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ONWARD 2023 Full Year Financial & Operating Results and 2024 Year-to-Date Operating Highlights Update

Thu, Apr 25, 2024

[Aditi Roy]

Welcome ONWARD's 2023 Full Year Financial and Operating Results and Year-to-Date 2024 Operating Highlights 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, CFO. Dave and Khaled will give a presentation, after which they will be pleased to take your questions. I will now hand the call over to Dave Marver, CEO of ONWARD Medical.

[Dave Marver]

Thank you, Aditi, and welcome all of you. Thank you for joining us on this beautiful spring day. We scheduled this 2023 update a bit later than we would ordinarily hold it. We wanted to make sure that our recent financing did not occur during a closed period, so that certain members of the Board and management could participate in that financing, which was something we were very keen to do.

So today we're going to provide a 2023 business update. We're going to share the 2023 business results. We're going to provide a 2024 year-to-date business update, and then a 2024 outlook. We'll also be pleased to answer your questions, of course. So as usual, I'm just going to start with a few slides that provide an overview of the Company for those of you who are new to this story, new to the company. We were founded in 2015. We have around 100 people. We're headquartered in the Netherlands, but many of us are in Switzerland at our science and engineering center. We also have a growing presence in the US anchored by an office in Boston, Massachusetts. We did an IPO in October 2021. We're currently listed on Euronext Brussels and Amsterdam. And we're now covered by five equity research analysts from Stifel, Bryan Garnier, Degroof Petercam, Kepler Cheuvreux, and KBC.

As a company, we have two purpose-built technology platforms. They both stimulate the spinal cord to restore movement and other functions after spinal cord injury. We're a very innovative company; we have 10 FDA Breakthrough Device Designation awards and almost 250 issued patents worldwide. We have one pivotal study complete with positive top line results. And we expect to start our second pivotal

study late this year. We're launching into a large total available market. And importantly, we expect to transition from a development-stage to a commercial-stage Company later this year. In fact, our first revenues are expected in the fourth quarter of this year.

Our vision is that empowered by movement, people with spinal cord injury will enjoy life in all ways that matter to them. And we can enable that through one of our two technology platforms, which are both very flexible. We have ARC-EX®, which is our external stimulator. At left and right you can see our implantable platform, which is something we call ARC-IM®. I'm holding up ARC-IM for the camera here so that you can see the size, and I'll also hold up ARC-EX here as well. So what is our focus? We have those two platforms. Well, it's very clear. In the short term -- in fact, this year -- we expect to commercialize the ARC-EX. In late 2026, we expect to commercialize ARC-IM. And then once both of those platforms are commercially available, we then want to broaden the label and expand into adjacent populations, such as Parkinson's disease. We can also expand the platforms to include potentially an implanted brain-computer interface that would work in concert with our ARC-IM platform; that's something we call ARC-BCI™. More detail on that later in the presentation.

This is a great time to engage with the Company because 2024 promises so many important milestones. Along with the expected commercial launch of ARC-EX, you have the De Novo request submission, which is already complete. You have FDA clearance and then first commercial sale. And then with ARC-IM, we expect to commence our global pivotal study called Empower BP. With that will come the IDE submission, IDE approval, and then first patient or participant enrollment. And of course, we're going to continue to enroll participants in our brain-computer interface study throughout the year, which tends to be kind of a newsworthy or news-making event.

This is our current pipeline, I mentioned that our two platforms afford us great flexibility. You can see how many of these indications or recovery targets have already advanced to the human proof-of-concept stage. But we're being very focused as a Company. I think that's what you would want for us as a scale-up. So we're generally spending money just on these top two indications in gray: that's upper limb function with the external device and better blood pressure regulation with ARC-IM, our implantable device. And I think many of you from the general public or the investment community probably think of spinal cord injury and you think the number one priority is helping people walk again. But indeed, there are many other issues that are of even more importance to people with spinal cord injury. And that's why our first indication that we're pursuing with our ARC-IM is improved blood pressure regulation.

I'd like to show you a video that was filmed recently in the Netherlands for one of the first participants to receive our ARC-IM Therapy to improve blood pressure regulation. Watch this and listen to her story. Her name is Julie.

[Participant Testimonial Video]
I was very homebound. I didn't leave my home very much, couldn't do anything basically, was in bed most of the time or in the couch or in my chair, but then with my legs up, because otherwise I would just faint maybe 10 times a day, maybe 12 times a day. It was no life, to be honest. And when the researchers turned the stimulation on for the first time, I was still in the ICU. And I remember to feel the

energy rushing through my body for the first time in nine months at that time. It was an amazing feeling. And I saw my blood pressure value on the screen next to me rising to a normal level. It was like a sort of rebirth to me. And that meant the start of my real recovery journey. Of course, I needed some time to adapt to the system and to learn how to work with it. But I immediately saw the opportunities coming back. I could immerse myself into rehabilitation, build muscle mass, have a social life again, go out with friends and family. And it also allowed my brain to function again. Since November, I've restarted my PhD at FWO, which is just amazing. It was impossible before the surgery.

[Dave Marver]
So very powerful. And we're keen to get that started in pivotal trials later this year and ultimately commercialize that blood pressure therapy.

Last year was very eventful. We achieved a lot. We strengthened the management team, we were awarded new Breakthrough Device Designation awards from the FDA. I'm going to focus though on those that are bracketed in red. You'll see in May, that *Nature* published a paper showing that a wireless brain-computer interface could be used in concert with ARC-IM Therapy to improve a person's ability to walk more naturally. Also in August, there was the first in-human use of our ARC-BCI platform to restore upper extremity function -- so arm, hand, and finger movement – after SCI. In September, we announced an agreement with a US third-party logistics provider, which will provide rapid US government contract access for us once we have FDA clearance – more information on that to follow. And in November, we announced a grant from the Michael J. Fox Foundation to support additional research to determine whether our therapies could be helpful to those with Parkinson's disease.

Alright, let's explore some of these in more detail. First, this is our ARC-BCI platform. It consists of an implanted brain-computer interface. So, this is a recording device that is placed on top of the dura on the motor cortex. This records brain signals -- the intention to move. Our system then translates those signals into specific instructions for our ARC-IM device, which then stimulates the spinal cord to effect thought-driven movement. These are the two devices that I just mentioned, it's a real photo of them. This is our ARC-IM IPG, or Neurostimulator. And then this is the brain-computer interface that sits on the motor cortex.

We are actually very well-positioned in this BCI space. At left, you can see there are multiple companies racing to develop brain recorders. These are today being used to control computer peripherals, so computer mice, keyboards, voice generators. We’re the only ones using these brain signals to restore movement of the human body. And that's a unique capability that we have. We also have a system in ARC-IM that is already architected to be BCI-ready. It can receive wireless signals from other devices at a high data rate, low latency, low power consumption. So, we can either develop our own system, we can partner with one of these companies, or we can set up sort of a plug-in situation where we can receive information from any of them to restore movement of the human body. We'll wait and see. In the meantime, we're progressing with additional implants funded by the Christopher Reeve Foundation and the European Innovation Council. Whenever we have news in BCI, it's covered all over the world, which is great for recruiting. It's great for brand-building, and I think it will introduce some marketing efficiencies for us going forward. It’s something that we’re very keen to take full advantage of.

This is the Lovell relationship that I mentioned before that we put in place last year. Lovell is a service-disabled, veteran-owned small business and they will serve as our sales partner to the US military hospital system. We will maintain the relationship, we'll do the selling, but Lovell will manage logistics and fulfillment, both to US government customers and our commercial customers in the US. That helps us manage some of the operational elements of our US launch and commercialization, and gives us rapid access to US government purchasing contracts, purchasing vehicles, shortly after we have FDA clearance. So, it's a really important building block for our planned commercialization in the US later this year.

Also in November, some important announcements around Parkinson's disease. A proof-of-concept was published in *Nature Medicine*. And we also received grant funding through our partner at .NeuroRestore, it was $1 million, so one of the larger grants that is awarded from the Michael J. Fox Foundation -- this will support the implant of six people with an ARC-IM system over the course of this year and next, and the study is expected to have a one-year follow up. So we'll complete it by the end of 2025, maybe early 2026. So, another exciting pipeline opportunity for ONWARD that can contribute to future value.

Now I'd like to turn things over to Khaled Bahi, who will announce last year's results.

[Khaled Bahi]
Thank you, Dave. Let me start by sharing some profit and loss numbers for 2023. We closed 2023 with revenues and other income of half a million euros, which is less than 2022 at 2.1 million, and which is also less than the September year-to-date numbers, due to change in recognition of other grant income. This had no impact on our cash flow statement though. It is neutral. The total operating expenses for 2023 increased by 5% against 2022. That's 36 million (euros). And we're mainly driven by preparation activities for the commercial launch of ARC-EX and this is seen in the increase of marketing expenses, which increased from 2 to 2.9 million, and general and administrative expenses, which increased up to 11.3 million (euros) and which includes supply chain and manufacturing operations. The R&D expenses, including clinical, were stable at 18.8 million (euros) and still represent more than 50% of the total operating expenses. The net loss for 2023 was 36.2 million (euros) against 32.8 million (euros) in 2022, and the increase is due to the lower grant income and the higher operating expenses. You can turn now to the cash flow statements. I'll say that we have quite a good command of our cash flow, with a cash burn in Q4 2023 of 7 million (euros), in line with the Q3 2023 cash burn. The total cash consumption for 2023 was 32 million (euros), so we had 18 million in the first half of 2023 and 14 million in the second half. The cash balance at the end of the year was 29.8 million euros. And together with the gross proceeds from the capital raised in March 2024, we have a pro forma ending balance, which is close to 50 million, or 49.8 million (euros) to be exact. And that will fuel our operations into mid-2025. Back to you, Dave.

[Dave Marver]Thank you, Khaled. Now for the 2024 year-to-date business update.

It's been already an eventful start to the year. In January, we announced that we expanded our ARC-IM clinical feasibility study for blood pressure regulation to the Netherlands, so that prepares us to start our

Empower BP pivotal study, we're able to start up at another center and get them enrolling and active. That's important for us for the future. In February, KBC Securities initiated research coverage with a Buy rating. Along with that came quite a bit of retail investor interest and it improved our liquidity quite a bit. So that was impactful, I think over and above a typical initiation of coverage. Also in February, we announced our 10th FDA Breakthrough Device Designation award – importantly for the brain-computer interface therapy – and in March shortly after that we were accepted into the FDA's new TAP program. We were only the second BCI company accepted into the TAP program, which is a new program that FDA has that's intended to streamline commercialization of innovative new therapies and technologies. In March, we announced that we raised €20 million euros in equity capital by way of an accelerated bookbuild and a public offering in France. And then, just after the Easter weekend holiday in very early April, we announced that we submitted our De Novo application to FDA for our ARC-EX system. In April, Stifel initiated research coverage as well, with a Buy rating; this is the first US investment bank to initiate coverage of ONWARD. So, we now have five covering research analysts.

A bit more detail about those that were bracketed in red. This is the successful €20 million euro capital raise that we executed, despite what are still challenging market conditions for pre-revenue med tech companies. The takeaway here was €20 million euros in gross proceeds. We fully subscribed the upsize option, so we started at 15 million, added 5 million and fully subscribed that. We executed a separate public offering with retail investors in France, the notion being that we wanted to continue to increase liquidity. And that's an initiative that is continuing to get our attention. And we expect the net proceeds to extend our current cash runway into mid-2025. The Use of Proceeds are as you would expect, so fund R&D; establish our commercial organization in preparation for our expected US launch later this year; continue to build out our quality operations and other infrastructure capabilities; and then fund working capital requirements.

A bit more information about the ARC-EX De Novo submission. First of all, ARC-EX is a breakthrough therapy. It's the first spinal cord stimulation therapy to restore hand and arm function after SCI. This is the first commercial product for ONWARD Medical, and submitting this De Novo application and getting it approved will allow us to market ARC-EX Therapy to improve or restore hand and arm function after spinal cord injury in the United States. We expect the FDA review to take between six and nine months; therefore, we expect commercial launch in the US in the fourth quarter. For the rest of the year, we've already submitted the De Novo application for regulatory clearance for ARC-EX, we expect shortly the publication of the Up-LIFT pivotal study. We also expect, of course, FDA clearance and first commercial sale of ARC-EX. That alone would be a whole cadre of important milestones, but then we also have ARC-IM and its associated milestones. They include: first participant enrollment in the early feasibility study sponsored by the grant from the Michael J. Fox Foundation; potentially an interim results publication for the first 14 people who have received the ARC-IM Therapy for improved blood pressure regulation; the IDE submission and approvals to allow us to conduct the Empower BP pivotal study, starting late this year; first participant enrollment in that study; and we also are hoping to get the first in-human use of ARC-IM Therapy for addressing incontinence in the SCI population. And then of course, additional implants for BCI. So, a year full or rich with potential news flow here. We're going to stay busy, obviously.

Thank you for your attention. We'll take some questions, Roderick. Let's just pause for about 30 seconds and wait for the questions to populate, and feel free to enter them via the Q&A or raise your hands to let me know that you have a question and we'll open up the mic. I see Thomas from KBC has raised his hand. Roderick, let loose the hounds there. Okay, I think Thomas you're open. Go ahead.

[Thomas Vranken, Sell-Side Analyst, KBC Securities]
Thanks for taking my questions. Two from my side. The first one, I just wanted to zoom in a little bit more on ARC-EX and the commercial launch. Just wanted to check how you think about timelines. And given that when an approval would occur, how quickly would you actually be able to commercialize? Does that mean that basically you can start selling the next day? Or would there still be certain actions or specific milestones or anything to be taken between approval and launch?

[Dave Marver]
We could start selling the next day, Thomas, to clinic customers in the US. It will take some time for us to be able to sell to the military hospital system in the US, because the product has to be added to the contracts at Lovell, so that could take some time. And there is the potential that we would have a big upside surprise in terms of timing, and we may not have product on the shelf. So, we're being quite aggressive and trying to have some launch quantities in place in case we get a positive surprise. But, I think it will generally be ready for an approval or clearance in the fourth quarter.

[Thomas Vranken, Sell-Side Analyst, KBC Securities]
Thank you. And perhaps as a follow up question, I also wanted to zoom in a bit on the blood pressure control. I understand that the Empower BP, the pivotal trial, is expected to start later this year. And you mentioned that there will also be some kind of interim data on HemON. I just wanted to check what kind of data we could expect there. And you already mentioned 14 patients. So just have a bit of an idea of what that readout might look like.

[Dave Marver]
Well, the manuscripts are nearly final. There are two. One describes let's say the interim results from the first 14 people to receive the therapy and how the therapy has impacted them in terms of their improved blood pressure regulation, quality of life, and so on. The second describes the mechanism of action responsible for those improvements. So, I don't want to say too much more about those two publications, but I think that the community will find them extremely interesting.

[Thomas Vranken, Sell-Side Analyst, KBC Securities]
Okay, very clear. Thank you very much.

[Dave Marver]
Okay, let me see here. Any other hands raised? I don't have visibility. I see three hands raised. Okay, Maria from Bryan Garnier. .Your mic is open, Maria.

[Maria Vara, Analyst, Bryan, Garnier & Co.]

Well, first, congratulations on all the achievements for this year. And you know, I just wanted to zoom in a little bit into the BCI side of the story. You had, you got, a Breakthrough Device Designation and also got into the TAP program from the FDA. I know this gives you certain advantages in the regulatory and commercial pathway, but maybe you can tell us a bit more if you're already leveraging this program and how do you aim to progress on this?

[Dave Marver]
Yeah, at this point, we haven't. I think that both of those programs are going to pay dividends or provide benefits in the future. In the meantime, we're taking advantage of the grant funding from the European Innovation Council and some others to continue to implant people and learn from those implants as part of our early feasibility studies. Again, we're the only ones on Earth who are able to use those brain recordings or intentions from an implanted BCI to restore movement. And we want to continue to gain in our understanding of how those recordings can be used to enhance ARC-IM Therapy. So far, there's only been one person who has been implanted to restore mobility and another person who has been implanted to restore upper limb function. And so, it's still very early days. The TAP program is nice because it gives us early and facilitated access to payers and providers. And this would be a brand-new therapy, I mean, indeed a breakthrough therapy in all definitions of the word. So, there are many questions that need to be answered around reimbursement and the whole care pathway, and so on for BCI-augmented therapies. So, not a lot of specifics today in terms of how the Breakthrough Device Designation is helping us or the TAP program is helping us, but we're very happy that we have them. And we think that they're going to provide a lot of benefit in the future.

[Maria Vara, Analyst, Bryan, Garnier & Co.]
Okay, thank you. That's clear. And then also, you mentioned, you know, the landscape of the different BCI players. And of course, ONWARD in a sense is on a different side of the story, as you're enabling, well, their recovery of mobility and all of that. I know, at the moment you're looking at them from a distance, but I was wondering if you're already engaged in conversations for any potentially strategic moves, or for now you're just focusing on developing the technology, and then you will see longer on the way.

[Dave Marver]
I would say, Maria, we have a stage-appropriate corporate development initiative around BCI that allows us to establish contact, regular contact, with these companies, monitor their progress, and explore opportunities for collaboration. I attended and spoke at the BCI Society last year, when it was held in Europe. So, we're very active in the area. But at this point, I don't have anything that I would be keen to announce. And we continue, as I said, to progress with our early feasibility clinical work using the BCI from Clinatec in Grenoble, which has five-year human data. It's relatively non-invasive, it sits on the dura, and it provides sufficient resolution to drive mobility. So, for now, that's a great solution. But, again, we have I think the benefit of being able to sit back a bit, wait and see how things develop before we kind of finalize our partnering path and strategy with respect to BCI.

[Maria Vara, Analyst, Bryan, Garnier & Co.]
Okay, that's clear. Well, thank you very much. That's all from my side.

[Dave Marver]
Thank you, Maria. Roderick, will you open the mic for Mr. Ed Hall of London, England.

[Ed Hall, Analyst, Stifel]
Dave, thanks for taking my questions. Just a couple from my side. I guess first off, we've obviously just heard about the BCI space, but I was wondering if you could share some more information on the potential of this therapy in Parkinson's, freezing of gait, and I guess the work you've done in SCI and how that could be leveraged in this indication or any other potential indications? And then my second question would be on ARC-EX commercial plans, sort of looking at the agreement you have with Lovell to improve your access to the market. But I guess my question would be on sort of sales force requirements that you believe you'd need to achieve your targets for year one and onwards.

[Dave Marver]
Yeah, nice use of the word “onwards” there. Thank you, Ed. So, Parkinson's disease is very interesting. As you know, spinal cord injury is our north star. This is our priority. This is an historically underserved population of people, a devastating injury for those injured and their caregivers, and we believe we can build a successful and enduring business by focusing on them. However, with Parkinson's, and particularly in addressing freezing of gait, we have the potential to use the same hardware – so the same ARC-IM system and administer the same therapy by stimulating in a precise way in the lumbar spinal cord – to address freezing of gait. So, there's a lot of overlap and efficiency, and this would allow us to target a large adjacent population and help those people, and at the same time improve our value and economics, which allows us to invest more in R&D to serve the SCI population. So, we think that this is a smart pursuit, especially as it is largely funded by grants. You know, the Michael J. Fox Foundation grant is enabling the next six implants for the most part, so it's a really efficient way for us to explore efficient expansion into an adjacent population. Now, could the Parkinson's ARC-IM opportunity benefit from a BCI? Potentially, yes. You know, currently, a person with Parkinson's disease would trigger stimulation with ARC-IM with a smartwatch – it's one of the nice parts about our system is it can be turned on and off and controlled by a smartwatch, which the participants really like. And in lieu of that, the system can be turned on or off with thought and modulated with thought. So, as much as that could be of benefit for people with SCI, this same benefit could be offered to people with Parkinson's, potentially a smoother, more natural movement, and then the convenience of just turning it on or off with the power of thought. So -- to be determined. These next six implants for Parkinson's disease will be done without a BCI. And I think that's the right first step. And then later, if BCI-augmented therapy matures for spinal cord injury, this ARC-BCI, we can potentially look at its application in Parkinson's disease, as well. Moving on to your question about ARC-EX commercialization, yeah, our intent is to is to be conservative. You know, we have a lot of pent-up demand. The community is well-aware of our therapy, we've been attending congresses for years, of course, we have our partnership with the Christopher Reeve Foundation, and then with the various advocacy groups and patient associations in Europe, such as the German Spinal Injury Association, Wings for Life, etc. So, we don't have to necessarily generate awareness like a typical novel med tech company would have to do. We also, as you know, Ed, we have concentrated number of call points. At first in the US, we're going to focus on what we call “tier one accounts,” those are the VA hubs centers, our Up-LIFT clinical study sites, investigational sites, and then other influential high-volume sites. So, we don't need a large sales force at the beginning, maybe six to ten people. We'd like to start with a small group, just because we want to

learn as well – we want to see which archetype is most effective, where the locations work most effectively, etc., and then change and adapt and optimize as we go. And we also don't want to deploy a big sales force up front and burn cash in today's environment. So, for that reason, we're going to start with a relatively small group and then optimize from there.

[Ed Hall, Analyst, Stifel]
Perfect, that's very clear. Thanks.

[Dave Marver]
Thank you. Any other hands up? Let's see, Cosmo Rizzi asked a question as well. The question is about I think you're asking for sales guidance and cash burn there. So, we've not guided yet on 2025 cash burn. I think you can expect a modest increase relative to this year because we'll be spending on Empower BP (our pivotal study) and gearing up to commercialize. So, we'll be standing up a commercial organization and all of the attendant infrastructure, customer support, tech support, order entry fulfillment, and so on. So, a modest increase in cash burn again, we've not quantified that in terms of guidance. We also have not yet guided around sales expectations. So, until such time as we do, I would refer you to any of the five research analysts who are covering the stock today. Again, that's Stifel, Kepler, KBC, Degroof Petercam, and Bryan Garnier. That's the best source of guidance today. As we approach the fourth quarter, yes, of course, we'll begin to clarify guidance around cash burn and revenue for next year. But we are an early-stage company, even though we have been listed for two and a half years. And so, we want to be careful about the guidance that we provide. And I don't want to go out there with guidance too early, because there's a lot to be learned.

Okay, so any other hands up? Thomas, you still have a hand up? Do you have another question?

[Thomas Vranken, Sell-Side Analyst, KBC Securities]
I just wanted to zoom in a little bit more on what you mentioned earlier, taking into account sales and marketing to evolve in 2024 and 2025 you mentioned scaling up the organization? Could you provide a bit more granularity on what exactly that means? And how, how we added the magnitude of those of that scaling up? Thank you. Yeah,

[Dave Marver]
Again, I prefer not to provide too much granularity; we'll do that in future months as we get closer to launch. As I indicated, the numbers or the scale of the initial deployment is going to be fairly modest, so probably six to ten people in the US, two to three people in Europe, and then we'll see how it goes. And if things go very well, then we can quickly scale from there. The sorts of people that we envision hiring and recruiting are not difficult to find, again, we are going to be establishing our first channel to the SCI clinic. This is not an area where you have a lot of competition, you know, there aren't a lot of big mech tech companies that have this channel. So, these are not going to be like super difficult people to recruit and for whom we're going to have to pay really expensive salaries. So, so none of those concerns, you know, we don't have them. And I'm not saying it's going to be easy, but I think it's going to be relatively straightforward, and I prefer to provide more information at a later date.

[Thomas Vranken, Sell-Side Analyst, KBC Securities]

Okay, thank you.

[Dave Marver]
Okay, so I think that's everything. Thank you, everyone, for joining. We appreciate it and we appreciate your support as well. For more information, visit our website at onwd.com or follow us on social media, ONWD Empowered, across all of the channels. Okay. Thanks so much.