

2023
Annual
Report

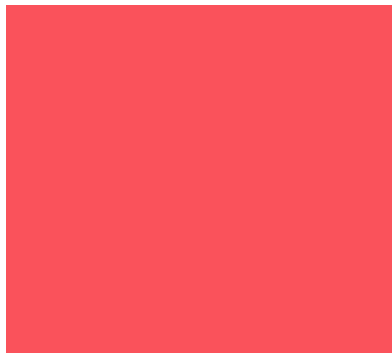
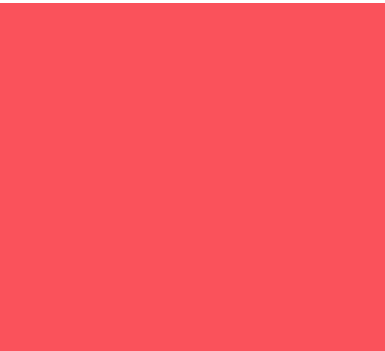
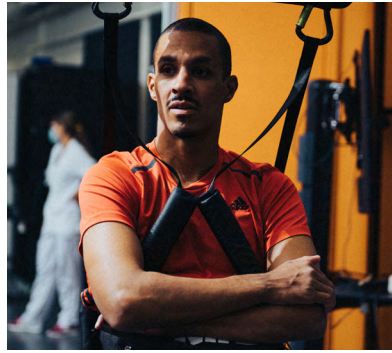


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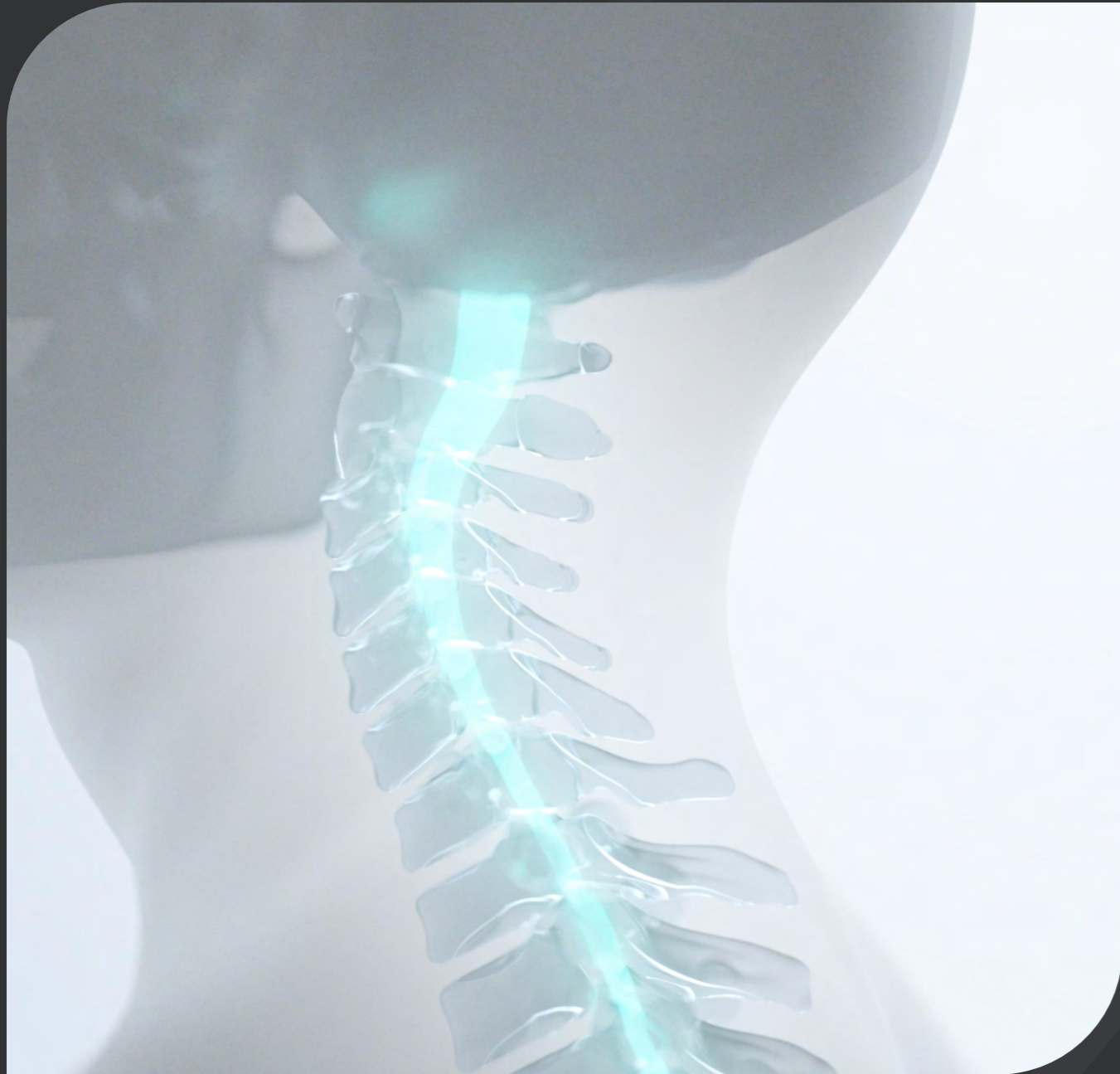
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In this Annual Report 'ONWARD', 'the Company', 'the Group', 'we', 'us' and 'our' are used interchangeably to refer to ONWARD Medical N.V. and/or any of its subsidiaries, in general or where no useful purpose is served by identifying the particular company.

European single electronic reporting format (ESEF) and PDF version. This is a copy of the annual financial report of ONWARD Medical N.V. for the year ended 31 December 2023. This version has been prepared for ease of use and does not contain ESEF information as specified in the Regulatory Technical Standards on ESEF (Delegated Regulation (EU) 2019/815). The official ESEF reporting package is available on our website at this [link](#).



ONWARD[®]



ONWARD
at a Glance

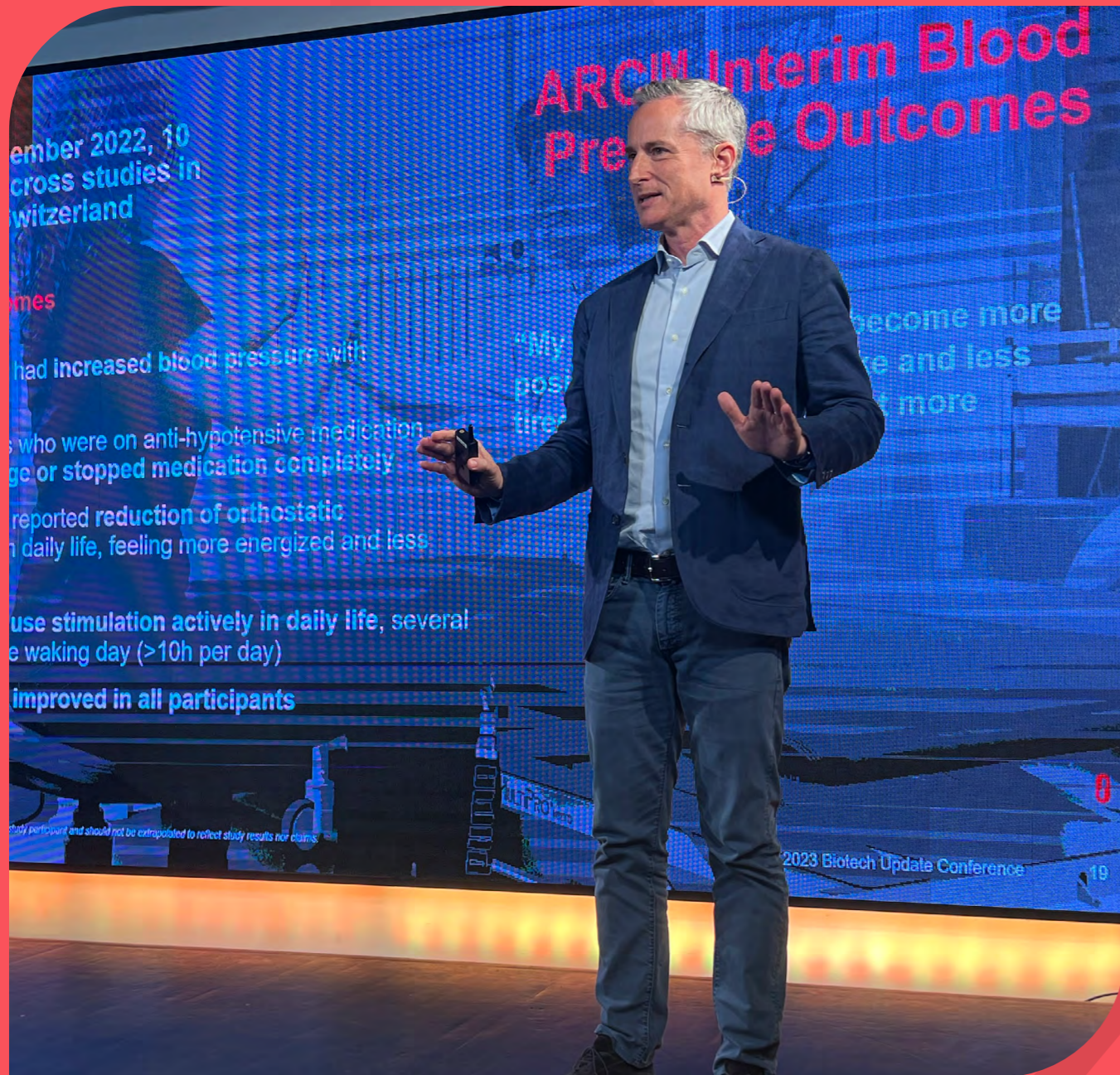
ONWARD at a Glance

- Founded in 2015
- 108 employees¹
- HQ in Eindhoven, the Netherlands
- Science and Engineering Center in Lausanne, Switzerland
- US office in Boston, Massachusetts
- IPO 2021, Euronext Brussels and Amsterdam; EUR 150M+ raised since inception¹
- Technology: 2 purpose-built neuromodulation platforms that stimulate the spinal cord via external (ARC^{EX}®) or implantable (ARC^{IM}®) technologies; ARC^{IM} is also being studied in combination with a brain-computer interface (BCI) called ARC^{BCI}™

- Innovation: 10 US FDA Breakthrough Device Designations and 240+ issued patents²
- Clinical validation: One pivotal trial completed with positive top-line results reported for ARC^{EX}; positive interim outcomes also reported for ARC^{IM} blood pressure regulation indication
- Market opportunity: Large total available market (EUR 19B+) with limited competition; strategic relationship with Christopher & Dana Reeve Foundation
- Commercialization: Launch and sale of first commercial product expected in the US in the second half of 2024; deep pipeline; clear reimbursement pathway

¹As of 31 December 2023

²Issued patents include EP country validations



Message from the Chairman & CEO

Message from the Chairman & CEO

Dear Shareholders, Colleagues, Partners, and Collaborators,

Our vision is that empowered by movement, people with spinal cord injury (SCI) will enjoy life in every way that matters to them.

Our team is pursuing this vision with urgency and determination, developing our investigational technology platforms with the intent to commercialize and make our solutions broadly available starting in the second half of 2024 in the United States and thereafter in Europe. Though our current focus is the US and Europe, we hope to eventually expand globally to positively impact the lives of the 7,000,000 people worldwide living with spinal cord injury.

ONWARD is a pioneer and a leader in our field. We have been awarded 10 US Food and Drug Administration (FDA) Breakthrough Device Designations across our two ARC Therapy™ technology platforms. These awards recognize the innovative nature of our work and its potential to address large unmet needs. The intellectual property underlying these innovations was invented by the talented ONWARD engineering team, while other patents have been exclusively licensed from top neuroscience research universities around the world.

We are aided in the pursuit of our mission by our many strong relationships with global SCI advocacy groups, such as the Christopher and Dana Reeve Foundation in the US.

2023 was an important and eventful year for ONWARD, filled with achievements and milestones across our range of activities:

- We continued to advance our development programs, validated by publications in leading peer-reviewed journals and fueled by grant awards to support our progress in developing therapies for restoring upper and lower limb mobility, improving blood pressure regulation, and exploring the use of brain-computer interface technology to augment ARC Therapy.
- We made excellent progress with our implantable spinal cord stimulation platform, ARC™, announcing the first-in-human use of our ARC™ Lead and completing development of the ARC™ Neurostimulator in preparation for our pivotal trial to evaluate ARC™ Therapy for regulating blood pressure after SCI. This global trial is called Empower BP and is planned to start in late 2024.
- In May, the journal *Nature* published results of our 2021 feasibility study pairing a brain-computer interface (BCI) with our ARC™ Therapy, highlighting the first time ever that a paralyzed human regained thought-driven control over their lower limbs, including when walking. Later in 2023, we announced the successful first-in-human use of ARC™ Therapy paired with a BCI to restore thought-driven movement of the upper extremities. We call this BCI-enabled therapy, ARC^{BCI}.
- The prestigious journal *Nature Medicine* also published an inspiring account of the first person living with Parkinson’s disease to receive ARC™ Therapy, resulting in his ability to walk without the previously noticeable gait interruptions.



Message from the Chairman & CEO

- We released additional positive results from the Up-LIFT pivotal study that investigated ARC^{EX} Therapy to improve upper extremity strength and function after SCI. Our clinical partners presented these results at several prestigious conferences, including the American Academy of Neurology Meeting, the Paralyzed Veterans of America Conference, and the International Spinal Cord Society Scientific Meeting.
- Despite our many 2023 achievements, one disappointment was the delay in our expected US launch of the ARC^{EX} System. We postponed this planned launch in order to update the device’s printed circuit board assembly. The launch of the ARC^{EX} System is now on track for the second half of 2024. In fact, we submitted the De Novo application to the FDA in late March 2024 to gain authorization to market the device in the US. We intend to hire a field sales organization to align with the 2H 2024 launch date.
- We added 50+ new patents to our portfolio in 2023, bringing our total number of issued patents to more than 240 worldwide.

As we conveyed last year, it is a privilege to lead this company with its many wonderful employees, research collaborators, and business partners. Our work is important and meaningful, and together we are focused on creating sustainable long-term value, while positively impacting the lives of people with SCI and those who care for them.

We are proud of our many achievements in 2023 and we have an ambitious set of goals for 2024 and beyond. Please sign up for updates on our website or follow ONWARD on social media so we can keep you informed of our progress throughout the year.

Warm regards,

Jan Øhrstrøm & Dave Marver



Jan Øhrstrøm
Chairman

Dave Marver
CEO





ONWARD®

Achievements
in 2023

Achievements in 2023

Innovation, Clinical, and Regulatory Developments (see Operational Review for additional details)

Together with research partners at École Polytechnique Fédérale de Lausanne (EPFL), Lausanne University Hospital (CHUV), and NeuroRestore, ONWARD continued to make strong progress in our quest to develop therapies to help people with SCI and movement disabilities such as Parkinson's disease. The past year's achievements include:

- At the American Academy of Neurology Annual Meeting, neurosurgeon Dr. James Guest of the University of Miami and the Miami Project to Cure Paralysis shared that in addition to meeting all primary safety and effectiveness endpoints, the Up-LIFT pivotal (safety and effectiveness) study demonstrated that 72% of participants responded to ARC^{EX} Therapy¹.
- *Nature* reported on the progress of a 2021 feasibility study pairing ARC^{IM} Therapy with a brain-computer interface (BCI) for the first time, which resulted in an individual gaining thought-driven, augmented control over when and how he moved his paralyzed legs. ONWARD also completed the successful first-in-human use of an implanted BCI paired with ARC^{IM} Therapy to help a person with SCI recover thought-driven movement in their arms and hands.
- We completed the successful first-in-human use of our ARC^{IM} Lead, designed to deliver targeted ARC Therapy to the area of the injured spine responsible for a specific function, such as blood pressure regulation.
- *Nature Medicine* reported on the first-in-human use of ARC^{IM} Therapy to address gait challenges related to Parkinson's disease.
- We were awarded five new Breakthrough Device Designations (BDDs) by the US Food & Drug Administration for our ARC Therapy platforms, bringing ONWARD's total BDDs to 9 at the end of 2023. A 10th BDD was added for ARC^{BCI} in February 2024.





ARC



Achievements in 2023

Intellectual Property

- ONWARD added 50+ patents to its formidable IP portfolio. The IP portfolio now totals more than 240+ issued patents worldwide.

Commercial

- In September, we announced a partnership with Lovell Government Services (Lovell), a Service-Disabled Veteran-Owned Small Business (SDVOSB). Lovell is a government vendor and third-party logistics provider partnering with more than 100 US healthcare providers. The two-year distribution agreement gives ONWARD contract access to the US Veterans Health Administration, the world’s largest healthcare system providing SCI care, and the US Department of Defense Military Health System, the world’s largest military healthcare provider.

Corporate

We continued to enhance our organizational capabilities and augment our leadership team in preparation for commercialization of our initial therapy, expected in the second half of 2024. We also enhanced ONWARD’s visibility in the financial markets:

- In Q1, we strengthened our leadership team, appointing Erika Ross Ellison as Vice President, Global Clinical, Regulatory, and Quality, and Sarah Moore as Vice President, Global Marketing. Erika joined ONWARD from Abbott Neuromodulation, where she was Director, Global Clinical & Applied Research, and has extensive previous experience in bringing both Class II and III neuromodulation therapies to market. Sarah came to ONWARD from Nevro, an implantable neuromodulation company, and has more than 20 years of experience in new product development and commercial marketing in medical devices, including at Johnson & Johnson.
- In Q3, Robert Odell joined ONWARD as Vice President of Operations. Robert was formerly President and Chief Operating Officer of Cardiac Insight, Inc., a successful startup that created and introduced cardiac monitoring technology. Prior to that, he served as COO of Cardiac Science Corporation, a publicly traded manufacturer of Class II and Class III medical devices. He brings to ONWARD decades of technology and leadership experience in the medical device industry.
- In Q3, Lara Smith Weber stepped down as Chief Financial Officer (CFO) to pursue a new opportunity in the Boston area where she resides. Khaled Bahi joined ONWARD as Interim CFO. Previously, Khaled served as CFO of Lausanne-based Symetis, acquired by Boston Scientific in 2017 for USD 435 million, and Paris-based Stilla Technologies. He was also a finance leader with Fresenius Medical Care in Europe, Latin America, Middle East, and Africa. Khaled brings more than 20 years of finance experience in the industry.
- In April, Bryan, Garnier & Co, a leading investment bank focused on growth companies, reinitiated research coverage of ONWARD.

¹A responder was defined as meeting or exceeding the minimally important difference criteria for at least one strength outcome and at least one functional performance outcome.







ONWARD[®]

2024
Outlook

2024 Outlook

Innovation, Clinical, and Regulatory

- ONWARD submitted a De Novo application for FDA clearance for the ARC^{EX} System in late March 2024, with an anticipated marketing authorization to commercialize the platform in the US in the second half of 2024. We also aim to apply for CE mark and European authorization in 2025.
- Based on positive feedback from potential customers on the value of the ARC^{EX} System, expected to be the first-ever spinal cord stimulation therapy to improve hand and arm function after SCI, we anticipate a list price of USD 30,000. In addition, we expect to supplement revenue by offering tiered service packages.
- ONWARD expects to announce detailed results from its Up-LIFT pivotal (safety and effectiveness) study in 2024, concurrent with publication of the study in a major scientific journal. We have already announced that the study met both primary safety and effectiveness endpoints and that 72% of participants responded to ARC^{EX} Therapy. A responder was defined as meeting or exceeding the minimally important difference criteria for at least one strength outcome and at least one functional performance outcome.
We intend to present the Up-LIFT findings and additional insights in several podium presentations to support study investigators in peer-reviewed publications in 2024.
- ONWARD plans to apply for FDA Investigational Device Exemption approval and aims to begin its global pivotal trial for ARC^{IM}, called Empower BP, in the second half of 2024. Empower BP is designed to provide the necessary evidence to ultimately submit a pre-market approval (PMA) application to the FDA and other global regulatory bodies.

- We intend to gain additional clinical data and experience with our implantable ARC^{IM} System in 2024, with several implants planned with support from the Michael J. Fox Foundation for Parkinson’s Research and several ARC^{IM} System implants planned in combination with an implanted brain-computer interface (BCI) with support from the European Innovation Council. This combined system is called ARC^{BCI}.

Corporate

- At year end 2023, we anticipated our cash position would fuel operations through the end of 2024. In March 2024, we completed a EUR 20M equity financing that strengthened our cash position to support investments in product development, clinical trials, operational capabilities, and commercial capabilities. We will continue to pursue opportunities to further strengthen our cash position.

Forward-looking information / statements

This document contains certain forward-looking statements with respect to the financial condition, results of operations and business of ONWARD and certain of our plans and objectives with respect to these items. In particular, the words “expect”, “anticipate”, “estimate”, “may”, “should”, “could”, “would”, “believe”, “outlook”, “potential”, “will”, “planned”, “pipeline”, “seek” and similar expressions are intended to identify forward-looking statements. By their nature, forward-looking statements involve risk and uncertainty because they relate to events and depend on circumstances that will occur in the future.

Actual results may differ materially from those expressed in these forward-looking statements, and you should not place undue reliance on them. For a discussion of factors that could cause future results to differ from such forward-looking statements, see also the Risk Management and Control section of this Annual Report. For this reason, we can offer no assurances that the forward-looking statements published here will prove correct at a future date, and ONWARD assumes no duty to update any such forward-looking statements.



ONWARD[®]



Overview

Overview

The Case for Innovative Therapies

Seven million people worldwide have a spinal cord injury (SCI)¹, and the annual global incidence of new injuries exceeds 768,000. In the US and Europe alone, approximately 650,000 people live with SCI, and the annual incidence of new cases is about 50,000 (31,800 in Europe and 18,000 in the US).

While most people associate SCI with paralysis and loss of sensation, there are often other accompanying challenges such as infection, incontinence, pressure sores, poor blood pressure regulation, and loss of sexual function. As a result, the quality of life following spinal cord injury can be quite poor for the injured and their caregivers. SCI is also an expensive condition, with high losses in productivity and healthcare expenditures. The average lifetime cost to support a person with a severe SCI can exceed USD 5M. Injuries to the spinal cord occur primarily as a result of accidents and falls and disproportionately affect young men.

While conventional rehabilitation provides important benefits, most people reach a plateau in their progress after three to six months. Thereafter, many of those injured face decades of continuing challenges, declining quality of life, and dependence on others. ONWARD seeks to solve this unmet need by delivering durable therapies to improve strength, function, and independence, including for those injured many years ago.

¹Kumar et al. 2018, *Traumatic Spinal Injury: Global Epidemiology and Worldwide Volume* (traumatic spinal injury is broader than traumatic spinal cord injury).



A large unmet medical need

Market



¹2022 NSCISC Annual Statistical Report Complete Public Version

²European prevalence calculated by annual Incidence* 25 years of additional lifetime expectancy

³Kumar et al. 2018, Traumatic Spinal Injury: Global Epidemiology and Worldwide Volume (traumatic spinal injury is broader than traumatic spinal cord injury).



Damage to the spinal cord resulting in loss of function

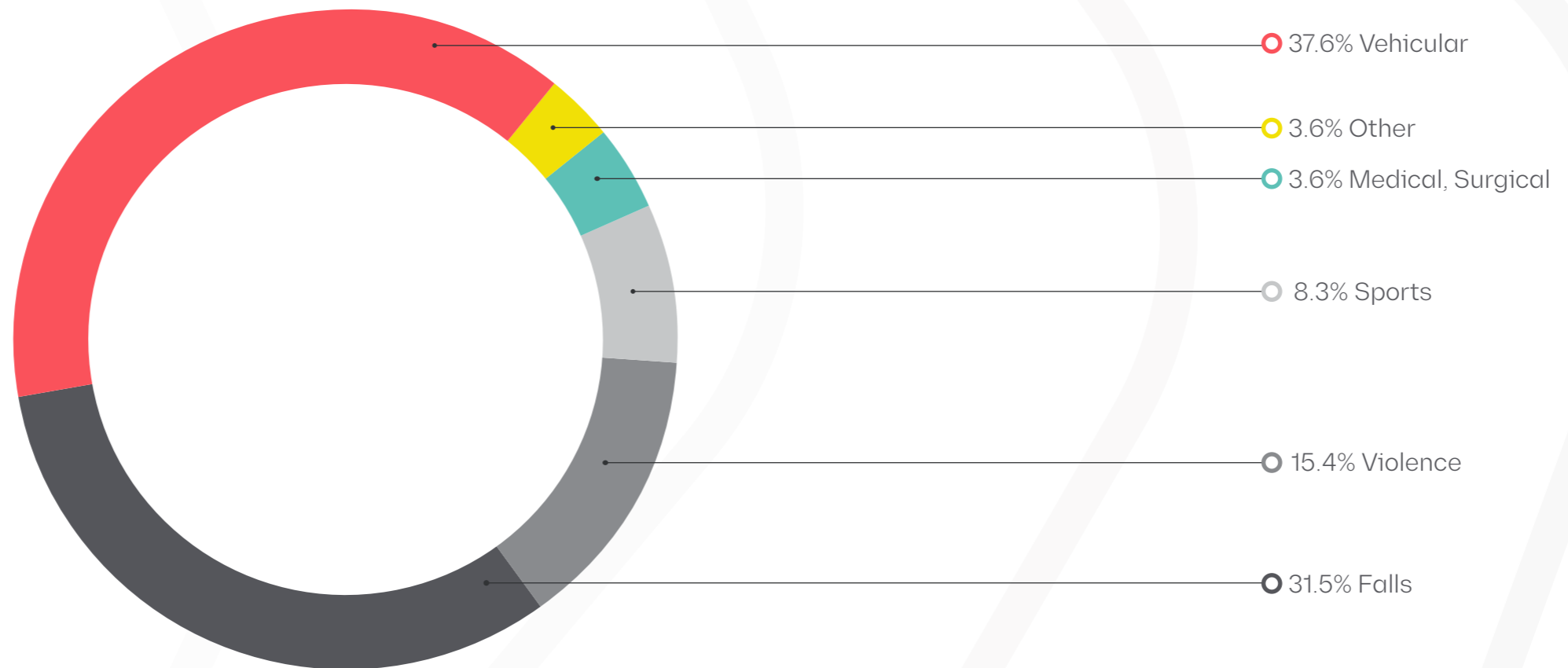
SCI Causes & Patient Profile

Profile of SCI Patient

- Nearly half of the injuries occur between the ages of 16 and 30 years¹
- 79% of new SCI cases are male²

Currently, the neuromodulation market is comprised primarily of revenues from spinal cord stimulation for pain management and deep brain stimulation for Parkinson's disease, essential tremor, dystonia, and epilepsy. The market is forecast to **reach USD 14.8B by 2030 and is expected to grow to exhibit a CAGR of 12.2% over the same period³.**

SCI Causes



¹2022 NSCISC Annual Statistical Report Complete Public Version

²NSCISC Traumatic Spinal Cord Injury Facts and Figures at a Glance (2023 SCI Data Sheet)

³Global News Wire - Vantage Market Research (November 2023)



Overview

Opportunity to create new segment, stimulating the spinal cord for movement and autonomic functions

ONWARD is pioneering a new segment within neuromodulation, by stimulating the spinal cord to restore mobility and autonomic functions in people with SCI, and potentially also those with stroke and Parkinson’s disease.

Neurostimulation has emerged as a dynamic field for treatment of a range of clinical conditions



Spinal cord stimulation and Deep Brain Stimulation (DBS) are most well-developed current applications



Growth Trends:

- Rising prevalence of neurological disorders
- Increasing capital availability
- Emergence of minimally invasive approaches

¹Sources: Global News Wire – Vantage Market Research, 2022; Fortune Business Insights Spinal Cord Stimulation Market; Harmsen, Irene E et al. “Trends in Clinical Trials for Spinal Cord Stimulation.” Stereotactic and functional neurosurgery vol. 99, no. 2, 2021, pp. 123-134; Johnson, Rhaya L, and Christopher G Wilson. “A review of vagus nerve stimulation as a therapeutic intervention.” Journal of inflammation research vol. 11, 2019, pp. 203-213; Mayo Clinic

Neurostimulation Market

FDA Approved

Deep Brain Stimulation ○
 Depression, Dystonia, Epilepsy, Essential tremor, Obsessive-compulsive disorder, Parkinson’s disease

Hypoglossal Nerve Stimulation ○
 Sleep apnea

Vagus Nerve Stimulation ○
 Depression, Epilepsy

Spinal Cord Stimulation ○
 Pain management

Sacral Nerve Stimulation ○
 Fecal incontinence, Urinary incontinence

Emerging

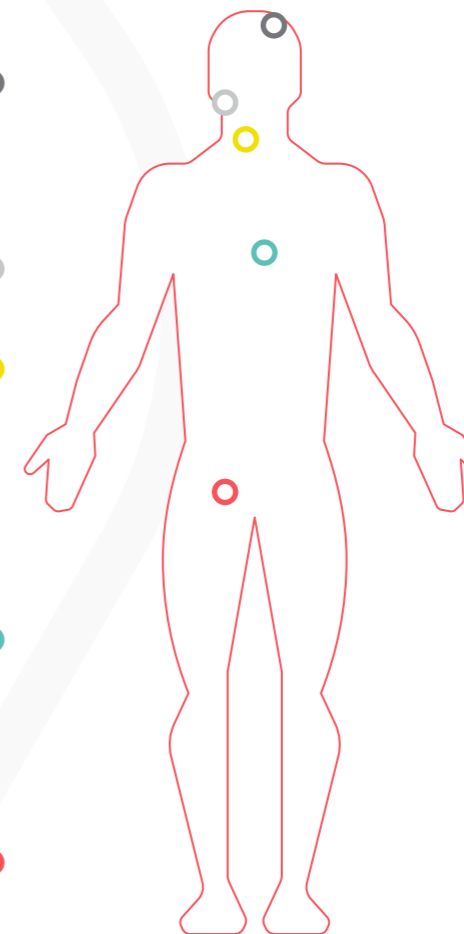
○ **Deep Brain Stimulation**
 Addiction, Autism, Chronic pain, Cluster headache, Dementia, Depression (major), Huntington’s disease, MS, Stroke, Tourette syndrome, Traumatic brain injury, Sleep disorder

○ **Vagus Nerve Stimulation**
 Alzheimer’s, Anxiety, Cardiovascular disease, Diabetes, Lung injury, Obesity, Pain management, Stroke

ONWARD Focus

○ **Spinal Cord Stimulation**
 Bladder and bowel control, Blood pressure control, Mobility, Sexual function, Spasticity, Trunk control, Upper limb function

○ **Sacral Nerve Stimulation**
 Interstitial cystitis



Overview

Our vision

Empowered by movement, people with spinal cord injury will enjoy life in every way that matters to them.

Our team is pursuing this vision with urgency and determination, developing ARC Therapy with the intent to commercialize and make our solutions broadly available starting in the second half of 2024 in the United States (US) and then expanding into other regions. Our goal is to reach as many of the 7,000,000 people worldwide with spinal cord injury (SCI) as possible.

The work to complete and commercialize our ARC Therapy platforms is aided by 10 FDA Breakthrough Device Designation awards (the tenth was awarded for our ARC^{BCI} System in February of 2024). While many of these innovations were created by our R&D team, others have been exclusively licensed from top neuroscience research universities around the world, underscoring ONWARD as a pioneer and a leader in our space.

We are supported in our pursuits by our many strong relationships with SCI advocacy groups across the globe, such as the Christopher and Dana Reeve Foundation in the US. We are grateful for these partnerships and the insights they provide.

At ONWARD, our mission is to enable people with SCI to regain movement and other bodily functions so they can enjoy life in every way that matters to them. We develop and plan to commercialize therapies that address major challenges faced by people with SCI, leveraging the Company’s ARC^{IM} and ARC^{EX} platforms to address a broad spectrum of injury locations and impairment severities. While our primary objective is to serve the needs of people with SCI, we envision that our therapies may also benefit other populations with similar challenges, such as people who have suffered a stroke or who have Parkinson’s disease or other neurodegenerative disorders. We also aim to reward those who invest their capital, time, and ideas in ONWARD, while engaging in sustainable, equitable, and inclusive business practices.

Our strategy

Our objective is to build an enduring, impactful, and successful medical device company that creates sustainable long-term value and makes a meaningful difference in the lives of people with SCI and those who care for them.

We are focused on the following priorities as we pursue this objective:

- Short term (2024): Commercially launch our external ARC^{EX} System, starting with strength and function of the hands and arms as our first indication in the US. Begin our Empower BP pivotal clinical trial to evaluate implantable ARC^{IM} Therapy for regulating blood pressure after SCI.
- Medium term (2026): Commercially launch our implantable ARC^{IM} System, starting with improved blood pressure regulation as our first indication.
- Long term (2026+): Expand labeling (new indications and populations) and platforms.

To execute our strategy;

- We work with leading neuroscience researchers across the globe to identify breakthrough therapies for people with SCI and other movement-related disorders for which our therapies have shown promise.
- We leverage our R&D, clinical, and regulatory capabilities to develop proprietary technologies that are well suited to deliver our breakthrough therapies at scale, and we protect these innovations with rigorous IP prosecution.
- We plan to commercialize these breakthrough therapies in our target markets, using a direct channel to SCI clinics with rehabilitation programs and hospitals with neurosurgery expertise.



Stages for the execution of our strategy



Advanced Scientific and Clinical Research Network

ONWARD has relationships with leading academic research centers throughout the world. Our primary relationship is with the ONWARD co-founders and their highly productive laboratory at .NeuroRestore, a research initiative of CHUV and EPFL. .NeuroRestore is led by Professor Grégoire Courtine and neurosurgeon Dr. Jocelyne Bloch. In 2014, Professor Courtine and Dr. Bloch co-founded ONWARD's predecessor entity alongside other researchers in neuroscience and neurosurgery. Professor Courtine also serves as ONWARD's Chief Science Officer on a part-time basis.

Through its network of advanced research facilities in Switzerland, .NeuroRestore's research activities span basic science, preclinical research, and human proof-of-concept studies. Several projects with potential for commercialization have already progressed to the human proof-of-concept stage. ONWARD selects the most promising of these projects to develop and commercialize, based primarily on clinical results and commercial viability. Our ARC Therapy platforms can be leveraged for each of the indications with minor software and firmware modifications.

The .NeuroRestore team has published extensively in some of the most prestigious scientific journals. In 2023, they published groundbreaking research on the use of a brain-computer interface (BCI) paired with ARC™ Therapy to enable a participant to walk with augmented control of his paralyzed legs. Researchers at .NeuroRestore also published a pioneering study using ONWARD ARC™ Therapy to address gait challenges related to Parkinson's disease.



9 indications under clinical or pre-clinical evaluation, with 3 in current roadmap

Current Pipeline

Platform	Indication	FDA BDD ¹	Pre-Clinical	Human PoC	Clinical Feasibility ²	Pivotal
ARC ^{EX}	Upper Limb	✓	○	○	○	○
ARC ^{IM}	Blood Pressure	✓	○	○	○	○
ARC ^{IM}	Mobility / Second Indication	✓	○	○	○	○
ARC ^{EX}	Mobility	✓	○	○	○	○
ARC ^{IM}	Parkinson's – Mobility	✓	○	○	○	○
ARC ^{IM}	Bladder	✓	○	○	○	○
ARC ^{IM} BCI	Mobility	✓	○	○	○	○
ARC ^{IM} BCI	Upper Limb	✓	○	○	○	○
ARC ^{DBS}	Mobility	✓	○	○	○	○

Human PoC expected in 2024³

✓ BDD Granted² ○ Current Roadmap ○ Label Expansion ○ Platform Expansion

● Short and medium term focus ○ Funded primarily through grants and research partners

Note: The company may modify the pipeline based on clinical progress and marketplace considerations
¹BDD = FDA Breakthrough Device Designation. ONWARD has been granted four additional BDDs for ARC^{EX} Bladder, ARC^{EX} Blood Pressure, ARC^{EX} Spasticity and ARC^{IM} Spasticity
²Includes both early feasibility (typically before device design finalized) and feasibility (near-final or final device design) studies
³Funded by Christopher & Dana Reeve Foundation grant



Current competition is standard of care:
3-6 months of rehab followed by costly
support for activities of daily life



ARC EX

Similar Pre-Commercial Technologies

- **Intellectual property** controlled by University of California, Los Angeles (UCLA) and ONWARD
- Limited **funding** raised to date¹
- **Academic** management teams

Note: For investigational use only
¹Less than \$4M raised by Company A in private capital as of February 2024 (source: PitchBook); Company B's total funding not sufficiently material to be tracked by PitchBook
 *Potential future competitors could include Medtronic, Abbott and/or Boston Scientific.

Competition



ARC IM

No Direct Competitors

Potential future competition* from spinal cord stimulators for pain and other existing indications

- Currently **supporting academic research** with existing technology
- **Several years** required to reach parity with ONWARD and market a competing technology
- Likely to **enter space via M&A**, leveraging balance sheets



Technology, research, and medical expertise across continuum of research stages



CHUV – Lausanne
University Hospital of Lausanne #9 worldwide Newsweek magazine



EPFL
EPFL – Geneva
More than 2,000 scientists
#1 Neuroscience hub in Europe

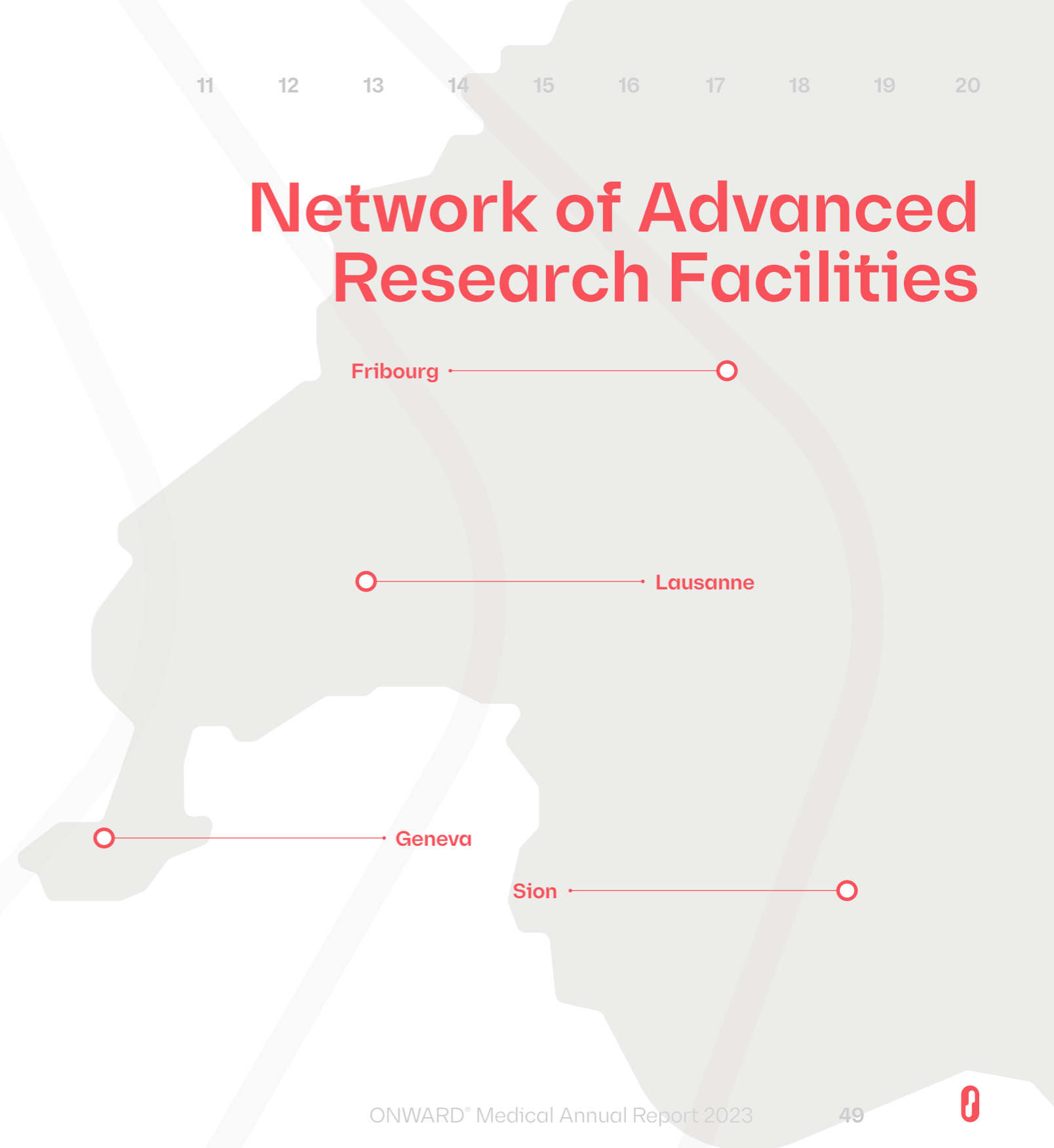


suva
Suva – Sion
Specialized Center for Acute Spinal Cord Injury

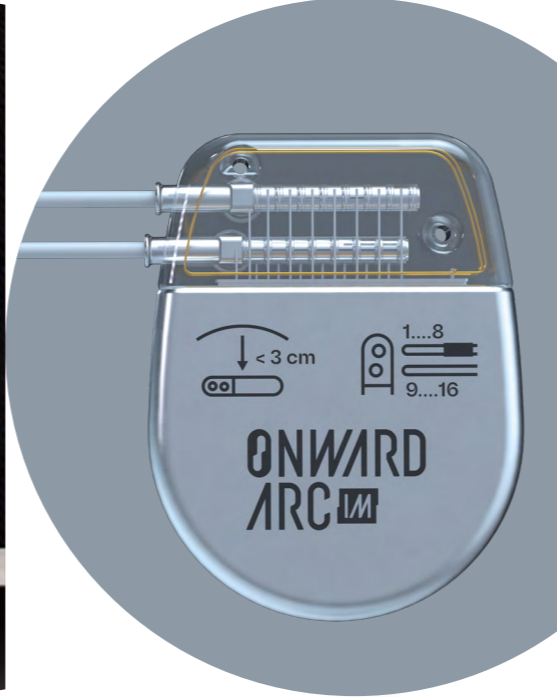
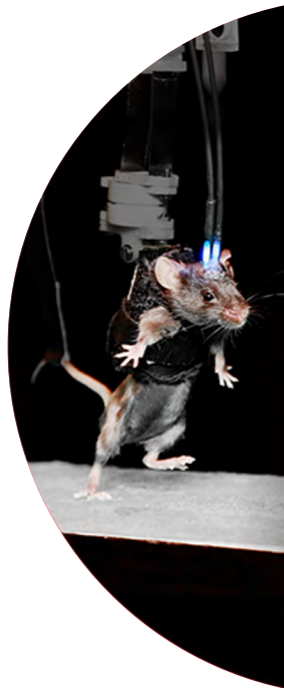


UNIFR – Fribourg
University of Fribourg
Pre-Clinical Center

Network of Advanced Research Facilities



Overview



ONWARD

Basic Mechanisms

Preclinical Therapy

Translation Scale Up

Clinical Proof of Concept

Commercial Engine Therapy



Overview

ARC Therapy: A breakthrough in neuromodulation technology

ONWARD ARC Therapy is targeted, programmed stimulation of the spinal cord to restore movement, function, and independence in people with SCI. It can be delivered by an implantable platform, called ARC^{IM}, or an external, transcutaneous platform, called ARC^{EX}.

Spinal cord injury disrupts the brain-body connection

When the spinal cord is injured, communication between the brain and the parts of the nervous system located beneath the lesion is interrupted, either completely or partially. The person may lose all feeling or movement¹ – or both – in these areas. Functions and organs controlled by the autonomic nervous system may also be affected, leading to difficulty with breathing, swallowing, regulating blood pressure, sexual arousal, and bowel and bladder function.^{2,3} This disruption of the body-brain feedback loop can cause a host of debilitating conditions. People with SCI at the thoracic or cervical level are most affected by this loss of function.

Nevertheless, even in cases of complete SCI, some neural pathways in the spinal cord remain intact but hypoactive. At present, rehabilitation approaches aim to mobilize these latent nerve connections and promote regeneration through intensive physiotherapy. Unfortunately, these activity-based therapies have limited benefits for people who cannot produce movements voluntarily. Some symptoms and conditions can be managed with medication, such as antispasmodics to reduce involuntary muscle contractions, or with devices, such as catheters to facilitate urination. However, these solutions can be cumbersome and carry the risk of harmful side effects.

There is an urgent need for more effective therapies that enable people with SCI to live more independent, high-quality lives. This is where ONWARD ARC Therapy has the potential to make a dramatic impact.

ARC Therapy activates intact nerve fibers with biomimetic stimulation

As detailed in the previous section, our ARC Therapy is based on pioneering research led by Professor Courtine and Dr. Bloch over the last two decades to pinpoint the location of neurons in the spinal cord responsible for triggering movement and function.⁴

By delivering precisely timed and programmed electrical impulses to specific areas of the spinal cord, ARC Therapy mimics the natural pattern of nerve signals sent by the brain. When combined with voluntary efforts to move, this enables users to improve motor control in the arms, legs,⁵⁻⁷ or trunk,⁸ making daily activities, like moving in and out of a wheelchair, much easier. In addition, ARC Therapy has the potential to improve the management of internal functions, such as regulation of blood pressure,⁹ and improved bowel and bladder control.

Most participants in clinical trials using ARC Therapy regain some degree of independent movement, even when stimulation is switched off. ARC Therapy stimulates intact nerve fibers responsible for carrying messages from the body back to the spinal cord (afferent nerves), and “retrains” them to perform a different function, demonstrating the plasticity of the nervous system.

¹A. S. Burns, R. J. Marino, A. E. Flanders, and H. Flett, “Chapter 3 - Clinical diagnosis and prognosis following spinal cord injury,” in *Handbook of Clinical Neurology*, vol. 109, J. Verhaagen and J. W. McDonald, Eds. Elsevier, 2012, pp. 47–62. doi: 10.1016/B978-0-444-52137-8.00003-6.

²M. W. G. Brinkhof et al., “Health conditions in people with spinal cord injury: Contemporary evidence from a population-based community survey in Switzerland,” *Journal of Rehabilitation Medicine*, vol. 48, no. 2, pp. 197–209, Feb. 2016, doi: 10.2340/16501977-2039

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Overview

Developing Two Platforms to Deliver ARC Therapy

ONWARD has developed two platforms to deliver targeted, programmable ARC Therapy neurostimulation: a minimally-invasive implantable system, called ARC^{IM}, and a non-invasive, transcutaneous system, called ARC^{EX}. In addition, the Company is developing ARC^{BCI}, which adds an implantable brain-computer interface (BCI) to its ARC^{IM} platform. ARC^{EX}, ARC^{IM}, and ARC^{BCI} have all been awarded FDA Breakthrough Device Designation for a range of indications.

Both platforms contain the same basic elements: an electrical pulse generator, electrodes placed in proximity to the lesion on the spinal cord, and a programmer that enables clinicians to set stimulation therapy parameters and users to control their therapy within those parameters.

The two platforms share common components and have a similar user interface. This optimizes our use of development resources while providing users with a consistent, easy-to-use experience.

Implantable ARC^{IM}

ARC^{IM} is currently targeted toward regulating blood pressure after SCI and improving lower limb mobility. Other potential indications may be explored in the future, including SCI-related bladder control, spasticity reduction, improved sexual function, and upper limb mobility, each enabled by further development of our proprietary lead portfolio.

Implantable **ARC^{IM}** has four components:¹

- A **Lead** implanted near the spinal cord in the area of injury corresponding to the movement or function targeted by the therapy. We are currently developing a family of leads that are optimized for precise placement in different areas of the spinal cord, both in terms of their shape and the configuration of the electrodes.
- A **Neurostimulator** implanted under the skin and connected to the lead through a wire. When switched on, this device delivers precisely sequenced and calibrated bursts of electricity to specific electrodes in the lead.

- An external **Hub** that connects wirelessly to the Neurostimulator to turn therapy on or off, set or update the frequency and intensity of the impulses, recharge the device, and integrate external sensors via wireless connections and sensor-specific algorithms. The hub is worn on a belt around the waist..
- **Dedicated apps for efficiency and ease of use.** Apps are available for both clinicians and users of ARC Therapy. Clinicians use the professional app to create and adjust stimulation programs using a tablet connected wirelessly to the Hub, and users employ the personal app to control their therapy within clinician-prescribed programming parameters. The personal app is expected to be deployed on a mobile phone or smartwatch and enabled by voice commands as well.

Implantable ARC^{BCI}

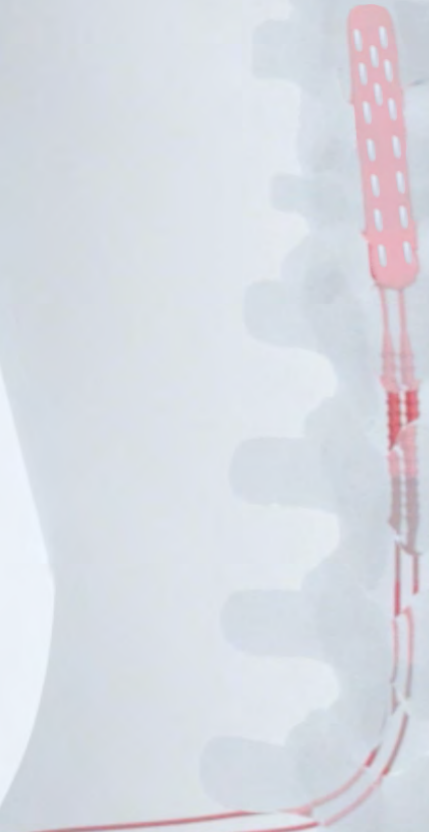
The **ARC^{BCI} System** is currently being investigated to enable thought-driven movement of the legs and upper extremities. This research is supported by grants from the European Innovation Council and the Christopher and Dana Reeve Foundation. The system consists of an implanted brain-computer interface (BCI) from CEA-Clinattec, Grenoble, France. The BCI is placed on top of the motor cortex, where it records brain signals that indicate the intention to move. The ARC^{BCI} System then uses artificial intelligence to decode those signals and translate them into instructions for our ARC^{IM} Neurostimulator, which sends electrical impulses to our ARC^{IM} Lead. Those electrical impulses are applied to the spinal cord, enabling thought-driven movement.



IPG and leads for direct, programmed stimulation of the spinal cord



- ARC™ Lead**
- Cervical Lead
 - Thoracic Lead
 - Lumbar 8-8 Lead
 - Lumbar 7-2-7 Lead
 - Sacral Lead



ARC™ Neurostimulator

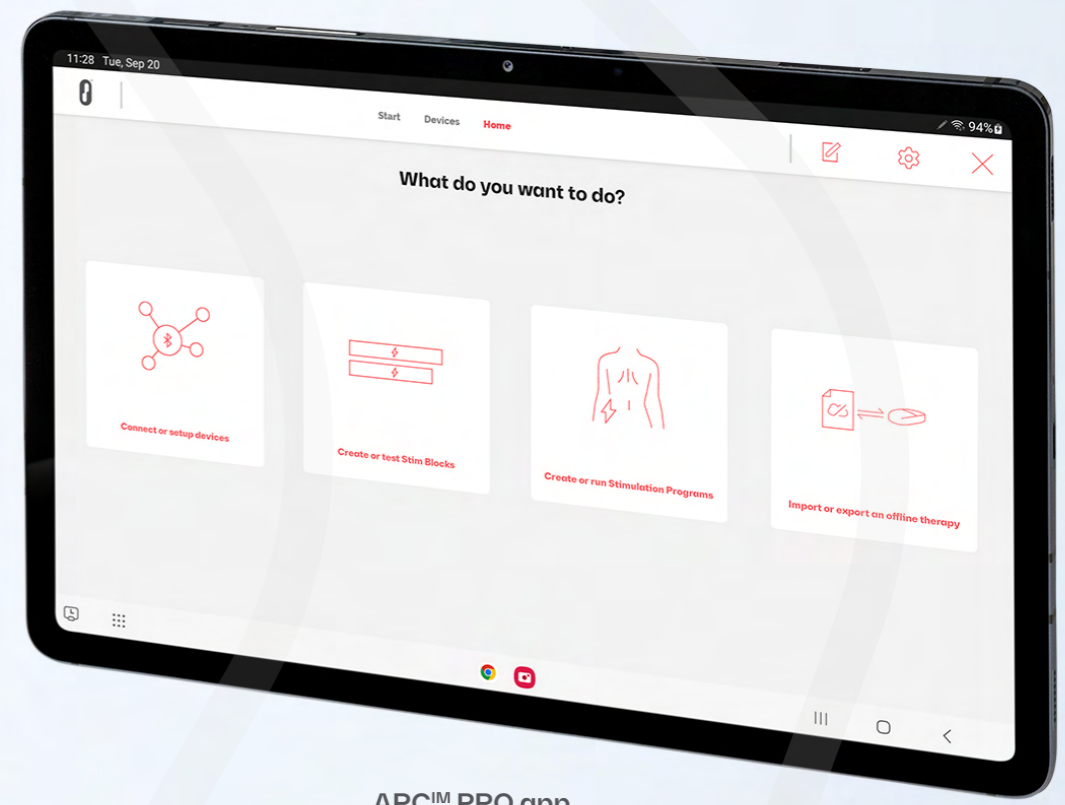


ARC™ Hub

myARC™ App
Via ARC™ Controller



ARC™ PRO app
Via ARC™ Programmer



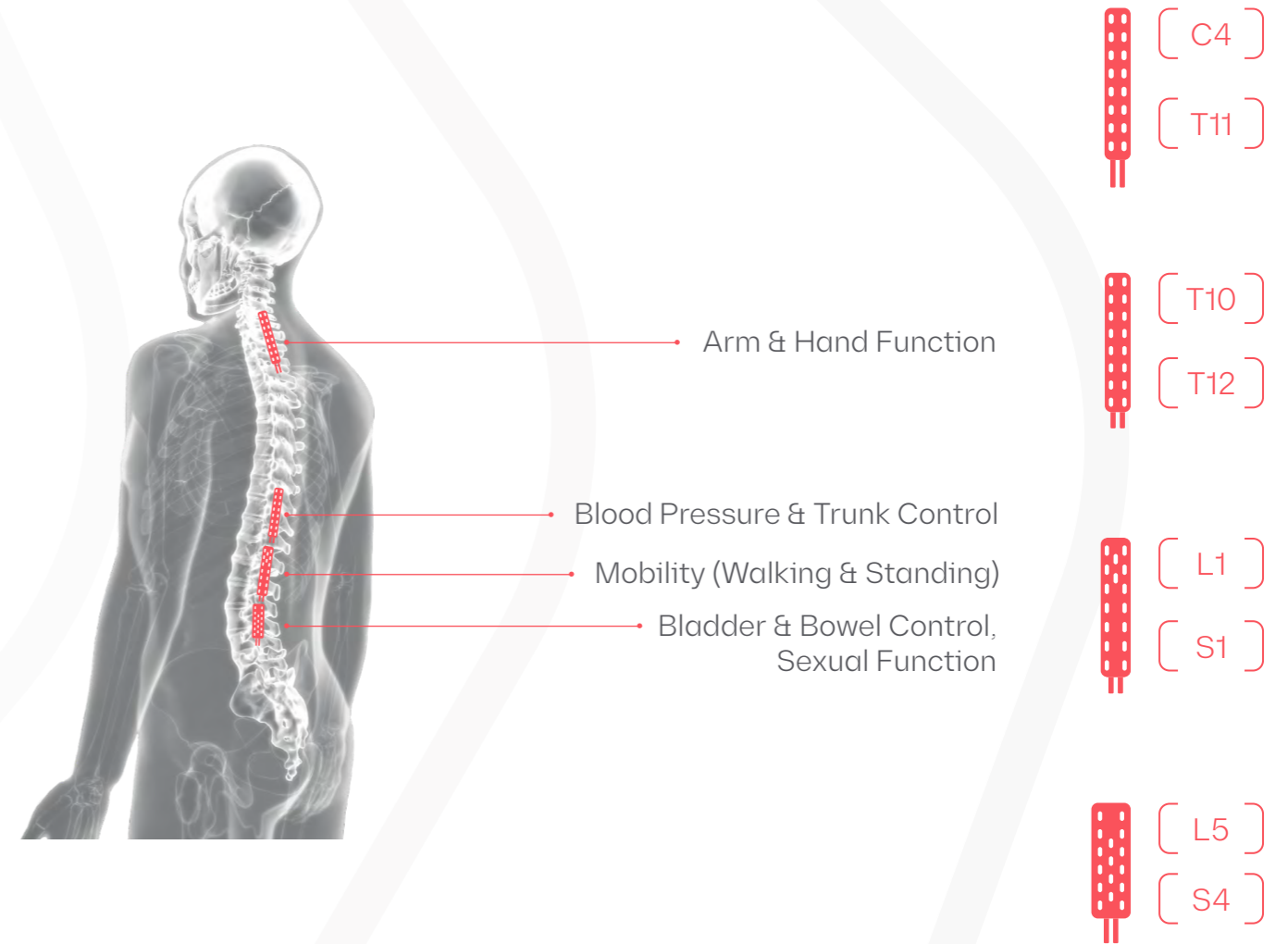
The renderings in the above graphic are illustrative; the design of commercial products may differ.

ARC™ Lead Placement



ARC™ Leads

ARC™ is currently targeted toward improving lower limb mobility and regulating blood pressure after SCI. Other potential indications may be explored in the future, including SCI-related bladder control, spasticity reduction, improved sexual function, and upper limb mobility, each enabled by further development of the ONWARD proprietary lead portfolio.





Think

An intention to move originates in the brain.

Decode

The brain-computer interface uses AI to decode that intention.

Move

The ONWARD® ARC™ platform converts that decoded information into precise stimulation of the spinal cord, resulting in thought-driven movement.



Overview

External ARC^{EX}

ARC^{EX} is expected to launch in the US in the second half of 2024 to improve strength and function of the upper limbs. It is built for use both for typical SCI rehabilitation during the chronic phase in the clinic and at home. In the future, ARC^{EX} may be used to target additional indications, such as bowel control and lower limb strength and function.

The **ARC^{EX} System** has three main components:

- A **Stimulator** that delivers programmed electrical impulses through the skin to the spinal cord.
- **Electrodes** placed externally on the skin of the neck near the area of the spinal cord that controls movement in the arms and hands.
- **Dedicated apps for efficiency and ease of use:** the **ARC^{EX} PRO app**, which connects wirelessly to the Stimulator to program the therapy and adjust parameters, and the **myARC^{EX} app** for users to easily control the stimulation during personal use in the home setting.

Three Priority Indications to Improve Quality of Life after SCI

Upper limb mobility (initial ARC^{EX} focus)

Since 2015, 60% of new SCIs in the US have resulted in some form of tetraplegia.¹ Injuries at the cervical level of the spine (C1-C7) can result in loss of sensory and motor connections to all areas below the neck, including the arms and legs. Without the use of our hands, most activities of daily life (such as grooming and eating) become extremely challenging. Better arm and hand function is therefore an important rehabilitation goal for a majority of people with SCI, consistently ranked ahead of walking or sexual function.²

In 2022, we completed follow-up in our Up-LIFT pivotal and LIFT Home clinical trials. The Up-LIFT study was designed to evaluate the safety and effectiveness of non-invasive electrical spinal cord stimulation administered by a clinical version of ARC^{EX} to treat functional deficits of the upper limbs in people with chronic tetraplegia. Positive topline results from the Up-LIFT study were announced in September 2022, showing that the study had met its primary effectiveness endpoint of improvement in upper extremity strength and function, with no reported serious device-related adverse events.

Blood pressure regulation (initial ARC^{IM} focus)

Hemodynamic instability, including the inability to regulate blood pressure following an SCI, has profound consequences in both the acute and chronic stages and affects nearly 40% of people with SCI.³ Immediately after injury, blood rushes to the area of the lesion and causes swelling, which starves the nerve cells of oxygen, compounding the initial damage. The outcome for many patients could be vastly improved if clinicians were able to intervene immediately to prevent inflammation by controlling blood pressure, blood flow, and oxygenation.

At the chronic stage, after the injury has healed, fluctuations in blood pressure drastically impact quality of life, especially for people with tetraplegia. It can cause a range of debilitating conditions, including stroke, fatigue, and hemodynamic instability which involves chronic hypotension, and a life-threatening form of hypertension known as autonomic dysreflexia.⁴ Chronic hypotension affects a person’s ability to perform everyday movements like sitting up or leaning over, and can inhibit their ability to engage in activity-based rehabilitation.

In 2022, we reported positive interim clinical outcomes from the first 10 people treated with implantable ARC Therapy to regulate blood pressure. ARC^{IM} Therapy immediately improved blood pressure levels in all study participants, who also reported fewer episodes of hypotension, improved quality of life, increased energy and vitality, and reduced dizziness. Based on these promising interim outcomes,⁵ our clinical feasibility study was extended to the Netherlands with the first implant performed in Q3 of 2023.

Lower limb mobility (secondary ARC^{IM} focus)

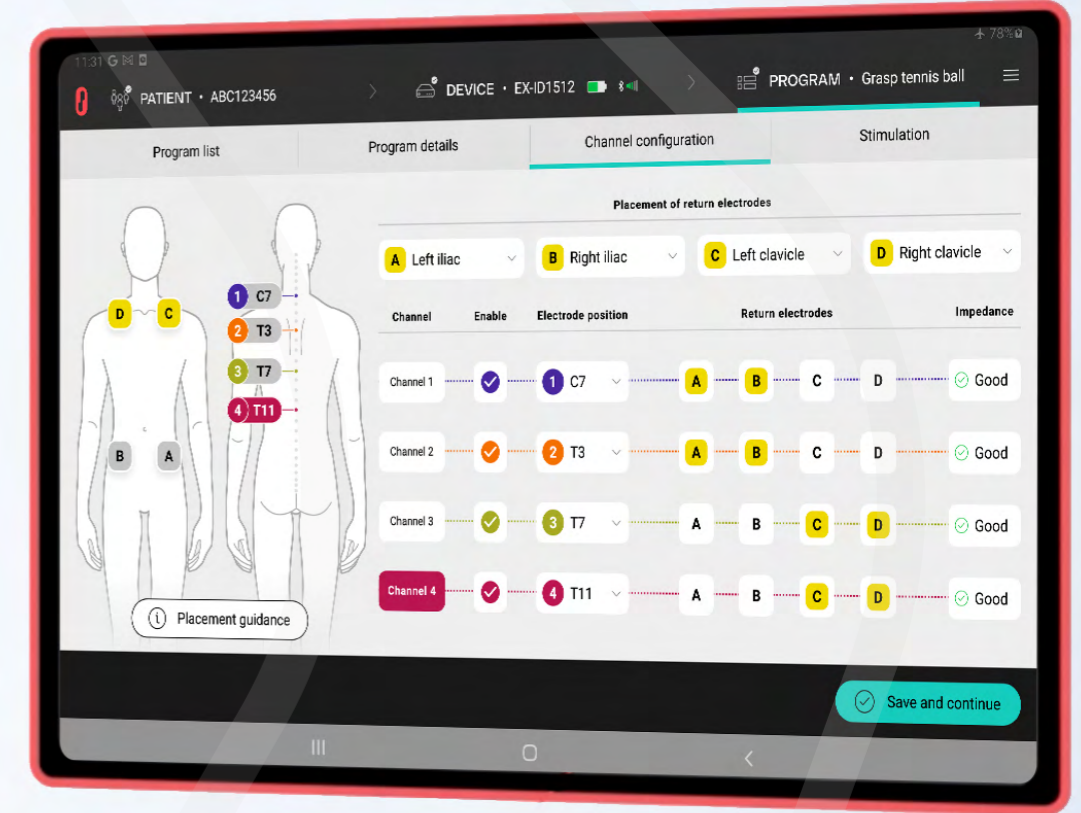
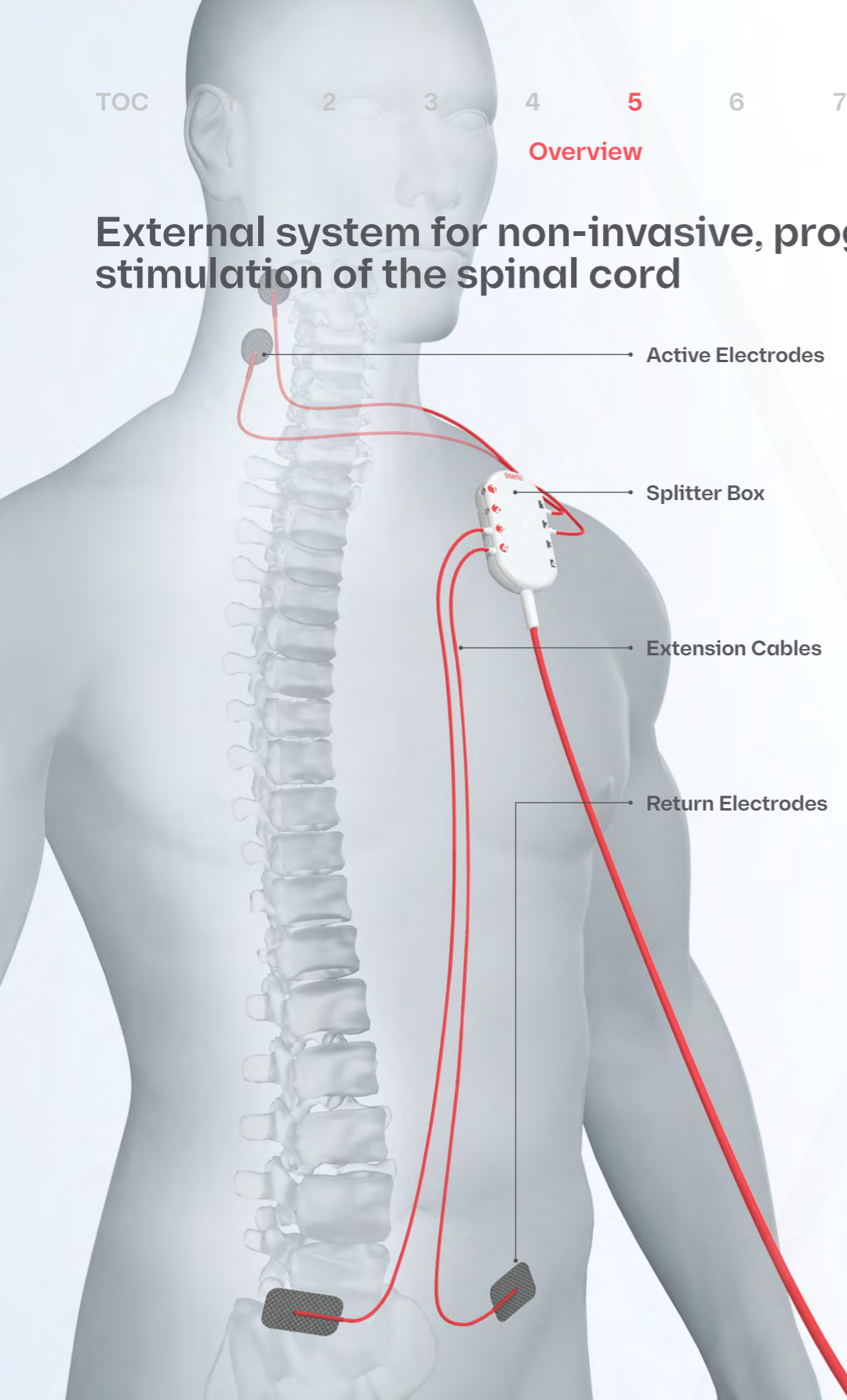
In addition to blood pressure regulation, we plan to further investigate the use of ARC^{IM} to improve mobility by restoring movement in the lower limbs. This will build on the success of STIMO, a first-in-human study that determined the safety and effectiveness of ARC Therapy to restore walking in individuals with chronic SCI resulting in complete or partial paraplegia.

Starting in 2016, the nine participants in this study received high-intensity neurorehabilitation that combined precisely timed epidural stimulation with over-ground, robot-assisted rehabilitation training. After completing the STIMO program, all participants reported improvements in mobility and substantial neurological recovery.



Overview

External system for non-invasive, programmed stimulation of the spinal cord



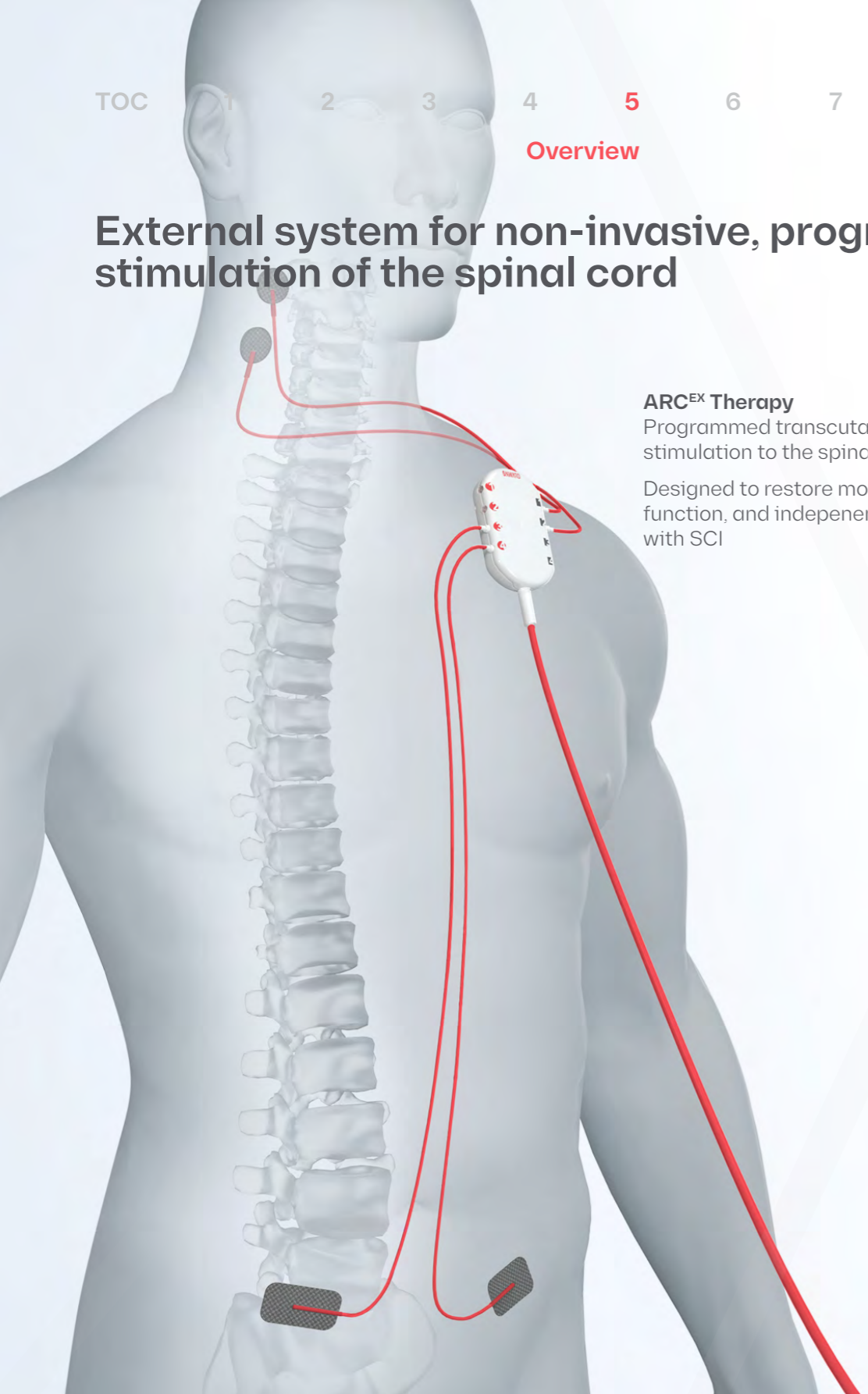
ARC EX PRO & myARC EX app
Via ARC EX Programmer



All ONWARD® therapies are investigational and not available for commercial use.



External system for non-invasive, programmed stimulation of the spinal cord



ARC^{EX} Therapy

Programmed transcutaneous electrical stimulation to the spinal cord

Designed to restore movement, function, and independence in people with SCI

ARC^{EX} Stimulator

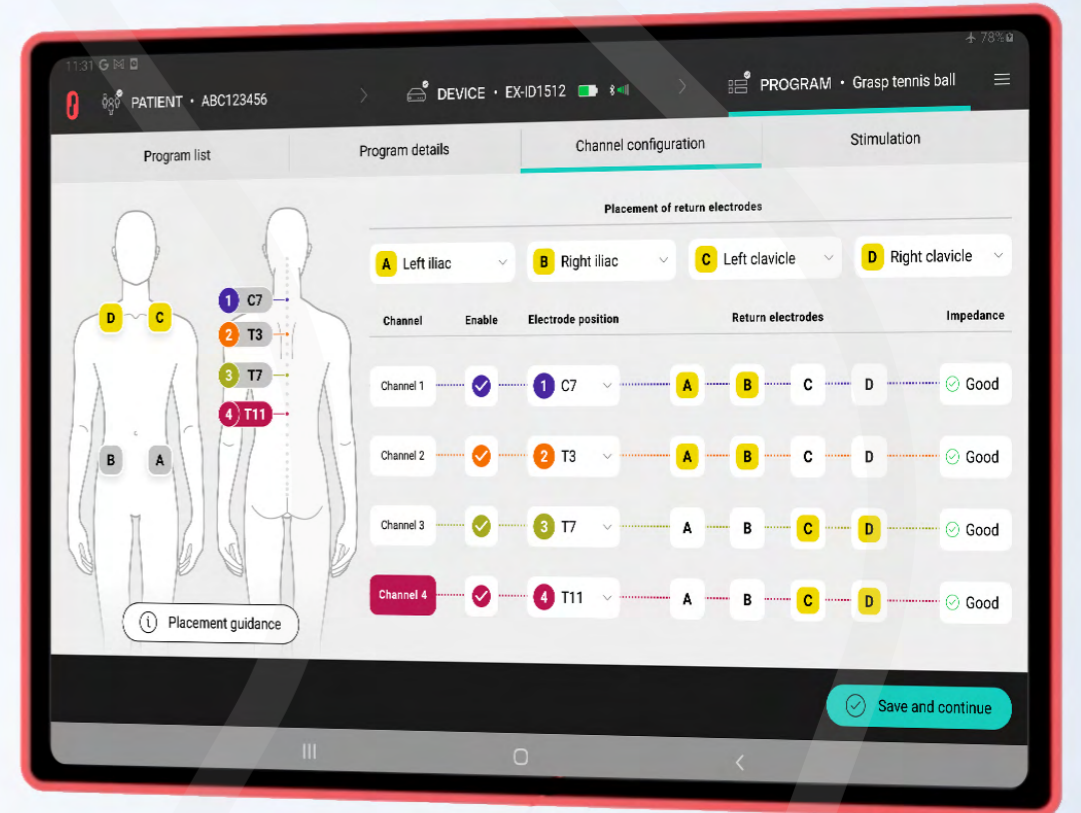


ARC^{EX} Therapy

Individual stimulation parameters can be optimized for each patient's unique needs

ARC^{EX} PRO & myARC^{EX} app

Via ARC^{EX} Programmer



All ONWARD[®] therapies are investigational and not available for commercial use.

Overview

Several were able to walk on a treadmill without using their hands for support and to stand and walk at will, even while the stimulation was inactive.

While walking may seem like an ambitious goal for many people with SCI, even modest gains in lower limb function can make a big difference. Incorporating ARC^{IM} Therapy in post-acute clinical rehabilitation programs has the potential to vastly improve long-term outcomes for the recently injured by promoting neurological recovery. Additionally, we envision that ARC^{IM} stimulation may someday be used “on the go” to enable a variety of everyday movements, including standing and movement of the lower limbs, as part of a person’s therapy and daily activities.

Additional Indications with Significant Clinical Impact Potential

ONWARD ARC^{IM} Therapy paired with brain-computer interface (BCI) to restore augmented mobility after SCI

In May, an article in *Nature* reported that a wireless BCI can use a person’s intention to move, originating in the brain, to control ARC^{IM} Therapy. Researchers reported that when paired with ARC^{IM} Therapy, an implanted BCI allowed an individual to gain augmented control over when and how he moved his paralyzed legs. The published data are part of an ongoing clinical feasibility study investigating the safety and preliminary effectiveness of brain-controlled spinal cord stimulation after SCI. The study is being coordinated by .NeuroRestore co-directors Professor Grégoire Courtine and Dr. Jocelyne Bloch, a neurosurgeon at Lausanne University Hospital (CHUV), in collaboration with Guillaume Charvet, Head of the Medical Device Development Lab at CEA-Leti/Clinattec.

ONWARD ARC^{IM} Therapy to restore mobility in people with Parkinson’s disease

In November, an article in *Nature Medicine* highlighted the potential for ONWARD ARC Therapy to address gait challenges related to Parkinson’s disease. The study participant described in the article has been living with Parkinson’s disease for nearly three decades. He has a severe gait disorder that has not responded to conventional therapies. After the introduction of ARC Therapy, followed by several weeks of rehabilitation, the participant was able to walk without the previously noticeable gait interruptions.

.NeuroRestore was awarded a USD 1 million grant from The Michael J. Fox Foundation for Parkinson’s Research (MJFF) to implant the ARC^{IM} System and in six additional participants with Parkinson’s disease to investigate the effect of ARC Therapy. This study will assist ONWARD in determining whether to conduct additional clinical trials with a view to commercialize ARC Therapy in the future for those living with Parkinson’s disease.

Clinical Trials and Regulatory Activity

The development, manufacture, and marketing of ONWARD ARC Therapy and associated technology is subject to government regulation in the United States, the European Union, the United Kingdom, and other countries. To apply for regulatory clearance or approval to market our new devices in any of these jurisdictions, we must complete extensive human clinical trials that demonstrate their safety and effectiveness.

Medical devices are regulated according to their risk level and require a certain level of supporting safety and effectiveness data to demonstrate their risk to benefit ratio for global regulatory authority consideration prior to market approval. ARC^{EX} is expected to be designated as a lower risk device (Class IIa) and ARC^{IM} is expected to be considered a higher risk device (Class III), requiring different levels of supporting clinical evidence. ONWARD continues to partner with regulatory authorities globally to ensure that clinical trials are designed and executed in accordance with the requirements for these different medical device classifications. For more information on ONWARD’s clinical trials, please refer to the relevant section in the operational review.

Commercialization

ONWARD does not currently offer any products for commercial sale. We have submitted ARC^{EX} System regulatory documentation to the FDA, with expected clearance for commercial sale in the second half of 2024. We subsequently expect to pursue regulatory clearance in select European markets. Our pivotal trial for the ARC^{IM} System, Empower BP, is expected to start in the second half of 2024. Empower BP will focus on the safety and effectiveness of ARC^{IM} Therapy for regulating blood pressure to achieve hemodynamic stability in patients after SCI. Our plans to commercialize our products depend on our ability to demonstrate their safety and effectiveness to regulatory authorities, as described in the previous section.



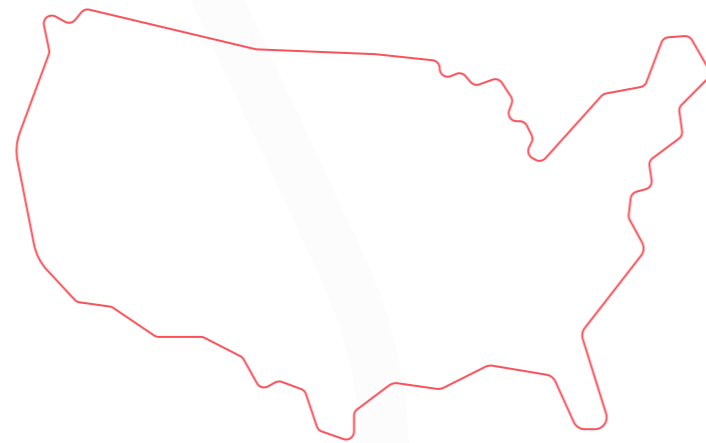
Pursue highly concentrated customer base with direct field organization

Commercial Strategy

Call Points

~330
(2023)

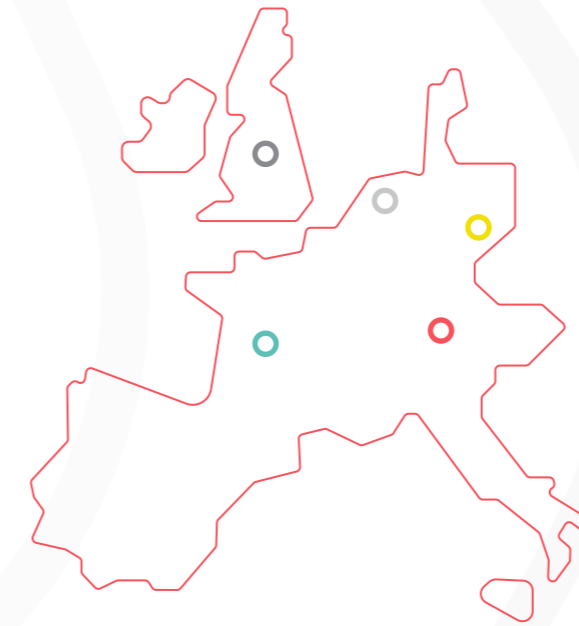
US



~250

Tier 1 and Tier 2 specialist rehab centers
Initial Focus: ~50 accounts including VA SCI hub centers, Up-LIFT investigational sites and other US flagship SCI clinics

Europe



~80

Specialist rehab centers
Initial Focus: ~30 accounts including DMGP member paraplegia centers in Germany, chiefly BG SCI Kliniks

- France (FR)
- Germany (DE)
- Netherlands (NL)
- United Kingdom (UK)
- Switzerland

Geographical Focus

US and select European markets with sophisticated neurorehabilitation infrastructure, clinical partnerships, and/or favorable reimbursement for medical innovation



Overview

Geographical focus and commercial objectives

We plan to market our ARC Therapy platforms in the US and Europe, where most people with SCI are cared for by a limited number of trauma and rehabilitation centers.

When people suffer an SCI, they typically undergo emergency surgery in a trauma center, after which they spend one week in intensive care. Subsequently, they begin acute phase rehabilitation training, lasting from three to twelve months, which is generally provided by specialized clinics with the necessary expertise and equipment. A year post-injury, people with SCI are considered to be in the chronic phase, after which many insurance companies cover only a limited amount of continued outpatient physical therapy for the purpose of maintaining strength and functional gains.

Based on market research and outcomes from our studies (including our Up-LIFT pivotal study), we believe people with SCI may benefit from ARC Therapy, even when applied many years after their injury. Given these promising outcomes and ongoing demand for innovative therapies in the rehabilitation space, it is likely that there is considerable demand that can be realized when we commercialize our first product, ARC^{EX}. In fact, those with chronic spinal cord injuries may reinitiate rehabilitation in response to the availability of these new therapies.

In the initial period following commercial launch of ARC^{EX}, our focus will be on the US and five select European markets: Germany, France, the UK, the Netherlands, and Switzerland. These markets were selected based on the sophistication of their rehabilitation and/or reimbursement infrastructure, the presence of ONWARD clinical study collaborators, and perceived demand for our investigational therapies. We may modify target markets or change the sequence of introductions to optimize likelihood of commercial success based on evolving considerations.

We plan to deploy a direct sales and service organization, given that the total number of facilities to be targeted – whether to market therapies or to support surgical interventions – is around 330. Where FDA clearance or approval or CE marking supports entry into non-target European or Asian markets, we will likely do so via a distribution partner.

ONWARD intends to continue to evolve its commercial strategy to optimize our probability of success.

Rehabilitation clinics

Our marketing efforts will focus on clinicians managing SCI patients in rehabilitation clinics. These include rehabilitation physicians such as physical medicine and rehabilitation (PM&R) physicians – also called physiatrists – as well as physical and occupational therapists who provide post-injury rehabilitation training and ongoing support to those who are chronically injured. The latter constitutes the largest pool of SCI patients globally.

We expect clinicians to use our therapies as follows:

- Use ARC^{EX} in clinics during therapy sessions
- Prescribe ARC^{EX} for use at home
- Refer patients to neurosurgeons and orthopedic spine surgeons for implantation of ARC^{IM}

There are a limited number of specialty rehabilitation clinics in our selected markets. In the US, there are approximately 250 Tier 1 and Tier 2 specialist rehabilitation clinics. Our initial focus will be on approximately 50 Tier 1 accounts including Veterans Affairs (VA) SCI hub centers, Up-LIFT investigational sites, and other US flagship SCI clinics. These clinics will provide a robust referral base for the ONWARD’s products and will serve as focused and fertile marketing targets.

In four of the five selected European markets, there are a total of 83 SCI specialty rehabilitation centers: 27 in Germany,⁶ 10 in the UK,⁷ 8 in the Netherlands,⁸ and 38 in France.⁹

Hospitals and ambulatory surgery centers

When patients are referred for an ARC^{IM} implant, surgery will likely be carried out on an outpatient basis in hospitals or ambulatory surgery centers (ASCs) by neurosurgeons or orthopedic surgeons focused on the spine. These surgeons are already familiar with neuromodulation and routinely perform implants for spinal cord stimulation to treat chronic pain. Primary targets will include those hospitals and ASCs with established neuromodulation referral pathways from physiatrists, as well as integrated SCI systems with multi-disciplinary approaches to caring for acute and chronic stages of SCI.



Specific customer targets at each stage in patient journey

Clinician Customers in Patient Journey

Acute Phase

Sub-Acute Phase

Intermediate Phase

Chronic Phase



Trauma Centers
Neurosurgeons, ortho/spine surgeons



SCI Rehabilitation Clinics
Rehabilitation physicians (physiatrists), therapists (PTs/OTs), and neurologists
Patients and caregivers



Physicians will prescribe ARC^{EX} for clinic or home use and refer patients for ARC^{IM} implants

Referral Pathway



Overview

Reimbursement

In both US and non-US markets, ONWARD’s ability to successfully commercialize our products depends on the availability of adequate financial coverage and reimbursement from third-party payors, including governmental payors, managed care organizations, and private health insurers. Third-party payors decide which treatments they will cover and establish reimbursement rates for those treatments, and they increasingly examine the cost-effectiveness of medical devices as well as safety and efficacy when making coverage and payment decisions.

The path forward in Europe is more varied than in the US, given that no uniform policy for coverage and payment exists across our European target markets and reimbursement can differ significantly from payer to payer. As such, our commercialization efforts to identify optimized pathways for reimbursement, coverage, and payment started in 2022 and will continue through 2024.

The first likely European market for ARC^{EX} is Germany, based on the initial evaluation criteria for reimbursement, the sophistication of SCI rehabilitation infrastructure, and the fact that the country has the largest SCI population. All five markets are also viable ARC^{IM} targets, with plans to further undertake reimbursement planning in 2024.

Reimbursement in the United States

ARC^{EX}

Upon FDA clearance of ARC^{EX} in the US, we plan to sell the devices to specialty rehabilitation clinics to be used in patient rehab sessions, as well as directly to SCI patients for personal use in the home as prescribed by rehabilitation physicians.

We believe we will have rapid access to almost one-third of covered lives in the US by targeting patients cared for by the Veterans Affairs (VA) healthcare system, those covered by workers’ compensation insurance, and the estimated 10-15% of patients with the means to self-pay for the ARC^{EX} System.

ARC^{EX} is designed as Durable Medical Equipment (DME) and will be categorized under a set of codes called HCPCS. Given the novelty of ARC^{EX} and its potential to restore upper limb strength and function after SCI (an indication that was awarded a Breakthrough Device Designation by the FDA), we plan to pursue a new HCPCS code for Medicare reimbursement. To support this effort, our clinical and economic evidence generation plan for ARC^{EX} includes the necessary data collection to achieve optimized coverage and reimbursement that reflects of the clinical benefit of the therapy in the US within five years. The Company plans to establish claims and invoicing history by focusing on patients with VA coverage, the world’s largest healthcare system providing care to Veterans with SCI.

ONWARD has partnered with Lovell Government Services (Lovell), a service-disabled veteran-owned small business (SDVOSB) to gain access to the VA market for ARC^{EX} sales for both in-clinic and home use. Under this agreement, Lovell will add ONWARD therapies to its relevant federal contracts once those technologies are authorized by the FDA for sale in the US. That is expected to provide the Company with rapid access to the Federal Supply Schedule (FSS), General Services Administration (GSA), Distribution and Pricing Agreement (DAPA), and Electronic Catalog Contract (ECAT).

In addition to the claims and invoicing data from sales to the VA, we also plan to capture patient-reported real-world evidence via an ARC^{EX} mobile companion app to strengthen coverage and payment opportunities with Medicare and private payors, which will ultimately give more than 90% of the total US SCI population access to ARC^{EX}.

In November of 2021, the Centers for Medicare and Medicaid Services (CMS) rescinded the Medicare Coverage of Innovative Technology (MCIT) final rule. This rule was originally proposed in September of 2020 to ensure Medicare coverage upon FDA clearance for devices which were awarded FDA Breakthrough Device Designation (BDD). Concerns regarding lack of controls to ensure Medicare populations were studied, and lack of a mechanism to remove coverage if safety concerns arise, were cited as reasons for repeal.

Despite the repeal, CMS reiterated its commitment in 2023 to create a pathway for coverage upon FDA clearance for devices with BDD and is working with industry



Overview

stakeholders, physician societies, and patient groups to develop an alternate pathway called Transitional Coverage for Emerging Technologies (TCET). While this pathway is still under consideration, it could positively affect devices with BDD, such as ARC^{EX}, by providing Medicare coverage from day one through a post-FDA clearance period.

ARC^{IM}

Procedure codes (CPT) exist today for physician, hospital outpatient, and ambulatory surgery center (ASC) payment for spinal cord stimulation (SCS) for chronic pain. However, we believe that ARC^{IM} may need to pursue separate coding, given the procedural intensity differences of implanting this novel technology compared to traditional SCS. With the potential for new codes, we will pursue provider payment levels commensurate with the value that ARC^{IM} provides to people with spinal cord injury (SCI), who otherwise have no treatment options. We are also designing our global pivotal clinical trial for stabilizing blood pressure after SCI, Empower BP, to take into account the data required to pursue a new procedural code for ARC^{IM}.

We believe patients will have rapid access to the ARC^{IM} System in the US by using a Category 3 code, which we expect will be available upon FDA approval of the initial indication.

Facility payments include the cost of the technology but not physician services, which are billed separately. Medicare pays the hospital outpatient department a single amount for the full system implant, while the ASC is paid separately for the lead and neurostimulator implantation. Private payers tend to pay ~25% more than Medicare, and Medicare payment systems tend to lag for new technology.

These facility payment systems are prospective and payment rates for a given procedure are based on historical claims data. Thus, the cost of new technology cannot be included in the current payment rates. Because the Centers for Medicare and Medicaid Services (CMS) employs a prospective payment system, the payment levels “underpay” for new technologies. To enable payment for new innovation, therefore, Medicare has established two pathways to potential incremental payment for the ARC^{IM} implant procedure, one for hospital inpatient and one for hospital outpatient procedures.

In the inpatient setting, Medicare’s New Technology Add-on Payment (NTAP) provides additional payment for implantable devices for a limited duration, typically up to two years. Similarly, Medicare provides a Transitional Pass Through (TPT) payment for the outpatient setting for three years.

ONWARD’s Breakthrough Device Designations for ARC^{IM} for multiple indications, including the expected first indication for hemodynamic stability after SCI, increase the probability of securing incremental payments in both settings and we plan to apply for both as appropriate.

Reimbursement in Germany

ARC^{EX}

While ARC^{EX} will be immediately available upon CE marking for clinics to purchase for use with patients during in-clinic rehabilitation sessions, preliminary analysis indicates that the timeframe for home-use reimbursement of ARC^{EX} will be up to two to four years from CE marking.

In Germany, medical devices in the outpatient and physician clinic setting require a new Einheitlicher Bewertungsmaßstab (EBM; Uniform Assessment Standard) code. Devices used in the home setting are governed by the Hilfsmittelverzeichnis (HMV), a positive coverage list for home-use medical equipment. HMV categories tend to be highly specific to indication; as a result, ARC^{EX} will likely need a new HMV category. To achieve a new product category, a positive evaluation by the Gemeinsamer Bundesausschuss (G-BA; Federal Joint Committee) will be necessary. Following successful inclusion in the home-use medical aids directory by the GKV-Spitzenverband, these products are recommended as reimbursable, but are subject to different price and contractual reimbursement rules and will be negotiated between statutory health insurance funds and medical suppliers as part of individual contracts for the provision of ARC^{EX}.

ARC^{IM}

Among our selected five entry markets in Europe, Germany has the largest population living with SCI and may offer the most accessible pathway for ARC^{IM}. Germany



Overview

operates a diagnosis-related group (DRG)-based system to compensate hospital inpatient admissions and provides an existing pathway for supplemental payment, or Zusatzentgelte (ZE), for high-cost medical services, such as the ARC^{IM} procedure.

For the regulation of blood pressure after SCI, diagnosis (ICD) and procedure codes (OPS) are already in place. They initiate a specific DRG and supplementary fee (ZE). The reimbursement of ZEs is negotiated by hospitals with the payors as part of the annual budget negotiations and depends on the additional costs for the new treatment compared to the costs defined in the DRG. This means that there is already a method of payment in place to reimburse hospitals for the costs of treatment with ARC^{IM}.

In Germany, it is also required that work-related spinal cord injuries be treated at one of nine national BG Clinics. These specialty clinics, which provide integrated surgical and rehabilitation services, also care for patients who are not injured on the job and are highly familiar with and skilled at the process of negotiating supplemental payment for their spinal cord injury patients.

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⁵ONWARD press release issued 8 December 2023 - ONWARD Reports Interim Clinical Outcomes for Implantable ARC Therapy Demonstrating Potential to Improve Blood Pressure Regulation after Spinal Cord Injury

⁶German-speaking Medical Society for Paraplegiology (DMGP)

⁷Medical Management Advice :: Royal National Orthopaedic Hospital (rnoh.nhs.uk)

⁸InSCI International Spinal Cord Injury Community Survey - Netherlands

⁹Nature Article: *Rehabilitation of SCI in France. There are 148 rehab clinics in France, but only 38 clinics treated six or more SCI in past year.*





ONWARD[®]

Culture at
ONWARD

Culture at ONWARD

With our compelling vision, highly innovative technology, and competitive rewards, ONWARD seeks talented and bold people who bring creativity to everything they do. Our Company is diverse, with 20 nationalities represented.

We strive to differentiate ONWARD as an employer of choice by creating a positive culture inspired by the ONWARD Code, which reinforces a culture of continuous learning, feedback, and development, providing the necessary tools and opportunities for people to enhance their skills and grow in their abilities and careers.

The ONWARD Code is communicated as part of employee onboarding and reconfirmed in our monthly all-company meetings. We believe it is important to cultivate an open and transparent culture that allows employees to express, in good faith, any concern they may have. Employees are encouraged to raise concerns without fear of retaliation, knowing that these will be treated confidentially, seriously, fairly, and promptly.

The ONWARD Code

We are OPEN

We seek great ideas from any source. We are hungry for feedback.
We accept criticism with humility.

We are TRUSTING

We assume positive intent. We count on each other to deliver.
We speak truth to our leaders and teammates.

We are COLLABORATIVE

We are a team. We find ways to work well together.
We value our external partnerships.

We are PASSIONATE

We admire the courage of those we serve.
We are driven to fulfill our Vision. We will not fail.

We are EMPOWERED

We encourage ideas. We allow mistakes.
Everyone is accountable.

We are COMMITTED

We pursue a noble cause. We are never distracted nor
deterred. We are grateful for the responsibility we shoulder.

We are PRAGMATIC

We find a way. We surmount obstacles. We find
fulfillment in overcoming.

We are INNOVATIVE

We dream big. Limits do not contain us.
Our imagination defines the possible.

Culture at ONWARD

Competitive hiring

We endeavor to attract the best candidates, people who are motivated by our vision and the opportunity to work on true breakthroughs, rather than incremental gains.

Our in-house recruitment capacity allows us to better control our hiring process and leverage our professional network and partnerships with key academic institutions to attract the greatest talents on the market.

Our employee referral program also incentivizes our employees to leverage the power of their networks to recruit people who are a good cultural and organizational fit.

We offer competitive compensation and benefits packages, which are key to attracting and retaining talent. Long-term incentives are offered to our senior management and key individuals as part of our remuneration philosophy. We encourage share ownership among all our employees through a stock-option plan. This aligns our long-term incentives with our long-term objectives, as grants are conditional on continued employment until the time of vesting.

A great place to work

In 2023, ONWARD continued to implement improvements to ensure a smooth and positive experience for new team members, including a check-in survey after the first 90 days of employment, employee journey interviews, and comprehensive offboarding interviews. These initiatives ensure that valuable insights are collected at every point in the employment lifecycle, enabling us to optimize our employment practices and organizational performance.

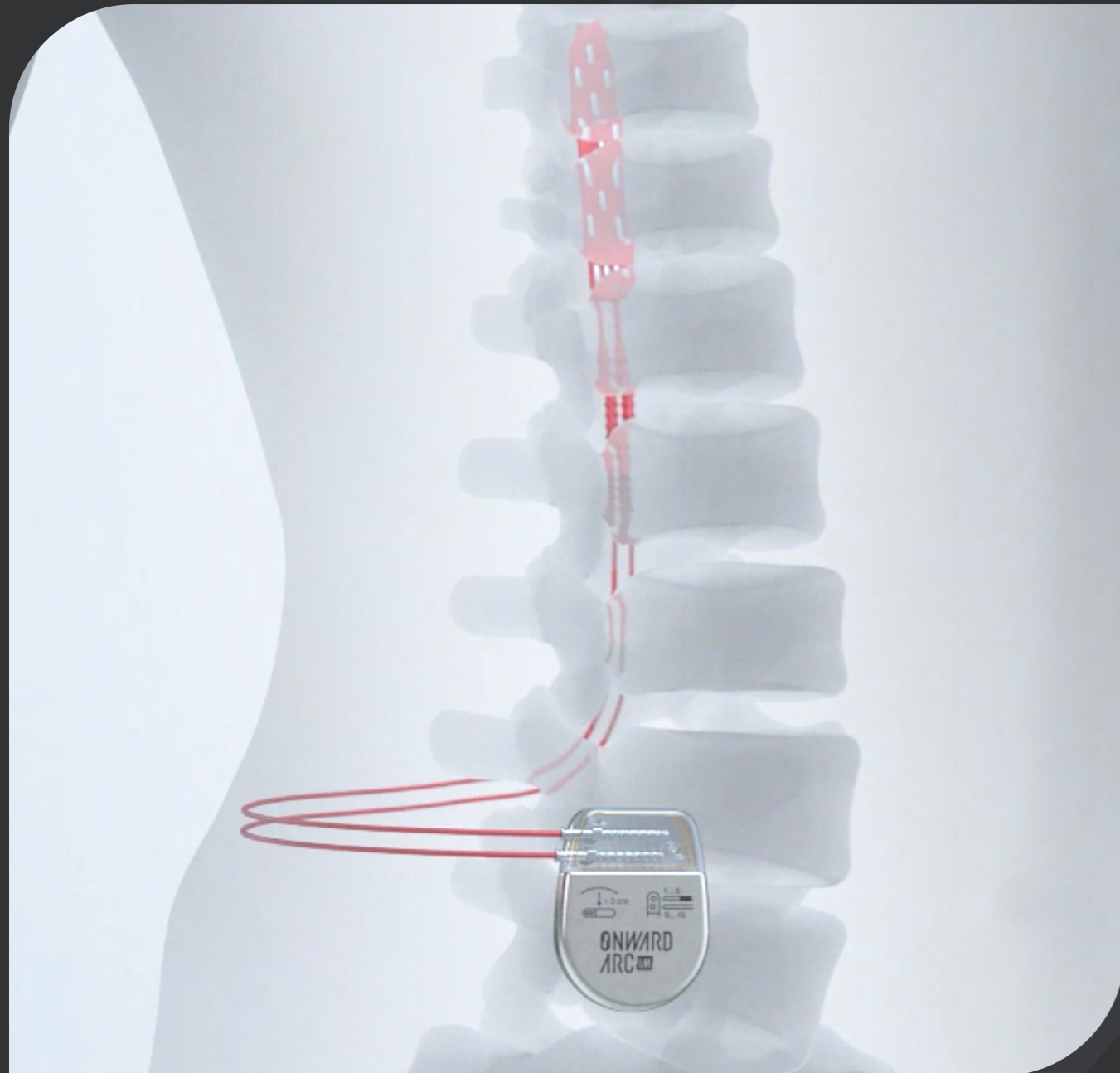
Also in 2023, a formal speaker series was added to monthly all-company meetings. Guest speakers included clinicians, people with lived experience of SCI and their caregivers, and leaders from key SCI advocacy groups. Their testimonials keep employees connected to the ONWARD vision and the meaning and urgency of what we do.

Employee well-being

The well-being of employees is important to us. Workshops and other activities centered on mental health and well-being continued to be offered in 2023. In addition, employees were offered more flexible, hybrid ways of working where possible, unless their work required access to specialized equipment and facilities, necessitating regular presence in the office.



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Privacy & Data Governance

Privacy & Data Governance

ONWARD is committed to ensuring that data security and confidentiality are built into our products and processes. The personal data we process in the course of our operations – including health and medical information – cover our suppliers and business contacts, applicants, visitors and website visitors, employees, and customers. When we collect patient health data, we do so with the sole purpose of continually improving the efficiency and safety of our therapies.

We are subject to various regional, national, and state laws that protect the confidentiality and security of patient health information, including patient medical records and other forms of personal information. We are committed to applying the two most rigorous privacy regulations to our global operations, namely the United States’ Health Insurance Portability and Accountability Act (HIPAA) and the European Union’s General Data Protection Regulation ((EU) 2016/679; GDPR). This legislation includes the data subject’s right to access or amend certain records containing protected health information or to request that their use or disclosure be restricted.

To that end, we have appointed an external Data Protection Officer. This service is provided by DPO Consulting, a firm with extensive experience in Data Protection Regulations. In addition, we have established a Data Privacy Committee and a Global Data Protection Policy implemented through a series of procedures and mechanisms to ensure compliance with GDPR and HIPAA, as applicable.

Through the creation of the position of VP of Legal, we are strengthening the integration of legal and privacy assessments across the organization in collaboration with the Data Protection Officer.

We have also strengthened the compliance of our products with cybersecurity and data protection requirements under GDPR and HIPAA. We have started to create traceability in accordance with relevant standards and build evidence that our products are compliant with the regulations. We continue to evaluate and improve our processes for compliance with GDPR and HIPAA requirements, as we prepare for commercialization in 2024. We are strengthening our data management and processes, and we regularly train our staff on security and privacy issues.



ONWARD[®]



Sustainability

Sustainability

Additional details regarding ONWARD's sustainability priorities, approach and performance can be found in a separate sustainability summary, available on ONWARD's investor website.

ONWARD is committed to being a responsible organization that creates sustainable long-term value for all stakeholders. Sustainability principles are integral to the way we do business. They are captured in the ONWARD Code, Articles of Association (AOA), Code of Conduct (COC), and the Company's culture, business practices, operations, and supplier agreements.

Sustainability Principles

ONWARD's sustainability strategy rests on five core principles:

- **Innovating for the underserved.** There is no cure for SCI. ONWARD therapies are among the first to offer the potential to help people with SCI regain movement and other functions, improving quality of life for a large, underserved group of people. The Company's products also have potential to benefit large populations of stroke sufferers and people with Parkinson's disease. Underscoring the innovative nature of its work, ONWARD has been granted 10 Breakthrough Device Designations (BDD) by the US FDA (as of February 2024) and have nearly 240+ issued patents worldwide. The Company continuously innovates and strives to get such designations for other indications to be able to make a difference in the lives of even more people.
- **Partnering with patient groups.** ONWARD enjoys excellent relationships with the world's leading patient advocacy groups for people with SCI. The Christopher and Dana Reeve Foundation, the world's largest such organization, is an investor in ONWARD. The Company also collaborates with Wings for Life in Europe, the

Sustainability

Praxis Foundation in Canada, and International Spinal Research Trust in the UK. This collaboration enables ONWARD to innovate in ways that make the greatest difference for people with SCI.

- **Attracting and retaining the best talent.** To deliver on its vision, ONWARD is committed to creating an unrivaled and inclusive environment for employees. The Company cares deeply about the well-being and continuous development of its staff as evidenced by the various programs that it has put in place, such as its well-being program. Having a highly motivated and engaged workforce enables the Company to retain and attract top talent. It also engages with people with SCI as consultants, enabling staff to have a better understanding of the challenges that they face. ONWARD recognizes and welcomes the value of diversity with respect to age, gender, race, ethnicity, nationality, sexual orientation, and other important cultural differences.
- **Minimizing our environmental footprint.** In its operations, the Company strives to reduce its carbon footprint by replacing air travel with videoconferencing except for the most pressing business needs, and by encouraging a hybrid workplace, thus reducing employees' commute. Additionally, ONWARD works with suppliers to minimize waste in the manufacturing process, consume electricity generated almost exclusively from renewable sources, and implement recycling programs in its offices.
- **Maintaining high ethical standards.** ONWARD strives to act with openness and integrity. The Company is committed to high ethical standards in dealing with business partners as outlined in the Code of Conduct, which covers anti-bribery and anti-money laundering, government relations and political affairs, and international business practices. The Code of Conduct ensures that employees understand what is expected of them when acting on behalf of the Company. ONWARD aims to comply with all applicable anti-bribery laws, including the US Foreign Corrupt Practices Act. The highest quality and safety standards are applied to all ONWARD's activities, and the Company ensures strong labor practices in our supply chain. ONWARD also works hard to secure key personal data and comply with GDPR (General Data Protection Regulations) and HIPAA, uphold human rights, and operate in geographies with a strong track record on this area.

ONWARD was awarded a bronze medal by EcoVadis in 2023, placing us in the top 40th percentile for Sustainability among companies in our field.





ONWARD®

Operational Review

Operational Review

Science and Intellectual Property

As the pioneer in its space, ONWARD has forged relationships and exclusively licensed important intellectual property from many of the world’s leading neuroscience research laboratories, such as Caltech US, University of California at Los Angeles US, University of Louisville US, and University of British Columbia (Canada).

The Company’s primary research partnership is with .NeuroRestore, a joint research initiative of EPFL and CHUV in Lausanne, Switzerland, with whom ONWARD has an exclusive IP licensing agreement. In 2021, the Company signed a framework agreement with .NeuroRestore governing future research initiatives, as well as contracts covering existing and ongoing research on blood pressure, mobility, brain-computer interfaces (BCI) and brain controlled spinal cord stimulation. In addition, ONWARD supported .NeuroRestore research on upper limb mobility and incontinence.

Benefitting from these research collaborations, and combined with its own innovations, the Company added 50+ patents to its formidable IP portfolio, which now totals 240+ issued patents, further reinforcing the Company’s pioneering science and first-mover advantage.

Research and Development

ONWARD’s engineering team made advancements across several development initiatives:

- ARC^{EX} System development: Considerable progress was made on all aspects of the system. The design is now complete and the System passed the Verification and Validation testing phase in early 2024. Work continues on design transfer, procuring production materials, and supply-chain activities.
- ARC^{IM} Lead development: The ARC^{IM} Thoracic Lead is under clinical investigation and has now been implanted as part of several clinical feasibility studies. Development and

verification of the two ARC^{IM} Lumbar Lead models are complete and are now ready for clinical investigation following notified body review.

ONWARD formed part of a research consortium of partners in the US, Canada, and Switzerland that has been awarded research funding by the US Department of Defense Advanced Research Projects Agency (DARPA) to advance innovative SCI therapies. In response to the DARPA Bridging the Gap Plus funding call, the consortium proposed developing a new clinical intervention to modulate blood pressure and spinal cord perfusion and oxygenation in the hours following SCI. The intervention included spinal cord stimulation using ARC^{IM}, combined with implanted sensors for blood pressure and spinal cord perfusion, as well as stem cells and scaffolds implanted in the lesion site to promote neural regrowth across the injury.

The DARPA grant was envisioned to be a five-year project (October 2021 to September 2025) for a total of USD 36M, of which ONWARD could potentially receive up to USD 6.3M.

To receive the funding in full, the Company had to meet specific milestones at each stage:

- Phase 1: System design, IPG software and firmware update for spinal cord stimulation for blood pressure control (already granted and funding received)
- Phase 2: System development completion (already granted and receipt of funding ongoing), development of a dedicated lead (contingent), and clinical evaluation in 10 chronic patients in Switzerland and Canada (contingent)
- Phase 3: US Food and Drug Administration (FDA) Investigational Device Exemption secured and clinical proof of concept demonstrated in at least one acute patient (to be granted)



Operational Review

ONWARD believes its involvement in the DARPA consortium has contributed to its leadership and expertise in blood pressure management. Unfortunately, due to funding limitations, the Company was informed the DARPA project will not advance to Phase 3.

Clinical and Regulatory

ONWARD’s clinical and regulatory team had a productive 2023, advancing ARC^{EX} and ARC^{IM} Therapy for initial indications and filling the Company’s pipeline with additional promising indications. With completion of the Up-LIFT pivotal study demonstrating the safety and effectiveness of ARC^{EX} and preparation for the upcoming ARC^{IM} Empower BP pivotal study, the team is poised to deliver on several major regulatory and clinical milestones in 2024.

ONWARD announced four new Breakthrough Device Designations (BDD) from the US Food and Drug Administration (FDA) in the first half of 2023. These included BDDs for the use of our ARC^{EX} platform for bladder control (awarded late 2022), alleviation of spasticity, and blood pressure regulation in people with SCI. We later received an additional BDD for its ARC^{IM} platform for spasticity in people with SCI. At the end of 2023, we had a total of nine BDDs, which afford us priority FDA review and the opportunity to interact with FDA experts throughout the premarket review phase prior to commercialization. We were awarded our 10th BDD in Q1 2024 for ARC^{BCI} therapy.

ARC^{EX} Therapy clinical trials

- In April, at the American Academy of Neurology Annual Meeting, Dr. James Guest, Professor of Neurological Surgery at the University of Miami and the Miami Project to Cure Paralysis, shared additional results from the Up-LIFT pivotal study that investigated the Company’s ARC^{EX} Therapy for improving upper extremity strength and function after SCI. In addition to meeting all primary safety and effectiveness endpoints, the study demonstrated that 72% of participants responded to ARC^{EX} Therapy, showing improvement in both strength and function.
- These results were presented by Dr. Guest and other lead study investigators at six prestigious conferences in 2023.

ARC^{IM} Therapy clinical trials

- In April, the *New England Journal of Medicine* highlighted the use of ONWARD’s innovative approach to treating orthostatic hypotension (low blood pressure) with ARC^{IM} Therapy in a patient with MSA-P, a form of Parkinson’s disease that affects the sympathetic nervous system.
- In May, the Company announced that its ARC^{IM} Therapy was paired with an investigational implanted wireless BCI, resulting in an individual gaining thought-driven, augmented control over when and how he moved his paralyzed legs. This breakthrough was published in the journal *Nature* and highlighted in major media outlets around the world.
- Also in May, we announced the successful first-in-human use of our investigational ARC^{IM} Lead to deliver targeted electrical pulses to the thoracic spinal cord at the location responsible for a specific function, such as blood pressure regulation. The ARC^{IM} Lead is a key component of the ONWARD ARC^{IM} System and is designed to deliver ARC Therapy generated by the ARC^{IM} Neurostimulator (IPG). Together, this purpose-built system is engineered to restore movement and function in people with SCI.
- In August, ONWARD marked the successful first-in-human use of an investigational implanted wireless BCI paired with ARC^{IM} Therapy to help a person with SCI recover use of paralyzed arms and hands with thought-driven movement. The implant was part of a clinical feasibility study with partners at CEA-Clinattec, CHUV, and EPFL that is supported by a grant from the European Innovation Council. BCI-augmented ARC^{IM} implants will continue throughout 2024 as part of this study.
- In November, ONWARD announced a publication in *Nature Medicine* using investigational ONWARD ARC Therapy to address gait challenges related to Parkinson’s disease. The breakthrough was covered widely by the global media, demonstrating the potential for ARC^{IM} Therapy to address mobility challenges stemming from Parkinson’s disease in addition to those resulting from SCI.



Operational Review

- Also in Q4, ONWARD research partner .NeuroRestore was awarded a USD 1 million grant from The Michael J. Fox Foundation for Parkinson’s Research (MJFF) to implant the ARC^{IM} System and investigate the effect of ARC Therapy in six additional participants with Parkinson’s disease. This study will assist ONWARD in determining whether to conduct additional clinical trials and potentially commercialize ARC Therapy in the future for those living with Parkinson’s disease.

ONWARD has had a highly productive year preparing for several key submissions and discussions with the FDA and EU-MDR in 2024 and beyond. The Company made clear progress in finalizing the study design and gearing up for FDA investigational device exemption (IDE) study submission and start of Empower BP, the pivotal clinical trial investigating the safety and effectiveness of ARCIM therapy on hemodynamic instability following SCI.

Quality

ONWARD has a global quality system for all company employees based in the US, the Netherlands, and Switzerland that complies with applicable regulations and standards related to the medical devices industry (MDR and QSR, respectively, for EU and USA). In 2018, the Company obtained the ISO 13485 certification for design and development. In 2022, the certification scope was expanded to include clinical applications targeted by ARC^{EX} Therapy and new activities to support the upcoming manufacturing and distribution of ARC^{EX} devices.

The most recent audit was conducted and passed in late 2023 by TÜV SÜD, a respected notified body with global reach for neuromodulation devices.

A Quality Plan was established to support the growth of the organization in the coming years, and to ensure the operational excellence of the teams and delivery of safe and effective therapies.

ONWARD has continued to strengthen its Quality function by hiring additional qualified leadership and staff, bringing competencies in medical software, supplier quality management, design control, and risk management.

Commercial operations

ONWARD does not currently offer any products for commercial sale. However, with successful FDA regulatory clearance, we plan to commercialize ARC^{EX} for improving strength and function of the upper extremities after SCI. Expected timing for US launch is in the second half of 2024, with launch in Europe to follow in the first half of 2025.

In late 2026, assuming positive clinical results from our Empower BP global pivotal trial and subsequent regulatory authority approvals, ONWARD aims to launch ARC^{IM} commercially in the US and select European markets to restore hemodynamic stability after SCI. Additionally, the Company will continue to investigate the use of ARC^{IM} for additional indications, for instance, to improve mobility by restoring movement in the legs and feet, with the goal of bringing these therapies to market in the near future.

Given the small number of centers and clinicians responsible for providing rehabilitation training, managing SCI patients, and performing accompanying surgeries, the Company plans to deploy its own direct sales and service organization in the United States and select European markets, and use distribution partners elsewhere, where appropriate.

Financing

To support operational goals, ONWARD will continue to invest in R&D activities, conduct clinical trials, and prepare for commercialization. The Company has successfully raised more than EUR 150M since its founding, with EUR 29.8M net cash (please refer to Non-IFRS financial measure included in Other Information for the definition of net cash) on the balance sheet at the end of 2023.

At the end of 2023, the Company expected its current cash to propel operations through the end of 2024. The Company successfully completed a EUR 20M equity financing in March 2024, extending its cash runway into mid-2025.



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Financial Review

Financial Review

This financial review should be read with the operational review and the Company’s consolidated financial statements in this Annual Report, which have been prepared in accordance with International Financial Reporting Standards (IFRS) as published by the International Accounting Standards Board and as adopted by the European Union and with Part 9 of Book 2 of the Dutch Civil Code.

EUR' Million	2023	2022
Total Revenues & Other Income	0.5	2.1
Total Operating Expenses	(36.0)	(34.2)
Research & Development Expenses	(13.8)	(13.1)
Clinical & Regulatory expenses	(4.9)	(5.7)
Marketing & Market Access Expenses	(2.9)	(2.0)
Patent Fees & Related Expenses	(1.5)	(1.5)
Quality Assurance Expenses	(1.5)	(1.2)
General & Administrative Expenses	(11.3)	(10.6)
Operating Loss for the Period	(35.5)	(32.0)
Net Finance Expense	(0.6)	(1.5)
Income Tax Expense	(0.1)	0.8
Net Loss for the Period	(36.2)	(32.8)
At	31 December	31 December
EUR' Million	2023	2022
Net cash position at the end of the period	29.8	61.8
Interest-bearing loans	(15.3)	(12.7)
Equity	17.9	52.6

Total Revenues & Other Income

Other income, mainly grant income, decreased because the grants received from European Innovation Council and SMEs Executive Agency (EISMEA) focusing on brain-computer interfaces are under review for amendment. The amendment is to align the funding received (and receivable) with the origin of the activities being performed. Activities in the European Union will continue to be funded by EISMEA. For the activities performed by the subsidiary in Switzerland, ONWARD is in discussion with a Swiss State Agency for replacement funding. We reassessed our original estimate for grant income recognition, and conservatively adjusted the income recognized based on the change in estimate to reflect the progress of the amendment and discussions at 31 December 2023. This includes a payable balance for the estimated portion of the advance received to be repaid. No new grants were awarded in 2023.

Research & Development Expenses

Research and development (R&D) expenses increased by 5%, from EUR 13.1M in 2022 to EUR 13.8M in 2023, driven mainly by the focused efforts to finalize all components of the ARC^{EX} platform for US FDA submission, as described in the operational review.

R&D expenses consist of product development, engineering to develop and support our products, testing, consulting services, and other costs directly attributable to the ARC technology platforms and related therapies. These expenses primarily include salaries for R&D staff and related expenses, including expenses for share-based compensation, and outsourced development expenses. These expenses do not meet the criteria for capitalization given the status of development activities.

R&D expenses also include the costs of sponsored research activities undertaken by universities with which ONWARD collaborates. This includes the close working relationship with one of the founders, Grégoire Courtine, CSO, Director at .NeuroRestore and Professor at EPFL.



Financial Review

Clinical & Regulatory Expenses

Clinical expenses decreased by 14%, from EUR 5.7M in 2022 to EUR 4.9M in 2023. Clinical expenses in 2023 relate to supporting clinical activities including consulting services and costs associated with the different ongoing studies for the regulation of blood pressure with ARCTM Therapy; preparation for our pivotal clinical study on blood pressure, Empower BP; and supporting FDA submission for ARC^{EX}. In 2022, expenses primarily related to the completion of the Up-LIFT pivotal and LIFT Home clinical trials. These expenses comprise employee salaries and related expenses, including share-based compensation, clinical trial management and monitoring, payments to clinical investigators, data management, and travel expenses to the various clinical trial locations.

Marketing & Market Access Expenses

Marketing and market access expenses increased by 45%, from EUR 2.0M in 2022 to EUR 2.9M in 2023. The increase in costs has been driven by market access investigative activities in Europe and the US as part of ARC^{EX} launch preparations, including market pricing studies and attendance at key events to build awareness of, and generate interest in, ONWARD ARC Therapy within the SCI Community. Employee costs increased to support the marketing effort required.

Patent Fees & Related Expenses

Patent fees and related expenses remained unchanged at EUR 2.0M in 2023. These expenses consist primarily of costs associated with obtaining and maintaining patents and other intellectual property included in ONWARD's growing portfolio.

Quality Assurance Expenses

Quality assurance expenses increased by 25% from EUR 1.2M in 2022 to EUR 1.5M in 2023. Quality assurance expenses are related to efforts to strengthen ONWARD's capability to meet quality and regulatory requirements in support of upcoming regulatory submissions and expected commercialization. These expenses include employee salaries and related expenses, including share-based compensation, consulting, testing, and travel related to quality and risk assurance activities.

General & Administrative Expenses

General and administrative expenses increased by 7%, from EUR 10.6M in 2022 to EUR 11.3M in 2023. As ONWARD prepares to launch its first commercial product, the Company has made investments in technology systems, consulted with specialists on licensing, legal, and regulatory compliance, and expanded its overall operational capabilities.

Net Finance Expense

The net financial expense decreased by 53%, from EUR 1.5M in 2022 to EUR 0.7M in 2023. The expense for 2022 relates to the innovation loan from RVO NL and bank interest paid on the positive cash balance in the first half of 2022. The Company has started investing excess cash in short-term deposits with reputable banks yielding interest income. In 2023, the interest earned has positively offset the interest expense on the innovation loan.

Income Tax Expense

The 2022 expense was mainly the result of the recognition of a deferred tax asset relating to the net operating losses in the US entity to offset the reversible temporary difference recognized as part of the purchase price allocation in 2019. The 2023 expense derives from the activities of the Swiss subsidiary.

Cash Position

The Company ended the year with a positive net cash balance of EUR 29.8M (2022: EUR 61.8M). The full amount comprises cash and cash equivalents since none of the short-term fixed deposits exceeds a period of 3 months.

The table below summarizes the Company's cash flows for the years 2023 and 2022.

EUR' Million	2023	2022
Net cash generated / (used) from operating activities	(32.2)	(26.7)
Net cash generated / (used) from investing activities	19.6	(20.4)
Net cash generated / (used) from financing activities	0.8	(0.6)
Effect of exchange rates on cash and cash equivalent	(0.1)	(0.0)



Financial Review

The cash outflow from operating activities increased from EUR 26.7M in 2022 to EUR 32.2M in 2023. The increase in cash used was attributable to higher operating costs, as explained above, offset by an increase in interest earned on short-term fixed deposits and an increase in non-cash adjustments relating to share-based compensation.

Cash flow from investing activities in 2023 reflects the withdrawal of fixed-term deposit investments offset by the acquisition of property, plant, and equipment.

The cash inflow in 2023 was from two additional installments received on the interest-bearing loans (see below) offset by the payment of the lease liability.

The impact of exchange rates amounted to EUR 113k for 2023.

Interest-bearing Loans

Interest-bearing loans increased by 20%, from EUR 12.7M in 2022 to EUR 15.3M in 2023. This is due to an increase in the loan capital amount of EUR 1.3M and interest that accumulated on the innovation loan from RVO NL (Dutch government).

Equity

The Company's equity at the end of 2023 remained positive at EUR 17.9M, decreasing by EUR 34.7M from the previous year. The movement is due to the loss for period of EUR 36.2M, adjusted for share-based compensation of EUR 2.6M, the actuarial loss on the remeasurement of post-employment benefits of EUR 0.9M, and currency translation differences of EUR 0.2M.



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Governance

Governance

General

ONWARD is a public limited liability company established under the laws of the Netherlands, with common shares listed on Euronext Brussels and Euronext Amsterdam. The Group is composed of ONWARD Medical N.V. (incorporated as a private limited liability company (B.V.) on 20 November 2015) and its wholly owned subsidiaries:

- ONWARD Medical S.A. (Swiss subsidiary established on 12 December 2014)
- ONWARD Medical Inc. (US subsidiary established on 13 September 2013)

The Company and its subsidiaries act as one company.

ONWARD's corporate governance is guided by the rules and principles set out in the Dutch Corporate Governance Code (the CGC), the Company's Articles of Association (AOA) and Dutch law. The AOA are available on the ONWARD website (onwd.com) under the Investors/Governance tab.

ONWARD maintains a Code of Conduct in order to promote a culture of good governance, excellence, and consistency that applies to all directors, officers, and employees. A copy of the Code of Conduct is available on the ONWARD website (onwd.com) under the Investors/Governance tab. The Code of Conduct outlines our commitment to be a responsible social partner and the way in which we attempt to interact with our stakeholders, including shareholders, suppliers, customers, employees, and SCI community. The Code of Conduct expresses our dedication to an economically, socially, and ethically sustainable way of working. The Board has received no indications that the Code is not effective or of any non-compliance.

Governance Framework

The Company's overall governance framework and key governance elements at each level are the following:

- For shareholders: the Articles of Association and Shareholder Dialogue Policy
- For the Board: the Board Rules, the Charter of the Audit Committee, the Charter of the Compensation Committee, and the Charter of the Nomination Committee

Board of Directors

ONWARD has a one-tier board consisting of one or more Executive Directors (*uitvoerend bestuurders*) and one or more Non-Executive Directors (*niet-uitvoerend bestuurders*), all of whom are individuals. Our CEO, as Executive Director, with the support of the Management Team, is charged primarily with the Company's day-to-day business and operations and the implementation of the Company's strategy. The Non-Executive Directors are primarily responsible for supervising the performance of the Executive Director.

In a one-tier governance structure such as that adopted by ONWARD, Non-Executive Directors and Executive Directors share responsibility for managing the company for those tasks and duties that are not delegated to one or more other specific Directors by virtue of Dutch law, the Articles of Association, or any other arrangement catered for therein (e.g., the Rules of the Board). It is therefore important that the Board ensure sufficient independent supervision by Non-Executive Directors.

In accordance with the CGC, the Board's role is to provide leadership and supervision to the Company on matters of strategy, risk management, and policies. It has overall responsibility



Governance

Composition of the Board of Directors

The Company has a one-tier Board consisting of 8 members.

for the management and control of the Company and is authorized to take all actions it deems necessary to achieve the Company’s purpose.

In performing their duties, Directors must be guided by the best interests of the Company and its stakeholders, including business partners, employees, and shareholders. The Board has drawn up Rules concerning its organization, decision-making, and other internal matters. These Rules are available on the ONWARD website (onwd.com) under the Investors/Governance tab.

The composition of the Board aims to ensure a broad diversity of experience, knowledge, and skills. The directors are appointed by the Company’s Annual General Meeting of shareholders upon nomination by the Board. The general meeting may dismiss a Director at any time by a two-thirds majority vote if less than half of the issued share capital is represented at the General Meeting, unless the resolution for dismissal is passed at the Board’s proposal.

Dutch law does not set a limit on the maximum number of consecutive terms that a Director may serve. According to the CGC, Non-Executive Directors may be elected for a maximum of two consecutive four-year terms and, subsequently, for a maximum of two consecutive two-year terms.

The Board meets as often as any Director considers necessary or appropriate. Resolutions are passed by a simple majority of votes cast. In the case of a tie in the vote of the Board, the resolution is not passed. Any resolutions concerning a material change to the character or identity of the Company or its business must be submitted to the Annual General Meeting for approval.

Name	Year of Birth	Nationality	Gender	Position	Year of First Appointed	End of Term
Jan Øhrstrøm	1957	Danish	Male	Independent Non-Executive Director & Chairperson	2016	Annual General Meeting of 2024
Dave Marver	1968	American	Male	Executive Director & CEO	2020	Annual General Meeting of 2025
Grégoire Courtine	1975	French	Male	Non-Executive Director & CSO	2016	Annual General Meeting of 2027 ^a
Ian Curtis	1968	British	Male	Independent Non-Executive Director & Vice-Chair	2019	Annual General Meeting of 2025
Fredericus Colen	1952	Dutch	Male	Independent Non-Executive Director	2017	Annual General Meeting of 2025
John de Koning	1968	Dutch	Male	Non-Executive Director	2016	Annual General Meeting of 2024
Kristina Dziekan	1968	German, Swiss	Female	Independent Non-Executive Director	2022	Annual General Meeting of 2026
Vivian Riefberg	1960	American	Female	Independent Non-Executive Director	2023	Annual General Meeting of 2027

^a: Reappointed at the Annual General Meeting held in 2023 for a period of four years.



Board Members’ Biographies

Jan Øhrstrøm has more than 30 years’ experience in the medical technology and pharmaceutical industries, with a proven track record of driving successful product approvals, private financings, and IPOs. He has held senior management roles at NovoNordisk, ProFibrix B.V., and ZymoGenetics, among others. He is currently Chairman of VarmX B.V., a company specializing in blood clotting agents, and is Chairman of Blaze Bioscience Inc. He holds an MD from the University of Copenhagen. Jan is the Board Chair, Chair of the Compensation Committee, and Chair of the Nomination and Corporate Governance Committee.

Dave Marver (CEO) is an accomplished chief executive and director with more than 25 years’ international experience in public, private, and emerging companies. He combines expertise in medical and consumer technology, wearables, and health monitoring. Previously, Dave spent almost 15 years with Medtronic, holding a variety of leadership positions in the US and Europe, including vice-president roles in sales, marketing, strategy, and business development. He then joined Nasdaq-listed Cardiac Science Corporation as CEO before co-founding two startups. He holds a BA in psychology from Duke University and an MBA from University of California, Los Angeles.

Grégoire Courtine is a full-time professor of neuroscience and neurotechnology at EPFL and Director of .NeuroRestore, a research center at EPFL and CHUV that develops innovative therapies using neurostimulation and other approaches. His groundbreaking research in neuroscience has been recognized by prestigious prizes including the Rolex Award, Schellenberg Research Prize, and Chancellor’s Award of the University of California. He holds a PhD in neurosciences from INSERM, Paris, and a PhD in medicine from the University of Pavia, Italy. As a founding Board member, Grégoire serves as a non-executive Director in addition to his role as CSO. Gregoire was reappointed for a second term at the Annual General Meeting in 2023.

Ian Curtis is a member of the Board of the Christopher and Dana Reeve Foundation and the International Spinal Research Trust. As the father of a young woman living with SCI, Ian is deeply committed to advancing research and treatment for SCI. He holds a BA in history from Durham University, is a fellow of the Institute of Chartered Accountants in England and Wales, former partner with PwC and Chairman of HPC plc. Ian is the Board Vice-Chair and Chair of the Audit Committee.

Fred Colen has more than 40 years’ experience in the medical device industry, with a track record of building strong organizations to bring new technology to market. Fred was the President and CEO of Neovasc Inc., a Canadian publicly traded company developing products for the cardiovascular marketplace, which was acquired by Shockwave Medical during 2023. Previously, he held senior executive roles at Boston Scientific and St. Jude Medical. He holds a MA in electrical engineering and specialized in medical technology from RWTH Aachen University, Germany. Fred is a Member of the Audit Committee and the Compensation Committee.

John de Koning is a General Partner at EQT Group (formerly LSP), one of the largest European investment firms providing financing for life sciences and healthcare companies. Since joining EQT Group in 2006, John has led some of its most successful investments and served on the board of several companies, including argenx, Merus, and Prosensa. He holds an MS in molecular biology from the University of Utrecht and a PhD in oncology from the Erasmus University Rotterdam. John is a Member of the Nomination and Corporate Governance Committee.

Kristina Dziekan is a senior advisor in market access, market development, and policy for life sciences companies. She previously served as She previously served in leadership roles as Head of Market Access, Government Affairs, and Tendering for Alcon’s Surgical Division in Europe, Senior Global Reimbursement and Health Economics Director for Medtronic Neuromodulation, and Health Outcomes Manager for GlaxoSmithKline in the UK and parts of Asia. She earned an MSc in health policy, planning, and financing from the London School of Economics, an MA in international economics and European Studies from Johns Hopkins University, a BA in philosophy, politics, and economics from Oxford University, and a Vordiplom in business administration and economics from Georg August University. Kristina is a Member of the Audit Committee.

Vivian Riefberg is currently the David C. Walentas Jefferson Scholars Chair Professor of Practice at the Darden School of Business at the University of Virginia and serves on the boards of Signify Health, K Health, and Lightrock, an impact investing firm, as well as the boards of the Public Broadcasting System (PBS), Johns Hopkins Medicine, the Lorna Breen Heroes Foundation, and the National Education Equity Lab. She is also an advisory board member for the Smithsonian’s planned American Women’s History Museum. She



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retired from McKinsey & Company in 2020 after 31 years, having served as co-leader of the US healthcare practice, leader of the public sector practice, and on McKinsey’s global board of directors. She previously served on the US National Institutes of Health (NIH) Clinical Center Board of Governors and the NIH Advisory Board for Clinical Research. She holds a BA, magna cum laude in history from Harvard-Radcliffe College and an MBA with distinction from Harvard Business School. Vivian is a Member of the Compensation Committee and the Nomination and Corporate Governance Committee.

Director Independence

In accordance with best practice provision 2.1.7 of the CGC, the majority of the Non-Executive Directors must be independent; at most, one Non-Executive Director does not have to meet the independence criteria. A Board member is considered “not independent” if he or she, a spouse, partner, or close family member (related by blood or marriage up to the second degree) meet any of the conditions listed below:

- Has been an employee or member of the management board of the Company, including associated companies (as referred to in Section 5:48 of the Financial Supervision Act Wet op het financieel toezicht/ Wft) in the five years prior to their appointment.
- Receives personal financial compensation from the Company, or an associated company, other than the compensation received for the work performed as a Board member.
- Has had an important business relationship with the Company or an associated company in the year prior to the appointment.
- Is an executive of a company in which a member of the management board of the company which he supervises is a non-executive Board member.
- Has temporarily performed management duties during the previous twelve months in the absence or incapacity of a member of the management board.
- Has a shareholding in the Company of at least 10%.

- Is a member of the management board or supervisory board, or a representative in some other way, of a legal entity that holds at least 10% of the shares in the company, unless the entity is a group company.

At the date of this Annual Report, the Board consists of eight members, of whom seven are Non-Executive Directors. Two of these Non-Executive Directors are deemed “not independent” based on meeting certain of the conditions above. Prof. Courtine, one of the Company’s founders, is considered “not independent” as he is the Chief Science Officer of the Company and receives personal compensation for such a role. John de Koning is considered “not independent” as he is a representative of a major shareholder holding at least 10% of the shares in the Company (EQT Group (formerly LSP)). The requirements for independence as per best practice provision 2.1.7 of the CGC are met.

Committees within the Board of Directors

The Board has established the following three committees:

- the Audit Committee
- the Compensation Committee
- the Nomination and Corporate Governance Committee

Non-Executive Directors are appointed to committees by the Board. The committees report their findings to the Board, which is ultimately responsible for all decision-making. The role, responsibility, and functioning of each committee is summarized below.



Audit Committee

The Audit Committee comprises three members: Ian Curtis (Chair), Fred Colen, and Kristina Dziekan.

In accordance with its charter, the Audit Committee is charged with the following matters:

- a. Monitoring the Board with respect to:
 - relations with the internal audit function and the external auditor, as well as compliance with recommendations and follow-up of comments
 - the Company’s funding
 - the application of information and communication technology by the Company, including risks relating to cybersecurity
 - the Company’s tax policy
 - b. Issuing recommendations concerning the appointment and the dismissal of the head of the internal audit function, as relevant, and reviewing and discussing the performance of the internal audit function.
- ONWARD has not yet established a separate internal audit function and the related responsibilities as per the charter do not apply.
- c. Reviewing and discussing the Company’s audit plan, including with the internal audit function and the external auditor.
 - d. Reviewing and discussing the essence of the audit results, also with the internal audit function, including:
 - flaws in the effectiveness of the Company’s internal risk management and control systems (“Internal Controls”)
 - findings and observations with a material impact on the Company’s risk profile
 - failings in the follow-up of recommendations made previously by the internal audit function

- e. Monitoring the audit of the Company’s annual accounts, annual report, and financial reporting processes, and making proposals to safeguard the integrity of these processes.
- f. Reviewing and discussing the effectiveness of the design and operation of the Internal Controls with the Board, the CEO, and the CFO, including identified material failings in the Internal Controls and material changes made to, and material improvements planned for, the Internal Controls.
- g. Reviewing and monitoring the independence of the external auditor, also considering any non-audit services rendered by the external auditor.
- h. Submitting proposals to the Board concerning the external auditor’s engagement to audit the Company’s financial statements, including the scope of the audit, the materiality standard to be applied, and the external auditor’s fees.

The members of the Audit Committee are appointed and dismissed by the Board. More than half of all its members, including the chairperson, must be independent within the meaning of the CGC and at least one committee member must have competence in accounting and/or auditing.

The Audit Committee shall meet as often as it determines is appropriate to carry out its responsibilities and each meeting shall be presided over by the chairperson and, in the absence of the chairperson, one of the other members shall be designated as the acting chairperson of the meeting.



Compensation Committee

The Compensation Committee comprises three members: Jan Øhrstrøm (Chair), Fred Colen, and Vivian Riefberg. In deviation from best practice provision 2.3.4/5.1.4 of the CGC, the Compensation Committee is led by Jan Øhrstrøm, who is also chairperson of the Board. (Refer to ‘Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code’). The Board considers that the experience and continuity of Dr. Øhrstrøm being chair of the Compensation Committee outweighs the disadvantages of him holding both positions.

In accordance with its charter, the Compensation Committee is charged with the following matters:

- a. Submitting proposals to the Board concerning changes to the Company’s compensation policy.
- b. Submitting proposals to the Board concerning the compensation of individual Directors, covering:
 - compensation structure
 - amount of the fixed and variable compensation components
 - applicable performance criteria
 - scenario analyses that have been carried out
 - pay ratios within the Company’s group
 - views of the Director concerned regarding the amount and structure of his or her own compensation
- c. The preparation of the Company’s compensation report for the Board.

Nomination and Corporate Governance Committee

The Nomination and Corporate Governance Committee comprises three directors: Jan Øhrstrøm (Chair), John de Koning, and Vivian Riefberg. Jan Øhrstrøm serves as chairperson of the Nomination and Corporate Governance Committee.

In accordance with its charter, the Nomination and Governance Committee is charged with the following matters:

- a. Drawing up selection criteria and appointment procedures for the Directors.
- b. Reviewing the size and composition of the Board and submitting proposals for the composition profile of the Board.
- c. Reviewing the functioning of individual directors and reporting on such reviews to the Board.
- d. Drawing up a plan for the succession of directors.
- e. Submitting proposals for (re)appointment of directors.
- f. Supervising the policy of the Board regarding the selection criteria and appointment procedures for the Company’s senior management and executive officers

Management Team

The Management Team is responsible for running the Company in accordance with the strategies, policies, and budgets determined by the Board. It has all powers except for those reserved for the Board and the General Meeting of shareholders by law and by the Company’s Articles of Association.

The members of the Management Team commit to carrying out their duties in accordance with the highest business, ethical, moral, and legal standards laid out in the Company’s Code of Business Conduct and Ethics (see onwd.com, Investors/Governance). They strive to lead by example by embodying the ONWARD code of values in everything they do. The Management Team meets at least once a week.



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Name	Position	Member Since
Dave Marver	Chief Executive Officer	2020
Grégoire Courtine	Chief Science Officer	2016
John Murphy	Chief Technology Officer	2020
Khaled Bahi	Chief Financial Officer	2023*
Erika Ross Ellison	VP Clinical, Regulatory & Quality	2023
Sarah Moore	VP Global Marketing	2023
Andy Dolan	VP Sales	2021**
Robert Odell	VP Operations	2023***

*Khaled Bahi joined as interim CFO on 1 October 2023, succeeding Lara Smith Weber who stepped down 30 September 2023.

**Andy Dolan stepped down as VP Sales on 26 January 2024.

***Robert Odell joined as VP Operations on 1 July 2023, succeeding Zouhir Mehta.

Biographies of the Management Team

Dave Marver (see biography p. 127).

Grégoire Courtine (see biography p. 127).

John Murphy has over 25 years of experience driving the development of medical implants and neurostimulation devices at LivaNova, Abbott, and Medtronic. His leadership expertise spans the continuum of R&D, with a focus on consumer-centric design, IP generation, and agile processes. Prior to joining ONWARD in 2020, John was the Chief Technology Officer of LivaNova Neuromodulation. He holds a BS in electrical engineering from the University of North Carolina at Charlotte and a PhD in production systems and robotics from EPFL.

Khaled Bahi brings more than 20 years of finance experience in the medtech industry. Early in his career, he was a corporate and investment banker with Crédit Lyonnais and the Industrial Bank of Japan. Prior to joining ONWARD, Khaled served as CFO of Lausanne-based Symetis, acquired by Boston Scientific in 2017 for USD 435 million, and Paris-based Stilla Technologies. He was also a finance leader with Fresenius Medical Care for 15 years in different corporate and regional roles in Europe, Latin America, Middle East, and Africa. Khaled holds a MSc in Physics from the ETH Zurich.

Erika Ross Ellison joined ONWARD from Abbott Neuromodulation, where she was Director, Global Clinical & Applied Research. Previously, as Neuroscience Director at Cala Health, she managed the scientific research program that led to de novo clearance and launch of the company’s neurostimulation technology. Erika also served as Deputy Director, Medical Device Innovation Accelerator, Department of Surgery and Assistant Professor, Department of Neurologic Surgery at Mayo Clinic. Erika holds a BSc in Biology and Business and an MSc in Molecular Biology from the University of Denver, and a PhD in Neuroscience from Mayo Clinic

Sarah Moore has over 20 years of experience in marketing and general management. Sarah comes to ONWARD from Nevro, an implantable neuromodulation company, where she served as Head of Commercial Marketing. Prior to that, she held various leadership roles in global marketing across multiple Johnson & Johnson medical device franchises, most recently as the business unit leader for J&J’s Advanced Imaging business. Sarah earned an MBA from Duke University and a BA in German from Washington and Lee University.

Andy Dolan has 20 years of experience in marketing, business development, and organizational leadership at medical device companies, both private and public. Before joining ONWARD in 2021, Andy held senior roles in sales and marketing at ReWalk Robotics, Boston Scientific, Johnson & Johnson, and Integra LifeSciences. He holds an MBA from the University of Massachusetts and a graduate certificate in bioengineering from Tufts University. He also serves as a United States Navy Reserve Public Affairs Officer.

Robert Odell brings to ONWARD decades of technology and leadership experience in the medical device industry. Prior to joining ONWARD, Robert was President and Chief Operating Officer of Cardiac Insight, Inc., a successful startup that created and introduced



disruptive cardiac monitoring technology. Prior to Cardiac Insight, he served as COO for Cardiac Science, a publicly traded manufacturer of Class II and Class III devices. Robert has held executive assignments in Operations, Engineering, Marketing, Business Development, Information Technology, and QA/RA with such notables as GE Healthcare, Siemens Medical Solutions, Philips Medical Systems, Medtronic, and Analogic. The foundation for his career is a degree in electrical engineering from Syracuse University.

Diversity and Inclusion

The diversity policy as adopted does not define specific targets. It is the ambition that both the Board and Management Team should comprise one-third of female members, while also ensuring diversity in terms of background, skills, and age. This policy is available on the ONWARD website (onwd.com) under the Investors/Governance tab. ONWARD’s Board consists of 6 male directors (1 being an executive director) and 2 female directors (both Non-Executive Directors), therefore 2 of the 5 Non-Executive Directors are female. The Management team consists of 6 male members and 2 female members. ONWARD will continue its efforts to recruit independent Directors and management team members with backgrounds that would help it achieve its independence and diversity ambitions. In deviation with best practice provision 2.1.6 of the CGC, the Company’s existing policy does not include specific goals for diversity and inclusion.

ONWARD takes pride in the inclusive culture it has created, founded on the principles of the ONWARD code. A culture where every employee feels valued and respected, has access to equal opportunities regardless of identity. In deviation with best practice provision 2.1.5 of the CGC, ONWARD’s efforts to create an inclusive culture have not yet been formalized within the diversity policy.

Stakeholder Dialogue

The Company has drawn up an outline policy for effective dialogue with stakeholders. The company is prepared to engage in a dialogue and will facilitate this dialogue unless, in the opinion of the Board and Management Team, this is not in the interests of the Company and its affiliated enterprise. This policy is available on the ONWARD website (onwd.com) under the Investors/Governance tab.

Conflicts of Interest

According to principle 2.7.4 of the CGC, the Company must report on directors’ conflicts of interest in transactions in its management report where the conflict of interest is of material significance to the Company or to the relevant director. Directors and members of management are expected to arrange their personal affairs so as to avoid conflict of interest. Any potential conflict of interest must be brought to the attention of the Board.

Certain directors and members of the Management Team have a direct or indirect beneficial interest in ONWARD’s share capital or serve as a representative of a legal entity that is a major shareholder. In their capacity as non-executive directors, their primary duty is to supervise the performance of the executive directors and the management of the Company and its business. A conflict of interest may arise if a decision aimed at contributing to the Company’s long-term and sustainable success negatively impacts its share price in the short term, thereby reducing the value of the shareholding of which the non-executive director is a representative.

As of 31 December 2023, the potential conflicts of interests between the duties to the Company of each of the directors and members of the Management Team and their private interests or other professional duties were as follows:

- a. Grégoire Courtine is the Chief Science Officer and a Non-Executive Director of the Company.
- b. John de Koning represents EQT, a major shareholder of the Company and Non-Executive Director of the Company.

No transactions that would result in a conflict of interest were reported to the Board in 2023.

Related Party Transactions

While ONWARD does not have a related party transaction policy, it complies with the recommendations of the Dutch Civil Code (DCC) in this respect.

The Dutch act to implement the EU Shareholder Rights Directive II (*Bevordering van de langetermijnbetrokkenheid van aandeelhouders*, “Dutch SRD Act”), which entered into



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force on 1 December 2019, added new rules on related party transactions to the DCC. These rules stipulate that “material transactions” with “related parties” that are not entered into within the ordinary course of business or not concluded on normal market terms must be approved by the Board and be publicly announced at the time of or before the transaction takes place. The Board is required to establish an internal procedure to periodically assess whether transactions with related parties are concluded in the ordinary course of business and on normal market terms.

In particular, all transactions between ONWARD and a shareholder holding 10% or more of issued share capital should be agreed on customary terms. Decisions to enter into such a transaction that is of material significance to the Company and/or to the shareholder concerned should be approved by the Board. Any such transaction should be disclosed in the Company’s Board report, together with an affirmative statement that these recommendations of the Code have been complied with.

No related party transactions with a shareholder holding 10% or more of the issued share capital were reported to the Board in 2023.

General Meeting

The main powers of the General Meeting relate to:

- the issuance of shares or rights to shares, restriction, or exclusion of pre-emptive rights of shareholders, repurchase of shares, and reduction of the issued share capital
- the amendment of the Articles of Association
- the appointment, suspension, and dismissal of members of the Board
- decisions of the Board involving a significant change in the Company’s identity of character
- the approval of the remuneration policy of the Board
- the adoption of the financial statements and declaration of dividends
- the appointment of the Company’s external auditor

The Annual General Meeting is held within six months after the end of the financial year to discuss and, if applicable, approve, the Annual Report, the Annual Accounts, and any of the other topics mentioned above.

The Annual General Meeting and, if necessary, other General Meetings, are convened by the Board. The agenda and explanatory notes are published on the Company website.

The last Annual General Meeting was held on 8 May 2023. The agenda, explanatory notes and minutes are published on the Company website. The next Annual General Meeting is scheduled for 14 June 2024.

Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code

ONWARD acknowledges the importance of good governance and is committed to adhering to the best practices of the CGC as much as possible. As of the date of this Annual Report, we report the following deviations from the CGC:

- **Best practice provision 2.1.5. and 2.1.6** The CGC provides that the diversity policy should include appropriate targets for inclusion and the creation of psychological safety. Despite ONWARD’s efforts to create an inclusive culture, this has not yet been formalized within the diversity policy. The CGC also requires that the policy includes clear goals for diversity and inclusion and a plan to achieve these. The existing policy does not include specific diversity and inclusion goals nor a plan for achievement. The Company will update the existing diversity policy to formally reflect its approach to inclusion, defining goals and a plan to achieve this for measurement in future.
- **Best practice provision 2.1.5. and 2.1.6** requires that the periodic evaluation of the functioning of the Board and Board committees should be performed under the supervision of an external expert. The 2023 evaluation was not performed under external supervision. External supervision will be considered for future evaluations.
- **Best practice provision 2.3.4/5.1.4.** The CGC provides that the Compensation Committee should not be chaired by the Chairperson of the Board. In deviation from the CGC, the Compensation Committee is chaired by the Chairperson of the Board. The Board considered that the experience and continuity of Jan Øhrstrøm being



chairperson of the Compensation Committee outweighs the disadvantages of him also being the Chairperson of the Board. For the reasons provided, the Company does not intend to fully comply with this best practice provision.

- **Best practice provision 3.1.2 v** The CGC recommends that variable remuneration should be linked to measurable performance criteria determined in advance. To align the employees' interest with the interests of the shareholders and to allow the participation in the long-term growth of the Company, options were granted to the Management Team (including the Executive Director). There are no specific performance conditions associated to these options, only a service condition. However, considering that the value of the option is linked to the share price of ONWARD, it includes an inherent performance criterion. Furthermore, the size of the stock option is linked to the position and job grade of the individual and is contingent on the performance of the individual. We will consider if more clear measurable performance criteria should be added to future grants.
- **Best practice provision 3.3.3.** The CGC recommends that shares held by a non-executive director in the company on whose Board of Directors they serve should be held as a long-term investment. The Company's Compensation Policy does not include such a requirement.
- **Best practice provision 4.3.3.** The CGC recommends that the General Meeting should be capable of passing a resolution cancelling the binding nature of a nomination or dismissal by simple majority, representing no more than one-third of the issued share capital. Under the Articles of Association, directors can only be appointed or dismissed by the General Meeting by simple majority of votes cast, provided that the Board proposes the appointment or dismissal. In other cases, the General Meeting can only pass a resolution to appoint or dismiss a director by a two-thirds majority representing more than half of the issued share capital. The Company deems this appropriate considering the remaining shareholdings and involvement of the Company's current significant shareholders.



ONWARD®

Risk Management & Control

Risk Management & Control

Analyzing, monitoring, and managing internal and external risks is crucial to ensuring that we meet our ambitious targets, that our financial information is reliable, and that our activities comply with all applicable laws and regulations. Current risks mainly concern research and development of our ARC Therapies, securing regulatory approvals, protecting our intellectual property, and maintaining equity in the Company's mid- to long-term financing.

The Management Team is responsible for developing, implementing, and operating adequate risk management and internal control systems. The Board has a control function with respect to these systems. Our risk-management and internal control systems are reviewed, updated, and optimized as an ongoing process based on internal evaluations, discussions with the Board and the Audit Committee, and audits from external parties.

The outcome of the annual risk review, as initiated in 2022, has been incorporated into this report. With the support of an external consultant, we formalized our internal control framework which will be implemented in 2024. Except for this, there were no major changes in the risk management and control systems in the year under review.

As ONWARD has not established a separate internal audit function, the Board annually assesses whether adequate alternative measures have been taken. Based on the Audit Committee's recommendations, Directors may consider whether it is necessary to establish an internal audit function. In 2023, no material failings in the internal risk-management and control systems were discovered.

It should be noted that these systems cannot provide absolute assurance that the Company will realize its targets, nor can they prevent all misstatements, errors, and non-compliances with legislation, rules, and regulations.



Risk Control Matters

The Company has deployed a risk detection, evaluation, and management system fitting to its size and history. The Board and Management Team continuously analyze potential risks, evaluate their (financial) impact and likelihood, and determine appropriate measures to minimize these risks. Risk assessments are updated in line with changing internal and external circumstances.

The Board and Management Team meet regularly to review developments, set targets and milestones, and evaluate progress towards realizing them. During these meetings, they also review ONWARD’s financial position and present budgets/cashflow forecasts, which are followed up and regularly adjusted to changing prospects. The Management Team monitors risks as they arise and evolve, assesses their development, and implements necessary countermeasures as required.

To manage our business risks, we use highly experienced staff and external consultants for our research and clinical studies. The results of our studies are monitored constantly, closely, and systematically. This enables us to react early to new findings, and to conduct pre-clinical and clinical activities. By closely monitoring the costs associated with these activities through our regular internal budget and monitoring processes, we can recognize any deviations from our financial plans early on and initiate appropriate countermeasures.

We are highly dependent on third parties to enable us to meet our regulatory requirements and our own quality standards. We therefore take special care in selecting our contractors. Major clinical trial and component service providers are selected through a stringent selection process driven by the Management Team, in which we assess the quality and experience of several candidates. We constantly review and assess the operational performance of the organizations we work with.

We work with only highly specialized consultants and attorneys to secure and monitor our intellectual property (IP). In addition, the Management Team regularly monitors ongoing patent protection and potential conflicts.

In relation to our financial reporting process, our risk-management and internal control systems are designed to provide reasonable assurance that our books and records accurately reflect the transactions necessary to permit preparation of financial statements; that the financial reporting is consistent and compliant with legal regulations and generally accepted accounting principles; and that published financial data do not contain any material misstatements. The systems also provide reasonable assurance that all receipts and expenditures are only made by people authorized to do so and that assets are safeguarded. To manage risks associated with valuation uncertainties, we engage specialists with the required skills to assist with these valuations for financial reporting purposes. This includes but is not limited to the valuation of the defined benefit obligation and the determination of the fair value of options granted.

As part of this system, we have adopted various internal rules and regulations, including standard operating procedures, the dual-control principle, spot checks, automated expenses reimbursement tooling, internal contract approval processes, and signatory rules.

Risk Appetite

Our risk appetite differs according to the various risk categories ONWARD is exposed to, namely:

- **Risks related to our business, strategy and industry** include adverse, unexpected developments resulting from internal processes, people, and systems or from our external research partners and external events, which are linked to the operation of the business. We are prepared to take moderate risks to achieve our ambitions and to balance risk and long-term reward.
- **Risks related to legal and government regulation** relate to unanticipated failures to comply with applicable laws and regulations. We aim to minimize these risks by aiming to comply fully with these laws and regulations.
- **Risks related to intellectual property.** We aim to minimize these risks, only accepting a low level, to ensure that intellectual property is protected.



Risk Management & Control

- **Risks related to our financial position, need for additional capital, and taxation** occur in connection with funding, treasury, tax, accounting, and reporting. ONWARD is prudent with respect to these financial risks, with the aim of maintaining long-term solvency. We are committed to transparent and truthful accounting and reporting that allow users of financial statements to make decisions considering these risks. We currently do not engage in any hedging activities. Our financial risk management is set out in note 4.3 of our consolidated financial statements.

Description of the Principal Risks Associated with the Company’s Activities

at all the FDA clearance and CE-mark for its platforms in different indications in the US and the EU. ONWARD proactively manages this risk through a dedicated skilled regulatory team, continuous communication, and mitigating quality issues with our third-party suppliers.

The following section describes the main risks and uncertainties that we consider the major threats to achieving our objectives and that may affect the future operating and financial performance on the Company and the value of an investment in the Company’s securities. Additional risks and uncertainties not presently known, or that management currently believes to be immaterial, may also have an adverse effect on our business, financial condition, results of operations, and prospects. If any of those risks or uncertainties occur, the price of the Company’s securities may decline and subscribers for the Company’s securities could lose all or part of their investment. All of these risks are contingencies which may or may not occur and have not been listed here.

Risks Related to the Company’s Business, Strategy & Industry

The Company wholly depends on the success of two investigational devices, the ARC^{IM} and ARC^{EX} platforms. Even if the Company completes clinical development and obtains favorable clinical results for the initial indications it is pursuing, it may not be able to obtain regulatory clearance or approval for, or successfully commercialize, its ARC^{IM} and ARC^{EX} platforms.

ONWARD currently has two investigational devices in clinical development – the ARC^{IM} and ARC^{EX} platforms – and our business depends almost entirely on the successful clinical development, regulatory clearance or approval, and commercialization of these investigational devices, which may never occur. We currently have no products available for sale, generate no revenues from sales of products, and may never successfully develop marketable products.

Our ARC^{IM} platform will require substantial additional clinical development, testing, manufacturing process development, and regulatory clearance or approval before we are permitted to commence their commercialization. For example, before obtaining Premarket Approval Application (PMA) approval from the FDA for our ARC^{IM} platform, we must show, among other things, that the product is safe and effective for use in each target indication, a process that can take many years.

If we opt to seek approval via the FDA’s Humanitarian Device Exemption (HDE) pathway for the commercial sale of ARC^{IM}, we must show through extensive pre-clinical testing and clinical trials that the product candidate does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, considering the probable risks and benefits of currently available devices or alternative forms of treatment.

Of the substantial number of medical devices in development in the US, only a small percentage successfully complete the regulatory clearance or approval process required by the FDA and become commercialized. Similarly, many medical devices currently in development will ultimately not obtain the certificate of conformity required for commercialization in the European Economic Area (EEA). Therefore, even if we obtain the requisite capital to continue funding our development and clinical programs, we may be unable to successfully develop or commercialize our ARC^{IM} and ARC^{EX} platforms or any other product candidate.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult, or rendered impossible, by multiple factors outside the Company’s control. This could significantly delay the completion of such trials or may cause the Company to abandon one or more clinical trials.



Risk Management & Control

ONWARD may encounter delays or difficulties in enrolling – or may be unable to enroll – a sufficient number of patients to complete any of its clinical trials on its current timelines, or at all. Even once candidates are enrolled, the Company may be unable to retain a sufficient number of patients to complete any of its trials.

Patient enrollment in clinical trials, and completion of patient follow-up, depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, eligibility criteria for the clinical trial, patient compliance, competing clinical trials, and clinicians’ and patients’ perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be cleared or approved for the indications we are investigating.

Patients may be discouraged from enrolling in ONWARD’s clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor’s product candidate. Patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to the products. Delays in patient enrollment, or failure of patients to continue participating in a clinical trial, may delay commencement or completion of the clinical trial, increase in the costs of the clinical trial, or result in failure of the clinical trial.

Since some of the indications that our investigational devices are intended to treat are limited, ONWARD expects only a subset of patients with spinal cord injury (SCI) to be eligible for its clinical trials. The protocols for our clinical trials generally mandate that a patient cannot be involved in more than one clinical trial for the same indication. Therefore, subjects who participate in ongoing clinical trials for products that compete with our investigational devices are not eligible to participate in our clinical trials. ONWARD cannot guarantee that any of its programs will identify a sufficient number of patients to complete clinical development, pursue regulatory clearance or approval, or market its investigational devices, if cleared or approved.

An inability to recruit and enroll a sufficient number of patients for any of its current or future clinical trials would result in significant project delays, or may require us to abandon one or more clinical trials altogether, which could impact ONWARD’s ability to develop its investigational devices and may have a material adverse effect on its business, results of operations, and financial condition.

If cleared or approved, the Company may not be able to successfully commercialize its ARC^{EX} and ARC^{IM} platforms. Failure to gain market acceptance would impact the Company’s revenues and may materially impair its ability to continue its business.

Even if ONWARD receives regulatory clearances or approvals, the commercial success of our products will depend in part on their acceptance by critical stakeholders as a therapeutic and cost-effective alternative to competing products and treatments for people with SCI. Critical stakeholder to adopt our therapies include medical professionals working in the rehabilitation clinic setting (such as physicians, physical therapists, occupational therapists, neurologists, and physiatrists), functional neurosurgeons, patients, third-party payors such as health insurance companies, and other members of the medical community. There can be no assurance that medical professionals, hospitals, and rehabilitation clinics will adopt the use of ARC^{EX} and ARC^{IM} and establish training and procedures to implement them. Market acceptance of, and demand for, any product we may develop and commercialize will depend on many factors, both within and outside of our control. Payors may view new or recently launched products, or products where limited clinical data is available, as investigational, unproven, or experimental, and on that basis may deny coverage of procedures involving use of these products or require additional clinical trials and data before providing coverage. If our investigational devices fail to gain market acceptance, ONWARD may be unable to earn sufficient revenue to continue our business.

If the Company obtains clearance or approval for its products, their commercial success will depend in part on the level of reimbursement it receives from third parties for the cost of its products to users.

In most markets, third parties such as health insurers, government-managed healthcare schemes, or managed care organizations decide which treatments they will cover and



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how much of the cost they will reimburse. These reimbursement systems vary widely, meaning that approval for reimbursement must be obtained on a country-by-country basis. ONWARD’s business could be adversely affected if hospitals or other users are not able to obtain and maintain coverage and adequate reimbursement for procedures using our devices.

Additionally, third-party payors, especially in the US, are increasingly examining not only product safety and effectiveness but also their cost-effectiveness when making coverage and payment decisions. It is uncertain whether ONWARD’s current products, or any planned or future products, will be viewed as sufficiently cost-effective to warrant coverage and adequate reimbursement levels in any given jurisdiction.

The Company relies on a limited number of third-party suppliers and contract manufacturers to produce and assemble its products. Loss or degradation in performance of these suppliers and contract manufacturers could have a material adverse effect on the Company’s business, financial condition, and results of operations. Reliance on a limited number of third-party suppliers and in some cases single-source suppliers, makes the Company vulnerable to supply shortages and problems and price fluctuations, which could further harm our business.

We rely on a limited number of third parties, some of whom are sole suppliers, to purchase materials and components, and/or to manufacture and assemble our ARC^{EX} and ARC^{IM} platforms. Our ability to supply our products for clinical trials and, ultimately, to market them and to develop future products, depends on the availability of sufficient quantities of materials, components, and manufacturing services that meet regulatory requirements. While we seek to maintain sufficient levels of inventory at all times, this may not fully protect us from supply interruptions.

Our suppliers and contract manufacturers have generally met our demand for their products and services on a timely basis. However, relationships with suppliers may be disrupted due to a number of factors, such as unforeseen events that delay production or a decision by either party to terminate the relationship.

If that occurs, we are confident that we will find alternative suppliers to meet all our needs. However, due to the relatively low volume of orders and the bespoke nature of our

requirements, establishing new relationships would be a time-consuming and expensive process. We would need to verify that the new supplier or third-party manufacturer maintains their facilities, procedures, and operations in accordance with ONWARD’s quality standards and all applicable regulatory requirements. In addition, our contract manufacturers could require that we move production to a different facility or use alternative materials or components. Any of these events could require us to modify the designs or specifications of our products, and to secure new regulatory approval before implementing the change, which could result in further delay or a refusal to grant clearance.

The Company’s operations and reputation may be impaired if its information technology systems fail to perform adequately or if it is the subject of a data breach or cyberattack.

Our information technology (IT) systems are essential to the successful operation of our business. We seek to allocate and manage the necessary resources to build, maintain, and protect our IT systems and infrastructure, as well as oversee third-party service providers. Any failure of our IT systems to perform as anticipated could disrupt our operations and result in transaction or reporting errors that could harm our business.

Our IT systems may be vulnerable to cyberattacks or other security incidents, service disruptions, or other system or process failures. Such incidents could result in unauthorized access to vendor, consumer, or other types of confidential data, as well as disruptions to operations. While we have experienced such incidents in the past, none have been material to date.

We rely on third-party vendors for some of our IT processes and data management needs, which makes our operations vulnerable to a failure by any one of these vendors to perform adequately or to maintain effective internal controls.

To address these risks, we maintain an information security program that includes updating technology, developing security policies and procedures, implementing and assessing the effectiveness of controls, conducting risk assessments of third-party service providers, and adopting business processes designed to mitigate the risk of security breaches. However, there can be no assurance that these measures will prevent or limit the negative impact of a future incident on our operations or business reputation.



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A pandemic, epidemic, or outbreak of an infectious disease in Europe, the US, or worldwide, including the outbreak of the novel strain of coronavirus disease (COVID-19), could adversely affect the Company's business.

A future wide-scale outbreak of infectious disease similar to COVID-19 could negatively affect our business in numerous ways. Our sales representatives, clinical specialists, and other personnel may be unable to travel and access customers for training and case support. Our production schedule may be affected if suppliers cannot manufacture or deliver parts and components on time. Pandemic-related restrictions could lead to, inventory shortages or obsolescence; delays in approval of our devices by regulatory authorities; delays in decisions by insurance companies regarding coverage of our products; delays in clinical trials; delays in growing our sales organization; adjustments or disruptions to the business of third parties we work with, including suppliers, medical institutions, and clinical investigators; decreases in collectability of our account receivables due to the adverse impact of the pandemic on our clients' cash flows; and reduced capacity of our suppliers to advance our investigational devices through clinical trials.

While it is difficult to predict the potential economic impact and duration of a future outbreak, the current pandemic has resulted in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction could have an adverse effect on our long-term business as hospitals reduce capital spending.

To the extent that a pandemic adversely affects our business and financial results, it may also heighten many other risks described in this section, including those relating to incurring future operating losses, advance of the ARC^{EX} and ARC^{IM} platforms through regulatory pathways, and, if cleared or approved, successful commercialization, supply chain, and distribution channels.

The Company's success depends on its ability to retain its management, consultants and other key personnel.

ONWARD depends on its senior management as well as key scientific personnel. In 2020, Dave Marver was appointed as Chief Executive Officer. ONWARD's Chief Scientific Officer,

Prof. Courtine, has been on the team since inception, in 2015, and currently serves as a consultant. The loss of any members of senior management or key scientific personnel could harm our business and significantly delay or prevent the achievement of research, development, or business objectives.

Our future success also depends on our ability to attract, hire, train, and retain other highly skilled scientific, technical, marketing, managerial, and financial personnel, as well as sales personnel once commercialization begins. Although we will make every effort to hire and retain qualified employees whose experience and abilities meet our needs, there is no assurance that we will succeed. Competition for personnel in the medical technology industry is intense, and any failure to attract and retain the necessary personnel would have a material adverse effect on our business.

The Company may face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than it does.

Currently, ARC^{IM} does not have any direct commercial competitors. However, several large medical technology companies market spinal cord stimulation platforms for different indications, such as pain management. Though we believe our IP rights would prevent competitors from being able to commercialize similar devices utilizing ONWARD's IP-protected waveform, there can be no guarantee that we will be able to enforce our IP rights. The outcome of any potential IP dispute to protect our rights is hard to predict, and an adverse result could negatively impact our position in the competitive landscape of SCI therapies.

Current therapeutic options and technological approaches for people with SCI include exoskeletons, functional electrical stimulation FES, epidural electrical stimulation EES, peripheral nerve stimulation PNS, scaffolds, and stem cells. Additionally, there are numerous pharmacological treatments available for people with SCI to address symptoms of associated comorbidities such as spasticity, blood pressure, and mood disorders.

In general, the medical device industry is subject to intense competition and rapid and significant technological change. ONWARD has many potential competitors, including specialized biotechnology firms, academic institutions, government agencies, and private



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and public research institutions. These competitors may have significantly greater financial and technical resources than ONWARD, and superior experience and expertise in research and development, pre-clinical testing, design and implementation of clinical trials, regulatory processes and approval for products, production and manufacturing, and sales and marketing of approved products. Smaller or early-stage companies and research institutions may prove to be significant competitors, particularly if they have collaborative arrangements with larger and more established medical device companies.

The Company’s business involves the use of hazardous materials such as lithium batteries and the Company and its third-party manufacturers must comply with environmental laws and regulations, which may be expensive and restrict how it does business.

ONWARD’s activities and those of our third-party manufacturers’ may involve the controlled storage, use, and disposal of hazardous materials. For example, our ARC^{IM} and ARC^{EX} investigational devices use lithium batteries. ONWARD and our third-party manufacturers are subject to federal, state, local, and foreign laws and regulations governing the use, generation, manufacture, storage, handling, and disposal of these hazardous materials. The Company currently carries no insurance specifically covering environmental claims relating to the use of hazardous materials. Despite the safety procedures put in place by ONWARD and its manufacturers for handling and disposing of these materials and waste, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling, or disposal of hazardous materials. In the event of an accident, state or federal or other competent authorities may curtail ONWARD’s or its manufacturers’ use of these materials and interrupt their business operations, which could adversely affect our business.

Healthcare reform initiatives and other administrative and legislative proposals in the United States may adversely affect the Company’s business, financial condition, results of operations and cash flows in one of its key markets.

There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of healthcare and, more generally, to reform the US healthcare system. Certain proposals could limit the prices we are able to charge for our products, or the coverage and

reimbursement available for our products, and could limit the acceptance and availability of our product candidates. The adoption of proposals to control costs, such as the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “Affordable Care Act”), could have a material adverse effect on ONWARD’s business, financial condition, and results of operations. There is no certainty that the Affordable Care Act, as currently enacted or as amended in the future, will not harm our business and financial results, and it is not possible to predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. It is not possible to predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- ONWARD’s ability to set a price that it believes is fair for its products
- ONWARD’s ability to generate revenue and achieve or maintain profitability
- The availability of capital

Further, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several US Congressional inquiries, as well as proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, may prevent or limit ONWARD’s ability to generate revenue and attain profitability.

In the European Union, there are currently no concrete legislative proposals in this regard. However, the cost-effectiveness of healthcare is part of the EU agenda on effective, accessible, and resilient health systems. This does not exclude that legislation



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on maximum pricing for medical devices (e.g., in terms of their reimbursement) may be applied or developed at the national level.

Interruption or distress in the supply chain due to geopolitical, climate-related, and other uncertainties beyond the Company’s control.

Geopolitical uncertainties and other business threats could damage or disrupt ONWARD’s operations and those of our suppliers, partners, or collaborators. Interruptions to our operations could adversely affect the anticipated timing, completion, and/or results of clinical trials, and potential future commercialization efforts. Geopolitical tensions could lead to sharply rising energy prices, which would have a negative impact on raw materials of our products. Uncertainty in global markets may have a wide impact on the availability and price of various materials and services and may also sustainably affect global financial markets. Cost inflation may negatively impact our cash reach, while capital markets disruptions may adversely affect our future financing possibilities. All these changes may materially affect ONWARD’S business and negatively affect its liquidity and financial position. Climate change presents risks to our operations, including the potential for additional regulatory requirements and associated costs. The potential for more frequent and severe weather events and water availability challenges could impact our facilities and those of our suppliers. We cannot provide assurance that physical risks to our facilities or supply chain due to climate change will not occur in the future. We have assessed the impact of climate-related risks on our Financial Statements and conclude that the effects of climate-related risks do not have a material impact on accounts and disclosures, including judgements and estimates in the Financial Statements.

Risks Related to Legal & Government Regulation

The Company must obtain FDA clearance or approval before it can sell any of its products in the US, and CE Certification before it can sell any of its products in the European Union (EU). Approval of similar regulatory authorities in countries outside the US and the EU is required before it can sell its products in countries that do not accept FDA clearance or approval or CE Certification. The Company may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of its products if such clearance or approval is denied or delayed.

ONWARD is seeking De Novo classification by the FDA to market ARC^{EX} for use in clinics in the US. If this is granted, we intend to pursue additional regulatory clearances, including for at-home use. ARC^{IM} is a Class III device that will require PMA approval to be marketed in the US, while for at least one indication, it may pursue HDE approval. In Europe, under the MDR, ARC^{EX} is expected to be designated as a Class IIa device and ARC^{IM} as Class III.

The development, manufacture, and commercialization of our products are subject to government regulation. In the US, Europe, and most other countries, ONWARD must complete rigorous pre-clinical testing and extensive clinical trials that exhibit the safety and effectiveness of our devices before we can apply for regulatory clearance or approval to market them. Regulatory bodies such as the FDA may limit approval to specific indications, restrict the distribution of a device, or refuse to grant clearance for additional or expanded indications, which could limit our potential revenues.

The road to regulatory approval of a new medical device is long, expensive, and uncertain. The FDA and other regulatory authorities can delay, limit, or deny approval, grant of a De Novo classification, or clearance of a device for many reasons, including:

- Inability to show that the products are safe or effective for their intended uses (or, for a 510(k) device, that they are substantially equivalent to the predicate)
- Disagreement with the design or implementation of clinical trials or the interpretation of data
- Serious and unexpected adverse device effects experienced by participants in clinical trials
- Insufficiently supportive data from pre-clinical studies and clinical trials
- Inability to show that the clinical and other benefits of the device outweigh the risks
- Failure of manufacturing process or facilities in meeting applicable requirements
- Changes in policies or regulations that increase cost of compliance or render clinical data and filings insufficient for approval or clearance



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Despite the time, effort, and cost invested, our investigational devices may not pass these stringent regulatory hurdles, which could harm our business. In addition, regulatory authorities may place restrictions on the indicated uses of the device, limiting its market size. If the FDA requires us to go through a longer, more rigorous process than expected for future products, or for modifications to existing products, their introduction could be delayed or cancelled, which could adversely affect our ability to grow our business.

In the EEA, compliance with the requirements of the Council Directive 93/42/EEC (EU Medical Devices Directive) is a prerequisite to be able to affix the Conformité Européenne (CE) mark to our products, without which they cannot be sold or marketed in the EEA. The EU Medical Devices Directive is being replaced by a new Medical Devices Regulation (MDR) in the EEA (Regulation (EU) 2017/745). The MDR, which became fully applicable on 26 May 2021, imposes the same basic requirements as the EU Medical Devices Directive (MDD), but is generally more stringent, especially in terms of risk classes and the oversight provided by notified bodies that perform conformity assessments of devices.

Following its departure from the EU, on 31 January 2020, the UK continued to follow the same regulations as the EU during a transitional period, which ended on 31 December 2020. Since then, all medical devices must be registered with the Medicines and Healthcare products Regulatory Agency (MHRA) before being sold on the UK market.

European CE marks continued to be recognized in UK until 30 June 2023, after which a UK Conformity Assessed (UKCA) mark has been required for a medical device to be marketed in the UK. Since the new MDR will not automatically apply in the UK, regulation of medical devices in the UK may diverge from EU regulations in the future. On 28 November, 2022, the Swiss Parliament reached a key decision by instructing the Swiss Federal Council to adapt national laws to enable Switzerland to accept medical devices with FDA approval.

In general, if ONWARD fails to remain compliant with all applicable European laws and regulations, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EEA, adversely affecting our business. Similarly, our ability to market our products in the UK could be affected by any failure to maintain compliance with UK regulations.

The clinical development process required to obtain regulatory clearances or approvals is lengthy and expensive, with uncertain outcomes. Data generated in clinical trials is subject to interpretation by EU regulators, the FDA, and foreign regulatory authorities. If clinical trials of the current ARC^{EX} platform and ARC^{IM} platform and future products do not produce the results necessary to support regulatory clearance or approval, De Novo classification, or clearance in the US or with respect to the Company's current or future products elsewhere, it will be unable to commercialize these products. It therefore may incur additional costs or experience delays in completing, or ultimately be unable to complete and commercialize those products.

Significant setbacks or failure can occur at any time during the clinical development process, adversely affecting the cost, timing, or successful completion of trials. The following circumstances could harm our ability to complete development or commercialize our products:

- The FDA may reject our investigational device exemption (IDE) application and notify us that we may not begin investigational human clinical trials
- Regulatory authorities may disagree as to the design or implementation of our clinical trials
- Regulators and/or institutional review boards (IRBs) may not authorize us or our research partners to begin or continue a clinical trial at a particular site
- We may be unable to agree on acceptable terms with prospective contract research organizations (CRO) and clinical trial sites, the terms of which can vary significantly and require long negotiations
- Clinical trials may produce negative or inconclusive results, or we may not agree with regulatory authorities on the interpretation of these results; consequently, we may decide, or be required by regulators, to conduct additional clinical trials or abandon the development of a product
- The number of subjects or patients required for clinical trials may be larger than we anticipated, enrollment in these trials may be insufficient or slow, and/or the number



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of trials being conducted at any given time may be high, resulting in fewer available patients for our clinical trial, or patients may drop out at a higher than expected rate

- Our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all
- We may have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks
- We may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance
- We may be required to terminate clinical research for various reasons, including safety issues or non-compliance with regulatory requirements
- The cost of clinical trials may be greater than anticipated
- Clinical sites may not adhere to the clinical protocol or may drop out of a trial
- We may be unable to recruit a sufficient number of trial sites or trial subjects
- Regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes; the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate, or not available at an acceptable cost
- Approval policies or regulations may change in a manner that renders our clinical data insufficient for approval
- Our current or future products may have undesirable side effects or other unexpected characteristics

We depend on CROs to conduct clinical trials in a timely manner and in compliance with good clinical practice (GCP) requirements. If a CRO fails to comply fully with GCP standards or experiences delays in conducting the trial, this could result in increased costs and/or program delays. In addition, conducting clinical trials in countries outside the

US and Europe may entail additional delays, shipment costs, or regulatory requirements, as well as risks associated with clinical investigators who are unknown to the FDA, or with different standards of diagnosis, screening, and medical care. Any of these occurrences could adversely affect our business, financial condition, and results of operations.

We may from time to time publicly announce the date at which we expect to reach various clinical, regulatory, or product development milestones. These could include the submission of an IDE application to the FDA to begin a clinical trial, the enrollment of patients in a trial, or the release of data from clinical trials. However, the actual timing of these milestones may vary dramatically compared to our estimates, in some cases for reasons beyond our control, potentially delaying the commercialization of our products or causing our share price to decline.

Failure to comply with post-marketing regulatory requirements could subject the Company to enforcement actions, including substantial penalties, and might require the Company to recall or withdraw a product from the market.

If we receive regulatory clearance or approval for our investigational devices, we will be subject to ongoing and pervasive regulatory requirements governing, among other things, their manufacture, marketing, labeling, packaging, advertising, medical device reporting, sale, promotion, registration, storage, distribution, and listing. For example, ONWARD must submit periodic reports to the FDA as a condition of PMA approval. These reports include safety and effectiveness information about the device after its approval. Failure to submit such reports or to do so in a timely manner could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

In addition, the PMA approval for ARCTM Therapy may be subject to several conditions of approval, including a post-market extended follow-up of the premarket study cohort. Any failure to comply with the conditions of approval could result in the withdrawal of PMA approval and the inability to continue to market the device. Adverse outcomes in these studies could also be grounds for withdrawal of approval of the PMA.

The regulations to which ONWARD is subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability



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to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after the proper regulatory authorization to market a device has been obtained, we have ongoing responsibilities under FDA and EU regulations and applicable laws and regulations of other countries.

Any failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state, EU or national regulatory authorities. Sanctions could include warning letters, fines, injunctions, consent decrees or civil penalties; recalls, termination of distribution, administrative detention, or seizure of products; suspension of one or more clinical studies; customer notifications, repair, replacement or refunds; restriction, partial suspension or total shutdown of production; delays in or refusal to grant requests for future regulatory approvals of new products, uses, or modifications to existing products; withdrawals or suspensions of current regulatory approvals; prohibitions on sales, imports, or exports of our products; FDA refusal to issue certificates to foreign governments needed to export our products for sale in other countries; and criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition, and operating results.

Even if cleared or approved by regulatory authorities, the Company's products may cause or contribute to adverse medical events or be subject to failures or malfunctions that the Company is required to report to the FDA. If it fails to do so, the Company would be subject to sanctions that could harm its reputation, business, financial condition, and results of operations. The discovery of serious safety issues with its products, or a recall of its products, either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on the Company. In the course of conducting our business, the Company must adequately address quality issues that may arise with the ARC^{EX} and ARC^{IM} systems, including defects in third-party components included in our products. Additionally, even if free of quality issues, our products may not meet the expectations of physicians or patients with respect to achieving desired results.

The internal procedures designed to minimize risks that may arise from quality issues may not sufficiently eliminate or mitigate occurrences of these issues and associated liabilities.

Moreover, even in the absence of quality issues, we may be subject to claims and liability if our products' performance does not meet physicians' or patients' expectations.

In the event that we receive clearance or approval by regulatory authorities, we will be subject to the FDA's medical device reporting regulations and similar foreign regulations. This will require us to report to the FDA when we become aware of information that reasonably suggests that our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if it were to recur, could cause or contribute to a death or serious injury. The timing of this obligation to report is triggered by the date we become aware of the adverse event, as well as the nature of the event. We may inadvertently fail to report adverse events within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as such, or if the adverse event is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, civil monetary penalties, revocation of device approvals, seizure of our products, or delay in clearance or approval of modifications to our products.

The FDA and foreign regulatory authorities have the power to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product, or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall of our products must be based on a finding that there is reasonable probability that they may cause serious injury or death. We may also choose to voluntarily recall products if any material deficiency is found. A government-mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects, or other deficiencies or failures to comply with applicable regulations. Depending on the corrective action that we take to redress deficiencies or defects that may occur in the future, the FDA may require, or we may decide, that we need to obtain new approvals for our products before marketing or distributing the corrected device. Seeking such approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we fail to adequately address problems associated with our products, we may face additional regulatory enforcement action.



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Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. In the future, ONWARD may initiate voluntary withdrawals or corrections to our products that we may determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and subject us to enforcement action. Such a recall announcement could harm our reputation with customers, potentially lead to product liability claims, and negatively affect sales. Any lawsuit or corrective action, whether voluntary or involuntary, would require the dedication of considerable time and capital, possibly impacting our financial results.

Additionally, the identification of undesirable side effects or other previously unknown problems caused by our products could lead to a number of negative consequences. Among others, regulatory authorities might withdraw approvals; impose product recalls; require us to add warnings, contraindications, or narrower indications in the product labeling, or to issue of field alerts to physicians and pharmacies; require us to create a guide outlining the risks of such side effects for distribution to patients; impose limitations on how we promote our products; require us to change the way the product is administered or modify the product; and/or require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Any of these requirements could prevent us from achieving or maintaining market acceptance of our products, substantially increase the costs of commercializing our products, or impacts our sales. The demand for our products could also be negatively impacted by any adverse effects of a competitor’s product or treatment.

If the Company or its suppliers fail to comply with FDA regulatory requirements, or if it experiences unanticipated problems with any cleared or approved products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain regulatory clearance or approval, as well as the manufacturing processes, reporting requirements, post-approval clinical data, and promotional activities for such a product, will be subject to continued regulatory review and oversight by the FDA. In particular, ONWARD and its third-party suppliers will be required to comply with the FDA’s Quality System Regulations (QSR). These FDA regulations cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage, and shipping of products. Compliance with applicable regulatory requirements is subject to continual

review and is monitored rigorously through periodic inspections by the FDA. If we, or our manufacturers, fail to adhere to QSR requirements, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances and approvals, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition and results of operations.

In addition, ONWARD and its suppliers are required to comply with Good Manufacturing Practices for the manufacture of our products, and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, and shipping of any product for which we obtain clearance or approval.

The FDA audits compliance with the QSR and other similar regulatory requirements through periodic announced and unannounced inspections of manufacturing and other facilities. If ONWARD or one of its suppliers fail to comply with applicable statutes and regulations administered by the FDA, or the fail to timely and adequately respond to any adverse inspectional observations or product safety issues, this could result in any of the following enforcement actions:

- Untitled letters, warning letters, fines, injunctions, consent decrees, and civil penalties
- Unanticipated expenditures to address or defend such actions
- Customer notifications or repair, replacement, refunds, recall, detention, or seizure of our products
- Operating restrictions or partial suspension or total shutdown of production
- Refusing or delaying our requests for premarket approval of new products or modified products
- Withdrawing PMAs that have already been granted
- Refusal to grant export approval for our products
- Criminal prosecution



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Any of these sanctions could have a material adverse effect on our reputation, business, results of operations, and financial condition.

Risks Related to the Company’s Intellectual Property (IP)

It is difficult and costly to protect its IP and its proprietary technologies, and the Company may not be able to ensure their protection.

We rely on a combination of patents and trade secrets to protect the IP related to our proprietary technologies. Patents and other proprietary rights provide uncertain protections, and we may be unable to protect our IP for various reasons, including complex factual and legal issues that create uncertainty as to the validity, scope, and enforceability of a particular patent. As a result, we may be unsuccessful in defending our patents and other proprietary rights against third-party challenges, which could have a material adverse effect on our business.

Patents do not automatically provide a competitive advantage. Competitors may be able to design around our patents and develop products that provide comparable or superior outcomes. Any changes we make to our products, including design improvements that we believe make them more marketable, may not be covered by previously licensed patents. We may be required to file new applications and/or seek other forms of protection covering these alterations.

Changes in either patent laws or their interpretation in the US and other countries may diminish our ability to stop third parties from making, using, selling, or importing products that infringe on our IP. Infringement and/or misappropriation suits are expensive and time-consuming to prosecute and could result in a court deciding that one or more of our patents is invalid, unenforceable, or both. Even if the validity of our patents is upheld, a court may refuse to stop the other party from using the technology on the grounds that their activities are not covered by the patents.

In the future, we may obtain certain IP related to our technology from third parties. If that is the case, we cannot be certain that these third parties took the necessary actions to maintain the IP rights or that their transfer to us was proper and effective. As a result, we

may be subject to claims challenging their ownership or enforceability, which would limit our ability to prevent competitors from making or selling duplicate or similar technologies for which, or in countries where, we have no patent protection.

In addition to patents, we rely on trade secrets to protect our technology. We have established policies to protect our trade secrets, but these may not be effective in preventing misappropriation or unauthorized disclosure. Litigating a trade secret claim is expensive and time-consuming, and the outcome may be unexpected. In addition, courts outside the US are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop knowledge and/or methods allowing them to create substantially similar products or services without misappropriating our trade secrets.

Patent terms may be inadequate to protect the Company’s competitive position on its future products for an adequate amount of time.

In both the US and Europe, a patent’s lifespan is generally 20 years from its earliest filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering the Company’s future products are obtained, once the patent has expired, it may be open to competition.

ONWARD’s current patent portfolio will begin to naturally expire in 2031. However, given the amount of time required for the development, testing, and regulatory review of new products, certain patents protecting our future products may expire before or shortly after commercialization begins. As a result, our patent portfolio may not provide the Company with sufficient rights to exclude others from commercializing similar or identical products for a sufficient amount of time.

Risks Related to the Company’s Financial Position, Need for Additional Capital & Taxation

The Company has incurred significant operating losses since inception, expects to incur operating losses in future, and it may not be able to achieve or sustain profitability.

ONWARD is a medical technology company with no commercial operating history. To date, we have substantially invested all of our efforts in the research and development of, and in seeking regulatory clearance or approval for, our ARC^{EX} and ARC^{IM} platforms. We are



Risk Management & Control

not profitable, have incurred losses each year since beginning operations in 2014, and have no commercial operating history upon which to evaluate our business and prospects. Any predictions of future success, performance, or viability may not be as accurate as they could be if the Company had a longer operating history or commercial revenues.

ONWARD has not yet derived sufficient revenues to support operations, as our activities have consisted of developing our technology and conducting pre-clinical studies and clinical trials. As of 31 December 2023, the loss for the period amounted to EUR 36.2M. These losses have resulted primarily from costs incurred in the development of the ARC^{EX} and ARC^{IM} platforms, and from general and administrative costs associated with operations.

The current or future clinical trials of any current or future investigational devices are, and the manufacturing and marketing of any such investigational devices will be, subject to extensive and rigorous review and regulation by the FDA and other government authorities in the US and in other countries where the Company intends to test and, if cleared or approved, market such investigational devices. We expect our operating expenses to continue to increase as we;

1. Continue research and development activities for our ARC^{EX} and ARC^{IM} technology platforms and related technologies
2. Seek FDA regulatory clearances and approvals for the ARC^{EX} and ARC^{IM} platforms or other future investigational devices in the US, regulatory approvals in Europe, and potentially other regulatory approvals in other jurisdictions
3. Build our commercial infrastructure
4. Incur additional operational costs associated with being a public company

As a result, ONWARD expects to continue to incur operating losses for the foreseeable future. The expected future operating losses, combined with prior operating losses, may adversely affect the market price of our Ordinary Shares and our ability to raise capital and continue operations.

We expect sales of our ARC^{EX} and ARC^{IM} platforms, if cleared or approved, to account for the majority of our future revenue. If the ARC^{IM} and/or ARC^{EX} platforms do not achieve regulatory

clearance or approval, or if the platforms do not generate sufficient revenue, the Company may not be able to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability in subsequent periods or on an ongoing basis. In this case, it will be more difficult for us to finance our business and realize our strategic objectives, which would have a material and adverse effect on our business, financial condition, and results of operations and would cause the market price of our Ordinary Shares to decline.

The Company will require additional capital to finance its planned operations, which may not be available to it on acceptable terms or at all. Raising additional capital may cause dilution to our existing shareholders.

As of 31 December 2023, ONWARD had net cash of EUR 29.8M. Based on cash flow forecasts for 2024, this will be sufficient to meet our capital requirements and fund our operations to the end of 2024. We have based these estimates on assumptions that may prove to be incorrect and could spend our available financial resources much faster than currently expected. Additional funding was raised in March 2024 that will fund operations for at least 12 months from the date of this Annual Report.

Our expenses will also increase substantially in connection with any potential commercialization of our products in the US and Europe, including the hiring of qualified and sales personnel. Additional expenditures will include costs associated with manufacturing and supply, expenses related to the deployment of a direct sales and service organization, costs and expenses incidental to being a public company, and general operations. In addition, other unanticipated costs may arise.

ONWARD's present and future funding requirements will depend on many factors, including:

- Continuing our research and development efforts, completing ongoing and planned clinical trials, and applying for (i) De Novo classification granting marketing authorization for ARC^{EX} for use in clinics, and thereafter 510(k) clearance for use of ARC^{EX} in the home, and (ii) PMA approval, which will be required for ARC^{IM}, though we expect to pursue approval to legally market at least one indication via HDE



Risk Management & Control

- Conducting additional clinical trials of our ARC^{EX} and ARC^{IM} platforms for future indications
- Our ability to retain and compensate the highly qualified personnel necessary to execute our plans
- If cleared or approved, the costs associated with manufacturing, selling, and marketing our products in Europe and the US, as well as other foreign jurisdictions, including the cost and timing of implementing our sales and marketing plan and expanding manufacturing capabilities
- Our ability to effectively market and sell, and achieve sufficient market acceptance and market share for our products
- The costs to maintain, expand, and defend the scope of our IP portfolio, as well as any other action required in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other IP rights
- The emergence of competing technologies and other adverse market developments, and the need to enhance our products and/or develop new products to maintain market share
- Our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements
- Our need to implement additional internal systems and infrastructure, including financial and reporting systems, incidental to being a public company

ONWARD will likely need to raise additional capital. If we do so through public or private equity offerings, the ownership interest of existing shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect these shareholders' rights. If the Company raises additional capital through debt financing, we may have to provide new liens on our assets and be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or liens, making capital expenditures, or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances,

or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our ARC^{EX} and ARC^{IM} platforms, technologies, future revenue streams, or research programs, or grant licenses on terms that may not be favorable to us. In addition, the exercise by our employees of stock options under stock option plans within the scope of existing and/or future management or employee participation would lead to a dilution of the shareholders.

If we are unable to obtain adequate financing when needed, and on terms that are acceptable to us, we may have to delay, reduce the scope of, or suspend the implementation of our sales and marketing plan and our ongoing research and development efforts, which would have a material adverse effect on our business, financial condition, and results of operations.

The Company's operating results may vary significantly from period to period, which may negatively impact the price of its Ordinary Shares in the future.

ONWARD's financial and operating results may fluctuate from period to period due to, among others:

- The cost of obtaining and maintaining FDA and other regulatory clearances or approvals for our ARC^{EX} and ARC^{IM} platforms, as well as any other future indication we may seek to develop our investigational devices to address
- Potential revenue generated by sales of our ARC^{EX} and ARC^{IM} platforms for cleared or approved indications, if any
- Expenses incurred in manufacturing and selling our ARC^{EX} and ARC^{IM} platforms, if cleared or approved
- Costs associated with scaling up and expanding our manufacturing capacity
- Costs associated with building and expanding our sales and marketing efforts in the US, Europe, and internationally
- Costs associated with conducting research and development efforts for future improvements to, or versions of, our ARC^{EX} and ARC^{IM} platforms



Risk Management & Control

- Cost of complying with regulatory requirements
- Costs associated with capital expenditures
- Costs associated with any future litigation
- Costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our IP rights, and defending any IP-related claims
- The severity, duration, and impact of the COVID-19 pandemic, which may adversely impact our business and planned development and future commercialization of our ARC^{EX} and ARC^{IM} platforms

Due to these and other factors, it is likely that ONWARD will experience fluctuating revenues, operating results, and cash flows. In that case, period-to-period comparisons of financial results may not necessarily be meaningful, and results of operations in prior periods should not be relied upon as an indication of future performance, as this will not meet investor expectations or those of public market analysts. Unanticipated or new information may cause investors and analysts to revalue our business, which could cause a decline in the price of our Ordinary Shares.

The Company's ability to use its net operating losses and research and development credit carryforwards to offset future taxable income may be subject to certain US federal income tax and Dutch tax limitations.

In general, under Sections 382 and 383 of the US Internal Revenue Code of 1986, as amended, a corporation that undergoes an “ownership change” – generally defined as a greater than 50% change by value in its equity ownership over a three-year period – is subject to limitations on its ability to use its pre-change net operating losses (NOL) and its research and development credit carryforwards to offset future taxable income. The Company’s existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if it undergoes an ownership change, our ability to use NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Internal Revenue Code.

In addition, our ability to deduct net interest expense may be limited if the Company has insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. Future changes in share ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Internal Revenue Code.

For these reasons, in the event that ONWARD experiences a change of control, we may not be able to use a material portion of the NOLs, research and development credit carryforwards, or disallowed interest expense carryovers, even if we attain profitability.

The Company's results may be impacted by changes in foreign currency exchange rates.

If ONWARD’S investigational devices are cleared or approved and we commence commercial operations, we may enter into a number of transactions denominated in various currencies, which could expose the Company to changes in currency exchange rates. We do not currently engage in any hedging transactions. If we are unable to address these risks and challenges effectively, our international operations may not be successful and our business could be harmed.

If securities or industry analysts do not publish research or reports about the Company's business or industry, or if such analysts (if any) change their recommendations regarding the Ordinary Shares adversely, the market price and trading volumes of the Ordinary Shares could decline.

The trading market for the Ordinary Shares will be influenced by the research and reports that securities or industry analysts publish about ONWARD’s business or industry. If securities or industry analysts do not publish or cease to publish research or reports about ONWARD’s business or industry, we could lose visibility in the financial markets, which could cause the market price or trading volume of the Ordinary Shares to decline. Also, if one or more of the analysts covering our business or industry recommends selling Ordinary Shares, or if negative research is published on the industry or geographic markets we serves, the market price of the Ordinary Shares could decline.





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Investor
Relations

Investor Relations

We engage in and maintain open dialogue with investors and analysts through several communication channels, including the Annual General Meeting, roadshows, investor conferences, presentations, and webcasts.

Up-to-date financial information about ONWARD is published on our Investor Relations website (ir.onwd.com). Investors and analysts are encouraged to visit the website regularly for detailed coverage of the share price, shareholder meetings, half-year and annual results, press releases, presentations, webcasts, and investor relations events.

Financial Calendar 2024

- **25 April:** Annual Report publication
- **13 June:** Annual General Meeting
- **17 September:** Interim Report publication

Closed periods based on the 2024 financial calendar are:

- 26 March – 24 April 2024
- 18 August – 16 September 2024

Dividend Policy

ONWARD has not declared or paid dividends on its shares in the past and does not currently have the intention to pay dividends. Any declaration of dividends will be based on the Company's earnings, financial condition, capital requirements, and other factors considered important by the Board.

Dutch law and ONWARD's Articles of Association do not require the Company to declare dividends. Currently, the Board expects to retain all earnings, if any, generated by ONWARD's operations for the development and growth of the business and does not anticipate paying dividends to shareholders in the near future.

Under the terms of the Innovation loan received from the RVO NL (Dutch Government), ONWARD is not allowed to pay dividends until the Innovation loan has been repaid.

Capital Structure & Voting Rights

ONWARD's authorized share capital (maatschappelijk kapitaal) amounts to EUR 12,225,000 divided into 50,937,500 Ordinary Shares and 50,937,500 Preferred Shares with a nominal value of EUR 0.12 each. All of the issued Ordinary Shares are fully paid-up and represent capital in the Company. Each shareholder of the Company is entitled to one vote per share. No shareholders have any voting rights different from any other shareholder. At 31 December 2023, 30,184,388 Ordinary Shares represented all issued capital.

The Board is authorized by a resolution of the General Meeting to issue shares, or grant rights to subscribe for shares, limited to 10% of the issued share capital. A separate resolution of the General Meeting is not required for the issuance of shares under this authorization.



Investor Relations

The Board remains of the view that it is in the company’s best interests to be able to react promptly when business opportunities arise that require the issuance of Ordinary Shares. For this purpose the Board was also authorized to issue Ordinary Shares, or grant rights to subscribe for shares, for an additional 50% of the Company’s issued share capital in connection with a potential capital raise. A separate resolution of the General Meeting is not required for the issuance of shares under this authorization.

There are no convertible securities or securities with warrants in the Company. No shareholders have any voting rights different from any other shareholder, and no voting rights are limited in any manner.

ONWARD is not aware of any agreements that may result in a limitation of the transferability of voting rights on shares in its capital.

Shareholder Structure

Pursuant to the Dutch Financial Supervision Act (Wet op het financieel toezicht), substantial holdings in the Company must be disclosed to the Netherlands Authority for Financial Markets (Stichting Autoriteit Financiële Markten, AFM). According to the register kept by the AFM, the following shareholders disclosed that they have a direct or indirect (potential) interest of between 3% and 25% in the Company’s total issued share capital as of 31 December 2023:

- INKEF Capital B.V. (12.11%)
- LSP Advisory B.V. (11.76%)
- Gimv (Private Equity) (10.61%)
- Wellington Partners GmbH (8.74%)
- Invest-NL N.V. (3.60%)
- Dave Marver (CEO) (3.16%)

Listing

Shares of ONWARD Medical N.V. trade on Euronext in Brussels (primary listing) and Euronext Amsterdam (secondary listing) under the symbol “ONWD.”

Share Price



Analyst Coverage

ONWARD was covered by three brokers at the end of 2023.

Broker	Analysts
Degroof Petercam	David Seynnaeve, PhD
Kepler Cheuvreux	Jon Berggren
Bryan, Garnier & Co	Maria Vara

In February 2024, KBC Securities initiated research coverage of the Company.

In April 2024, Stifel initiated research coverage of the Company.



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Report of the Non-Executive Directors

Report of the Non-Executive Directors

Below is the report of the Non-Executive Directors of the Company for the financial year 2023, as referred to in best practice provision 5.1.5 of the Corporate Governance Code (CGC).

Supervision by the Non-Executive Directors

The Board has a duty to ensure that the actions of the Executive Director and Management Team align with the company’s strategic priorities and values. The Non-Executive Directors supervise the policies implemented by the Executive Director and Management Team, and the general affairs of the Company and its affiliated entities.

The Board has remained closely involved in the strategy and monitoring the progress as the Company prepared for to submit a De Novo application for FDA clearance for the ARC^{EX} system through frequent discussions with the Executive Director and Management Team. Throughout these dialogues, the Board took the responsibility of challenging and testing the propositions made supporting the company’s overall goal of bringing a commercial solution to an underserved community.

With a view to maintaining supervision of the Company, the Non-Executive Directors regularly discussed strategic matters with the Executive Director and Management Team during Board meetings. During these meetings, the Board was updated on development, clinical and commercial launch activities, and the status of potential funding opportunities. The Board received a comprehensive overview of the developments, achievements, challenges, and opportunities in each respective functional area.

The Board has allocated certain specific responsibilities to the Audit Committee, Compensation Committee, and Nomination and Corporate Governance Committee. Further details on how these Committees have carried out their duties are set forth in the sections below pertaining to each committee. The Non-Executive Directors have been regularly informed by each committee of the results and recommendations of these meetings in accordance with best practice provision 2.3.5 of the CGC, and the conclusions of those committees were considered when drafting this report of the Non-Executive Directors. The Non-Executive Directors were able to review and evaluate the performance of each Committee. There is no need to amend the size or composition of any of the above committees.

Audit Committee

In 2023, the Audit Committee held six meetings (attendance details provided in the table below). During its meetings, the Audit Committee among others reviewed and discussed the financial reporting process, the 2022 full year and 2023 half year results and reports, the internal control processes and ongoing improvements, and the funding/financing requirements. The Audit Committee assessed the declarations regarding internal control and risk- management in the 2022 Annual Report. It also discussed the cooperation with the external auditor of the Company. The external auditor attended all the Audit Committee meetings and presented the audit plan for 2023. The Audit Committee reported systematically to the Board of Directors, making recommendations and issuing advice for approval (where applicable), and ensured the cooperation of the Management Team and the finance department of the Company where required.



Report of the Non-Executive Directors

Compensation Committee

In 2023, the Compensation Committee held three meetings (attendance details provided in the table below). The Compensation Committee discussed and approved the achievement of the 2022 company goals and related variable remuneration of the Executive Director. It supervised the preparation of the Compensation report that was subsequently approved by the Board and included in the 2022 Annual Report. The Compensation Committee set the 2023 company goals and objectives (the progress of which was reviewed by the committee throughout the year). Moreover, it reviewed and discussed the remuneration policy and the individual remuneration of the members of the Board, the Board committees and the Executive Director. The Compensation Committee reported systematically to the Board of Directors and ensured the cooperation of the Board, Management Team and the People and Culture team of the Company where required.

Nomination & Corporate Governance Committee

In 2023, the Nomination and Corporate Governance Committee held two meetings (attendance details provided in the table below). The Nomination and Corporate Governance Committee discussed the composition and size of the Board of Directors, Board committees and Management Team and led the search for open senior leadership positions. It discussed the HR and operational strategy of the Company, as well as succession planning. It supported the Board evaluation exercise. The Nomination and Corporate Governance Committee reported systematically to the Board of Directors and ensured the cooperation of the Board, Management Team and the People and Culture team of the Company where required.

Evaluation

The Board is responsible for the quality of its own performance. Once per year, it discusses its own performance and the performance of its individual members and committees.

Adhering to good governance, the Non-Executive Directors performed a Board effectiveness assessment on a no-name basis in Q4 of 2023 based on a detailed questionnaire completed.

The assessment focused on five categories of Board governance:

1. Information sharing between the Company and Board
2. Chairing of the Board and Board culture
3. Composition of the Board
4. Accountability
5. Standard of conduct

The outcomes were discussed at the following Board meeting, recommendations for improvement were identified and a defined list of next steps agreed upon.

It was concluded that both the Board and its committees perform well and operate efficiently.

Contrary to the requirement of best practice provision 2.2.6 of the CGC, the 2023 evaluation was not performed under the supervision of an external expert. This will be considered for future evaluations.

Internal Audit Function

As per the Audit Committee’s recommendation, the Board concluded that – due to the size of the Company – it does not yet require an internal audit function. The Board has assessed whether adequate alternative measures have been taken and will reconsider annually if it is necessary to create an internal audit department.

In reaching this conclusion, the Board took into consideration that the Company has provided for management to support the assessment and testing of our risk-management and control systems.



Independence of the Non-Executive Directors

Each Non-Executive Director has a duty to the Company to properly perform the duties assigned to them and to act in the Company’s corporate interest. Under Dutch law, the Company’s corporate interest extends to the interests of all stakeholders, including shareholders, creditors, and employees.

The Board confirms that the Non-Executive Directors meet the independence requirements of the CGC. For details, refer to Director Independence included in the Governance section.



2023

Meetings of the Board & Committees

Member & Principal Position	Independent According to DCGC	Board of Directors		Audit Committee		Compensation Committee		Nomination & Corporate Governance Committee	
		% of Attendance at Meetings	Member	Attendance % at Meetings	Member	Attendance % at Meetings	Member	Attendance % at Meetings	
Dave Marver Executive Director & CEO	No	100%							
Jan Øhrstrøm Non-Executive Director & Chairperson	Yes	100%			X ^a	100%	X ^a	100%	
Grégoire Courtine Non-Executive Director and CSO	No	100%							
Ian Curtis Non-Executive Director and Vice-Chairperson	Yes	100%	X ^a	100%					
Fredericus Colen Non-Executive Director	Yes	100%	X	100%	X	100%			
John de Koning Non-Executive Director	No	100%					X	100%	
Kristina Dziekan Non-Executive Director	Yes	100%	X	100%					
Vivian Riefberg^b Non-Executive Director	Yes	100%			X	100%	X	100%	
Number of Meetings Held:		5		6		3		2	

^a: Chairperson of the respective committee.

^b: Vivian has attended all Board and Compensation Committee meetings since 26 September 2022. Vivian also joined and attended all Nomination and Corporate Governance Committee meetings since her appointment at the AGM in May 2023.



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Board of Directors' Statements

Board of Directors' Statements

The Board of Directors' Report (the Report), consisting of pages 4-183 inclusive and such parts of the financial statements as referred to in the Report, comprise the Bestuursverslag, as defined in Article 2:391 of the Dutch Civil Code (DCC).

In accordance with best practice provision 1.4.3 of the Dutch Corporate Governance Code (CGC), the Board of Directors state that, to the best of its knowledge:

- The report provides sufficient insights into any failings in the effectiveness of the internal risk-management and control systems with regard to the risks as referred to in best practice provision 1.2.1. In the 2023 financial year, no material failings have been detected or reported;
- The aforementioned systems provide reasonable assurance that the financial reporting does not contain any material inaccuracies. Details are set out in the Risk Management and Control section;
- Based on the current state of affairs, it is justified that the financial reporting is prepared on a going concern basis. At the end of 2023, the Company expected its current cash to propel operations through the end of 2024. The Company successfully completed a EUR 20M equity financing in March 2024, extending its cash runway into mid-2025. The cash and cash equivalents including the offering in March 2024 supports the going concern basis; and

- The report states the material risks, detailed in the Risk-Management and Control section, as referred to in best practice provision 1.2.1, and the uncertainties, to the extent that they are relevant to the expectation of the company's continuity for the period of twelve months after the preparation of the report.

With reference to Section 5.25c, Paragraph 2c of the Financial Markets Supervision Act, the Board states that, to the best of its knowledge:

- The consolidated financial statements as at and for the year ended 31 December 2023 – which have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union and with Part 9 of Book 2 of the DCC -- give a true and fair view of the assets, liabilities, financial position, and loss of the Company and the undertakings included in the consolidation taken as a whole.
- The Report provides a fair view of the situation on the balance sheet date and of developments during the financial year of the issuer and of its affiliated companies, whose information has been included in its financial statements, together with a description of the main risks the issuer faces.

Amsterdam, 24 April 2024 – **Board of Directors**



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Remuneration Report

Remuneration Report

This report provides an overview of the remuneration of the Board in 2023 and explains how this relates to the Company's policy regarding the remuneration of its Non-Executive and Executive Directors (the Compensation Policy), which was previously adopted at the Company's 2022 Annual General Meeting (AGM). The adoption of the 2022 report was through an advisory vote with 87.9% of voting in favor of adoption.

The 2023 Remuneration Report has been prepared in line with Section 2:135b of the Dutch Civil Code (DCC) and best practice provision 3.4.1 of the Corporate Governance Code (CGC). This report will be submitted to the 2024 AGM for an advisory vote. The Company's 2024 AGM is scheduled for 14 June.

The Compensation Policy is available on the ONWARD website (onwd.com) under Investors/Governance tab.



Executive Director Remuneration

The annual remuneration of the Executive Director comprises the following two components:

- Fixed remuneration, comprising an annual base salary and optional benefits, such as medical insurance, life insurance, retirement benefits, travel expenses, and/or representation allowances
- Variable remuneration, comprising an annual performance-based compensation (depending on the individual's achievement and corporate objectives as defined on an annual basis) and share-based remuneration

Fixed Remuneration

The amount of the fixed remuneration depends on the Executive Director's function and responsibilities and on typical compensation levels in the industry and the market, especially in comparison to similar listed companies in the MedTech sector. The fixed remuneration is paid out as a monthly salary.

Variable Remuneration

Short-term variable remuneration consists of annual performance-based compensation (a bonus) defined on a yearly basis. The Company currently only considers corporate objectives. Corporate objectives are centered around strategic clinical and development deliverables, including key regulatory milestones, operational and commercial readiness, and people and financing goals. These objectives are measured via a set of specific targets that help track progress towards their completion.

Long-term variable remuneration consists of periodic grants of stock options that vest monthly over a four-year vesting period. For more details, refer to Note 2.9 in the Consolidated Financial Statements. Stock options create an ownership opportunity for executives linked to the long-term performance of the Company's share price, aligning their interests with those of shareholders over the options' 10-year term. If the share price does not increase from the date of grant, no value is realized under the scheme.

Stock options are commonly leveraged as the primary equity vehicle among our industry peer group in Europe and the US. Award sizes are determined at the point of grant in relation to competitive award values and percentage of ownership delivered within our peer group.

The Company has implemented share-based remuneration as follows:

- Share-based remuneration takes the form of options for shares
- These options may not be transferred, pledged, or otherwise encumbered; subject to, among others, the applicable yearly exercise periods, they may be exercised for up to 10 years after the grant date once vested
- In cases of termination of an Executive Director's management agreement (other than termination by the Executive Director for good cause) who holds share options, or if that Executive Director is dismissed, such options are subject to reverse vesting (and as such will be forfeited) over a period of 36 months after their grant
- This plan is not based on the achievement of specific performance-related Key Performance Indicators (KPI's); however, the size of the stock option grant is linked to the position's job grade and is contingent on an individual's performance in the previous calendar year
- The plan is based on the premise that stock options contain an inherent performance criterion for the recipient, who is invested in the successful performance of the Company, thereby leading to an increase in the share price

There are no specific performance conditions associated with this plan, only a service condition. This deviates from the requirements of best practice provision 3.1.2 v of the CGC. In addition, refer to the section "Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code" of the Governance section for further information.



The following awards have been granted to the Company’s Executive Director. The main conditions for exercising these options are described above.

Executive Director	Financial Year	Grant Date	Type of Security	Options Vested / Unvested	Exercise Price	Expiration Date
Dave Marver	2021	15/12/2021	Stock Options	Vested: 95,957 Unvested: 92,043	EUR 9.70	15/12/2031
Dave Marver	2023	03/01/2023	Stock Options	Vested: 0 Unvested: 385,000	EUR 6.12	03/01/2033

Reduction or Claw-Back of Variable Remuneration

Pursuant to Dutch law, the variable remuneration of the Executive Director may be reduced, or the Executive Director may be obliged to pay part of their variable remuneration to the Company, if certain circumstances apply as follows:

- Test of reasonableness and fairness: According to Dutch law, the Board may adjust any variable remuneration payable to an Executive Director to an appropriate level if payment of the variable remuneration is deemed unacceptable according to the criteria of reasonableness and fairness
- Claw-back: Under Dutch law, the Board has the authority to recover from an Executive Director any variable remuneration paid based on incorrect financial or other data

Contribution to Long-Term Performance & Value Creation

Remuneration of the Executive Director is consistent with and supports ONWARD’s strategy. It also supports our ongoing efforts to improve our overall performance, facilitate growth and sustainable success, and enhance our long-term value and interests.

As a result, our compensation packages are designed to enable us to compete in a global market, including the challenging US labor market. We aim to attract top talent to execute our long-term strategy and create sustainable value and growth in the best interest of the Company and stakeholders. Executive compensation packages were reviewed in Q4 of 2022 and 2023 respectively, based on benchmarks provided by AON, an independent third party.



Executive Director’s Remuneration

A detailed breakdown of the Executive Director’s remuneration is presented in the table below:

EUR'000	Dave Marver CEO	
	2023	2022
Base Salary	425	410 ^a
Pension Benefits	64	44
Other Benefits	78	109
Total Fixed Compensation	567	563
	34%	39%
Annual Performance-Based Compensation	200	398
Share-Based Remuneration / Stock Options	916	469
Total Variable Compensation	1,116	867
	66%	61%
Total Compensation	1,683	1,430

^a: The increase in the base salary was to align the salary of the CEO with ONWARD’s peer group based on benchmarking performed by an external consultant.

Scenario Analyses

the annual performance-based compensation was discussed by the Compensation Committee in 2023 to assess if there are any risks that the performance criteria could lead to inappropriate outcomes. The Compensation Committee concluded that the range of potential remuneration outcomes were reasonable considering the current maturity and activities. The Compensation Committee makes recommendations to the Board, however, the final decision regarding percentages based on achievements relating to executive compensation will remain up to the discretion of the Board.

Performance Assessment

The Board determines the Executive Director’s variable remuneration (whereby the Executive Director has not taken part in the discussions and decision-making by the Board) based on an annual performance assessment and professional judgment. Variable remuneration is linked to the individual’s performance against a set of financial and non-financial goals that supports and is consistent with the Company’s strategy and long-term interests.

These goals include, among other topics, performance, business development, strategy, investor relations, and general management. Risk alignment is considered in target setting to promote sound and effective risk management. Variable remuneration is paid out according to how the Company’s business develops, the scope of the Executive Director’s achievement, and the realization of the Company’s general objectives.

In 2023, the Board approved a set of company goals for our Executive Director, containing both financial and non-financial KPIs in the following functional areas:

- **Clinical & Development:** These goals require cross-functional collaboration between clinical, regulatory, and product development teams to ensure progress toward FDA submission milestones while adhering to regulations and guidelines throughout the development process. Product development activities are tracked, and product performance is optimized during the relevant development and validation stages.



- **Operational & Commercial:** These goals focus on preparedness for manufacturing and assembly, including supplier readiness and process development activities. They include implementation of a sufficiently robust quality management system (QMS) to ensure compliance with regulatory requirements. They also include supporting readiness for market entry and executing necessary training and support activities following commercial launch.
- **People:** This goal's focus is to recruit and retain the talent required to execute the Company's strategies.
- **Strategic & Financial:** This goal is to secure additional funding to support the Company's strategies.

Performance Criteria Functional Area	Criteria Weight	On-target Performance	Actual Performance	Measured Performance
Clinical & Development	40%	100%	55%	22%
Operational & Commercial	30%	100%	44%	13%
People	10%	100%	120%	12%
Strategic & Financial	20%	100%	0%	0%
Total				47%
Corresponding amount (EUR'000)				200

After the conclusion of the financial year, the Board assesses to what extent the performance criteria have been met and determines the measured performance percentage and corresponding amount for the Executive Director. Bonus compensation is at the discretion of the Compensation Committee and, ultimately, the Board.

Evaluating the Executive Director's performance against the performance criteria set forth at the beginning of 2023, the Remuneration Committee recommended, and the Board granted the CEO a variable compensation payout of 47% of target for 2023.

Non-Executive Director Remuneration

It should be in the Non-Executive Directors' interest to focus on the Company's sustainable and long-term successful development. As such, the Company believes that fixed remuneration for the Non-Executive Directors is effective. Regardless of their remuneration, all Non-Executive Directors are entitled to reimbursement for their travel expenses.

The fees are as follows:

EUR'000	Chairman	Member
Board of Directors	45	45
Audit Committee	12	6
Compensation Committee	10	5
Nomination and Corporate Governance Committee	8	4



Remuneration Report

Determination of Non-Executive Directors' Remuneration

Non-Executive Director remuneration amounted to:

In EUR

Name	2023	2022	2021
Jan Øhrstrøm^a	160,889	208,134	533,577
Gregoire Courtine^b	512,297	300,725	980,918
Fred Colen^c	66,149	59,839	96,820
Kristina Dziekan	51,000	26,538	-
Vivian Riefberg^d	95,414	25,275	-

a: Compensation includes cost of stock options EUR 49,314 (2022: EUR 94,755) and the reimbursement of travel expenses EUR 3,575 (2022: EUR 5,379).

b: Compensation includes the remuneration paid in relation to his role as CSO EUR 143,837 (2022: EUR 146,124), as well as the vesting of stock options under the long-term incentive plan EUR 368,460 (2022: EUR 154,601).

c: Compensation includes the reimbursement of travel expenses EUR 10,149 (2022: EUR 3,839).

d: Compensation includes cost of stock options EUR 23,252 (2022: EUR 6,941) and the reimbursement of travel expenses EUR 20,162 (2022: EUR 5,291). Served as interim Director since 26 September 2022 and was appointment as Director at the 2023 Annual General Meeting.

Liability Insurance (D&O) and Indemnity

The Company maintains D&O insurance covering the Executive Directors and all Non-Executive Directors.

Pursuant to Article 23 of the Articles of Association, the Directors are indemnified, held harmless, and reimbursed by the Company for all expenses, financial effects of judgments, fines, and amounts paid in settlement actually and reasonably incurred by them in connection with an action, suit, proceeding, or investigation against them in their capacity as Executive or Non-Executive Director.

Historical Development

The table below provides an overview of the annual compensation of the Executive Director and full-time equivalent (FTE) employees for the financial years 2023 and 2022. The amounts mentioned in the table are gross amounts before the impact of social-security or income-tax deductions.

EUR'000	2023	2022	2021	2020
Net loss of the period	36,181	32,772	34,314	20,014
Executive Director	1,683	1,430	3,331	1,008 ^a
<i>Annual change</i>	18%	-57%	230% ^a	
Average FTEs	104.5	86.6	76.7	55
<i>Annual change</i>	21%	13%	-11%	
Remuneration of FTEs	21,498	18,282	15,519	8,534
<i>Annual change</i>	23%	18%	82%	
Average remuneration per FTE	206	212	202	155
<i>Annual change</i>	-3%	4%	104%	
Pay Ratio	8	7	16	13 ^b
<i>Annual change</i>	21%	-59%	62%	
Non-Executive Directors	886	621	1,616	959
<i>Annual change</i>	43%	-62%	69%	

a: The CEO was appointed on 1 July 2020.

b: For a meaningful comparison, as the CEO was appointed on 1 July 2020, the 2020 pay ratio was calculated by extrapolating the CEO remuneration in 2020 for 12 months (EUR 2,016 thousand).



Pay Ratio

Based on best practice provision 3.4.1 of the CGC, the Company shall disclose the pay ratio between the remuneration of the Executive Directors and that of a representative reference group of Company employees and, if applicable, comment on any important variation in pay ratios compared to the previous financial year.

The reference group includes the Company's entire workforce expressed in the form of full-time equivalent (FTE) employees. The FTE of each employee is calculated based on the number of hours an employee works in each period, compared to the maximum number of hours/periods allowed, as per the local law prevalent in the country of operation. As of 31 December 2023, there were 99.2 FTEs (2022: 96.1).

Pay ratios are calculated based on the average remuneration received by employees of the reference group. The remuneration taken into account is the amount received during the year concerned. If all or part of the remuneration was paid in a foreign currency, the exchange rate used was the average exchange rate of the relevant currency into euros for the year ending 31 December 2023.

The Company used both fixed and variable remuneration components in determining the pay ratio for a given year. The pay ratio disclosed by the Company reflects the previous financial year. The average Executive Director-to-employee pay ratio stands at 8 in 2023, compared with 7 in 2022. The variance from 2022 to 2023 is driven by the cost of stock options awarded on 3 January 2023, this is a non-cash component of the CEO's variable compensation. The variance from 2020 to 2021 and 2021 to 2022 is due to the successful IPO in October 2021 that positively impacted the performance-based remuneration and triggered the accelerated vesting of the Employee Investment Plan.



Financials

Consolidated Financial Statements

Consolidated Statement of Profit & Loss

For the Year Ended 31 December

All amounts in EUR '000

	Notes	2023	2022
Grants & Other Income	2.1	532	2,148
Total Revenues & Other Income		532	2,148
Research & Development Expenses	2.2,2.8	(13,841)	(13,138)
Clinical & Regulatory Expenses	2.3,2.8	(4,911)	(5,747)
Marketing & Market Access Expenses	2.4,2.8	(2,943)	(1,951)
Patent fees & Related Expenses	2.5,2.8	(1,509)	(1,549)
Quality Assurance Expenses	2.6,2.8	(1,464)	(1,228)
General & Administrative Expenses	2.7,2.8	(11,327)	(10,563)
Total Operating Expenses		(35,995)	(34,176)
Operating Loss for the Period		(35,463)	(32,028)
Financial Income	4.5	972	62
Financial Expense	4.5	(1,583)	(1,572)
Net Finance Expense		(611)	(1,510)

Consolidated Financial Statements

Consolidated Statement of Comprehensive Income

For the Year Ended 31 December

All amounts in EUR '000

	Notes	2023	2022
Net Loss for the Period		(36,181)	(32,772)
Remeasurement of post-employment benefits	5.0, 2.10	(928)	427
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods (net of tax)		(928)	427
Currency translation differences		(155)	602
Other comprehensive income that will be reclassified to profit or loss in subsequent periods (net of tax)		(155)	602
Total Comprehensive Result for the Year, Net of Tax		(37,264)	(31,743)
Attributable to:			
Equity holders of the parent		(37,264)	(31,743)
Non-controlling interests		-	-
		(37,264)	(31,743)

Consolidated Statement of Financial Position

For the Year Ended 31 December

All amounts in EUR '000

	Notes	2023	2022
Assets			
Non-Current Assets			
Intangible assets	3.0	9,804	10,158
Property, plant & equipment	3.1	609	415
Right of use assets	3.2	1,483	1,681
Deferred tax assets	2.10	310	163
		12,206	12,417
Current Assets			
Indirect tax receivables	3.3	117	709
Receivable from related parties		37	251
Other current assets	3.4	1,501	1,456
Fixed term deposits	3.5	-	20,000
Cash and cash equivalents	3.5	29,768	41,760
		31,423	64,176
		43,629	76,593



Consolidated Financial Statements

Equity & Liabilities

Equity & Reserves

Issued capital	4.0	3,622	3,622
Share premium	4.0	155,249	155,249
Other reserves*	4.0	4,488	2,079
Retained earnings		(145,428)	(108,319)
Total Equity Attributable to Shareholders		17,931	52,631

Non-Current Liabilities

Interest-bearing loans	4.2	15,255	12,656
Deferred tax liability	2.10	631	670
Lease liability	3.2	1,051	1,294
Post-employment benefits	5.0	2,081	1,121
		19,018	15,741

Current Liabilities

Income tax liabilities		221	219
Lease liability	3.2	568	427
Trade payables	3.6	1,369	1,909
Other payables	3.7	4,522	5,666
		6,680	8,221
		43,629	76,593

*Other reserves include the foreign currency translation reserve that qualifies as a legal reserve under Dutch Law.



Consolidated Statement of Changes in Equity

All amounts in EUR '000

	Notes	Issued Capital	Share Premium	Other Reserves*	Retained Earnings	Total Equity
As at 1 January 2022		3,622	155,249	(214)	(75,974)	82,683
Loss for the year 2022		-	-	-	(32,772)	(32,772)
Other comprehensive income		-	-	602	427	1,029
<i>Total comprehensive result</i>		-	-	602	(32,345)	(31,743)
Share-based payments: LTIP	2.9	-	-	1,691	-	1,691
As at 31 December 2022	4.0	3,622	155,249	2,079	(108,319)	52,631
As at 1 January 2023		3,622	155,249	2,079	(108,319)	52,631
Loss for the year 2023		-	-	-	(36,181)	(36,181)
Other comprehensive income		-	-	(155)	(928)	(1,083)
<i>Total comprehensive result</i>		-	-	(155)	(37,109)	(37,264)
Share-based payments: LTIP	2.9	-	-	2,564	-	2,564
As at 31 December 2023	4.0	3,622	155,249	4,488	(145,428)	17,931

* Other reserves include the foreign currency translation reserve that qualifies as a legal reserve under Dutch Law.



Consolidated Statement of Cash Flows

For the Year Ended 31 December

All amounts in EUR '000

	Notes	2023	2022
Cash Flows from Operating Activities			
Loss for the Period Before Taxes		(36,074)	(33,538)
Adjusted for:			
◦ Depreciation and impairment of property, plant and equipment and right-of-use assets	3.1, 3.2	726	735
◦ Share-based payment transaction expense	2.9	2,564	1,691
◦ Post-employment benefits		76	154
◦ Net finance costs		611	1,510
◦ Other non-cash items		197	106
Changes in working capital:			
Increase (-) Decrease (+) in Trade and other receivables		491	140
Increase (+) Decrease (-) in Trade and other payables		(1,654)	2,813



Consolidated Financial Statements

Interests received														916					15
Interests paid														-					(229)
Income tax paid														(106)					(49)
Bank charges paid								4.5						(17)					(33)
Net cash generated/(used) from operating activities														(32,270)					(26,685)
Cash flows from investing activities																			
Investments in fixed assets								3.1						(422)					(386)
Investments in intangible fixed assets								3.0						-					(31)
Investment in fixed term deposits								3.5						-					(20,000)
Withdrawal of term deposits														20,000					-
Net cash generated/(used) from investing activities														19,578					(20,417)
Cash flows from financing activities																			
Proceeds from interest-bearing loans								4.2						1,292					-
Payment of principal portion of lease liabilities								3.2						(479)					(557)
Proceeds from issuance of shares														-					-
Transaction costs on issuance of shares								4.0						-					-
Net cash generated/(used) from financing activities														813					(557)
Movement in cash and cash equivalents																			
Cash and cash equivalents at 1 January														41,760					89,443
Effect of exchange rates on cash and cash equivalents														(113)					(24)
Changes in cash and cash equivalents during the period														(11,879)					(47,659)
Cash and cash equivalents at 31 December								3.5						29,768					41,760



ONWARD[®]

Notes to the Consolidated Financial Statements



Notes to the Consolidated Financial Statements

1. General Information & Basis of Preparation

1.0 Corporate Information

General

Onward Medical N.V. (“ONWARD”) is a public limited company under Dutch law (naamloze vennootschap). The registered office is located at Schimmelt 2, Eindhoven, the Netherlands. ONWARD is registered in the Commercial Register of the Chamber of Commerce under number 64598748.

ONWARD and its subsidiaries (the “Group”) are developing both an Implantable Neurostimulation System (INS) and a non-invasive system for electrical stimulation of specific areas of the spinal cord.

The financial statements for the year ended 31 December 2023 have been prepared by the Board of Directors and were authorized for issue on 24 April 2024. The financial statements will be submitted for adoption to the General Meeting on 14 June 2024.

1.1 Group Information

Information about subsidiaries

The consolidated financial statements of the Group include:

- ONWARD Medical SA, Switzerland (holding 100%)
- ONWARD Medical Inc, United States of America (holding 100%)

1.2 Basis of Preparation

The consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards (IFRS) and IFRIC interpretations as adopted by the European Union and with Part 9 of Book 2 of the Dutch Civil Code.

The consolidated financial statements have been prepared on a historical cost basis, unless otherwise stated. Income and expenses are accounted for on an accrual basis. The consolidated financial statements provide comparative information in respect of the previous period.

The consolidated financial statements are presented in euros and all values are rounded to the nearest thousand (EUR 000), except when otherwise indicated, and for the number of shares and the per share amount. Due to rounding, amounts may not add up to totals provided.

1.3 Basis of Consolidation

The consolidated financial statements comprise the financial statements of the Group and its subsidiaries as at 31 December 2023. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. Specifically, the Group controls an investee if and only if the Group has:

- Power over the investee (i.e., existing rights that give it the current ability to direct the relevant activities of the investee)

- Exposure, or rights, to variable returns from its involvement with the investee, and
- The ability to use its power over the investee to affect its returns

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control. Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary.

Profit or loss and each component of other comprehensive income (OCI) are attributed to the equity holders of the parent of the Group. When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with the Group's accounting policies. All intragroup assets and liabilities, equity, income, expenses, and cash flows relating to transactions between members of the Group are eliminated in full-on consolidation.

1.4 Going Concern

In determining the appropriate basis for preparing the financial statements for the year ended 31 December 2023, Management considered the cash flow forecasts over a time horizon of one year after the date of these financial statements. The 2024 cash flow forecasts, include significant expenses and cash outflows in relation to -among others- the ongoing clinical trials, the continuation of research and development projects and FDA submission and approval for the ARC^{EX} indication. Inherent uncertainties in these forecasts may have an impact on the Company's cash position. To continue development and reach commercialization as planned, the Company will need to attract additional funding in future. The Company's long-term success and existence is contingent on achieving FDA approval and CE mark of its products.

At 31 December 2023 the Company had cash and cash equivalents of EUR 29.8M. This was expected to fund operations to the end of 2024. On 25 March 2024, the Company



completed a private placement and French retail public offering, adding EUR 20M gross to the year-end cash position. The cash and cash equivalents including the offering in March 2024 amounted to EUR 42M at 31 March 2024.

The Company believes that this cash position, after the offering, will be sufficient to meet the Company's capital requirements and fund its operations for at least 12 months as from the date of this Annual Report. We anticipate this would extend our cash runway to May 2025. The Company is currently in the process of attracting additional funding, which would extend the runway to Q3 2025. In case this or other funding opportunities are not successful, management sees cost savings opportunities to further extend the cash run rate beyond May 2025.

In view of the above, and notwithstanding a loss brought forward of EUR 145M as of 31 December 2023, the consolidated financial statements have been prepared on a going concern basis.

1.5 Summary of Material Accounting Policies

a) Current Versus Non-Current Classification

The Group presents assets and liabilities in the statement of financial position based on current/non-current classification. An asset is current when it is:

- Expected to be realized or intended to be sold or consumed in normal operating cycle
- Held primarily for the purpose of trading
- Expected to be realized within twelve months after the reporting period, or
- Cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period

All other assets are classified as non-current.

A liability is current when:

- It is expected to be settled in normal operating cycle
- It is held primarily for the purpose of trading
- It is due to be settled within twelve months after the reporting period, or
- There is no unconditional right to defer the settlement of the liability for at least twelve months after the reporting period

The Group classifies all other liabilities as non-current.

Deferred tax assets and liabilities are classified as non-current assets and liabilities.

b) Foreign Currencies

The Group's consolidated financial statements are presented in euros, which is also the parent company's functional currency. For each entity, the Group determines the functional currency and items included in the financial statements of each entity are measured using that functional currency.

Transactions & Balances

Transactions in foreign currencies are initially recorded by the Group entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currencies are retranslated at the functional currency spot rate of exchange at the reporting date.

Differences arising on settlement or translation of monetary items are recognized in profit or loss with the exception of monetary items that are designated as part of the hedge of the Group's net investment of a foreign operation. These are recognized in other comprehensive income until the net investment is disposed of, at which time, the cumulative amount is reclassified to profit or loss. Tax charges and credits attributable to exchange differences on those monetary items are also recorded in other comprehensive income.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates as at the dates of the initial transactions. Non-monetary



Notes to the Consolidated Financial Statements

items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value is determined. The gain or loss arising on translation of non-monetary items measured at fair value is treated in line with the recognition of gain or loss on change in fair value of the item (i.e., translation differences on items whose fair value gain or loss is recognized in other comprehensive income or profit or loss are also recognized in other comprehensive income or profit or loss, respectively).

Any goodwill arising on the acquisition of a foreign operation and any fair value adjustments to the carrying amounts of assets and liabilities arising on the acquisition are treated as assets and liabilities of the foreign operation and translated at the spot rate of exchange at the reporting date.

Group Companies

On consolidation, the assets and liabilities of foreign operations are translated into euros at the rate of exchange prevailing at the reporting date and their income statements are translated at the monthly average exchange rates.

The exchange differences arising on translation for consolidation are recognized in other comprehensive income. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is recognized in profit or loss.

1.6 Significant Accounting Judgments, Estimates & Assumptions

The preparation of the Group’s consolidated financial statements requires Management to make judgments, estimates, and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and the disclosure of contingent liabilities, at the end of the reporting period. However, uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of the asset or liability affected in future periods.

The Group based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or

circumstances arising beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of revision and the future periods if the revision affects both current and future periods.

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date, that are most relevant to the carrying amounts of assets and liabilities within the next financial year, are included in each of the respective notes as referenced below:

Research & Development	Note 2.2
Share-Based Payments	Note 2.9
Impairment of Intangible Assets	Note 3.0
Post-Employment Benefits	Note 5.0
Taxes	Note 2.10

1.7 New Accounting Standards & Developments

1.7.1 New and Amended Standards and Interpretations

Several amendments applied for the first time in 2023:

- IFRS 17 Insurance Contracts, effective 1 January 2023
- Disclosure of Accounting Policies - Amendments to IAS 1 and IFRS Practice Statement 2, effective 1 January 2023
- Definition of Accounting Estimates - Amendments to IAS 8, effective 1 January 2023
- Deferred Tax related to Assets and Liabilities arising from a Single Transaction – Amendments to IAS 12, effective 1 January 2023



Notes to the Consolidated Financial Statements

None of these had a material impact on the consolidated financial statements of the Group in 2023.

1.7.2 Standards Issued but Not Yet Effective

The new and amended standards and interpretations that are issued, but not yet effective, up to the date of issuance of the Group’s financial statements are listed below. The Group has not early adopted any standards, interpretations or amendments that have been issued but are not yet effective. The Group intends to adopt these new and amended standards and interpretations, if applicable, when they become effective.

- Classification of Liabilities as Current or Non-current - Amendments to IAS 1, effective 1 January 2024
- Lease Liability in a Sale and Leaseback – Amendments to IFRS 16, effective 1 January 2024
- Disclosures: Supplier Finance Arrangements - Amendments to IAS 7 and IFRS 7, effective 1 January 2024
- Lack of exchangeability – Amendments to IAS 21, effective 1 January 2025
- Sale or Contribution of Assets between an Investor and its Associate or Joint Venture - Amendments to IFRS 10 and IAS 28. In December 2015, the IASB postponed the effective date of this amendment indefinitely pending the outcome of its research project on the equity method of accounting.

Based on the nature and impact of each of the new standards, amendments and/or interpretations, the Group expects no material impact considering the circumstances as at the date of the Annual Report.

2. Results of The Year

2.0 Segment Reporting

Based on the organizational structure, as well as the nature of financial information available and reviewed by the Company’s chief operating decision-makers to assess performance and make decisions about resource allocations, the Company has concluded that its total operations represent one reportable segment and that the consolidated disclosures address the requirements.

	2023	2022
Non-current assets		
Netherlands	118	61
Switzerland	2,273	2,194
United States of America	9,815	10,162
Non-current assets	12,206	12,417

2.1 Revenues & Other Income

Accounting Policy: Government subsidies are recognized where there is reasonable assurance that the subsidy will be received, and all attached conditions will be complied with. When the subsidy relates to an expense item, it is recognized as income on a systematic basis over the periods that the related costs, for which it is intended to compensate, are expensed. Any outstanding receivables related to these subsidies are recorded as grants receivable. The government subsidies are presented on a gross basis except for the WBSO (“Wet Bevordering Speur & Ontwikkeling”) that is presented on a net basis with the expensed amount for personnel expenses.

	2023	2022
Government subsidies (EU)	464	2,044
Other income	68	104
Total revenues and other income	532	2,148



Notes to the Consolidated Financial Statements

Government subsidies have been received for the research and development of several development projects. There are no unfulfilled conditions or contingencies attached to these subsidies.

Grants	Total Grant*	Recognized as Grant Income 2023	Recognized as Grant Income 2022	Recognized as Grant Income cumulative before 2022	Grant received in advance as per 31-12-2023
CONFIRM	416	–	(12)	416	–
SWISS LOCAL (one-offs)**	–	–	85	65	–
PREP2GO	362	15	104	243	–
DARPA	3,004	419	1,412	1,173	–
ZonMW	250	83	83	83	–
EISMEA – Reverse Paralysis***	292	(237)	273	–	183
EISMEA – NEMO BMI***	144	(85)	85	–	108
Eurostars Impulse	500	160	14	–	–
Rewire	347	56	–	–	122
SH-ARC	500	53	–	–	60
Total		464	2,044	1,980	473

* Please refer to the terms and conditions of the subsidies included below.

** Except for the Swiss local grant received by ONWARD Medical SA (In Switzerland), all other grants were received by ONWARD Medical N.V. (In the Netherlands).

*** Refer to EISMEA pending amendment note included below

Terms & Conditions

CONFIRM

This Eurostars funding agreement with the Swiss Innovation Agency Innosuisse for a total amount of EUR 416k started in May 2019 and ended in October 2021, with follow up reporting resulting in the additional 25.75% granting of the allocated amount. The remainder of the grant was receivable in 2022 after submission of the final report. Due

to lesser expenses declared, the final amount was decreased. In this project, ONWARD collaborated with Inomed A.G., Universitätsklinikum Heidelberg, and EPFL to develop an intra-operative neuromonitoring system and algorithms facilitating the surgical implantation of ARC^{IM}.

PREP2GO

This Eurostars funding agreement with the Netherlands enterprise agency RVO for a total amount of EUR 348k started in April 2020 and ended in September 2022. An amount equal to 90% of the grant is paid during the grant period in tranches in 2020, 2021, and 2022. The remaining 10% of the grant is payable after evaluation of the final report. In this project, ONWARD collaborated with Zurich Medtech A.G., IT'IS Foundation, Universitair Medisch Centrum Utrecht and EPFL to automatize the simulation framework that was developed in the RESTORE project, to facilitate the pre-operative planning for ARC Therapy for clinicians.

DARPA

The DARPA grant is a five-year project that started in October 2020. The award has been divided into 3 phases. The funding agreement for phase 1 and phase 2 was approved for a total amount of EUR 3.172M (or USD 3.402M). The grant amounts are being charged on a monthly basis over the period based on actual costs incurred. In this project, ONWARD is collaborating with a large consortium of academic partners, companies, and consultants to develop a new clinical intervention to modulate blood pressure and spinal cord perfusion and oxygenation in the hours following SCI. This corresponds to a roadmap development of ARC^{IM} to be used in the hours following SCI. ONWARD completed its contributions to the DARPA project in 2023 within the final cumulative amount being recognized amounting to EUR 3.004M (or USD 3.307M). The US government has announced that the DARPA project is cancelled and phase 3 will not continue.

ZonMW

This Dutch funding agreement is with the Netherlands Organisation for Health Research and Development for a total amount of EUR 250k that started in January 2021 and ends in January 2024. An amount equal to 80% of the grant is being paid during the grant period



in three equal tranches in 2021, 2022, and 2023. The remaining 20% of the grant will be paid after submission of the final report. In this project, ONWARD is collaborating with the University of Bordeaux, CHUV, and EPFL to develop a research interface for ARC^{IM} and evaluate its use to alleviate locomotor deficits in Parkinson's disease.

EISMEA – Reverse Paralysis

The European Innovation Council and SMEs Executive Agency (EISMEA) awarded a grant to support the development of an innovative Brain-Spine Interface technology for restoring mobility and upper limb function. The EUR 3.6M grant was awarded to ONWARD and its research partners EPFL, CEA-Clnatec and Sint Maartenskliniek. Under the terms of the award, ONWARD receives EUR 1.2M. The project started 1 May 2022 and has an end date of 30 April 2025, a duration of 36 months. ONWARD has received 75% as prefinancing; an additional 15% is receivable 90 days after the first periodic reporting, and the final payment 90 days after receiving the second periodic reporting. See note EISMEA pending amendment.

EISMEA – NEMO BMI

The European Innovation Council and SMEs Executive Agency (EISMEA) awarded a grant to support the development of Motor Brain-Machine Interfaces (BMIs). BMIs translate brain neural signals into commands to external effectors. The NEMO BMI project will conduct the exploration of assistance-free and easy-to-use portable neuroprosthetics including wireless neuronal activity recorder, a real-time neuronal activity decoder based on integrated technologies, and a spinal cord stimulator. The EUR 3.8M grant was awarded to ONWARD and its research partners Ecole Polytechnique Federale de Lausanne (EPFL), Commissariat à l'Énergie Atomique et aux énergies alternatives (CEA), and Institute of Information and Communication Technologies (IICT). Under the terms of the award, ONWARD receives EUR 1M. The project started 1 October 2022 and has an end date of 30 September 2025, a duration of 36 months. ONWARD has received 75% as prefinancing; an additional 15% (up to 90% of the total grant) is receivable 90 days after the first periodic reporting, and the final payment is receivable 90 days after receiving the second periodic reporting. See note below, EISMEA pending amendment.

EISMEA Pending Amendment

The Company was awarded two grants from the European Innovation Council and SMEs Executive Agency (EISMEA), Project 101057450 – ReverseParalysis and Project 101070891 – NEMO BMI. Both projects work on the development, refinement, and clinical validation of a brain-computer interface for reversing paralysis after SCI. During the application process for both projects, the Company's research and development activities were primarily based at its headquarters in Eindhoven, the Netherlands, however, the Company opened an office and shifted R&D activities to Lausanne, Switzerland to be closer to its primary clinical partner, EPFL. The Company's headquarters are in the Netherlands and will continue to be responsible for the launch of products on the European market as legal manufacturer, ensuring European patients across the European Union benefit from these projects. Both projects were applied for and awarded to the Company. While there are personnel in the Netherlands office working on both ReverseParalysis and NEMO-BMI, certain R&D personnel are now located in Switzerland. The Company recognized grant income, in terms of the accounting policy in the Financial Statements, assuming that the effort and hours of Swiss employees could be leveraged under the definition of an affiliated entity or a beneficiary. During the first yearly project review of ReverseParalysis, the EISMEA project coordinators inquired about the location of personnel whose hours were declared. As Switzerland is not in the European Union and no longer associated to the European Horizon framework, ONWARD Medical SA cannot be added as a beneficiary in the grant agreement and have funding dispersed by the EISMEA. An amendment to the grant agreement is required to show what work and budget has been/will be transferred from the Dutch entity to the Swiss entity. The EISMEA will only fund the work to be performed in the Netherlands (EU). The grant amendment has been drafted and submitted to EISMEA for review. The Company has started discussions with a Swiss State Agency (SSA) regarding replacement funding. This SSA is an organization in Switzerland that covers costs associated with work done by Swiss entities in innovation Horizon Europe. A formal application with SSA can only be submitted, once the amendment with EISMEA has been approved. For the year ended 31 December 2023, the Company updated the grant income recognized to take into account this change in recognition in accordance with IAS 8.34 as required by IAS 20.32. This resulted in the reversal of grant income that is expected (but not yet confirmed) to be taken over by SSA. An accrual for EUR 1,358k was also raised



for the advance received, which the Company expects to repay to EISMEA following approval of the amendment. The impact on grant income recognized for the year ended 31 December 2022 amounted to EUR 325k.

Eurostars Impulse

The Eurostars Independent Evaluation Panel has provided a subsidy for a total amount of EUR 500k that started 1 December 2022 and ends 30 November 2025, a duration of 36 months. The Impulse project focuses on closed-loop control of blood pressure for people with SCI.

ReWIRE

ONWARD has joined other global neuroscience and rehabilitation stakeholders to create ReWIRE, a groundbreaking initiative aimed at equipping next-generation scientists with the skills to develop therapeutic solutions for patients with paralysis caused by SCI. ReWIRE will build on recent technological breakthroughs by leveraging multiple PhD projects that will drive effective combinatorial treatments for SCI. The project is funded by the European Research Executive Agency (REA) as part of the Marie Skłodowska-Curie Actions (MSCA) Doctoral Networks for an amount of EUR 360k and started in 1 January 2023 and ends 31 December 2026.

SH-ARC

The Eurostars Independent Evaluation Panel has provided a subsidy for a total amount of EUR 500k that started 1 April 2023 and ends 31 March 2026, a duration of 36 months. SH-ARC works to integrate NUSHU sensorised shoes in a clinical-grade neuroprosthesis that will utilize spinal cord stimulation to alleviate parkinsonian gait deficits.

2.2 Research & Development Expenses

Accounting Policy: Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset when the Group can demonstrate:

- The technical feasibility of completing the intangible asset so that it will be available for use or sale
- Its intention to complete and its ability to use or sell the asset
- How the asset will generate future economic benefits
- The availability of resources to complete the asset
- The ability to measure reliably the expenditure during development
- The ability to use the intangible asset generated

Significant Estimate: The Group has evaluated the nature of the project research and development costs and concluded that all expenses incurred were related to research and pre-development of future products. Therefore, all costs have been expensed and are recognized in the statement of profit and loss.

	2023	2022
Staff expenses	9,200	8,385
Operating expenses	4,641	4,753
	13,841	13,138

The Company’s research and development expenses consist primarily of the cost of external suppliers and third-party contractors involved in the design and development of the ARC^{EX} and ARC^{IM} systems, as well as employee-related expenses including salaries and benefits. The increase in 2023 is driven by advancements made on our ARC^{EX} and ARC^{IM} platforms and preparing for FDA submission of ARC^{EX} in the first half of 2024.



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2.3 Clinical & Regulatory Expenses

	2023	2022
Staff expenses	3,472	3,204
Operating expenses	1,439	2,543
	4,911	5,747

The Company’s clinical and regulatory expenses consist of the employee-related expenses including salaries and benefits for employees working on clinical trials. Clinical expenses in 2023 primarily relate to the clinical proof-of-concept studies, HemonNL and supporting the preparation of ARC^{EX} for FDA submission.

2.4 Marketing & Market Access Expenses

	2023	2022
Staff expenses	1,830	949
Operating expenses	1,113	1,002
	2,943	1,951

The Company’s marketing and market access expenses include the investigating activities on the future therapy reimbursement performed by third-party consultants and attendance of key events to create awareness within the SCI community of our ARC therapies and technology.

2.5 Patent fees & Related Expenses

	2023	2022
Staff expenses	373	400
Operating expenses	1,136	1,149
	1,509	1,549

The Company’s patent fees and related expenses include the cost for patent prosecution applications, consulting fees for new innovative ideas, as well as annuity maintenance fees and license fees for existing ideas, related employee expenses, including salary and benefits in the area of business development.

2.6 Quality Assurance Expenses

	2023	2022
Staff expenses	1,204	1,045
Operating expenses	260	183
	1,464	1,228

Quality assurance expenses consist primarily of quality control and quality assurance expenses. These expenses include employee expenses, including salary benefits for personnel, consulting, testing, and travel expenses.

2.7 General & Administrative Expenses

	2023	2022
Staff expenses	5,419	4,299
Depreciation and amortization	726	735
Other operating expenses	5,182	5,529
	11,327	10,563

The Company’s general and administrative expenses consist of employee expenses, including salary and benefits for personnel and contractors in executive, finance, accounting, tax, and human resources, as well as operating expenses relating to audit, legal, and supply chain.



2.8 Employee Benefit Expenses

Accounting Policy:

Short-Term Employee Benefits

Short-term employee benefits include salaries and social security contributions, social taxes, paid vacation, and bonuses. They are recognized as expenses for the period in which employees perform the corresponding services. Outstanding payments at the end of the period are shown as other current liabilities.

Post-Employment Benefits

Group companies operate various pension schemes. The schemes are funded through payments to insurance companies or trustee-administered funds, determined by periodic actuarial calculations. The Group has both defined benefit and defined contribution plans.

Defined Contribution Plan

A defined contribution plan is a pension plan under which the Group pays fixed contributions into a separate entity. The Group has no legal or constructive obligations to pay further contributions if the fund does not hold sufficient assets to pay all benefits to employees relating to employee services in the current and prior periods. For defined contribution plans, the Group pays contributions to publicly or privately administered pension insurance plans on a mandatory, contractual, or voluntary basis. The Group has no further payment obligations once the contributions have been paid. The contributions are recognized as personnel expenses in the consolidated income statement when due.

All related expenses are recognized in the consolidated statement of profit and loss. Contributions payable or prepaid contributions as at year-end are recognized under accruals and deferred income, and prepayments and accrued income, respectively.

Defined Benefit Plan

The Group operates a defined benefit pension plan in Switzerland, which requires contributions to be made to a separately administered fund. The cost of providing benefits under the defined benefit plan is determined using the projected unit credit method.

Remeasurements, comprising of actuarial gains and losses are recognized in the statement of financial position with a corresponding debit or credit to retained earnings through OCI in the period in which they occur. Remeasurements are not reclassified to profit or loss in subsequent periods.

Past service costs are recognized in profit or loss on the earlier of:

- The date of the plan amendment or curtailment, and
- The date that the Group recognizes related restructuring costs

Net interest is calculated by applying the discount rate to the net defined benefit liability or asset. The Group recognizes the changes in the net defined benefit obligation due to service costs comprising current service costs, past-service costs, gains and losses on curtailments and non-routine settlements as part of operating expenses, and the net interest expense or income as part of net finance costs in the consolidated statement of profit and loss.

Significant Estimate: The cost of the defined benefit pension plan and the present value of the pension obligation are determined using actuarial valuations. An actuarial valuation involves making various assumptions that may differ from actual developments in the future. These include the determination of the discount rate, future salary increases, mortality rates, and future pension increases. Due to the complexities involved in the valuation and its long-term nature, a defined benefit obligation is sensitive to changes in these assumptions. All assumptions are reviewed at each reporting date.

	2023	2022
Wages and salaries	15,356	11,653
Social security costs	1,512	1,275
Pension costs – defined benefit plan	720	604
Pension costs – other	69	82
Share-based benefit expenses	2,564	1,691
Other labor costs	1,277	2,977
	21,498	18,282



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The increase in wages and salaries is driven by the composition of new hires versus leavers and not full-time equivalents. This shift in expertise aligns with the Company’s strategic goals. As at 31 December 2023, the Group employed 99.2 full-time equivalents, including white-collar employees and contractors. The following table presents a breakdown of the Company’s full-time equivalents as at 31 December 2023 and 2022:

	2023	2022
Research & Development	50.0	48.8
Clinical & Regulatory	14.6	18.9
Marketing & Market Access	5.0	3.8
Patent Fees & related	1.0	1.0
Quality Assurance	8.8	7.8
General & Administrative	19.8	15.8
	99.2	96.1

As at 31 December 2023, the Company had 11.9 full-time equivalents located in the Netherlands (2022: 16.3), 75.3 full-time equivalents located in Switzerland (2022: 68.3), and 12 (2022: 11.5) full-time equivalents located in the United States.

2.9 Share-Based Payments

Accounting Policy: Employees (including senior executives) of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments (equity-settled transactions).

Equity-Settled Transactions

The cost of equity-settled transactions is determined by the fair value at the date when the grant is made using an appropriate valuation model.

That cost is recognized, together with a corresponding increase in other reserves in equity, over the period in which the performance and/or service conditions are fulfilled in employee benefits expense. The cumulative expense recognized for equity-settled

transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group’s best estimate of the number of equity instruments that will ultimately vest. The statement of profit or loss expense or credit for a period represents the movement in cumulative expense recognized as at the beginning and end of that period and is recognized in operating expenses.

No expense is recognized for awards that do not ultimately vest, except for equity-settled transactions for which vesting is conditional upon a market or non-vesting condition. These are treated as vesting irrespective of whether or not the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

When the terms of an equity-settled award are modified, the minimum expense recognized is the expense had the terms not been modified, if the original terms of the award are met. An additional expense is recognized for any modification that increases the total fair value of the share-based payment transaction or is otherwise beneficial to the employee as measured at the date of modification.

Significant Estimate: The Group measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. Estimating fair value for share-based payment transactions requires determination of the most appropriate valuation model, which is dependent on the terms and conditions of the grant.

Long-Term Incentive Plan (LTIP)

The LTIP plan is aimed at aligning the employee’s interest with the interests of the Shareholders and to allow the employee to participate in the long-term growth of the Company. The LTIP is an omnibus plan with the flexibility to issue different type of equity incentives.

ONWARD awarded options over its Ordinary Shares to participants (referred to as the “Award” or “Grant”) on the Grant Dates as specified in the table below. Each option represents the right to receive one Ordinary Share of ONWARD against payment of the



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exercise price. The options expire 10 years after the Grant Date and become exercisable on vesting. The Grant is subject to continued provision of services to the Company under a graded vesting schedule, with 25% of the Grant vesting on the first anniversary of the Grant Date, and the remaining 75% of the Grant vesting in equal, monthly tranches over the three years following the first anniversary of the Grant Date (i.e, 2.083% per month). The number of options that will vest and become unconditional is only subject to a continued service condition. All options granted have the same conditions. Options do not settle automatically and are exercised at the option of the participant.

Financial Year	Grant Date	Type of Security	Number of Options Granted	Exercise Price	Expiration Date	Fair Value
2021	15/12/2021	Stock Options	612,000	EUR 7.41	15/12/2031	EUR 4.89
2022	1/4/2022	Stock Options	169,800	EUR 7.64	1/4/2032	EUR 4.18
2022	26/9/2022	Stock Options	166,350	EUR 5.70	26/9/2032	EUR 3.19
2023	3/1/2023	Stock Options	978,050	EUR 6.12	3/1/2033	EUR 3.37
2023	28/2/2023	Stock Options	132,000	EUR 4.95	28/2/2033	EUR 2.73
2023	3/7/2023	Stock Options	308,175	EUR 5.18	3/7/2033	EUR 2.85

This fair value per option has been applied to the options granted for the recognition of the share-based payment expense recognized:

	2023	2022
Share-based payment expense	2,564	1,691
	2,564	1,691

The table below summarizes the number and weighted average exercise prices (WAEP) of, and movements in, share options during the year:

	2023 Number	2023 WAEP	2022 Number	2022 WAEP
Outstanding at 1 January	873,125	EUR 7.41	612,000	EUR 9.70
Granted during the year	1,418,225	EUR 5.81	336,150	EUR 6.68
Forfeited during the year	(462,700)	EUR 6.90	(75,025)	EUR 9.40
Exercised during the year	-	-	-	-
Outstanding at 31 December	1,828,650	EUR 6.85	873,125	EUR 7.41

	2023 Number	2023 WAEP
Exercisable at 31 December 2023	298,961	EUR 9.10
Exercisable at 31 December 2022	143,089	EUR 9.70

The weighted average remaining contractual life for the share options outstanding at 31 December 2023 was 8.79 years (2022: 9.2 years).

The weighted average fair value of options granted during the year was EUR 3.20 (2022: EUR 3.69).



The range of exercise prices for options outstanding at the end of the year was EUR 4.95 to EUR 9.70 (2022: EUR 5.70 to EUR 9.70).

The fair value of the awarded options was determined by applying a Binomial Option Pricing Model that allows for exercising of the option before the end of the option's life.

As the options cannot be exercised between the Grant Date and the vesting date, the Hull-White binomial formula, commonly used to value American options, was used. With the Hull-White model the impact of a certain time-based event – such as a vesting period, or an early exercise – can be taken into account.

Due to the different vesting dates for the different tranches in the option, we have calculated the unique option values per tranche according to each vesting date. The total option value per employee is then derived using a weighted average overall calculated option value for each vesting date.

The following parameters were used in the option model for the calculation of the fair value of the options as per each grant date:

	2023-07	2023-02	2023-01	2022-09	2022-04
Fair value on date of measurement (EUR)	2.85	2.73	3.37	3.19	4.18
Share price (EUR)	5.18	4.97	6.12	5.70	7.64
Exercise price (EUR)	5.18	4.95	6.12	5.70	7.64
Expected volatility	56.10%	57.20%	57.80%	59.30%	59.20%
Term of the option	4 ^a	4 ^a	4 ^a	4 ^a	4 ^a
Expected dividend	-	-	-	-	-
Risk-free interest rate	2.44%	2.65%	2.38%	2.1%	0.55%
Time to expiration	10	10	10	10	10

a: Vesting period is 1 – 4 years and depends on the vesting date of the specific tranche.

2.10 Income Tax

Accounting Policy:

Current Income Tax

Current income tax assets and liabilities for the current period are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted, at the reporting date in the countries where the Group operates and generates taxable income.

Current income tax relating to items recognized directly in equity is recognized in equity and not in the statement of profit or loss. Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

Deferred Tax

Deferred tax is provided using the liability method on temporary differences between the tax basis of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

Deferred tax liabilities are recognized for all taxable temporary differences, except:

- When the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss
- In respect of deductible temporary differences associated with investments in subsidiaries, associates and interests in joint ventures, deferred tax assets are recognized only to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilized



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Deferred tax assets are recognized for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the deductible temporary differences and the carry forward of unused tax credits and unused tax losses can be utilized, except:

- When the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.
- In respect of deductible temporary differences associated with investments in subsidiaries, associates and interests in joint ventures, deferred tax assets are recognized only to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilized.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilized. Unrecognized deferred tax assets are reassessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realized or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Significant Estimate: The Group has losses before tax which arose in the Netherlands that are available to offset against future profits of the Dutch entity in which the loss arose. However, these losses may not be used to offset taxable income elsewhere in the Group. The Group evaluated and judged that at this moment it is not sufficiently likely that future profits will be generated in the Dutch entity that can offset a deferred tax asset.

All Switzerland operations have a cost-plus agreement. The taxable amounts are settled. There are no NOLs. Last fiscal year settled is 2021. Due to expected profits based on the cost-plus the Swiss deferred tax assets relating to temporary differences have been recognized.

NOLs in the US entity prior to 2018 can be carried forward for 20 years. NOLs after 2018 can be carried forward indefinitely, limited to 80% of taxable income. On the acquisition of ONWARD Medical Inc. (formerly known as NeuroRecovery Technologies Inc) a deferred tax liability was recognized for the intangible asset (in-process R&D) identified in the PPA. In 2022, the Company, after reassessment, recognized a deferred tax asset of EUR 987k in the US entity that offsets the deferred tax liability as allowed under IAS 12, with no impact on previously reported results.

	2023	2022
Current income tax	(148)	(185)
Deferred income tax	41	951
Total corporate income tax in profit and loss	(107)	766
Current income Tax charge at tax rate of 25.8%	9,307	8,653
Tax rate differences in foreign jurisdictions	152	208
Non-deductible expenses	(662)	(433)
Non-recognized deferred tax asset on temporary differences	66	(111)
Non-recognized deferred tax asset on permanent differences	(203)	-
Net operating losses not recognized	(8,709)	(8,527)
Recognition of prior year deferred tax adjustments	-	976
Other	(58)	-
	(107)	766

The effective tax rate was -0.3% in 2023 (2022: 2.3%), which is lower than the statutory income tax rate of 25.8% (2022: 25.8%) in the Netherlands. The difference is primarily due to the net operating losses and temporary differences for which no deferred tax asset can be recognized. The uncertainty is based on insufficient evidence of future sources of



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income to support the realization of a deferred tax asset due to the Company being loss-making with limited tax planning opportunities.

Recognized Deferred Tax Assets & Liabilities

2023	Assets	Liabilities	Net
Intangible assets, including Goodwill	–	(1,639)	(1,639)
Right of use assets	–	(209)	(209)
Lease liability	228	–	228
Post-employment benefits	291	–	291
Losses available for offset against future Taxable income	1,008	–	1,008
Set-off of deferred tax	(1,217)	1,217	–
Net deferred tax liability	310	(631)	(321)

2022	Assets	Liabilities	Net
Intangible assets, including Goodwill	–	(1,656)	(1,656)
Right of use assets	–	(235)	(235)
Lease liability	240	–	240
Post-employment benefits	157	–	157
Losses available for offset against future Taxable income	987	–	987
Set-off of deferred tax	(1,221)	1,221	–
Net deferred tax liability	163	(670)	(507)

	2023	2022
Opening balance at 1 January	(507)	(1,991)
Recognized in profit & loss	41	951
Remeasurement (gain)/loss on actuarial gains and losses in OCI	125	(59)
Foreign currency translation difference	20	26
Addition	–	–
Reclassification	–	566
Net deferred tax liability at 31 December	(321)	(507)

Of the estimated amount of tax losses carried forward and available as at 31 December 2023, a deferred tax asset of EUR 1,007k has been recognized to offset the reversal of temporary differences in the US. For the remaining unused operating losses in the Netherlands of EUR 120M (2022: EUR 91M) and in the US of EUR 28.5M (2022: EUR 16M) no deferred tax is recognized. These losses can be carried forward indefinitely subject to local tax rules, except for approximately EUR 3.1M of losses in the US, which can be carried forward for 20 years (ultimately by 2037).

The Company offsets tax assets and liabilities if it has a legally enforceable right to set off current tax assets and current tax liabilities, and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same tax authority.

The deferred tax liability initially arose on the acquisition of NRT Inc (subsequently renamed to ONWARD Medical Inc.).

3. Non-Current Asset & Working Capital

3.0 Intangible Assets

	2023	2022
Goodwill	1,845	1,902
In-Process R&D	5,698	5,873
License fees	2,261	2,383
Net book value at 31 December	9,804	10,158

Goodwill

Accounting Policy: Goodwill is initially measured at cost, being the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests, and any previous interest held, over the net identifiable assets acquired and liabilities assumed. If the fair value of the net assets acquired is in excess of the aggregate consideration transferred, the Group reassesses whether it has correctly identified all of the assets acquired and all of the liabilities assumed, and reviews the procedures used



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to measure the amounts to be recognized at the acquisition date. If the reassessment still results in an excess of the fair value of net assets acquired over the aggregate consideration transferred, then the gain is recognized in profit or loss.

After initial recognition, goodwill is measured at cost less any accumulated impairment losses. For the purpose of impairment testing, goodwill acquired in a business combination is, from the acquisition date, allocated to each of the Group's cash-generating units that are expected to benefit from the combination, irrespective of whether other assets or liabilities of the acquiree are assigned to those units.

Where goodwill has been allocated to a cash-generating unit and part of the operation within that unit is disposed of, the goodwill associated with the disposed operation is included in the carrying amount of the operation when determining the gain or loss on disposal. Goodwill disposed in these circumstances is measured based on the relative values of the disposed operation and the portion of the cash-generating unit retained.

	2023	2022
Cost	1,902	1,702
Accumulated changes	-	-
Net book value at 1 January	1,902	1,702
Additions	-	-
Foreign currency translation difference	(57)	200
Impairments	-	-
Net change	(57)	200
Cost	1,845	1,902
Accumulated changes	-	-
Net book value at 31 December	1,845	1,902

In-Process R&D

Accounting Policy: The cost of in-process R&D acquired in a business combination is the fair value at the date of acquisition.

Following initial recognition of the development expenditure as an asset, the asset is carried at cost less any accumulated amortization and accumulated impairment losses. Amortization of the asset begins when development is complete and the asset is available for use. It is amortized over the period of expected future benefit. Amortization is recorded in operating expenses. During the period of development, the asset is tested for impairment annually.

	2023	2022
Cost	6,025	6,261
Accumulated changes	(152)	(152)
Net book value at 1 January	5,873	6,109
Foreign currency translation difference	(175)	334
Additions	-	-
Reclassification	-	(570)
Amortization for the year	-	-
Impairments	-	-
Net change	(175)	(236)
Cost	5,850	6,025
Accumulated changes	(152)	(152)
Net book value at 31 December	5,698	5,873

License Fees

Accounting Policy: License fees for the exclusive right to certain patents, critical in the development of the ARC Therapies, are capitalized and measured at cost on initial recognition. Following initial recognition of the license fees as an asset, the asset is carried at cost less any accumulated amortization and accumulated impairment losses.



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Amortization of the asset begins when development of the ARC Therapies (ONWARD R&D) is complete, and the asset is available for use. It is amortized over the period of expected future benefit. Amortization is recorded in operating expenses. During the period of development, the asset is tested for impairment annually.

	2023	2022
Cost	2,383	2,218
Accumulated changes	-	-
Net book value at 1 January	2,383	2,218
Additions	-	31
Foreign currency translation difference	(72)	134
Reversals	(50)	-
Amortization for the year	-	-
Impairments	-	-
Net change	(122)	165
Cost	2,261	2,383
Accumulated changes	-	-
Net book value at 31 December	2,261	2,383

In 2023, the Company reassessed the capitalization of the annual license fee component and reversed amounts previously capitalized (EUR 50k) to profit and loss.

Impairment Assessment

The in-process R&D was acquired through the acquisition of GTX Medical SA (now ONWARD Medical SA) and the business combination with NRT Inc. (now ONWARD Medical Inc.). The value of the in-process R&D is contingent on the success of the FDA approval of the NRT product. In terms of the NRT acquisition agreement, ONWARD also received and assumed responsibility for the exclusive license agreements with the Regents of the University of California (“UCLA”) and the California Institute of Technology (“Caltech”). In terms of these agreements, the occurrence of the IPO triggered the change in ownership clauses and resulted in additional payments to be made. These payments, as well as the annual license fee payments, are recognized as a separate class of intangible assets.

As per the accounting policies above goodwill, in-process R&D and license fees are tested for impairment annually. ONWARD performed its annual impairment test at year-end (consistent with the prior year) based on the most recent budgets and forecast calculations.

Significant Estimates: Key assumptions used in the impairment test was the growth rate and the rate for discounting the projected cash flows.

- Cash flows are based on the expectation of receiving FDA approval. Revenue is only expected to occur towards the end of 2024. This is a one-year delay from previous expectations because of delayed submission of the Company’s first De Novo product application for clearance to the FDA. Upon FDA clearance, sales will start in the US focusing on patients with Veterans Affairs (VA) coverage, and home use will follow. CE marking is expected in 2025, after which, sales in Europe will follow. Operating costs will increase to support sales and marketing efforts, as well as to maintain ongoing development and clinical research, including the next pivotal trial. Based on management’s estimate, EBITDA is not expected to be positive prior to 2027.
- Cash generating unit: As stated in the Annual Report, ONWARD has developed two targeted, programmable neurostimulation platforms: an implantable system, ARC^{IM}, and a non-invasive, transcutaneous system, ARC^{EX}. Both systems contain the same basic elements: an electrical impulse generator, electrodes placed in proximity to the spinal cord, and a programmer that enables clinicians to set stimulation therapy parameters and allows users to control their therapy within those parameters. The two ARC Therapy platforms share common components and have a similar user interface. This optimizes the use of development resources while providing users with a consistent, easy-to-use experience. Based on the aforementioned, in the pre-commercial phase the Company is viewed as one cash generating unit.
- Growth rate estimate: Rate is based on published industry research.
- Discount rate: Discount rates represent the current market assessment of the risks specific to ONWARD. The discount rate calculation is based on the specific circumstances of the Group and is derived from its weighted average cost of capital (WACC). The WACC measures the expected returns required by both debt and equity investors of a company, weighted by their respective contributions of capital.



The cash flow projections were determined using management’s internal forecasts that cover an initial period from 2024 to 2031, after which a terminal value was calculated. Using projected cash flows covering a period of more than five years is not considered unusual for pre-commercial lifescience companies. Due to long development timelines and regulatory approval requirements, it is not atypical for Companies in the industry to use a period that extends beyond five years. The values assigned to the key assumptions represent management’s assessment of future expectations. ONWARD performed a sensitivity analysis and noted that a reasonable change in either the discount rate (to 20%) or terminal growth rate (to 0%), or both the discount rate (to 20%) and terminal growth rate (to 0%), would not cause the carrying amount to exceed its recoverable amount. As shown by recent history, should the expected revenues move out by another year, this would not cause the carrying amount to exceed its recoverable amount.

	2023	2022
Discount rate	13.4%	14.3%
Terminal value growth rate	1.70%	1.70%

3.1 Property, Plant & Equipment

Accounting Policy: Property, plant, and equipment is stated at cost, net of accumulated depreciation and accumulated impairment losses, if any. Such costs include the cost of replacing part of the property, plant, and equipment and borrowing costs for long-term construction projects if the recognition criteria are met. When significant parts of property, plant, and equipment are required to be replaced at intervals, the Group recognizes such parts as individual assets with specific useful lives and depreciates them accordingly. Likewise, when a major inspection is performed, its cost is recognized in the carrying amount of the plant and equipment as a replacement if the recognition criteria are satisfied. All other repair and maintenance costs are recognized in profit or loss as incurred.

Property, plant, and equipment transferred from customers is initially measured at the fair value at the date on which control is obtained.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets as follows:

- Office equipment – 3 years
- Leasehold improvements – 5 years

The useful life of leasehold improvements is the same or less than the lease term.

An item of property, plant, and equipment and any significant part initially recognized is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss arising from derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the income statement when the asset is derecognized.

The residual values, useful lives, and methods of depreciation of property, plant, and equipment are reviewed at each financial year end and adjusted prospectively, if appropriate.



Cost

	Office Equipment	Leasehold Improvements	Total
At 1 January 2022	802	-	802
Additions	121	265	386
At 31 December 2022	923	265	1,188
Additions	352	70	422
Disposals	-	-	-
At 31 December 2023	1,275	335	1,610

Depreciation

	Office Equipment	Leasehold Improvements	Total
At 1 January 2022	(612)	-	(612)
Depreciation for the year	(135)	(26)	(161)
At 31 December 2022	(747)	(26)	(773)
Depreciation for the year	(141)	(87)	(228)
At 31 December 2023	(888)	(113)	(1001)

Net Book Value

	Office Equipment	Leasehold Improvements	Total
At 31 December 2022	176	239	415
At 31 December 2023	387	222	609

3.2 Right of Use Assets & Lease Liabilities

Accounting Policy: The Group assesses at contract inception whether a contract is, or contains, a lease. That is, if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

Group as a Lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognizes lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

Right-of-Use Assets

The Group recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and accumulated impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the initial measurement amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date, less any lease incentives received.

Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease term and the estimated useful lives of the assets.

If ownership of the leased asset transfers to the Group at the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

Lease Liabilities

At the commencement date of the lease, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and



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amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be exercised by the Group and payments of penalties for terminating the lease, if the lease term reflects the Group exercising the option to terminate.

Variable lease payments that do not depend on an index or a rate are recognized as expenses (unless they are incurred to produce inventories) in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the lease payments (e.g., changes to future payments resulting from a change in an index or rate used to determine such lease payments), or a change in the assessment of an option to purchase the underlying asset. The Group's lease liabilities are included in lease liabilities.

Short-Term Leases & Leases of Low-Value Assets

The Group applies the short-term lease recognition exemption to its short-term leases of office space (i.e., those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered to be low value. Lease payments on short-term leases and leases of low-value assets are recognized as expense on a straight-line basis over the lease term.

Right-of-Use Assets

The Group entered into a five-year lease for offices in Lausanne, Switzerland in November 2021. This lease is classified as a right-of-use asset. The office lease in Eindhoven, in the Netherlands, ended in October 2023 and was classified as a short-term office lease. In November 2023, a new lease was entered into for the Eindhoven office for one year.

Key movements relating to right-of-use assets are presented below:

	2023	2022
Net book value at 1 January	1,681	2,190
Additions	299	90
Depreciation for the year	(497)	(575)
Onerous lease contract	–	(24)
Net book value at 31 December	1,483	1,681

The office buildings are leased for office space. The lease in Lausanne includes an extension option exercisable up to one year before the end of the non-cancellable lease term. The lease in Eindhoven includes an extension option for an additional one year; the extension was included in the calculation of the right-of-use asset recognized over a full period of two years.

Lease Liabilities

The maturity of the lease liability in relation to the office building is as follows:

	2023	2022
Less than one year	568	427
One to five years	1,051	1,294
More than five years	–	–
Total lease liability	1,619	1,721



Notes to the Consolidated Financial Statements

Movement of the Lease Liability

	2023	2022
Balance as at 1 January	1,721	2,214
Additions	299	90
Onerous lease contract	-	(26)
Interest accretion	69	84
Repayments	(548)	(641)
Foreign currency impact	78	-
Total lease liability	1,619	1,721

The incremental borrowing rate applied is 4% for the Lausanne office and is 7.4% for the Eindhoven office.

On 1 November 2022, the Group entered into a short-term office lease for 12 months for which the Group elected not to recognize a right-of-use asset and lease liability. Amount recognized in relation to this short-term lease amounted to EUR 8.8k.

For the maturity analysis of the undiscounted cash flows, refer to note 4.3.

3.3 Indirect Tax Receivables

The tax receivables consist of refundable VAT and are collectable within 12 months. The decrease in the receivable is a direct result of quarterly filing of VAT returns and claims received throughout the year.

3.4 Other Current Assets

	2023	2022
Advance payments	936	905
Grants and other receivables	260	266
Rental guarantee	305	285
	1,501	1,456

The Group provided a guarantee of EUR 305k (2022: EUR 285k) to fulfill collateral requirements relating to the Lausanne office rental agreement. This guarantee places no restriction on the cash position and is payable on demand if the Company fails to meet its commitments. Advance payments mostly relate to prepaid D&O insurance for which the premium decreased in 2023.

3.5 Cash and Cash Equivalents and Fixed Term Deposits

Accounting Policy: Cash and short-term deposits in the statement of financial position comprise cash at banks and on hand, and short-term deposits with a maturity of three months or less, that are readily convertible to a known amount of cash and subject to an insignificant risk of change in value.

For the purpose of the consolidated statement of cash flows, cash and cash equivalents consist of cash and short-term deposits as defined above, net of outstanding bank overdrafts, as they are considered an integral part of the Group's cash management.

	2023	2022
Cash at bank	3,568	21,760
Short-term deposits	26,200	20,000
Cash and cash equivalents	29,768	41,760
Fixed term deposits	-	20,000
	-	20,000
Cash and cash equivalents and fixed term deposits	29,768	61,760

Cash at banks earns interest at floating rates based on daily bank deposit rates. Short-term deposits are made for varying periods of between one day and three months, depending on the immediate cash requirements of the Group, and earn interest at the respective short-term deposit rates.

Fixed term deposits represent deposits made for varying periods exceeding three months but less than 12 months from inception.



At 31 December 2023, the Group had no bank overdrafts. All cash is freely at the disposal of the company.

3.6 Trade Payables

Trade payables and accrued expenses are non-interest bearing and are normally settled on 30-90 day terms. The decrease is a direct result of delay in ARC^{EX} and the timing of settlement.

3.7 Other Payables

The other payables can be broken down as follows:

	2023	2022
Wage tax and social security	485	466
Grants received in advance	473	1,328
Bonus	1,243	1,856
Invoices to be received	538	732
Other	425	1,284
Grant-related payable	1,358	-
	4,522	5,666

The decrease in Other Payables is due to decrease in the bonus accrual and amounts that were due to subcontractors (on grants) paid in early 2023. An accrual was raised in response to the pending grant amendment with EISMEA, refer to Note 2.1 EISMA, and is the estimated amount the Company may be required to repay for grant amounts received in advance in 2022.

4. Financing, Financial Risk Management & Financial Instruments

4.0 Issued Capital & Reserves

Share Capital & Share Premium

Accounting Policy: Ordinary Shares are classified as **share capital**. Equity instruments are recorded at the proceeds received, net of direct issue costs.

The share premium represents the amount by which the fair value of the consideration received exceeds the nominal value of shares issued. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

The authorized share capital (“maatschappelijk kapitaal”) amounts to EUR 12,225,000 divided into 50,937,500 Ordinary Shares and 50,937,500 Preferred Shares with a nominal value of EUR 0.12 each.

At 31 December 2023, 30,184,388 Ordinary Shares were issued (31 December 2022: 30,184,388 shares). All of the issued Ordinary Shares are fully paid-up and represent capital in the Company. No shareholders have any voting rights different from any other shareholder.

Other Reserves

	Currency Translation Differences	Stock Compensation Reserve	Total Other Reserves
Balance at 1 January 2022	(283)	69	(214)
Share-based payment expense: LTIP	-	1,691	1,691
Currency translation differences	602	-	602
Balance at 31 December 2022	319	1,760	2,079
Share-based payment expense: LTIP	-	2,564	2,564
Currency translation differences	(155)	-	(155)
Balance at 31 December 2023	164	4,324	4,488



Currency Translation Reserve

Exchange gains and losses arising from the translation of the functional currency of foreign operations to the reporting currency of the parent are accounted for in this legal reserve. In the case of the sale of a participating interest, the associated accumulated translation differences are transferred to the profit and loss account and presented therein as part of the result on the sale.

The foreign currency translation reserve relates to the investment in United States.

Stock Compensation Reserve

The stock compensation reserve is used to recognize the value of equity-settled share-based payments provided to employees, including key management personnel, as part of their remuneration.

4.1 Earnings Per Share (EPS)

Accounting Policy: Basic EPS is calculated by dividing the profit for the year attributable to ordinary equity holders of the parent by the weighted average number of Ordinary shares outstanding during the year.

Diluted EPS is calculated by dividing the profit attributable to ordinary equity holders of the parent (after adjusting for interest on the convertible Preference shares) by the weighted average number of Ordinary shares outstanding during the year plus the weighted average number of Ordinary shares that would be issued on conversion of all the dilutive potential Ordinary shares into Ordinary shares.

The objective of determining diluted EPS is to reflect the maximum possible dilutive effect arising from potential Ordinary shares outstanding during the period. The Group is currently loss-making and there are currently no anti-dilutive potential Ordinary shares to be considered. Therefore, diluted EPS is disregarded for 2023. The share options granted under the LTIP (refer to Note 2.9) could have a potential dilutive effect in the future, but had no impact in 2023.

There have been no other transactions involving Ordinary shares or potential Ordinary shares between the reporting date and the date of authorization of these financial statements.

The following tables reflect the income and share data used in the EPS calculation:

Profit (Loss) Attributable to Ordinary Shareholders

	2023	2022
Profit (loss) for the year, attributable to equity holders of the parent	(36,181)	(32,772)

Weighted-Average Number of Ordinary Shares

	2023 Thousands	2022 Thousands
Weighted average number of ordinary shares for basic EPS	30,184	30,184

4.2 Financial Liabilities

Accounting Policy:

Financial Instruments – Initial Recognition & Subsequent Measurement

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity. Financial assets and financial liabilities are initially recognized when the Company becomes a party to the contractual provisions of the instrument.

Financial Liabilities

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, payables, or as derivatives designated as hedging instruments in an effective hedge, as appropriate. A financial liability is classified



as FVPL if it is classified as held-for-trading, it is a derivative or it is designated as such on initial recognition. Financial liabilities at FVPL are measured at fair value and net gains and losses, including any interest expense, are recognized in profit or loss. Other financial liabilities are subsequently measured at amortized cost using the effective interest method. Interest expense and foreign exchange gains and losses are recognized in profit or loss. Any gain or loss on derecognition is also recognized in profit or loss.

All financial liabilities are recognized initially at fair value and, in the case of liabilities at amortized cost, net of directly attributable transaction costs.

The Group's financial liabilities include trade payables, other payables, loans, and borrowings.

For purposes of subsequent measurement, financial liabilities are classified in two categories:

- Financial liabilities at fair value through profit and loss
- Financial liabilities at amortized cost

Financial liabilities at fair value through profit or loss (FVPL)

Financial liabilities at fair value through profit or loss include financial liabilities held for trading and financial liabilities designated upon initial recognition as at fair value through profit or loss.

Financial liabilities are classified as held for trading if they are incurred for the purpose of repurchasing in the near term. This category also includes derivative financial instruments entered into by the Group that are not designated as hedging instruments in hedge relationships as defined by IFRS 9. Separated embedded derivatives are also classified as held for trading unless they are designated as effective hedging instruments.

Gains or losses on liabilities held for trading are recognized in the statement of profit or loss.

Financial liabilities designated upon initial recognition at fair value through profit or loss are designated at the initial date of recognition, and only if the criteria in IFRS 9 are satisfied. The Group has not designated any financial liability as at fair value through profit or loss.

Financial Liabilities at Amortized Cost

This is the category most relevant to the Group. After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortized cost using the effective interest rate ("EIR") method. Gains and losses are recognized in the profit or loss when the liabilities are derecognized, as well as through the EIR amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the EIR. The EIR amortization is included as finance costs in the statement of profit or loss.

Derecognition

A financial liability is derecognized when the obligation under the liability is discharged or cancelled or expires. When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as the derecognition of the original liability and the recognition of a new liability at fair value. The difference in the respective carrying amounts is recognized in the statement of profit or loss.

Offsetting of Financial Instruments

Financial assets and financial liabilities are offset and the net amount is reported in the consolidated statement of financial position if there is a currently enforceable legal right to offset the recognized amounts and there is an intention to settle on a net basis, to realize the assets and settle the liabilities simultaneously. No offsetting is currently applied.

	2023	2022
Balance as at 31 December	15,255	12,565



	Innovation Loan
Balance as per 1 January 2022	11,451
Loan amount received	–
Interest/cumulative dividend accrued during the year	1,205
Balance as per 31 December 2022	12,656
Loan amount received	1,292
Interest accrued during the year	1,307
Balance as per 31 December 2023	15,255

Innovation Loan

On 5 February 2016, the Group was granted a loan from RVO NL (Dutch Government) of EUR 10M payable according to a set payment scheme. The loan is advanced in installments based on progress. In 2023, two installments were received amounting to EUR 1.3M.

The loan carries interest at 10% per annum and is accrued on a yearly basis.

The current redemption plan for the loan is as presented below:

Date	% of Loan Amount
1 January 2026	15.0
1 April 2026	15.0
1 July 2026	17.5
1 October 2026	17.5
1 January 2027	17.5
1 April 2027	17.5
1 July 2027	All due interest

Certain Intellectual Property (patents registered), have been pledged to the RVO NL in case of default of repayment of the loan. These patents have not been capitalized as at 31 December 2023.

4.3 Financial Risk Management Objectives & Policies

The Group’s principal financial liabilities comprise of loans and borrowings and trade and other payables. The main purpose of these financial liabilities is to finance the Group’s operations and to provide guarantees to support its operations.

The Group is responsible for implementing and evaluating policies which govern the funding, investments, and any use of derivative financial instruments. The Group is exposed to various risks. The Group monitors risk exposure on an ongoing basis, as summarized below:

Capital Management

Capital includes issued capital, share premium, and all other equity reserves attributable to the equity holders of the parent. The primary objective of the Group’s capital management is to continue as a going concern while maximizing shareholder value. The Group manages its capital structure and will consider adjustments in light of changes in economic conditions. To maintain or adjust the capital structure, the Group may issue new shares.

Liquidity Risk

The Group manages liquidity risk by continuously monitoring forecast and actual cash flows. The Group’s objective is to maintain a balance between continuity of funding and flexibility through the use of subsidies and grants, and sufficient progress towards regulatory approval, which is related to future financing rounds.

Cash is invested in low-risk investments such as short-term bank deposits or savings accounts. The Group mainly makes use of liquid investment in current accounts (in Euros) or short-term deposit accounts. The ability of the Group to maintain adequate cash reserves to support its activities in the medium term is highly dependent on the Group’s ability to raise additional funds.

The following table details the undiscounted remaining contractual maturity for the Group’s financial liabilities with agreed repayment periods, including both interest and principal cash flows:



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As at 31 December 2023:

	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years	Total
Innovation loan	-	6,500	14,295	-	20,795
Lease liability	615	1,084	-	-	1,699
Trade payables	1,369	-	-	-	1,369
Total	1,984	7,584	14,295	-	23,863

As at 31 December 2022:

	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years	Total
Innovation loan	-	-	19,298	-	19,298
Lease liability	512	1,452	-	-	1,964
Trade payables	1,909	-	-	-	1,909
Total	2,421	1,452	19,298	-	23,171

Market Risk

Market risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in market prices. The Group’s activities may expose it to changes in foreign currency exchange rates and interest rates. The Group is not exposed to any equity price risk or commodity price risk, as it does not invest in these classes of investments.

Credit Risk

Because of the absence of sales to third parties and therefore trade receivables, credit risk arises mainly from cash and cash equivalents and deposits with banks and financial institutions. The Group only works with international reputable commercial banks and financial institutions when investing surplus funds. Short-and fixed-term deposits are

subject to approval in line with internal policy. The Group holds accounts with ING, Belfius, UBS, First American Bank, Deutsche Bank and Banque Cantonale Vaudoise (BCV). The number of banks and financial institutions is to minimize concentration risk and therefore mitigate financial loss through a counterparty’s potential failure to make payments.

Currency Risk

Currency risk is the risk that reported financial performance, or the fair value or future cash flows of a financial instrument, will fluctuate because of changes in foreign exchange rates. The Group is exposed to currency risk for the activities mainly in the US, as the accounting is performed in US dollars, whereas the functional currency of the Group is the euro. The risk is currently managed by replenishing the US bank account at regular intervals to account for both the positive and negative changes.

4.4 Fair Value & Fair Value Hierarchy of the Financial Statements

Accounting Policy: All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 – Quoted (unadjusted) market prices in active markets for identical assets or liabilities
- Level 2 – Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable
- Level 3 – Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable



The carrying amounts and fair values of the Group's financial instruments are as follows, including its fair value hierarchy:

2023	Carrying Amount	Estimated Fair Value
Financial liabilities		
Innovation credit loan (Level 2)	15,255	15,460
Total financial liabilities	15,255	15,460

2022	Carrying Amount	Estimated Fair Value
Financial liabilities		
Innovation credit loan (Level 2)	12,656	13,689
Total financial liabilities	12,656	13,689

Management has assessed that the fair values of cash and cash equivalents, accounts payable, taxes and social securities and other payables approximate to their carrying amounts largely due to the short-term maturities of these instruments.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale. The following methods and assumptions were used to estimate the fair values:

The fair value of Innovation credit loan and due interest have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities.

During the period, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.

4.5 Financial Income & Expense

Accounting Policy: Interest income is recognized by applying the effective interest rate, except for short-term receivables when the effect of discounting is immaterial. The Company's financial assets include cash and cash equivalents and other long term and current receivables.

Borrowing costs directly attributable to the acquisition, construction, or production of an asset that necessarily takes a substantial period of time to get ready for its intended use or sale are capitalized as part of the cost of the asset. All other borrowing costs are expensed in the period in which they occur. Borrowing costs consist of interest and other costs that an entity incurs in connection with the borrowing of funds.

	2023	2022
Interest income from deposits	972	62
Interest on loans	(1,307)	(1,205)
Interest post-employment benefits	-	-
Interest banks	-	(226)
Interest on lease liabilities	(69)	(84)
Exchange losses	(190)	(24)
Bank charges	(17)	(33)
Net Finance expense	(611)	(1,510)

5. Other Disclosures

5.0 Post-Employment Benefits: Defined Benefit Obligation

Accounting Policy: Group companies operate various pension schemes. The schemes are funded through payments to insurance companies or trustee-administered funds, determined by periodic actuarial calculations. The Group has both defined benefit and defined contribution plans.



Defined Benefit Plan

The Group operates a defined benefit pension plan in Switzerland, which requires contributions to be made to a separately administered fund. The cost of providing benefits under the defined benefit plan is determined using the projected unit credit method.

Remeasurements, comprising of actuarial gains and losses, are recognized in the statement of financial position with a corresponding debit or credit to retained earnings through OCI in the period in which they occur. Remeasurements are not reclassified to profit or loss in subsequent periods.

Past service costs are recognized in profit or loss on the earlier of:

- The date of the plan amendment or curtailment, and
- The date that the Group recognizes related restructuring costs

Net interest is calculated by applying the discount rate to the net defined benefit liability or asset. The Group recognizes the changes in the net defined benefit obligation due to service costs comprising current service costs, past-service costs, gains and losses on curtailments and non-routine settlements as part of operating expenses, and the net interest expense or income as part of net finance costs in the consolidated statement of profit and loss.

	2023	2022
Plan assets	4,289	3,879
Obligation	(6,370)	(5,001)
Net liability	2,081	1,121

A defined benefit plan is a pension plan that is not a defined contribution plan. Typically, defined benefit plans specify an amount of pension benefit that an employee will receive upon retirement, typically dependent on one or more factors such as age, years of service, and compensation. The benefits paid to employees in Switzerland qualify as a defined benefit plan.

The pension plan for Swiss employees (“the Pension Fund”) is a defined benefit plan. The Pension Fund provides benefits for retirement, disability, and surviving dependents that meet or exceed the minimum benefits required under the Federal Law on Occupational Retirement, Survivors’ and Disability Insurance (“BVG”), including the legal coordination charge, which is also insured. The monthly premium to fund the Pension Fund’s benefits is split equally between the employer and the employees. Contributions, which vary by the age of the employees, range from 6-13% of the covered salary and are credited to the employees’ individual retirement savings accounts. The Pension Fund is responsible for capital investments and pursues an investment strategy with a prescribed investment policy. The Group assumes an average retirement age of 64 (female) and 65 (male), respectively. Upon retiring (including early and partial retirement), insured persons are entitled to a lifelong retirement pension if employees do not choose to withdraw the entire balance, or portion thereof, of their individual retirement savings accounts in the form of a capital payment.

The Pension Fund is administered by Allianz Suisse, Switzerland, which is legally separate from the Group and is governed by a foundation board. In addition, there is a pension fund commission comprised of two employee and two employer representatives. The duties of the foundation board, as well as the pension fund commission, are laid out in the BVG and the specific pension fund rules. They are required by law to act in the best interest of the participants and are responsible for setting certain policies (e.g. investment, contribution, and indexation policies) for the Pension Fund. At least four times a year, the foundation board, as well as the pension fund commission, meet to analyze consequences and decide on adjustments in the investment strategy.

Pursuant to the BVG, additional employer and employee contributions may be imposed whenever a significant funding deficit arises in accordance with the BVG. In addition to investment risk, the Pension Fund is exposed to actuarial risk, longevity risk, currency risk, and interest rate risk.

In addition to the pension plan for Swiss employees, a defined benefit plan for Swiss management also provides retirement benefits and risk insurance for death and disability for components of remuneration in excess of the maximum insurable amount of salary under the plan described above.



Notes to the Consolidated Financial Statements

Movement of Net Defined-Benefit Liability

	2023	2022
Balance as at 1 January	1,121	1,388
Service costs	652	562
Admin costs	45	43
Past service costs	23	-
Employee benefit expenses	720	605
Net interest costs/(income)	15	3
Included in statement of profit and loss	735	608
Actuarial gains/(losses)		
- Financial assumptions	932	(1,956)
- Demographic assumptions	-	-
- Experience adjustment	(449)	1,286
- Return on assets excluding interest income	321	184
	804	(486)
Exchange rate differences	80	65
Included in statement of comprehensive income*	884	(421)
Contributions by employer	(659)	(454)
Balance as at 31 December	2,081	1,121

*Excluding tax impact

The principal assumptions used in determining post-employment (pension) benefit obligations for the plan are shown below:

	2023	2022
Discount rate	1.35%	2.30%
Salary increase	2.50%	2.50%
Interest credit rate	1.00%	1.00%
Mortality base table	BVG2020	BVG2020
Longevity improvement	CMI2018; 1.25%	CMI2018; 1.25%

A quantitative sensitivity analysis for significant assumptions as at 31 December is shown below:

	2023	2022
Discount rate		
+ 25bps	(271)	(190)
- 25bps	292	203
Salary increase		
+ 25bps	119	84
- 25bps	(113)	(80)
Interest credit rate		
+ 25bps	101	76
- 25bps	(98)	(73)
Mortality base table		
Life expectancy + 1 year	44	27
Life expectancy - 1 year	(42)	(26)

The sensitivity analyses have been determined based on a method that extrapolates the impact on the defined benefit obligation as a result of reasonable changes in key assumptions occurring at the end of the reporting period. The sensitivity analyses are based on a change in a significant assumption, keeping all other assumptions constant. The sensitivity analyses may not be representative of an actual change in the defined



benefit obligation as it is unlikely that changes in assumptions would occur in isolation from one another.

The following are the expected payments or contributions to the defined benefit plan in future years:

	2023	2022
Within the next 12 months	350	281
Between 2 and 5 years	1,702	1,426
Beyond 5 years	3,172	2,540
Total expected payments	5,224	4,247

The average duration of the defined benefit plan obligation at the end of the reporting period is 18 years (2022: 16 years).

Plan Assets Allocation

The asset allocation in the Swiss pension plan at 31 December was as follows:

	2023	2022
Bonds	2,709	2,309
Equities	-	-
Loans	93	134
Mortgages	507	504
Real Estate	922	872
Cash, derivatives and funds	58	60
	4,289	3,879

Plan assets in 2023 and 2022 do not include property occupied by or financial instruments issued by ONWARD.

5.1 Commitments & Contingencies

Legal Claim Contingencies

As at December 31 2023, the Group had no legal claim contingencies.

Guarantees

The Group has provided a guarantee to Wincasa for EUR 305k as collateral for the lease of the office space in Lausanne and paid a deposit of EUR 8k to SPACES for the lease of the office space in Eindhoven.

Royalties

The Group has entered into three license agreements with EPFL that will pay out royalties in case the Company is able to generate revenues in the future for products directly linked to these licenses. The royalty scheme with EPFL is based on net sales. To date, no royalties have been paid as there is no product generating revenue.

On 27 September 2019, Neurorecovery Technologies Inc. (now ONWARD Medical Inc.) entered into a license agreement with the Regents of the University of California acting through Technology Development Group UCLA campus granting an exclusive license on certain patents in certain fields of neuromodulation and spinal cord stimulation, and a non-exclusive license on certain other patent rights. Various revenue milestone payments are due under the exclusive license and royalty payments are due under the non-exclusive license. The agreement contains various milestone and diligence obligations ranging from USD 10k to USD 50k payable upon entering a phase III clinical trial, regulatory approval, and/or first commercial sale. To date, none of the milestones triggering the obligations have occurred.

On 8 October 2019, Neurorecovery Technologies Inc. entered into a license agreement with the California Institute of Technology (Caltech), the latter on behalf of various intellectual property owners, including UCLA, University of Louisville, DEI and USC, granting an exclusive license on certain technology in certain fields of epidural and transcutaneous neuromodulation and a non-exclusive license of certain other intellectual property.



Various revenue milestone payments, diligence obligations, and royalty payments are due under the license. These payments range from USD 20k to USD 75k payable upon FDA approval, CE Mark, and/or first commercial sale. To date, no payments are outstanding for requirements that have been met.

5.2 Related Party Transactions

Note 1.1 provides the information about the Group’s structure including the details of the subsidiaries. Transactions between the Company and its subsidiaries have been eliminated on consolidation and are not disclosed in the notes.

The Group considers the Board and the Management Team to be key management as defined in IAS 24 ‘Related parties.’ Full details of the remuneration of the board (CEO and non-executives) are included in the Remuneration report.

	Salary, Bonuses & Other (Short-Term Employee Benefits)	Pension Premiums (Post-Employment Eenefits)	Share-Based Payment	Total
2023				
Management Team, excluding CEO	2,827	98	643	3,568
CEO	703	64	916	1,683
Non-Executive Directors	445	-	441	886
	3,975	162	2,000	6,137

	Salary, Bonuses & Other (Short-Term Employee Benefits)	Pension Premiums (Post-Employment Eenefits)	Share-Based Payment	Total
2022				
Management Team, excluding CEO	2,574	105	596	3,275
CEO	917	44	469	1,430
Non-Executive Directors	364	-	256	621
	3,855	149	1,321	5,326

5.3 Events After the Reporting Period

On 25 March 2024, ONWARD issued a total of 4,444,444 new Ordinary shares at a price per share of EUR 4.50 as part of an accelerated bookbuild offering through a private placement with institutional investors, certain founders, management, and members of the Board of Directors (4,307,641 shares) and a separate public offering with retail investors in France (136,803 shares). The total capital raised was EUR 20 million.

On 15 January 2024, the Group granted 710,975 stock options to the Management Team, including the CEO, CTO, and CSO with an exercise price of EUR 2.94. The conditions of the existing plan as explained in Note 2.9 apply to this grant.



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Company Financial Statements

Company Statement of Income

For the Year Ended 31 December

All amounts in EUR '000

	Notes	2023	2022
Grants		532	2,076
Total operating income	B	532	2,076
General and administrative expenses		(29,679)	(31,003)
Total operating expenses	C	(29,679)	(31,003)
Operating result for the period		(29,147)	(28,927)
Net finance expense	D	(392)	(1,453)
Result before tax		(29,539)	(30,380)
Income tax expense	E	-	-
Share in result from participating interests	F	(6,642)	(2,392)
Result after tax		(36,181)	(32,772)

The notes on pages **305** to **315** are an integral part of these separate financial statements.



Company Balance Sheet

(Before appropriation on result)

For the Year Ended 31 December

All amounts in EUR '000

	Notes	2023	2022
Assets			
Non-current assets			
Tangible fixed assets	G	118	61
Financial fixed assets	H	807	1,139
		925	1,200
Current assets			
Trade and other receivables	I	26,748	16,900
Fixed term deposits	J	-	20,000
Cash at bank and in hand	J	13,854	31,501
		40,602	68,401
		41,527	69,601



Company Financial Statements

Equity & Liabilities

Equity and reserves

	K		
Issued capital		3,622	3,622
Share premium		155,248	155,249
Other reserves		4,199	1,760
Legal reserve: Currency translation differences		165	319
Retained earnings		(109,122)	(75,547)
Result for the year		(36,181)	(32,772)

Total equity		17,931	52,631
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Provisions	L	5,233	256
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Non-current liabilities	M	15,297	12,656
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Current liabilities	N	3,066	4,058
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		41,527	69,601
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The notes on pages **305** to **315** are an integral part of these separate financial statements.



Notes to the Company Financial Statements

A. Presentation of Financial Statements and Recognition and Measurement Principles

The description of the activities of ONWARD Medical NV (the company) and the company structure, as included in the notes to the consolidated financial statements, also applies to the company financial statements.

The company is the sole shareholder of the following subsidiaries:

- ONWARD Medical SA, based in Switzerland
- ONWARD Medical Inc, based in the United States of America

These separate financial statements have been prepared in accordance with Title 9, Book 2 of the Dutch Civil Code. For setting the principles for the recognition and measurement of assets and liabilities and determination of results for its separate financial statements, the Company makes use of the option provided in section 2:362(8) of the Dutch Civil Code. This means that the principles for the recognition and measurement of assets and liabilities and determination of the result (hereinafter referred to as principles for recognition and measurement) of the separate financial statements of the Company are the same as those applied for the consolidated EU-IFRS financial statements. These principles also include the classification and presentation of financial instruments, being equity instruments or financial liabilities. In case no other principles are mentioned, refer to the accounting

principles as described in the consolidated financial statements. For an appropriate interpretation of these statutory financial statements, the separate financial statements should be read in conjunction with the consolidated financial statements.

Information on the use of financial instruments and on related risks for the group is provided in the notes to the consolidated financial statements of the group.

B. Operating Income

Operating income relates to grant and other income received. Government subsidies have been received for the research and development of several development projects. There are no unfulfilled conditions or contingencies attached to these subsidies.

	2023	2022
Government subsidies (EU)	464	1,972
Other income	68	104
Total revenues and other income	532	2,076

Company Financial Statements

(In EUR 000)

Grants	Total Grant*	Recognized as Grant Income 2023	Recognized as Grant Income 2022	Recognized as Grant Income cumulative before 2022	Grant received in advance as per 31-12-2023
PREP2GO	362	15	104	243	-
DARPA	3,004	419	1,412	1,173	-
ZonMW	250	83	83	83	-
EISMEA – Reverse Paralysis	292	(237)	273	-	183
EISMEA – NEMO BMI	144	(85)	85	-	108
Eurostars Impulse	500	160	14	-	-
Rewire	347	56	-	-	122
SH-ARC	500	53	-	-	60
Total		464	1,972	1,499	473

C. Operating Expenses

Operating expenses by nature are as follows:

	2023	2022
Wages and salaries	(1,242)	(1,797)
Social security costs (includes WBSO benefit)	54	32
Pension costs – other	(69)	(82)
Share-based benefit expenses	(148)	(1,691)
Other labor costs	(724)	(1,739)
Other operating expenses	(27,492)	(25,515)
Depreciation and amortization	(58)	(211)
	(29,679)	(31,003)

The increase in Other operating expenses is driven by Research and Development expenses due to advancements made on our ARC^{EX} and ARC^{IM} platforms (mainly in

Switzerland) which increased the charge from Switzerland to the Netherlands under the existing agreement.

During 2023, the Company had on average 15.9 full-time equivalents located in the Netherlands (2022: 16.3), 74.2 full-time equivalents located in Switzerland (2022: 68.3) and 14.5 (2022: 11.5) full-time equivalents located in the United States.

D. Net Finance Expense

	2023	2022
Interest income	891	52
Interest on loans	(1,307)	(1,434)
Interest banks	-	-
Interest on lease liabilities	(5)	-
Exchange losses	35	(48)
Bank charges	(6)	(23)
Net Finance expense	(392)	(1,453)

The decrease is the result of interest income earned from positive cash balances in 2023.

E. Income Tax Expense

	2023	2022
Current income tax	-	-
Deferred income tax	-	-
Total corporate income tax in profit and loss	-	-
Current income tax charge at tax rate of 25.8%	7,621	7,838
Non-deductible expenses	(38)	(436)
Non-recognized deferred tax asset on temporary differences	66	(111)
Non-recognized deferred tax asset on permanent differences	(203)	-
Net operating losses not recognized	(7,446)	(7,291)



Company Financial Statements

The effective tax rate was 0% in 2023 (2022: 0%), which is lower than the statutory income tax rate of 25.8% (2022: 25.8%) in the Netherlands. The difference is primarily due to non-deductible expenses relating to share-based compensation and the net operating losses for which no deferred tax asset can be recognized. The uncertainty is based on insufficient evidence of future sources of income to support the realization of a deferred tax asset due to the Company being loss-making with limited tax planning opportunities.

For the unused operating losses of EUR 120M (2022: EUR 91M) no deferred tax is recognized. These losses can be carried forward indefinitely subject to local tax rules.

F. Share in Results from Participating Interests

An amount of EUR 6.642M (2022: EUR 2.392M) of share in results from participating interests relates to Group companies.

G. Tangible Fixed Assets

Cost

	Office Equipment	Right-of-use-asset	Total
At 1 January 2022	1,171	–	1,171
Additions	18	–	10
Disposal	(465)	–	(465)
At 31 December 2022	716	–	716
Additions	18	97	114
Disposal	–	–	–
At 31 December 2023	734	97	830

Accumulated Depreciation

	Office Equipment	Right-of-use-asset	Total
At 1 January 2022	(974)	–	(974)
Depreciation for the year	(102)	–	(102)
Disposal	421	–	421
At 31 December 2022	(655)	–	(655)
Depreciation for the year	(49)	(9)	(58)
Disposal	–	–	–
At 31 December 2023	(704)	(9)	(713)

Net Book Value

	Office Equipment	Right-of-use-asset	Total
At 31 December 2022	61	–	61
At 31 December 2023	30	88	118

H. Financial Fixed Assets

Financial fixed assets consist of participating interests in Group companies. Financial fixed assets are accounted for in the Company financial statements at net asset value. They are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount.



Company Financial Statements

	2023	2022
Cost	1,139	2,459
Accumulated impairments	-	-
Net book value at 1 January	1,139	2,459
Revaluations through OCI	(928)	858
Exchange differences	(155)	172
Group share-based payment scheme	2,416	-
Share in result of participating interests	(6,642)	(2,392)
Addition: license fees paid on behalf of subsidiary	-	-
Provision: negative participating interest	4,977	42
Net change	(332)	(1,320)
Cost	807	1,139
Accumulated impairments	-	-
Net book value at 31 December	807	1,139

The Company has the firm intention to support its subsidiary, ONWARD Medical Inc, to meet its obligations to third parties. A provision has been recognized for the negative value of the investment to the amount of EUR 4,977k (2022: 42k).

I. Trade & Other Receivables

Amounts due from Group companies are recognized initially at fair value and subsequently at amortized cost. Amortized cost is determined using the effective interest rate. The Company recognized a credit loss for financial assets (such as a loan) based on an expected credit loss (ECL), which will occur in the coming twelve months or – after a significant decrease in credit quality or when the simplified model can be used – based on the entire remaining loan term.

For intercompany receivables, the ECL would be applicable as well, however this could cause differences between equity in the consolidated and separate financial statements. For this reason, the Company elected to eliminate these differences through the respective receivable account in the separate financial statements.

	2023	2022
Indirect tax receivable	76	458
Receivables from related parties – group companies	25,596	15,174
Receivables from related parties – other	37	190
Other	239	257
Advance payments made	800	821
	26,748	16,900

The Company funds the operations of the subsidiaries. The increase in the receivable is a result of the increase in operations in 2023.

J. Cash at Bank, in Hand & Fixed Term Deposits

	2023	2022
Cash at bank	2,654	21,501
Short-term deposits	11,200	10,000
Cash at bank and in hand	13,854	31,501
Fixed term deposits	-	20,000
	-	20,000
Cash at bank, in hand, and fixed term deposits	13,854	51,501

Cash at banks earns interest at floating rates based on daily bank deposit rates. Short-term deposits are made for varying periods of between one day and three months, depending on the immediate cash requirements of the Group, and earn interest at the respective short-term deposit rates. Fixed term deposits are made for period exceeding three months but less than one year and earn interest at the respective fixed term deposit rates.

At December 31 2023, the Group had no bank overdrafts. All cash is freely at the disposal of the company.



K. Shareholders' Equity

For the statement of changes in equity for the year ended 31 December 2023, please refer to the consolidated statement of changes in equity in the consolidated financial statements. Additional information on the shareholders' equity is disclosed in note 4.0 of the consolidated financial statements.

L. Provisions

	2023	2022
Opening balance as at 1 January	256	214
Negative participating interest	4,977	42
Balance as at 31 December	5,233	256

The Company has the firm intention to support its subsidiary, ONWARD Medical Inc, to meet its obligations to third parties. A provision has been recognized for the negative participating interest to the amount of EUR 5,233k (2022: 256k).

The amount is considered current.

M. Non-Current Liabilities

	2023	2022
Balance as at 31 December	15,297	12,656

	2023
Innovation Loan	12,656
Loan as at 1 January	12,656
Loan amount received	1,292
Interest/cumulative dividend accrued during the year	1,307
Long term lease liability	42
Net book value as 31 December	15,297

N. Current Liabilities

Amounts due to Group companies recognized as financial liabilities at amortized cost as per the policy in the consolidated financial statements.

	2023	2022
Trade payables	734	1,899
Tax liabilities	4	63
Payables from related parties	-	-
Other payables	970	2,096
Grant-related payables	1,358	-
	3,066	4,058

O. Compensation of the Board Of Directors

The members of the Board and the Management Team are considered key management personnel as defined in IAS 24 'Related party disclosures.' For details on their remuneration, reference is made to note 5.2 of the consolidated financial statements. Full details of the remuneration of the board (CEO and non-executives) are included in the Remuneration report.

P. Fees for Audit & Other Services

In accordance with article 382.a of Part 9, Book 2, of the Netherlands Civil Code, the total audit cost can be specified as follows:

Ernst & Young Accountants LLP

	2023	2022
Audit of financial statements	259	478
Audit of special purpose financial statements	-	-
Other assurance services	-	8
	259	486



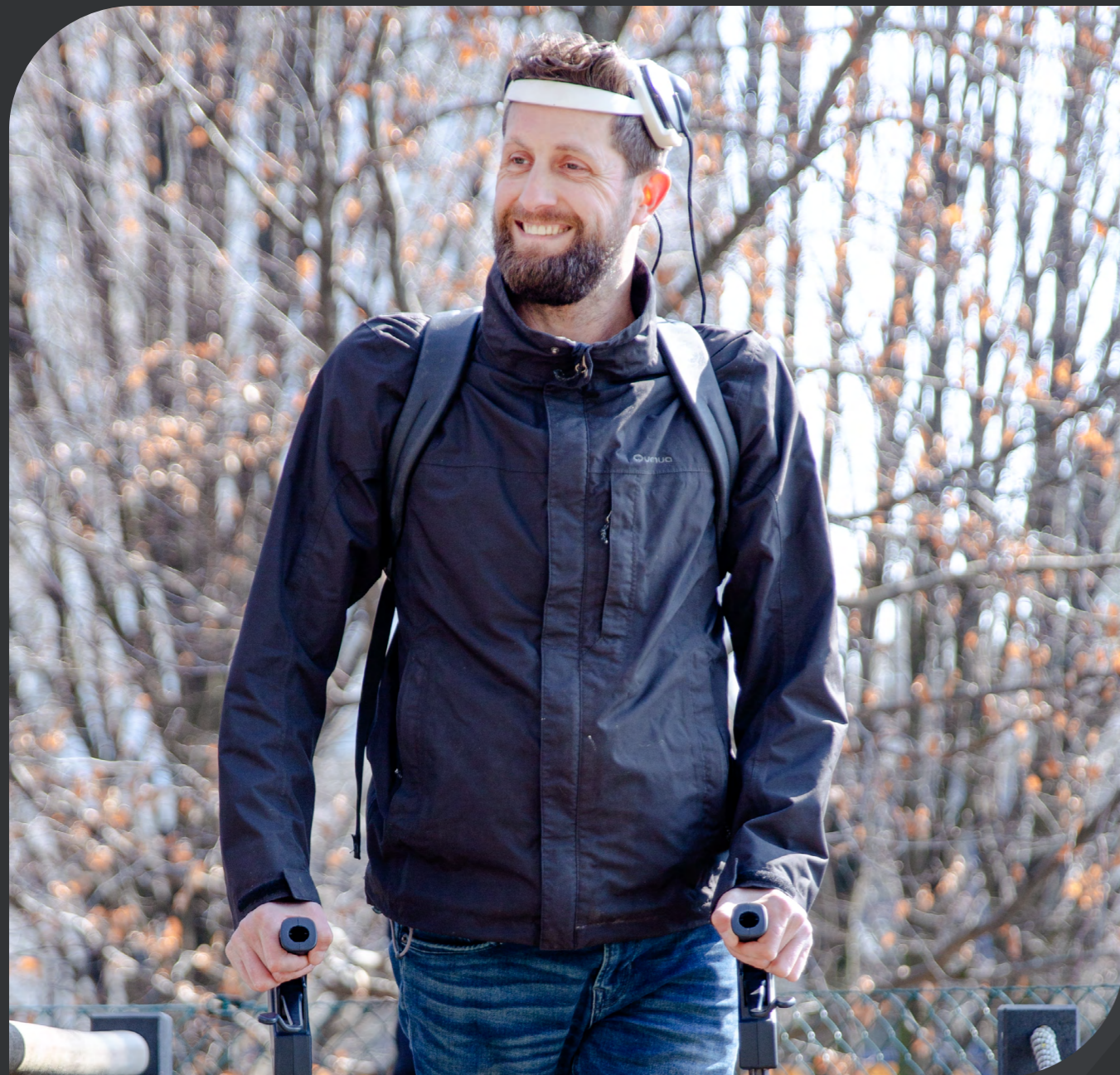
Q. Subsequent Events

For subsequent events, please refer to Note 5.3 of the Consolidated Financial Statements.

R. Proposed Appropriation of Result

The Board of Directors proposes to deduct the net loss in full to the retained earnings.





ONWARD[®]

Other
Information

Other Information

Independent auditor's report

To: the shareholders and board of directors of ONWARD Medical N.V.

Report on the audit of the financial statements 2023 included in the annual report

Our Opinion

We have audited the financial statements 2023 of ONWARD Medical N.V. based in Amsterdam, the Netherlands.

The financial statements comprise the consolidated and company financial statements.

In our opinion:

- The accompanying consolidated financial statements give a true and fair view of the financial position of ONWARD Medical N.V. as at 31 December 2023 and of its result and its cash flows for 2023 in accordance with International Financial Reporting Standards as adopted in the European Union (EU-IFRSs) and with Part 9 of Book 2 of the Dutch Civil Code
- The accompanying company financial statements give a true and fair view of the financial position of ONWARD Medical N.V. as at 31 December 2023 and of its result for 2023 in accordance with Part 9 of Book 2 of the Dutch Civil Code

The consolidated financial statements comprise:

- The consolidated statement of financial position as at 31 December 2023
- The following statements for 2023: the consolidated statement of profit and loss, comprehensive income, changes in equity and cash flows
- The notes comprising material accounting policies and other explanatory information

The company financial statements comprise:

- The company balance sheet as at 31 December 2023
- The company statement of income for 2023
- The notes comprising a summary of the accounting policies and other explanatory information



Basis for our opinion

We conducted our audit in accordance with Dutch law, including the Dutch Standards on Auditing. Our responsibilities under those standards are further described in the Our responsibilities for the audit of the financial statements section of our report.

We are independent of ONWARD Medical N.V. (‘the company’) in accordance with the EU Regulation on specific requirements regarding statutory audit of public-interest entities, the Wet toezicht accountantsorganisaties (Wta, Audit firms supervision act), the Verordening inzake de onafhankelijkheid van accountants bij assurance-opdrachten (ViO, Code of Ethics for Professional Accountants, a regulation with respect to independence) and other relevant independence regulations in the Netherlands. Furthermore we have complied with the Verordening gedrags- en beroepsregels accountants (VGBA, Dutch Code of Ethics).

We believe the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Information in support of our opinion

We designed our audit procedures in the context of our audit of the financial statements as a whole and in forming our opinion thereon. The following information in support of our opinion and any findings were addressed in this context, and we do not provide a separate opinion or conclusion on these matters.

Our understanding of the business

ONWARD Medical N.V. and its subsidiaries (the ‘group’) are developing both an Implantable Neuro-stimulation Systems (INS) and a non-invasive system for electrical stimulation of specific areas of the spinal cord.

We determined materiality and identified and assessed the risks of material misstatement of the financial statements, whether due to fraud or error in order to design audit procedures responsive to those risks and to obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion.

Materiality

Materiality €1,100,000 (2022: €890,000)

Benchmark applied 3% of operating expenses

Explanation R&D companies such as ONWARD Medical N.V. which are in the start-up phase, report no or modest revenues. The stakeholders expect the entity to operate at a loss during the R&D phase. The value that owners or others generally attribute to these entities is primarily based on the promise of future success of the products. Based on these factors we deem operating expenses to be a suitable basis, as it is one of the most important measures of the company’s performance.

We have also taken into account misstatements and/or possible misstatements that in our opinion are material for the users of the financial statements for qualitative reasons.

We agreed with the audit committee of the board of directors that misstatements in excess of €55,000, which are identified during the audit, would be reported to them, as well as smaller misstatements that in our view must be reported on qualitative grounds.

Scope of the group audit

ONWARD Medical N.V. is at the head of a group of entities. The financial information of this group is included in the consolidated financial statements.

Because we are ultimately responsible for the opinion, we are also responsible for directing, supervising and performing the group audit. In this respect we have determined the nature and extent of the audit procedures to be carried out for group entities. Decisive were the size and/or the risk profile of the group entities or operations. As the processes of ONWARD Medical are highly centralized and all transactions are initiated, recorded, processed and reported on central level we have applied a centralized audit approach on the full group consisting of 3 components in which all audit procedures are performed by the same team.



In total these procedures represent 100% of the group’s total assets, operating expenses and net loss.

By performing the centralized procedures mentioned above at all components of the group, together with additional procedures at group level, we have been able to obtain sufficient and appropriate audit evidence about the group’s financial information to provide an opinion on the consolidated financial statements.

Teaming and use of specialists

We ensured that the audit team included the appropriate skills and competences which are needed for the audit of a listed client in the medical technology industry. We included specialists in the areas of IT audit, forensics, share based payments, valuation of intangible assets and income tax.

Our focus on fraud and non-compliance with laws and regulations

Our responsibility

Although we are not responsible for preventing fraud or non-compliance and we cannot be expected to detect non-compliance with all laws and regulations, it is our responsibility to obtain reasonable assurance that the financial statements, taken as a whole, are free from material misstatement, whether caused by fraud or error. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

Our audit response related to fraud risks

We identified and assessed the risks of material misstatements of the financial statements due to fraud. During our audit we obtained an understanding of the company and its environment and the components of the system of internal control, including the risk assessment process and management’s process for responding to the risks of fraud and monitoring the system of internal control and how the board of directors exercises oversight, as well as the outcomes.

We refer to section “Risk Management and Control” of the board of director’s report for management’s (fraud) risk assessment.

We evaluated the design and relevant aspects of the system of internal control and in particular the fraud risk assessment, as well as the code of conduct. We evaluated the design and the implementation of internal controls designed to mitigate fraud risks.

As part of our process of identifying fraud risks, we evaluated fraud risk factors with respect to financial reporting fraud, misappropriation of assets and bribery and corruption in close co-operation with our forensic specialists. We evaluated whether these factors indicate that a risk of material misstatement due to fraud is present.

We incorporated elements of unpredictability in our audit. We also considered the outcome of our other audit procedures and evaluated whether any findings were indicative of fraud or non-compliance.

We addressed the risks related to management override of controls, as this risk is present in all companies. For these risks we have performed procedures among other things to evaluate key accounting estimates for management bias that may represent a risk of material misstatement due to fraud, in particular relating to important judgment areas and significant accounting estimates as disclosed in Note 1.6 to the financial statements including research & development, share-based payments, impairment of intangible assets, post-employment benefits and income taxes. We have also used data analysis to identify and address high-risk journal entries and evaluated the business rationale (or the lack thereof) of significant extraordinary transactions, including those with related parties. We considered available information and made enquiries of relevant executives and directors.

The fraud risks, we identified, enquiries and other available information did not lead to specific indications for fraud or suspected fraud potentially materially impacting the view of the financial statements.



Our audit response related to risks of non-compliance with laws and regulations

We performed appropriate audit procedures regarding compliance with the provisions of those laws and regulations that have a direct effect on the determination of material amounts and disclosures in the financial statements. Furthermore, we assessed factors related to the risks of non-compliance with laws and regulations that could reasonably be expected to have a material effect on the financial statements from our general industry experience, through discussions with the board of directors, reading minutes, and performing substantive tests of details of classes of transactions, account balances or disclosures.

We also inspected internal lawyers’ letters and correspondence with regulatory authorities. We remained alert to any indication of (suspected) non-compliance throughout the audit. Finally we obtained written representations that all known instances of non-compliance with laws and regulations have been disclosed to us.

Our audit response related to going concern

The board of directors made a specific assessment of the company’s ability to continue as a going concern and to continue its operations for the foreseeable future. As disclosed in Note 1.4 to the financial statements, as a result of the completed private placement and French retail public offering in March 2024, the Company believes that its cash position will be sufficient to meet the Company’s capital requirements and fund its operations for at least 12 months as from the date of preparing the financial statements. Furthermore is stated that to continue development and reach commercialization as planned the Company will need to attract additional funds in the future and that the Company’s long term existence is contingent on achieving FDA approval and CE mark on its products. The financial statements have been prepared on a going concern basis.

We discussed and evaluated the specific assessment with the board of directors exercising professional judgment and maintaining professional skepticism. We considered whether the board of directors’ going concern assessment, based on our knowledge and understanding obtained through our audit of the financial statements or otherwise, contains all relevant events or conditions that may cast significant doubt on the company’s

ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor’s report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion.

Based on our procedures performed, we did not identify material uncertainties about going concern. Our conclusions are based on the audit evidence obtained up to the date of our auditor’s report. However, future events or conditions may cause a company to cease to continue as a going concern.

Our key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements. We have communicated the key audit matter to the board of directors. The key audit matter is not a comprehensive reflection of all matters discussed.

The nature of this key audit matter did not change in comparison with previous year.



Valuation of intangible fixed assets

Note 3.0 intangible assets

Risk

At year-end 2023, ONWARD Medical N.V. carried an intangible asset balance of € 9.8 million, consisting of goodwill (€ 1.8 million), capitalized in-process R&D (€ 5.7 million) and capitalized license fees (€ 2.3 million). The goodwill as well as the capitalized in-process R&D and license fees relate to the acquisition of ONWARD Medical Inc in 2019. In accordance with EU-IFRS, ONWARD Medical N.V. is required to perform an impairment test on an annual basis. The impairment test is significant to our audit because the assessment process is complex, requires management judgement and is based on assumptions that are affected by expected future market conditions. For these reasons, we consider this a key audit matter.

Our audit approach

As part of our audit procedures we audited the assumptions and methodologies used by the company, and also the robustness of the planning process to evaluate whether the company is able to prepare reliable estimates.

The value of the in-process R&D is contingent on the success of the US Food and Drug Association (FDA) approval and CE mark of the company’s products, as well as successfulness of bringing the products to the market.

In order to assess the reasonability of input data, the valuation model and the discount rate we have, among other procedures:

- verified the appropriateness and consistent application of the impairment model and related inputs;
- compared the data with external data such as expected inflation rate, external market growth expectations and market capitalization of the Company;
- analyzed the sensitivities in the company’s impairment testing model.

We specifically focused on the risk of not achieving regulatory approvals and whether a reasonable possible change in the assumptions could trigger an impairment.

We also evaluated the adequacy of the company’s disclosure in note 3.0 of the annual report, including disclosures regarding assumptions and sensitivities as well as consistency between the going concern forecasts as disclosed in Note 1.4 and the inputs in the company’s impairment testing model.



Key observations

We have evaluated management’s key assumptions and estimates to be within an acceptable range. We agree with management’s conclusion that no impairment of intangible assets is required and conclude that the disclosures in note 3.0 of the annual report are in accordance with EU-IFRS.

Report on other information included in the annual report

The annual report contains other information in addition to the financial statements and our auditor’s report thereon.

Based on the following procedures performed, we conclude that the other information:

- is consistent with the financial statements and does not contain material misstatements
- contains the information as required by Part 9 of Book 2 of the Dutch Civil Code for the Board of Director’s report and the other information as required by Part 9 of Book 2 of the Dutch Civil Code and as required by Sections 2:135b and 2:145 sub section 2 of the Dutch Civil Code for the remuneration report.

We have read the other information. Based on our knowledge and understanding obtained through our audit of the financial statements or otherwise, we have considered whether the other information contains material misstatements. By performing these procedures, we comply with the requirements of Part 9 of Book 2 and Section 2:135b sub-Section 7 of the Dutch Civil Code and the Dutch Standard 720. The scope of the procedures performed is substantially less than the scope of those performed in our audit of the financial statements.

The board of directors is responsible for the preparation of the other information, including the Board of Directors’ report in accordance with Part 9 of Book 2 of the Dutch Civil Code and other information required by Part 9 of Book 2 of the Dutch Civil Code. The board of directors is responsible for ensuring that the remuneration report is drawn up and published in accordance with Sections 2:135b and 2:145 sub section 2 of the Dutch Civil Code.

Report on other legal and regulatory requirements and ESEF

Engagement

We were engaged by the general meeting as auditor of ONWARD Medical N.V. on 11 October 2021, as of the audit for the year 2021 and have operated as statutory auditor ever since that date.

No prohibited non-audit services

We have not provided prohibited non-audit services as referred to in Article 5(1) of the EU Regulation on specific requirements regarding statutory audit of public-interest entities.

European Single Electronic Reporting Format (ESEF)

ONWARD Medical N.V. has prepared the annual report in ESEF. The requirements for this are set out in the Delegated Regulation (EU) 2019/815 with regard to regulatory technical standards on the specification of a single electronic reporting format (hereinafter: the RTS on ESEF).

In our opinion the annual report prepared in the XHTML format, including the partially marked-up consolidated financial statements as included in the reporting package by ONWARD Medical N.V., complies in all material respects with the RTS on ESEF.

The board of directors is responsible for preparing the annual report, including the financial statements, in accordance with the RTS on ESEF, whereby the board of directors combines the various components into a single reporting package.

Our responsibility is to obtain reasonable assurance for our opinion whether the annual report in this reporting package complies with the RTS on ESEF.

We performed our examination in accordance with Dutch law, including Dutch Standard 3950N, “Assurance-opdrachten inzake het voldoen aan de criteria voor het opstellen van een digitaal verantwoordingsdocument” (assurance engagements relating to compliance with criteria for digital reporting). Our examination included amongst others:



- Obtaining an understanding of the company’s financial reporting process, including the preparation of the reporting package
- Identifying and assessing the risks that the annual report does not comply in all material respects with the RTS on ESEF and designing and performing further assurance procedures responsive to those risks to provide a basis for our opinion, including:
 - Obtaining the reporting package and performing validations to determine whether the reporting package containing the Inline XBRL instance document and the XBRL extension taxonomy files, has been prepared in accordance with the technical specifications as included in the RTS on ESEF
 - Examining the information related to the consolidated financial statements in the reporting package to determine whether all required mark-ups have been applied and whether these are in accordance with the RTS on ESEF.

Description of responsibilities regarding the financial statements

Responsibilities of the board of directors for the financial statements

The board of directors is responsible for the preparation and fair presentation of the financial statements in accordance with EU-IFRSs and Part 9 of Book 2 of the Dutch Civil Code. Furthermore, the board of directors is responsible for such internal control as the board determines is necessary to enable the preparation of the financial statements that are free from material misstatement, whether due to fraud or error.

As part of the preparation of the financial statements, the board of directors is responsible for assessing the company’s ability to continue as a going concern. Based on the financial reporting framework mentioned, the board of directors should prepare the financial statements using the going concern basis of accounting unless the board of directors either intends to liquidate the company or to cease operations, or has no realistic alternative but to do so. The board of directors should disclose events and circumstances that may cast significant doubt on the company’s ability to continue as a going concern in the financial statements.

The non-executive board members of the board of directors are responsible for overseeing the company’s financial reporting process.

Our responsibilities for the audit of the financial statements

Our objective is to plan and perform the audit engagement in a manner that allows us to obtain sufficient and appropriate audit evidence for our opinion.

Our audit has been performed with a high, but not absolute, level of assurance, which means we may not detect all material errors and fraud during our audit.

Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements. The materiality affects the nature, timing and extent of our audit procedures and the evaluation of the effect of identified misstatements on our opinion.

We have exercised professional judgment and have maintained professional skepticism throughout the audit, in accordance with Dutch Standards on Auditing, ethical requirements and independence requirements. The Information in support of our opinion section above includes an informative summary of our responsibilities and the work performed as the basis for our opinion.

Our audit further included among others:

- Performing audit procedures responsive to the risks identified, and obtaining audit evidence that is sufficient and appropriate to provide a basis for our opinion
- Obtaining an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company’s internal control
- Evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the board of directors



- Evaluating the overall presentation, structure and content of the financial statements, including the disclosures
- Evaluating whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation

Communication

We communicate with the audit committee of the board of directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant findings in internal control that we identify during our audit.

In this respect we also submit an additional report to the audit committee of the board of directors in accordance with Article 11 of the EU Regulation on specific requirements regarding statutory audit of public-interest entities. The information included in this additional report is consistent with our audit opinion in this auditor's report.

We provide the audit committee of the board of directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the audit committee of the board of directors, we determine the key audit matters: those matters that were of most significance in the audit of the financial statements. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, not communicating the matter is in the public interest.

Eindhoven, 24 April 2024

Ernst & Young Accountants LLP

Signed by J.C.F. Lemmens



Profit Appropriation

Pursuant to the Articles of Association, the profits shown in the Company’s annual accounts in respect of a financial year shall be appropriated as follows, and in the following order of priority:

- to the extent that any Preferred Shares have been cancelled without full repayment as described in the Articles of Association and without any such deficit subsequently having been paid in full, an amount equal to any such (remaining) deficit shall be distributed to those who held those Preferred Shares at the moment of such cancellation becoming effective;
- to the extent that any Preferred Distribution (or part thereof) in relation to previous financial years has not yet been paid in full as described in the Articles of Association, an amount equal to any such (remaining) deficit shall be distributed on the Preferred Shares;
- the Preferred Distribution shall be distributed on the preferred shares in respect of the financial year to which the annual accounts pertain;
- the Board shall determine which part of the remaining profits shall be added to the Company’s reserves; and
- subject to a proposal by the Board of Directors to that effect, the remaining profits shall be at the disposal of the General Meeting for distribution on the Ordinary Shares.

Special Statutory Voting Rights

There are no special statutory voting rights.

Shares Carrying Limited Economic Entitlement

The Preferred Shares in the Company’s capital carry a limited entitlement to the Company’s profit and reserves. As at 31 December 2023, no Preferred Shares in the Company’s capital were issued.

Branches

The Company has no branches. The statutory list of all subsidiaries and affiliated companies, prepared in accordance with the relevant legal requirements (Netherlands Civil Code, Part 9 of Book 2, Sections 379 and 414), forms part of the notes to the consolidated financial statements.

Non-IFRS Financial Measure

This Annual Report contains a financial measure that is not a measure of liquidity under IFRS. This is commonly referred to as non-IFRS financial measure.

Although the non-IFRS financial measure presented is not a measure of liquidity under IFRS, the Company uses this measure to monitor the underlying performance of its business and operations. This measure has not been audited or reviewed by the Company’s external auditor. Furthermore, the measures may not be indicative of the Company’s historical operating results, nor is this measure meant to be predictive of the company’s future results. This measure is presented in this Annual Report because the company considers it an important supplemental measure for evaluating the company’s liquidity.

Net Cash

The Company discloses the following as net cash for the measurement and explanation of liquidity:

	2023	2022
Cash at bank	3,568	21,760
Short-term deposits	26,200	20,000
Cash and cash equivalents	29,768	41,760
Fixed term deposits	–	20,000
	–	20,000
Net cash	29,768	61,760



Definitions and Abbreviations

The following definitions are used in this report:

510(k)
Clearance under Section 510(k) of the FDCA (US)

BDD
Breakthrough Device Designation - Designation given by the FDA to allow a timely access to devices providing a more effective treatment or diagnosis of life-threatening diseases by speeding-up their development, assessment, and review

Brain – Computer Interface (BCI)
Electrical signal produced by the brain is recorded by a device and is then translated into a signal allowing the stimulation of the spinal cord, enabling thought-driven restoration of movement

Caltech
California Institute for Technology

Cardiovascular
Relating to the heart and blood vessels

CARF
Commission of Accredited Rehabilitation Facilities

CE
Conformité Européene

Cervical
Relating to the neck or located around the neck area

DCGC
The Dutch corporate governance code issued on 8 December 2016

Chairperson
The Chairperson of the Board

CHUV
Centre Hospitalier Universitaire Vaudois

CRO
Contract research organizations

CSO
Chief Scientific Officer

DARPA
The US Department of Defense Advanced Research Projects Agency

EBITDA
Earnings before interest, tax, depreciation and amortization

EEA
European Economic Area

EPFL
École Polytechnique Fédérale de Lausanne

Epidural
Placed or administered outside the dura mater

FDA
U.S. Food and Drug Administration

FDCA
U.S. Federal Food, Drug, and Cosmetic Act

FTE
Full time equivalent personnel

GCP
Good Clinical Practice

HDE
Humanitarian Device Exemption

HIPAA
Health Insurance Portability and Accountability Act

Hypertension
Higher blood pressure than normal range

Hypotension
Lower blood pressure than normal range

IPG
Implantable pulse generator

Lesion
A damaged region in the body

LTIP
Long-Term Incentive Plan

Lumbar
Relating to the lumbar region of the back

MDR
Medical Device Regulation

Medical Devices Regulation
Regulation (EU) 2017/745



MHRA
Medicines and Healthcare products Regulatory Agency (UK)

Neurodegenerative
Characterized by the degeneration of the nervous system

Neuromodulation
Field of bioengineering implicating technologies impacting neural interfaces

Neuroprosthetic
Device used to restore function in the body via the interface of electrodes and the nervous system

Neurostimulation
Application of an electrical stimulation inducing modulation or activation of the nervous system for a therapeutic effect

Neurorehabilitation
Supervised program of training to restore function to patients who suffered from a neurological disorder

NHS
National Health Service – in the United Kingdom: refers to the publicly funded healthcare systems

Orthostatic hypotension
Hypotension caused by transition to an upright position

Paraplegic
Someone affected by paralysis (partial or complete) of the lower half of the body due to an injury or disease of the spinal cord

Perfusion
Passage of a fluid (blood, water) through blood vessels, tissue or organ

PMA
Pre-market approval

QSR
Quality System Regulations

Reeve Foundation
Christopher and Dana Reeve Foundation

RVO
Rijksdienst voor Ondernemend Nederland

Scaffold (cellular)
Scaffolds engineered to induce cellular interactions contributing to the formation of new functional tissues

SCI
Spinal Cord Injury – damage to the nerves in the spine that circulate signals from the brain to and from the body. It can be caused by a trauma or a disease. This damage can lead to temporary or permanent dysfunctions

Spasticity
Abnormal increase in muscle tone usually caused by nerve damage and can be associated with pain

STIMO
STImulation Movement Overground (title of clinical study)

Tetraplegic (Quadraplegic)
Someone affected by paralysis (partial or complete) of upper and lower limbs due to injury or disease of the spinal cord

Thoracic
Related to the thoracic region of the back

Transcutaneous
Penetrating through the skin. For example: transcutaneous stimulation is stimulation delivered through the skin via electrodes placed on the skin

UCLA
University of California, Los Angeles

Up-LIFT
Pivotal study to evaluate the Company’s ARC^{EX} Therapy

Vascular
Relating to blood vessels



ONWARD

Forward to **2024**

