ONWARD Q3 Business Update

Thu, Nov 16, 2023

[Aditi Roy]
Welcome to ONWARD's Q3 2023 Business Update webinar. I'm Aditi Roy, Vice President of Communications at ONWARD. A reminder that today's event will contain forward looking statements, which often differ from actual results. Any forward looking statements communicated today reflect the company's current views and are subject to risks and uncertainties. Today's call will be hosted by Dave Marver, CEO and Khaled Bahi, interim CFO. Dave and Khaled will give a brief presentation, after which they will be pleased to take your questions. Should you wish to learn more about the company after today's call, please visit our website at www.onwd.com, where you can sign up for updates. Please also follow us on social media, where our handle for all major platforms is "ONWDempowered". Thanks for joining us. I will now hand the call over to Dave Marver, CEO of ONWARD Medical.

[Dave Marver]
Thank you, Aditi, and thank you everyone for joining us today for this Q3 Update. Some of you are new to the Company, new to this story. I'm just going to begin with a few introductory slides about the Company first -- ONWARD at a glance. So, we were founded in 2015. We have about 110 people working now on the team. We're headquartered in Eindhoven, the Netherlands, but we have a Science and Engineering center in Lausanne, Switzerland and we have an office in Boston, Massachusetts, USA. We did an IPO in October of 2021, we've raised about $170 million, or 150 million euros since inception. We have two purpose-built neuromodulation platforms and they both stimulate the spinal cord to restore movement, independence, and so forth after spinal cord injury. We're a very innovative company. We have nine FDA Breakthrough Device Designation awards, and now over 390 issued or pending patents, including more than 230 issued. We're increasing our body of clinical evidence. We have one pivotal study [for our external platform], complete with positive top-line results and a nice responder rate. And we have released positive interim outcomes from the first indication for our implantable platform as well. We intend to launch into a large total available market of about $20 billion. We expect first commercial sale the second half of next year, so likely within the next 12 months. And we have a nice, important relationship with the Christopher and Dana Reeve Foundation, which is the world's largest advocacy group, for SCI [spinal cord injury] and paralysis.

Our vision is that empowered by movement, people with spinal cord injury will enjoy life in every way that matters to them. Some want to stand and walk again. Others want to move their hands and arms more effectively, more independently. Others want to be able to go to the bathroom without having to insert a catheter or have a caregiver insert a catheter. And fortunately, our therapies have the potential to help in every one of these areas. And we have that flexibility, because we have two technology platforms as I mentioned before, the implantable platform called ARC^{IM} and the external platform called ARC^{EX}.

Alright, now on to the Q3 Update, where we continued to make very strong progress across the Company starting in August with the first-in-human use of the ARC^{IM} in combination with a BCI, or brain-computer interface, to restore movement of the upper extremities - the hands, arms, and fingers - after spinal cord injury. So, a really exciting milestone that we'll discuss in more detail in a few moments. In September, we signed an important agreement with a third-party logistics provider in the US that will provide us with rapid access to US government purchasing vehicles. Again, really important for commercialization, something we expect second half of next year. And so, we were very pleased to have that in place now. Also in September, we began an early feasibility clinical study for ARC^{IM} mobility, or the walking indication - more details to follow. And we expanded our ARC^{IM} clinical feasibility study where we're exploring use of our therapy to better stabilize blood pressure after SCI. Throughout the quarter, we were issued 33 additional patents.

Also in November, there was an exciting development in *Nature Medicine*, one of the world's preeminent science and medical journals. [*Nature Medicine*] published a manuscript detailing use of our ARC^{IM} Therapy to help people with Parkinson's disease with their gait disturbances, their walking disturbances. And as part of that, we announced that our research partners at .NeuroRestore, as well as ONWARD, were granted a $1 million grant to support six more implants with the ARC^{IM} System to further explore the viability of using ARC^{IM} Therapy to address gait challenges in Parkinson's disease. So, let's go through each of those in detail starting with the ARC^{IM} BCI implant in August for upper extremity function. At left, you can see our ARC^{IM} Neurostimulator, which is actually quite small. And then the BCI that's implanted on top of the dura and replaces a portion of the skull. The way this works is that the implanted brain-computer interface records brain activity, it sends that activity - the intention to move - to our system, which decodes those signals and translates them into specific stimulation instructions. And in that way, a person's thoughts are translated into stimulation parameters that affect movement, even long after paralysis. This was covered across the world, in a number of global [media] outlets, you see six of them here. And ONWARD enjoyed mentions in most of these, which is nice for us and a good appreciation of the work. But in my view, this is also a marketing efficiency. We can raise awareness for the Company, clinicians, people with SCI, their caregivers. They're increasingly aware of ONWARD and our work. So, we're going to have to invest less in the future when we commercialize in raising awareness for this and other therapies. There's a real impact from the PR here, and I want to give Aditi Roy, whom you met at the onset of the call, a lot of credit for this.

Again, we announced this new commercial partnership with Lovell in the US, one of the service-disabled, veteran-owned small businesses that has a preferred contracting position. They're going to be our VA - Veterans Administration Health Care System - sales partner that will promote the therapy, will maintain the customer relationship. Lovell, as 3PL, will manage the logistics and fulfillment to both federal government customers and our commercial customers. So, they're going to fill an important role for us in the US. And as I mentioned before - perhaps the most important part of this relationship - is that it gives us access to US government purchasing vehicles shortly after we receive 510K clearance - *de novo* clearance - next year.

We also began an ARC^{IM} mobility early feasibility study. We've done early feasibility studies before. Many of you are familiar with the STIMO [trial]. Multiple publications in *Nature* came out of the STIMO trial, but that was done with highly modified, commercially available pain stimulators - the firmware was

changed. There were some hardware modules that were inserted in the system to allow real-time control, which is quite important. There was a lot of latency in the system. Well, now the ARC^{IM} Neurostimulator is done, it's ready. It's been implanted for the blood pressure indication. Now it's being implanted for the mobility indication and the participants are gaining an improved user experience - functional improvements. And this study is just contributing to the overall body of experience with ARC^{IM}. And we can use these safety and effectiveness data for discussions with FDA about upcoming pivotal studies. Also this quarter, we expanded our blood pressure early feasibility study called HemON, which had been performed exclusively in Switzerland [to-date]. We've since expanded that to a center in the Netherlands called St. Marten's clinic. This is a really important milestone because we're ramping up another center in another country. It's a very nice precursor to when we're going to have to ramp up 10 to 15 centers for the global pivotal trial that we're calling Empower BP, [for] which we expect to commence enrollment in the second half of next year. We're amassing a lot of good data from the early feasibility study HemON and now HemON-NL. That's helping us shape the design of Empower BP, inform our discussions with FDA, and as a result Empower BP I think is going to be a much more powerful and important study for us when it gets going next year.

The IP portfolio, which has always been a strength of ONWARD - really a first mover advantage for us. As the leading player in this space, we've been able to go out there and secure seminal IP, whether it's our own native IP or, or important breakthroughs that have been created at the world's leading neuroscience labs. We now have exclusive commercialization rights surrounding that IP. And so we added another 33 patents this quarter. And they covered a number of different things. Most importantly, is this closed loop control of stimulation. Many of our indications, particularly those that involve restoration of movement, really rely on and are optimized by this real-time control, the ability to inform how stimulation is done via feedback from an accelerometer, maybe from a B2B Blood Pressure Sensor, or from a brain-computer interface. And so this is quite important IP and we can continue to add to the estate. Also, our most recent announcement, which was in November, was another *Nature* publication, this time *Nature Medicine*, where ARC Therapy showed it could address gait challenges in Parkinson's disease. So, people with Parkinson's disease, at first they tend to present with tremor and then later they have these gait challenges, principally something called freezing of gait, where if they encounter, let's say, a threshold in a doorway or in an elevator, or there's another pathway that might have an obstacle, their body will just freeze, and it can result in falls, which are unpleasant, but also expensive to the healthcare system. And the use of ARC Therapy, in this case, stimulating the lumbar spinal cord in the same way that we stimulate for our mobility indication after SCI shows that it addressed these gait challenges in this one study participant. Now we're going to use a $1 million grant from the Michael J. Fox Foundation for Parkinson's Research. This is the actor from *Back to the Future* and *Family Ties.* If you're of my vintage, you know him from that show. And we're going to do six additional participants over the course of 2024 [with that grant]. For each of them receiving the ARC^{IM} System, there'll be a one year follow up. So, we expect results from this so that we'll have that study completed by the end of 2025. For us, this is a really good example of leverage. We have the ARC^{IM} System already developed for SCI, we know how to stimulate the spinal cord for SCI. We do it the same way for Parkinson's and it gives us access to a large adjacent population in a really efficient way. So again, just one patient so far written up in *Nature Medicine,* it's early days. We're going to learn a lot from the next six and it's nice that these next six patients will be - at least the study will be - underwritten by non-dilutive funding.

Now, I'd like to invite Khaled Bahi up to give the financial update.

[Khaled Bahi]
Thank you, Dave. So, we closed the third quarter of 2023 with the cash balance of 36.8 million [Euros], which represents a cash burn in Q3 2023 of 7 million. That's a lower cash burn than the average quarterly burn that we had in the first half of the year, which was 9 million Euros and this is due to lower operating expenses and working capital management. We also confirm our guidance that the current cash position will fuel our operations through the end of 2024. Back to you, Dave.

[Dave Marver]
Thanks, Khaled, short but important content. Okay, now for the outlook and what has been achieved thus far in 2023. What can you expect for the next month or so and into 2024? Here, it gives us some sense of pride to see a lot of “completes” written on there in the first two rows. Going forward, we are very excited to share more detailed results from the Up-LIFT pivotal study that was done to study the effectiveness of the ARC^{EX} Therapy to improve the strength and function of the upper extremities. We're waiting until the manuscript is published and we're aiming quite high in terms of the caliber of publication there. That's why it's taking a little bit longer than I think we would have hoped but, but again, we're very much looking forward to getting those data out into the public domain. We’re also very much looking forward to submitting for the *de novo* application for regulatory clearance of ARC^{EX}. For the first indication, that being the upper limb indication, I mentioned on the last call, we were addressing an issue with the printed circuit board, making very good progress on that. I'm not prepared to change guidance at this point, we're still guiding that we will submit in the first half, and we'll get approval in the second half. [I] hope to have more specificity for you as we get into the first quarter of next year. But we're again pleased with the progress that we're making there.

We also look forward in the first quarter, potentially second quarter, to the first enrollment in that Parkinson's disease, mobility, early feasibility study that I just discussed - that's underwritten by the Michael J. Fox Foundation - the first of six participants that we plan to implant next year. And we look forward to beginning enrollment in the second half in the Empower BP pivotal study. That [Empower BP] will be our second pivotal study as a Company. Up-LIFT is done with positive top line results and strong responder rate. This [Empower BP] will be the first pivotal study for the ARC^{IM} implantable device [Neurostimulator] and system. So, looking forward to getting that started. I would also say it's not written here, but sometime during the course of next year, we're expecting that there'll be publication in a peer reviewed journal of some consequence of the interim results from HemON and some of the other studies that were looking at the blood pressure stability indication for ARC$^{IM.}$ So probably we'll add that to the slide before it's uploaded to the website this evening. Okay, so that's the end of the prepared remarks. And then myself and Khaled would be very pleased to take your questions as they arise. And I think I'm going to stop sharing as well, just so I can engage a little bit more easily. No questions thus far. But I know, David will have one and maybe Ed, maybe John, maybe Maria. So, we'll just give it a moment.

There's David, I knew he'd be first. All right, David, what can we do for you?

[David Seynnaeve]
Good afternoon, Dave. Thanks. Thanks for the presentation. Just a few questions regarding blood pressure management. So first, what are your expectations for the data from the human study, especially in terms of efficacy? Like do you expect to see inline with the interim data release end of last year, blood pressure improvements in pretty much all patients who end up enrolling? And then perhaps secondly, to what extent the FDA will also weigh in on more functional and strength measures related to strong trunk stability For example, in their decision to let you advance straightaway in a pivotal design, because as I understand it now from the slides, you will only have additional interim data at the time of submitting your dossier to the FDA, right?

[Dave Marver]
Yeah, so I can't give away too much in terms of the alignment of the interim data that we intend to submit for publication next year. And the outcomes that we released in December, other than to say that we continue to be, I think, very encouraged by the viability and impact of this therapy on people with SCI. Having a larger body of early feasibility data is really helpful. We've learned a lot about what this therapy can do. And indeed, the potential impact may be broader than we initially envisioned. So, I want to wait to provide more detail around what I just described, certainly wait for the manuscript, but I want to at least imply that the additional data has been reinforcing, encouraging, and I think offers upside versus the way we thought about the therapy in the past. Moreover, having this body of early feasibility data helps us in our discussions with FDA. It will help us size the pivotal study in Empower BP, I think, in a favorable way. It will also help us design the endpoints, the outcomes measures, some of the secondary measures that we're collecting. It's been really, really beneficial, let's say. We're going to start enrollment late next year, second half versus first half, but it's going to be a much better study as a result of it. I don't know if I answered your question in full David, but I hope it was helpful nonetheless.

[David Seynnaeve]
Nope. This was great. Thanks, Dave.

[Dave Marver]
Sure. Okay, what else is coming? Okay, I see Ed Hall has a hand up. Ed Hall from Stifel.

[Ed Hall]
Dave, can you hear me?

[Dave Marver]
I can.

[Ed Hall]
Perfect. You were talking about in Empower BP just then. And I was wondering if you could spend a bit more information on the trial design. You mentioned its beginning enrollment next year. If you could give any sort of timelines on the actual trial, when you expect first sales on this particular trial? That'd be great.

[Dave Marver]
Yeah, I can't provide too much detail yet unfortunately. Because we're leveraging our Breakthrough Device Designation, we're having frequent and high-quality interactions with FDA, and a lot of this is getting to be in final form. It's just, I think, preliminary for me to discuss it. We continue to think it's going to be 10 to 15 - and I'm going give you broad parameters, excuse me - but 10 to 15 centers, worldwide, probably 10 in the US, between 50 and 100 participants likely.

And I really can't say more beyond that. I think in terms of the first commercial sale, probably I would say this: we're looking at early 2026, first half 2026. But I think please give me the flexibility to adjust that forward or backwards once we have more clarity from FDA.

[Ed Hall]
That's perfect. Thank you. And maybe one more. With a large number of Breakthrough Device Designations, as a Company, what is your - apart from your initial three indications - what would you say would be your key priorities in the number of indications afterwards sort of going forward? Or is it all focusing on the first three at the moment?

[Dave Marver]
I think for us, the real focus is on the first two. So just getting both platforms on the market, helping people, generating revenue, generating positive cash flow. Those are our focus as a business right now. So the upper extremity indication for ARC^{EX} and the blood pressure stability indication for ARC^{IM}. And thereafter, we've made good progress with mobility, obviously, with the published data, early feasibility work around mobility, but I want to keep our options open and prioritize commercialization of those therapies that are of foremost importance to people with paralysis. If we make good progress with something like urinary incontinence, or upper extremity function with a brain-computer interface, and those are really compelling and high impact therapies, I want to move those to the forefront after we get the initial two indications on the market, and we've demonstrated safety and so forth with both platforms. That's the way we're thinking about it.

[Ed Hall]
Perfect, thanks.

[Dave Marver]
Sure. I think we have a question from David Pepper. I think we've corresponded on email before, right, David?

[David Pepper]
Yes. Can you hear me?

[Dave Marver]
I can.

[David Pepper]

Oh, good. Perfect. Just a simple question. A patient or customer if you will, invokes the ARC^{EX} device. What would you think typically, you start using device, you see results immediately over the course of days, weeks, months? I mean, obviously, there's so many unknowns, but what was the thought process in terms of how the device is going to help a patient?

[Dave Marver]
Yeah, well, David, thank you for the question. If I recall correctly, forgive me if I'm wrong, but you or one of your family members has a spinal cord injury.

[David Pepper]
Yes, I am a potential customer, sir.

[Dave Marver]
Okay. Well, thank you for joining. And thanks for your engagement with us on all levels. It really depends. I would say, David, and we'll be able to discuss this in a lot more detail when the manuscript is published next year, but in this study, we enrolled 65 people with SCI, they were all - I'm going to use some terminology here for David that the financial folks may not understand - but everyone was AIS B through D. So, we didn't study completes in that study. We might do it after it's approved when it's a bit easier to do that.

Everyone used the [ARC-EX Therapy] therapy for two months. So, there were two months without use of the therapy, just to get people used to what was called [functional] task practice training, which is very detailed use of the fingers, and then they tended to plateau. And then we introduced the stimulation on top of that. And the response rate was different depending on the participants, again, I can provide more color later. So far, what we've announced is that almost three quarters of people, even long after the injury - the average time since injury was about six years - almost three quarters, showed improvements in strength and function in that two-month period. And, you know, the data so far again, I can't talk too much about it.

It's very possible that people who use it for an extended period of time continue to make gains. So that's as much as I can say. So far, the main point being that every person is different, and some people may use it every day, some people may use it once a week, twice a week, you know, you'll have your own experience, if you have the opportunity to use it. We just hope that it makes a difference for you.

[David Pepper]
Okay, thank you. Just for reference, I am AISD. So thank you so much.

[Dave Marver]
Okay. Oh, very good. Thank you for joining. Any other questions, Alex?

[Alex Casteau]
None so far. Okay.

[Dave Marver]
We'll just give it another minute here.

I'm just looking over at the Q&A screen. Alright. Okay, so that's that. Thanks again, everyone for joining us. We'll have a transcript available and deck - they'll both be posted on the investor section of the website later this evening or tomorrow, and please continue to follow us as Aditi suggested on our social media channels with the handle ONWDempowered. Thanks so much.