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ONCO.ST - Full Year 2020 Oncopeptides AB Earnings Call

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PRESENTATION

Operator

Welcome to the Oncopeptides Q4 conference call. (Operator Instructions)

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

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

Okay. Thank you. So good afternoon, and good morning to all. Really excited to provide this operational update on Oncopeptides, our Q4 report and reflecting back on an outstanding year that was 2020. And obviously, really excited about the year that lies ahead. So as a reminder, I'll be making some forward-looking statements, so please refer to some of our disclosures and filings for appropriate fair balance and currently on Slide 3. So I'm joined today by our Chief Medical Officer, Dr. Klaas Bakker; and also our Chief Financial Officer, Anders Martin-Lof. So we'll handle various sections of this particular update.

So moving forward to Slide 4. So as mentioned 2020 has been a transformational year for Oncopeptides, and we probably morphed into a fully integrated biopharmaceutical company. And had the opportunity in 2020 to beef up these 3 major sections of our company, the discovery and IND generation, our portfolio and life cycle development of melflufen, our lead product, and also looking forward to the commercialization side, a significant investment, and now we are prepared for our first commercial launch.

So our hope is this is the last quarterly update without revenues, which would be truly exciting for all of us, obviously.

So on the discovery IND generation side, as you know, we're looking at targeted therapies for hematologic diseases. And besides our product melflufen, we have a second product in the clinic now, OPD5 and look forward to bringing new chemical entities from our peptide drug conjugate platform. So very excited about the prospects for that, and we'll be guiding more specifically on developments there. We expanded our operation in Stockholm and have really beefed up our efforts in this discovery and IND generation area.

In the middle, as it relates to melflufen, focus on the relapsed/refractory multiple myeloma market, a huge global market, we recognize it growing to the range of $23 billion in the next couple of years. We have a very broad program. We're currently in priority review. And as you know, we have the PDUFA date that is just 1.5 weeks away. So very excited about that, and Dr. Bakker will get into some of the details here with respect to the life cycle plan. And then on the commercialization side, as you know, who follow our story closely, we are ramping up for the U.S. launch. We currently sit with a market cap of around $1.4 billion and our cash position at the end of Q4 is roughly $100 million. So really excited about moving forward.

So on Slide 5, we touch on Q4 and the highlights of Q4 and we did a lot of work regarding our commercial readiness, again, prepared for this FDA user fee date of February 28, which happens to be on a Sunday. So stay tuned for that news. We're poised for either Friday or Monday or earlier. Don't know the exact date. So we're pretty much to the finish line. It's an all or none proposition, but we're feeling good about where we are today. Really also pleased that in the fourth quarter, the full data set for the Verizon study was published in the Journal of Clinical Oncology. This is really an important aspect in launching a brand to have the black and white clinical data in its full glory that will be available for our team to provide to health care professionals in the U.S. and around the world for that matter. So that full data set being published in the Q4 was really a highlight.

At the ASH meeting, we saw the update on the ANCHOR trial and some of those details that really paved the way for the Phase III trial of LIGHTHOUSE and that trial has been opened. And in the fourth quarter, we had the first patient enrolled. This is a combination with daratumumab, which is a really exciting drug, really fast-growing drug and the synergistic combination of melflufen and daratumumab is quite encouraging, particularly when we look at the results of the ANCHOR arm relative to other products that have combined with daratumumab.

As I mentioned, with OPD5, the FDA accepted our IND application. So second drug in the clinic. So we're really playing out this peptide drug conjugate platform and are excited about a portfolio of products that could be in our future at Oncopeptides. We've also made nice progress in Europe and have discussed that a little bit, so we've switched our focus and strategy from an OCEAN-based filing to utilizing the HORIZON data. So that HORIZON data was so significant and really pleased to see the FDA's obvious acceptance of that to also utilize -- potentially utilize it with the EMA for an earlier launch than anticipated in Europe. So stay tuned, we'll continue to make progress and continue to guide on that front.

And finally, from a financial perspective, we announced a $40 million loan agreement with the European Investment Bank that really provides us some flexibility from a financing perspective as we move forward.

Moving ahead to Slide 6. Our commercial launch strategy and geographic expansion and really, we're focused on driving and maximizing shareholder value here. So obviously, U.S. go at it alone, launch ready, PDUFA date. I'm calling from our Boston-based headquarters, we've got a commercial presence. I'll go into that here in a little more detail, established across the United States, ready to launch melflufen into the marketplace.

As it relates to Europe, we're in that regulatory phase. We've made the early indication and strategic declaration that we intend to go at it alone, having grown from European roots in Scandinavia and Stockholm. We have the talent, and we believe the know-how to also go at it alone from a European point of view. You'll see some work to that end upcoming as we are recruiting leadership and expanding our talent and capabilities to commercialize the drug in Europe. Rapporteur and co-rapporteur were assigned in Q4 and we look forward to continued discussions there and providing updates as we move forward.

As it relates to Japan and other Asian opportunities, likely a partnering strategy as most biotech companies of our size would be thinking that way. We're looking at the current gaps, what we need to do from a clinical development perspective to have a full package for PMDA and for continued progress in Japan. We're engaging with KOLs and making sure our data is known in the Asian geography as well. So that's kind of our thinking from a geographic perspective.

Moving forward to Slide 7. We are paving the way for a successful launch and ready for that successful launch. Our organization has grown very significantly. We put the emphasis on a couple of different factors. One, we want experienced oncology, hematology professionals, and we have done that and secondly, we've made sure that we've also built into the team a lot of multiple myeloma expertise. So really pleased with the mix of folks that we have available. You see some of our leaders here and their backgrounds outlined.

And at the bottom of the slide, you see that we've attracted talent from the who's who related to the oncology, hematology space in the United States and globally. So really excited about the team and moving things forward.

So on Slide 8, just being now 2 weeks from the PDUFA date, just to provide a checklist here, field-based hiring done, both on the commercial and medical side, training, account profiling, so a lot of details regarding who we're calling on, the priority of this calling -- the call list, promotional materials submitting these materials in advance to the FDA will be under the Subpart H as an accelerated approval drug. So these materials need to go in with our filing, state licensures.

We've really put the emphasis on patients and we put patients first in Oncopeptides, so related to co-pay and really a white glove service as it relates to taking care of patients, communication with patients, making sure that they're getting the best possible experience that they can get in utilizing melflufen as part of their disease and multiple myeloma treatment, distribution strategy in place, GPO agreements in place, excited about some of the connections we have there, and what we're going to be able to do in the marketplace. Speakers, KOL engagement, supply chain preparedness, and really built a state-of-the-art system that is going to help our internal team communicate, understand dynamics, changes in the system, when there's a prescription there's alerts at the field level, and we're able to support, whether it be through our oncology nursing team or our oncology account managers or our medical science liaisons, people are aware, and we're there to support the health care professionals that are helping to support the patients.

So moving forward to Slide 9, connecting, again, the clinical development program, our excitement there with relapse refractory multiple myeloma market. And first of all, we have the HORIZON trial. And think about the fact that the HORIZON trial, when it was kicked off, we did not anticipate that this trial would rise to the level of leading to an early approval of the drug in the United States or Europe.

So outstanding data, focus on triple class refractory patients, this is obviously an area of high unmet need. We've kind of characterized this market in the U.S. as being roughly 20,000 patients, really key milestone for us in the first half of this year besides the launch is the OCEAN trial. So the head-to-head comparison with pomalidomide, moves us up in line of therapy.

So this more than doubles the number of patients that may be available to us from a labeling perspective. But also keep in mind what we put at the top of the slide here as we move up in therapy, not only do we expand the patient number, but also the expectations in terms of the duration of therapy on melflufen and the length of time in which a patient can benefit from the drug on average also increases significantly. So this speaks to a growing revenue opportunity as we continue to play out this clinical development plan.

So on the LIGHTHOUSE trial, the green box is the combination with either PI proteasome inhibitor or anti-CD38, obviously, LIGHTHOUSE is focused on daratumumab, again, an increased patient population and longer duration therapy, based on the outstanding data from ANCHOR that Dr. Bakker will speak to.

So with that, I will turn the program over on Slide 10 to our Chief Medical Officer, Dr. Klaas Bakker.

So thanks, Klaas.

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

Thanks, Marty, and good afternoon, good morning, everybody. If we go to Slide 11, please. So on Slide 11, we see the clinical development program of melflufen. And some of you may have seen this slide before. I will touch briefly on it, after which I will go into some details of the specific trials. So these are the studies that are currently ongoing. The O-12-M1 study on the far left was the dose finding study, HORIZON, obviously, our pivotal study for which we anticipate an approval soon.

The OCEAN study fully enrolled and slated for a readout in the first half of this year. ANCHOR are a very important combination trial where we combine melflufen with various backbone drugs in multiple myeloma, and then we have BRIDGE and PORT studies where we respectively look at patients with renal impairment. And we look at the possibility and feasibility of peripheral infusion of melflufen with PORT. And both BRIDGE and PORT may enable a label broadening in the future. As mentioned before, by Martin, LIGHTHOUSE trial started in Q4 last year, and very important for us moving forward as we aim to move upwards in the treatment trajectory.

We have started to also study melflufen in other indications. And the first one is where we had a trial ongoing is the ASCENT trial, and that is a trial in light chain amyloidosis. And we hope to provide you with some first results there by the end of this year.

If we go to Slide 12, please, and this is quite an exciting slide from our perspective because what you have seen before on Slide 11 was the known clinical development plan, but we are planning to expand both in multiple myeloma, but also in new indications. So if we first focus on myeloma, we will have a study specifically in patients with extramedullary disease. And as you may know, this is the most difficult-to-treat patient population

in multiple myeloma. And here, we will look at a combination study with bortezomib, melflufen, dexamethasone in soft tissue, extramedullary disease. And especially the soft tissue extramedullary disease is known to be very difficult to treat. But we were very encouraged by the data in extramedullary disease in Horizon. So this made us very excited about the opportunity to now have a study fully focused on extramedullary disease, and we expect to have the first patient in there in the second half of 2021.

Moving forward, we are looking actively at the combination study with an anti-BCMA agent, either a BiTE compound or a CAR T, and this will hopefully enable label expansions in the future in combination treatment, and this will be a very important study moving forward, where we anticipate the first patient in around year-end this year. That's for myeloma on the short term, but we're also expanding in new indications. And important to notice is that this is all based on highly encouraging preclinical data in these other indications.

Our company is focused on difficult-to-treat hematological diseases. We -- and the very encouraging data from our preclinical perspective, we have decided to move forward in acute myeloid leukemia, a disastrous disease, patient after 1 year has an overall survival of less than a year -- sorry, after the first treatment, and here, we will start a Phase I study in relapsed patients, and we expect the first patient in also around year-end this year.

And then based on the positive results that we have seen in non-Hodgkin lymphoma, we have decided to move forward with a Phase I/II study in relapsed diffuse large B-cell lymphoma, here, also an area of high unmet medical need, limited survival in relapsed patients, especially the relapsed high-risk patients. And here, we expect the first patient in the second half of 2021. So a lot of ongoing activity in the near future, all focused on, first, broadening our footprint in multiple myeloma, but also now focusing on other indications of high unmet medical needs.

If we go to Slide 13, please. This is where we have a snapshot about what we presented at ASH in December last year. And just very briefly, I think it's important to note that if we look at competitors like GSK, like Karyopharm, we actually had more presentations at ASH than these main competitors from us with 8 clinical presentations, 4 preclinical presentations and notably 1 overall presentation based on the daratumumab arm of ANCHOR. And if we speak more about ANCHOR, and here we go to Slide 14, please.

So ANCHOR, as mentioned, is a basket study. This is a Phase I/II study where we look at the combinability of melflufen with either bortezomib, VELCADE, or with daratumumab, DARZALEX. And these are patients who have undergone 1 to 4 previous line of therapy, and they should be refractory to either an IMiD or PI or both. So please note that all of these patients are refractory. We look at PFS from an efficacy perspective. And of course, we also look at early signal in overall survival.

And if we take a look at the results in the daratumumab arm on Slide 15, please. We see on the left hand, we see the so-called swimmer lane of the patients. So this is really all the individual patients depicted and their ongoing responses.

Currently, we see an overall response rate of 73%, which is very encouraging, and I will speak to that later when we make a comparison, the competition. But very importantly, a median PFS of almost 13 months, 12.9 months to be exact, and we still have patients ongoing. Overall survival, immature but still 18.4 months at the time of the data cut. All in all, very encouraging data. I'm very pleased with that and this laid foundation for our LIGHTHOUSE trial, on which I will speak shortly.

If we go to Slide 16, please. This is the responses in the bortezomib trial, we have now completed the Phase I part of the study with a 62% overall response rate. Also encouraging, most importantly, no new safety signals with both combinations, both with daratumumab and bortezomib. We have, from a safety perspective, the so-called go ahead to further expand our clinical footprint. And at this stage, the bortezomib combination is too early to have a median progression-free survival, but we are currently enrolling the Phase II part of the study.

Now what does that mean? And if we go to Slide 17, please. So Slide 17 shows, from the left to the right, the refractory status of the patient. As you may be aware of, a patient can be relapsed or refractory, but there is always a kind of level of refractory-ness. Is it all patients? Is it 60%, 80%. And that is very important. If you look at what does good look like? Because the earlier the patients, or the lesser refractory the patient, actually you expect better results. And if we then position ANCHOR, and that's above the blue arrow, and we compare that to the major trials of combinations with both bortezomib and daratumumab. We actually matched then to the refractory status that we have actually enrolled in this population. And

if we then look at the daratumumab arm, 30 months holds really well up with Eloquent 3, but also with the recently presented APOLLO data. And then for ANCHOR, a later patient population or refractory, 62% ORR.

So we feel very confident with these results from ANCHOR that we will be able to compete in this space as well. Next slide, please.

So LIGHTHOUSE, as mentioned, based on the previous mentioned results on ANCHOR, study of melflufen plus daratumumab versus daratumumab randomized 1:1. Importantly, the subcutaneous version of daratumumab, and this is really to expand our market potential, where we really hope to show an efficacious and safe combination. And the study is ongoing. Primary endpoint is PFS with secondary endpoints OS and study at this moment is recruiting patients.

Then to Slide 19, please, where I will briefly touch on the OCEAN study. We are very eagerly anticipating the results. We still expect that to be in the first half of this year. As said, fully enrolled trial, 495 patients melflufen dex versus pomalidomide dex, head-to-head, quite unique in this setting, not the typical triplet versus doublet with primary endpoint of PFS and secondary end point of overall survival. And this study basically is reaching its primary endpoint when we are either non-inferior or superior. And I'll talk about that a little bit in the next slide.

So if we go to Slide 20, please. So this is a graphical depiction of what a non-inferiority and a superiority result mean. So if we focus on the graph on the left lower side first, this is actually a slide where from left to right, the hazard ratio is depicted with 1.0 in the middle. And if you actually are at 1.0, that means that both drugs are performing identical in the study. To the left, with hazard ratios below 1.0, that means that melflufen does better, to the right pomalidomide does better. A superiority result would mean a hazard ratio below 0.8, and that is the dark green example. But importantly, a noninferiority result would still mean a hazard ratio between 0.8 and 1.0. So in both the non-inferiority and the superiority design melflufen will beat pomalidomide in the study, albeit with different levels of significance.

So pomalidomide as you know is widely used in RRMM. And we feel that both noninferiority result and the superiority result will significantly expand market opportunity. From a regulatory perspective, if you look at the superiority result that will lead to full approval in the U.S. as well as in the EU.

If we look at non inferiority. Well, it is sufficient in the EU for the FDA. That means that we will have to look at the totality of the data, which means that we look at the combined efficacy and safety results and this is then basically a negotiation with the agency, but something we feel very confident about should we reach that noninferiority result as well.

So with that event being the next big event from a clinical perspective, I would like to hand over now to Anders Martin-Lof, our CFO. Anders, over to you.

Anders Martin-Löf - *Oncopeptides AB (publ) - CFO*

Thank you, Klaas. If we turn to Slide 22, you see the figures for the year. First of all, you can see that the operating loss increased from roughly SEK 739 million in 2019 to SEK 1.6 billion in 2020. You saw the same trend during the last quarter of the year, where we went from SEK 244 million in Q4 2019 to SEK 511 million in Q4 2020.

I would say that the Q4 2020 costs were exceptionally high due to some accruals of R&D costs in the quarter. So that was quite a steep increase from the third quarter, but will not be sort of a similar increase going forward. If you look on the left-hand side, you see in the graph that R&D costs went from SEK 548 million to SEK 866 million. That's primarily then driven by the increase in clinical studies costs and drug supply, that was SEK 600 million roughly out of the SEK 866 million. And out of the SEK 600 million OCEAN -- the OCEAN trial (inaudible) and clinical supply make up for roughly half of SEK 314 million.

So it's a massive project for us that is now getting closer to completion. The marketing and sales costs went from SEK 127 million to SEK 456 million. That's, of course, risen of the buildup of our commercial and medical affairs infrastructure in the U.S. that was roughly 3/4 of the cost, so SEK 329 million out of the SEK 456 million was the U.S.-based organization. And all of this increase is, of course, driven by a massive increase of the company, both in marketing and sales, but also in R&D and have been here in Europe.

We went from 88 to 280 co-workers in 1 year, which is just astonishing to me. It will not be repeated next year. We will see some increases in marketing and sales that will continue. But looking forward to next year, I would say that R&D costs are going to be roughly in line with the 2020 cost in 2021, so will G&A that will also -- I think we will have a modest increase there. Whereas the marketing and sales costs will continue to increase. It was SEK 456 million in 2020. I think the cost was SEK 173 million in the fourth quarter.

That's the best approximation for where we're going. But I think that will increase slightly over the coming quarters, so to give you a view on basically where we end up for 2021.

Turning then to cash flow. We spent roughly SEK 1.3 billion in 2020. For the fourth quarter, the cash flow from operating activities was SEK 357 million. So that was a little increase from the third quarter. We were also hit by a negative exchange rate effect of SEK 53 million. So the current -- the total net cash decrease was SEK 411 million for the quarter. And that left us with a cash position of SEK 840 million as of December 31. You see where we have raised money in the year. And we also have then a EUR 40 million loan facility that we secured in October.

So all in all, we have before that -- we have roughly cash to go through the second quarter of the year, excluding the loan facility, and we sort of reiterate that guidance at this point.

I think that was all from me, and then I'll leave the word back to Marty to summarize.

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

Thanks, Anders. And moving then to Slide 24, you see the focus of the call here has been on the accomplishments in Q4. And then, of course, the emphasis here on Q1, potential accelerated approval in the U.S. and the commercial launch. So excited about those milestones. And then, of course, in the first half of '21 -- 2021 and more specifically in Q2, top line OCEAN results. So still tracking towards, as we know, this is an event-driven trial. We believe we're in a place where that guidance continues to work. So please look forward to the Phase III results, top line results being communicated on the OCEAN trial in the first half of 2021. We'll also continue, of course, with our second Phase III trial and look forward to very significant increases in our accrual to that trial and guiding towards getting last patient in the earlier part of 2022 on the LIGHTHOUSE trial. And we see a number of other things that will contribute to our progress that will impact the label, impact perceptions of melflufen, and to expand our opportunities in bringing new peptide drug conjugates to patients throughout the world.

So I think I'll stop there, and we'll move to the question-and-answer phase of the call. So thank you.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

(Operator Instructions) Our first question comes from the line of Viktor Sundberg from ABG Sundal Collier.

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

So you said that the FDA will come with their decision on a Sunday. Do you think they would press release if either a CRL or approval came during the weekend? Or do we have to wait until Monday? Have you looked at any other approvals and so on to maybe understand it better.

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

Yes. Good question. Yes. I think it's -- look, it's just kind of the way the math worked out, the calendar worked out. I don't think there'll be anything on a Sunday. So we would more anticipate something either on Friday or Monday, but there's no real way of telling. That's what the assumption we're on track. And from our perspective, everything seems to be in place, but you never know until you get there. But I would not expect that to happen over the weekend from an FDA perspective.

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

Okay. Great. And on OCEAN also a question, could you perhaps be a bit more specific what kind of discussions you would have with the FDA, if you would reach noninferior results? Have you had any strategy in mind since before and how you would approach that result to the FDA in order to get approval.

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

Yes. So I'll start and then maybe ask Klaas to comment. So from an FDA perspective, the typical agency response is, it will be a data-driven decision. So I think it's a matter of, let's see the data, the compelling nature of the data. This is a large trial, head-to-head comparison against a very important and growing product. Pomalidomide now $3 billion worth of usage around the world. So very important drug in multiple myeloma. We're excited about the opportunity to show that for either non-inferior or superior to it in the selected patient population. So I don't know that I could say anything above and beyond data-driven decision, but we certainly would be encouraged by something a hazard ratio that doesn't quite meet the 0.8 and believe that, that would open up an interesting discussion with the agency. Klaas?

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

Yes, I completely agree, Marty. I think one thing to consider there is that there will always be a decision on the benefit of risk totality. And this is where it is good to keep in mind the very tolerable nature of melflufen. So this will not only look at the efficacy, which in itself is already -- would be, I would say, stunning if we would beat pomalidomide, but it will also then look -- the agency will also look at the safety there. And we feel we have a very good and tolerable drug there. So that's kind of the general picture that I would paint.

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

And just a question on the hazard ratio. I think before you communicated, if I don't remember -- or if I'm not mistaken that the hazard ratio or the primary internal was a hazard ratio of 0.7. Is that not correct or?

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

Klaas?

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

The hazard ratio where we reached -- yes, the hazard ratio where we reached statistical significance is 0.8.

Operator

Our next question comes from the line of Chris Uhde from SEB.

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

I have a few short questions. So can you comment at all on what do you see as the likelihood at this point, very close to FDA decision of getting either the data or language in the actual indication on the label for extramedullary disease subtypes or high-risk cytogenetics, and then I guess I just roll them off. In terms of potential to expand ANCHOR to add more arms, basically, other combinations, possibly larger groups, is that something for us to look forward to? And then might you do a trial just collecting stem cells after melflufen exposure to try to -- an easy, relatively low-risk way to demonstrate difference from melflufen. Those are my questions.

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

Okay. Thanks, Chris. I'll take the first one and then turn it over to Klaas. Certainly commenting on the specifics of the label and where we're at is not something I'd feel comfortable with at this point in time. I think from a general perspective, if we think about the HORIZON trial, we took on all-comers and really had a high percentage of patients that were extramedullary disease, a high percentage of patients that were high risk, we outlined it at the ASH program, high percentage of patients that were alkylator refractory. And what we see is a consistency of efficacy and that benefit risk profile throughout those subpopulations. It's important to note that with an accelerated approval, one typically does not get subpopulation called out specifically in any way from an indication perspective. So it probably is unreasonable to think about those types of call-outs, but the opportunity again, to promote, reflecting on the HORIZON trial and those patient types that were in the HORIZON trial, we would believe we'd have the opportunity to promote specifically to those patients. Klaas, as it relates to the ANCHOR expansion?

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

Yes. Thanks, very good question. Yes, we are looking at other combinations as well, other potential combinations. With regards to the daratumumab and bortezomib arms, those won't be further expanded. On daratumumab, we basically expanded with the LIGHTHOUSE trial, future results of the bortezomib arm also be that compelling, we may build on the results there with bortezomib. But in the meantime, we are also adding newer agents to look at the safety and efficacy there as well. On the question about looking into the bone marrow of patients, yes, we are actually ramping up our translational research in general in the company. We have now established a translational research group as well. And one of the things that we will be specifically looking at is the impact of melflufen on the bone marrow, but also on the clonal evolution before, during and after treatment. So a very good question. And yes, we look into that.

Operator

Our next question comes from the line of Rene Wouters from Kempen.

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

So the first one is with regards to the planned future studies. Do you have certain BiTE's or CAR Ts already in mind for the multimyeloma combination study. And will you chose one compound to combine with? Or do you rather want to study with multiple combos? And then I have a follow-up.

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

I'll turn that one to Klaas.

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

Yes. Thank you. And currently, I'm unable to comment on the specific agents that we have in mind but we're actively investigating various options there. We're looking for -- in principle, we are looking at a compound, which we believe is the best combination for melflufen and not so much as a signal seeking trial with various compounds. I hope that answers your question.

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

That's helpful. And then the follow-up question is about your strategy in Japan. You elaborated already a little into it during the call, but when do you expect that we can have more specific guidance and/or a partnership being announced?

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

Could you just repeat the first part of that, Rene? I missed the...

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

Yes, sure. So I think you already elaborated on some of the plans that you have in Japan for melflufen. But when can we expect to hear more about that?

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

Yes. I think as we've -- looking at the major inflection points in milestone, our focus has been on kind of the U.S. launch. And then the OCEAN data being a big driver of potential value, whether that be partnerships in Japan or thinking about other regional opportunities. So our focus has been on those 2 milestones, but we'll begin shifting our attention, obviously, with approval in the U.S. and moving forward in Europe. Getting the -- getting our product and leveraging the results of the HORIZON trial and the OCEAN trial as quickly as possible will become more and more important to us and those other geographies will come in more focus in the quarter or 2 ahead.

Operator

Our next question comes from the line of Boris Peaker from Cowen.

Boris Peaker - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

First question on manufacturing. Can you comment who manufacturers melflufen and what are the key steps or if there are parties involved? And has the FDA inspected the manufacturing facility already?

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

Yes. I'll volley that one to Anders for us.

Anders Martin-Löf - *Oncopeptides AB (publ) - CFO*

So the drug substance is produced by Chemoswed in Southern Sweden and the drug product is currently produced by Cenexi in Belgium. Cenexi in Belgium has been inspected by the FDA in the beginning of 2020. So we're not expecting a repeat of that inspection for our approval.

Boris Peaker - *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

And my second question, in terms of the commercial expectation, I'm sure a lot of investors are going to be looking at XPOVIO as a guide. Is it reasonable to anticipate you guys to beat XPOVIO even in the first initial few quarters? Or how are you thinking about that?

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

Well, I think as we -- good question, I think as we look at the profiles of the two drugs, we believe our drug is superior. Obviously, we're launching into a little bit different marketplace with them being a competitor that they didn't have to face and also belantamab being approved in the space. But certainly, our ambitions, midterm and long term, for sure, are -- that we see melflufen being a superior backbone product with a benefit risk profile that we think is better than selinexor.

Operator

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

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

Got a couple. So firstly, just to Anders, I think, on the cost base.

Just curiously, I think I'm right in saying, and you could add a bit, but I think you said sales and marketing will likely further grow on the fourth quarter run rate. I guess, getting just curious, does that assume you do continue hiring European infrastructure? Or is that just based on the sort of U.S. alone? And I think you said the U.S. is SEK 329 million of the spend this year. But if you can just confirm that, that was the number you said.

And then just continuing in Europe, you obviously gave some helpful details in terms of the field-based team in the U.S. any sort of initial guide you can give us in terms of what you would be thinking in terms of Europe and how that team may differ in size versus the U.S.

And then just lastly, just with regards to when we think about the OCEAN readout. I guess, curious there in terms of what you would give us in terms of the granularity there, should we anticipate just a headline press release? Or are you -- will you provide more details than that, do you think, in the press release that's announced with the decision there?

I'm sorry, just finally as well on the U.S. approval. Are you ready to go and ship drug, just get on the ground as soon as the 28 Feb or whenever it happens? Or should we anticipate a little while after that before the actual first patient is able to receive drug in the U.S.

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

Yes. I'll take the last one first, then maybe go over to Anders on the costs. Well, maybe I'll touch on the European just a little bit, then I'll turn it over to Anders on costs and to cost on the OCEAN point. So yes, within a couple of weeks, I would say, there's the -- once we get the approval, we have to print the labels, put the labels on the drug, and then get them into the distribution system. We believe that, that can happen within 2 business weeks. So there won't be any big delay there.

As it relates to Europe and the projections on sales force size, too early to tell. There are different ways in which our strategy can go. Stay tuned on that from a go-forward basis. Maybe this ties a little bit into what Anders will talk about. But as our strategy plays out on the regulatory front, we will phase in investment accordingly. So right now, we don't have a big build in Europe that's currently in the plan. That will be based on the opportunities, near-term opportunities playing out.

So with that, I'll turn it over to Anders to touch on the costs.

Anders Martin-Löf - *Oncopeptides AB (publ) - CFO*

Thanks, Marty. And yes. So starting then with the SEK 456.5 million that we had in marketing and sales cost in 2020, roughly, you're correct, roughly SEK 329 million of those were in the U.S. So then try to figure out what's going to happen in the 2021, it's probably more relevant to look at the Q4 cost of SEK 173 million. That number will increase somewhat. The full organization was not there, the full quarter in the U.S. So we will see some increase in the U.S., and we'll add some positions in the U.S. during the year. And then towards the end of the year, we will most likely have some people in Europe. It really depends on what happens in terms of EMA probability if we can get accelerated approval or not. So we're not sure really what will happen there. But if you assume that we will go up maybe 10%, 15% from the Q4 rate and apply that as a proxy for next year, that probably gives you the right ballpark figure for the full year number. I hope that helps.

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

Klaas, on the OCEAN results?

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

Yes. Sure. And you may appreciate that for these types of big Phase III studies, it's an awful lot of data that comes in at various time points. So as soon as we are able to communicate the primary endpoint and whether we reach that or not, that will be something we press release. For more detailed data, we would anticipate that to be shared at a conference in the future.

Operator

We have no more questions from the line. I will hand it back to our speakers.

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

Okay. Thank you. And thanks to everyone. Obviously, a good quarter for us and looking forward to even a more exciting first quarter here in 2021 in the 6 weeks that -- or so that remain. And certainly, I've been doing this for a long time, and I can look at 2021 from an Oncopeptides perspective and here out of the gate with a Phase III readout in the first half of the year, potential U.S. launch, progress in Europe, really, really exciting year.

So look forward to continuing to update everyone on the story and the milestones as we move forward with our ambition to bring melflufen to patients around the world. So thank you for continue digging in and covering Oncopeptides and look forward to future discussions. Thank you very much.