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EDITED TRANSCRIPT

ONCO.ST - Q1 2021 Oncopeptides AB Earnings Call

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PRESENTATION

Operator

Hello, and welcome to the Oncopeptides Q1 Report 2021. (Operator Instructions) Today, I'm pleased to present CEO, Marty Duvall. Please go ahead with your meeting.

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

Thank you, and good morning to everyone. Marty Duvall, CEO of Oncopeptides, really pleased to be with many of you again this morning, this time to talk about our Q1 results. And I'm sure we'll have the opportunity also to touch on some of the discussions from yesterday and the top line release of the OCEAN trial.

So on Slide 2, participants joining me in today's call are Dr. Klaas Bakker, our Chief Medical Officer; and our Chief Financial Officer, Anders Martin-Löf, almost gave him a promotion there.

And on Slide 3, as a disclaimer, we're going to be making some forward-looking statements, so please look online for fairness, accuracy and balance.

And let's move then to Slide 4. So I think the key takeaways that we want you to walk away from on this update is that we are excited about the launch of PEPAXTO in the United States. It's off to a very strong start. I'll provide some details regarding things like the awareness of our drug among our targeted customers, which is at 90%, which I think is pretty much where anyone would be happy with that level of awareness. In terms of our reach to customers, and I'll talk a little bit more about this as it relates to COVID-19. Over 90% of our top-tier targets have been reached, as we've reported in our release, and we opted to provide a little bit of clarity, and a lot of my discussion will include April because the view was 6 weeks of ramp would be much easier to interpret. So you see our -- in our release, USD 2.3 million of net sales in March, followed by an increase to USD 3.3 million in April. We are on track. We track our uptake relative to number of unique accounts. We think that breadth of prescribing the drug is really important, and we match this against the highest-performing analogs in relapsed/refractory multiple myeloma. And we think the fact that 6 weeks in, we have 100 unique accounts ordering the drug. We believe that to be very strong.

We know that the Phase III OCEAN data with the positive top line results, this comparative data versus pomalidomide, will certainly have an impact when this data is presented in a peer review conference and will begin to change what's already a very strong perception of PEPAXTO in the market. So I'll provide some glimpse of some primary marketing research here that will kind of provide some perspective on that. And we think those 2 things combined put us on a path to make PEPAXTO a foundational treatment in relapsed/refractory multiple myeloma.

So the next slide is our agenda. So I will talk about the launch success in building momentum. Then Klaas Bakker will provide an R&D update, including a reiteration of the OCEAN top line results and some of the key highlights from an R&D perspective. Then, Anders Martin-Lof will provide the financial update, our quarterly results, milestones, news flow and some adjustments to our calendar as it relates to future earnings calls.

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So with that, I'll move into the launch update, and we can flip forward to Slide 7. So just as a reminder, we were very pleased to get accelerated approval on February 26 by the FDA. Just as a reminder, on the label indication, it's in relapsed/refractory multiple myeloma, triple class refractory population, in patients who have received at least 4 prior lines of therapy. So this was based on a subpopulation from the HORIZON study, a group of 97 patients, which included a very high percentage of patients with extramedullary disease.

So as we've kind of talked about the efficacy data in the marketplace, we certainly point out that this is a group of patients with extremely high unmet need. And as we released early to keep it in perspective and why I talked about 6 weeks of drug availability is the commercial availability of PEPAXTO, began around March 15. So a very expedited product of getting up -- or process of getting the drug into the U.S. market through customs, labeled into our distribution channel and ready for patients to be treated just in a couple of weeks. So very excited about that.

On Slide 8, I just wanted to provide a little bit more clarity on the account-based approach that we're using to ensure an optimal customer experience. And I put into the slide here the size of the footprint that we currently have with our oncology account managers, sales representatives, approximately 40 spread out across the country. And really, we see them as the quarter back in terms of our customer interactions. But they have a tremendous amount of support around them, including key medical affairs functions, the medical science liaison team of about 10; oncology nurse educators, which you're doing -- that team is doing a fabulous job in the marketplace, helping with dosing and administration, talking about side effect management, et cetera. So really outstanding group of nurses that are also helping our oncology account managers. We have some key customer marketers that are really driving a lot of programming across the country, be that through advisory boards or other group customer meetings, speaker programs, they're doing an outstanding job. Of course, we have a headquarters team here in Boston and also a team of national account executives that includes the market access team, and we'll talk about the great work that they've done, making sure that every patient has access to PEPAXTO in the U.S. marketplace.

So we've also included a series of pictures here, and that's really a statement about the changing environment here in the United States and really excited about that, launching into a COVID world that is evolving. And with that comes a different experience as it relates to interacting with customers. I would say, by and large, we're moving from a 20-80 mix of in-person to virtual to more of a 50-50 blend. And we do see the light at the end of tunnel -- the tunnel here in terms of this normalizing in the United States. And I've had the pleasure of joining Mohamed Ladha in our leadership team to meet with our sales team, field team around the country and talk about the launch of PEPAXTO and also take the opportunity to meet with customers when we're able to do so as we do this tour.

So moving forward to Slide 9. I want to provide a reiteration of our strategy. And our strategy is really a two-pronged approach, now being one of the drugs that's approved with -- in the triple-class refractory marketplace for multiple myeloma. On the left-hand side, we see those 3 classes that dominate the prescribing pattern over the past decade plus, the image, the PIs, anti-CD38 led by daratumumab. And in today's marketplace, we see mostly a recycling of these classes through the patient -- the management of a patient through many lines of therapy. But now we have the availability of products with new mechanisms of action, and we joined that class as PEPAXTO. We also have, belantamab, selinexor, ide-cell or Abecma that is launched recently. So our two-pronged strategy is, first, to position ourselves strongly and become a treatment of choice amongst these products with new mechanisms of action. And the second strategic initiative here is to stop the recycling of old classes. And that ties directly into the results that we see in the OCEAN trial. Keep in mind that trial is in failure in patients who have failed lenalidomide, and we see a randomization to a new mechanism of action, PEPAXTO, or the same mechanism of action with pomalidomide. And the results that we shared yesterday show that the patient experience, ability to induce a response, a longer progression-free survival is improved by switching mechanism of action. So certainly, we will use that Phase III trial as we move forward to help bolster this strategy and expand the use of PEPAXTO.

So moving forward to Slide 10. So to reiterate some of the numbers here in terms of being off to a very strong start. So as it relates to our revenue metrics, the USD 5.6 million in net sales is over the first 6 weeks of commercial availability. I had mentioned the number of unique accounts, 100. We'll take a look at some of those accounts, high-profile counts, both in the community and academic center. And also that we've shipped greater than 700 vials of PEPAXTO, the 20-milligram vials into the distribution channel here in the United States in the first 6 weeks of availability.

As it relates to the field team and the activity of the field team, the team is doing an excellent job, prioritizing and meeting with top-tier customers. We've seen more than 90% of our targeted top-tier customers in these first 6 weeks. As mentioned, the 90 -- or greater than 90% customer awareness among this target audience is excellent. And the payer coverage at 97% highlights some of the other key metrics and key successes out of the gate here with the launch of PEPAXTO.

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Moving forward to Slide 11. We were very pleased, just a couple of weeks into post-approval -- post accelerated approval in the U.S. that the NCCN included PEPAXTO in the guidelines, Category 2a. Uniform consensus that PEPAXTO is indeed a treatment of choice for relapsed and refractory multiple myeloma. So certainly, that's helping us to build confidence, become part of pathways within the United States treatment community and will also help us on a global stage to build our product.

Moving forward to the next slide. So a little bit of color here on the payer coverage, with 97% of payers covering PEPAXTO to the label or better. So in this particular case, I'm pleased to report that we've had 0 coverage issues in the first 6 weeks of product availability. And this is really a tribute to the outstanding early payer engagements by that national accounts team that I talked about. So tying in the first bullet point here, the number of interactions, compliant interactions that occurred to help prep the marketplace, convey results of the HORIZON trial to payers, paving the way for this coverage to be seamless to make sure that the product was available to customers upon launch. We're not seeing any issues as it relates to payments to providers. We're very pleased to see that PEPAXTO is on 98% of electronic medical record systems by the end of April. So just reinforcing the bottom line here is no reimbursement challenges to date. We're extremely excited about what that means in terms of patients who need PEPAXTO are able to get PEPAXTO.

So turning to the next slide. Just want to reinforce on this 100 unique accounts, a really impressive breadth in the use of PEPAXTO. And we've talked about the importance of academic centers, but also community practices based on the profile of our drug. And as we look at some of the who's who as it relates to both community practices around the country as well as academic institutions, I think you see a very impressive snapshot of some of the customers that are utilizing PEPAXTO today. So on the community side, the standouts, Florida cancer Specialists, Texas Oncology, the Cancer Center of Kansas; and you see some of the premier academic institutions in Memorial Sloan Centering, Dana Fiber here in Boston, MD Anderson, UCSF, University of Pennsylvania and others. So really pleased with the breadth of experience being gained, the number of unique accounts. This is going to help fuel sales trends in the future, the consult of academic physicians gaining experience with PEPAXTO, and their discussions and influence on community physicians is all part of this uptake process through the launch of a drug, and we feel we're in a very good and growing position as it relates to that.

Flipping over to Slide 14, just wanted to provide a little bit more detail around the targeting and the execution by our outstanding field sales team. So on the left-hand side of the slide, you see, from an account perspective, there are about 5,200 accounts that we are targeting. From a priority perspective, it's about 1,500 that are most important. We believe those 1,500 represent about 80% of the multiple myeloma prescribing activity in the United States. The breakout here is about 1,050 of these accounts are community-based accounts and 450 are academic. And on the right-hand side of the slide, you see in the bar chart, the percent reach from our sales team that's been achieved through the first couple of months of availability. So this is through the April 30th time frame. So as an example, the decile 9% to 10%, 94% of those targets have been called on at least once during this 2-month time frame, 91% for decile 7 and 8. So very pleased with our execution and calling on on-the-top accounts.

Flipping over to the next slide. Looking at the messaging and key customer insights, we feel that the receptivity to our drugs and the messaging has been very strong. The unique mechanism of action is playing out well. This balance of efficacy and tolerability and also the convenient dosing schedule is a key part of that. The unique mechanism of action, of course, we're emphasizing this peptide drug conjugate platform, and all that does in terms of allowing for the cytotoxic payload to be more preferentially delivered directly into the tumor cells, emphasizing the strong efficacy, emphasizing the indication statement in patients eligible for therapy, the manageable safety profile of the drug and the ease of use in terms of this once-monthly 30-minute infusion schedule is all playing out quite well.

On the next slide, this is interesting data that comes from a proprietary marketing research that I mentioned earlier at the outset of the call. And this study was done last month with approximately 60 physicians that are on our call list. And these physicians were asked to rate the attributes. Several attributes is listed here on the slide for individual drugs. So in this case, it's a comparison of PEPAXTO to pomalidomide. They were asked to rate these drugs on a 7-point Likert scale where 1 was the drug does not exhibit strong attributes in this area, and 7 is an extreme -- the drug -- or this particular attribute is extremely strong for the drug. So the ratings here, the percent of physicians surveyed who deemed on the 7-point Likert scale that the product was a 6 or 7. So very strongly related on the attribute. So 2 observations comparing PEPAXTO to pomalidomide. I think on one hand, we can say that what a great job the team is doing, from our publications team to our sales team, to our MSL team in terms of describing the data that's available on PEPAXTO. The top 2 boxes are very strong as it relates to PEPAXTO on progression-free survival, overall survival, response rate, duration, et cetera. But we also see that we fall short of pomalidomide, not unexpected, right? Pomalidomide is the most widely prescribed drug in relapsed and refractory multiple myeloma. So I think this then speaks to the OCEAN study. And having a head-to-head

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comparison with the leading drug in the category will help to drive the perception of PEPAXTO relative to pomalidomide forward. And we believe that what occurs when that happens in terms of mindset is preferential choice of one drug over another. So we're excited about where we sit today as it relates to the perception of the drug, but have also great hope as we look to build PEPAXTO as a foundational treatment in relapsed/refractory multiple myeloma.

Flipping forward to the next slide. Just want to emphasize the fact that we believe we're particularly well-positioned in community-based care. Obviously, the academic market will be important to us, but just wanted to provide a little bit of flavor on the community-based care. So on the left-hand side of the slide, you see the use of doublets like PEPAXTO/dex and the percent by line of therapy. And what you see is that the use of monotherapy or doublet therapy is much higher in later lines of therapy. That plays well to our profile, our approval, efficacy in later lines of therapy, manageable safety profile, convenient administration and better compliance as we look into the later lines of therapy. And we're really pleased on the right-hand side of the slide. When we look at the accounts, the 100 accounts that have prescribed PEPAXTO or unique users of PEPAXTO through the first 6 weeks, 65% are in the community setting and 35% in the academic setting. So we are beginning to build that footprint and that uptake in the community setting where we feel our product will play particularly well. Of course, we also want to be in the academic centers, and our development plan is focused to help us in creating a data on combination usage that will also improve utilization in that area.

Looking forward to the next slide, I want to touch just a little bit on the European organization and what's going on there. So we're excited about our progress as it relates to Europe. The top hand slide -- top portion of the slide focuses on some of the communication we've had regarding submission. But here, we forecast, when we expect CHMP decision and potential approval of the product in Q2 of 2021. So likewise, below that, we are beginning our organizational buildup. We've announced the hiring of our outstanding leadership team in March of 2021. We're in the process of doing the work necessary to prepare for launch readiness in one of the early launch countries, which, of course, will be Germany. So we are on track and thinking and projecting in terms of a launch in Germany in 2021.

And I did want to highlight before moving forward that we do have an early access program that is now open in Europe. And I'm very pleased to response that we have patients on drug in all of the -- each of the EU-5 countries. And this program is growing on a month-to-month basis, and we're really excited about the interest. It really speaks to the -- again, to the global unmet need. In this particular case, the unmet need in the EU; and the positive receptivity to a unique agent like PEPAXTO in Europe. So very excited about the groundwork being laid in Europe.

Flipping then to Slide 19. So we're off to a great start with our launch. We're really excited about, of course, how our clinical development program ties into expanded market and expanded market opportunity, OCEAN. We've talked about pomalidomide, the largest -- one of the largest drugs or the largest drug in relapsed/refractory multiple myeloma, $3 billion worldwide, over $2 billion in the U.S., $600 million in sales attributed to the Pom/Dex combo. And of course, with our strong OCEAN results, we see ourselves playing very well against pomalidomide. And from a future perspective, we are linked to DARZALEX. So daratumumab is a $4.2 billion product. And we see an additional $600 million of utilization of the Pom/Dex combo adding daratumumab. So again, LIGHTHOUSE points to a major opportunity for us to impact more patients. So we look forward to realizing that as we continue on this path of making PEPAXTO a foundational treatment in relapsed/refractory multiple myeloma.

Slide 20 is one we've highlighted before. So with the HORIZON data, triple-class refractory population being about 20,000 plus, average duration of therapy, when we look back at the HORIZON study and patients in these later lines of therapy, according to our progression-free survival, would be in the 3- to 4-month range. When we look at moving up in line of therapy, not only do we increase the eligible population in the case of OCEAN to third-line plus, but the average duration of therapy would also increase. The same to be said for LIGHTHOUSE as we see from the ANCHOR study, the triplet combination of PEPAXTO/Dex with daratumumab provides a longer duration. So really excited about the continued work on the LIGHTHOUSE trial.

Flipping then to Slide 21. Just to put this in picture again, from an OCEAN perspective, pomalidomide, the largest drug, we see the strong sales growth from 2016 to 2020, $3 billion in global sales in 2020. On the right-hand side of the slide, from the intrinsic data set, we look at the third line plus patient market share and the portion that is highlighted in the top right-hand corner suggests that 33% of the use of -- or 33% of the patient market share is somehow tied to a Pom/Dex combination. So that speaks to the great opportunity, the significant opportunity, that is the data with the OCEAN trial.

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So Slide 22 kind of brings that fully into scope. We have a very -- an emerging profile, a growing and -- profile as we commercialize the drug in later lines of therapy. And the profile will continue to improve as we create and generate new data in earlier lines of therapy. OCEAN is the start of that, really setting a new bar with a head-to-head -- positive head-to-head comparisons to pomalidomide. LIGHTHOUSE will be our entrée into combination therapy.

So I'll stop there and turn the conversation over to Klaas to talk about the OCEAN top line results and some of our key R&D highlights.

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

Thank you, Marty, and I'm more than pleased to be able to speak again to the OCEAN top line results. And if we go to Slide #24, we see the overview of our clinical development program, which is currently ongoing. And when you look at the left, we see O-12-M1 followed by HORIZON, and then of course OCEAN, which is meant to be a confirmatory trial for HORIZON in the U.S., but also in the EU.

In addition, we have ANCHOR, the combination trial, where we show good combinability of muffle with various other trucks; and BRIDGE where we expect results soon in patients with renal impairment. When it comes to the administration mode, peripheral versus central infusion, PORT does provide data this year, which will hopefully support the use of melflufen also via a peripheral catheter.

LIGHTHOUSE, as mentioned, an important opportunity, and I will speak about that a little bit more. While is our first study in another indication being AL amyloidosis.

Now let's go to Slide 25. This, again, are the top line results for the primary endpoint of progression-free survival. And before I jump to the table, I think it is important to stress that once you do an add-on trial, so if you have a triplet versus a doublet with a hazard ratio of 1, that means the addition of the new drug does nothing. It's equal. So if you then look at successful drugs from a triplet perspective versus a doublet, you see a hazard ratio on average of 65% to 70%, so 0.65, 0.70.

Now what we do here with OCEAN is comparing head-to-head. There is no addition. So it's really a highly active drug, pomalidomide, where we actually, with PEPAXTO overachieve with a more than 40% improvement in median PFS, both per IRC and investigator-assessed results. On top of that, if we look at the overall response rate, we see a solid, above 30% number for melflufen versus a 26.5% for pomalidomide.

And if we then look to the next slide, where we try to put it a little bit into perspective our results. And I think this is -- slide is important, Slide #26. This is a slide which we showed earlier to talk about various scenarios for OCEAN. And if we went from the left to the right, that superiority, noninferiority, nonconclusive and inferiority. So as you can see, the noninferiority bar in black, the lowest bar, was kind of the average noninferiority result. If we look at the superiority bar, you will see that it just passes the 0.8 hazard ratio. If we then look at the actual OCEAN results, you see that we actually are on that line of 0.8. So where we previously stated, we consider a noninferiority result, a positive outcome when it comes to regulatory interactions because we believe the totality of the data speaks. And you'll see now how much we are into that noninferiority margin, tipping over to superiority in the investigator-assessed response. We are very pleased with this result. And we believe that -- and this is also exemplified by the early interactions that we have with key opinion leaders. And with that, I mean investigators those who trialed, who have been able to see the full data set because we are discussing it for publications, for conferences. And so far, also when compared to yesterday, there is a consensus that if the numbers, if you look at subgroups, et cetera, melflufen clearly beats pomalidomide in this trial from a physician's perspective. Looking at the data, everyone -- every single physician I spoke to, very impressed with the data. Hence, our forward to the scientific conference as soon as possible because we are eager to show the full results, which we believe are truly strong.

We then go to the next slide, Slide #27, the safety summary. Now this was an area of concern for some KOLs with OCEAN where they thought that pomalidomide would have a much better safety profile. It's a daily pill. It's considered to be very tolerable. And then we add an intravenous new peptide conjugate with alkylating properties and how could we stack up against pomalidomide, especially given the relatively high number of hematological tox, which we call paper tox because so far, it hasn't translated into more bleedings or infections. And the fact that we, in OCEAN, are able to confirm the safety profile of melflufen is just very positive because that, again, means that the AEs were very much clinically manageable and from a physician perspective, this is important.

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Pomalidomide, and this is really a surprise for physicians, had more infections than melflufen when we talk about grade III, grade IV infections. There was a significant delta here despite melflufen having higher levels of neutropenia. So we are very encouraged by this result. Similar levels of other non-hematological tox, no outliers there. And importantly, the discontinuation rates were similar. So despite the on paper, more tolerable profile of pomalidomide and the expectation of pomalidomide being a more easy or tolerable drug does not turn out to be true in OCEAN as the discontinuation rates for adverse events were similar in both arms.

So if we go to Slide 28, what does this mean for our regulatory interactions? And I know this is an area of high interest for everyone. But I can tell that we are currently in the process of engaging the FDA on the OCEAN data. We are planning for presentations at key conferences, and the publication is already in progress. We will file a supplementary NDA in Q4 2021. Preparations are underway, and we feel very strongly that in light of the totality of the data of the OCEAN trial that we will not only ask for a full approval, but also for a label change to earlier lines of treatment. Now this is not a given, but we feel very confident given the totality of the data that we have seen, and we have pressure checked it with KOLs, this is a really clinically meaningful result that we show with OCEAN. In the meantime, of course, we continue to focus on our commercialization efforts with PEPAXTO in the U.S., as Marty already alluded to.

But if we then go to the next slide, this is already our next Phase III trial, LIGHTHOUSE, currently enrolling; and also a randomized Phase III, melflufen plus daratumumab versus daratumumab, and this is really based on the positive data that we have seen from ANCHOR. The aim is to enroll 240 patients, again, with a primary endpoint of PFS, and this will give us a significant opportunity to increase the market potential. And if you then think about the fact that the current combination of pomalidomide, daratumumab. dexamethasone is used very often in relapsed/refractory multiple myeloma and one then considers the fact that we performed better than pomalidomide in the OCEAN study, there is an easy let to think that if we then show a superior outcome in the LIGHTHOUSE study that a combination with daratumumab is really feasible.

Then if we go to Slide 30, I'm very pleased to share that we have been accepted by EHA for several abstracts. One is the BRIDGE study. And we are looking forward to share this data because we believe that we have a very tolerable drug also in patients with renal impairment, and we are looking forward to present the data set of BRIDGE at EHA.

We, as previously announced, have also been looking into other indications or we are aiming to look in other indications. And here at EHA, we lay the foundation from a preclinical perspective, showing high efficacy in cytarabine and venetoclax resistant AML models. And as you will know, and otherwise, I will mention it in 2 slides, we are aiming to start our AML study later this year.

Also for DLBCL, we see some very encouraging preclinical data that will also be presented at EHA. And then really for -- regarding the new mode of action, melflufen is considered to be an alkylating drug, but we know it is in the nucleus, but there is no drug which has shown activity in the mitochondria. And if we look at that, it seems that also works on the DNA in the mitochondria of the cell, actually providing proof that it not only easily transfers as the cell membrane, but it also actually easily passes intracellular membranes, which is very important if you want to have the cytotoxic effect, not only in the nucleus, but also to the mitochondria.

Then at ESCO, Slide 31. ANCHOR, we will have a new update of ANCHOR data with particularly now also more data in the bortezomib arm. LIGHTHOUSE, an ongoing trial abstract where we will express full confidence in this study. And then we will have the analysis of the O-12-M1 and HORIZON study where we look at the activity of melflufen in relapsed/refractory multiple myeloma with alkylator use.

This is important since we believe that this is a key differentiator for melflufen when compared to alkylating drugs who would normally not work in this patient population.

So if we go to Slide #32, our planned future studies in new indications. As mentioned, AML, high unmet medical need, OS less than a year and we will have a Phase I/II study in relapsed patients where we expect a first patient in the second half of this year. And then the same is true for diffuse large B-cell lymphoma, high unmet medical need in the relapse setting, and this is also where we expect our first patient in the second half of 2021. So we feel that we built a foundation with OCEAN where we can now build from further to validate our peptide drug conjugate platform.

And with that, I'm happy to hand over to Anders Martin-Lof, our CFO. Anders, over to you.

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

Thank you, Klaas. If we turn to Slide 34, you see the numbers for the first quarter, and I'm happy then to be able to report revenues for the very first time. However, it was only for 2 weeks. So the SEK 19.4 million that we reported are not representative of a full quarter of revenues. So that's why we also presented the April data to give the shareholders some indication on where we are heading in terms of revenues. And for March, the revenues were 90.4 and for April 28.0, i.e., $2.3 million and $3.3 million.

To give you some color, roughly 70% of that was real demand, so not much stocking. Gross to net deductions were in the high teens. So nothing strange to report there really. And it's really hard to draw any conclusions from these numbers. I think the most important thing in the beginning of a launch is having clinics trying the drug for the first time. So we want to have as many clinics as possible trying the drug. And then when they have seen what it does for patients, they will start to implement or sort of expand the use of the drug in early lines of patients. So key number here is to see that we are in a high number of clinics, and we're then really happy with the number of roughly 100 clinics that Marty talked about. So a really strong start from a revenue perspective.

If we then turn to the costs, you see them on the left-hand side of the slide. We -- for the very first time -- in the really long time, at least, so declining R&D costs, going from SEK 230 million in 2020 to SEK 178.5 million in 2021, where marketing and sales costs are, of course, growing, thanks to the buildup of the U.S. organization that was just buzzing in 2020 and is now in full bloom in 2021. So roughly the same amount spent on R&D and marketing and sales.

So operating loss as a total declined then from the fourth quarter. So the operating loss was SEK 348 million. It was SEK 511 million in the fourth quarter and SEK 383 million in the third quarter. So a lot lower, and that difference is then explained by the lower R&D cost, where the OCEAN cost went down from SEK 78 million last year to SEK 49 million this year.

Cash flow from operating activities was SEK 386.7 million, so roughly SEK 400 million cash burn. And the cash position, as stated in the balance sheet, was SEK 372.5 million. However, that does not take into account the money that we raised through our capital raise that was decided in March, but concluded in April. So pro forma including the raise we had roughly SEK 1.4 billion in cash, and that does not include the EUR 40 million loan facility that we have with EIB, that is -- that remains unutilized.

Turning then to slide #35, you see the upcoming news flow. Maybe I should state that we have had a lot of interesting events, and we have delivered roughly on time in the last few quarters. So we're really happy with that.

If we look forward to what's happening next, we have the presentation of the OCEAN full data set at an upcoming conference that will, of course, be important. That's where we can really start to talk about the data to decisions, and that will have an impact also on sales since more and more doctors will learn more about the product, they are more likely to utilize it also in later lines.

In later in the year, we will also then have a submission for OCEAN in the fourth quarter. And then turning to 2022, we can then get the approval in the EU, as Marty already mentioned, with first sales in Germany, probably during the second quarter, and then we hope to get the extended label approved in the U.S. in the second half of 2022. So lots of things coming out.

So if you turn to Slide 36, I just want to mention that we have revised our reporting schedule. So you see the times on the slide here. So the second quarter report will be available on August 19. That will then potentially be the first time when we can see more of it -- of trend lines in our revenues. That will be followed by the Q3 report when you see the first 7 months of sales on November 4.

With that, I think I should turn back to Marty to sum up the quarter and where we stand on Slide 37.

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

Thank you, Anders, and thank you, Klaas as well. So on Slide 37, just pleased to come full cycle here in terms of being a fully integrated biotech company, again, going where -- not many get to be in terms of bringing a product from an idea stage through the bench into the clinic and now into the marketplace. And we're just so pleased to be able to make that happen. So with PEPAXTO, we are addressing a growing unmet need. We've had an outstanding first 5 months of 2021. Our center of focus is, of course, on the patients that we serve. I also want to recognize our Oncopeptides team, and it comes down to our core value, starting with the science, but the passion of the team, the courage of the team, the trust in one another and the collaboration is what's helping us to achieve these milestones. And we certainly appreciate the support of our investors as well.

And with that, we'll move into the Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from the line of Peter Welford from Jefferies.

Peter James Welford - *Jefferies LLC, Research Division - Senior Equity Analyst & European Pharmaceuticals Analyst*

Just 2 quick ones, please. Firstly, just with regards to the 70% real demand figure for the sales of the PEPAXTO that you cited. Was that relevant to March sales? Or was that referring to the March and April period together?

And then secondly, just on LIGHTHOUSE. I wonder if you can possibly talk about the statistical analysis plan for the LIGHTHOUSE trial and the powering and what you're assuming for the hazard ratio to that study? And when you anticipate that could potentially read out with data?

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

Thanks, Peter. And the figures that I covered were comprehensive through the 2 weeks in March and the 4 weeks in April, as it relates to the commercial uptake. And for LIGHTHOUSE, I turn that over to Klaas.

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

Thank you, Marty. Yes, for LIGHTHOUSE, we do expect currently to have the high-level results read by the end of 2022, beginning of 2023. With regards to the hazard ratio, we should for hazard ratio lower than 0.7 in that study.

Peter James Welford - *Jefferies LLC, Research Division - Senior Equity Analyst & European Pharmaceuticals Analyst*

And sorry, just going back to the -- sorry, the -- it wasn't so much the adoption. It was more the comments at the end, where I think the comment was that the sales figure that's been recognized in the P&L, around 70% of that, which I can to be real demand versus 30%, I presume is stocking. I just wonder to that a bit, sorry, that -- is that just referring to the March period -- the March sales?

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

I was just -- go ahead, Anders.

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

I was referring to combined March and April figures. It's slightly above 70% that is real demand.

Operator

And the next question comes from the line of Viktor Sundberg from ABG.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

So first one on sales. You mentioned in your report that in April, you had sales of SEK 21 million. That seems kind of flat compared to SEK 19 million from only 2 weeks in March. Any reason why we aren't seeing an accelerated sales curves? And maybe also what have you been seeing in the month of May so far to get a feel for what the sales curves looks like?

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

Yes. So good question. And no, I wouldn't look at this as flat. Remember, there's going to be a little bit of stocking that would take place in the first couple of weeks that would inflate the March figure. So I think that's the major explanation there.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Okay. And...

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

Also it relates to -- Yes, go ahead, sorry.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

No, if you had to comment on May sales, that would be interesting if you could give that?

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

Yes. We're not going to go that far and comment on May at this point.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Okay. Yes. And it also seems like oncologists prefer PEPAXTO in the community centers, but do not have access to REMS program. Any color on what like -- what the mix is for centers that prescribe PEPAXTO at the moment?

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

Yes. So we know from the initial approximately 100 unique accounts that 65% are in the community.

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Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Okay. And then also I had some questions on OCEAN since I had not the opportunity to take part in the webcast yesterday. So you said that you would file for a supplementary NDA in Q4 '21. Any reason for that time lag from when you report the results now? And what have you included in that time line? Like what kind of interactions have you anticipated? And what kind of additional data do you think that you need to provide?

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

Yes. Good question, and I'll start and then turn it over to Klaas. So there's not much time lag there. If you think about, we just got top line results just a couple of days ago. So fairly, fairly standard practice. But I'll let Klaas fill in some of the details.

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

Yes, right. And with the planned submission in Q4, there's actually no delay. Actually, the work for the submission has already begun way before the OCEAN high level results. It's just getting to chemical study report, which, in general, takes between 2 and 3 months before we have digested the data and have compiled this 200-page study report and then that needs to be translated in all kinds of modules for the FDA filing. I would say, from a pharma perspective, the time line that we are having is pretty aggressive, basically from high-level results to a submission. So there is no time lag. There was no need for new data. We're not waiting for anything else. We do have the data in hand. It's just which we now need to better understand them and put them into the right context for a submission. So the data that we need, we have.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Okay, because I was thinking of -- Karyopharm when they got their BOSTON trial, it just took 2 months before they filed for FDA, but of course, they met their primary endpoint of them. Is that the reason why it is a bit longer here or just help me understand that stuff?

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

No. If we would have that if we would have met our superiority per IRC that would not have changed the time lines at all. We are working for exactly the same time lines independent of the study result. Of course, if the study was negative, that would be another study. But now that we have a positive study, we believe the time lines do not change. Why Karyopharm? What did it in 2 months? I cannot comment on. But the 5 months that we're talking about here today is quite typical. So I have nothing else to comment on there.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Okay. And also, what have you pre-agreed with the FDA if you would read out non-inferior? Are there any agreements in place, what that would entail and so on? Or is it more an oral agreement between you and FDA for what would have happened in that case?

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

Well, it has always been on the table. And based on a non-inferior result, the agreement is to look at the totality of the data. And one can imagine that if you have a non-inferior result with a hazard ratio of 0.98 or 0.96 with a safety signal, then the FDA may not be that eager to give us full approval based on the noninferiority. Hence, they didn't want to sign up beforehand for a noninferiority study, giving us full approval. They would instead look at the totality of the data. That is the agreement we have. Now if you look to our noninferiority result, we are doing like the best noninferiority result you can have. We're tipping against superiority. So the efficacy is really there. And on top of that, we do not see any safety signals. In contrast, we are seeing less of some severe complications that are seen with pomalidomide. So when I say that we are very confident and positive in our interaction with the FDA, that is based on previous interactions. And if you look at the noninferiority result, it's not just

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noninferiority. It's also within non-inferiority, where are you. And on the scale from 0 to 100, we are almost close to 100 with this efficacy and safety result. Hence, are confident for a positive FDA interaction regarding our sNDA.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Okay. And maybe also a question from a clinician standpoint. Most pomalidomide regimens' guidelines are for combination treatment setting after lenalidomide failure. What are the arguments that you're hearing for switching out pomalidomide and melflufen if it's labeled noninferior, given that pom is oral, not an infusion, not with a PORT as of now at least, as you illustrated in your slides here?

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

So very briefly, new mode of action, switching drug class is considered to be an important one. It's patient adherent. With a pill, you never know if a patient takes the pill every day. We know from oncology studies that even in the oncology setting, there is between 60% and 70% compliance. Here, you have a once-monthly infusion, 30 minutes. So you know the patient gets the drug. You see the patient, and you know that the patient is treated. On top of that, and this is something that we hope to be able to disclose soon at the scientific conference. We have many efficacy parameters where we outperformed pomalidomide. So from that perspective, the physicians that we've spoken to so far, say, in this setting, I would clearly use melflufen over pomalidomide given what you have just showed me.

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

Maybe another -- an additional comment there, just around -- what we talked about yesterday was how important it is to establish single agent efficacy, right? And we did that with HORIZON in a non-randomized trial. So to randomize head-to-head, I mean we want to be a long-term foundational treatment in relapsed/refractory multiple myeloma. So with a starting point of beating a widely used agent, the most widely used agent in the world, is a very important part of that. So we'll build from there, right? We'll have combination data with daratumumab. As I mentioned, the pom/dex/dara combination is a big commercially used combination. We will have Pep/Dex with LIGHTHOUSE. We have it already with ANCHOR. So it's one step in the process. But any drug that's an important drug in the oncology/hematology world has demonstrated very strong single agent efficacy.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

Okay. And how data-driven do you think clinicians will be here at first, since we do not have any data for a combination with, say, melflufen, elotuzumab and dexamethasone, just making up a combination here? For example, would perform against the same combo with pomalidomide instead that is supported by the ELOQUENT study in this specific example.

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

So our immediate goals from a commercialization perspective aren't to switch out every pom/dex combo with PEPAXTO. Keep in mind, the slide that I shared that was showing the concentration of doublet use in later lines of therapy, there's significant opportunity to play with a doublet. So establishing PEPAXTO/dex as an important doublet and one that was a Viktor in a head-to-head trial is an important part of building the commercial momentum and uptake of the drug.

Viktor Sundberg - *ABG Sundal Collier Holding ASA, Research Division - Research Analyst*

And how much of doublet use if you stopped or, say, previously lenalidomide failure within a couple of months and so on. Do you have any feeling for that?

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

Well, I can get back to you on some of the specifics. I think if you flip back to one of the slides I showed, we looked at pom/dex alone being 12%, when we look across third line and later. But again, you've got a very high proportion of doublet use in those later lines of therapy.

Operator

(Operator Instructions) And as there seems to be no further questions, I will hand it back for any closing remarks.

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

Fantastic. So thanks, everyone, for joining us for these exciting announcements. It was a great first quarter. Second quarter is shaping up to be equally as strong, certainly highlighted by the OCEAN data, but also then our continued commercialization. So really look forward to future interactions and really appreciate your support and interest in Oncopeptides. Thank you very much, and have a great day.

Operator

This concludes our conference call. Thank you all for attending. You may now disconnect your lines.

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