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ONWARD MEDICAL SPEAKERS

Dave Marver, CEO

Amori Fraser, Senior Finance Director

GUEST SPEAKERS

Dr. Jocelyne Bloch, Neurosurgeon, Co-founder and ONWARD Medical Advisor

Gregoire Courtine Neuroscientist, Co-founder and Scientific Advisor

Dave Marver 00:04

Welcome to ONWARD's Q3 2024 Business Update. I am Dave Marver, CEO.

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, I have the privilege to introduce Amori Fraser, our Finance Director, as well as Dr. Jocelyne Bloch, Neurosurgeon, Co-founder and ONWARD Medical Advisor, as well as Gregoire Courtine Neuroscientist, Co-founder and Scientific Advisor. We will start with a presentation and prepared remarks, and then we would be pleased to take your questions.

As we normally do, for those of you who are new to the story, we're going to start out with an overview of the company. So, this is an at-a-glance slide or summary. You can see we were founded in 2015 by Professor Courtine and Dr. Bloch. We now have about 100 team members, headquartered in the Netherlands, but we have a science and engineering center in Switzerland, where we're currently broadcasting. And we have a growing US presence in anticipation of our forthcoming launch of the ARC-EX System. We listed on Euronext Brussels and Amsterdam in late 2021, and we recently added a Euronext Paris listing. And we currently enjoy research coverage from five equity research analysts, most recently from Stifel, also Bryan, Garnier & Co., KBC, Degroof Petercam and Kepler Cheuvreux. ONWARD has three purpose-built neuromodulation platforms, all of which stimulate the spinal cord to restore critical movement and function after spinal cord injury. ARC-EX delivers our ARC Therapy™ externally through the skin. ARC-IM is a fully implanted system, and we also have ARC-BCI, which pairs ARC-IM with an implanted brain-computer interface to restore thought-driven movement via our wireless DigitalBridge™. We're a very innovative company. We have 10 FDA Breakthrough Device Designation awards and over 270 issued patents worldwide. In terms of clinical progress, we've already demonstrated

the safety and effectiveness of ARC-EX Therapy for upper limb activities. That was demonstrated in our Up-LIFT pivotal study, the results of which were published in *Nature Medicine* in May 2024.

We also have positive interim results for ARC-IM and its initial indication that is addressing blood pressure dysregulation after spinal cord injury. Those were released in December 2022.

We are launching into a large total available market, 20 billion euros plus - or dollars plus, I should say - with limited competition. Our vision is that empowered by independence, people with spinal cord injury will enjoy life in the ways that matter to them. And we have developed, or are developing, three technology platforms that are very flexible and can indeed address many or all of the recovery targets that are prioritized by those with spinal cord injury. Here they are pictured: ARC-EX, ARC-IM, and then ARC-BCI. Even though we have a lot of recovery targets and a lot of activities here, we're very focused as a company and good stewards of capital. So, in the short term, our focus is commercializing ARC-EX. We then want to start the pivotal global study for ARC-IM and then get that commercialized in the mid-term that would put us in the traditional NASDAQ IPO, or M&A window. And then thereafter, we can easily expand indications, expand into adjacent populations, as well as expand the platform to include the brain-computer interface technology.

This is a list of all recovery targets for which we've achieved human proof of concept. Indeed, there is the last one here - bladder - we expect to do first in-human in 2025.

We as a company are focused on the top two, those in gray, and we are advancing the others in our pipeline with the benefit of grant funding. The company has received grants from DARPA, the US Department of Defense, the Michael J. Fox Foundation, the Christopher & Dana Reeve Foundation, and the European Innovation Council, to name just a few.

All right, now to the update. This was quite an eventful quarter for us, Q3. Starting left to right... so in July, we announced a publication in the journal *Neuromodulation* that contained programming suggestions for ARC-EX Therapy. [It] will be very helpful to clinicians and physical therapists once this device is authorized by the FDA and available in clinics. In July, we announced the publication of our annual sustainability summary for the full year 2023.

Many of you as individuals, if this is important to you, or if you represent institutional investors or funds, you have an ESG mandate, we certainly qualify. In September, we were awarded a grant from the Christopher & Dana Reeve Foundation to further use our brain-computer interface system to study upper extremity function. We also, in September,

announced the third implant of the ARC-BCI[I] System, or therapy to restore movement after spinal cord injury, movement driven by thought. In September we expanded, and not only do we have a listing on Euronext Brussels and Amsterdam, but we now have a listing on Euronext Paris. The company has deep ties to France. One of our founders, Gregoire Courtine, is a son of Dijon, and we have an important relationship now with CEA, the developer of the WIMAGINE® BCI. So, we wanted to expand the availability of our shares and drive more liquidity and investor participation in France. In October, we secured exclusive rights to the CEA WIMAGINE BCI technology. More to come on that. Also in October, we welcomed a new incoming board chair. That is Rob ten Hoedt who is a former Medtronic President. More to come on that. Also in October, we announced that we had successfully raised 50 million euros in an upsized fundraising initiative, and we added Ottobock as our largest investor. More to come on that. And in October, the ARC-EX System, in a nod to its innovation, was named one of Time Magazine's best inventions of 2024.

In November, we announced that we were awarded another grant, this one from the European Innovation Council, to address upper limb movement challenges after stroke. So, reinforcing that even though SCI is our North Star, our same hardware platforms and therapies can potentially be used to help people in large adjacent populations such as Parkinson's disease and stroke. All right, so let's go into more detail regarding those highlights that were bracketed in red, starting with our exclusive license of the CEA WIMAGINE BCI technology. We forged an exclusive license agreement to bring that technology in-house. This was my quote from the press release. “CEA’s Clinatec is a world-renowned biomedical research institute and its BCI is ideal for our applications. We can now develop a truly integrated system that is well suited for the type of study required to gain regulatory approval and bring a BCI-enabled system to market.” And then from my counterpart at CEA, Guillaume Charvet, who heads the Neurotechnology Biomedical Research Unit there, “The early clinical feasibility research demonstrates the remarkable potential of the ARC-BCI[I] System to restore thought-driven movement and function after paralysis... We are pleased to partner with ONWARD Medical.” So now I'm privileged to invite two of my colleagues, co-founders of ONWARD Medical who have pioneered this BCI research, Gregoire Courtine, Neuroscientist, and Dr. Jocelyne Bloch, Neurosurgeon, so come join me here on the camera. Thank you very much.

Gregoire Courtine 09:06

Good afternoon, everyone.

Dave Marver 09:08

So, I thought we'd just keep things informal today and do just a bit of an interview or discussion. Jocelyne, maybe you can explain how the WIMAGINE BCI is implanted.

Jocelyne Bloch 09:19

So, the WIMAGINE BCI is implanted in two parts. The first one is the ARC-IM that I implant above the region of the spinal cord, as that is controlling leg movements.

Dave Marver

Okay.

Jocelyne Bloch

And then the second surgery is to insert the BCI implant, as you said. It's a little bit like an electronic bone. It's not a very invasive surgery for me. I open the skin, I remove a piece of bone, and I replace it with this electronic bone that is then going to record the thoughts of the patient. Everything is closed, and that's it. The day after the surgery, the patient can go home.

Dave Marver

So, for a neurosurgeon like yourself, who's accustomed to working with devices, is this a difficult or easy implant procedure?

Jocelyne Bloch

So, the BCI, the brain implant, for me, is an easy procedure. You just have to know the anatomy and where the region of the brain that is controlling leg movement or hand movement is located, and then you center your cryotome in this region, and you don't even have to open the envelope around the brain that is called the dura, so everything is outside of the brain, so the risk is very minimal, and it's just a bone work.

Dave Marver

So, versus other BCI technologies, would you say this is relatively non-invasive?

Jocelyne Bloch

Absolutely. So the other technologies I know, and I've worked with are more invasive. It means that you implant electrodes in the brain of the patients. And this is more invasive, of course.

Dave Marver 10:52

Okay, so Gregoire, how does this BCI System, ARC-BCI, really work? How does this technology that Jocelyn just described result in thought-driven restoration of movement?

Gregoire Courtine

So, your whole idea is that with this BCI System, we are recording what is called local field potential.

Each electrode, there are 64 on this electronic board, records the activity of about 1000 neurons. And for these recordings, we have an artificial intelligence that decodes the intention to move. That means the legs or the upper limbs - and translates this intention to move into a stimulation at the correct location, correct parameter, correct timing, to elicit the desired movement. So digital bridge between the brain and spinal cord that turn the thought into actions.

Dave Marver

And why is the WIMAGINE BCI our preferred BCI at this point?

Gregoire Courtine

Yeah, we both have an argument for being in love with this device.

Jocelyne Bloch 11:55

For me, it's clearly the non-invasiveness and the fact that it's a very stable signal that we get all the time.

So, for me, those are the main features.

Gregoire Courtine

She would like to say the WIMAGINE concept was considered by a neurosurgeon, which is kind of unusual. Usually, it comes from someone who creates the technology. That's why she loves it, because they've considered this idea that “I need to implant this in 1000s of people,” so it's very resistant to a surgical mistake, in a way.

Dave Marver

This is the same neurosurgeon who invented DBS (deep brain stimulation) as well. So, he has a very good reputation.

Gregoire Courtine

Very clever.

Dave Marver

Now, Jocelyne talked about the stability of signals, and is that because, unlike other BCIs that penetrate the brain, and the brain sort of fights back to protect itself that can degrade signals - that doesn't occur here?

Gregoire Courtine

Exactly.

This is why I love this emerging system.

Jocelyne Bloch

Me too.

Gregoire Courtine

I know you do, but the relativity for an engineer is the best. So of course, this, like little wires that you penetrate, insert into the brain, are amazing to recover what is called a single unit, meaning individual neurons, which for research, is amazing. For clinical application it would be amazing if this signal will be stable over time. They decline.

So, at the beginning, it's like an epiphany, the honeymoon looks amazing. You have seen the data from Neuralink, you know the person can control a computer, play a video game, and then over the month it degrades, declines. It's frustrating. The patient expresses frustration. It Is completely different than WIMAGINE. Seven years of clinical data with highly stable signals.

Dave Marver

Yeah, I think that's important. So, these BCIs that penetrate the brain, those signals can degrade. That does not occur so far with the WIMAGINE BCI. Seven-year human safety data and solid signals, very good. So how are we using the BCI today in your research, and how do you foresee we might use it in the future?

Gregoire Courtine

So currently, I mean, the first step for us is the restoration of walking. That was the first application, as you probably have all seen. The patient took the first step. Jocelyne implanted the second participant, a woman with a complete spinal cord injury. So, the most extreme severity of spinal cord injury, no sensation, no movement below the injury. And in this case, both of them think about the movement, they stimulate themselves, and they can stand, take voluntary steps, and adjust the height of the steps to accommodate the leg movement to the environmental constraint.

Dave Marver

So, two so far for leg mobility, or locomotion, and then ...

Jocelyne Bloch

There was one patient so far for upper extremity movement. It's exactly the same principle, except that in that case, you record the region that is controlling upper extremity movement, and you stimulate the region of the spinal cord that is controlling also the upper extremity movement. And the link is exactly the same. So, the principle is the same. So far, we've implanted one patient. Soon we'll have a second one, in January. And it's very impressive to see how we can train them the same way and how independent they get for different movements, for daily activities.

Dave Marver

And more implants are coming, right? We collectively are benefiting from a grant from the Christopher & Dana Reeve Foundation, which will support several hand and arm functions for BCI...

Gregoire Courtine

Up to eight for the upper limb, probably four for the lower limb. And we also have support from the European Union to test the same concept to improve the recovery after stroke. It's a very exciting time for brain controlled-spinal cord stimulation.

Dave Marver 15:34

Well, very good. Well, I'm very grateful to you for founding ONWARD Medical. I enjoy working with you and thank you for joining me today. Thanks very much. All right, that was a treat.

Moving on, just a bit more detail on the why. You heard about the clinical and scientific rationale behind our decision to license this WIMAGINE BCI exclusively and make it an ONWARD technology, but for us as a business, this enables us to be first to market with a BCI enabled system to restore thought-driven movement after paralysis or movement disabilities. You heard about the potential applicability in stroke, for example. It also gives us full control over a technology that really is the best fit for ONWARD indications, and it gives us an opportunity to develop a truly integrated system under one quality system single interface.

So, this also provides an advantage to us as we prepare to initiate a global clinical trial for this technology at some point in the future. And you heard that this is, you know, it's a very fertile area. A lot of people have an interest in it, and as a result, we can indeed attract grant funding to support the research. You heard two such examples from Gregoire

Courtine from the European Innovation Council and the Christopher & Dana Reeve Foundation. So, we can advance this technology, learn, and move it forward in the pipeline with the benefit of grant funding. So certainly, that's an advantage.

Also in this quarter, as I mentioned, we have continued to strengthen and evolve our board. So, I'm very pleased that Rob ten Hoedt is joining us as incoming Chairman. Rob is a former Medtronic president and ex-Executive Committee Member. He has 30 years of experience in MedTech, a successful track record in technology development, commercialization and business model innovation. Also, he's an industry leader. He was long-time chairman of MedTech Europe, the association representing the medical technology industry here in Europe. I've known Rob for 25-30 years and I'd lost touch with him. I saw him in Geneva airport about a year ago and started my pursuit. And I'm very pleased that he decided to join us. He's very much captivated by the mission and excited to re-engage with a company at our stage. It reminds him of Medtronic in the early days. Also, we've recruited Rahma Samow, who's a commercial expert and community builder. She's currently a sitting CEO of ClearChoice Dental Implant Centers, which is a US-based dental implant provider. She's a digital health and direct-to-consumer business leader, and also has an esteemed background as a former member of the Executive Management Board of Straumann Group, and also, she spent 15 years with Siemens Healthineers. So, two additions that are going to strengthen our board as we transition from a development phase to a commercial stage company.

Also, the capital raise, which was big news this year. We raised 50 million euros in an upsized capital increase. Part of that raised was a strategic investment from Ottobock. They're a global leader in prosthetics, orthotics and exoskeleton technology. They're now the number one shareholder of the company - around 10% of our shares - and this initiates a strategic relationship with the company. I'll get more into that in the next slide. This financing was important. It extends our runway for two years or more. And, in addition to bringing Ottobock onto the cap table, we recruited several new high quality, long-only and sector specialist investors. So a very good, high-quality financing for the company. In terms of Ottobock, we are grateful for the investment, but we're also excited about the opportunities to collaborate with them. This is a company with over 100 years of experience serving people with movement disabilities. They are a global leader in prosthetics, orthotics, exoskeleton technologies, serving the same people that we are working so hard to serve, and they have scale. They are a private company so many of you maybe have not heard of them, but they operate in 60 countries - with 9000 employees, over 400 brick and mortar patient care centers, one and a half billion euros in annual turnover, and nearly 300 million in adjusted EBITDA. So, a financially strong company and partner, as well. As I mentioned before, they're now our largest shareholder with just

around 10% of our outstanding shares, and we are going to take this opportunity now to explore commercial and development collaborations that will benefit both companies. On the right side of the slide, you see a quote from the Ottobock owner. This is a family-owned company, been in the family for 100 years. Professor Hans Georg Näder is their owner and chairman. What he said, “ONWARD Medical has the potential to become a gamechanger in the therapy of spinal cord injuries with its innovative solutions Our investment in ONWARD is an investment in the future of medical technology.” So we're very pleased to be working with Ottobock. We appreciate the investment very much. Also recognizing that we could represent the future of medical technology is Time Magazine, which recently named the ARC-EX system one of the best inventions of 2024. And we believe in this system very much as well. We're very keen to make it available to people with spinal cord injury, and we're hopeful that it occurs just in the coming weeks.

Now for a financial update, I'm pleased to welcome Amori Fraser. This is perhaps the last quarter where we restrict the financial update to just cash. Hopefully we'll have a bit more to talk about going forward. Amori, take it away.

Amori Fraser 21:39

Thank you, Dave. We closed the third quarter, the end of September, with a cash balance of 23.2 million, representing a cash burn of 8.9 million. The 8.9 million cash burn includes transaction costs that related to the debt financing we concluded in the second quarter. And net to these transaction costs, the cash burn is in line with the historical averages from previous quarters. Following our successful capital raise in October, our cash balance for last week closed at 65.8 million. And, as Dave mentioned, we are confident that our cash position will fund our operations for two years or more. Back to you, Dave.

Dave Marver

Thank you, Amori. And we won't always provide our most recent cash balance, but we thought that it was particularly salient today, given that we just had the financing, and we have a much stronger cash position than we did at the close of the third quarter. All right. Now, moving on to the outlook as usual, there's a lot of upcoming news flow and several important catalysts. They include FDA clearance of the ARC-EX System, and the first commercial sale of that system. And then we're keen to also make the technology available in Europe. So, we look forward to announcing MDR submission, CE mark certification, and first commercial sale of ARC-EX in Europe. As mentioned before, our therapies and our systems that we've developed for SCI have the potential to also help people with Parkinson's disease. So, we have an ongoing clinical feasibility study for

Parkinson's disease mobility. We look forward to announcing that first patient enrollment in the near future. And also, we expect detailed results from the first 14 people who have received our ARC-IM therapy to address blood pressure dysregulation. That should be published in a top-tier medical journal in the coming weeks or months. Now, staying on the theme of ARC-IM, we're also keen to get that global pivotal study started. We call it Empower BP. So, we look forward to announcing IDE submission, IDE approval, and first patient enrollment in that study, which will be a global study with centers in the US, Canada and Europe. We also want to continue to use ARC-IM to explore future indications and clinical feasibility studies. As I mentioned before, we look forward to enrolling a patient in a bladder study. This is under-active bladder, another category in which we don't have competition, because the incumbents are addressing over-active bladder. And then, of course, we'll announce additional implants for ARC-BCI as they arise. So, a lot is going on here. We're going to stay busy. So that's the end of the prepared remarks, and I'd like to open it up for questions now, so you can either raise your hand and we'll call on you, or we're happy to also take questions through the chat function.

I already see one question coming in, which is, at what stage are you in obtaining approval to introduce ARC-EX to the European market? Are you first waiting for FDA approval? And if so, why aren't you doing both at the same time? Okay, fair question. Yeah, indeed, we want to get

FDA approval first, or FDA authorization - De Novo authorization for ARC-EX. Our regulatory group is quite busy getting the IDE prepared so we can initiate the pivotal global study for ARC-IM called Empower BP. So, we're doing two things at once already. Three things would really be too much for a company of our size. We're trying to be, again, efficient stewards of capital and not take on too much or add too many resources. So once both of those processes are well in hand, and we have FDA authorization to market ARC-EX in the US, then we will pursue

CE mark certification in Europe. So, this is something that we're guiding will occur in the first half of next year, so that we can have authorization to make ARC-EX available in CE mark countries in the second half of next year.

Okay, got another question here that came in from David Pepper, who's a frequent guest of these calls. Will ARC-EX initially [be] deployed at clinics versus home?

Indeed, that is our expectation. We want to get started in the clinics. Those are our anchors. That's where people with spinal cord injury will first experience the therapy, learn about it. Their stimulation parameters can be established in the clinic. So, we're going to ramp up relatively slowly, starting in a select number of clinics, expanding from there, and then making the device available for home use. So that's the current plan, David.

Okay, any other questions, maybe from our analysts. Okay, I see there they are. All right, let's start with Thomas. You were first - Thomas from KBC.

Can you open Thomas's mic?

Thomas Vranken, KBC 26:55

Hello. Can you hear me?

Dave Marver

Yes. Go ahead. Thomas.

Thomas Vranken

Perfect. Yeah.

First of all, congrats on another strong quarter, and thanks for taking my question. A couple of questions from my side, the first one is indeed on the FDA approval, could you share some sentiment on your level of confidence that the approval would still come before year end, which is pretty much 30 days from now? What makes you so confident that it will arrive within that time frame, and then I'll have some follow up questions later as well.

Dave Marver

We remain confident that we'll receive the authorization this calendar year. That has been our guidance for several months now, and we've learned nothing that would provoke a change in that guidance. This is one of our 10 Breakthrough Device Designation awards. So, we have frequent and high-quality interaction with the FDA. And again, I don't want to say anything more, but at this point, we continue to believe that FDA authorization is likely this calendar year.

Thomas Vranken

Okay, thank you. And if I could make use of the fact that the KOLs are there as well, maybe a couple of questions for them. Perhaps for Dr. Bloch, could you give a bit of an indication of how easy it is for a neurosurgeon to be trained to implant the full ARC-BCI system, including both the brain chip and the neurostimulator. And from a patient perspective, how long do they require hospitalization before and after the procedure, and what the main risks could be. And then perhaps, to Professor Courtine, I was wondering if you could share your views on where you currently see at the biggest potential for ARC-BCI from a clinical or from an academic point of view across the different indications - SCI, stroke, Parkinson's, maybe others. And why? Thank you.

Dave Marver

So, do you want Dr. Bloch to focus just on ARC-BCI, Thomas?

Thomas Vranken

Well, it would be interesting to make a comparison as well, of course, with the other technologies, if that's possible. Thank you.

Jocelyne Bloch 29:02

So, I believe that it's an easy technology to teach to other neurosurgeons If I compare it to DBS, for example, which requires many more years of training to be a good DBS surgeon. Here this craniotomy is pretty easy to perform. As I said, probably for me, the most important thing is just to localize it well. But then to perform the surgery is an easy procedure that can be taught to everyone. And

I would say that it's again, teamwork. So, the surgeon himself will not be able then to do all the decoding and to do all the work, but the work of the surgeon is easy work. So then for the hospital stay, you asked me, so every procedure that is not in the brain, the hospital stay is pretty short.

So, in general, they spend one night after the surgery in the hospital, and we perform a CT scan the day after just to make sure that we have no complications. And the complication we could expect would be a little hematoma or an infection. The infection would come later on, but the hematoma can be detected the day after the surgery, and if we don't find anything, the person can go home.

Dave Marver

And I think that's going to be market dependent, Thomas. Maybe in the US, it'll be viewed as a 23-hour procedure, just the spinal implant, because that's customary for pain.

All right.

Gregoire Courtine 30:38

If I take on the second question.

First, academically, since you asked, I think that the concept of a digital bridge between the brain and spinal cord to restore movement is probably the only grade of neuro prosthetics. Everybody's dream is to achieve that. When Elon Musk announced he would

do that for many, many years, he was the only one who actually did it so far, the proof of concept, and we believe that ONWARD can take it to the commercial application as a first iteration. But in parallel, as academics, we are continuously innovating and bringing this technology even more advanced. What does that mean? That means that we are already creating some chips to do all the decoding directly on the device. We are bringing all the next generation AI - so developing what we call brand GPT - to use all the large language models to learn the language of the human brain and have the decoding even more robust. And we are already testing all these types of applications in non-human primate models. So, you need to anticipate that ONWARD will continuously innovate and iterate additional technology that will be more and more effective in this area of research.

Dave Marver 31:48

And his other question was, do you see applicability beyond SCI into other movement disabilities?

Gregoire Courtine

So, we have known the proof of concept in human post-spinal cord injury, upper limb and lower limb. We also have for Parkinson's disease. Recently, two weeks ago, three weeks ago, Jocelyn implanted in a new participant with Parkinson's disease with the ARC-IM system. It has been a great success so far. So, it alleviates the gait disorder, reduced freezing of gait, and we already have the intention to be able to use the BCI in this concept. Meaning, with the electrode or deep brain stimulation that just input in the subthalamic nucleus, we can actually detect the intention to walk, the gait disorder, and tune the stimulation in real time.

Dave Marver

Don't give away too much,

Okay, thank you, Gregoire. All right, let's see. I think we have-Ed is next. Ed Hall from Stifel.

Your mic is open now, Ed.

Ed Hall, Stifel 32:52

Thanks, Dave. I guess the first question was similar to Thomas's. I guess looking at the concept, maybe from the financial side, with the use of proceeds now with the recent transaction, and how do you view the pipeline, now? Obviously, you've got two in gray, let's say, but a fair amount of white space. So, what do you see as a priority to get into the clinic? I guess, beyond this blood pressure indication? I guess with the backdrop of having in license, the BCI implant made progress in other areas, like sacral and then adjacently in

stroke and Parkinson's. From a financial perspective- I guess we've already asked the scientific - but from a financial perspective, what is the most interesting for you, Dave?

Dave Marver 33:31

Yeah. I mean, first, I want to reiterate that we expect to spend our capital on the indications in gray. We need to successfully commercially launch ARC-EX globally, we need to successfully execute the pivotal study for ARC-IM, called Empower BP. And in the meantime, we're very fortunate that we benefit from grant funding to advance the other recovery targets in the pipeline, many of which were just discussed. Some involve BCI. Some involve ARC-IM alone. Some are ARC-EX alone. And as those mature, and as our financial situation evolves, and we begin to generate our own cash and so on, we can commercialize more and more of those. So that's the idea. In terms of what's compelling. You know, as I've said before, SCI is our North Star, that's our reason for being, our raison d'etre, and we're going to continue to serve that community. But there are really compelling business opportunities in these adjacent populations, such as stroke and Parkinson's, so if we can indeed pursue those as well, without losing focus on SCI, then that's what we're going to do.

Ed Hall 34:43

Perfect. And then maybe just back on the WIMAGINE device. You're now working along this route with this BCI implant. But my understanding, it's not an exclusive agreement, per se. You can, in theory, work with other implants, so let's say Synchron or Paradromics.

So Neuralink suddenly get more progressed. How transferable is the ARC stimulation programs with other BCI implants? Maybe this is a question for Dr. Courtine.

Dave Marver 35:12

Well, the ARC-IM here is agnostic. It can receive wireless data with low latency from any of those devices. As we've discussed, we believe at this point that WIMAGINE is, without question, the best device currently for our intended use. That doesn't mean that in the future, we might not do something a bit different. But I think for the foreseeable future, we want to make this digital bridge work with WIMAGINE. So, I think we're in a very good situation. We now have brought in house really the only clinically viable BCI for indication. It's ours now, and we can turn that into a product. In the meantime, in the future, we stay abreast of developments, keep in touch with all the industry players, and we make the best possible decision at that point in time.

Ed Hall 36:08

Perfect. Thank you very much.

Dave Marver

Yes, my pleasure, Maria. I'm sorry I had you wait. Maria from Bryan Garnier.

Maria Vara, Bryan Garnier 36:17

Hi Dave, yeah. Yes, perfect. Thank you. No worries. Congratulations again for another super productive quarter. You know, maybe I would like to touch on the fact that you added Ottobock as a strategic partner, as an investor. You know, you mentioned potential synergies and R&D and commercialization. I know maybe you haven't discussed it already with Ottobock, but you know, as we are getting closer to ARC-EX clearance, maybe you can tell us a bit about what could look like the commercialization synergies with Ottobock for ARC-EX.

Dave Marver 36:57

Yeah, I think the first thing I want to say is that Ottobock has shown to be a really excellent and respectful partner. I mean, they're obviously quite a bit bigger than us, but they want to work with us to identify collaborations that are indeed win-wins that benefit both companies. You know, one can envision on the go-to-market side of things, they have a global footprint. They operate in 50 countries, so maybe by leveraging their distribution network, we can more quickly enter and access some of these global markets that we otherwise would have to put off for several years. Even just looking in the US, they already have an embedded presence in clinics, leading clinics such as Shirley Ryan in Chicago. They have deep relationships with all of the VA, the military hospital hub systems. So, there are opportunities for them to make introductions for us, to have joint programs where we talk about our technology.

Even seminars and education sessions for people who have injuries. Those are all sorts of easy things to envision. On the technology side, they have an exoskeleton that could potentially be used as an adjunct to our therapy, maybe to get people who receive ARC-IM for mobility up on their feet and moving more quickly and easily. They're leaders in prosthetic limbs. Maybe in the future, those can be powered with a brain-computer interface as well, leveraging our capabilities and know-how. There's a lot of things that we've discussed that are super interesting. I think that anyone could probably intuit. I'm not giving anything away. That isn't to say we're going to do any of these things that I've mentioned, but I'm just explaining some possibilities.

Maria Vara 38:43

All right, yeah, that's helpful. And maybe, when we're looking now, you know, only a few weeks ahead of the of the commercial launch, could you share any level of demand that you're already kind of estimating, if you've already had contact with clinics that you run the pivotal study or other clinics outside of the of the study?

Dave Marver 39:06

Yeah, thanks for your question, Maria. You know, we're not allowed to promote the device at all until such time as we get FDA market authorization. So, I really can't comment on demand other than it's natural to assume that clinics who are participants in our Up-LIFT pivotal study are likely to be sources of demand for the device. We also have received inbound inquiries from people with spinal cord injury, their caregivers, so we have a long list of folks whom we can notify once we have authorization to market the device. So, I think there's probably a lot of latent demand, nothing I can quantify, because we've not been out there discussing or promoting the device at this point,

Maria Vara 39:52

All right, and then maybe, just to wrap it up, about the European preparations for submitting the regulatory processes. You mentioned in the press release that you're expecting to submit for CE mark in H1 and potentially receiving approval in H2. Any commercial plans or strategies already designed for the European markets, considering, you know, we're talking about more difficult reimbursement schemes depending on countries?

Dave Marver 40:22

Yeah, sure. I think step one is to get regulatory approval, to get CE marking, maybe follow that up with authorization to market it in the UK, now that they're no longer part of Europe and in the meantime, we will put more structure around the go to market. Our current intent is to start in the large markets, chiefly Germany, where reimbursement looks like it's really not bad. And then we'll go from there, looking opportunistically at the market sizes, reimbursement regime, ease of access, things of that nature. We'll also look at the rest of the world. There are geographies that accept FDA authorization, that accept CE marking, and so we'll look to add distribution partners in those markets that might be sort of easy paths to revenue, as long as it doesn't distract us from our geographies of primary focus, those being the US and Western Europe.

Maria Vara 41:25

All right, that was very helpful. Thank you very much.

Dave Marver

My pleasure. Okay, I think we have a question from David from Degroof Petercam.

David, you are live.

David Seynnaeva, Degroof Petercam 41:38

Good afternoon.

Regarding Empower BP, perhaps, how are you thinking about its primary endpoint? In case you can already comment on that. Of course, will this be more functional or still, you know, blood pressure related, and how long is the study expected to last? More or less? Thank you.

Dave Marver 41:58

We're going to provide more information on Empower BP once we have the IDE approved by the FDA. I think to do so now, given there still might be some shaping and modification, would be premature. I am confident, however, saying that blood pressure dysregulation is the primary focus and will shape the primary endpoint, and I'll stop there, but more to come, David. Don't we have enough to talk about?

David Seynnaeve 42:29

You definitely do. Thank you, Dave.

Dave Marver

Okay, all right, but good try.

Let me see if anything else came in that I want to address.

Yeah, there's a question about manufacturing. I'll just generally state that we use CDMOs. So, contract manufacturing partners who have a long history in the medical technology space. Most of them are based in Europe. One of them is a major contract manufacturer based in the US, all selected by our leadership, who've been in the industry for a long time. So that's the philosophy there.

Okay, Thomas has another question here about the two plus years of cash runway. Does that include any capital from Runway Growth Capital. This is the debt financing instrument into which we entered in June that gives us access to up to 52 and a half million euros of capital. The first tranche we pulled down, it was 16 million euros that was used to retire our previous debt, which was an innovation loan from the Dutch government, which we took out in 2016.

Amori, does the two plus years of runway include any of the Runway tranches? If so, which ones, tranche two, tranche three,

Amori Fraser 43:52

So, it includes tranche two, tranche three and tranche four, which we expect to unlock in the next two years, over the next two years.

Dave Marver 44:02

Yep. Okay, so I think, what time is it? Team? I think that's probably it.

Yep. Thank you so much for joining. We appreciate it, and hopefully we'll have some big and important news upcoming. Thanks for your support. Oh, I'm supposed to read this. We don't have Aditi today. She has the week off. It's American Thanksgiving. You don't get to hear her professional voice. You just get to hear mine. I think I'm supposed to tell you for more information, visit the website, o, n, w, d.com, or follow us on LinkedIn, ONWARD Empowered, o, n, w, d, empowered, that's our handle. See you in a quarter.