example, postponing projects, and we have a higher increase in place. And we feel confident that we now have runway through the second quarter of 2022. And of course, there is a lot of upside to that scenario as well. It could well be that thing going out really, really well with the FDA, and we can start selling during 2022 in an expanded label. But we're also then planning for the worst case scenarios as well. So we have lots of continuity trends in place, no matter what the OCEAN outcome will be.

With that, I will turn the word back to Marty to conclude with some comments.

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Thank you, Anders, and also thanks to Klaas. So on Slide 24, just a reminder on our key takeaway messages. Our first full quarter with revenue, the double-digit demand growth on a month-to-month basis is exciting. Our quarterly sales numbers as presented. The OCEAN data, that study meeting the primary endpoint, very, very important. Some of the secondary endpoints along the efficacy parameter also trending in the right direction, but also this comment on the overall survival in the ITT population and the important safety communication, as pointed out by Klaas, which has also resulted in the clinical hold. So really important for us as we look at the second half of 2021 to progress on those critical work streams and the partial clinical hold, in particular, is important.

And we're very excited about the IMW meeting and the reveal of the details of the OCEAN trial in an oral presentation at that meeting. It does appear that, that presentation will take place on a Saturday. So right now, we're targeting a webcast to provide more details and perspective following the meeting in Vienna.

So with that, I'll turn it over to the operator as we move towards our Q&A. Thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question is from Adam Karlsson of ABG Sundal Collier.

Adam Karlsson - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Just a couple, if I could. Firstly, just on what Klaas was describing with the possible outcomes and scenarios from the FDA interactions. My question is given that the OCEAN that it was meant to serve 2 purposes, firstly, convert the paces accelerated approval into full approval and then also broaden the label. My question is that to what extent these -- are these interlinked and could the outcome be that the FDA is able to convert the accelerated approval but not accept the sNDA or vice versa? Can you speak to how you view the possibility of this and whether you feel more or less confident in either of these processes?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Yes. Thanks, Adam. And I'll actually turn that over to Klaas to provide his perspective.

Klaas Bakker - *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

Yes, absolutely. And thanks, Adam. It's a good question. These 2 are quite interlinked, to be honest. It's all about reaching a common understanding of the data with the agency. If we agree on what this data means, there is a high likelihood that if it can serve as an sNDA to confirm the HORIZON data, there is a high likelihood that, that may also have implications for the label. Right now, it's unlikely that we have a scenario where it would only result in an sNDA, but without a label change. But that is, as said, within the boundaries of the so-called first scenario, if that makes sense.

Adam Karlsson - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Right, okay. And then just one more, if I could. In the Q1 report, we got the sales for April and just if one backs out the May-June sales from that in today's figures, it would appear as though the actual sales are decelerating during the quarter. I'm just trying to -- but of course, that could be due to destocking effect in April and so on. But just trying to understand how that squares with the month-to-month growth that you're seeing in vials shipped. Is it the case that the vials shipped measure is looking at shipments from your distributors to the actual clinics, while the sales are being recorded when you send the vials to the distributors and you make actual sales?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Yes. Great question, Adam. And you're exactly right. So if -- as the presentation is available, if you flip back to 9, Slide 9, you'll see that demand trend. And just to reiterate, so those aqua or blue bars are actually the pull-through demand coming from distributors into accounts. So this is the true utilization of the product as it goes from a hospital or a community practice into a patient. So what we see is that consistent growth in demand March, April, May through July, and the big jump from June to July is the fundamental demand for the product. When we look to what's reported from a net revenue perspective, it's the shipments to the distributor that get recognized. And early on, some of the fluctuations and are pointing out in our Q2 report of inventory kind of moving around, had to do with a little bit to do with some of the -- some short-dated products that we had to utilize at the launch that once we had a second batch, there was a replacement of some of those vials.

So what you see in the gold bar that's part of that slide, Slide 9, is the ending inventory position of the distribution network on a month-to-month basis. So you see that changing. And obviously, in July, you see 173 in the inventory against that 456 in demand. So this is where we're suggesting now we're more in that typical 1 to 2 week and more 2 weeks, in this case, inventory position. So that's exactly where we want to be.

Operator

Our next question is from Patrik Ling of DNB Markets.

Patrik Ling - *DNB Markets, Research Division - Senior Analyst Healthcare*

A couple of questions for me as well. I mean I can start with partial clinical hold. I mean, if I remember correctly, when the FDA has received its the final information from the companies, they have normally 30 days to actually respond or come with a suggestion or a solution. Have you sent the final information to them? Or is that something that we're still waiting for?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Yes, so I can take that and Klaas, please comment. So that's good to hear from you, Patrik, as well. The -- that's something that's working through the day -- it's so critical, the understanding of the data and the FDA understanding of the data. So a lot of the exchange and correspondence between FDA and Oncopeptides at this point has been more around the data, the OCEAN data. So once we reach that common understanding, that will generate the ability to move forward. So we feel like we know where this is going, but certainly, we need the agency to have their time and to appropriately review.

Klaas, additional comments, thoughts there?

Klaas Bakker - *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

Yes. I think it's pretty -- if I take a step back before you send in a complete response package, you do want to know that you are kind of on common ground with the agency. Otherwise, you put a lot of work in a response that may not fly at all. So what we're doing is, first, to try to get to that common understanding then to send in that full clinical response. And then indeed, as you mentioned, that 30 days kick in. We're now really into that space where we are reaching that common understanding, which then also helps us to finalize our complete response letter.

Patrik Ling - *DNB Markets, Research Division - Senior Analyst Healthcare*

So would you say that the way that you're handling it with intense contact between you and the FDA makes it maybe more likely that they will be able to respond to you within or shorter than in the 30 days, because you -- as you say, you have a common ground? Or will they still utilize the full 30 days, you think? Because that comes back to what you talked about before that you hope to have some sort of solution to this in September, whether that is (inaudible)?

Marty J. Duvall - *Oncopeptides AB (publ) - CEO*

That is still within the possibilities. I would mean a resolution of the partial clinical hold, as I said, it's just one of the timelines, I expect in Q4 to be reasonable within timelines. You should know that a complete response letter, it's called a letter, but it's a package that easily has more than hundreds of pages of specific amendments details that are important. So to say that it is within 30 days is reasonable. And I don't dare to speculate if it will be shorter than that 30 days, given the amount of data that we sent over.

Patrik Ling - *DNB Markets, Research Division - Senior Analyst Healthcare*

Okay. Do you still think it's realistic to file based on the OCEAN data in Q4, as you talked about before, or is that something that's been moved forward or pushed back in time?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

I think we really -- what is critically important right now before we look at filing. I mean, if you file, you file for something. You need to know where you are with the agency before we file. If we file, we want to do that in a situation where we have reasonable certainty that the file will be successful. So the exact filing of what we file is also dependent on what we agree with the FDA. The first step is now to get the clinical hold lifted. And once that hurdle is cleared, we have a much better understanding. I think Q4 for a filing, dependent on what filing that may be, is not realistic at this stage. And I would guide to the first half of next year, there for a potential filing.

Patrik Ling - *DNB Markets, Research Division - Senior Analyst Healthcare*

Okay, great. Then I also have a question regarding your comments in the report about July that it's up month-over-month by 32% despite this clinical hold. And -- but the official statement from the FDA came pretty late in July, I mean, you were out talking, but do you think that you actually still saw a full effect of that on your sales development? Or do you think that is something we should expect in August instead?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

No, good point, Patrik, and did need to confuse that a little bit. So the partial clinical hold announcement came early in the month. And as you're mentioning, the FDA, the FDA safety communication came towards the end of the month. So the majority of the demand creation efforts in the month of July occurred without that safety communication as a backdrop. So a little too early to tell. Obviously, we're only a couple of weeks beyond that. So I don't want to speculate further, but I think it's safe to assume that it would have some impact on the demand trends. So I wanted to really characterize the trend that we're seeing in the first 3.5 months, 4.5 months, I guess, in this case, where one would expect to see patients beginning to continue therapy as we add new patients on. And I think that's reflected in the demand trend that we're seeing through July. So thanks for pointing out that clarification on timing, I think that's important for everyone to understand.

Operator

Our next question is from Christopher Uhde of SEB.

Christopher Winston Uhde - *SEB, Research Division - Analyst*

I guess, the impact on sales was the first one you've now answered that. But the other question I have is, so you mentioned possibility of a new trial and I was actually wondering whether changes to LIGHTHOUSE might be sufficient to address such an issue, hypothesis generation or whether the trial itself would -- as it's currently designed, could be sufficient? Or do you think that you would need an altogether new trial? And if that would be the case, well, I mean, let's say, what do you think of the odds of the first scenario or the second scenario?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Yes. Thanks, Christopher. I'll let Klaas address that one, and then we'll look to you for a follow-up.

Klaas Bakker - *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

Very relevant question. I think it's important to acknowledge that every patient on a clinical trial is a patient who puts his or her thrust in the research that is ongoing. So all patients that have been accrued through LIGHTHOUSE right now deserve that their response so to say, on treatment also is taken into account. So we, as well as the agency have a mutual, I would say, need to get the most out of LIGHTHOUSE in terms of regulatory implications, whether that will result in a modified design, I don't dare to speculate right now. But it is obviously something that is on the table as we speak.

Operator

Our next question is from René Wouters from Kempen.

René Wouters - *Kempen & Co. N.V., Research Division - Research Analyst Life Sciences*

Just a quick question on the subgroup. So you indicated that you're still very confident that there are certain subgroups that might significantly benefit from treatment with Pepaxto. I was just wondering whether these subgroups will be easily identifiable before you initiate treatment?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Yes, good question. I will -- Rene, I'll turn that over to Klaas for comment.

René Wouters - *Kempen & Co. N.V., Research Division - Research Analyst Life Sciences*

Yes, good question, very identifiable, I would say, it's very easy to identify these patients. We're not looking at patients with a genetic alteration that you need to look for. It's a large subgroup within a study that has met its primary endpoint. So I would -- again, we want to take that step back and look at OCEAN as a positive study from a primary endpoint perspective, where we do see benefit not in just from subgroups, but in one, if not the most important subgroup right from the start. So we are very confident that identification of patients won't be an issue at all in this subgroup.

Operator

(Operator Instructions) We have a question from Fredrik Gustafson, a retail investor.

Fredrik Gustafson, retail investor

With regards to the maturity of overall survival, I think the data cut off was in February, so that's quite some time. Are you considering to maybe update the overall survival that with regards to the discussion with the FDA? Or is that something you see upcoming, especially notice you mentioned that the filing might shape off into 2022?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Yes. Good question, Fredrik. And certainly, I don't want to dismiss the ITT result by overemphasizing immaturity, but I'll let Klaas speak to any further data cuts and the importance of that relating to communication with regulatory agencies.

Klaas Bakker - *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

Yes. And the answer is, there will be a later overall survival cut inevitably. We need to command what the best timing of that new data cut is, whether it impacts the current, I would say, ongoing dialogue with the FDA, the answer is actually no. But I can assure you that there will be a later readout given the results that we saw in the initial readout. But I don't dare to speculate about when that will be.

Fredrik Gustafson, retail investor

Okay. I'll just add one second question. So the subgroup, it's fairly big. And I think HR between 0.5 to 1.5. Obviously, the data is coming, so we'll see it anyway. But just wondering, if you have those magnitudes of significant of Hazard ratios on both large subgroups, isn't it possible but you will have confidence in significance also in that subgroup of interest?

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Yes, Fredrik, so I'll give a global comment on it and then ask for Klaas to clean up anything I say. I think one of the -- the first key here is -- and putting this in the context of discussions with regulatory bodies. And from an FDA and EMA as an example, have very different guidance regarding subgroups and approvals of subgroups and how things look. From an FDA perspective, the real importance is the intent-to-treat population, the primary endpoint and then this secondary endpoint of overall survival in line. So from their standpoint, there needs to be first a view that the study was indeed positive as they then consider future implications. From an EMA perspective, there are different regulations regarding subgroups and some of those finer details. So as you mentioned some of the specifics regarding underlying confidence intervals and subgroups that may become more important from an EMA perspective than it is from an FDA perspective. But I'll defer here to Klaas to provide some of his perspective as he thinks through this as well.

Klaas Bakker - *Oncopeptides AB (publ) - Executive VP & Chief Medical Officer*

Yes. And basically, the short answer to your very specific question is, yes, we do see confidence interfolds below 1 and above 1 in totality, which speaks to the strength of the data in that subgroup. We're not just talking about a minor difference here. We talk about significant differences. Hence, our interest to show this data at IMW for everyone to get to the same page as well when it comes to data interpretation. But thanks, very good question.

Operator

There are no further questions at this time. So I'll hand back over to our speakers.

Martin J. Duvall - *Oncopeptides AB (publ) - CEO*

Okay. Well, thank you very much. Thanks to everyone for your engagement and following up our story. As mentioned, a pivotal quarter for us, Q2, important inflection point going forward. And hopefully, you get a sense for our confidence in the data and confidence in the team and in melflufen and the value and hope that we can bring to patients. Do want to just make sure in closing here that I thank the entire One Oncopeptides team. Certainly, now as we have ongoing interactions with 2 regulatory authorities. There becomes a large burden that we're up to and of course, these are both important, very important steps as we look to our ambition of treating more patients with relapsed/refractory multiple myeloma, not only in the United States, but around the world and would also like to thank our team here in the United States that have successfully launched the product and are growing demands and working each and every day to make sure that our health care professionals around the world understand our product and understand the current situation. So much appreciated.

So with that, looking forward to our next webcast opportunity, which, as mentioned, will be immediately following the important IMW meeting in Vienna, the first week of September. So thanks, everyone. Take care, and have a great afternoon and a great morning. Bye now.