**Edited Transcript Nyxoah Fireside Chat**

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Participants:
**Olivier Taelman**, *Nyxoah - CEO*

Fireside Chat Moderator:
**Adam Maeder,** *Piper Sandler - Research Analyst | Medical Technology*

**Adam Maeder:**
Good morning and good afternoon, depending on where you are. I wanted to start by saying, welcome to the 2020 Piper Sandler Healthcare Conference.

My name is Adam Maeder and I'm one of the medical technology equity research analysts here at Piper Sandler. I'm very pleased to introduce the management team from Nyxoah. With us we have Olivier Taelman, CEO.

Olivier, thanks so much for being here with us this year.

**Olivier Taelman - CEO:**
Thank you for inviting us. Thank you.

**Adam Maeder:**
Of course. So, Olivier, I think many US and European investors are familiar with Nyxoah. But can you please introduce the company for those that are newer to its story. I think it'd be helpful to get just a one or two minute background commentary on the company itself, the technology and also the recent IPO.

**Olivier Taelman - CEO:**
My pleasure. So Nyxoah was founded in 2009 by the serial , Robert Taub. The company is headquartered in Belgium, we have subsidiaries in Israel, Australia and most recent also in the US. By the end of this year, or we will have 80 employees around the globe. When Nyxoah was founded, it was founded from a blank sheet of paper, addressing a huge unmet need in the obstructive sleep apnea market where CPAP therapy is the golden standard. The challenge and the ambition of Nyxoah was to develop a neurostimulation unique bilateral minimum invasive system. And by doing this we challenge ourselves by having it at least as equal or even more performant than the existing hypoglossal nerve stimulation therapies out

there. And we wanted to put the patient more centric, providing the patient with more autonomy.The result was that we ended up with a bilateral stimulation, where our competitors are working with unilateral stimulation.

And we also ended up with an external power source, which has an impact on the patient having a less invasive surgery, going much faster, 60 minutes skin to skin time. And besides having the power and the battery externally, we also have the software externally.

If you look at the obstructive sleep apnea market in total, and we talk about prevalence, you know it's a huge market. With over 40 million people that would be eligible to treat, suffering from moderate to severe obstructive sleep apnea. If we look at the incidence number It's up to 500,000 annualy eligible to treat people only in the US. If we look at the other focus geographies, being Europe for Nyxoah combined with Australia and New Zealand, it's a compatible number.

And most recently, and that was also one of your question, we went from a private company to a public company. We did a Euronext IPO, where we raised $100 million, we were five times oversubscribed, we had at the high end of the company valuation with a strong geographical spread onboarding a lot of US investors, of which Deerfield Capital is one of our anchor investors. So we're extremely pleased and we will go into extremely challenging times.

**Adam Maeder:**
Great. Well, that was really helpful overview of the company and the recent progress that you've been making. So congratulations there.
My next question is on commercialization. You have CE Mark approval, so it'd be helpful just to kind of get a better sense for where you are today in terms of the commercial launch and where do you plan to go over the next 12 months or so.

**Olivier Taelman - CEO:**
As you correctly mentioned, we obtained CE mark approval in 2019. Our international commercial strategy is very straightforward. We want to go deep, not going wide when it comes to therapy penetration. As you know, international commercialization goes hand in hand with obtaining reimbursement, country by country. In some countries it can go fast, in other countries it's extremely slow. We focused on the larger European countries. We do not want to reinvent the wheel. Where there is already an existing reimbursement coding for hypoglossal nerve stimulation, we want to end up using the same coding. That brings us to Germany. It's one of the largest European markets and we were able to obtain reimbursement there 12 months after CE Mark. Using the same coding as our competitor, at the same price point. So also from a procedural perspective, we are at a comparable OPS coding.

Now, how do we define success or future success in this specific German market? Also, there we want to be straightforward. I think sometimes simple objectives are the best ones, and we have identified success as becoming market leader in the centers of excellence in Germany by the end of 2021.

Next to being a fast follower we also want to show that we can lead, that we can demonstrate leadership by entering in markets in Europe where there is no hypoglossal nerve stimulation. We identified France as our focus market. And there we want to enter under a special innovation budget called Forfait Innovation. What does it mean ? It means that we will have a predefined number of implants that will be reimbursed by the French healthcare authorities, while we are building specific French clinical evidence.

So that's in a nutshell our reimbursement and commercialization strategy - go deep versus going wide, be a fast follower where there is coding, with Germany as our primary market. And then we want to demonstrate leadership in France through the Forfait Innovation.

**Adam Maeder:**
Okay, great, that it's very helpful. And I think that all makes sense to me.
I guess the next question I have is, just maybe tell us a little bit more about the commercial organization. Do you have a direct sales team or are you using a distributor model? So, what does that look like today and how will you build a commercial organization going forward ?

**Olivier Taelman - CEO:**
Well, as I mentioned it just a couple of minutes ago we want to go deep versus going wide. So it means that we have invested in creating competitive commercial sales structure in Germany. In order to reach our objective, and that is becoming within 12 months the market leader in centers of excellence.

On the other hand, we also built what we call a more European sleep experts team. Meaning that it is a training and education team focused on trouble solving when it's needed, focusing on training and educating new surgeons and getting them familiar with our therapy. And of course, supported by a strong marketing team. Moving forward, we will continue investing in building commercial competitive organizations in countries where we obtain reimbursement.

And over time we want to build an international and an US specific commercial organization. We are focusing on going in the larger markets direct.

We have one specific country - it's Spain, because the reimbursement structure is very specific there, where we also are exploring an indirect model, but that's the only place where we are going indirect and in all the other countries, we will be direct.

**Adam Maeder:**
Okay, that's very helpful. And maybe this is that was a good segue into the US pivotal trial, which is called DREAM. So, I wanted to just ask about the progress there. Are you able to tell us how many sites are active today? How many patients have you enrolled and more broadly, how should investors think about US commercial approval and launch timelines ?

**Olivier Taelman - CEO:**
Well, so when we obtained from the FDA the IDE pivotal study approval in June this year, this was a huge milestone for Nyxoah. This was something we were working on, because as you know even better than I do, the US market is the place to be for treatment of obstructive

sleep apnea and it's an important market space and Nyxoah also wants to be in the US. Well, in this IDE pivotal study we have today thirteen active sites.

We already implanted the first DREAM patient. Just recently, November 16 to be very precise. In total we want to continue having up to 19 US participating sites in combination with six international sites, of which four are in Australia and two are in Europe. We need to have all 134 patients. Looking at our timelines. We want to finish the enrollment by the end of Q2 2021. Then we will of course need to generate 12 months patients follow up data, that will bring us to the end of Q2 2022 and as of then the FDA negotiations will start. So, we feel confident that we can be commercially available in the US somewhere mid 2023.

**Adam Maeder:**
Okay, great. That was very helpful. And I wanted to ask about the the body clinical evidence that you have today, that's supporting your Genio® product. So, maybe just remind us what the efficacy and safety profile of your product looks like. What you saw on the CE MARK trial, which was called BLAST OSA and then you also have a European post market study that you're running . So, maybe talk about the CE Mark trial results and then talk about the importance of the European post market study that you're running. And when we might see that data come available.

**Olivier Taelman - CEO:**
When we are talking about the BLAST OSA study, this study demonstrated safety and efficacy in a cohort of 27 patients and was leading to CE Mark that we have obtained in 2019. Now these data are publicly available and they were published in the European Respiratory Journal. When I'm saying 27 patients' cohort, It's a limited patient cohort and we do realize this. So, that is also why we immediately have launched the EliSA study, where we are building long term evidence on safety and efficacy, we increase the volume up to 110 patients and we are having 20 centers involved spread over more than five different European countries. What we are measuring is 12 months, three-year and eventually five-year follow up. So that's what we are doing.

When we look at the BLAST OSA study data I want to refer to the six-month data and we compare with other competitors out there, we can say that BLAST OSA was a confirmation of the fact that hypoglossal nerve stimulation is effective and performant for obstructive sleep apnea patients. But we have to stay humble, of course, also if you compare our cohort with the competitive cohort, which is much larger. But the results were extremely strong, comparable and they were so significant that the notified body immediately granted us CE Mark approval.

**Adam Maeder:**
Okay great, thanks for that background. And then one thing I think that's interesting, at least from my vantage point is, that you're also running an early feasibility type trial to evaluate the efficacy and safety and concentric collapse patients, which are not treated today commercially with hypoglossal nerve stimulation devices. So, anything you can share about those results today and what's your level of confidence that this patient population can be treated effectively with your Genio product?

**Olivier Taelman - CEO:**
Yes. So before I go into this study. This study is called better sleep and it's conducted in Australia. This is completely linked to the bilateral stimulation aspect where we are unique in offering this to patients. Because we believe, together with a physician group, that it's worth studying a bilateral stimulation effect also for the complete concentric collapse patients that are currently contraindicated for hypoglossal nerve stimulation, as it's today.
Well, we also know that this patient population is really significant. We are talking about 25 to 30% of the existing population that is suffering from CCC.

Maybe a scope for you today is the fact that we just closed the enrollment last week, so we had to implant 44 patients, study enrollment is closed and now all the patients' data are starting to get analyzed, patients follow up is taking place and normally we will report on six-month data by May 2021.

If we can show that the data are really illustrating that we can also offer solutions for this specific complete concentric collapse patient group, that would be a confirmation that bilateral stimulation is really performant. But even more. It would also take away a huge hindering factor today, being the DICE examination that a patient has to undergo to identify if he is CCC or not. So this drug-induced sleep endoscopy will also vanish. And this is something that a lot of physicians and also a lot of patients are waiting for. What I can tell without revealing too much, and maybe you have to look a little bit at the smile that I'm having, is that the first results that we are seeing are really, really promising.

**Adam Maeder:**
Okay, that's great to hear. And maybe if I can just ask one follow up there. Just curious. If the Better Sleep results are positive, do you think that's the amount of clinical evidence that you need to potentially expand the label in Europe, or do you need to run us a subsequent study to build out additional clinical evidence? And then I guess I'll lump another follow up in there. Just thinking about the US pathway. What would potentially need to be done to get that indication on label with with FDA?

**Olivier Taelman - CEO:**
Those are all excellent questions. So first of all, let me try to answer. Looking at market by market. So in Europe, we will immediately, of course, go for a therapy indication expansion with the notified body. We have already or we are already in discussion on how this would look like, but it will lead to a full therapy indication expansion done by the European notified body, that is one thing.

As a consequence of this, we can make the decision as a company to go back to FDA. And also start including CCC patients in our DREAM IDE study. This is a decision that we need to further explore, but it can be done. If we go for that decision, of course, and the outcome of the DREAM study is including CCC patients, that would give us a huge advantage because we will not only be able to treat non CCC, but also CCC patients. But once again, I do not want to jump ahead of decisions. So first of all, let's wait and see the data from the Better Study study, next have it leading to a therapy indication expansion in Europe by discussion with the notified bodies, and then we will decide based on this whether we include them in our FDA trial or not.

**Adam Maeder:**
Sure. Okay. Well, that's totally fair and I appreciate the incremental color there Olivier. So maybe we can talk a little bit more about the technology itself.
So let's talk about the technical specs, maybe just talk about the key components, the features and the potential advantages of Genio® and you touched on this a little bit earlier, but really want to flash that out a little bit more

**Olivier TAELMAN - CEO:**
In fact, we have three key elements of our Genio® system. The first one is the implantable stimulator. It's a passive device. So, we do not implant the battery. It's passive device that will be activated by an external power source through an energy transfer, through using induction.

Coming back to the implantable stimulator, there are some specifications. So first of all we have paddle electrodes. We have two paddles with each time two electrodes. So we're talking about two paddle leads with four electrodes in total.

The way the surgeon is implanting this, and we always want to be very visual, in fact, he positions the implantable stimulator as a saddle on a horse on top of the genioglossus muscle. The big advantage is that we just need to put the electrodes in contact with the nerve. We do not need to have cuff electrodes to make sure that the electrodes are staying in place. Surgeon just positions and snuggles the device as a saddle on a horse on the muscle. We suture the paddles also onto the muscle, so that the electrodes are staying in contact. Even when there is a muscle movement it will always result in a good contract. So I think that is important.

And then we'll go into the second component which is the activation chip. The activation chip is outside the body and it contains the brain and the power of the system. When I say power I mean the battery that is outside the body. When I say brain I mean the software.

What is the big advantage for the patient? First of all, the surgery only has one incision. There is no tunneling, there are no leads. It goes really fast, 60 minutes skin to skin time. That's what we are seeing with experienced surgeons.

The next thing by having your power source external is that, if for some reason, it needs to be replaced you do not need to come back to the hospital and undergo surgery, we will simply ship you a new one. And also on top of this having the power and the brain software outside the body allows for software upgrades to be done remotely. It can be done very easy and it also gives the physician the opportunity to interact with the patient, using a cloud-based platform and not needing to see the patient coming back to the hospital. And I think if there is one thing that Covid 19 is teaching us is the fact that you can monitor and manage your patients remotely. This is a really big advantage, both for the physician and for the patients.

And last, because I was mentioning three key components, of course we have also the rechargeable unit. So a Genio® implanted patient before going to bed puts the activation chip under the chin. That will activate the passive implantable stimulator and in the morning when

they wake up, they just recharge their battery externally and they are all set to go the next evening.

**Adam Maeder:**
Okay, great. That was a very helpful overview on the technology. And one thing I wanted just to dive a little bit deeper on was bilateral hypoglossal nerve stimulation, which Genio® uses. The competition Inspire and LivaNova's ImThera, they use unilateral so maybe just help us kind of better understand why the company decided to stimulate patients bilaterally. You touched on the Better Sleep study, which it sounds like you think bilateral stimulation can better suit the concentric collapse patients, but do you think you'll have better efficacy with bilateral stimulation, maybe just talk through kind of why that's the mechanism of action for the Genio® product.

**Olivier Taelman - CEO:**
Before I answer the question. As you mentioned, we are competing with one company mainly that is offering unilateral stimulation. And I want to start by applauding the company for paving the way, by having hypoglossal nerve stimulation embraced by the medical community. And also, most recently, specifically in the US or they are paving the way with payers. So really, this is a huge job and a lot of heavy lifting. That being said, they're also using a pacemaker platform technology.
Now if you look a little bit more specific at the hypoglossal nerve you will see that it's comprised of two branches, a left one and a right one. If we offer a bilateral stimulation, what Nyxoah is doing, this is much more physiological than unilateral stimulation, resulting in a much more symmetric tongue contraction. And I think this is really important. So in fact, we try to mimic nature by stimulating both branches of the hypoglossal nerve and when we do this, we are seeing that also the symmetric tongue contraction, in fact, is creating stronger pull on the upper airway, resulting in a very strong airway opening. Once again, we are developing more clinical evidence to support this mechanism of action and this is what we will show when we publish also on the Better Sleep study results.

**Adam Maeder:**
Okay, it's very helpful. And, you know, maybe we have just, I think, three or four minutes left here, so I'm going to try and sneak in two more questions.
This may be a little bit of a premature question but you know the lion's share of the commercial market opportunities is in the United States. I think everyone is aware of that. So I'm gonna ask a question on reimbursement.
How do you think about the reimbursement pathway or strategy and the US market? Do you think you'll be able to use the existing CPT codes for reimbursement of Genio®?

**Olivier Taelman - CEO:**
So I first of all, we only expect to be commercially available somewhere mid 2023, so it gives us some time to do some further work. We are currently working with some of the best US payer experts to identify our reimbursement strategy, but we will also act in the US as a fast follower and we feel confident that we will be able to obtain similar reimbursement levels as competition.

**Adam Maeder:**
Okay that's helpful. And maybe just one last one. Investors are always thinking about act two or three just from a technology standpoint. So I'll ask you, what about the Nyxoah pipeline, maybe just help us understand where you're going to take this technology going forward in terms of future generation devices iterations to the current technology just anything you can share with us would would be much appreciated.

**Olivier Taelman - CEO:**
Okay, one of the outcomes of our successful IPO is the fact that we are significantly investing in further scaling up. When we look at R&D we invested significantly in the team. We are currently developing of second generation implantable stimulator. And we are working really hard on adding monitoring features providing the patient with even more autonomy, we think this is something really important. You will see those monitoring features coming out phased during 2021. And other last thing once again, driven by Covid 19 is that we are investing also further in a digital care platform, so that the physician can further follow up a patient remotely. Today we already Wi Fi, we have Bluetooth, but there is also still some room to even make it more user friendly or patient friendly to say it like this. So that's what we are working on currently.

**Adam Maeder:**
Okay, great. Well, I think that's a good place to stop. I want to say thanks again Olivier for joining us today and talking about the Nyxoah story.
Congratulations on all the success and the recent IPO and I want to thank everyone who took the time to watch our discussion today. So we'll conclude there. Thanks. Thanks so much, appreciate it.

**Olivier Taelman - CEO:**
Thank you again for the invitation. Thank you.