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ONWARD MEDICAL SPEAKERS

Dave Marver, CEO

Amori Fraser, Senior Finance Director

Sarah Moore, VP Marketing

Aditi Roy, VP Communications

Aditi Roy 00:34

Welcome to ONWARD® Medical's 2024, Half Year Financial Results and Operating Highlights webinar. I'm Aditi Roy, VP of Communications at ONWARD Medical. 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, who will be joined by Amori Fraser, Finance Director, and Sarah Moore, VP of Marketing. Dave, Amori, and Sarah 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 01:19

Well, thank you, Aditi, and what I normally do, for those of you who are new to the story, is just give you a brief overview of the company. So here's our “at a glance" slide. You can see we were founded in 2015. We have around 100 people at this point. We're headquartered in the Netherlands, but we have a large Science and Engineering Center in Switzerland and a growing presence in the US. We listed on the Amsterdam and Brussels exchanges in October 2021, and we're currently followed by five equity research analysts, most recently, Stifel and KBC. We have three purpose-built neuromodulation platforms, and they all stimulate the spinal cord to restore movement and other functions after spinal cord injury (SCI): ARC$^{EX®}$, which delivers the stimulation externally; ARC$^{IM®}$, which delivers the stimulation via a fully implanted platform; and then we've started to combine ARC^{IM} with an implanted brain-computer interface, which is something called ARC$^{BCI™}$, to enable thought-driven restoration of movement. We are a very innovative company. We have 10 FDA Breakthrough Device Designation awards, and now over 270 issued patents worldwide. We've made excellent progress on the clinical study front. Indeed, we have one pivotal study complete that was called Up-LIFT, and the results were published in *Nature Medicine* earlier this year. And we've also derisked our second indication for ARC^{IM} by releasing interim results. We're launching into a large, total available market, as you see here, $20 billion, nearly 19 or actually, 20 billion euros. And importantly, we expect to cross a critical milestone as a company. We expect our first commercial sale just in the coming months here in the fourth quarter, which is quite important for us. That's after FDA clearance of our ARC^{EX} platform. Our vision is that empowered by independence, people with spinal cord injury will enjoy life in the ways that matter to them, and we do that via these three platforms that I explained earlier. Here they are pictured. So ARC^{EX} at left, the external platform. ARC^{IM} in the

center, which is the fully implanted platform, and then combining ARC^{IM} with a brain-computer interface constitutes the ARC^{BCI} platform. We have many things that we can pursue as a company in terms of indications that would make a meaningful difference in the lives of people with SCI, but we're being very focused, very good stewards of our capital. And in fact, our current focus this year is to commercialize the external platform ARC^{EX}. We also want to begin in the course of the next several months, the pivotal study for ARC^{IM} and then commercialize that in the 2026-2027 timeframe. And then longer term, once those two platforms are approved and on the market, we can expand indications for both. They're both highly flexible, and indeed, we also want to continue exploring the effectiveness and the safety of the ARC^{BCI} platform. This is our current pipeline. As I mentioned before, we have many recovery targets. You can see we've advanced to the human proof-of-concept stage across nearly all of these. We are, however, primarily spending money and using our capital for just these first two, which is the upper limb indication for ARC^{EX} and the blood pressure indication for ARC^{IM} and as I said before, we've completed the pivotal trial for one, and we expect to start the pivotal trial for the second in the coming months, likely early 2025. And now let's talk about what happened in the first half, shall we? So a lot of important achievements, primarily the De Novo submission [for US market clearance], but let's run through them here.

In January, we announced that we expanded our clinical feasibility study for ARC^{IM} blood pressure to the Netherlands. So now the study is enrolling in two different sites, and that is a really nice precursor or preparation for the eventual start of our pivotal study, again, which we expect probably in the first quarter of next year. We're learning how to spool up another site, train them, get them enrolling, and so on. In February, KBC initiated with a buy rating. In February, we were also awarded our 10th Breakthrough Device Designation from the FDA. This one for the ARC^{BCI} platform. We were also accepted into a new program that the FDA has in place to streamline commercialization, and indeed, we were only the second company - BCI company - admitted into that program, which underscores our leadership in the space. In March, we completed a €20M equity financing, which was an ABB and public offering in France. And then in April, we submitted our De Novo application to the FDA for the ARC^{EX} platform. So that clock is now ticking and we're eager to hopefully get clearance for that device and begin commercializing late this year. Also in April, Stifel initiated coverage, also with a buy rating. In May, we published the detailed results from the Up-LIFT pivotal study for ARC^{EX} in *Nature Medicine*. More to come on that. And in June, we entered into a debt financing arrangement with Runway Growth Capital, which is one of the leading growth capital providers in the US, for up to 52 and a half million euros. So that's also quite important for us, introducing sort of a maturity into our cap table and flexibility in our pursuit of capital going forward.

So, a bit more on the De Novo submission here. As you know, the ARC^{EX} is one of our breakthrough therapies, one of the therapies for which we have Breakthrough Device Designation from the FDA. This is the first spinal cord stimulation therapy to restore hand and arm function after SCI. It's also our first commercial product, so important for a number of different reasons. We submitted this De Novo application to the FDA to allow us to market ARC^{EX} to restore hand and arm function after SCI. This review is expected to take eight or nine months. That's normal for a De Novo submission of this nature. Therefore, we expect clearance and commercial sale to follow in Q4. These are some of the results that were included in the detailed *Nature Medicine* publication in June. We showed that 90% of participants improved either strength or function, 87% reported improvements in quality of life, and the responders were observed up to 34 years after an injury. Why is this important? Well, today's standard of care is a person has an injury, they undergo emergency surgery, they're in rehabilitation for

normally three months, and then they're sent home because nothing else can be done for them. So three months and you're done. And here, in this study, as published in *Nature Medicine*, we showed that even people up to 34 years after an injury could respond to ARC^{EX} Therapy. There were some other benefits observed as well. First, no serious adverse events - device-related adverse events - were observed. Study participants also reported reduced spasm, improved sleep, and improved upper body sensation, including the sense of touch. And the improvements were meaningful, such as they regained the ability to lift a filled cup or push a button on a remote control or pick up an object with a fork. So, improvements that could be meaningful in one's ability to independently conduct activities of daily life.

We also executed the debt financing with Runway Growth Capital, where we have access now to up to 52 and a half million euros in tranches that are tied to business achievements, which you can see down here. That gives us flexibility, so we can pull down debt financing, or we can pursue equity financing in the future, whatever is best for the company at the time. We do have a strong shareholder base. You can see the publicly disclosed shareholders here, including many of Europe's leading Life Science VCs, Invest-NL, some leading family offices, including the Onassis Foundation. This is the Christopher Reeve Foundation's first ever investment in a for-profit company. They're the number one advocacy group for spinal cord injury in the world. So that's really an important strategic investor. Here's some of the equity capital markets investors. Management and the board also participated in the most recent financing in March and continue to hold a significant stake. And then we have here in free float, about 42%. We also have many quite impressive and pedigreed investors in Europe and the US who are not on the Public Register, and so we can't mention them here, but they also strengthen our cap table. As I mentioned before, we are listed in Brussels and Amsterdam, and we have five equity research analysts currently covering the stock. They each maintain a buy rating, and you can see the average target price is 13 and a half euros, so that's quite a premium over today's trading price. Now to talk about the results from a finance perspective, I welcome Amori Fraser.

Amori Fraser 11:29

Hey, Dave. It's my pleasure to take you through the financials for the first half year of 2024. Revenues and other income totaled 0.2 million euros. This consists of royalties and grant income recognized from existing grant agreements. During the first half of 2024, the company recorded operating expenses of 19 million euros. This is 0.7 million euros below the same period last year. The operating expenses included an additional 0.9 million euros allocated to the clinical, regulatory, and quality efforts driven by the De Novo submission of our ARC^{EX} system, as explained by Dave. At the same time, research and development expenses were reduced by 1.5 million euros as a result of this shift in focus in the first half of 2024, supporting the regulatory process. The operating loss realized for the first half year was 18.7 million euros, and this is very much comparable to 2023. The net finance income for the first half of 2024 reached 0.2 million euros. This marks an improvement from the 0.5 million euro expense in the previous year, and this was driven by the interest that we earned on cash balances, as well as favorable exchange rates offset by the accrued interest on the RVO loan. On the interest-bearing loan side, the balance at 30 June represents the RVO loan only. As stated in the events after reporting period note in the half year report, the recognition of the debt financing from Runway Growth Capital was contingent upon the repayment of the RVO loan. The necessary conditions were fulfilled on the second of July only, so at this time, the repayment of the RVO loan was completed, and the new loan with Runway Growth was recognized, so after the 30

June mark. If we move on to the next slide, the company reported a cash balance of 32.1 million euros at the end of June. This is an increase from the 29.3 million or 29.8 million euros at the end of 2023. This increase of 2.3 million euros reflects the proceeds from the March capital raise and is offset by the operating expenses we incurred. The increase in our cash burn in the second quarter is due to transaction and seasonal costs. We expect that our current cash will fund operations until the spring of 2025. Back to you, Dave.

Dave Marver 14:06

Thank you, Amori. So this update is occurring in September, and it's a first-half update. We've stayed busy, so we've continued to achieve important milestones. So in July, there was another Up-LIFT study-related publication in the journal *Neuromodulation*. So this highlighted learnings about how to program the device to optimize programming, and this will be, I think, very useful - once we get FDA clearance and commercialized - to give researchers and clinicians a set of programming parameters with which to start. Also in July, we announced publication of our annual sustainability summary, and we were awarded, along with our partners, a grant from the Christopher Reeve Foundation to further study our ARC^{BCI} platform in additional humans. So more details to follow on the latter two of those. First on the sustainability front. Again, we published our annual sustainability study this fall. We did earn EcoVadis Bronze, which rates us in the top 40% in our industry for sustainability performance. I just want to note here, it's actually very challenging for a small and emerging company to score well - this well - on ratings schemes such as this, because you're often rated on tracking and other things that it just doesn't make sense for us to do at this juncture. So we're really pleased with this bronze rating at this point, and the new measures that we put in place to strengthen sustainability include policies around stakeholder dialogue, environment, management, data privacy, and so on. And then again, in preparation for our expected commercialization, we have codes of conduct now in place for marketing to healthcare professionals, interactions with third parties, etc. So I would encourage you, if you have further interest in this, to review the full sustainability summary, which is on our website, in the - I think on the main website, right Alex - investor section. Okay, he whispered investor section, so that's where you can find it. And some highlights are on the right-hand column: 88% of purchased electricity is from renewable sources, 45% of supervisory and manager roles are held by women, and 50% of the of our top earners as well are women. We also, just last week, announced that ourselves and our partners at .NeuroRestore and CEA-Clinatec were awarded a grant from the Christopher Reeve Foundation, the world's largest advocacy group for SCI. This will enable us to do more clinical feasibility research on the ARC^{BCI} system, particularly use of the hands and arms, which is the number one priority. This is the top recovery target desired by people with tetraplegia. And here's a quote from the Chief Science Officer of the Reeve Foundation, Marco Battista: “This grant reflects our vision to facilitate rapid scientific advancement to address the unmet needs of individuals living with SCI… We look to forward to working with ONWARD Medical in learning more about the potential for BCI technology to meet those challenges.”

All right, so now outlook. What do we want to expect to continue, what milestones do we want? Pardon me, what milestones do we want to continue to achieve in the coming months? Well, already we submitted ARC^{EX} for regulatory submission. Already we published the Up-LIFT pivotal study manuscript in *Nature Medicine*. What's to come? Well, hopefully FDA clearance and first commercial sale of ARC^{EX} in the US, also first participant enrollment in the ARC^{IM} early feasibility study for Parkinson's mobility, which is an interesting future expansion opportunity that we're exploring. Also, an interim results publication for the blood pressure indication for ARC^{IM}. So this would be on the first 14 patients to receive the therapy. We're expecting that to be

published in a top-tier, peer-reviewed journal in the very near future. We also want to submit the IDE - or investigational device exemption - application to FDA, so we could start our pivotal study for ARC^{IM}, get that approved, and then have first participant enrollment. We want to look at using ARC^{IM} Therapy to explore whether it can help with bladder control in this population. So, we expect first in-human there, clinical feasibility study in the next several months, and then additional implants - upper limb and mobility for ARC^{BCI} - as supported by the new Reeve Foundation grant. So very, very busy, lots of news flow and milestones to come.

We have a very strong management team here. Often the bankers and investors remark to me that for a European company at this stage, we really have a world-class management team. And so I want to look for ways to feature that team and expose them to you here so you can see our bench strength. So helping me to outline our commercial plans for ARC^{EX} - again, we expect this in the fourth quarter, following FDA clearance - is Sarah Moore. Sarah comes to us after a long career with JNJ, where she launched scores of new medical and other technologies. She also has neuromodulation experience, and she's going to run you through the next set of slides, and then I'll join her here for questions. So welcome, Sarah Moore.

Sarah Moore 19:52

Thank you, Dave. It's nice to be here with everyone today, and I'm looking forward to walking through the ARC^{EX} commercial plans. One quick housekeeping item - can I advance the slides myself? Perfect. Okay, great. Let's dive right in. I'm going to start with customer targeting and sales deployment. And this first slide is important because it talks about why the rehabilitation clinics are so central to our commercialization strategy. In addition to being customers who will purchase the ARC^{EX} devices and use them in the clinics with the people with SCI whom they care for, they also are going to be the springboard for our home use. ARC^{EX} used in the home requires a prescription, but it also allows a patient to continue to make gains in the home. And as they make those gains, our rehabilitation professionals will continuously make therapy adjustments as needed for those patients. And in the future, as we think about our implantable platform that Dave just spoke about - ARC^{IM} - the rehabilitation professionals will be the ones who refer patients to surgeons for implant and also they provide a continuous care pathway for the patients for post-op, or post-implant, care and therapy adjustments.

So, talking about the clinics and how important they are. This slide gives you an idea of how many clinic targets we have in the US and Europe. What I love about this, as Dave mentioned, I have a background in surgical or medical technologies, typically to hospitals, and that's where you have a sales force calling on more than 6,000 hospitals in the US, more than double that across varying countries in Europe. But in rehabilitation, we're very lucky to have a more clustered group of rehabilitation centers - it's about 450 in the US and about 80 in Europe. That makes for a much more efficient direct sales force impact. And for those of you who've joined us in the past, you may notice that 450 is a little higher. That's because we have added some general rehabilitation centers and also some activity-based therapy clinics that typically see multiple types of patients, but that include patients with spinal cord injury. So now that we've talked about the number of targets, our initial focus is really going to be our Up-LIFT pivotal trial centers, who are already familiar with ARC^{EX}, and other US flagship or reference SCI clinics, and then also the VA hubs. There are about 25 Veterans Affairs spinal cord injury-focused hubs, and they coordinate the care for more than 40,000 Veterans with SCI on an on an annual basis - those who are receiving benefits.

Let's talk more about the sales force deployment. It's an exciting time. We're starting to hire our sales force, and as we just discussed, those initial targets - the SCI flagship centers, pivotal trial sites, and the VA hubs - there are about 75 of those. So, when we launch, we expect to have six to ten sales reps when we start, and they'll have about ten accounts - each of them will have about ten accounts that they call on. Obviously, there's a large number of expansion targets, so as we move towards scale and we move deeper into these SCI and other general rehabilitation clinics, which include, obviously the VA spokes that take care of SCI patients, we plan to ramp our sales force accordingly. We could see up to 25 sales reps calling on 20 to 25 accounts at that point. Okay, and I mentioned we'd started hiring our sales force. We have two leaders on board already. We have Blake Pokress, who's our area VP of Sales and will be leading the initial sales reps in the US. He comes to us with almost 20 years of commercialization of med devices, primarily in orthopedics, and focused on sales and sales leadership. He was most recently at Integrum, where he worked with physical therapy clinics as well as Veterans. Integrum is a limb loss company, so he focused on that population as well. We've also hired Sarah Montana, who brings more than 15 years of sales, marketing, and commercial operations experience. She's our director of sales and customer advocacy and has been standing up our CRM and all of our commercial operations as we prepare for clearance and commercialization. We have one sales rep in the queue very close to being hired - I'm expecting that to happen by October 1. And then we have a robust pipeline of talent - qualified candidates in the pipeline that we're going to quickly add as we ramp towards those initial six to ten sales hires. I'll just mention that we have a plan for customer service specialists and customer advocates, as well as additional field sales, as we talked about on this slide previously.

It's worth mentioning that we also have a partnership with Lovell. Lovell is a service-disabled Veteran-owned small business, and they are both our contracting partner in the VA to help us secure government contracts so that we can sell to the VA and the DoD, but also they serve as our third-party logistics partner for all commercial and government accounts throughout the United States. So they're very important - a very important partner to us.

Okay, I'd like to share a little bit more about how our customer training plans are shaping up. First of all, we've talked about how important the clinics are to our commercialization plans, and that starts with our training of clinical staff. So, we really have two objectives. We want to ensure seamless integration into existing clinical workflows and we also want to build a group of engaged and inspired clinicians. Most of that is important, as you'll see in the next slide, because they will then become the point of contact for or the springboard for home use, and they will be the center then of that home use and preparing all of the patients to take it home and use the ARC^{EX} System independently. Our clinic training consists of three program components: a digital starter kit, so an introduction to the product and also to the processes about how you create stimulation programs for patients. We'll send that after a clinic has purchased a device, and before we move into that second component, which is the hands-on training. Hands-on training will be delivered probably about half a day by one of our ONWARD-certified internal trainers. And then we're encouraging, or we will encourage once we're in the market, clinicians to bring patients in for the rest of the day and to start building some of that experience with ARC^{EX}. And of course, we will have an online library of resources built on pivotal clinical trial best practices or also on early learnings from the market.

Okay, so clinics are important. They're the center here. Once we've trained that clinician, as we mentioned, they will prescribe a device. They'll evaluate a patient for home use, prescribe a device for home use. The patient then takes the product home after being trained by the clinician. At launch, we will provide the clinical staff, as well as a champion, a clinical champion,

who will be identified during the initial training to be that point of contact and expert with ARC^{EX}. But we'll also have our field team readily available for initial cases and to provide continuing support. And we have a staffed help desk that will help to answer clinical as well as technical questions. As clinics gain that experience, they become the first point of contact for the patients who are using the device at home, but of course, ONWARD will come together with them to create patient education days and provide that ongoing support as they see patients back, provide therapy adjustments, and maintain that care continuum.

I think the next slide is very, it's very near and dear to my heart because one of the most exciting parts about being at ONWARD the last year and a half has been hearing from all of the clinicians, the administrators, the SCI Community - which is, you know, people with SCI, their caregivers, friends and family - about the potential they see in ARC^{EX}. When we think about positioning ARC^{EX} in the market as the first available spinal cord stimulation system for spinal cord injury, you can see here, it's naturally positioned right in the middle of other commonly used medical devices or rehabilitation equipment in the home. So, it falls nicely there, and I think it's further supported by the excitement among clinicians and the community. In fact, in our primary market research, speaking with clinicians and economic stakeholders in the US and Germany, they all assigned a $50,000 or more value to the ARC^{EX} System. It's been fun to hear those stories.

And since we just talked about that value, I think it's important to end with a little bit more about market access. So, obviously, clinics can buy the ARC^{EX} System outright with their existing capital budgets. They will then bill for therapy sessions. It's a standard existing code for attended therapy sessions with a device. But we really see three waves of [home use] market access or reimbursement decisions coming over the next few years. At launch, obviously self-pay patients can purchase a device. Patients who are recipients of Workers' Compensation can purchase a device. But in the Veterans Affairs system, we also - in our market research and our conversations on the upstream side - we've read about their statutes that provide home rehabilitation equipment and also just the history of the VAs in providing rehabilitation equipment for their Veterans with SCI, so we believe that we can access that initial one-third of the of the eligible market right there, from the beginning in year one. The second wave I would say, is private payors. It typically takes five years to get broad private payor coverage. However, we plan to employ a third party to help us with prior authorizations and appeals support. And we expect that to help provide some coverage on a case-by-case basis as early as year one, and then it will expand over time. We'll work towards that. And finally, Medicare is a large portion of this population, and Medicare typically requires a couple of years of invoicing history. So among those, in years one to three, we plan to capture that invoicing history and apply for a new Durable Medical Equipment reimbursement code with Medicare. The reason we believe that's important is because of the value of ARC^{EX}. We think it's going to be the first on the market to restore upper limb function. And so really, we're looking for a new code that is more aligned with the value of ARC^{EX}. And so we expect that to come in years three and four. And that means that at the end of year four, up to three quarters of the market could have reimbursement for ARC^{EX}, which puts us into those expansion targets. So that one's important to our strategy - it's why we're focused on the VAs and also focused on these big, flagship clinics with lots of different types of covered lives in them from the beginning.

I'm going to end by just thanking you all for your time. I think we're excited at ONWARD because we have our targets, we have our plans in place. We're finalizing our training. We have a better understanding of the market. We have salespeople who are onboarded and we'll be continuing to do that. Now, we're just anxiously awaiting our ARC^{EX} clearance from the FDA and

then shortly thereafter to submit for regulatory approval in Europe. So, thank you, and Dave, I'll hand it back to you.

Dave Marver 33:21

Thank you, Sarah. Really nice job. You can see why I'm so proud of the management team here, and they're really going to help us fulfill our mission. Sarah, by the way, she's American, but she's lived and worked in Switzerland. She's fluent in German, so that's going to really help the company advance our goals in Europe's largest market. Okay, so we're just waiting for the questions to populate. So the usual cast of characters, our research analysts, I'm sure, will be typing soon. Okay, we have some already. All right, let's start with Jacob from KBC. Jacob, what's on your mind?

Jacob Mekhael, KBC 34:06

For Thomas Vranken from KBC. Hope you're all well. I had a few questions, if I may. I think the first one was, you mentioned that you expect to have the first revenues in the second half of 2024 for ARC$^{EX.}$ So I'm just curious, how much demand have you already received ahead of the potential approval? And then perhaps another question on that point is, how quickly do you expect to be able to ship the products once the approval has happened? Are there any additional steps that you need to do with the sites post the approval to be able to give the product to patients?

Dave Marver

Yeah, thank you, Jacob. I hope Thomas is enjoying his holiday. So there's a lot of - we consider a lot of - pent up demand. We've been contacted by 1000s of people around the world who have spinal cord injury who are almost continually online, searching for solutions because of today's standard of care, which is, as I mentioned before, you have three months of rehab, you're sent home, and you're told nothing else can be done for you. And so by virtue of this - of the Up-LIFT study results and the publication in *Nature Medicine* in which we detailed that 72% of the participants improved strength and function, 90% improved strength or function, 87% improved quality of life - you can imagine that there's a lot of interest in this therapy. So of course, we haven't been out there marketing the device because we don't have FDA clearance, but we have received a lot of inbound interest from patients, and we're also educating clinicians as we go to conferences, as we've done over the past few years. In terms of the introduction itself, we have guided consistently that we expect clearance in the fourth quarter, not the second half, but the fourth quarter. And indeed, if the eight-or nine-month typical timeline for a De Novo submission holds true, that's going to be the case. We are planning to have inventory on hand in that time frame, ample inventory on hand in that time frame. But I would temper expectations, because we want to launch this to a finite number of centers. As Sarah mentioned, there's 75 targets for us, the military hospital system, or the VA hubs, the Up-LIFT centers, and other large centers of note and we want to get those in there and make sure that these centers are trained well, and the adoption goes very smoothly. So I would, I guess I would guide you to put the vast majority of any initial revenue into 2025.

Jacob Mekhael 36:59

Okay. Thank you very much.

Dave Marver 37:00

You bet. David Seynnaeve from Degroof Petercam, you're up. Let's see, okay. Your mic's lifted. Good to go.

David Seynnaeve, **Degroof Petercam** 37:09

Hey. Good morning. Good afternoon. Dave and Amori, just perhaps on the FDA feedback, right? Could you, could you perhaps elaborate a bit on the feedback you might have received by the US regulator at this point, especially on the home use application, because I remember they had like 75 days to get back to you with any potential questions following submission of your De Novo dossier, and then potentially also, secondly, with the funds you have now available, how many of these tier one accounts - you said 75 - will you be able to target and market the device to and train clinicians at?

Dave Marver

Yeah, thank you, David. So first, we're not going to disclose any further details around the FDA process or communications with the agency. I just want to reiterate that we continue to affirm the previous guidance that we expect clearance in the fourth quarter. So nothing changed. No change at this point. In terms of the launch and the targeting of the first 75 accounts, indeed, we believe that we have sufficient funding for that, because we're going to initially deploy six sales reps, and six sales reps, we believe, can quite effectively launch the product to these first 75 accounts. But as Sarah said, at least it was indicated in one of her slides, we're going to be flexible. So we're going to add people as needed once we learn sort of what's expected in terms of the clinic ramping up and the training burden and requirements. Because clearly, we don't want to restrict demand in any way, so we're just trying to be smart about it. Deploy six reps at the beginning, and then we can scale from there up to 20 or 25 as Sarah mentioned.

David Seynnaeve

Okay, thank you.

Dave Marver

Yeah, all right. Looks like we have Maria from Bryan Garnier

Maria Vara, Bryan Garnier 39:23

Okay. Well, thank you first for this presentation and super detailed commercial plan for ARC^{EX}. It's really helpful. Just want to touch on that first. So you define these two phases let's say, of targeting clinics, the initial focus on 75, right, followed by, well, the bigger market. What do you think is the timing for this initial focus phase, and then, you know, the scale-up phase, and then how this will translate in sales and marketing expenses for the coming, let's say, 12 months.

Dave Marver 39:55

Okay, so I'm going to have Sarah talk about the phasing. When might we begin to add more reps, or transition from one to two. And then Amori, maybe you can give a little bit of guidance around the sales and marketing expense. Probably might be a little difficult, because we haven't got it on 2025 yet. I'm looking at Amori over here. But let's start with Sarah.

Sarah Moore 40:18

Sure - the timing in terms of moving from that initial launch period with the 75 targets into the 375. We expect a sale of ARC^{EX} to take anywhere from a few weeks, three weeks - if it's an upfront purchase – and two to three months, if a clinic is looking to basically do an evaluation period if they're less familiar with ARC^{EX} Therapy. So given that, I think that in the initial period, we want to make sure we do that really well, because it is that springboard for the large majority of SCI patients. So, I expect that to take 2025 - through the end of 2025 - for us to really target those accounts. I'm never going to limit anyone from going into another account, so I won't put a time limit on when we would start into those expansion targets. But I see the VA as a natural progression. We'll get into the 25 hubs in the initial few months, and then the hubs naturally send patients back home to spokes. So I do expect to start pulling in some of those spoke accounts early next year, in the first 12, you know, starting this year in the first 12 months. And I'll just say that we will add, as Dave mentioned, we'll add reps as we go. We have a pretty good idea of what we need to start, and then we'll add them as we ramp up and learn about the market.

Dave Marver 41:46

Thank you. And Amori, yeah, I guess try to answer the question without giving guidance. Good luck.

Amori Fraser

Yes. So definitely in terms of what we are planning and what we've mentioned, so there will be a bit of a change in our cost structure, if I can call it like that. So to support the expectations for sales and marketing, there will be an increase in those costs. Similarly, as we expect to also ramp up on Empower BP, there will be an increase in clinical costs. And we have worked closely with Sarah and her planning to kind of ensure that we have included her expectations of how she planned to do the hiring in our expectations for 2025.

Dave Marver 42:28

Okay, thank you.

Maria Vara 42:30

Thank you very much. That was very helpful. Also, because I think that we haven't really talked about this topic in terms of the manufacturing and supply chain operations, now that you're going to start to scale up the commercial side, any insights on how you will proceed in these and you know, as you also mentioned the sustainability report, what are the considerations from the manufacturing and supply chain?

Dave Marver 42:54

Yeah, so are you asking Maria about ARC^{EX} specifically at this point?

Maria Vara 42:59

Yeah, specifically, ARC^{EX}.

Dave Marver

Okay, excellent, yeah. We're continuing to get our stimulation driver from Demcon in the Netherlands. That's a CDMO whom we've disclosed in the past in our public filings. And then we're intending to do assembly and final kitting in our ONWARD facility here that gives us more control over the entirety of the supply chain and assembly process. And then we're intending to build quite a bit of inventory upfront, so ample inventory that will allow us to respond to, let's say, demand that we don't expect, or the need for more evaluations, or longer evaluations than we expect. So we're doing our best to allow for any contingencies that we may encounter during the launch process because you never know. You can plan as best you can, but ultimately, it's important to be prepared. And then we'll ship product over to Lovell, who do the logistics and fulfillment in the US. And then for European customers, we'll ship directly from an ONWARD facility when that happens. Is that the only question? Somehow, I'm feeling there was a second one in there. Is that good?

Maria Vara 44:24

Also, the ESG impact, I consider that all of these were already considered within your sustainability report, and you don't see any major

Dave Marver 44:33

No, not at all. No, no, no, of course, not, no. But thank you.

Maria Vara 44:39

All right, maybe, maybe lastly question on the ARC^{IM}, the HemON study that you initiated in the Netherlands. We know that we expect some data in Q3 on the other patients, if you can give a bit of an update on how the Dutch study is going, and when we could see some data on that as well. Or any learnings that you can share.

Dave Marver 45:02

Yeah, so we're anticipating a peer-reviewed publication on the first 14 participants in the early feasibility clinical research on blood pressure therapy. Probably October. Could be September. Could be November. Difficult to give you an exact date when it comes to a publication like that, so I would say Q3, Q4 should be very enlightening. At this point, I'm not going to disclose anything specific about the HemON NL center and those implants.

Maria Vara 45:44

All right. Thank you very much. That will be all.

Dave Marver 45:49

Okay, I don't think we've heard from Ed Hall yet, so let's open it up for Ed from Stifel.

Ed Hall, Stifel 45:55

Perfect. Thanks, Dave. Thanks, Amori. Just a couple of questions. First, just on the ARC^{EX} and I guess home use indications, what's your best views that the sort of percentage of patients that enter the clinic actually get prescribed a device to take home? And I guess just drilling into the financials of this, is this going to be a lease model? Is this going to be on your balance sheet or does the clinic purchase this and lease it on their balance sheet, and I guess sort of pricing differences that you expect for clinics purchasing for themselves, or for patients to take home. I guess that would just be my first question.

Dave Marver 46:33

Okay, let's see. I got the second and third part, leasing versus purchased and the price difference for clinic versus home. Forgive me, what was the first one?

Ed Hall 46:44

I guess just your best views of the percentage of the clinic actually get a device to take home.

Dave Marver 46:52

Yeah, that's a that's a good question. So I don't think we want to disclose our internal model. Your model is probably as good as any, Ed. The way I look at it, though, is that if you look at the responder rate, 72% of participants had improvement in strength and function, and 90% had improvement in strength or function. And this is a population, this chronic population, whom we'd studied, there really is no alternative for them. There's nothing available that can have that effect. Moreover, when we started the trial, it was a new technology, new therapy for all the investigators, and so I think that they learned how to optimize it over the course of time during the study. They put many of those learnings into the *Neuromodulation* publication. So if you look at those numbers, 72%, 90%, and you consider that maybe it could be even better in the real world, I don't know. Maybe. Then I think you can calculate a take home rate. That's up to you. I mean, I've given you the parameters, maybe, to help you think about it. Certainly, the economics will also play a part. You know, within the VA, there are really no limitations on the ability to prescribe at home and it should be paid for from the onset. But, you know, in the first few years, we'll be dealing with other limitations. We'll be able to, you know, Workers' Compensation will pay. There'll be some self-pay, and the rest will have to fight for a little bit on a case-by-case basis. So that could be a bit of a limiter there, too. So now you have the full suite of considerations, and we all look forward to the number you come up with, Ed.

As far as lease versus buy, our assumption is that the clinics themselves will purchase the device, and so we'll recognize revenue from the onset. And normally what happens, and this is the case for devices far more expensive and far less efficacious than ours, at least from the *Nature* paper results, they're able to buy them, and they're able to buy them with their own capital equipment budgets or with the support of donations. And there are a lot of nonprofits out there that support these organizations in their purchase of equipment such as this. We're not really seeing economic constraints that would inhibit the purchase of this device in clinics. So at this point, we don't foresee that we need to have a lease model. In terms of the pricing at home, I think we want to stay silent on pricing. We don't want to disclose any more than we already have. I will say this, though, just to help you with your model, that the home device - or personal device - will be a bit less full-featured than the clinic device because the clinic devices are intended to be used across several patients a day, whereas the home device is intended to be used for one person. So that might allow some discrimination, but I don't want to get any further than that.

Ed Hall 49:53

Perfect. That's great, and then maybe just turning to actually slide nine. You showed the map of your indications and the clear priority and blood pressure and ARC^{EX}. But how should we look at this, the mobility indication for ARC^{IM} at the moment, I guess with the STIMO feasibility trial been run, how should we look at this one? It seems like quite a lot has already been done, or the groundwork has already been laid. So just curious to hear your thoughts.

Dave Marver 50:23

Yeah, indeed, Ed. You know, we haven't talked a lot about what's next in terms of what ONWARD chooses to put through a pivotal study and commercialize for ARC^{IM} after blood pressure. You're absolutely correct that there is a lot of very good and compelling foundational work already done on the mobility indication from the STIMO study and the multiple publications

that resulted. So it's up to us. You know, we've been very busy for a company our size to have two different platforms, indeed, almost a third with ARC^{BCI}. We're taking on a lot, and it's my job to make sure we're focused at this point on the things that are going to reach the market and generate revenue, so we can afford to bring forward all of these other indications that can help so many people. But you're absolutely right when we have the time and resources to scope and define what's next for ARC^{IM} , some sort of mobility indication is an excellent candidate.

Ed Hall 51:23

That's perfect. Thank you very much, guys.

Dave Marver 51:25

Thank you. We have a couple of questions that have come in, not from the equity research analysts. I think I'm just going to read these, if it's okay. The first is, are we going to go to Brazil with ARC^{EX}? So our focus again, just to follow up on the theme that I just explored with Ed, we need to be focused, and so our focus at this point is on the US and Western Europe for commercialization. However, we will be exploring distribution relationships that would allow us to access other compelling markets around the world. Brazil is one of them. Japan is another. MENA region is another. So I would say certainly yes, and that's the other question that came in - any plans to use distributors to increase market access? Certainly, absolutely. But you know, we want to focus first on exploiting our own direct channel, learning what we can to optimize things, and in the meantime, we're filling the queue with reputable and reputable distributors who have strong ethos and can do an effective job for us in these other major markets around the world. Okay, anything else come in? Okay, I think that concludes things, so on behalf of Sarah and Amori, thank you for joining us. And I think, Aditi, you're going to come back to close things out here.

Aditi Roy 52:52

Yes, I should be on screen right now. Thank you so much Dave, Amori, and Sarah. To sign up for company updates, come to www.onwd.com. You can also follow us on social media. Our handles are onwdempowered. That's o, n, w, d, empowered. Thank you for joining our 2024 Half Year Financial Results and Operating Highlights Webinar. Have a great week.