

43rd Annual J.P. Morgan

HEALTHCARE CONFERENCE

January 13-16, 2025 | The Westin St. Francis San Francisco, California



Onward Medical

Onward Medical presentation delivered at the 43rd Annual J.P. Morgan Healthcare Conference on Wednesday, January 15, 2025 at 10:30 AM

Thomas: Good morning, everybody. I hope you're all enjoying the JP Morgan Healthcare Conference 2025. Next presentation is by ONWARD Medical. I'm very pleased to introduce the CEO, Dave Marver.

Dave Marver: Thank you, Thomas, and thanks to all of you for choosing to join us today. Nice to see all of you. ONWARD is a very cool company. I'm incredibly lucky to lead it. It's one of the most innovative companies that you'll encounter.

We have 10 FDA breakthrough device designation awards, already almost 280 patents, and we got our first "TIME" magazine best invention of the year last year as well. We're also a truly mission-driven company. You'll see that.

The community that we're seeking to serve, those with spinal cord injury and their families, they've been for decades without viable options. They have injuries, they're in rehab for a few months, and they're told to go home. Nothing else can be done for them.

We have a real opportunity to make a difference here. Along those lines, following the requisite forward-looking statement slide, I thought it would be interesting to start with a video. We got our first FDA approval actually just a few weeks ago in late December. We are a platform company, which is unusual in med tech.

We have three technology platforms, and the first was FDA approved in December. It was a de novo authorization, and this is some of the media coverage that followed.

[video starts]

Michael: Now to a new device just cleared by the FDA that could be a game changer for the roughly 300,000 Americans with spinal cord injuries. Will Reeve sat down with one of the first patients to use this new spinal stimulation technology, and he's here with more. Will, good morning to you. I know this story is near and dear to your heart, my friend.

Will Reeve: It is, Michael. It means a lot to me personally as the son of a man with a spinal cord injury, and I know that being able to regain any movement is a massive development for a person with a spinal cord injury. And that's what this device showed it can do. It brings back certain mobility and with it, a new level of freedom and hope.

In one terrible moment, the woman you are about to meet lost her parents, her ability to move, and she thought her future. But now the future is here.

Man 1: This morning, a breakthrough for people living with spinal cord injuries.

Woman 1: This is one of the most meaningful steps I can think of for the spinal cord injury community, and it works. It gives us hope.

Michael: Based on the results of a pivotal trial published in "Nature Medicine," the FDA announcing it has cleared a spinal cord stimulation technology from Swiss company Onward. The device called ARC EX helps paralyzed people regain some mobility in their arms, hands, and fingers and freedom. Freedom to go from this to this.

Man 2: Oh, yeah. That's crazy.

Man 3: ARC EX is simply electrodes attached to the skin on the back of the neck. It runs all the time, and it makes it easier for people to move. We found that the majority of participants improved strength, sensation, and hand function to a significant degree.

Man 4: Jesse Owen was paralyzed 12 years ago when a tree fell and crushed the car she was riding in with her parents. ARC EX now offering her life changing possibilities.

Man 5: What can you do now that you couldn't do prior to this?

Woman 1: I can paint with my hands now. I can open a jar of peanut butter. I could feed my kids because the amount of function I had in my hands changed. It wasn't perfection, but it was enough to make meaning in my life.

Man 5: What hope does this device provide to you?

Woman 1: The future of spinal cord injury treatment is being written right now. This is the

moment, and this provides the hope and the stepping stone to start that journey.

Man 5: Full disclosure, I am a board member of the Christopher and Dana Reeve Foundation, which has partnered with Onward, the makers of this device. The ARC EX will be available in some rehab clinics early next year, and they'll continue to ramp up production to get it out further.

In mid-2025, Onward hopes for FDA clearance to get this into people's homes. Guys, progress in spinal cord injury research is usually measured in decades, so this is a long time coming. To be able to say, this is here and is getting out to people who need is a big moment.

Man 6: There have been a lot of advances lately.

Man 5: Yeah, there are. Technology is really accelerating everything, most of all hope.

Man 6: We're happy to see that.

Woman 2: Such a hopeful message. Thank...

[video ends]

Dave: Very pleased to get that FDA approved and begin our commercialization. If you're just meeting the company for the first time, it's a good time to engage because of everything that has been occurring. This is a slide that just shows our highlights from the second half of the year, and I'll talk about these in more detail throughout the presentation.

We secured exclusive rights to our own brain computer interface technology, so this enables thought-driven restoration of movement. We also continue to upgrade our board. We recruited a new chairman, Rob ten Hoedt, who just retired as president of Medtronic International and also long-time chairman of MedTech Europe, which is the equivalent of AdvaMed over there.

So very well-connected, smart, creative person. I'm delighted to be working with him. We also raised approximately \$50 million late in the year, equity capital, anchored by a strategic called Ottobock, which is a fantastic German family-owned company. Again, more details to follow. Then, of course, we received the FDA approval for ARCEX in late December.

Why are we here? We're here because there is no cure for spinal cord injury. It's a huge unmet need. Most people associate a spinal cord injury with paralysis and loss of sensation, but if you

know anyone with an injury, you know that it affects so many other functions -- incontinence, loss of sexual function, poor blood pressure regulation, poor temperature regulation.

These are all things that really impact the person's ability to get through activities of daily life, and so assistance is often required to help them get through their day. You can see the incidence and prevalence numbers here. There are seven million people worldwide with a spinal cord injury. Just in the US and Europe alone, 650,000 people.

By the way, it does look promising that these same technology platforms and approaches may help people also with Parkinson's disease and stroke, so the numbers have the potential to expand greatly from here.

It's an expensive injury, as well -- a lot of healthcare utilization, a lot of need for outside support. The average lifetime cost to support someone with tetraplegia is over \$5 million. If we can offset some of that by introducing independence and greater function, that can also be a win for the payers in healthcare systems worldwide.

Indeed, our vision is that, empowered by independence with our therapies, empowered by movement and independence, people with spinal cord injury will enjoy life in the ways that matter to them. Some of them want to walk again, but others prioritize being able to go to the bathroom without having to insert a catheter, restoring sexual function, hand function, for example, and we want to help people in any of those ways.

These are the three technology platforms that we're in the process of developing and have largely developed, starting with the ARCEX. As you heard, this is now commercial. We have FDA approval for this. It was a de novo authorization.

The pivotal study results were published in "Nature Medicine," so one of the world's leading scientific journals. We're going to pursue additional indications and expand the label by leveraging investigator-initiated studies. It's an easy device to study, because it's an external stimulator.

We also have our own implantable platform, our own purpose-built IPG and family of leads. The first indication we're pursuing with this platform is blood pressure instability following a spinal cord injury. We expect IDE approval and to start that global pivotal study the middle of this year, so get that started. Those of you who are generalists or do biotech, that's the equivalent of a phase 3 pivotal study.

Actually, we've been implanting it since early 2022, so we're using this in clinical feasibility studies to look at blood pressure, lower limb mobility, also upper extremity mobility, in SCI and Parkinson's disease. It's a very versatile device that gives us a chance to have a very broad label over time.

Recently, we've been combining the ARCIM platform with an implanted brain-computer interface to enable thought-driven movement, much more natural movement, a true digital bridge. We've implanted three people, so far, for both mobility and upper extremity movement. More to come on that.

It's an attractive market if you're a scale-up company. A lot of these markets, if you're a small company, you really have no chance going up against these big multinational incumbents. We don't have a lot of the traditional barriers that are faced by emerging med-tech. Let me just run through some of these.

First of all, it's a big TAM. Just for our first few indications, it's a \$20 billion TAM. If you look at our pipeline and everything that we're already exploring in clinical feasibility studies, the TAM expands to over \$100 billion.

We also don't have to spend a lot of marketing dollars, a lot of capital on marketing, because there's a high level of awareness within the spinal cord injury community -- clinicians, patients, and their families. You saw our ability to garner earned media as well. I mean, that was one story on Good Morning America, but we've been on BBC, CNN, and so on.

That, to me, is a big advantage because you do see in [inaudible] some companies spending a very high percentage of revenue on sales and marketing. This is not a need that I foresee for us. We also don't have to build a huge sales organization.

We don't have thousands of call points, clinics, and hospitals, nor do we have to reach thousands of physician specialists. These clinics that care for people with spinal cord injury, there are about 500 of them in the US and Europe.

We can deploy our own field sales and service organization, build our own channel which will provide us advantage over time. We don't have a big training burden, so we don't have to put surgeons through an expensive, burdensome training program. PTs and OTAs, physical therapists, they already deal with stimulation technologies in the course of their work.

The surgeons here, the functional neurosurgeons, already know how to implant a device like this for pain. For them, it's an easy incremental addition to their practice. We also have favorable reimbursement pathways in the US and other major markets, so we can use existing codes or operate without a code for a while.

I'll get into more detail on that. Quite importantly, very limited competition and safeguards against future or emerging competition once we demonstrate that this is indeed an attractive market. That includes proprietary technology, a lot of IP, as I mentioned, almost 280 issued patents, a lot of our know-how, and then establishing this channel.

First channel of its kind I think is also an important defense. Let's run through now the technology in a bit more detail and you saw some of this in the opening video. This is the ARC-EX stimulator. It's about the size of a tablet computer. It sits actually on the desk, and it's not a wearable. It's not designed to be used 24 hours a day.

It's designed to be used for an hour a day, so episodically. You saw, when it's on, a person can move in a way they otherwise could not move. By moving that way, they can train performing that movement and they recover the function once the device is off.

This makes rehabilitation effective for the first time in the chronic spinal cord population. This device connects to leads that are placed on the skin near the area of the spinal cord that's responsible for the function we're trying to restore. Here, we're trying to restore hand function that's controlled in the cervical spinal cord.

Then the PT or the clinician uses this tablet programmer to define the stimulation parameters. Big TAM here, so six billion dollars. About 200,000 people, just in the US and Europe, are medically eligible for this based on the first indication.

Here is some of the results from our pivotal study called Up-LIFT that was published in "Nature Medicine" middle of last year. It met all the primary and secondary endpoints. 90 percent of participants improve either strength or function. This is a group of people for whom nothing is available that can do this.

87 percent improve quality of life, and we saw responders up to 34 years after an injury, not 3 months or 6 months after an injury, but 34 years after an injury. We also, in addition to no serious device-related adverse events, the participants reported reduced spasm, improved sleep,

improved sensation and touch.

Meaningful improvements, by the way. The ability to lift a filled cup, push a button on a remote control, pick up an object with a fork. Stuff that matters in daily life. This is the implanted platform ARC-IM, we call it. We have our own purpose-built IPG and family of leads. It's controlled and recharged wirelessly through the skin using this hub.

The patient can control and titrate the therapy with a smartwatch, and the clinician, again, can define the programming parameters using this tablet programmer. The first indication we're pursuing here might surprise you, because we do have some clinical feasibility evidence around helping people stand and walk again, but we chose to be first with managing blood pressure instability.

Big TAM again, 215,000 people in the US and Europe are medically eligible. Again, I'm going use one more video here which I think can explain far better than I could why this blood pressure instability, why addressing this is so important for people with spinal cord injuries.

[video begins]

Patient: I was very homebound. I didn't leave my home very much. Couldn't do anything, basically. Was in bed most of the time, or in the couch, or in my chair, but then with my legs up because, otherwise, I would just faint, maybe 10 times a day, maybe 12 times a day.

It was no life, to be honest. When the researchers turned the stimulation on for the first time, I was still in the ICU, and I remember to feel the energy rushing through my body for the first time in nine months at that time. It was an amazing feeling, and I saw my blood pressure value on the screen next to me rising to a normal level.

It was a sort of rebirth to me, and that meant the start of my real recovery journey. Of course, I needed some time to adapt to the system and to, yeah, learn how to work with it, but I immediately saw the opportunities coming back.

I could immerse myself into rehabilitation, build muscle mass, have a social life again, go out with friends and family, and it also allowed my brain to function again. Since November, I've restarted my PhD at LWO, which is just amazing. It was impossible before the surgery.

[promotional video ends]

Dave: This is a young woman, early twenties. She was injured in a car accident while on vacation in the Balkans and literally could not get out of bed because of this blood pressure instability, it's called orthostatic hypotension, so it's tied to posture or postural changes.

Often, when they try to transition from their bed, when they're sleeping in the morning, to a wheelchair, it can take 45 minutes, even longer, because they're continually fainting and [inaudible]. Her life was very, very bad, and then now you can see she's recovered her vitality, and she's back in her PhD program. This is the sort of recovery that we want to enable with this therapy.

We're prioritizing this because...And to me, it's commercially viable, it's impactful. It really makes quite a difference. You don't need to rehab a lot afterwards, grow muscle mass back, and so forth. Cardiac dysfunction is actually the leading cause of death in people with SCI.

This blood pressure instability affects three quarters of people after spinal cord injury, and the indication that we're seeking to pursue here includes both this orthostatic hypotension low blood pressure, but also these dangerous spikes in blood pressure that people with spinal cord injury have because their body cannot cope with an autonomic signal such as a full bladder or an itch. They get this spike that can lead to stroke and thrombotic events.

This was validated, at least our approach was validated, by another "Nature" paper in 2021 and also by a DARPA grant to support our development of this platform, which indicates to me this is a significant problem among our veterans with spinal cord injury.

Another big TAM as you can see, so over seven billion, 222,000 medically eligible in the US and Europe alone. We also have helped people with spinal cord injury, even complete spinal cord injury, recover the ability to stand and walk again.

This is something that we would like to introduce. It could be our second indication with the ARCIM system. Multiple "Nature" papers that describe the mechanism that we're employing to do this. Very interesting.

Then, as I mentioned at the onset, we've been combining ARCIM with an implanted brain-computer interface to enable a true ONWARD DigitalBridge, so, really, bypassing the injury digitally. Recording a person's intention to move with the BCI, translating those signals into instructions for our spinal cord stimulator, which then stimulates the spinal cord to create thought-

driven movement.

We've done three people so far -- two for mobility, one for upper extremity function. We've published on one so far, another Nature paper, and we expect to implant 10 or 15 more people, with the benefit of grant funding from the Christopher Reeve Foundation, for example, and the European Innovation Council.

This is an exciting area. I think there's a lot of hype in this area. We have, though, a unique and meaningful application for these brain signals, so a bit more on this.

I think ONWARD is actually quite well-positioned, strategically, relative to others. If you follow this at all, there are multiple companies racing to develop a brain recording device or platform mainly to control computers, computer peripherals, voice generators.

We're the only ones that are using BCI technology to restore movement of the human body, and that's really our unique expertise. Last year, we secured the exclusive rights to a BCI technology from a French biomedical Institute. It's the same institute that spun out deep brain stimulation, so they've got a long history in neurotechnology.

Our implantable platform, our ARCIM, is built to be BCI ready. It's built to receive instructions from other devices and sensors, and it's agnostic, as well. We believe strongly in the BCI that we brought in-house.

We think that's going to enable us to be first-to-market with a meaningful therapy. In the future, as other technologies develop, there's nothing that precludes us from also plugging into those brain recordings, as well.

I like where we're positioned here, and I don't think we're necessarily getting the value that we deserve for the progress that we've made. I think that's maybe some latent value and upside. We're now commercial, obviously, as of late last year, and what are people saying? There's a lot of enthusiasm among the patient groups.

This is the Reeve Foundation. Their chief science officer said, "This is the first-ever therapeutic option for SCI. It shatters decades of belief that these injuries were untreatable. The impossible is now possible."

The German association, "I've been following this for over 20 years. Nothing like this has been

brought to the clinical setting." Wings for Life out of Austria, "This is our most visible success." Again, we don't have to spend a lot of capital on marketing. We've already been contacted by thousands of patients.

Also, the go-to-market, as I mentioned earlier, is really straightforward. There's a limited number of rehabilitation clinics, and they're really at the core of what we're trying to do over the next several years. They will decide whether to, of course, purchase a device for use in the clinic, or prescribe one for use in the home, when the label expands to that.

They'll also refer patients to neurosurgeons in the area for the implanted device, at which time they'll come back for ongoing care. This channel that we're putting in place to build trusting, enduring relationships with these clinics, very strategic for us. Very strategic.

We've already hired our initial sales organization. You can see the regions here. Also, again, reinforcing limited number of call points in the US and Europe, and we're going to be really focused at first on the top 75 accounts in the US. Those are our pivotal study sites.

Also, these hubs within the VA system that focus on spinal cord injury, as well as other flagship centers. Starting with six reps, increasing to 12 throughout the course of the year. Let's learn. Let's see where to deploy them, what the archetype is.

Then, later, we'll expand to the other 375, which includes VA spoke centers, other rehabilitation centers. Eventually, we think for this first platform, ARCEX, we'll have 20 or 25 reps here, and then we'll increase the size of the field organization in preparation for the implantable introduction.

This is a very complicated slide for a setting like this, but I want you to show that we've put thought into the reimbursement pathway. The reimbursement doesn't really matter for clinic purchases. They can use their capital equipment budgets.

For home use, personal use, we're actually going to not pursue a Medicare code, a HCPCS code, for two-and-a-half years, because we want to establish invoicing history at our desired price point.

We have the luxury of being able to do that because so many of our patients are cared for by the VA or workers' comp, and we also think some percentage of them can self-pay because they have legal settlements or access to GoFundMe campaigns that will support the purchase of devices. Thereafter, we'll seek the Medicare code.

Then, private payers are really the wild card. Typically, they follow Medicare, but given the sympathetic nature of our patient population and really the compelling results we're seeing, I think, on a case-by-case basis, we can get the private insurers to step in here. Maybe we can convince them to make coverage decisions, as well. That's really upside for us.

Also, given that we're now commercial, need to pay some attention here in the deck to our operations considerations. We've put in place a scalable manufacturing process using easily sourced standard components and raw materials.

We're leveraging a contract manufacturer that has ample capacity, and then we're doing the final kitting and assembly ourselves in our headquartered facilities. It takes less than an hour. Again, not a constraint, but we can control the quality at that time. Then also, to further mitigate risk, we're building early, so ahead of demand, and in large lots to ensure consistency.

We get the stimulation engine from a CDMO in particular, in the Netherlands, and then other suppliers contribute to the device. Then after assembly, in rest of the world, we're going to ship directly. In the US, actually, we have quite an important relationship with a distributor partner called Lovell, and this is owned by a former military veteran who has preferred contracting status with the VA.

Indeed, because of that, we're already on the VA contract, just days after we got FDA approval. We can start selling into the VA right away. Very unusual, and a real advantage that we've gained via this relationship.

In terms of team, I didn't introduce myself too much, but I've been in med-tech my whole career. First half was with Medtronic in the US and Europe, in cardiac management, cardiac surgery, diabetes, sales, marketing strategy, product strategy, business development. I also ran a NASDAQ-listed company, founded a couple of startups, and I joined ONWARD four and a half years ago and returned to Europe at that time.

Rob, I mentioned, our new chairman, impeccable credentials and also just an outstanding guy. A very strong team, and that speaks to the mission. We can attract people here who know how to do it and want to make a true difference.

I should also comment a bit on Ottobock. We did raise the \$50 million in equity financing last year, and Ottobock anchored it. I hadn't heard much about them before I started this outreach. It's a private company, but global leader in prosthetics, direct in 60 countries.

In the US, they have 400 company owned centers where these prosthetics are fitted, 9,000 employees, very profitable, almost \$300 million in EBITDA, and they're now our largest shareholder. It's a good partnership. We're just going to sit down and figure out, what can we do together that would provide advantage to both of us.

Nothing forced. Nothing compelled. Just a good, supportive partner that's been in the field for over a hundred years and has a lot of domain expertise. They consider what we're doing to be a game changer.

There was a lot of news flow last year. I started with the big four bits of news flow from the second half of the year. It's not going to stop. We're going to have continued catalysts, enabled by these three platforms we have.

With ARCEX, we still want to get home use, or personal use, added to the label this year. Along with that, the bits are home use submission, home use authorization. Also, European approval, so the MDR submission, CE Mark, and first commercial sale outside the US.

With the ARC-IM, the implantable platform, we're doing early feasibility clinical work in Parkinson's Mobility funded by the Michael J. Fox Foundation. We also have an important clinical results publication from the clinical feasibility work.

Heading into the pivotal study, we will publish in a top-tier journal the results from the first 14 people to receive this therapy. Then associated with the pathway to getting ARC-IM approved in the US, IDE submission, approval, and first participant enrollment.

Also, this year, we want to use ARC-IM on bladder function, this under active bladder. See if we can eliminate the need for people to insert a catheter six and eight times a day to urinate, which leads to frequent infection and antibiotics courses and sometimes hospitalization. This is also grant funded from the Christopher Reeve Foundation.

Then we'll continue to do ARC-BCI implants. Again, grant funded. It's really a nice model. A lot of our pipeline activities, they advance with the benefit of grant or non-dilutive funding, so we can be very focused in the deployment of our own capital on things that are closer to commercialization. All right. Thomas, take it away.

Thomas: Thanks very much, Dave. How much time do we have left?

Assistant: 10 minutes.

Thomas: 10 minutes. Great, so we have time for a few more questions. Is there anything from the floor to kick us off? Yeah?

Dave: Stein from the Netherlands.

Audience Member: You briefly spoke about competition, but when do you realistically think you will face it and from who?

Dave: It depends on the platform. With the external device, there are actually two very small companies that have spun out of University of California that are working on similar external stimulation devices.

We've actually already exclusively licensed the intellectual property from University of California. We think we're in quite a strong position from an IP perspective, notwithstanding scale advantage, experienced management team, being first to market, all of those advantages as well.

Really when talking about competition on the implantable side, one has to envision that the current active implantable companies, maybe like a Medtronic, Abbott, or Boston, may view this as an attractive new category and they may want to enter the space.

They would have to modify their hardware, conduct clinical studies. They'd have to navigate our very large IP portfolio, and they'd have to develop the know-how as well. Having been in strategy for Medtronic for a while, I can just tell they prefer to use their balance sheet and try to buy us at that point.

Not that we want to sell. We think we can create an independent, autonomous, very viable business given everything that we have going, but this is how we're thinking about competition.

I did spend some time already on competition with the BCI where, again, all those companies, for the most part, are working on different things. Our unique place in that space is our knowledge of how to restore movement of the human body using a BCI. I don't view them as competition really. We'd like to see the field develop more fully, but we feel very secure in where we sit there.

Audience Member: Thank you.

Thomas: Yeah. At the front there.

Audience Member: Now you commercialize in the US. You're a Netherlands company?

Dave: Yes.

Audience Member: How is the US structure building out now that this is going to be a primary focus at least in the commercialization side? How is that going to build out now in the US? I think you have an office in Boston, and where do you go from there relative to the US company versus a Netherlands company, and things you might be doing in Europe relative to getting approvals?

Dave: Jerry, it's a little complicated, I have to say. We were founded in Switzerland by neurosurgeons and neuroscientists at the leading engineering school there and hospital there. Then the first professional CEO actually moved the company to the Netherlands.

When I came aboard, I moved a lot of it back so we could work really closely with those researchers and improve our velocity and so on. We're domiciled in the Netherlands, but we have significant operations in Switzerland, and now significant operations in the US as well.

What's in the US? Mainly a field sales and service organization and a clinical trial engine. In addition, a lot of the management team are Americans who have experience working in Europe, because it can be actually challenging to find Europeans who have experience commercializing the US, so we've gone the other way. That's me for example, but that's our archetype for management.

I think it's going to continue to evolve that way. We'll have the customer facing sales and clinical group here and then the management functions largely over there. At a certain point, we might simplify things a bit, we'll see. We are Euronext listed today, but we're obviously exploring coming over to Nasdaq at the right time. I think hence the invitation from JPMorgan to present here today.

Audience Member: Is it the US subsidiary actually?

Dave: Yeah, we have an Inc, of course. We have a Delaware Corp here.

Audience Member: You're located here or you're located there?

Dave: I'm over there, actually. I'm in Switzerland. Yes?

Audience Member: Dave, firstly, thank you. The clips in the video specifically were very, very moving. I just wanted to actually that got me thinking from the ARC-EX and ARC-IM products that you do have, are there any additional indications? Because you did mention a few, but just wanted to understand what other applications is something that you guys are looking at or could look at.

Dave: It's early days, but this external device, now that it's approved, it's fairly easy to use it in research settings to explore other indications. We're partnering with a number of different centers around the world who have grant funding and we're supporting them with devices to facilitate these studies and identify additional indications.

You'll see people looking at using the ARC-EX device for upper arm function for stroke, for example, for blood pressure, for mobility. We've seen restoration of sexual function, body temperature regulation.

My perspective on that is let's see where the data takes us. It's a pretty efficient way for us to determine the next label. If the data is good on one of these and it's something that's prioritized by the community, then we'll do it.

With the implantable device, that's class three. I think we have to be a bit more intentional about what we do. We have the benefit of being able to gather clinical feasibility study data up to 10, 15 patients using grant funding.

There again, we're using our implanted platform in Parkinson's for blood pressure and mobility and in spinal cord injury for mobility of our extremity function and then starting this year, incontinence. Underactive bladder, again, not competing with Axonics, now Boston Scientific or Medtronic there.

That's the way we're thinking about it. If we come back in a year, maybe the picture will become more clear. We're not forced or compelled to make that decision today either. Again, let's see where the data takes us. Thank you, Viram.

Audience Member: Maybe one from the podium. I think you spoke a little bit, Dave, about the BCI and you've in-licensed the BCI. Why that specific BCI, and why was it suited to the applications that you're pursuing?

Dave: Yeah. Thank you. There are lots of different BCIs out there. Some are intravascular, some are penetrative, so they're robotically delivered and then hundreds of electrodes are woven into the brain itself. Others are these thin film structures that are deployed with a catheter and unfoil underneath the dura. I think they're all interesting, but none of them are really ready to do what we need to do.

They all have, I think, at this point still some fundamental questions associated with them. And so, in this BCI that we brought in-house, this is a relatively simple device that sits on top of the dura. It doesn't penetrate that lining of the brain nor does it penetrate the brain, and it also already has seven years of human safety data.

It gives us enough resolution to power what we need powered. Enough information to restore movement. For us, it was a relatively easy decision to bring that out so that we could develop a platform under our quality system with an integrated bit of hardware and software.

They're all very well-funded at nice valuations. If any of them make a lot of progress, great. We're going to continue to chat with them, but we're very pleased with the partner we have now.

Thomas: Thank you. Are there any more questions from the floor? OK. I think we can leave it there then. Onward Medical and Dave Marver, thank you very much.

Dave: Thank you, Thomas. Thank you.

[applause]



*Webcasting and transcription services
provided through MAP Digital, Inc.*