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SPEAKERS

Dave Marver, Lara Smith Weber, Aditi Roy, Khaled Bahi

Aditi Roy 00:01
Welcome to ONWARD's 2023 Half Year Results and 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, Lara Smith Weber, our departing CFO, and Khaled Bahi.

Dave Marver 00:37
Well, thank you, Aditi very much. Thank you to all of you who are joining us today. We have some disappointing news today, but mostly good news. And we look forward to sharing this update with you. Again, Aditi went through the forward-looking statements. From today you'll be hearing from myself, Lara, and you'll be meeting Khaled, and for some of you this is an introduction to the Company. So I just wanted to spend a short time just reviewing some basic information about ONWARD. We were founded in 2015. We have about 110 people currently, our headquarters are in the Netherlands, but we have a science and engineering center in Lausanne, Switzerland and a growing presence in the US centered in Boston, Massachusetts. We did an IPO in late 2021, were listed on the Euronext, and we've raised $170 million since inception. We have two technology platforms. One is implantable. It's called ARC-IM and the other is external called ARC-EX. And they both stimulate the spinal to restore movement and function after spinal cord injury. We're a very innovative company, we have nine FDA Breakthrough Device Designation awards, and now over 360 issued or pending patents, 200 of which are now issued. We have an increasing body of clinical evidence that validates our therapies. We have one pivotal study already complete called Up-LIFT, where we reported positive top line results and a positive responder rate. Earlier this year, we have positive interim results from the first therapy that we're pursuing with our ARC-IM implantable system. We expect to commercialize into a large total available market. Our first commercial sale is expected now in the second half of 2024. And we have a very valuable relationship with the Christopher and Dana Reeve Foundation. Our vision is that empowered by movement, people with spinal cord injury will enjoy life in every way that matters to

them. And we're pursuing that vision using two technology platforms again, as I referred to in the opening, one is called ARC-IM -- that's our implantable system -- the other is called ARC-EX -- that's our external system. All right. Now on to the first half update. A lot of progress here as you can see, and I'm going to go into more detail about each of these. But starting in January, we continue to strengthen our management team with the addition of two new leadership team members. We also were awarded three additional FDA Breakthrough Device Designation Awards, bringing our total now to nine. We shared additional results from the Up-LIFT pivotal trial, that being the responder rate. Our lead, the ARC-IM Lead, was used in a human for the first time back in May. Also in May, there was a major publication in the world's preeminent science journal called *Nature* detailing the first in human use of a brain computer interface in conjunction with our ARC Therapy™ to restore the ability to walk more naturally, after spinal cord injury. We did that with our partners at Clinatec, EPFL and the CHUV. In May, we also announced that we have an expected cash runway through the end of next year. Bryan Garnier, a leading European Investment Bank reinitiated coverage of the Company with a buy rating. And in June actually year to date, we've been awarded again 39 additional patents. So let's go through those in a bit more detail. I've highlighted here in color, the two new members of the Leadership Team. First Erika Ross Ellison, our Vice President of Clinical, Regulatory and Quality, she's really brought a lot to the Company. She formerly led Abbott's Neuromodulation Clinical function, she was also neuroscience director at Cala Health, which is a class 2 or external stimulation company. So really she has ideal overlap the two platforms that we're planning to introduce. Prior to that she was on the faculty of Neurosurgery at the Mayo Clinic where she earned her PhD, as well Sarah Moore joined us in February. She's our Vice President of Global Marketing as well, she has brought a lot to the Company. She was formerly at Nevro. So she has neuromodulation expertise. But prior to that she spent a long time at Johnson and Johnson and she's probably launched 20 different therapies and medical devices over the course of her career. So very pleased to have those two onboard and they're making a difference. I mentioned that we added three more Breakthrough Device Designation awards, those of you who are generalists, this is really a nice thing. It results in increased interaction with the FDA, an accelerated approval process, potentially some reimbursement advantages as well. You'll note that the last two Breakthrough Device Designations pertain to the indication spasticity for both the external and implantable platforms. And we haven't talked a lot about spasticity. But it's really a big problem among those with spinal cord injury. And you'll see here in the second bullet that one in five people with SCI have ongoing functional limitations related to spasticity. So we're very pleased to have been awarded these two additional BDDs. And we look forward to sharing more about our explorations around spasticity in the future. I mentioned before that we shared additional information about our pivotal study called Up-LIFT earlier this year, you already knew from last year that we met our primary endpoint we had we announced positive top line results, we've since announced the responder rate, which was 72%. By responder, we mean that these people who have chronic spinal cord injury showed the increase both strength and function as a result of their exposure to ARC Therapy in the Up-LIFT trial. So three quarters of these people or nearly three quarters had that benefit. And this is really important because this is a population, people with chronic injury, that really have no therapies that are viable for them that can increase strength and function long after spinal cord injury. In May of this year, we also announced that our ARC-IM Lead was implanted in humans for the first time. This was part of the HemON study. So used in combination with our ARC-IM IPG to address blood pressure instability. This is something that affects three quarters of people with spinal cord injury. Big problem. This lead is part of our ARC-IM portfolio. So if you've been part of these discussions, you know that we're developing a

whole family of leads, each of them is optimized for placement in a different area of the spinal cord. The leads are purpose designed, so they have the geometry to capture the spinal cord anatomy that we want to capture in order to restore given movement, or function. We also in May announced this first in human combination of ARC-IM Therapy with a brain computer interface. And this is part of a research initiative that we're undertaking with Clinatec out of France, and then EPFL and the CHUV here in Switzerland. And here's the first time somebody was able to walk again with the benefit of spinal cord stimulation with our precise targeted ARC-IM Therapy, and a brain computer interface. That walking or mobility was triggered with the power of thought. And this person already had a spinal cord stimulator going back to 2017. The addition of the BCI from Clinatec allowed him to walk more naturally, he could pause, he could control his stride length, he could surmount more difficult obstacles, including climbing stairs for the first time. So very promising research. We're now in the process of doing four more implants with Clinatec and EPFL and the CHUV, two for upper extremity, two for mobility. And I have more to say about that a bit later. We also continue to enhance our IP portfolio: 39 new patents were added in the first half of this year, really illustrating our first-mover advantage, we're pioneering this area, we've been able to build our own IP state as well as exclusively license important IP from leading neuroscience research facilities around the world like Caltech, like EPFL. And for the first time we have more than 200 issued patents. So, we're quite proud of this portfolio. We think it's going to be a quite sustained competitive advantage for us. Now on to the financial results. And here I'd like to hand the mic over to Lara Smith Weber, our departing CFO, take it away.

Lara Smith Weber 09:47
Thanks, Dave. Let me take you through the financials for the first half year of 2023. Revenues and other income came in at 0.9 million Euros and consist mainly of grants from DARPA, and two grants focusing on our brain computer interface. Our operating expenses were 19.7 million Euros for the period, up 3.6 million Euros versus the first half of 2022. R&D expenses increased with the advancement of our two platforms, ARC-EX and ARC-IM. As we move forward to commercialization, we also increased costs for operations and quality, both of which are included in G&A, as well as marketing and market access. The resulting loss for the period was 18.8 million Euros. The cash position at the end of June was 43.8 million Euros. That has changed from 61.8 million Euros at the end of 2022. The cash burn of 18 million Euros is for operating purposes. I'd also like to reconfirm our cash guidance that we expect our cash positions to fuel operations through the end of 2024. And before I hand it back over to Dave, I would like to say that this is the last time I will be presenting the financials to you. I'll be leaving ONWARD at the end of the month to pursue a new opportunity in Boston, which is where I live. While it's better for me, personally, I'm very sad to leave ONWARD, an amazing company. I'm very thankful to Dave, to the Board to have had this opportunity and will be rooting for the Company from the sidelines and wish ONWARD all the best.

Dave Marver 11:45
Ah, well. Thank you, Lara, you've done a great job for us. We really appreciate your effort. It's disappointing, but certainly understandable, it's a lot easier to ride your bike to the company headquarters rather than crossing the Atlantic. And I think when you joined the Company, we had hoped that we could migrate to NASDAQ relatively quickly. But obviously, the markets have been shut down for a while. So, it's been difficult for you personally and professionally to travel so much. And thank you for the effort that you you've made on that front and you'll be missed. Okay, so we certainly

don't stop at the first half. What is the 19th of September now, so almost done with the third quarter here. And we've continued to make progress. So, I want to spend a bit of time just outlining that progress with you. In August, we executed the first in human use of the ARC-IM BCI platform to restore arm, hand, and finger movement after SCI. So we talked earlier about the *Nature* paper that detailed the use of a BCI in combination with our spinal cord stimulator to restore movement. Now we've also done an implant with a Clinatec BCI to restore the ability to move one's hands, arms, and fingers. This is something that we have been awaiting with a lot of anticipation. And I'll have more to share about that in the coming weeks certainly. We also in September just this month, in fact, last week, completed an agreement with a 3PL, a third party logistics provider who has an excellent sort of position with US government contracting vehicles or purchasing agreements. And this is quite important for us because it means that shortly after FDA clearance will have access to all of those purchasing vehicles and US government purchasers such as the VA hospital system can therefore purchase our device very soon after FDA clearance. So, this is a quite important, quite important milestone for us as we progress toward commercialization. Now, digging into some of these, these are the two devices that were implanted in August as part of that ARC-IM BCI procedure. At left, you can see the ARC-IM neurostimulator or IPG and at right you can see the Clinatec BCI. So, the IPG is implanted in the abdomen and then a lead is placed on the spinal cord. So sort of our standard ARC-IM implant, the BCI the way that works is that a portion of the skull is removed. The Clinatec BCI sits on top of the dura and it replaces the skull and the skin and hair grow on top of it. So it's really a relatively noninvasive way of implanting a BCI, they have five-year human data. Really a nice design that we've been using. This is the ARC-IM BCI the way we think about it. So a person thinks, so an intention to move originates in the brain, the BCI in our system then uses AI, Artificial Intelligence, to decode that thought, or intention. And then our platform, the ARC-IM platform converts that decoded information into precise stimulation of the spinal cord, resulting in thought-driven movement. That's how that works. Here's some more detail about the agreement with the 3PL. This is a unique type of 3PL, it's a service-disabled veteran owned small business. So there'll be our sales partner they have built in advantages in terms of government procurement. We'll promote the therapy, we'll maintain the customer relationships, so we'll do the sort of simply put the sales and training, they'll manage logistics and fulfillment to both the federal government customers and our regular commercial customers, very efficient group at Lovell. So we're pleased to have all of that out of the way. And again, it gets us that much closer to commercialization. All right, now, I wanted to update you on how we're doing in the road to commercialization. So I'll be chatting a bit about the development path and also the commercial path. Here's some of the disappointing news. And that is that the ARC-EX program is going to be somewhat delayed, we had been guiding that we expected to release this probably in the first half of next year, we've now guided that that's going to be likely in the second half. Why? The reason is that we've identified in the printed circuit board, that there's an opportunity for us to better insulate the high voltage components from the low voltage components. This is not something that we identified until really the last minute, we'd done pre-compliance testing with two different certification houses, we used outside consultants who are experts in the field. And prior to initiating sort of this final safety testing called IEC 60601. Just in talking about this with some other experts, we determined you know what we can make this safer. And that's something that we want to do. This is our first ever device, it's a in some cases vulnerable population, we want to do the right thing, even though it is a disappointment, I'm sure to all of you and to the SCI community that we likely won't be able to launch this until the second half of next year. You know, we have a board member who is the former Chief Technology Officer of Boston

Scientific, he heard about this issue and dug into it. And he described it as really unique and unforeseeable. Because this is a unique device. It's a breakthrough device. There hasn't been a therapy like this before. So sometimes these things happen. We take ownership and responsibility for it. We think it's a narrow, fixable issue. And, and it's really the last thing that we have to get done in order to get this submission to the FDA, and then commercialize the device once it's approved, I wanted to give you sort of an idea of what the remaining roadmap is in order to address the issue. As you can see, here we are today. So we're in the process of updating the design to better insulate the high voltage circuits, then we need to manufacture some of the boards, bring them up and integrate them with the firmware and software and so forth. And then repeat the verification and compliance testing. And indeed, indeed obtain that final 60601 certification. And then with all of that in hand, we can submit to FDA for FDA clearance and then a quarter or two later, submit for CE mark. And that's why we've shifted things to second half of next year for FDA and then Europe, one to two quarters later. Okay, so that's development. Now let's move on to commercialization. And here's I think, some some good news. First of all, we've and this is a credit goes to Sarah Moore, our new VP of Global Marketing, because she's taken a very disciplined approach to pricing. We've gone out, we've had extensive, facilitated conversations with physical therapists, with SCI clinics, and other providers and tried to gauge how are they viewing ARC-EX Therapy? What value are they attaching to this, and here are some of their comments. It's unlike anything currently on the market. This allows the patient to continue to improve at home and therefore optimize their time in the clinic. This makes me feel like I'm part of the solution because I can bring my own experience and troubleshooting to bear. This product is important to my facility because it gives us a new and exciting solution to talk about. I want my patients to experience independence again. And this product provides hope to a unique community that does not always feel heard. In fact, the clinical benefit is 10 out of 10. Two more here. This is a real tool for functional recovery. And we have electrical stimulation but nothing like this. That's the real summary here, they view this -- clinical and economic stakeholders -- as unique and high value.

Dave Marver 20:00

We also, of course, talk to the advocacy groups like the Reeve Foundation, like Wings for Life, and so on. Here's what they're saying: functional recovery, once deemed impossible, may now be in reach. This is from the Chief Scientific Officer of the Christopher and Dana Reeve Foundation. I've been following this closely for over 20 years, nothing like this has been brought to the clinical setting. This is from Kevin Schultes, who chairs the German Spinal Injuries Association. And this is our most visible success, that's from the CEO of European Wings for Life. So a lot of enthusiasm among clinicians and patient groups. We also took a look at the landscape of other devices that are sold into rehabilitation clinics and home and homes for rehabilitation. None of them can do what our device has been shown to do in the pivotal trial thus far that is to restore function. And yet you can see they're selling from $20,000 $45,000, and so on. And we think ARC-EX, based on the value, based on where it says competitively is fairly priced at $30,000 US per unit, that's enough to get us the value that we think we deserve, while also making sure that it's affordable and accessible for the people who need it and the clinics who are so devoted to the care of the SCI community. We also we expect offer optional tiered service packages as well. So that's another opportunity to increase revenue with each unit. So very rigorous scientific approach. We think it's fair. It incorporates value and the competitive landscape. Another important development, just in terms of our launch preparation is taking a look at the market access pathway. So how many covered lives will we have access to shortly after clearance of ARC-EX,

and this is another positive story. So we look at phase one. So that's year one. Almost immediately after FDA clearance, we think that we'll have access to almost a third of the market in the US. How? Well, by virtue of the agreement that we signed with Lovell, we'll have access to the entire VA system, very shortly after FDA clearance. We'll also have access to those people who are covered by workers compensation claims almost immediately, really day one after clearance. And then we think there's a certain percentage of people who have the means to purchase device via self pay. And they can also use crowdfunding and other resources to do that. So, this is how we roll up to about 30% of the covered lives in the first year or so. We then want to apply for a CMS code. We want to wait two years to do that. Because we want to establish our own pricing history before CMS sort of assigns us a reimbursement rate. At that time, usually, the private payers follow Medicare, some private payers may pay for it right away, by the way, but at that time, we expect to reach roughly three quarters of covered lives. Again, this is fairly short, if you look at the landscape of innovative or breakthrough medtech in the US. And then thereafter we would expand beyond that. So I wanted to walk you all through our thinking and what we've discovered by working with market access experts around the world. We also have a quite a strategic board member Kristina Dziekan, who joined us last year, she used to be Vice President of Market Access for Medtronic globally, as well as Alcon. So she's brought a lot of expertise in this area, to our Board of Directors. Lastly, I think lastly, now almost lastly, we've updated our TAM in large part, based on the new pricing assumptions. The current TAM for the existing indications, our pipeline, and the significant increase is one you see in line one where the TAM increased because the pricing inception assumption has increased. So now the TAM and this is just the US and Europe by the way, just these indications, we would say is roughly a bit over $20 billion dollars. We also have taken a look at what we think are available market opportunities for interesting things in the pipeline and I would flag for example, using ARC-EX where we expect our investigative initiated study in the US with a lab with a strong reputation globally. I also would point to using ARC-IM to pursue restoring bladder function. This is a big, big problem for people with spinal cord injury, they normally have to insert a catheter or have a caregiver insert a catheter in order for them to avoid their bladders which is inconvenient and unpleasant but it can lead to urinary tract infection, frequent use of antibiotics and hospitalization. So, definitely something that we're keen to address. Also, Parkinson's mobility, so addressing freezing of gait with spinal cord stimulation using ARC-IM Therapy, I would look for some news about that near future, you see the progress that we're making, and our leadership in the brain computer interface realm. This last row here represents what we think is the incremental revenue opportunity if a BCI is paired with spinal cord stimulation. So, our traditional ARC-IM Therapy for mobility or restoration of upper extremity function. Okay, you saw in our press release that we have Lara departing. And I'm actually very pleased to have found I think we're lucky to have found a very strong and capable pair of hands locally, here. What, 20 minutes from the office, he lives. And so I'd like to introduce to you, Khaled Bahi who's who's with me here in the office, and he'll tell you a bit about himself.

Khaled Bahi 26:15

Thank you, Dave. Yes, so I'm Khaled, very pleased to be here. I have a bit more than 20 years of med tech experience. I spent 15 years with the German company, Fresenius, in different corporate roles in Germany. And I was also CFO of the French operations. And then I joined cardiovascular company called Symetis in Lausanne, so very happy also to be back in Lausanne, that was at the end of a quite exciting IPO process acquired by Boston Scientific for $435 million. So as I said, I'm very, very happy to

be back in Lausanne and very glad to be with ONWARD. I think the Company has a great mission. And I'm looking forward to contributing to achieving the projects. Thank you.

Dave Marver 27:04
All right. Thanks, Khaled. What Khaled didn't mention is that the Symetis story was quite interesting and that they'd prepared for an IPO. And the day before the listing, is when Boston Scientific came and acquired them. So he went through all that work and didn't have the, I think resulting pleasure of running a listed company. Okay, now for our outlook, sort of what's going forward. We've already completed several important milestones this year, we shared additional results from the Up-LIFT study, we completed first in human use of the ARC-IM Lead, there was the major BCI publication in *Nature* that was accompanied by a lot of media attention. And also, very recently, first in human use of ARC-IM BCI for upper extremity function. Going forward this year and into next year, you can expect us to share more detailed results from the Up-LIFT pivotal study that would be shortly after the publication. Also, we of course, expect to submit for regulatory clearance for the upper limb indication for ARC-EX. So that's our filing for FDA approval and then subsequently, CE mark for the ARC-EX. We expect to start early feasibility clinical study for the mobility indication with our ARC-IM. So ARC-IM, our IPG, our purpose designed IPG we've been using for blood pressure, but we expect to use this IPG again, purpose designed for this indication, for mobility for the first time here very shortly. We also expect next year to begin our pivotal clinical study for the blood pressure indication as well. So that's the first indication we're pursuing with the ARC-IM platform. And of course, we're going to pursue opportunities to further strengthen our balance sheet and extend our cash runway. For those of you who are more clinically oriented, I thought it would be useful just to share a snapshot of where we are in terms of our clinical experience to date. So, you can see we've are up to what nearly 120 people who've been treated with our ARC-EX Therapy. And now with ARC-IM Therapy, we're at roughly 25 people. So our clinical evidence is our body of clinical evidence is really growing significantly. So what's next you can see the newsflow is going to continue. We've done all of these things already in 2023 and 2024. There's more to come. And then some other things that you can expect that aren't in this table is more detail on the ARC-IM BCI implant that I just shared with you for upper extremity function. More news about our progress using ARC-IM Therapy for Parkinson's disease for mobility. And also we expect some major news coverage about the Company in the US. Okay, so with that, I think I'm going to stop sharing. And take all of your questions. Okay. Hands up so far, Alex? Yeah, yes, David?

30:18
Good afternoon. Can you hear me?

Dave Marver 30:19
Yes, yes, I can now.

30:21
Thank you for the presentation, Dave. So I actually have two questions. So first of all on the pricing. So you mentioned a 30k list price for the US now based on the input from customers, clinicians and so on. I was wondering if you have done a similar exercise for the EU? And if so, if you have any new prices, but as well for this market? And then also if there's any, you know, updated thoughts on ARC-IM pricing now as well.

Dave Marver 30:51
Sure, yeah, first of all, nothing new on ARC-IM. I think we'll get to that when we're a bit further along. In terms of the pricing analysis that we did, let's say the homework that went into the pricing, we did speak with clinics and clinicians, from the US and Europe. And so at this point, we're expecting that to be a global list price. And, and so we'll make adjustments as needed by market, but that's our current expectation. And we want to withhold price discipline, at least for the first couple of years because CMS, the US Federal Government reimbursement agency does use historical pricing as its reference. So it's important that we stay disciplined and adhere to the list price as closely as we can.

31:41
Okay, okay. And then, secondly, if you can select spectrum data from the blood pressure management studies, like HeMON, for example, this year, and which steps you still need to take before launching the pivotal Empower study, like do you still await for example, the full data set from HeMON on before launching it? Or how does that exactly work?

Dave Marver 32:03
Yeah, thanks. So HeMON is, is progressing very nicely. And in fact, we plan to open up an additional European site here in the near future. And then the investigators are working hard on a publication in order to get the results from the first, let's say 10 to 15 participants published. At that time, I would expect us to release a fulsome set of data about the study or about the results of the therapy, the impact of the therapy, leading into the initiation of the pivotal study, again, called Empower BP, it's possible we can release some additional interim results, maybe top line results prior to that publication. If you recall, last December, we released interim results for the first 10 patients or participants. So, we'll do what we can to bring further insight to that study and those results. But we're very pleased with how things are progressing. In terms of the pivotal study called Empower BP. Again, taking advantage of the advantages offered by the Breakthrough Device Designation, we are in regular contact with the FDA, Erika Ross Ellison, our new VP of Clinical, Regulatory, and Quality, has excellent rapport with those scientists and administrators. And we're at this time just I would say refining the clinical trial design and outcomes measures. And we're getting close. So again, we're really grateful for the degree of collaboration and the support that we're receiving from FDA, they recognize that this is a community in a population that is really in need of compelling solutions. And I think that they want to help us along here. So, nothing to report yet, but I hope to have something maybe by year end. We want to have our next sprint meeting with FDA first before I share anything.

34:02
Okay, thanks Dave.

Dave Marver 32:04
Thank you, David. Okay, I have one from Nial here. Okay, I have a question from you on the market, commercialization path in the Europe in the UK. So let me address that. Thank you for your question. So, it's a bit of a pendulum, some decades, it's easier to commercialize in Europe, some decades it's easier to commercialize in the US. Currently, it's easier to commercialize in the US. And that is because the new medical device regulation in Europe has more complexity, and more requirements than the

FDA’s requirements for a *de novo* submission. So that's why this time we expect to commercialize in the US first, and we're guiding that we would expect CE mark to follow in the two quarters thereafter. We have every expectation of commercializing in major European markets, that’s part of the plan. We've done market access studies in these markets. We've talked to customers there, we've conducted clinical research in these markets. So it's definitely part of our plan. But unfortunately, it just takes longer than the FDA these days and until the regulations change, that's just our reality. Let me move on to John. From Kepler Cheavrux. John, do you have a question? Can you light up his mic, Alex?

35:28
Hi, Dave, can you hear me?

Dave Marver 35:30
Yes.

35:31
Okay. So I was wondering how many of the 45,000 US veterans with spinal cord injury that could be reached through this agreement with Lovell? Well, and then also a follow up in terms of uptake? I mean, do you expect there will be large orders soon after FDA clearance? Do you expect uptake to be through Lovell to be more gradual? Thanks.

Dave Marver 36:04
Sure. Well, so really, all 42,000 are eligible candidates for our therapies, it's just that I'd say two thirds of them are in the system already and one third are out of the system. So they're cared for by the VA, but they in a way given up because there until now hasn't been a therapy that can help people with chronic spinal cord injury. And so the introduction of ARC-EX and ARC-IM creates an opportunity for clinicians at the VA to pull those people back and expose them to ARC-EX and ARC-IM Therapy. The VA also has a, I'd say, a very well-developed home treatment regime. And so within the VA, we expect to have, I would say even a larger proportion of people using ARC-EX at home in comparison to in the general population. The other thing that we're observing with ARC-EX so far is that the people who use it are not plateauing. They're continuing to gain function. And that means that people who are in the system at the VA or even in private clinics, will be able to stay in the system and continue to have the Therapy paid for by insurers. In terms of the uptake for VA, we don't expect that the sort of the national VA will place one large order rather, we expect that each VA facility will manage its own purchases, both for its clinics and for use in the homes of the people whom they're serving. In recognition of this, we've actually laid out our sales territories to align with the major VA hub centers, there are about 25 of these VA hub centers where most of the veterans with SCI are cared for, we want to make sure that those are priority for our salespeople that will be calling on VA centers, they'll be calling on the Up-LIFT clinical sites and they'll be calling on other high volume centers. That's the current plan. Okay, any follow up, John? Is that good?

38:11
That's clear. Thank you.

Dave Marver 38:13

Okay, thanks. All right. I think I see Maria's I think that's Maria, from Bryan Garnier. Want to light up her mic, please.

38:24
Hello Dave. Can you? Can you hear me?

Dave Marver 38:26
Yes.

38:27
Yes. Well, thank you for the extensive update, I wanted to to ask you a little bit more about the BCI, the current partnership that you have with with Clinatec, how you see that partnership moving forward. And you know, we have seen also some some updates from other companies operating on the BCI space. And I was wondering if you can give us a quick overview of how you see ONWARD positioned within this space.

Dave Marver 39:03
Oh, well, thank you for your question, Maria, I think ONWARD is positioned in a very unique way. Because no other company can do what we do. We know how to stimulate the spinal cord to restore movement. And we have the opportunity to pair our device with a number of different brain computer interfaces. They're all focused on recording brain activity. And our device has sort of BCI-ready architecture that allows it to receive wireless data with very low latency, low power consumption, from a device like a BCI. So we're really well positioned that way. We have enjoyed our partnership so far with Clinatec, as well as EPFL. Clinatec is close by you know, they're just right across the border in France. They have been doing this for a long time. They have five-year human data, as I said, their device is relatively speaking, noninvasive, and we have grant funding along with Clinatec to do four more human BCI implants. So that's been a fruitful relationship for us. And it's one that we're keen to deepen and further explore. Having said that, there are lots of other BCI companies, some of them are on the call today. We have cordial relationships with all of them, we want to stay up to date, abreast of their developments. So that we can be in a position when we start our pivotal trial if it involves the BCI, be in a position to use the best possible BCI for the people whom we're trying to serve. Today, that's Clinatec, we think it’s likely going to continue to be Clinatec, but we're keeping our options open.

40:42
All right, thank you.

Dave Marver 40:43
Sure. With pleasure. I have a question here, as well about what we're thinking about the mark in Asia? Very good question. Obviously, there are a lot of people with SCI and paralysis and Parkinson's disease in Asia. Just now as a scale up company, we want to be as focused as we can be, I think we're already taking on a lot. We have two different technology platforms we intend to launch in the US and Europe, a lot of companies at our stage would pick one platform, one geography, so we're already doing a lot. It's already a complex business. I think that as we contemplate how we would enter Asia, it would likely be with a partner. In my experience, that's the best way to enter Japan and China in any

case. And so we're keen to start those conversations at the appropriate time. And if something happens there, obviously, we'll announce it. So please be sure we are not ignoring Asia, I know that there are people who need these therapies there. But in order to get there, we have to build a healthy and vibrant business and sort of build the foundation of the business first in the US and Europe. Okay, anything else come in, Alex?

Dave Marver 42:01
I see that. Sure. I see Ed Hall, Ed Hall has a question as well. Ed. Nice to hear from you. Did you turn on his mic, Alex? All right, Ed, we're ready for you.

42:21
Perfect. Hi, guys. So just a quick question on my side. In terms of sort of pricing. We look at pricing of some of the home device versus clinic. If there's a price disparity there, that you mentioned that there could be sort of sort of bundling effects, and maybe sort of going into sort of recurring revenues once the products on the market. Do you have any sort of ideal in terms of software bundling or any sort of way that you can make this more of a reoccurring revenue going forward?

Dave Marver 42:55
Yeah, thank you, Ed. You know, at this point, we don't expect a meaningful difference in pricing between clinic and home, the devices themselves are likely to differ in part, the clinic devices, we expect we'll have more sort of a broader set of programming parameters and flexibility. In terms of the the opportunity for recurring revenue or ancillary revenue over and above just the sale of the capital equipment. Well, there's, first of all, there's the optional service plans, those are customary for equipment like this, and we expect to offer those for clinic and home use. So that's a nice way to have some recurring revenue alongside the device. Also, we don't expect a lot of revenue from the electrodes we want those to be affordable for people in the home certainly, but there'll be some.

43:53
Perfect. Thank you.

Dave Marver 43:56
Okay, let me see. I think we have a few more questions here. Siamak, do you want to ask your question? Can you light up? We're looking for you on here. Bear with us. Okay, there we go. Alright, Siamak, you're allowed to talk now.

44:27
Hello, yep. In spite of all of this good news, I don't see the share price is benefited from, what is the reason, what do you think?

Dave Marver 44:38
Well, obviously the share price performance is disappointing for all of us. There are a few things at work. Maybe one of the analysts would like to help but certainly you can take a look at what we have achieved since the IPO. And this call is representative of all the updates, we've had just a steady drumbeat of milestones and achievements. Notwithstanding today's news about the delay, which is

disappointing, I think en masse, we've done nothing but grow the body of clinical evidence. You know, we finished the ARC-IM device, it's been used in a human, have been used in the human. Same with the lead, we have positive, pivotal study results, we've strengthened the team, we've added to the IP portfolios, we've forged partnerships, all the things that you would want to see from a company that is scaling, we've demonstrated. So, there are two things at work. One is it the sector just hasn't done well. If you look on Euronext, the sort of smaller market cap Life Science devices, life science companies and med tech companies, they're all down just about the same percentage that we're down. And so the sector just isn't in favor right now, I think we've been pulled down in some respects by the performance of the biotech sector, where a lot of those companies are short on cash, some of them are trading for less than cash. So it's just a sector wide phenomenon. Again, disappointed for you, we want you guys, all of you on the call to have your investments have a nice return. But I think it's important that we're all aligned here…at the IPO most the vast majority of our investors were, were long term holders, they had a long term view, and they see that, that this Company with its proprietary technology, with the IP estate that we have, with the absence of competition, meaningful competition, with huge unmet need we have, and also the just the attractiveness of the space – neuromodulation -- with active implantables, we have every opportunity to build a very valuable business over time. So, I guess I would ask you to sort of adopt the philosophy I have, which is we just continue to do the right things over time, we'll have a valuable Company. That's my hope and expectation. And I really do appreciate your patience. I think we are doing the right things. A lot of the stock performance and pricing is driven not by our institutional investor transactions, but by very small retail transactions, we don't have a lot of trading volume. And so, I'm going to sort of step up my activities around engaging with retail investors, particularly around Europe to see if that can have an impact. But I share your disappointment, but ask that you just hang with us long term because you have a very, very highly committed group of people here that are working extremely hard with, I think, good clay. And we're going to build a very valuable company here and get you a nice return.

47:51
Thank you so much.

Dave Marver 47:53
Sure. Okay, I think that's it. Anything else come in? Yeah. Yeah. Nial, you asked about our ARC-EX forecasts, we really haven't provided any forecasts or got it on sales volume. So, we'll leave that to you. But the TAM, the market opportunity, does assume that everyone who's eligible would have a device in their home. So, I think that may have been what you were asking. Indeed, yes. The TAM is for both clinic and in home and it assumes full penetration, which is how TAMs are normally calculated. Of course, our sales forecasts are going to be far more measured and conservative, we'll be looking at conservative penetration assumptions, we'll be looking at the then accessible market based on payer behavior and so forth. Okay, anything else come in? Last minute? I don't think you had a chance to see Khaled because I was sharing my slides that maybe Khaled, you come up and get to know you a little bit, when I shared the screen, they couldn't see you.

Khaled Bahi 49:05
Okay.

Dave Marver 49:06
This is Khaled.

Khaled Bahi 49:08
Hi everybody.

Dave Marver 49:09
All right. So again, thanks, everyone for joining. Again, sorry about the postponement of ARC-EX, we're trying to do the right thing here and introduce the safest possible device. So obviously, it's a disappointment to us to also have to delay it but I hope you understand and also appreciate if you look big picture at everything that we're achieving and accomplishing. I think we again remain a very special and well positioned company here. So, thank you for your support. Thanks.