

# Annual Report

2024

**ONWARD  
MEDICAL**



# Table of Contents

1 ONWARD at a Glance 5

2 Message from the Chairman & CEO 11

3 2024 Achievements 17

4 2025 Outlook 31

5 Overview 35

6 Culture 85

7 Privacy & Data Governance 93

8 Sustainability 97

9 Operational Review 103

10 Financial Review 111

11 Governance 119

12 Risk Management & Control 141

13 Investor Relations 181

14 Report of the Non-Executive Directors 187

15 Board of Directors' Statements 195

16 Remuneration Report 199

**Financials**

17 Consolidated Financial Statements 215

18 Notes to the Consolidated Financial Statements 233

19 Company Financial Statements 301

20 Other Information 321

*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. ONWARD, ARC<sup>EX</sup>, ARC<sup>IM</sup>, ARC<sup>BCI</sup>, and the stylized O-Logo are proprietary and registered trademarks of ONWARD Medical. Unauthorized use is strictly prohibited.*

*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 2024. 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<sup>®</sup>



ONWARD  
at a Glance

# ONWARD at a Glance

- Founded in 2015
- Currently listed on Euronext Brussels, Amsterdam, and Paris (Euronext: ONWD)
- ~100 employees<sup>1</sup>
- **Global presence:**
  - HQ in the Netherlands
  - Science and Engineering Center in Switzerland
  - US-based field Clinical and Sales organizations
- **Technology:**

3 purpose-built neuromodulation platforms that stimulate the spinal cord to restore movement and other critical functions lost after spinal cord injury (SCI) and other movement disabilities:

  - ARC<sup>EX</sup> System, an external platform that stimulates through the skin
  - ARC<sup>IM</sup> System, an investigational implanted neuromodulation platform
  - ARC<sup>BCI</sup>, an investigational implanted platform that combines the ARC<sup>IM</sup> System with an implanted brain-computer interface (BCI) to restore thought-driven movement via our wireless ONWARD DigitalBridge™

- **Innovation & IP:**

10 FDA Breakthrough Device Designations and 150+ issued patents<sup>1,2</sup>
- **Clinical validation:**
  - Safety and effectiveness of ARC<sup>EX</sup> System for upper limb mobility<sup>3</sup> demonstrated in Up-LIFT clinical trial; results published in *Nature Medicine*, May 2024
  - Positive interim results for ARC<sup>IM</sup> Therapy to improve blood pressure regulation
- **Market opportunity:**

\$17B+ / €15B+ total addressable market with limited competition
- **Commercialization:**

ARC<sup>EX</sup> System received FDA De Novo classification and US market authorization in December 2024 for use in the clinic setting; limited US launch planned in Q1 2025 followed by full launch in Q2 2025; plan to seek CE Mark certification to commercialize in Europe in 2025.

<sup>1</sup>As of 31 December 2024

<sup>2</sup>Number excludes EP country validations; company has 290+ issued patents including EP country validations

<sup>3</sup>Indication as per FDA authorization is to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive)



# Forward-Looking Information / Statements

This document contains certain forward-looking statements, beliefs and opinions with respect to the financial condition, expected results of actual and planned operations, business and objectives of ONWARD. In particular, the words “expect”, “anticipate”, “estimate”, “may”, “should”, “could”, “would”, “believe”, “outlook”, “potential”, “will”, “plan”, “pipeline”, “seek”, “intend”, “aim”, “explore”, and similar expressions are intended to identify forward-looking statements. By their nature, forward-looking statements involve several risks, uncertainties and assumptions because they relate to events and depend on circumstances that may or may not occur in the future.

Actual results may differ, also 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.





# Message from the Chairman & CEO

# Message from the Chairman & CEO

Dear Shareholders, Colleagues, Partners, and Collaborators,

Our vision is both ambitious and essential: Empowered by independence, people with spinal cord injury (SCI) will enjoy life in the ways that matter to them. In 2024, this vision became a reality as we achieved US FDA approval and recorded our first commercial sales of the ARC<sup>EX</sup> System – a breakthrough technology proven to enhance hand strength and sensation for individuals with SCI.

SCI is a life-altering condition, not only for those directly affected but also for their loved ones. For too long, individuals with SCI have been told nothing can be done to restore their ability to move, feel, or improve their quality of life. Today, that narrative is changing and with ~650,000 people living with SCI in the United States and Europe – 9 million worldwide – the need for innovation has never been greater. The impact of our work is already being recognized. Upon learning of the FDA’s approval of the ARC<sup>EX</sup> System, Maggie Goldberg, President & CEO of the Christopher & Dana Reeve Foundation, described it as a “watershed moment for the SCI Community.”

2024 was an important and impactful year for ONWARD Medical and we expect to sustain our positive momentum in 2025:

## Key 2024 achievements

### FDA approval & commercial launch

The US FDA’s De Novo authorization of our ARC<sup>EX</sup> System in December 2024 marked a pivotal moment in our Company’s history. We promptly initiated commercial operations, achieving our first sales to the University of Washington School of Medicine and the Next Steps Chicago rehabilitation clinic. These initial clinics will serve as centers of excellence, helping to establish ARC<sup>EX</sup> Therapy as a new standard of care for upper limb rehabilitation after SCI.

To support our commercial launch, we have hired a specialized sales team focused on supporting leading rehabilitation centers across the United States. Initial feedback from clinicians and patients has been very positive, reinforcing our confidence in this therapy’s commercial potential.

### Breakthroughs in implantable therapies and brain-computer interface (BCI) technology

We continued to advance our pipeline of future therapies, through clinical studies using our ARC<sup>IM</sup> and ARC<sup>BCI</sup> Systems to explore the feasibility of these platforms to address a number of indications (recovery targets) for people with SCI and Parkinson’s disease.

Our BCI program made strong advancements, with additional clinical study enrollments, a grant from the Christopher & Dana Reeve Foundation, and an exclusive license to the WIMAGINE<sup>®</sup> BCI technology. These developments position us to be first-to-market with a BCI-enabled system to restore thought-driven movement after paralysis.



**Message from the Chairman & CEO**

**Strengthening our financial position**

We strengthened our financial position through strategic partnerships and capital raises, including a EUR 50 million capital increase that brought in Ottobock SE & Co. as a strategic investor. This partnership with a global leader in prosthetics and orthotics technology provides both capital and strategic value as we scale our commercial operations and global distribution capabilities.

**Industry recognition**

Our achievements have not gone unnoticed – TIME Magazine named our ARC<sup>EX</sup> System one of the Best Inventions of 2024, and we received a silver medal from EcoVadis, placing us in the top 15% of companies assessed for sustainability practices.

**Building on 2024 momentum: our vision for 2025**

We enter 2025 with strong momentum and clear objectives. Building on our initial success in the clinic setting, we plan to expand the ARC<sup>EX</sup> System’s US regulatory label to include use in the home setting, which would significantly increase our addressable market. We are also pursuing CE Mark certification to allow commercialization in Europe and select other markets.

Our commercial strategy for 2025 includes:

- Expanding our US field organization to cover additional rehabilitation centers, broadening patient access to ARC<sup>EX</sup> Therapy
- Establishing a network of centers of excellence to demonstrate the clinical and economic benefits of the ARC<sup>EX</sup> System, encouraging its adoption as a new standard of care
- Implementing comprehensive training programs for clinicians and rehabilitation specialists to ensure best – in – class patient outcomes
- Building relationships with US payers to ensure broad access to the ARC<sup>EX</sup> System
- Preparing for commercial launch in Europe following expected CE Mark certification by hiring leaders with direct and indirect sales management experience

**Expanding our pipeline beyond ARC<sup>EX</sup>**

Beyond ARC<sup>EX</sup>, we plan to initiate the Empower BP global pivotal trial for our ARC<sup>IM</sup> System to address blood pressure instability after SCI. Our research pipeline remains robust, with planned studies in Parkinson’s disease supported by the Michael J. Fox Foundation, and continued development of our ARC<sup>BCI</sup> System.

As your new Chairman and continuing CEO, we are honored to lead ONWARD during this transformative period. We extend our heartfelt gratitude to our employees, research collaborators, investors and business partners whose dedication make these achievements possible. Most importantly, we thank the SCI Community for its trust and partnership in pursuing our Mission.

We invite you to follow our progress through our website and social media channels as we build sustainable value while positively impacting the lives of people with SCI and those who care for them.

Warm regards,



**Rob ten Hoedt, Chairman**  
**Dave Marver, Chief Executive Officer**





ONWARD®

2024  
Achievements

# 2024 Achievements

## Full Year 2024 and Year-to-Date 2025 Highlights

### Clinical and Development

- In January 2024, the Company announced the expansion of its HemON clinical feasibility study with the addition of Sint Maartenskliniek in the Netherlands. This additional site prepares the Company for the expected 1H 2025 initiation of a global pivotal trial called Empower BP to assess the safety and efficacy of ARC<sup>IM</sup> Therapy to improve blood pressure stability.
- In February 2024, the Company announced it has been awarded Breakthrough Device Designation (BDD) by the US Food and Drug Administration (FDA) for the investigational ARC<sup>BCI</sup> System, which uses brain-computer interface (BCI) technology in conjunction with its investigational ARC<sup>IM</sup> Therapy to restore thought-driven lower limb mobility after SCI, creating the ONWARD DigitalBridge<sup>TM</sup>. This is the Company's tenth BDD.
- In March 2024, ONWARD was accepted into the US FDA's new Total Product Lifecycle Advisory Program (TAP) for the development of its ARC<sup>BCI</sup> System, becoming only the second BCI company to join the program.
- In April 2024, the Company announced it had submitted a De Novo application to the US FDA to obtain regulatory authorization to begin marketing its non-invasive ARC<sup>EX</sup> System in the United States. Authorization was awarded in Q4 2024.
- In May 2024, the Company announced the publication of its Up-LIFT pivotal trial results in *Nature Medicine*. The study achieved all primary and secondary safety and effectiveness endpoints, and ARC<sup>EX</sup> Therapy demonstrated significant improvements in upper limb strength, function, and sensation among people with chronic tetraplegia due to cervical SCI.





ARC 



**2024 Achievements**

- In July 2024, the Company announced a publication in *Neuromodulation: Technology at the Neural Interface*, summarizing effective stimulation parameters informed by the Up-LIFT and LIFT Home studies, and a decision-making framework for clinical implementation of ARC<sup>EX</sup> Therapy.
- In September 2024, renowned neurosurgeon Dr. Jocelyne Bloch performed another successful implant of the ARC<sup>BCI</sup> System at Centre Hospitalier Universitaire Vaudois (CHUV) in Lausanne, Switzerland.
- Also in September 2024, the Company announced a USD 1.1M grant from the Christopher & Dana Reeve Foundation to expand an ongoing clinical feasibility study exploring the use of ARC<sup>BCI</sup> Therapy to restore thought-driven use of the hands and arms after SCI. The grant will support four additional study participants to be implanted with the ARC<sup>BCI</sup> System.
- In October 2024, ONWARD signed an exclusive license with the French Alternative Energies and Atomic Energy Commission (CEA) to develop and commercialize the investigational WIMAGINE<sup>®</sup> BCI as part of the Company’s ARC<sup>BCI</sup> System. This exclusive license positions the Company to be first to market with a BCI-enabled system to restore thought-driven movement after paralysis.
- In November 2024, the Company announced a grant from the European Innovation Council (EIC) to study the use of ARC<sup>BCI</sup> Therapy to restore upper limb movement after stroke.
- In December 2024, the Company’s De Novo application was granted by the US Food and Drug Administration (FDA) and the Company received market authorization for its ARC<sup>EX</sup> System.
- In February 2025, results from the investigator-sponsored Pathfinder2 Study were published in *Neuromodulation: Technology at Neural Interface*, highlighting the benefits of sustained access (at least one year) to ARC<sup>EX</sup> Therapy.
- In March 2025, the Company announced two new grants to support studies using its ONWARD ARC<sup>IM</sup> System to help people with Parkinson’s disease: A USD 1M grant from

The Michael J. Fox Foundation for Parkinson’s Research to address mobility challenges and a US Department of Defense grant of ~USD 1.5M to address blood pressure instability.

- Also in March 2025, the Company announced the first-in-human use of its investigational ARC<sup>IM</sup> Lumbar Lead, designed to be used as part of the ARC<sup>IM</sup> System to restore standing, stepping, and lower limb mobility.

**Intellectual Property**

In 2024, ONWARD added 20 patents to its IP portfolio. It now has more than 150 issued patents, excluding EP country validations. Including EP country validations, the Company exited 2024 with more than 290 issued patents, strengthening the Company’s first-mover advantage.

**Commercial Developments and Industry Recognition**

- In October, the Company’s ARC<sup>EX</sup> System was named one of TIME Magazine’s Best Inventions of 2024.
- In December 2024, the Company earned the first commercial sales of its ARC<sup>EX</sup> System to UW Medicine (University of Washington) and Next Steps Chicago, a community-based rehabilitation clinic.
- In January 2025, the Company’s ARC<sup>EX</sup> System was added to US Veterans Affairs (VA) online procurement platforms, allowing the VA and other government agencies to purchase the breakthrough technology. This is the first major benefit resulting from the Company’s partnership with Lovell Government Services, a Service-Disabled Veteran-Owned Small Business (SDVOSB).

**Corporate**

- In February 2024, the Company announced that KBC Securities initiated research coverage with a Buy rating.
- In March 2024, the Company completed a EUR 20M equity financing that strengthened its balance sheet to support investments in product development, clinical studies, and operational and commercial capabilities.



**2024 Achievements**

- In April 2024, the Company announced that Stifel, a US-based full-service investment bank, had initiated research coverage with a Buy rating. The Company now has five banks providing equity research coverage, each with Buy ratings.
- In June 2024, the Company signed a debt financing agreement for up to EUR 52.5M with US-based lender Runway Growth Capital.
- In July 2024, the Company published its 2023 Annual Sustainability Summary, underscoring its commitment to integrating responsible and sustainable practices into all aspects of its business.
- In September 2024, the Company added a Euronext Paris listing, highlighting the Company’s strong French roots and significant ties to France, including its close partnership with CEA (see Clinical and Development section above).
- In October 2024, the Company announced medtech leader Rob ten Hoedt, former Medtronic President and Executive Committee member and longtime Chairman of MedTech Europe, joined its Board of Directors as incoming Chairman (he was elevated to Chairman in December 2024).
- Also in October 2024, the Company successfully raised EUR 50M including a cornerstone investment from Ottobock SE & Co., a global leader in prosthetics, orthotics, and exoskeleton technology. Ottobock acquired c.10% of ONWARD Medical N.V.’s share capital, initiating a strategic relationship to support the Company’s commercialization of the ARC<sup>EX</sup> System and other important development, clinical, and commercial activities.
- In December 2024, the Company was awarded a silver medal by EcoVadis, the world’s largest provider of business sustainability ratings. The award placed ONWARD in the top 15% of companies assessed by EcoVadis that year.







ONWARD<sup>®</sup>

2025  
Outlook

# 2025 Outlook

We expect to achieve several important milestones in 2025:

## Engineering, Clinical, and Regulatory Developments

- The Company has a robust pipeline of indications that can be pursued using one or more of its technology platforms. These indications primarily target spinal cord injury, but several also show promise in potentially addressing movement or functional challenges resulting from Parkinson’s disease, stroke, and other movement disabilities. The Company expects to announce major advancements in this pipeline, including first-in-human use of its technology for new indications and/or populations.
- The Company plans to submit a 510K application to the US FDA to expand the ARC<sup>EX</sup> System label to include use in the home setting, building on the current authorization for use in the clinic setting.
- The Company expects to publish detailed results from ongoing clinical feasibility studies exploring the use of the ARC<sup>IM</sup> System to stabilize blood pressure after spinal cord injury.
- The Company anticipates receiving an Investigational Device Exemption (IDE) from FDA so it can begin its global pivotal trial for the ARC<sup>IM</sup> System, called Empower BP.
- The Company expects to submit an application for CE Mark certification so it can begin commercializing the ARC<sup>EX</sup> System in Europe and other CE Mark countries.
- The Company expects to initiate a clinical feasibility study involving first-in-human use of the ARC<sup>IM</sup> System to explore its potential to restore bladder function in people with SCI.
- The Company expects to advance its research pipeline with additional ARC<sup>IM</sup> System implants with financial support from the Michael J. Fox Foundation for Parkinson’s Research and US Department of Defense, and additional ARC<sup>BCI</sup> implants financially supported by the European Innovation Council and the Christopher & Dana Reeve Foundation.

## Commercial Developments

- Pending FDA authorization and label expansion, the Company plans to expand US marketing of the ARC<sup>EX</sup> System to the home setting, an expansion that would significantly broaden access and treatment options for people with SCI.
- Pending CE Mark certification, the Company plans to expand marketing of the ARC<sup>EX</sup> System in Europe and other select geographies.
- The Company plans to expand its US field organization. It also plans to establish direct and indirect sales channels outside the US.

## Corporate Developments

The Company expects to explore advantageous engineering and commercial collaboration activities with its new strategic investor, Ottobock, and other potential partners worldwide.



ONWARD<sup>®</sup>



Overview

# Overview

## The Case for Innovative Therapies

Nine million people worldwide have a spinal cord injury (SCI)<sup>1</sup>, and the annual global incidence of new injuries exceeds 750,000. In the US and Europe alone, approximately 650,000 people live with SCI, and the annual incidence of new cases is approximately 30,000.

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<sup>2</sup>. 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.

<sup>1</sup>Liu et al. 2023 Spinal cord injury: global burden from 1990 to 2019 and projections up to 2030 using Bayesian age-period-cohort analysis.

<sup>2</sup>NSCISC Traumatic Spinal Cord Injury Facts and Figures at a Glance (2023 SCI Data Sheet); estimated lifetime costs for a person aged 25 at the time of injury with injury severity AIS ABC; costs for a tetraplegic person calculated as the average cost for a person with high tetraplegia and a person with low tetraplegia.



## A large unmet medical need

# Market



<sup>1</sup>2023 NSCISC Annual Statistical Report Complete Public Version and European prevalence calculated by annual incidence\* 30 years of additional lifetime expectancy: annual incidence considered using average across >25 papers on SCI incidence within Europe and European countries

<sup>2</sup>2023 NSCISC Annual Statistical Report Complete Public Version and European annual incidence considered using average across >25 papers on SCI incidence within Europe and European countries



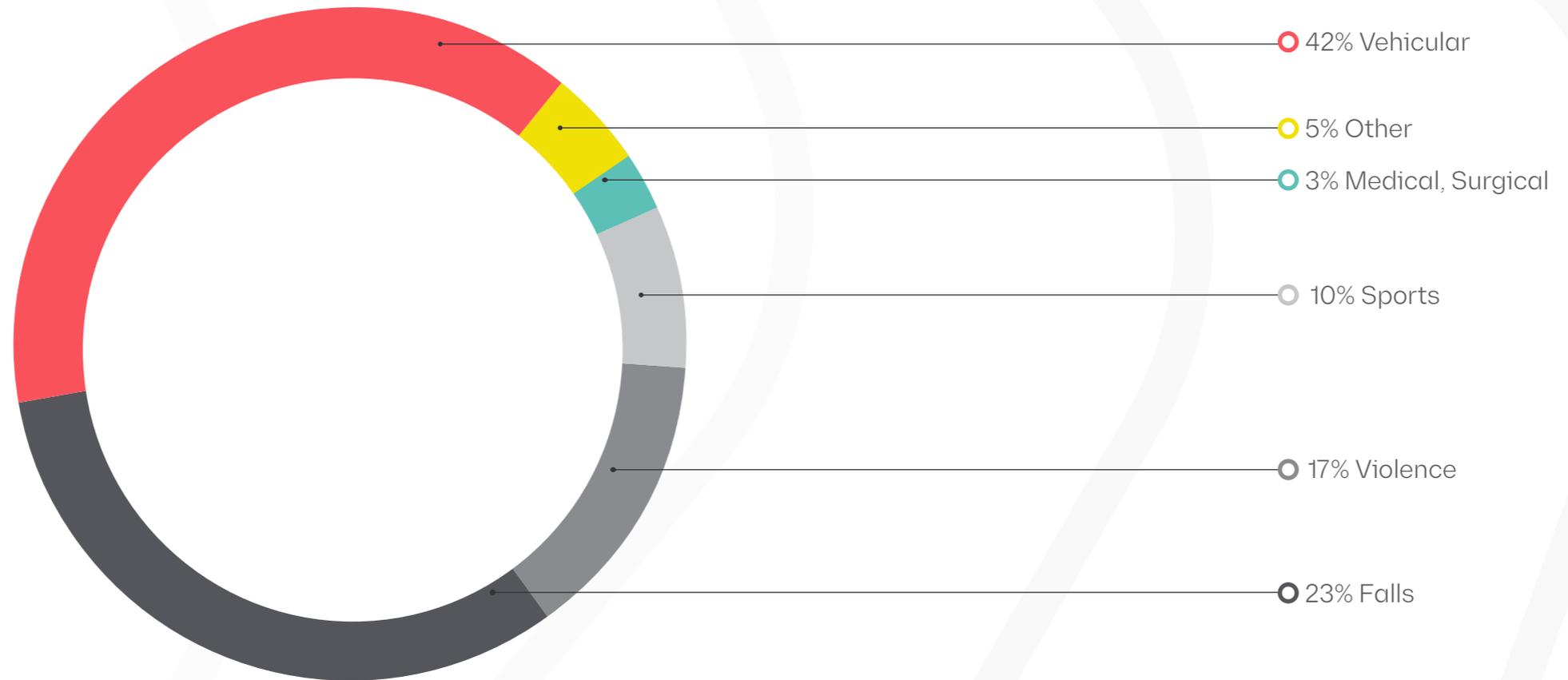
## Damage to the spinal cord resulting in loss of function

# SCI Causes & Patient Profile

### Profile of SCI Patient

- Nearly half of the injuries occur between the ages of 16 and 30 years<sup>1</sup>
- 80% of new SCI cases are male<sup>1</sup>

### SCI Causes



<sup>1</sup>2023 NSCISC Annual Statistical Report Complete Public Version



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 is among the most well-developed current applications



### Growth Trends:

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

<sup>1</sup>Sources: Global News Wire – Vantage Market Research, 2024; Fortune Business Insights Spinal Cord Stimulation Market, 2025; 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

<sup>2</sup>The ARC<sup>EX</sup> System is intended to deliver programmed, transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive)

# 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

**ONWARD Focus**  
Hand strength and sensation<sup>2</sup>

**Sacral Nerve Stimulation** ○  
Fecal incontinence, Urinary incontinence

## Emerging

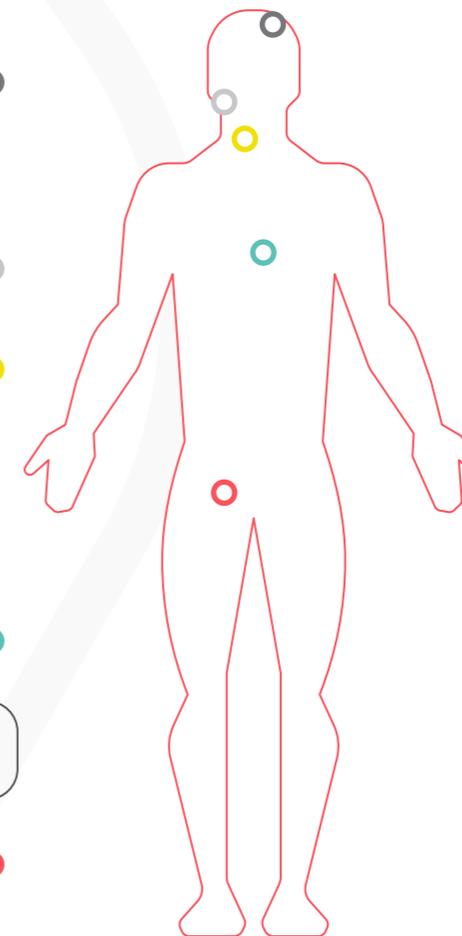
**Deep Brain Stimulation** ○  
Addiction, Autism, Chronic pain, Cluster headache, Dementia, Depression (major), Huntington’s disease, MS, Stroke, Tourette syndrome, Traumatic brain injury, Sleep disorder

**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 independence, people with spinal cord injury will enjoy life in the ways that matter 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. We were pleased to start this process following US FDA approval of the ARC<sup>EX</sup> System in the US in late 2024. Our goal is to bring our innovative solutions to as many of the 9,000,000 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<sup>BCI</sup> System in February of 2024). While many of these innovations were created by our R&D team, others have been exclusively licensed from the 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 United States. We are grateful for these partnerships and the insights they provide.

At ONWARD, our vision is to enable people with SCI to regain movement and other bodily functions so they can enjoy life in the ways that matters to them. We develop and commercialize therapies that address major challenges faced by people with SCI, leveraging the Company’s ARC<sup>IM</sup>, ARC<sup>EX</sup>, and ARC<sup>BCI</sup> platforms to target a broad spectrum of injury locations and 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. 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 other movement disabilities, and in the lives of those who care for them.

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

- Short term: Gain commercial traction with our external ARC<sup>EX</sup> System, starting with hand strength and sensation as our first indication in the United States. Begin our first FDA Investigational Device Exemption (IDE) study, Empower BP, to evaluate implantable ARC<sup>IM</sup> Therapy for stabilizing blood pressure after SCI.
- Medium term: Commercially launch our implantable ARC<sup>IM</sup> System, addressing blood pressure instability after SCI as our first indication.
- Long term: Expand labeling (new indications and populations) and platforms, including our ARC<sup>BCI</sup> System.

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 commercialize these breakthrough therapies in our target markets, using direct and indirect channels 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 research centers around the world. This includes a close relationship 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 and Dr. Bloch continue to provide counsel to the Company as Science and Medical Advisors, respectively.

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 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 BCI paired with ARC™ Therapy to enable a participant to walk with augmented control over his paralyzed legs. Researchers at .NeuroRestore also published a pioneering study using ONWARD ARC™ Therapy to address gait challenges related to Parkinson's disease.

ONWARD partnered with leading clinical research institutions for its Up-LIFT pivotal trial, the results of which were published in Nature Medicine in 2024. The study met all primary safety and effectiveness endpoints, with no serious device-related adverse events and a majority (72%) of participants with chronic tetraplegia due to spinal cord injury achieving clinically meaningful improvements in both strength and function. Participants also achieved significant and clinically meaningful improvements in sensation following ARC<sup>EX</sup> Therapy. Building on this work, ONWARD also collaborated with experts to develop a clinical programming framework for non-invasive transcutaneous spinal cord stimulation (tSCS) to further support the successful clinical implementation of this novel technology. This framework, published in Neuromodulation, outlines stimulation parameters demonstrated to restore upper extremity function in ONWARD's clinical trials and within the broader body of literature. The programming framework was found to be safe, well tolerated, and offers a practical foundation for the clinical use of tSCS in treating cervical spinal cord injury.



One commercial indication and 8 additional indications under clinical or pre-clinical evaluation

# Current Pipeline

Platform	Indication	FDA BDD <sup>1</sup>	Pre-Clinical	Human PoC	Clinical Feasibility <sup>2</sup>	Pivotal	Commercial
ARC <sup>EX</sup>	Hand Sensation & Strength	✓	○	○	○	○	○
ARC <sup>EX</sup>	Mobility	✓	○	○	○	○	○
ARC <sup>IM</sup>	Blood Pressure	✓	○	○	○	○	FDA IDE approval expected 1H 2025
ARC <sup>IM</sup>	Mobility / Second Indication	✓	○	○	○	○	○
ARC <sup>IM</sup>	Parkinson's – Mobility		○	○	○	○	○
ARC <sup>IM</sup>	Bladder	✓	○	○	○	○	Human PoC expected in 2025 <sup>3</sup>
ARC <sup>BCI</sup>	Mobility	✓	○	○	○	○	○
ARC <sup>BCI</sup>	Upper Limb		○	○	○	○	○
ARC <sup>BCI</sup>	Stroke – Upper Limb						Human PoC expected in 2025 <sup>4</sup>

- ✓ BDD<sup>1</sup> Granted
- 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  
<sup>1</sup>BDD = FDA Breakthrough Device Designation. ONWARD has been granted four additional BDDs for ARC<sup>EX</sup> Bladder, ARC<sup>EX</sup> Blood Pressure, ARC<sup>EX</sup> Spasticity and ARC<sup>IM</sup> Spasticity  
<sup>2</sup>Includes both early feasibility (typically before device design finalized) and feasibility (near-final or final device design) studies  
<sup>3</sup>Funded by Christopher & Dana Reeve Foundation grant, conducted by EPFL  
<sup>4</sup>Funded by European Innovation Council grant



## Limited competition with safeguards against future competition

# Competition



ARC<sup>EX</sup>

### Potential Competition

- Two companies with similar technology
- **None has received FDA approval<sup>1</sup>**
- **Intellectual property** controlled by ONWARD Medical under exclusive license from UCLA
- Less institutionalized companies with academic founder-led management teams and limited **funding** raised to date<sup>2</sup>



ARC<sup>IM</sup>

### 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 Medical and market a competing technology
- Likely to **enter space via M&A**, leveraging balance sheets



ARC<sup>BCI</sup>

### No Direct Competitors

- Focus of other BCI companies is to record brain signals to establish the capability to **control or communicate with computers**
- ONWARD Medical has **unique focus on restoring movement** of the human body and WIMAGINE BCI has been successfully implanted in 3 humans for this purpose
- WIMAGINE BCI is ideal current technology, but our **ARC<sup>BCI</sup> System is agnostic and flexible**, providing opportunity to partner with others in the future

ONWARD Medical's first-mover advantage has provided path to large and formidable IP position with 150+ patents<sup>3</sup>

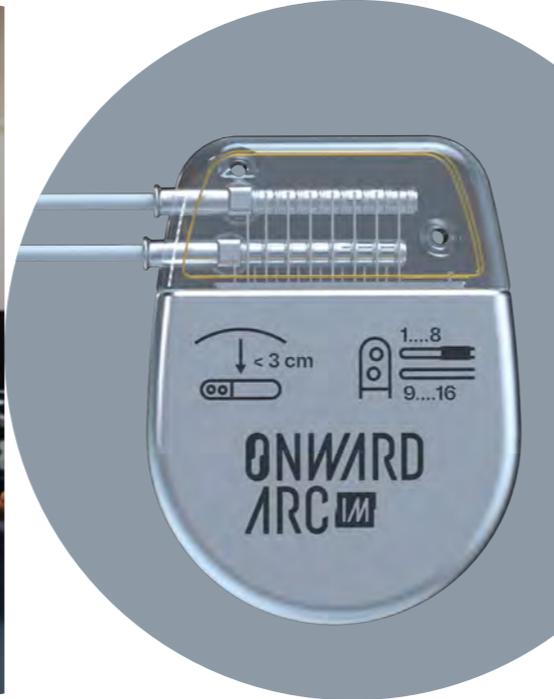
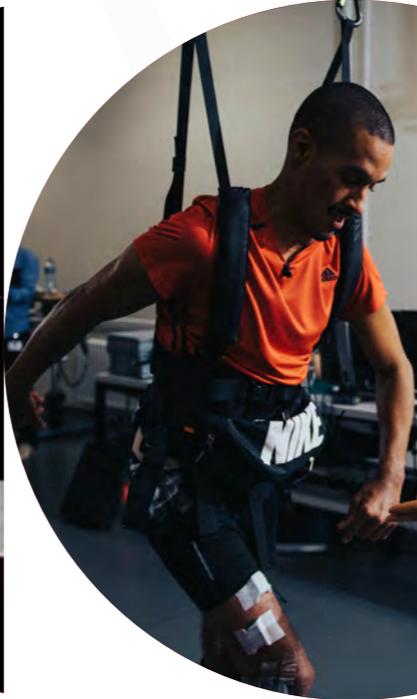
*Note: ARC<sup>IM</sup> and ARC<sup>BCI</sup> are investigational devices, not available for commercial use. The ARC<sup>EX</sup> System is intended to deliver programmed, transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive).*

<sup>1</sup>One has announced CE Mark certification in April 2025

<sup>2</sup>Less than \$4M raised by Company A in private capital as of March 2025 (source: PitchBook); Company B claims \$30M+ raised to date although no material funding tracked by Pitchbook

<sup>3</sup>Patent figures as of end of Q4 2024, excluding EP country validations; company has 290+ issued patents including EP country validations





**ONWARD**

**Basic**  
Mechanisms

**Preclinical**  
Therapy Development

**Clinical**  
Proof of Concept

**Pivotal**  
Evidence Generation

**Commercial**  
Launch



## ARC Therapy: a breakthrough in neuromodulation technology

ONWARD ARC Therapy applies targeted, programmed stimulation of the spinal cord to restore movement, independence, and health in people with SCI. The stimulation can be delivered by an implantable platform, called ARC<sup>IM</sup>, or an external, transcutaneous platform, called ARC<sup>EX</sup>. Additionally, our ARC<sup>BCI</sup> platform pairs ARC<sup>IM</sup> with an implanted brain-computer interface to restore thought-driven movement via our wireless ONWARD DigitalBridge<sup>TM</sup>.

### 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 movement<sup>1</sup> – or both – in these areas. Functions and organs controlled by the autonomic nervous system may also be affected, leading to difficulty with breathing, swallowing, stabilizing blood pressure, sexual arousal, and bowel and bladder function.<sup>2,3</sup> 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. Currently, 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.<sup>4</sup>

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,<sup>5-7</sup> or trunk,<sup>8</sup> 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,<sup>9</sup> 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.

<sup>1</sup>A. 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.

<sup>2</sup>M. 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

<sup>3</sup>M. Walter and A. V. Krassioukov, “Autonomic Nervous System in Paralympic Athletes with Spinal Cord Injury,” *Phys Med Rehabil Clin N Am*, vol. 29, no. 2, pp. 245–266, May 2018, doi: 10.1016/j.pmr.2018.01.001.

<sup>4</sup>Kathe, C., Skinnider, M.A., Hutson, T.H. et al. The neurons that restore walking after paralysis. *Nature* 611, 540–547 (2022). <https://doi.org/10.1038/s41586-022-05385-7>

<sup>5</sup>F. B. Wagner et al., “Targeted neurotechnology restores walking in humans with spinal cord injury,” *Nature*, vol. 563, no. 7729, pp. 65–71, Nov. 2018, doi: 10.1038/s41586-018-0649-2.

<sup>6</sup>E. Formento et al., “Electrical spinal cord stimulation must preserve proprioception to enable locomotion in humans with spinal cord injury,” *Nature neuroscience*, pp. 1–49, 2018, doi: 10.1038/s41593-018-0262-6.

<sup>7</sup>H. Lorach, G. Charvet, J. Bloch, and G. Courtine, “Brain–spine interfaces to reverse paralysis,” *National Science Review*, vol. 9, no. 10, p. nwac009, Sep. 2022, doi: 10.1093/nsr/nwac009

<sup>8</sup>A. Rowald et al., “Activity-dependent spinal cord neuromodulation rapidly restores trunk and leg motor functions after complete paralysis,” *Nat Med*, pp. 1–12, Feb. 2022, doi: 10.1038/s41591-021-01663-5.

<sup>9</sup>Squair, J.W., Gautier, M., Mahe, L. et al. Neuroprosthetic baroreflex controls haemodynamics after spinal cord injury. *Nature* 590, 308–314 (2021). <https://doi.org/10.1038/s41586-020-03180-w>



**Overview**

**Developing three platforms to deliver ARC Therapy**

ONWARD has developed three technology platforms to deliver ARC Therapy: an implantable system called ARC<sup>IM</sup>, an external system called ARC<sup>EX</sup>, and an implantable system called ARC<sup>BCI</sup>, which adds an implantable brain-computer interface (BCI) to the ARC<sup>IM</sup> platform. ARC<sup>EX</sup>, ARC<sup>IM</sup>, and ARC<sup>BCI</sup> have all been awarded FDA Breakthrough Device Designation for a range of indications.

All three platforms contain the same basic elements: an electrical pulse generator and a programmer that enables clinicians to set stimulation therapy parameters and users to control their therapy within those parameters. The ARC<sup>BCI</sup> has an additional brain-recording component.

The three 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.

**External ARC<sup>EX</sup> System**

The ARC<sup>EX</sup> System is our FDA approved external stimulator that is intended to improve sensation and strength of the hands following SCI. ONWARD is currently investigating how ARC<sup>EX</sup> may be used to target additional indications, such as bowel control and lower limb strength and function in the future.

The ARC<sup>EX</sup> 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<sup>EX</sup> PRO app, which connects wirelessly to the Stimulator to program the therapy and adjust parameters, and the myARC<sup>EX</sup> app for users to easily control the stimulation during personal use in the home setting.

**Implantable ARC<sup>IM</sup> System**

The ARC<sup>IM</sup> System is an implantable system currently being used to explore a series of potential indications in clinical feasibility studies. The first target indication for ARC<sup>IM</sup> is addressing blood pressure instability after SCI. We expect to start a global pivotal study for this indication in 2025. Other potential indications may be explored in the future, including SCI-related bladder and bowel control, spasticity reduction, improved sexual function, and upper and lower limb mobility (standing and walking), each enabled by further development of our proprietary lead portfolio and in some cases including a BCI.

The ARC<sup>IM</sup> System has four components:<sup>1</sup>

- A **Lead** implanted on the spinal cord in the area responsible for driving 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, varying in shape and electrode configuration.
- 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.



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

**ARC<sup>EX</sup> Therapy**  
Programmed transcutaneous electrical stimulation to the spinal cord

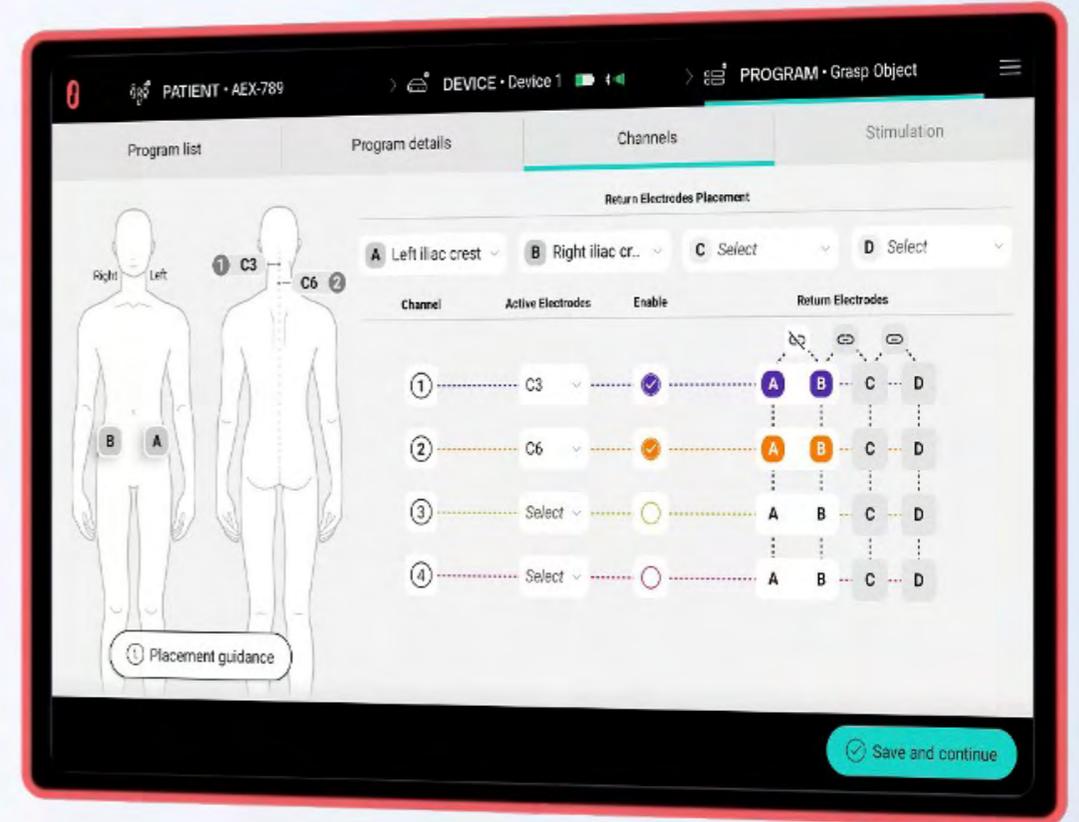
ARC<sup>EX</sup> Stimulator



One of TIME Magazine's Best Inventions of 2024



External Platform



**ARC<sup>EX</sup> Therapy**  
Individual stimulation parameters can be optimized for each patient's unique needs

**ARC<sup>EX</sup> PRO & myARC<sup>EX</sup> app**  
Via ARC<sup>EX</sup> Programmer

Note: The ARC<sup>EX</sup> System is intended to deliver programmed, transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive).

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



## Implantable Platform

- ARC<sup>IM</sup> Lead**  
Cervical Lead  
Thoracic Lead  
Lumbar 8-8 Lead  
Lumbar 7-2-7 Lead  
Sacral Lead



ARC<sup>IM</sup> Neurostimulator

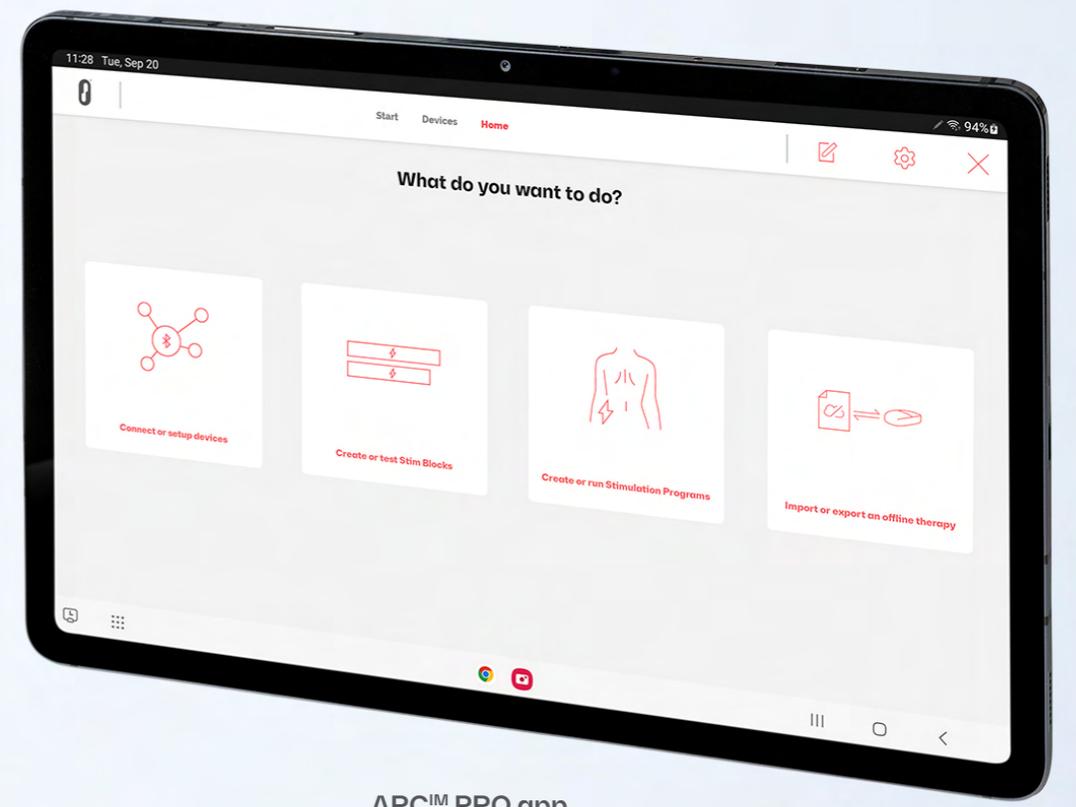


ARC<sup>IM</sup> Hub

myARC<sup>IM</sup> App  
Via ARC<sup>IM</sup> Controller



ARC<sup>IM</sup> PRO app  
Via ARC<sup>IM</sup> Programmer



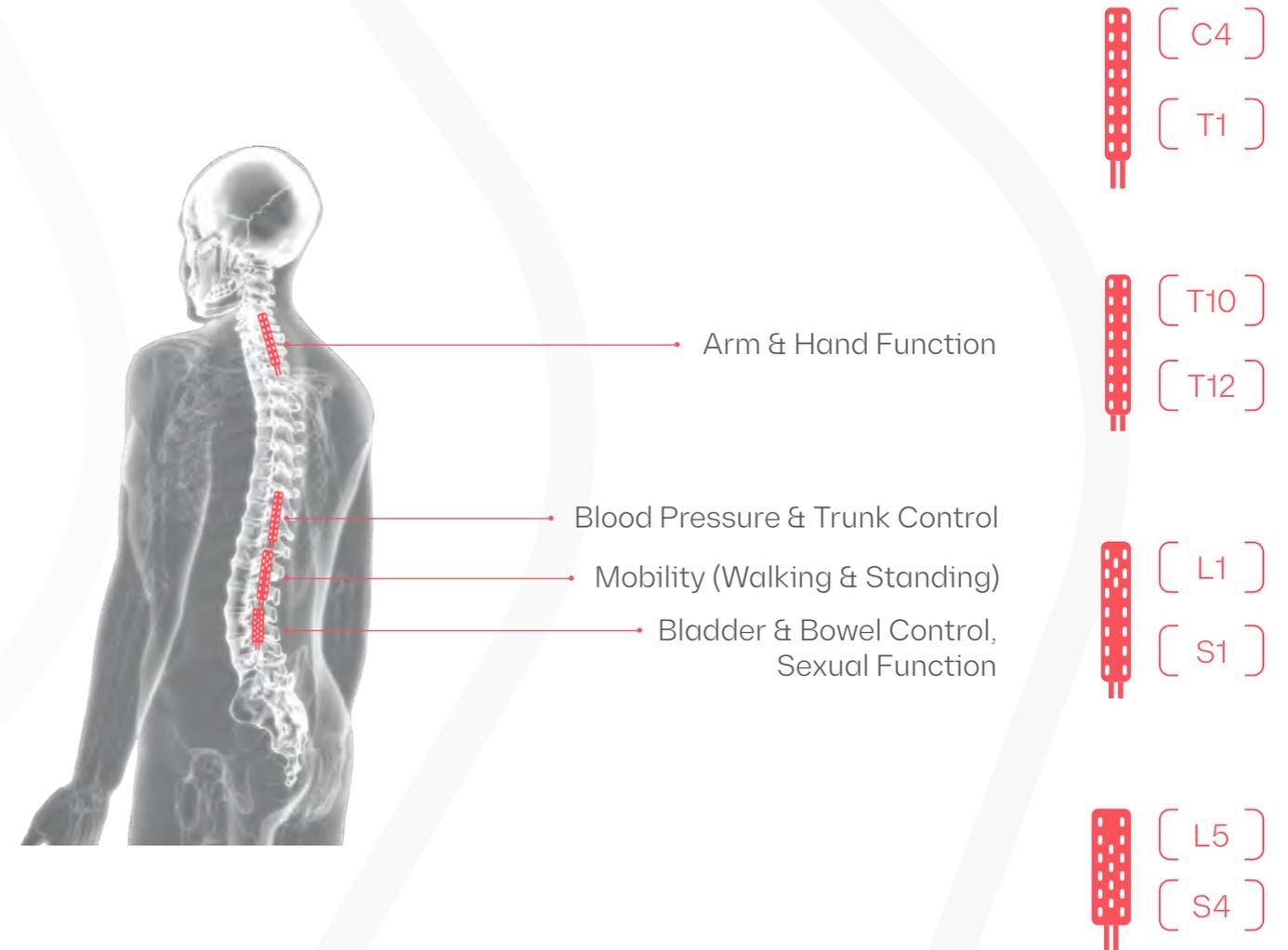
Note: For investigational use only; IPG = Implantable Pulse Generator

# ARC™ Lead Placement



## ARC™ Leads

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



Overview

# Brain and spinal cord are reconnected by our ONWARD DigitalBridge™ to restore thought-driven movement



## Implantable Platform Powered Externally by AI

### ARC<sup>BCI</sup> Brain Implant



**Think**  
An intention to move originates in the brain.

### ARC<sup>BCI</sup> Wearable Data Station

Lightweight cap with embedded electronics and battery wirelessly powers the WIMAGINE brain implant. The cap collects brain activity, streamed wirelessly to the ARC<sup>BCI</sup> programmer.

### Move

The ONWARD ARC<sup>IM</sup> System precisely stimulates the spinal cord to produce intended movement.

### ARC<sup>IM</sup> Lead

- Cervical Lead
- Thoracic Lead
- Lumbar 8-8 Lead
- Lumbar 7-2-7 Lead
- Sacral Lead

### ARC<sup>BCI</sup> Neurostimulator

Generates precise stimulation delivered through ARC<sup>BCI</sup> Lead.



### ARC<sup>BCI</sup> Hub

Wirelessly charges and communicates with neurostimulator.



ARC<sup>BCI</sup>™ Programmer

**Overview**

**The ARC<sup>BCI</sup> System**

The ARC<sup>BCI</sup> System is an implantable system 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) developed by CEA-Clinattec, Grenoble, France, which the Company exclusively licensed in 2024. The BCI is placed on top of the motor cortex, where it records brain signals that indicate the intention to move. The ARC<sup>BCI</sup> System then uses artificial intelligence to decode those signals and translate them into instructions for our ARC<sup>IM</sup> Neurostimulator, which sends electrical impulses to our ARC<sup>IM</sup> Lead. Those electrical impulses are applied to the spinal cord, enabling thought-driven movement.

**Two Priority Indications to Improve Quality of Life after SCI**

**Hand strength and sensation (initial ARC<sup>EX</sup> focus)**

Since 2015, 60% of new SCIs in the US have resulted in some form of tetraplegia.<sup>1</sup> 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 hand strength and sensation is therefore an important rehabilitation goal for a majority of people with SCI, consistently ranked ahead of walking or sexual function.<sup>2</sup>

**Blood pressure instability (initial ARC<sup>IM</sup> 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%<sup>3</sup> of people with SCI.<sup>4</sup> Immediately after injury, blood rushes to the lesion area 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.<sup>5</sup> 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<sup>IM</sup> 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,<sup>6</sup> our clinical feasibility study was extended to the Netherlands with the first implant performed in Q3 of 2023.

We expect additional results from our clinical feasibility studies for blood pressure instability to be published in a peer-reviewed journal in 2025.

<sup>1</sup>National Spinal Cord Injury Statistical Center (NSCISC), *Facts and Figures at a Glance*, Birmingham, AL: University of Alabama at Birmingham, 2021

<sup>2</sup>Candy Tefertiller, PT, DPT, PhD, NCS, Executive Director of Research, Craig Hospital, presented at Unite2Fight Paralysis Conference, 2020. Adapted from Anderson (2004). *Targeting Recovery: Priorities of the Spinal Cord-Injured Population*. *J Neurotrauma*. 21(10): 1371-83

<sup>3</sup>Company data, epidemiology data from 2023 NSCISC Annual Statistical Report Complete Public Version

<sup>4</sup>Krassioukov A., Claydon V.E. The clinical problems in cardiovascular control following spinal cord injury: an overview. *Prog Brain Res*. 2006;152:223-9. doi: 10.1016/S0079-6123(05)52014-4. PMID: 16198703

<sup>5</sup>Carlozzi, N. E., Fyffe, D., Morin, K. G., Byrne, R., Tulsy, D. S., Victorson, D., Lai, J.-S., & Wecht, J. M. (2013). Impact of blood pressure dysregulation on health-related quality of life in persons with spinal cord injury: Development of a conceptual model. *Archives of Physical Medicine and Rehabilitation*, 94(9), 1721–1730. <https://doi.org/10.1016/j.apmr.2013.02.024> Wecht, J. M. (2022). Management of blood pressure disorders in individuals with spinal cord injury. *Current Opinion in Pharmacology*, 62, 60–63. <https://doi.org/10.1016/j.coph.2021.10.003>

<sup>6</sup>ONWARD 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



**Overview**

**Additional indications with significant potential**

**ONWARD ARC™ Therapy to restore mobility in people after SCI**

We plan to further investigate the use of ARC™ to restore the ability to stand and/or walk after SCI by restoring movement in the lower limbs. This will build on the success of STIMO, a clinical feasibility study that determined the preliminary feasibility 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. 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™ 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™ 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.

**ONWARD ARC™ Therapy paired with brain-computer interface (BCI) to restore augmented mobility after SCI**

In May 2023, an article in *Nature Medicine*<sup>1</sup> reported that a wireless BCI can record a person’s intention to move to control ARC™ Therapy. Researchers reported that when paired with ARC™ 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™ Therapy to restore mobility in people with Parkinson’s disease**

In November 2023, an article in *Nature Medicine*<sup>2</sup> 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™ System 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. The study is underway with the first participant implanted in late 2024.

**Clinical trials and regulatory activity**

The development, manufacture, and marketing of ONWARD’s ARC Therapies and associated technologies 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.

<sup>1</sup>Non-invasive spinal cord electrical stimulation for arm and hand function in chronic tetraplegia: a safety and efficacy trial | *Nature Medicine*

<sup>2</sup>A spinal cord neuroprosthesis for locomotor deficits due to Parkinson’s disease | *Nature Medicine*



Build enduring relationships with priority target customers; high customer concentration

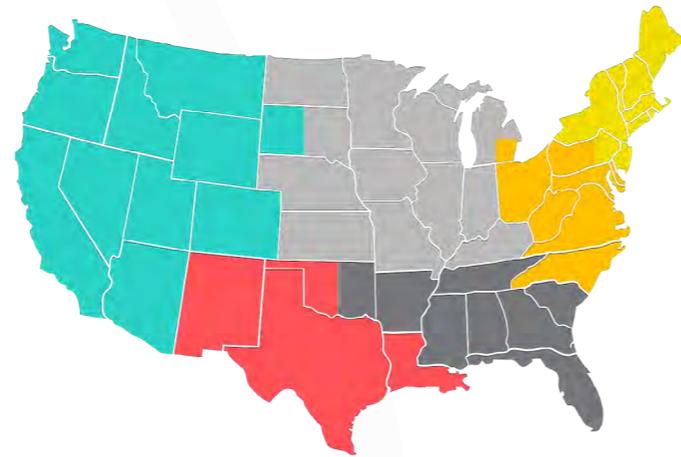
Call Points

~500

Geographical Focus

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

US



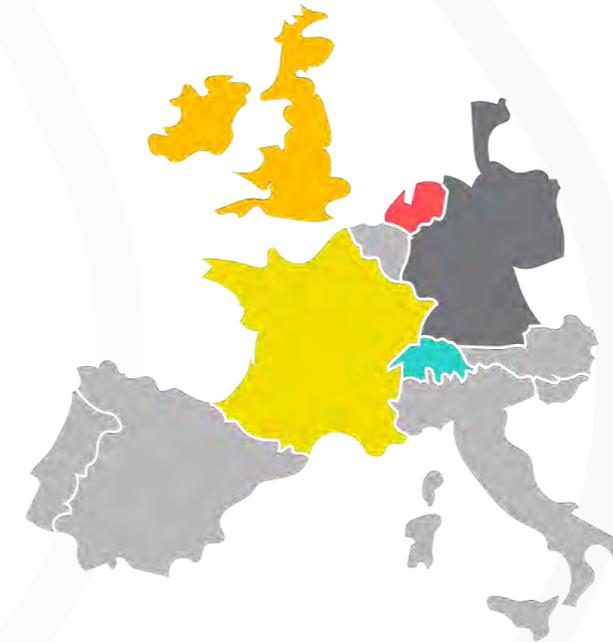
~450

Tier 1 and Tier 2 specialist rehab centers

**Initial Focus:** ~75 Tier 1 accounts including VA SCI hub centers, Up-LIFT investigational sites and other US flagship SCI clinics

**Sales force deployment:** Expect to start with 6 Sales Reps

Europe



~80

Specialist rehab centers

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

**Sales force deployment:** Expect to start with 2-5 Sales Reps in Europe and UK

# Targeting & Channel Strategy

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



**Overview**

Medical devices are regulated according to their risk level and require extensive supporting safety and effectiveness data to demonstrate their risk to benefit ratio for global regulatory authority consideration prior to market approval. ARC<sup>EX</sup> is generally designated as a lower risk device (Class II) and ARC<sup>IM</sup> is expected to designate 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.

**Commercialization**

The Company’s commercialization strategy is to deliver on its mission to empower independence and enable people with spinal cord injury (SCI) to enjoy life in the ways that matter to them. It intends to lead the development of a USD 17 billion market opportunity and address the significant unmet needs of the SCI population. The key tenets of the company’s commercial strategy that will drive success are as follows:

- Deliver Robust science, differentiated technology and compelling evidence to substantiate the effectiveness and safety of its products and enable timely regulatory approvals and reimbursement coverage in key geographies
- Drive market access in the US and European markets and opportunistically pursue other geographies
- Develop technologies and indications in a sequenced manner, always in close partnership with the SCI community and aligned with the needs and priorities of people with SCI
- Bring a partnership mindset to the way we build our sales and marketing organization, hiring a team with rehabilitation, trauma and neuroscience expertise and people-centric values
- Target initially the top rehabilitation and SCI centers of excellence in the US and Europe.

**ARC<sup>EX</sup>**

Just days after the US Food and Drug Administration (FDA) granted de novo classification for the ARC<sup>EX</sup> System on December 19, 2024, ONWARD announced the first commercial sales of its ARC<sup>EX</sup> System in the United States. The ARC<sup>EX</sup> System is currently authorized for clinic use in the United States, and the Company anticipates authorization for home use in 2025. ONWARD Medical plans to seek CE Mark certification in early 2025, with commercial launch in Europe expected in 2H 2025.

**ARC<sup>IM</sup>**

As described in prior sections, our initial focus for ARC<sup>IM</sup> is blood pressure instability. Our pivotal trial for the ARC<sup>IM</sup> System, Empower BP, is expected to start in the first half of 2025. Empower BP will focus on the safety and effectiveness of ARC<sup>IM</sup> Therapy for management of blood pressure instability in patients after SCI. We expect to commercialize ARC<sup>IM</sup> after successful completion of the Empower BP pivotal trial and subsequent FDA PMA approval.

**Geographical focus and commercial objectives**

Our plans depend on our ability to demonstrate the safety and effectiveness of our products to regulatory authorities.

The initial commercial focus is the US and Europe, where most people with SCI are cared for by a limited number of trauma and rehabilitation centers that can be served by a direct field organization. In the short to medium term, the Company may also opportunistically explore geographic expansion into countries where FDA approvals and CE Mark certification are accepted or where the regulatory burden is low. The Company will use direct or indirect channels, as may be appropriate.

**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.



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

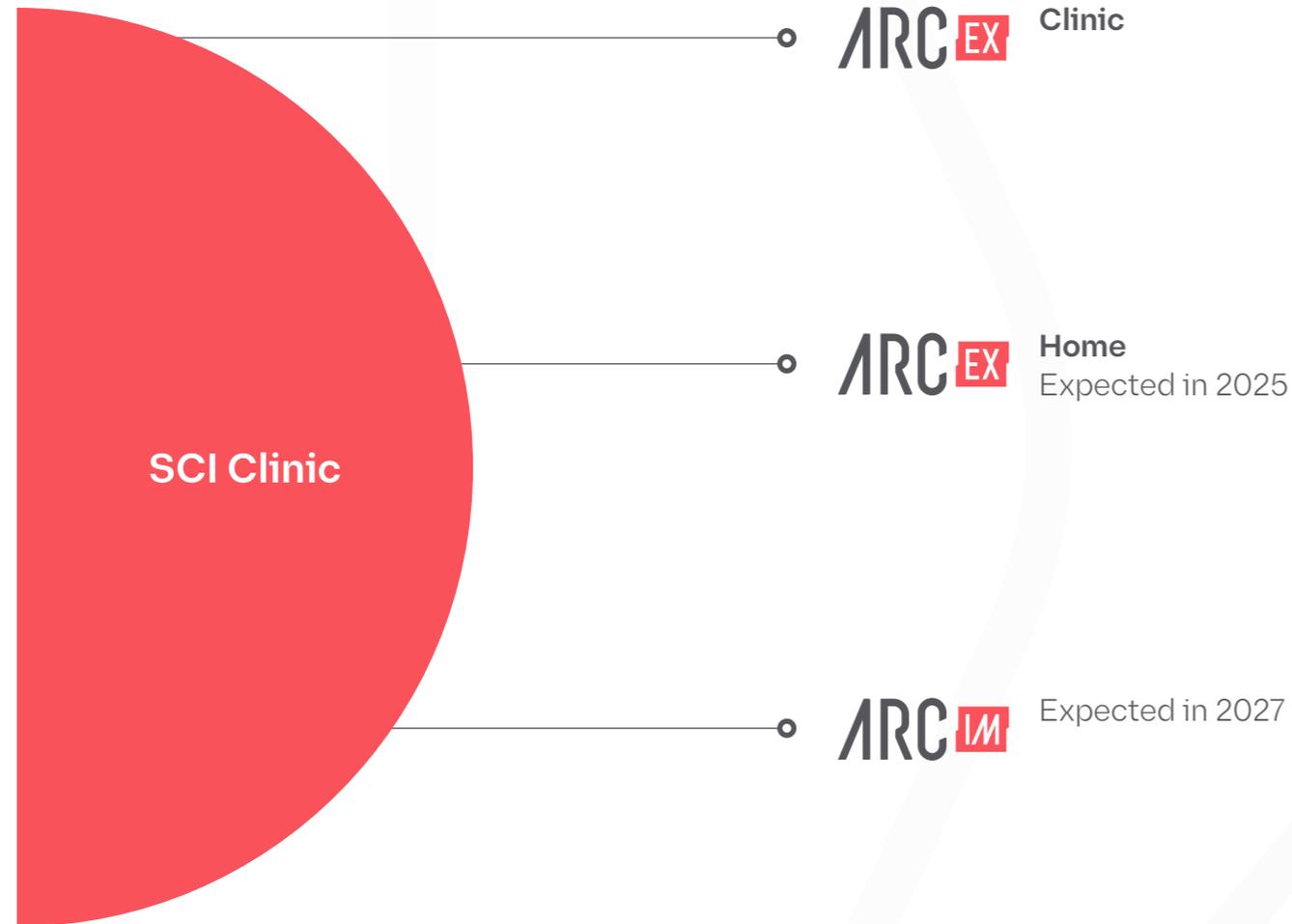


**SCI Rehabilitation Clinics**  
Rehabilitation physicians (physiatrists), therapists (PTs/OTs), and neurologists  
Patients and caregivers



Current focus are SCI rehabilitation clinics which are at the core of ONWARD's commercialization strategy

# Rehabilitation Clinic Importance



- Clinics to **purchase ARC<sup>EX</sup> devices** as capital equipment for in-clinic use and bill for **therapy sessions**
- Opportunity to re-engage chronic patients not currently undergoing care
- Reimbursement: No new reimbursement code required for clinic sales
- Clinics to **prescribe home use** of ARC<sup>EX</sup> for **new patients** or **chronic patients** not currently undergoing care
- Clinics can bill for **evaluation, set-up, and training**
- Reimbursement: **30% of patients in US** expected to have **access** to home use without a new code
- Clinics to **refer patients to neurosurgeons and ortho/spine surgeons** for ARC<sup>IM</sup> implants
- Patients will return to clinics for ongoing care and therapy adjustments
- Reimbursement: Apply for **new codes in US** and **leverage procedural codes** in largest **European market**

Note: ARC<sup>IM</sup> and ARC<sup>BCI</sup> are investigational devices, not available for commercial use. The ARC<sup>EX</sup> System is intended to deliver programmed, transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive).



Physicians will prescribe ARC<sup>EX</sup> for home use and refer patients for ARC<sup>IM</sup> implants

# Referral Pathway



**Overview**

We expect clinicians to use our therapies as follows:

- Use ARC<sup>EX</sup> in clinics during therapy sessions
- Prescribe ARC<sup>EX</sup> for use at home
- Refer patients to neurosurgeons and orthopedic spine surgeons for implantation of ARC<sup>IM</sup> and ARC<sup>BCI</sup>; patients will then return to clinics for ongoing care

Specialty rehabilitation clinics are the referral base for ONWARD’s therapies. As there are a limited number of specialty rehabilitation clinics in our selected markets, they provide a robust, focused and fertile market. In the United States, there are approximately 450 specialized rehabilitation clinics. Our initial focus will be on approximately 75 accounts including Veterans Affairs (VA) SCI hub centers, Up-LIFT investigational sites, and other US flagship SCI clinics.

In Europe, there are approximately 80 specialized rehabilitation clinics in major markets.

**Reimbursement & Market Access strategy**

ONWARD is executing a region-specific reimbursement strategy to ensure timely and sustainable market access for ARC Therapy across the United States and key European markets. Our approach targets all relevant payer channels – public and private – while also leveraging partnerships and alternative funding opportunities to ensure broad patient access.

**United States**

In the U.S., ONWARD has taken significant steps to establish early market access for ARC<sup>EX</sup> following its FDA authorization in December 2024. Through our strategic partnership with Lovell Government Services, a service-disabled veteran-owned small business (SDVOSB), ARC<sup>EX</sup> was successfully added to the VA Federal Supply Schedule (FSS) and GSA Advantage – two key procurement platforms for federal healthcare providers. These listings enable streamlined purchasing by Veterans Affairs (VA) hospitals, Department of Defense (DoD) facilities, and other federal buyers.

Lovell continues to support our expansion within federal channels, with pending applications for the DAPA (Distribution and Pricing Agreement) and ECAT (Electronic Catalog) systems.

These platforms grant access to a large population of individuals living with SCI – particularly veterans – and support the generation of early invoicing and claims data, which are critical for building the evidence base required for broader reimbursement submissions.

Our U.S. reimbursement roadmap includes:

- Category III CPT code application for ARC<sup>IM</sup> to enable early access post-FDA approval.
- New HCPCS code submission for ARC<sup>EX</sup> to support Medicare and commercial DME coverage.
- Potential New Technology Add-on Payment (NTAP) and Transitional Pass-Through (TPT) applications to bridge reimbursement gaps in both inpatient and outpatient settings.
- Feasibility assessment of CMS’s Transitional Coverage for Emerging Technologies (TCET) pathway and Coverage with Evidence Development (CED), both of which may be applicable given ARC<sup>IM</sup>’s Breakthrough Device Designation and expected clinical impact.

ONWARD is engaging with a full spectrum of payer stakeholders, including Medicare, Medicaid, commercial insurers, workers’ compensation payers, auto and accident insurers, the VA, etc.. In parallel, we are leveraging alternative funding sources such as SCI-focused foundations, military insurance, and dedicated government and private programs to support access for underserved populations.

**Germany**

Germany is expected to be the first European market to adopt both ARC<sup>EX</sup> and ARC<sup>IM</sup>, given its advanced SCI rehabilitation infrastructure and comprehensive reimbursement framework. ARC<sup>EX</sup> is anticipated to be immediately reimbursed for in-clinic use following CE mark approval. For home use, ONWARD is preparing for registration in the Hilfsmittelverzeichnis (HMV) – the official list of durable medical equipment reimbursable by public insurers – and anticipates a 2–4 year pathway pending evaluation by the G-BA.

ARC<sup>IM</sup> is expected to be reimbursed under Germany’s DRG-based inpatient payment system, with additional support from supplemental payments (Zusatzentgelte) to reflect the cost and complexity of the implant procedure. These pathways are well established e.g. in BG Clinics,



**Overview**

which specialize in spinal trauma and rehabilitation and are experienced in negotiating reimbursement for advanced technologies.

Alternative funding options in Germany include workers' compensation (DGUV), private health insurance, disability insurance, and support from SCI-specific charitable foundations. These mechanisms may accelerate access while formal reimbursement reviews are underway.

**Europe (Beyond Germany)**

Across other major European markets, ONWARD is pursuing country-specific reimbursement strategies based on the respective national frameworks. While Europe lacks a unified reimbursement model, we are building targeted access plans that focus on:

- Public health insurers
- Private payers
- Workplace and accident insurance funds
- Disability and long-term care insurers
- Military and veteran health systems
- Charities and SCI foundations that provide financial assistance

These efforts began in 2022 and will continue through 2025 and beyond, with each market approached based on its readiness and strategic alignment with ONWARD's commercial goals.

**Looking ahead**

ONWARD has already achieved key milestones in building a sustainable reimbursement foundation, including government procurement access in the U.S., clinical market entry for ARC<sup>EX</sup>, and advanced planning for broad-based reimbursement across Europe. Our strategies are tailored to each region's regulatory and payment realities and aligned with the clinical value of our innovations.

We are actively collaborating with the full ecosystem of reimbursement stakeholders – from public insurers and private payers to specialty clinics, SCI organizations, and federal healthcare providers – to ensure ARC Therapy is accessible to those who need it. At the same time, we are generating real-world evidence, including patient-reported outcomes, to meet growing demands for value-based reimbursement.

Our goal is to enable broad, equitable access to ARC<sup>EX</sup> and ARC<sup>IM</sup> while ensuring ONWARD is compensated fairly for delivering transformative outcomes for people living with spinal cord injury.



ONWARD<sup>®</sup>



Culture

# Culture

At ONWARD, we aim to attract talented and ambitious individuals who bring creativity to everything they do by offering a compelling vision, groundbreaking technology, and competitive rewards. Our team reflects a rich diversity, with 20 nationalities represented.

We strive to position ONWARD as an employer of choice by fostering a positive culture rooted in the principles of the ONWARD Code. This code emphasizes continuous learning, constructive feedback, and professional development while providing the tools and opportunities for employees to enhance their skills and grow their careers.

As part of our culture, the ONWARD Code is used to recognize employees whose behaviors and actions exemplify one or more of its tenets. The Code is introduced during onboarding and reaffirmed in our monthly company-wide meetings. It serves as a foundation for fostering an open and transparent work environment where employees feel confident expressing concerns in good faith, knowing these will be addressed confidentially, seriously, fairly, and without fear of retaliation.



# 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**

The Culture Club, a team-driven initiative, reinforces our cultural values, fosters collaboration, and strengthens shared understanding. It also supports charitable SCI-focused events in partnership with organizations such as Wings for Life and the Christopher & Dana Reeve Foundation.

**Competitive hiring**

At ONWARD, we recruit from a global talent pool and we strive to attract top talent—individuals inspired by our vision and driven by the opportunity to achieve true breakthroughs rather than incremental progress.

Our recruitment capabilities enable us to maintain full control over the hiring process, leveraging our professional networks and partnerships with leading academic institutions to identify and secure the best candidates available.

We also recognize the value of employee networks through our referral program, which incentivizes employees to recommend candidates who align well with our organizational culture and values.

To attract and retain exceptional talent, we offer competitive compensation and benefits packages. As part of our remuneration philosophy, we provide long-term incentives to senior management and key contributors. Additionally, we promote employee share ownership through a stock-option plan, ensuring alignment between our long-term objectives and incentives. Grants under this program are contingent upon continued employment until vesting, reinforcing a commitment to shared success.

**A great place to work**

ONWARD places a strong emphasis on employee engagement and the continuous improvement of the employee experience. In 2024, we introduced several initiatives to gather feedback and foster a positive work environment such as bi-yearly pulse surveys with results analysis done by dedicated workgroups that propose actionable recommendations, a new biweekly initiative gathering quick insights to monitor employee sentiment more frequently, an anonymous platform allowing employees to share ideas and suggestions freely.

These efforts complement our ongoing improvements to the employee lifecycle experience that includes a check-in survey for new hires at key milestones: the end of first week, after one month, and after three months, as well as employee journey interviews and comprehensive offboarding interviews. These measures ensure valuable feedback is collected at every stage of employment, enabling us to refine our practices and enhance organizational performance.

**Employee well-being**

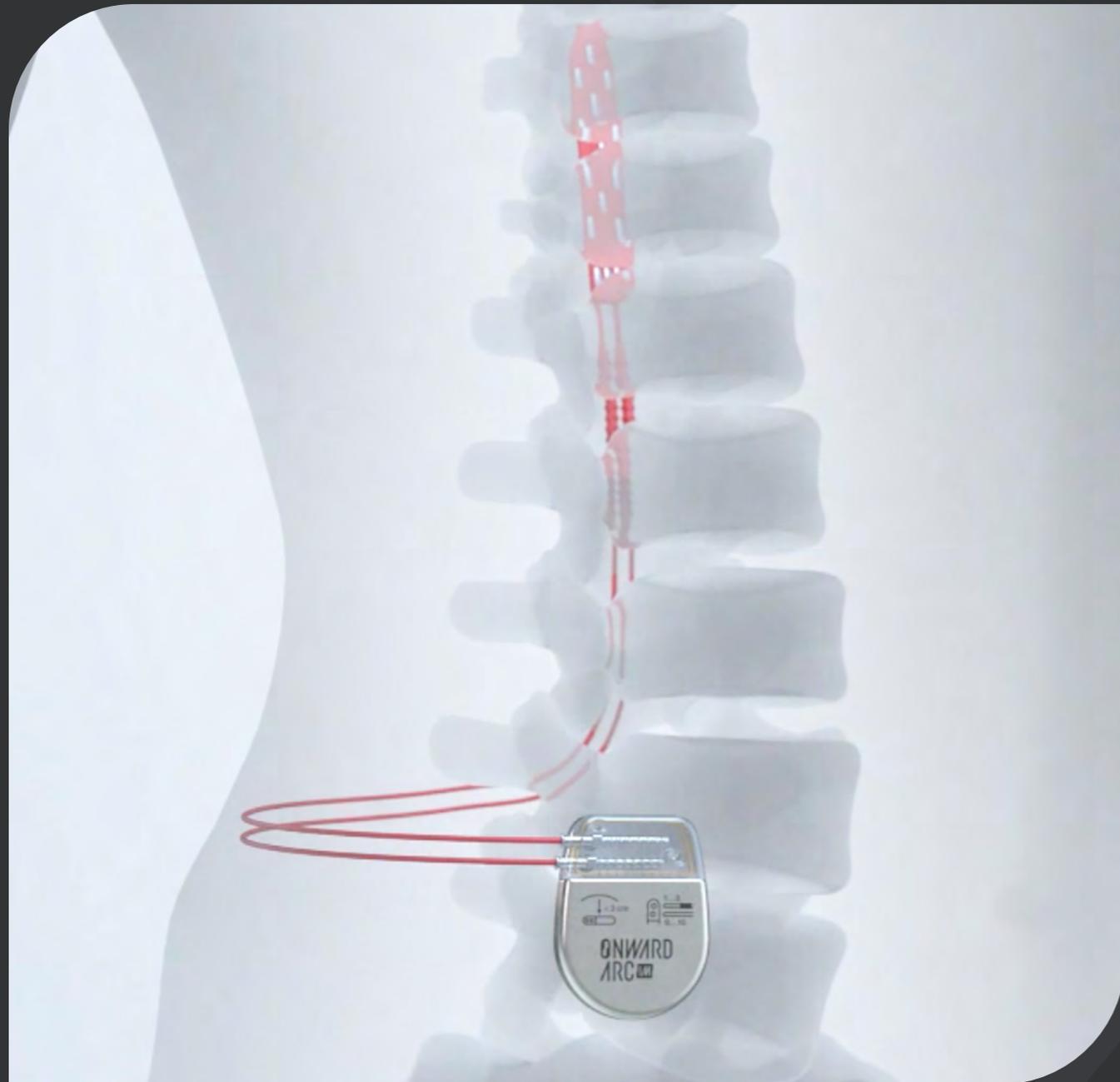
In 2024, we launched several initiatives to enhance employee well-being and support a healthy work-life balance. These efforts included the establishment of a Zen Zone in our Lausanne office, providing employees with a dedicated space for relaxation and mindfulness.

We also continued to offer flexible hybrid working arrangements where possible, enabling employees to better balance their personal and professional commitments.

Additionally, we introduced a variety of activities and programs to promote well-being, such as well-being challenges, sports events in support of the SCI community, and the dissemination of educational resources during special months and weeks dedicated to mental health awareness and work-life balance. These initiatives reflect our commitment to fostering a positive and supportive work environment for all team members.



ONWARD<sup>®</sup>



# Privacy & Data Governance

# Privacy & Data Governance

ONWARD is committed to ensuring that cybersecurity and privacy are built into our products and processes. The personal data we process in the course of our operations – including health and medical information – pertains to 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 assessing and continually improving the efficiency and safety of our existing and investigational 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.

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

Through the position of VP of Legal, we have strengthened 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 established traceability in accordance with relevant standards and built evidence that our products are compliant with the regulations. We continue improving our processes for compliance with GDPR and HIPAA requirements, creating a robust data privacy platform which supports the commercial launch of ARC<sup>EX</sup> in the US in late 2024. We are strengthening our data management and processes, we regularly train our staff on security and privacy issues and employ best practices for the administration of our systems and infrastructure.



ONWARD<sup>®</sup>



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 how 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 Parkinson's disease patients. 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 has nearly 290+ issued patents worldwide (including EP validations). 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 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 Praxis Foundation in Canada, and International Spinal Research Trust in the UK. By collaborating with these groups, ONWARD is able to innovate in ways that make the greatest difference for people with SCI.

Sustainability

- **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.

In 2024, ONWARD Medical was awarded a silver medal by EcoVadis, the world's largest provider of business sustainability ratings. The award places the Company in the top 15% globally of companies assessed by EcoVadis in the past 12 months. The EcoVadis assessment evaluates 20+ sustainability criteria across four core themes: Environment, Labor & Human Rights, Ethics, and Sustainable Procurement. More than 130,000 companies globally have been rated by EcoVadis.





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. 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, 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’s formidable IP portfolio totals 290+ issued patents, including EP country validations, further reinforcing the Company’s pioneering science and first-mover advantage.

## Research and Development

In 2024, ONWARD’s engineering team made advancements across several development initiatives:

- ARCEX System development: Development was completed in 2024. Design verification and validation activities, including user-centric summative studies, were completed, and the design transfer to manufacturing was executed. This included preparation of production materials and supply-chain activities. Work continues to enable scaling production volumes in anticipation of robust market demand. Additionally, a digital platform for collecting, storing, and analyzing data is under development and will continue in 2025.

This platform will serve as a foundation for delivering an enhanced user experience and improved customer support capabilities.

- ARC<sup>IM</sup> System development: The ARC<sup>IM</sup> platform has continued to evolve and mature with completion of several technological updates, including enhancements supporting clinical research activities, user experience, system performance, and incorporation of features informed by insights gained from field use. The technology is expected to advance in early 2025 to the stage at which it can support inclusion in the Empower BP pivotal study, which is scheduled to commence in 2025.
- ARC<sup>BCI</sup> development: The company has signed an exclusive agreement with CEA to develop and commercialize the investigational WIMAGINE<sup>®</sup> BCI technology. Technology transfer and development activities are planned to begin in 2025.
- Engineering Operations: The R&D department has undergone adjustments to better align cross-functional teams across all levels of the organization. These updates aim to optimize the product lifecycle, clarify roles and responsibilities within functions, and strengthen collaborations among various stakeholders, while fostering the progression of our development and research initiatives. Our commitment to continuous improvement will continue to drive organizational maturity throughout 2025.

ONWARD is also engaged in several joint research activities, with significant milestones achieved throughout 2024:

- Brain controlled locomotion: The first study participant was successfully implanted in the Think2Go clinical feasibility trial, marking a key step in evaluating the potential of ARC<sup>BCI</sup> Therapy to restore thought-driven lower limb function in individuals with spinal cord injuries.



**Operational Review**

- Brain controlled upper limbs and partnership with the Christopher and Dana Reeve Foundation: The first study participant was enrolled in the UP2 clinical feasibility trial completing the clinical protocol and marking a key step in evaluating the potential of ARC<sup>BCI</sup> Therapy to restore upper limb function in individuals with spinal cord injuries. The Christopher and Dana Reeve Foundation provided funding enabling the inclusion of a total of 7 participants in this trial.
- Spinal cord stimulation to facilitate locomotion in individuals living with Parkinson’s disease and partnership with the Michael J. Fox Foundation: ONWARD received ethical approval for the SPARKL study, a clinical feasibility study which aims to test the effectiveness of ARC<sup>IM</sup> Therapy in addressing locomotor deficits in individuals with Parkinson’s disease. This milestone was underscored by the successful implantation of the study’s first participant last year.
- Spinal cord stimulation for blood pressure regulation in individuals living with Parkinson’s disease and partnership with the US Department of Defense (DoD): ONWARD secured funding from the US DoD to initiate a clinical feasibility study in late 2024 exploring the use of ARC<sup>IM</sup> Therapy to address blood pressure instability in individuals living with Parkinson’s disease, reflecting the potential of our therapies to address a range of critical health challenges.
- Brain controlled spinal cord stimulation after stroke and funding from the European Innovation Council (EIC) and from Switzerland State Secretariat for Education, Research and Innovation (SERI): The Company was awarded a highly competitive grant to support a pioneering project that will evaluate the use of ARC<sup>BCI</sup> Therapy in a clinical feasibility study for improving upper and lower limb functions in individuals living with subcortical stroke.

**Clinical and Regulatory**

ONWARD’s clinical and regulatory team had a productive 2024, ending the year with the FDA De Novo authorization to market the ARC<sup>EX</sup> System in the United States. Additionally, the team advanced the Company’s clinical understanding of ARC<sup>IM</sup> in addressing hemodynamic instability in preparation for the IDE submission and commencement of Empower BP in 2025.

We were awarded our 10<sup>th</sup> BDD in Q1 2024 for ARC<sup>BCI</sup> therapy. These BDD awards us priority FDA review and the opportunity to interact with FDA experts regarding our therapies throughout the premarket review phase prior to commercialization.

The Company is engaging in discussions with the FDA and EU-MDR in preparation for a series of 2025 submissions pertaining to home-use for ARC<sup>EX</sup> in the US, market authorization in Europe for ARC<sup>EX</sup>, and commencement of the Empower BP pivotal study.

**Quality**

ONWARD has a global quality system that encompasses activities in the United States, the Netherlands, and Switzerland and complies with applicable regulations and standards related to the medical devices industry (MDR and QSR, respectively, for EU and US). In 2018, the Company obtained ISO 13485 certification for design and development. In 2022, the certification scope was expanded to include clinical applications targeted by ARC<sup>EX</sup> Therapy and new activities to support the manufacturing and distribution of ARC<sup>EX</sup> devices.

The most recent ISO audit was conducted and passed in late 2024 by TÜV SÜD, a respected notified body with global reach for neuromodulation devices.

**Commercial operations**

Just days after the US FDA granted De Novo classification for the ARC<sup>EX</sup> System on December 19, 2024, ONWARD announced the first commercial sales of the ARC<sup>EX</sup> System in the United States. The ARC<sup>EX</sup> System is currently authorized for clinic use in the United States, and the Company anticipates authorization for home use in 2025. ONWARD Medical plans to seek CE Mark certification in 2025, with commercial launch in Europe expected in the second half of 2025.

Assuming positive clinical results from our Empower BP global pivotal trial and subsequent regulatory approvals, ONWARD aims to launch ARC<sup>IM</sup> commercially in the United States in 2027 and select European markets thereafter to restore hemodynamic stability after SCI. Additionally, the Company will continue to investigate the use of ARC<sup>IM</sup> and ARC<sup>BCI</sup> 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.



**Operational Review**

The Company plans to deploy its own direct sales and service organization in the United States and select European markets, and use distribution partners in most other geographies.

**Supply Chain / Manufacturing**

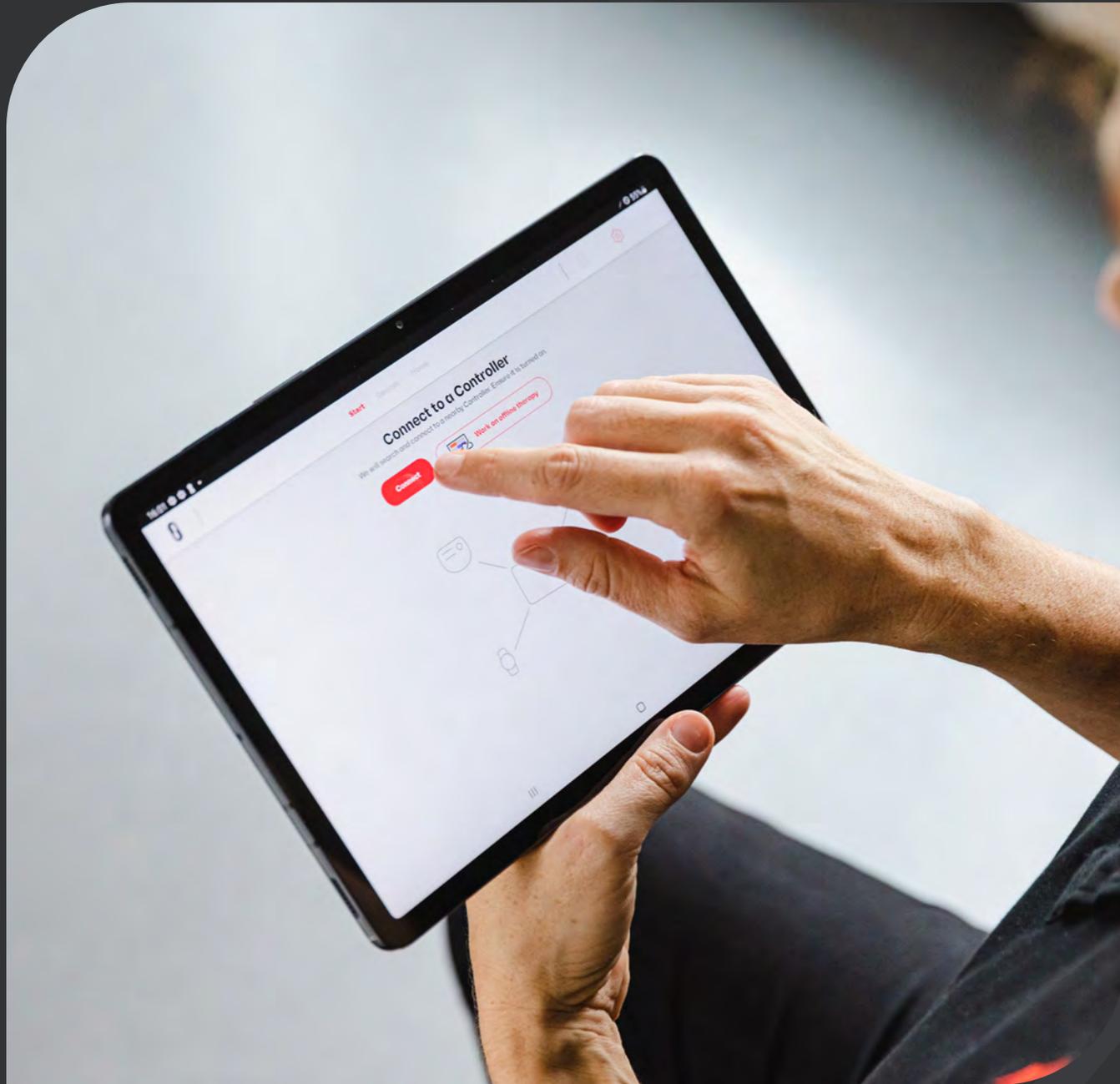
The company has forged relationships with leading, medtech-focused contract manufacturing organizations (CMOs) to assist with the manufacture of products and product components. Selected CMOs undergo a rigorous screening and selection process and are subject to robust quality and performance monitoring. ONWARD conducts regular supplier audits and will continue its supplier vigilance programs in 2025. The Company maintains market surveillance of components to monitor quality and supply issues, and explores alternative sourcing options, paying particular attention to costs and delivery timelines. There are no critical supplier changes expected in 2025 and no known shortages of components or materials.

**Financing**

To pursue its strategy and operational goals, ONWARD will invest in R&D, conduct clinical trials, and drive commercialization of the recently FDA-approved ARC<sup>EX</sup> System. The Company successfully completed two equity financing rounds in 2024, raising a total of €70 million. Net cash on the balance sheet at the end of 2024 was €60 million net cash (please refer to Non-IFRS financial measure included in *Other Information* for the definition of net cash). As part of the October 2024 equity financing, ONWARD added Ottobock SE & Co. KGaA as a strategic investor.



ONWARD<sup>®</sup>



# 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	2024	2023
<b>Total Revenues &amp; Other Income</b>	<b>1.7</b>	<b>0.5</b>
<b>Total Operating Expenses</b>	<b>(36.6)</b>	<b>(36.0)</b>
Research & Development Expenses	(12.4)	(13.8)
Clinical & Regulatory Expenses	(4.8)	(4.9)
Marketing & Market Access Expenses	(3.4)	(2.9)
Patent Fees & Related Expenses	(1.4)	(1.5)
Quality Assurance Expenses	(2.0)	(1.5)
General & Administrative Expenses	(12.6)	(11.3)
<b>Operating Loss for the Period</b>	<b>(34.9)</b>	<b>(35.5)</b>
Net Finance Expense	(0.9)	(0.6)
Income Tax	0.0	(0.1)
<b>Net Loss for the Period</b>	<b>(35.7)</b>	<b>(36.2)</b>
At	<b>31 December</b>	<b>31 December</b>
EUR' Million	<b>2024</b>	<b>2023</b>
<b>Net Cash Position at the end of the Period</b>	<b>60.0</b>	<b>29.8</b>
<b>Interest-bearing Loans</b>	<b>(14.0)</b>	<b>(15.3)</b>
<b>Equity</b>	<b>48.1</b>	<b>17.9</b>

## Total Revenues & Other Income

In 2024 the Company successfully negotiated an amendment with the European Innovation Council to reflect the origin of the activities performed, and was able to secure replacement funding from the Swiss State Agency (SERI) for activities conducted in Switzerland. As a result, grant income has been recognized in 2024 to reflect progress on the Reverse Paralysis grant from inception through the end of 2024. This represents approximately €1M of the 2024 income. Additionally, following FDA clearance on 19 December, the Company realized the sale of two ARC<sup>EX</sup> devices, generating €77k in revenue. This marks an important milestone in the Company’s transition to commercial operations.

## Research & Development Expenses

Research and development (R&D) expenses decreased by 10%, from €13.8M in 2023 to €12.4M in 2024. The decrease is due to a reduction in external costs while employee costs remained relatively stable. The shift reflects a greater allocation of internal resources to R&D activities, resulting in lower reliance on external expenditures.

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, Science Advisor, Director at .NeuroRestore and Professor at EPFL.



**Financial Review**

**Clinical & Regulatory Expenses**

Clinical expenses decreased by 3%, from €4.9 million in 2023 to €4.8M in 2024. In 2024, clinical expenses were primarily driven by efforts to support the FDA submission for ARC<sup>EX</sup>, reflecting its priority within our overall strategy. Additional costs were incurred for ongoing clinical activities, including consulting services and study-related expenses, as well as preparations for our pivotal Empower BP study. 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 14%, from €2.9M in 2023 to €3.4M in 2024, reflecting the activities necessary to prepare for regulatory clearance and ensure marketing readiness to support commercialization. This includes participation in leading industry forums to increase awareness and engagement around ONWARD ARC Therapies in the SCI community. Employee costs increased as the company expanded its marketing capabilities and began hiring sales representatives to facilitate ARC<sup>EX</sup> sales.

**Patent Fees & Related Expenses**

Patent fees and related expenses remained in line with prior year from an external cost perspective. These expenses consist primarily of costs associated with obtaining and maintaining patents and other intellectual property included in ONWARD's growing portfolio, including the newly acquired exclusive rights to Clinatec's WIMAGINE<sup>®</sup> Brain-Computer Interface (BCI) Technology.

**Quality Assurance Expenses**

Quality assurance expenses increased by 38% from € 1.5M in 2023 to € 2M in 2024. Quality assurance expenses are related to efforts to strengthen ONWARD's capability to meet quality and regulatory requirements in support of regulatory submissions and manufacturing of the ARC<sup>EX</sup> system that received clearance for clinic use in the US in December 2024. 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 11%, from €11.3M in 2023 to €12.6M in 2024. As ONWARD transitions to a commercial organization, the Company has made significant investments to establish its manufacturing capabilities. This includes scaling production processes, securing supply chain resources, and ensuring operational readiness to support the launch of ARC<sup>EX</sup>. Additionally, the Company continued investing in technology systems and expanded its overall operational infrastructure, including internal licensing and legal compliance, to support commercialization. Employee costs include one-off bonus compensation in recognition of the fundraising efforts in 2024.

**Net Finance Expense**

The net financial expense increased by 48%, from €0.6M in 2023 to €0.9M in 2024. Interest expense is divided between the innovation loan from the RVO NL that was repaid in July and replaced with a debt facility from Runway Growth. The Company continued to invest excess cash in short-term deposits with reputable banks yielding interest income.

**Income Tax**

In 2024, the Company recorded a tax benefit compared to the tax expense in 2023. This shift was primarily driven by the correction of income taxes in the U.S. for 2023, along with the recognition of the 2024 tax expense in both the U.S. and Switzerland. This is offset by the increase in deferred tax asset balance reflecting the recognition of deferred tax assets on state tax losses in the US. Another factor contributing to the increase in the deferred tax asset balance is the rise in the post-employment benefit liability in Switzerland. The 2023 tax expense was mainly driven by the activities of the Swiss subsidiary.

**Cash Position**

The Company ended the year with a positive net cash balance of € 60M (2023: € 29.8M). The full amount comprises cash and cash equivalents since none of the short-term fixed deposits exceeds a period of 3 months.



## Financial Review

The table below summarizes the Company's cash flows for the years 2024 and 2023.

EUR' Million	2024	2023
Net cash generated / (used) from operating activities	<b>(31.8)</b>	<b>(32.2)</b>
Net cash (used) / generated from investing activities	<b>(0.2)</b>	<b>19.6</b>
Net cash generated / (used) from financing activities	<b>62.6</b>	<b>0.8</b>
Effect of exchange rates on cash and cash equivalent	<b>(0.4)</b>	<b>(0.1)</b>

Cash outflow from operating activities decreased from € 32.2M in 2023 to € 31.8M in 2024. The decrease in operating cash flows is primarily attributable to changes in working capital, specifically an increase in trade and other payables.

Cash flow from investing activities in 2024 reflects the acquisition of property, plant, and equipment.

The cash inflow in 2024 is attributable to the two rounds of equity financing raised net of transaction costs. The Company also repaid the innovation loan from RVO NL and replaced this with the debt facility from Runway Growth.

The impact of exchange rates amounted to € 373k for 2024. This is mainly due to the strengthening of the Swiss Franc.

### Interest-bearing Loans

Interest-bearing loans decreased by 6%, from €15.3M in 2023 to 14M in 2024. The innovation loan from RVO NL (Dutch government) was repaid in July and replaced with debt financing from Runway Growth. The new facility is structured in multiple tranches, with funding availability tied to the achievement of specific milestones. Warrants were also issued to Runway Growth amounting to €0.4M. The costs of the warrants was set off against the loan. As of the end of 2024, the first tranche has been drawn, and the second tranche has been unlocked following the achievement of the FDA clearance milestone.

### Equity

The Company's equity at the end of 2024 increased with €30.1M closing with a positive balance of €48.1M. The movement reflects a net increase primarily driven by the successful equity fundraising rounds, which contributed €64M net of transaction costs. This was partially offset by the net loss for the period of €35.7M. Additionally, share-based compensation of €2.7M contributed to the increase, while the remeasurement of post-employment benefits and currency translation differences resulted in a net decrease of €1.2M

ONWARD<sup>®</sup>



Governance

# Governance

## General

ONWARD is a public limited liability company established under the laws of the Netherlands, with common shares listed on Euronext Brussels, Amsterdam and Paris. 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 DCGC), 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 DCGC, 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 DCGC, 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
<b>Rob ten Hoedt</b>	1960	Dutch	Male	Independent Non-Executive Director & Chairperson	a	a
<b>Dave Marver</b>	1968	American	Male	Executive Director & CEO	2020	Annual General Meeting of 2025
<b>Grégoire Courtine</b>	1975	French	Male	Non-Executive Director & Science Advisor	2016	Annual General Meeting of 2027
<b>Ian Curtis</b>	1968	British	Male	Independent Non-Executive Director & Vice-Chair	2019	Annual General Meeting of 2025
<b>John de Koning</b>	1968	Dutch	Male	Non-Executive Director	2016	Annual General Meeting of 2027
<b>Kristina Dziekan</b>	1968	German, Swiss	Female	Independent Non-Executive Director	2022	Annual General Meeting of 2026
<b>Vivian Riefberg</b>	1960	American	Female	Independent Non-Executive Director	2023	Annual General Meeting of 2027
<b>Rahma Samoa</b>	1979	German	Female	Independent Non-Executive Director	b	b

a: Interim Chairman and Director (expected to be nominated for appointment at our 2025 Annual General Meeting). Rob succeeds former Chairman Jan Ohrstrom that resigned from the Board of directors effective 6 December 2024  
 b: Interim Director (expected to be nominated for appointment at our 2025 Annual General Meeting)



**Board Members’ Biographies**

**Rob ten Hoedt** as a former Executive Committee Member at Medtronic, Rob brings an impressive track record in technology development and business-model innovation. He was previously Executive Vice President & President of Global Regions at Medtronic, overseeing the Americas, EMEA, and Asia Pacific. Rob was Chairman of the Board of MedTech Europe, the industry association for medical technology in Europe; he is the current Chairman of Medmix in Switzerland, and serves on the boards of Fagron International and NLC Health. Rob holds a degree in Commercial Economy from H.E.A.O., and a Master’s in Marketing from NIMA Business School in the Netherlands. Rob is the Board Chair, a Member of the Compensation Committee and the Nomination and Corporate Governance Committee.

**Dave Marver** (CEO) is an accomplished chief executive and director with 30 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 ground breaking 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 Science Advisor. Gregoire was reappointed for a second term at the Annual General Meeting in 2023.

**Ian Curtis** is a director of SCI Ventures, a venture capital firm that invests in companies focused on treatments for paralysis. He is a member of the board of the Christopher & Dana Reeve Foundation and the International Spinal Research Trust. Ian is also the chairman of

HPC plc, a UK-based engineering company. He is a graduate of Durham University, a fellow of the Institute of Chartered Accountants in England and Wales, and a former partner with PwC. Ian is the Board Vice-Chair and Chair of the Audit 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 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 Waystar (WAY:Nasdaq), K Health, Accompany Health and Lightrock, an impact investing firm, as well as the boards of the Public Broadcasting System (PBS), Johns Hopkins Medicine, and the National Education Equity Lab. She is also an advisory board member for the Smithsonian’s planned American Women’s History Museum. She 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 in the Americas, and on McKinsey’s global board of directors. She previously served on the US National Institutes of Health (NIH) Clinical Center



**Governance**

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 Chair of the Compensation Committee and Chair of the Nomination and Corporate Governance Committee.

**Rahma Samow** is currently President and CEO of ClearChoice Dental Implant Centers, a US-based provider of dental implant therapy and tooth replacement services with over 2,000 employees. Prior to ClearChoice, she served on the Executive Management Board of the Swiss-based Straumann Group. She also had a 15-year career with Siemens Healthineers, where she held various roles in sales, marketing, and communications in their digital health business, with geographic responsibilities spanning the US, Germany, Middle East, and Africa. Ms. Samow holds a Diploma in Medical Radiology, Radiation Therapy, and Nuclear Medicine Technology from the Medical University of Bonn, Germany. Rahma is a Member of the Audit Committee.

**Director independence**

In accordance with best practice provision 2.1.7 of the DCGC, 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 Science Advisor 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 in the Company (EQT Group (formerly LSP)). The requirements for independence as per best practice provision 2.1.7 of the DCGC 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), Kristina Dziekan and Rahma Samow.



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.

**Governance**

- 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 DCGC 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: Vivian Riefberg (Chair), Ian Curtis, and Rob ten Hoedt.

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:



**Governance**

**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.

<b>Name</b>	<b>Position</b>	<b>Member Since</b>
<b>Dave Marver</b>	Chief Executive Officer	2020
<b>Erika Ross Ellison</b>	VP Clinical & Regulatory	2023
<b>Robert Odell</b>	VP Operations	2023
<b>Julien Camisani</b>	VP Engineering	2024
<b>Lorenzo Fanti</b>	VP Legal	2024
<b>Amori Fraser</b>	Senior Finance Director	2024
<b>Julie Crom</b>	Director: People & Culture	2024
<b>Alexandre Casteau</b>	Head of Strategy & Corporate Development	2024

- 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: Vivian Riefberg (Chair), Ian Curtis, and Rob ten Hoedt.

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



**Biographies of the Management Team**

**Dave Marver** (see biography p. 125).

**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. She is the current President of IEEE EMBS, the world’s largest international society of biomedical engineers. 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.

**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.

**Julien Camisani** brings more than twenty years of experience, fifteen of which are in the life sciences industry, where he has been instrumental in inventing, developing, marketing, and sustaining advanced laboratory, medical and bio-manufacturing technologies. Prior to joining ONWARD Medical, Julien led diverse and global teams, and managed large-scale projects with proven leadership across research and development, manufacturing, intellectual property and product management for companies like Cytiva, GE Healthcare and Biosafe. He holds dual master’s degrees in Embedded Systems from the University of Lugano, collaborating with ETH Zurich and Politecnico di Milano, complemented by an MBA from the University of Cumbria and a professional certificate in Technology Road mapping and Strategic Innovation from MIT.

**Lorenzo Fanti** is a dual-qualified US and English attorney with nearly 15 years of experience specializing in pharmaceuticals and medtech. Prior to joining ONWARD Medical, Lorenzo served as worldwide Legal Head, Ophthalmology ad interim at Novartis Pharmaceuticals, and, prior to that, he was Country Legal Head for Chile ad interim for the Novartis group of companies. He has held various roles with increasing responsibility at Novartis, including in the Neuroscience franchise, where he contributed to the launch of innovative migraine treatments. Early in his career, he was a Trademark Paralegal with Sandoz, and he trained with Allen & Overy LLP in London. He holds an LL.B. from the University of Wales.

**Amori Fraser** serves as the Finance Director at ONWARD Medical, leveraging over 18 years of experience in both finance and auditing. Prior to her current role, she worked as a Senior Manager at EY, specializing in financial reporting, regulatory compliance, financial analysis and internal controls serving multi-national listed groups. Amori’s experience in auditing and finance enables her to drive efficient financial operations and support the company’s growth initiatives. Amori holds a BComHons degree in Accounting Sciences from the University of Pretoria and is a qualified Chartered Accountant (CA) with the South African Institute of Chartered Accountants (SAICA).

**Julie Crom** has more than 10 years of experience in Human Resources in the medical devices industry. Prior to joining ONWARD Medical, Julie served as Healthcare & Life Sciences Practice Lead at Michael Page, a leading recruitment company in Europe. In her role, she supported middle-to-large medical device companies in recruitment and organizational strategy. Julie holds an MSc in International Business Management from INSEEC business school.

**Alexandre Casteau** brings extensive healthcare corporate strategy expertise. A former management consultant with McKinsey & Company, Alexandre spent several years advising global life science businesses on growth strategy and large-scale transformations. He also launched and led the McKinsey Switzerland startup/scaleup service line, providing a differentiated strategy consulting offering to help early-stage, fast-growing companies scale. Earlier in his career, Alexandre held a variety of roles at Endeavor, Rocket Internet SE and Société Générale Corporate & Investment Banking. He holds an MBA from INSEAD and an MSc from MIT.



**Uniqueness and opportunity**

We believe that unique life experiences and viewpoints strengthen decision-making, so we aim to build a Board and Management Team made up of individuals with varied backgrounds and perspectives. Although the current policy does not set specific targets, the ambition remains for both the Board and Management Team to include at least one-third female members, while also maintaining a balanced mix of backgrounds, professional expertise, and age profiles. This policy is available on our **website**.<sup>1</sup> ONWARD’s Board consists of 5 male directors (1 being an executive director) and 3 female directors (all Non-Executive Directors). The Management team consists of 6 male members and 3 female members. ONWARD’s continued efforts to recruit independent Directors and management team members contributed to the Company achieving its ambitions for independence and broad representation. In deviation from best practice provision 2.1.6 of the DCGC, the Company’s existing policy does not include specific objectives related to the composition of the Board. ONWARD values the collaborative and transparent culture it has cultivated, guided by the principles set out in the ONWARD Code. It is a culture that encourages mutual respect, professionalism, and fairness, where all employees are supported in contributing to the Company’s success. In deviation from best practice provision 2.1.5 of the DCGC, ONWARD’s approach to fostering this culture has not yet been formally documented within a policy framework.

**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 our **website**.<sup>1</sup>

**Conflicts of Interest**

According to principle 2.7.4 of the DCGC, 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 2024, 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 Science Advisor 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 2024.

**Related Party Transactions**

While ONWARD’s related party transaction policy is to comply 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 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.

<sup>1</sup><https://ir.onwd.com/corporate-governance>



**Governance**

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 2024.

**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 13 June 2024. The agenda, explanatory notes and minutes are published on the Company website. The next Annual General Meeting is scheduled for 11 June 2025.

**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 DCGC as much as possible. As of the date of this Annual Report, we report the following deviations from the DCGC:

- **Best practice provision 2.1.5. and 2.1.6** The DCGC provides that the diversity policy should include appropriate targets for inclusion and the creation of psychological safety. While ONWARD fosters a collaborative and respectful work environment, this approach has not yet been formally documented within the current policy framework. The DCGC recommends that such a policy include clearly defined objectives and an implementation plan. The Company’s existing policy does not yet contain these elements. ONWARD intends to update its policy to better reflect its values and practices, including the establishment of measurable goals and a structured plan to support continued progress in this area.
- **Best practice provision 3.1.2 v** The DCGC 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 is 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 DCGC 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 DCGC 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<sup>®</sup>

# Risk Management & Control

# Risk Management & Control

Effectively identifying, assessing, and managing internal and external risks is critical to achieving our strategic objectives, ensuring the reliability of our financial reporting, and maintaining compliance with all applicable laws and regulations. Our primary risk areas remain focused on the research and development of ARC Therapies, securing regulatory approvals, protecting intellectual property, and ensuring the Company’s financial stability in the mid- to long-term.

The Management Team is responsible for developing, implementing, and maintaining robust risk-management and internal control systems, while the Board provides oversight of these processes. These systems are continuously reviewed and refined based on internal evaluations, discussions with the Board and Audit Committee, and external audits.

The findings from our 2024 annual risk review are reflected in this report. Over the past year, we successfully implemented our internal control framework and conducted a self-assessment to evaluate its effectiveness. This assessment highlighted areas where further refinement is needed, which we aim to address in 2025. Additionally, we plan to explore an independent assessment to validate compliance with the framework. As we move forward, the framework will also be updated to reflect new processes following FDA clearance and the commercialization of our first product.

Since ONWARD does not have a dedicated internal audit function, the Board conducts an annual review to determine whether alternative measures are sufficient. Based on the Audit Committee’s recommendations, Directors may evaluate the necessity of establishing an internal audit function. In 2024, no material deficiencies in our risk-management and control systems were identified.



**Risk Management & Control**

While these systems strengthen our ability to achieve strategic goals and regulatory compliance, they cannot provide absolute assurance against all risks, misstatements, or instances of non-compliance. We remain committed to continuously enhancing our approach to risk management and internal controls to support the long-term success of the Company.

**Risk Control Matters**

The Company has implemented a risk detection, evaluation, and management system tailored to its size, operations, and growth stage. The Board and Management Team continuously assess potential risks, evaluate their financial impact and likelihood, and take proactive measures to mitigate them. Risk assessments are regularly updated in response to evolving internal and external conditions.

The Board and Management Team meet regularly to review developments, set strategic objectives, and track progress toward key milestones. These meetings also include assessments of ONWARD’s financial position, as well as the presentation and review of budgets and cash flow forecasts, which are continuously monitored and adjusted as needed. The Management Team remains vigilant in identifying and addressing emerging risks, adapting strategies, and implementing necessary countermeasures as required.

To effectively manage business risks, we leverage a combination of highly experienced internal experts and external consultants for research and clinical studies. Study results are closely and systematically monitored, allowing for timely responses to new findings and adjustments to preclinical and clinical activities as needed. Regular internal budgeting and financial monitoring enable early detection of deviations from financial plans, allowing for swift corrective actions.

Given our reliance on third parties to meet regulatory requirements and uphold quality standards, we apply a rigorous selection process when engaging contractors. The Management Team carefully evaluates and selects major clinical trial and component service providers based on their quality and expertise. We continuously review the performance of these partners to ensure alignment with our operational and compliance expectations.

To protect and monitor our intellectual property (IP), we collaborate exclusively with highly specialized consultants and legal experts. The Management Team also conducts ongoing reviews of patent protections and potential conflicts to safeguard our innovations.

In our financial reporting process, our risk-management and internal control systems are designed to ensure the accuracy and integrity of our financial data. These systems provide reasonable assurance that transactions are recorded correctly, financial reporting complies with legal and regulatory standards, and published financial statements are free from material misstatements. Additionally, controls are in place to ensure that receipts and expenditures are authorized and that assets are adequately safeguarded.

To manage risks related to valuation uncertainties, we engage specialists with the necessary expertise to support financial reporting valuations, including the assessment of defined benefit obligations and the fair value of options granted.

As part of our internal control framework, we have adopted various policies and procedures, including standard operating procedures, a dual-control principle, spot checks, automated expense reimbursement tools, internal contract approval processes, and clearly defined signatory rules. These measures help reinforce financial discipline and ensure compliance with governance standards.

**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 the company’s business, strategy & industry**

- **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**

A primary risk the Company faces is the timely attainment of regulatory approvals, including FDA clearance in the U.S and CE Mark certification in the EU, for its platforms across different indications. With FDA clearance now obtained for one of our products, new risks have emerged related to commercial acceptance and manufacturing scalability. The success of our commercialization efforts will depend on market adoption, reimbursement coverage, and the ability to scale production efficiently while maintaining quality standards.

To proactively manage regulatory risks, ONWARD relies on a dedicated and skilled regulatory team, maintains continuous engagement with regulatory bodies, and works closely with third-party suppliers to mitigate potential quality issues.

The following section outlines the primary risks and uncertainties that we consider significant threats to achieving our objectives. These risks may impact the Company’s future operational and financial performance, as well as the value of an investment in the Company’s securities. Additional risks and uncertainties, including those not currently known or considered immaterial at this time, could also adversely affect our business, financial condition, results of operations, and growth prospects. If any of these risks materialize, the price of the Company’s securities may decline, potentially resulting in partial or total investment loss.

While this list highlights key risk factors, it is not exhaustive, as unforeseen contingencies may arise that could further impact our business

*The Company partially depends on the success of two investigational devices, the ARC<sup>IM</sup> and ARC<sup>BCI</sup> 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<sup>IM</sup> and ARC<sup>BCI</sup> platforms.*

ONWARD currently has two investigational devices in clinical development – the ARC<sup>IM</sup> and ARC<sup>BCI</sup> 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 one product available for sale, that will generate revenues from sales of products, but this is our first product to commercialize and subject to risks of market acceptance, manufacturing as included in this report.

Our ARC<sup>IM</sup> 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<sup>IM</sup> 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.

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<sup>IM</sup> and ARC<sup>BCI</sup> 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.

*The ARC<sup>EX</sup> system and, if approved, the ARC<sup>IM</sup> and ARC<sup>BCI</sup> systems, will require market acceptance to be successful. Failure to gain market acceptance would impact the Company’s revenues and may materially impair its ability to continue its business.*

Even after receiving regulatory clearances or approvals (like for ARC<sup>EX</sup>), 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<sup>EX</sup> and ARC<sup>IM</sup> 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.

*Despite the Company obtaining clearance or approval for its products, the 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 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



**Risk Management & Control**

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<sup>EX</sup> and ARC<sup>IM</sup> 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.

*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



**Risk Management & Control**

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<sup>EX</sup> and ARC<sup>IM</sup> 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 Science Advisor, 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<sup>IM</sup> 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 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.*



**Risk Management & Control**

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<sup>IM</sup> (investigational device) and ARC<sup>EX</sup> we 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 the 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 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



**Risk Management & Control**

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.

*Failures by third parties may lead to higher development costs, delays in obtaining regulatory approvals or certifications, and setbacks or obstacles in commercialization.*

We rely—and may continue to rely—on third parties for critical aspects of our business, including conducting clinical trials, data collection and analysis, marketing, manufacturing, regulatory support, and other essential services. The success of our ARC Therapies depends on these partnerships, and any failure by third parties to meet their contractual obligations or regulatory requirements could lead to delays, suspensions, or even terminations of development activities or clinical trials.

Potential risks include insufficient time or effort dedicated to our projects, failure to adhere to clinical protocols or regulatory standards, compromised data quality or loss, financial instability of the third party, or the need to replace a provider. While we strive to ensure strong partnerships, we do not always have direct control over third party performance, and our agreements often allow them to terminate their commitments with notice. If a third party fails to fulfill its obligations or if an agreement is terminated, finding a suitable replacement on commercially acceptable terms may prove difficult, potentially leading to increased costs, regulatory delays, and setbacks in the commercialization of ARC Therapies.

Additionally, many of our third-party agreements include limitations on liability, which may restrict our ability to recover losses resulting from their performance failures. These factors could adversely impact our development timelines, regulatory approvals, and overall business operations.

*Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our ARC<sup>EX</sup> system and manage our inventory.*

To ensure adequate inventory supply of the ARC<sup>EX</sup> system in general and its components, we must forecast inventory needs and place orders with our suppliers based on our estimates of future demand for the ARC<sup>EX</sup> system and its components. To date, we have only sold two ARC<sup>EX</sup> systems. Our ability to accurately forecast demand for our ARC<sup>EX</sup> system could be negatively affected by many factors, including failure to accurately manage our commercialization strategy, an increase or decrease in customer demand for the ARC<sup>EX</sup> system, failure to accurately predict customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters, and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of the ARC Therapy brand. Conversely, if we underestimate customer demand for the ARC<sup>EX</sup> system, our third-party contract manufacturers may not be able to deliver products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are acceptable to us, or at all, or suppliers or third-party manufacturers might not be able to allocate sufficient capacity in order to meet our increased requirements, which could have an adverse effect on our ability to meet customer demand for the ARC<sup>EX</sup> system.

We intend to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions. As a result, we will be subject to the risk that a portion of our inventory may become obsolete or expire, which could affect our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

*Non-Compliance with Manufacturing Regulations Could Disrupt Our Business and Impact Product Availability*

We rely on third-party suppliers for the manufacturing and supply of the ARC<sup>EX</sup> system, and both our own and our suppliers' manufacturing practices are subject to extensive regulatory



**Risk Management & Control**

oversight. In the United States, medical device manufacturing must comply with the FDA’s Quality System Regulation (QSR), a stringent framework governing design, testing, production, quality assurance, labeling, packaging, storage, and distribution. Additionally, we must ensure that our suppliers maintain operations that meet both our internal quality standards and applicable regulatory requirements. The FDA enforces compliance through periodic inspections, which may be announced or unannounced, including audits of subcontractor facilities. Similar regulatory requirements exist in other jurisdictions, adding further complexity to compliance obligations.

Failure by us or our third-party suppliers to adhere to these regulations—including maintaining an adequate, up-to-date quality management system—could result in delays in the commercial availability of the ARC<sup>EX</sup> system, interruptions to clinical trials, or setbacks in obtaining or maintaining regulatory approvals. Non-compliance could also lead to regulatory actions, product supply disruptions, increased costs, loss of customer trust, and exposure to potential product liability claims, ultimately impacting sales and overall business performance.

*Dependence on suppliers for ARC<sup>EX</sup> system components and services poses operational and financial risks.*

The ARC<sup>EX</sup> system relies on specialized components and services, many of which are sourced from a limited number of suppliers. Any disruption in the supply of these critical elements—whether due to supplier decisions, capacity constraints, quality issues, or regulatory challenges—could negatively impact our business, financial condition, and operational results.

A number of ARC<sup>EX</sup> system components are currently sourced from single suppliers, and while we are working to qualify additional vendors, transitioning to new suppliers requires extensive evaluation, testing, and regulatory approval. This process can be time-consuming and costly, making it difficult to mitigate risks associated with supplier dependency. If a supplier is unable or unwilling to meet our demand, investigator-initiated studies, clinical trials for future indications, or commercialization efforts could be delayed or halted.

If we need to switch to an alternative supplier, we may face challenges such as extended lead times, higher costs, or regulatory requirements that delay market availability. Changes in supplier manufacturing processes or product design modifications may require new

regulatory approvals or certifications, further complicating supply continuity. Additionally, suppliers may discontinue key components or services before the ARC<sup>EX</sup> system reaches the end of its product life cycle, potentially forcing us to secure costly last-time buys, source alternatives at premium prices, or even halt product availability temporarily.

Any of these supply chain disruptions could result in production delays, increased costs, and reduced inventory availability, ultimately affecting our ability to meet market demand and achieve profitability.

*Global: Geopolitical and macroeconomic challenges*

The Company is also exposed to global economic and political risks, including U.S.-EU trade relations, geopolitical instability, and foreign exchange fluctuations.

- Geopolitical uncertainty: Conflicts and diplomatic tensions may disrupt global markets and supply chains. The Company remains flexible in sourcing and prepared to adapt procurement strategies if needed.
- U.S.-EU trade relations: Deteriorating diplomatic relations could lead to economic policies that impact operations. While no immediate disruptions are expected, the Company is evaluating diversification strategies to reduce reliance on any single market.

The Company closely monitors these evolving risks and engages with relevant stakeholders to anticipate impacts and adjust strategies, aiming to preserve stability and support continued growth.

**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.*



**Risk Management & Control**

ONWARD received De Novo classification clearance from the FDA to market ARC<sup>EX</sup> for use in clinics in the US. We intend to pursue additional regulatory clearances, including for at-home use. ARC<sup>IM</sup> is a Class III device that will require PMA approval to be marketed in the US. In Europe, under the MDR, ARC<sup>EX</sup> is expected to be designated as a Class IIa device and ARC<sup>IM</sup> 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

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.



**Risk Management & Control**

*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<sup>IM</sup> platform and future products (for ARC<sup>IM</sup> and ARC<sup>EX</sup>) 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 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.



**Risk Management & Control**

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 (like we have for ARC<sup>EX</sup> clinical use in December 2024), 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 ARC<sup>IM</sup> 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 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, and after being, 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<sup>EX</sup> and ARC<sup>IM</sup> 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.



**Risk Management & Control**

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.

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,



**Risk Management & Control**

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

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

*U.S.: Regulatory, tariff, and economic uncertainty*

The Company faces risks from evolving U.S. policies, including potential tariffs on European goods, reductions in federal healthcare and research funding, and economic uncertainties affecting market conditions.

- **Tariff Risks:** The Company believes that its products may qualify for an exemption from U.S. import duties under the Nairobi Protocol and is actively seeking clarification from U.S. Customs and Border Protection to confirm eligibility. Currently, products imported from the Netherlands are subject to a 10% tariff. The Company is still assessing the potential impact of this tariff but does not expect a significant impact.
- **Federal spending cuts:** Potential reductions in NIH and DoD funding could affect grants and clinical research. The Company is diversifying funding sources, including European grants, to mitigate this risk.
- **U.S. regulatory environment:** Recent developments, including policy discussions under Project 2025, may significantly alter the structure and functioning of U.S. federal agencies such as the FDA. This raises uncertainty around regulatory timelines, product clearances, and reimbursement. Potential federal budget constraints may also impact agency responsiveness, increasing risk for companies in the medtech sector. The Company continues proactive engagement with regulatory authorities to manage submission timelines effectively.

While these factors introduce uncertainty, the Company is actively mitigating risks through strategic planning, advocacy efforts, and financial diversification.

**Risks related to the company’s intellectual property (IP)**

*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.



**Risk Management & Control**

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.

*The Company licenses certain technology underlying the development of its investigational devices and the loss of the license would result in a material adverse effect on its business, financial position, and operating results and cause the market value of its Ordinary Shares to decline.*

The Company licenses technology from EPFL, UCLA, California Institute for Technology (“Caltech”), University of Louisville, University of Minnesota, University of Calgary and University of British Columbia that is integrated into its company portfolio under five licenses, each exclusive in the Company’s Field of Uses. Under the different license agreements, the Company has agreed to milestone payments and/or to meet certain reporting obligations. In the event that the Company were to breach any of the obligations under the agreement and fail to cure timely, EPFL, UCLA, Caltech, would have the right to terminate the agreement upon notice. In addition, EPFL, UCLA and Caltech have the right to terminate its license upon the bankruptcy or receivership of the Company. If the Company is unable to continue to use or license this technology on reasonable terms, or if this technology fails to operate properly, it may not be able to secure alternatives in a timely manner and its ability to develop its products could be harmed.

**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 technology platforms. We are 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.

Despite receiving FDA clearance to commercialise its first product (ARC<sup>EX</sup> for clinical use), deriving sufficient revenues to support operations are not imminent, as our activities continue to consist of developing our technology, conducting pre-clinical studies and clinical trials. As of 31 December 2024, the loss for the period amounted to € 35.7M. These losses have resulted primarily from costs incurred in the development of the ARC<sup>EX</sup> and ARC<sup>IM</sup> platforms, costs relating to the DeNovo submission of ARC<sup>EX</sup> for FDA clearance in 2024, preparing for manufacturing of ARC<sup>EX</sup> following FDA clearance 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<sup>EX</sup>, ARC<sup>IM</sup> and ARC<sup>BCI</sup> technology platforms and related technologies
2. Seek FDA regulatory clearances and approvals for the ARC<sup>EX</sup> (new indications), ARC<sup>IM</sup> and ARC<sup>BCI</sup> 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

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<sup>EX</sup> and ARC<sup>IM</sup> platforms to account for the majority of our future revenue. While ARC<sup>EX</sup> has received regulatory clearance for use in the clinic setting, all other



**Risk Management & Control**

pending regulatory approvals remain critical. If the ARC<sup>IM</sup> platform does not obtain clearance or approval, or if ARC<sup>EX</sup> sales do not generate sufficient revenue, the Company may face challenges in achieving 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 2024, ONWARD had net cash of € 60M. Based on cash flow forecasts for 2025, this is expected to be sufficient to meet our capital requirements and fund our operations to the end of 2026. 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.

Our expenses will also increase substantially in connection with the commercialization of ARC<sup>EX</sup> in the US, and potentially also in Europe after CE Mark certification is obtained, 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) 510(k) clearance for use of ARC<sup>EX</sup> in the home, and (ii) PMA approval, which will be required for ARC<sup>IM</sup>
- Conducting additional clinical trials of our ARC<sup>EX</sup> and ARC<sup>IM</sup> 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<sup>EX</sup> and ARC<sup>IM</sup> 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.



**Risk Management & Control**

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.

*Part of the Company's assets, including intellectual property is pledged to Runway Growth Capital LLC, and the enforcement of such pledge could substantially harm the future development and operations of the Company.*

The Company has secured a €52.5 million loan from U.S.-based lender Runway Growth Capital LLC (Runway). The facility is divided into five individual credit tranches. The first initial credit tranche of €16.0 was available upon signing of the Loan Agreement and drawn down immediately. Three subsequent credit tranches of €14.0 million, up to €5.0 million and up to €7.5 million will be available to be drawn by the Company until March 31, 2025 and July 31, 2026 respectively, in each case subject to the Company's achievement of certain milestones under the Loan Agreement. The milestone for the second tranche was met in December 2024, but the tranche has not been drawn yet. The fifth credit tranche of up to €10.0 million is uncommitted and available in the first quarter of 2027 upon the sole discretion of the Lender. The loan bears interest at a rate equal to Term Secured Overnight Financing Rate (SOFR) for a three month interest period (currently at 6.00% and subject to a 4.25% floor), plus a margin of 6.50%. The loan documents provide for a number of affirmative and negative covenants by the Company customary for financings of this type, including financial covenants relating to revenue, earnings before interest taxes, depreciation and amortization (EBITDA) and minimum liquidity targets. The loans advanced under the Loan Agreement are secured by a security interest in substantially all of the assets of ONWARD.

Should the Company default on the loan covenants, Runway could enforce its pledge on these assets, which could substantially harm the future development and operations of the Company.

*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<sup>EX</sup> and ARC<sup>IM</sup> 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<sup>EX</sup> and ARC<sup>IM</sup> platforms for cleared or approved indications, if any
- Expenses incurred in manufacturing and selling our ARC<sup>EX</sup> and ARC<sup>IM</sup> platforms, after 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<sup>EX</sup> and ARC<sup>IM</sup> platforms
- 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 a pandemic similar to COVID-19, which may adversely impact our business and planned development and future commercialization of our ARC<sup>EX</sup> and ARC<sup>IM</sup> 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



**Risk Management & Control**

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.*

Since the clearance of ARC<sup>EX</sup> by the FDA for use in clinics, we commenced commercial operations, we will enter into a number of transactions denominated in USD (initially) but also expanding to various currencies, which can 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 the Company or a Group Company breaches an obligation under the Group’s existing loan agreement, the Group may be required to repay the loan before it would ordinarily become due and the administrative and collateral agent under the loan agreement may dispose of the significant collateral the Group furnished to secure the loan.*

The Group is subject to financial and non-financial covenants under its existing loan agreement. A breach of any covenant or obligation could result in the lender exercising its rights under the loan agreement, including demanding immediate repayment of outstanding amounts before their scheduled maturity. In such a scenario, the Group may be required to secure alternative financing under potentially unfavorable terms or may face liquidity constraints that could impact its ability to fund operations and strategic initiatives.

Furthermore, the loan agreement is secured by significant collateral, and in the event of default, the administrative and collateral agent may exercise its rights to enforce security interests, which could materially impact the Group’s financial position and operations. The Group actively monitors compliance with its loan covenants and engages with its lenders to mitigate the risk of default. However, there can be no assurance that a breach will not occur in the future, particularly in the context of evolving business conditions, financial performance, or changes in the regulatory environment.

Additionally, the Group recently launched ARC<sup>EX</sup>, a novel product with no directly comparable market data to substantiate sales projections. While Management has developed revenue forecasts based on market research and initial customer interest, the absence of historical sales data introduces a significant degree of uncertainty regarding revenue generation. This uncertainty in cash flow forecasts is further compounded by the Group’s financing obligations, relating to maintaining compliance with loan covenants.

While the Group has remained in compliance with its loan covenants to date, future financial performance may impact continued compliance. Although the Group believes it has the necessary resources to fund operations for the foreseeable future, the heightened uncertainty surrounding revenue projections and financing obligations indicates the existence of material



**Risk Management & Control**

uncertainties, which may also cast significant doubt on the Group's ability to continue as a going concern. The financial statements have been prepared on a going concern basis, as outlined in the Accounting Policies section of the consolidated financial statements.





ONWARD<sup>®</sup>

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](https://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 2025

- 11 June: Annual General Meeting
- 16 September: Interim Report publication

Closed periods based on the 2025 financial calendar are:

- 30 March – 28 April 2025
- 17 August – 15 September 2025

## 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..

## Capital Structure and Voting Rights

ONWARD's authorized share capital (maatschappelijk kapitaal) amounts to € 18,000,000 divided into 75,000,000 Ordinary Shares and 75,000,000 Preferred Shares with a nominal value of € 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 2024, 44,628,832 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.

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.



**Investor Relations**

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 one or more potential capital raises or for other strategic purposes. The authorization was partially utilized for the capital transaction in October 2024. A separate resolution of the General Meeting is not required for the issuance of shares under this authorization.

During the year the Company issued warrants to Runway growth Capital LLC under the terms of the debt financing. 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 2024:

- Ottobock SE & Co. KGaA (10.08%)
- LSP Advisory B.V. (8.41%)
- INKEF Capital B.V. (8.19%)
- Gimv (Private Equity) (7.17%)
- Wellington Partners GmbH (4.22%)

**Listing**

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

**Share Price**



**Analyst Coverage**

ONWARD was covered by five brokers at the end of 2024.

Broker	Analysts
Stifel	Ed Hall, Dylan Van Haaften
Bryan, Garnier & Co	Maria Vara
KBC Securities	Thomas Vranken, Jacob Mekhael
Degroof Petercam	David Seynnaeve, PhD
Kepler Cheuvreux	Christophe Dombu



ONWARD<sup>®</sup>



# 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 2024, as referred to in best practice provision 5.1.5 of the Corporate Governance Code (CGC).

## Supervision by the Non-Executive Directors

The Board is responsible for ensuring that the Executive Director and Management Team align their actions with the company’s strategic priorities and core values. The Non-Executive Directors provide oversight of the policies implemented by leadership and monitor the overall direction of the Company and its affiliated entities.

The Board has remained actively engaged in the Company’s strategy, particularly as it advanced toward the De Novo application for FDA clearance of the ARC<sup>EX</sup> system. To maintain effective oversight, the Non-Executive Directors regularly reviewed strategic initiatives during Board meetings. These sessions provided updates on development progress, clinical and commercial launch activities, and potential funding opportunities. The Board received detailed insights into key achievements, challenges, and opportunities across all functional areas, ensuring informed decision-making and continued alignment with the Company’s long-term objectives.

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 2024, the Audit Committee convened six times (see attendance details in the table below). Throughout these meetings, the Committee reviewed and discussed key financial and operational matters, including the financial reporting process, the full-year 2023 and half-year 2024 results, internal control processes and ongoing enhancements, and the Company’s funding and financing needs. The Audit Committee also evaluated the statements on internal control and risk management included in the Annual Report and reviewed the Company’s collaboration with its external auditor. The external auditor attended all meetings, providing insights and presenting the audit plan for 2024.

The Audit Committee also evaluated the statements on internal control and risk management included in the Annual Report and reviewed the Company’s collaboration with its external auditor. The external auditor attended all meetings, providing insights and presenting the audit plan for 2024. Regular reports were provided to the Board of Directors, including recommendations and guidance for approval where necessary. The Committee worked closely with the Management Team and finance department to ensure effective oversight and implementation of key financial and governance initiatives.

## Compensation Committee

In 2024, the Compensation Committee met three times (see attendance details in the table below) the Committee reviewed and approved the achievement of the 2023 company goals and the corresponding variable remuneration for the Executive Director. It also oversaw the preparation of the Compensation Report, which was subsequently approved by the Board and included in the 2023 Annual Report.



The Committee established the 2024 company goals and objectives, monitoring progress throughout the year. Additionally, it reviewed and discussed the remuneration policy, as well as the individual compensation. The Compensation Committee provided regular reports to the Board of Directors, ensuring alignment and collaboration with the Board, Management Team, and the People & Culture team as needed.

### **Nomination & Corporate Governance Committee**

In 2024, the Nomination and Corporate Governance Committee met four times (see attendance details in the table below). The Committee also discussed the Company's HR and operational strategy, as well as succession planning, ensuring alignment with long-term objectives. Additionally, it supported the Board evaluation process.

The Nomination and Corporate Governance Committee provided regular updates to the Board of Directors and collaborated closely with the Board, Management Team, and People & Culture team as needed.

### **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 2024, facilitated by an external party, 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

## **Report of the Non-Executive Directors**

The outcomes were reviewed at the subsequent Board meeting, where key recommendations for improvement were identified, and a clear set of next steps was established.

Overall, it was determined that both the Board and its committees function effectively 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**

Based on the recommendation of the Audit Committee, the Board determined that, given the Company's current size, establishing an internal audit function is not yet necessary. Instead, the Board has evaluated whether sufficient alternative measures are in place and in making this decision, the Board considered the existing management processes that support the assessment and testing of the Company's risk-management and control systems.

### **Independence of the Non-Executive Directors**

Each Non-Executive Director is responsible for fulfilling their assigned duties with diligence and acting in the best interests of the Company. In accordance with Dutch law, this corporate interest encompasses the broader 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.



2024

# 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	
<b>Dave Marver</b> Executive Director & CEO	No	100%							
<b>Jan Øhrstrøm</b> Non-Executive Director & Chairperson	Yes	100%			X <sup>a</sup>	100%	X <sup>a</sup>	100%	
<b>Grégoire Courtine</b> Non-Executive Director & Science Advisor	No	100%							
<b>Ian Curtis</b> Non-Executive Director & Vice-Chairperson	Yes	100%	X <sup>a</sup>	100%					
<b>Fredericus Colen</b> Non-Executive Director	Yes	100%	X	100%	X	100%			
<b>John de Koning</b> Non-Executive Director	No	100%					X	100%	
<b>Kristina Dziekan</b> Non-Executive Director	Yes	100%	X	100%					
<b>Vivian Riefberg<sup>a</sup></b> Non-Executive Director	Yes	100%			X	100%	X	100%	
<b>Rob ten Hoedt<sup>b</sup></b> Non-Executive Director & Chairperson	Yes	100%			X <sup>a</sup>	100%	X <sup>a</sup>	100%	
<b>Rahma Samow<sup>c</sup></b> Non-Executive Director	Yes	100%							
<b>Number of Meetings Held:</b>		<b>7</b>		<b>6</b>		<b>4</b>		<b>3</b>	

a: Chairperson of the respective committee. Jan stepped down as Chairman of the board and the respective board committees effective 6 December 2024. He is succeeded by Rob as Chairperson of the board and Vivian as Chairperson of the respective committees.  
 b: As Interim Chairman and Director (expected to be nominated for appointment at our 2025 Annual General Meeting), Rob has attended all Board and committee meetings since October 2024.  
 c: As Interim Director (expected to be nominated for appointment at our 2025 Annual General Meeting), Rahma has attended all Board and committee meetings since December 2024.





ONWARD®

# Board of Directors' Statements

# Board of Directors' Statements

The Board of Directors' Report (the Report), consisting of pages 4-185 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 2024 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. This is based on the cash position and the expected cash flows of the company, also considering the risks and opportunities.
- 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 annual financial statements for the year ended 31 December 2024 – 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, 28 April 2025

**Board of Directors**



ONWARD<sup>®</sup>



# Remuneration Report

# Remuneration Report

This report provides an overview of the remuneration of the Board in 2024 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 2023 Annual General Meeting (AGM). The adoption of the 2023 compensation policy and report was through an advisory vote with 85% of voting in favor of adoption.

The 2024 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 2025 AGM for an advisory vote. The Company's 2025 AGM is scheduled for 11 June.

The Compensation Policy is available on the ONWARD website (**onwd.com**) under the 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 medical technology 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: 143,089 Unvested: 44,911	€ 9.70	15/12/2031
Dave Marver	2023	03/01/2023	Stock Options	Vested: 191,965 Unvested: 193,035	€ 6.12	03/01/2033
Dave Marver	2024	15/01/2024	Stock Options	Vested: 0 Unvested: 300,000	€ 2.94	15/01/2034
Dave Marver	2024	05/12/2024	Stock Options	Vested: 0 Unvested: 330,000	€ 4.77	05/12/2034

**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 are reviewed annually in Q4, based on benchmarks provided by AON, an independent third party. No adjustment was made to the executive compensation package for 2024.



**Executive Director’s Remuneration**

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

EUR’000	Dave Marver CEO	
	2024	2023
Base salary	425	425
Pension benefits	72	64
Other benefits	47	78
<b>Total fixed compensation</b>	544	567
	27%	34%
Annual performance-based compensation	489	200
Exceptional bonus <sup>a</sup>	250	–
Share-based remuneration / stock options	757	916
<b>Total variable compensation</b>	1,496	1,116
	73%	66%
<b>Total compensation</b>	2,040	1,683

*a: In recognition of the CEO’s exceptional contribution to the Company’s successful fundraising efforts, the Board awarded a discretionary bonus. This award reflects the critical role played in securing the necessary financing to support the Company’s strategic objectives. The bonus was granted as a one-time payment and does not form part of the regular variable remuneration structure. The decision was made in line with the Company’s remuneration policy and approved by the Board.*

**Scenario analyses**

A scenario analysis of the possible outcomes of the variable components and the impact on the annual performance-based compensation was discussed by the Compensation Committee in 2024 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 2024, the Board approved a set of company goals for our Executive Director, containing both financial and non-financial KPIs:

**Commercial launch**

Successful regulatory submission and clearance of ARC-EX, including the development of a digital solution for data analysis, advancing additional certification requirements, and the first commercial sale.



**Strengthening balance sheet**

Extending cash runway through successful funding initiatives, ensuring financial stability and operational continuity.

**Advancing pipeline**

Advance the Empower BP pivotal clinical trial by completing technical documentation, securing regulatory approval, and enrolling the first study participant, while simultaneously establishing a strategic roadmap for ARC-BCI technology development.

**Corporate**

Enhance sustainability and organizational efficiency by conducting an external sustainability assessment, implementing an improvement roadmap, and strengthening cross-functional teamwork through structured project governance.

Performance criteria functional area	Criteria weight	On-target performance	Actual performance	Measured performance
Commercial Launch	30%	100%	100%	30%
Strengthening balance sheet	25%	100%	175%	44%
Advancing pipeline	35%	100%	81%	29%
Corporate	10%	100%	125%	13%

**Total** **115%**

**Corresponding amount (EUR'000)** **489**

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 2024, the Remuneration Committee recommended, and the Board granted the CEO a variable compensation payout of 115% of target for 2024.

**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

*There were no changes to the fees for 2024.*



### Determination of Non-Executive Directors' Remuneration

Non-Executive Director remuneration amounted to:

In EUR

Name	2024	2023	2022	2021
<b>Jan Øhrstrøm<sup>a</sup></b>	130,765	160,889	208,134	533,577
<b>Gregoire Courtine<sup>b</sup></b>	661,177	512,297	300,725	980,918
<b>Fred Colen<sup>c</sup></b>	73,210	66,149	59,839	96,820
<b>Kristina Dziekan</b>	51,000	51,000	26,538	–
<b>Vivian Riefberg<sup>d</sup></b>	92,910	95,414	25,275	–
<b>Rob Ten Hoedt<sup>e</sup></b>	18,024	–	–	–
<b>Rahma Samow<sup>f</sup></b>	16,068	–	–	–

a: Compensation includes cost of stock options EUR 26,421 (2023: EUR 49,314) and the reimbursement of travel expenses. Jan resigned from the board effective 6 December 2024.

b: Compensation includes the remuneration paid in relation to his role as Science Advisor EUR 347,430 (2023: EUR 143,837), as well as the vesting of stock options under the long-term incentive plan EUR 313,747 (2023: EUR 368,460).

c: Compensation includes the reimbursement of travel expenses. Fred resigned from the board effective 6 December 2024.

d: Compensation includes cost of stock options EUR 12,157 (2023: EUR 23,252) and the reimbursement of travel expenses.

e: Interim Director and Chairman (expected to be nominated for appointment as Director at our 2025 Annual General Meeting).

f: Interim Director (expected to be nominated for appointment as Director at our 2025 Annual General Meeting). Compensation includes the reimbursement of travel expenses.

### 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 2024 and 2023. The amounts mentioned in the table are gross amounts before the impact of social-security or income-tax deductions.



**Remuneration Report**

EUR'000	2024	2023	2022	2021	2020
Net loss of the period	35,725	36,181	32,772	34,314	20,014
Executive Director	2,040	1,683	1,430	3,331	1,008 <sup>a</sup>
<i>Annual change</i>	21%	18%	-57%	230% <sup>a</sup>	
Average FTEs	99.36	104.5	86.6	76,7	55
<i>Annual change</i>	-5%	21%	13%	-11%	
Remuneration of FTEs	23,315	21,498	18,282	15,519	8,534
<i>Annual change</i>	6%	23%	18%	82%	
Average remuneration per FTE	235	206	212	202	155
<i>Annual change</i>	12%	-3%	4%	104%	
Pay Ratio	9	8	7	16	13 <sup>b</sup>
<i>Annual change</i>	5%	21%	-59%	62%	
Non-Executive Directors	948	886	621	1,616	959
<i>Annual change</i>	7%	43%	-62%	69%	

<sup>a</sup>: The CEO was appointed on 1 July 2020.

<sup>b</sup>: 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 DCGC, 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 2024, there were 102.55 FTEs (2023: 99.2).

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 2024.

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 9 in 2024, compared with 8 in 2023. The variance from 2023 to 2024 is due to an increase in the cost per FTE, and the exceptional bonus approved by the Board for the CEO following the successful fundraising in October 2024. 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	2024	2023
Revenue	2.1	77	-
Grants & Other Income	2.1	1,662	532
Cost of goods sold		(22)	-
<b>Gross Profit</b>		<b>1,717</b>	<b>532</b>
Research & Development Expenses	2.2,2.8	(12,442)	(13,841)
Clinical & Regulatory Expenses	2.3,2.8	(4,754)	(4,911)
Marketing & Market Access Expenses	2.4,2.8	(3,350)	(2,943)
Patent fees & Related Expenses	2.5,2.8	(1,441)	(1,509)
Quality Assurance Expenses	2.6,2.8	(2,016)	(1,464)
General & Administrative Expenses	2.7,2.8	(12,576)	(11,327)
<b>Total Operating Expenses</b>		<b>(36,579)</b>	<b>(35,995)</b>
<b>Operating Loss for the Period</b>		<b>(34,862)</b>	<b>(35,463)</b>
Financial Income	4.5	1,165	972
Financial Expense	4.5	(2,068)	(1,583)



# Consolidated Statement of Comprehensive Income

For the Year Ended 31 December

All amounts in EUR '000

	Notes	2024	2023
<b>Net Loss for the Period</b>		<b>(35,725)</b>	<b>(36,181)</b>
Remeasurement of post-employment benefits	5.0, 2.10	(1,565)	(928)
<b>Other comprehensive income that will not be reclassified to profit or loss in subsequent periods (net of tax)</b>		<b>(1,565)</b>	<b>(928)</b>
Currency translation differences		434	(155)
<b>Other comprehensive income that will be reclassified to profit or loss in subsequent periods (net of tax)</b>		<b>434</b>	<b>(155)</b>
<b>Total Comprehensive Result for the Year, Net of Tax</b>		<b>(36,856)</b>	<b>(37,264)</b>
Attributable to:			
Equity holders of the parent		(36,856)	(37,264)
Non-controlling interests		-	-
		<b>(36,856)</b>	<b>(37,264)</b>



# Consolidated Statement of Financial Position

For the Year Ended 31 December

All amounts in EUR '000

	Notes	2024	2023
<b>Assets</b>			
<b>Non-Current Assets</b>			
Intangible assets	3.0	10,425	9,804
Property, plant & equipment	3.1	471	609
Right of use assets	3.2	1,054	1,483
Deferred tax assets	2.10	568	310
		12,518	12,206
<b>Current Assets</b>			
Inventories	3.3	102	-
Indirect tax receivables	3.4	125	117
Receivable from related parties		36	37
Other current assets	3.5	3,313	1,501
Cash and cash equivalents	3.6	60,043	29,768
		63,619	31,423
		<b>76,137</b>	<b>43,629</b>



**Consolidated Financial Statements**

**Equity & Liabilities**

**Equity & Reserves**

Issued capital	4.0	5,355	3,622
Share premium	4.0	217,774	155,249
Other reserves*	4.0	6,770	4,488
Retained earnings		(181,845)	(145,428)
<b>Total Equity Attributable to Shareholders</b>		<b>48,054</b>	<b>17,931</b>

**Non-Current Liabilities**

Interest-bearing loans	4.2	13,972	15,255
Deferred tax liability	2.10	303	631
Lease liability	3.2	518	1,051
Post-employment benefits	5.0	3,999	2,081
		<b>18,792</b>	<b>19,018</b>

**Current Liabilities**

Income tax liabilities		200	221
Lease liability	3.2	597	568
Trade payables	3.7	1,269	1,369
Other financial liabilities	4.2	437	-
Other payables	3.8	6,788	4,522
		<b>9,291</b>	<b>6,680</b>
		<b>76,137</b>	<b>43,629</b>

\*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
<b>As at 1 January 2023</b>		<b>3,622</b>	<b>155,249</b>	<b>2,079</b>	<b>(108,319)</b>	<b>52,631</b>
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	<b>2.9</b>	-	-	2,564	-	2,564
<b>As at 31 December 2023</b>	<b>4.0</b>	<b>3,622</b>	<b>155,249</b>	<b>4,488</b>	<b>(145,428)</b>	<b>17,931</b>
<b>As at 1 January 2024</b>						
Loss for the year 2024		-	-	-	(35,725)	(35,725)
Other comprehensive income		-	-	434	(1,565)	(1,131)
<i>Total comprehensive result</i>		-	-	434	(37,290)	(36,856)
Issuance of share capital	<b>4.0</b>	1,733	68,267	-	-	70,000
Transaction costs related to issue of share capital	<b>4.0</b>	-	(5,742)	-	-	(5,742)
Share-based payments: LTIP	<b>2.9, 4.0</b>	-	-	1,847	873	2,720
<b>As at 31 December 2024</b>	<b>4.0</b>	<b>5,355</b>	<b>217,774</b>	<b>6,770</b>	<b>(181,845)</b>	<b>48,054</b>

\* 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	2024	2023
<b>Cash Flows from Operating Activities</b>			
<b>Loss for the Period Before Taxes</b>		<b>(35,765)</b>	<b>(36,074)</b>
Adjusted for:			
◦ Depreciation and impairment of property, plant and equipment and right-of-use assets	3.1, 3.2	898	726
◦ Share-based payment transaction expense	2.9	2,720	2,564
◦ Post-employment benefits		126	76
◦ Net finance costs		902	611
◦ Other non-cash items		143	197
Changes in working capital:			
Increase (-) Decrease (+) in Trade and other receivables		(1,857)	491
Increase (+) Decrease (-) in Trade and other payables		2,313	(1,654)



**Consolidated Financial Statements**

Interests received														686					916
Interests paid														(1,742)					-
Income tax paid														(167)					(106)
Bank charges paid									4.5					(20)					(17)
<b>Net cash(used)/generated from operating activities</b>														<b>(31,763)</b>					<b>(32,270)</b>
<b>Cash flows from investing activities</b>																			
Investments in fixed assets									3.1					(150)					(422)
Investments in intangible fixed assets									3.0					-					-
Investment in fixed term deposits									3.5					-					-
Withdrawal of term deposits														-					20,000
<b>Net cash generated/(used) from investing activities</b>														<b>(150)</b>					<b>19,578</b>
<b>Cash flows from financing activities</b>																			
Proceeds from interest-bearing loans									4.2					14,116					1,292
Repayment of principal portion of interest-bearing loans									4.2					(15,255)					-
Payment of principal portion of lease liabilities									3.2					(560)					(479)
Proceeds from issuance of shares									4.0					70,000					-
Transaction costs on issuance of shares									4.0					(5,741)					-
<b>Net cash generated/(used) from financing activities</b>														<b>62,560</b>					<b>813</b>
<b>Movement in cash and cash equivalents</b>																			
Cash and cash equivalents at 1 January														<b>29,768</b>					<b>41,760</b>
Effect of exchange rates on cash and cash equivalents														(372)					(113)
Changes in cash and cash equivalents during the period														<b>30,647</b>					<b>(11,879)</b>
<b>Cash and cash equivalents at 31 December</b>									3.6					<b>60,043</b>					<b>29,768</b>



ONWARD<sup>®</sup>



# 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 ideveloping and commercializing innovative therapies to enable functional recovery for people with Spinal Cord Injury (“SCI”). The Company’s technology platforms are based on ONWARD ARC Therapy (“ARC Therapy”), targeted, programmed electrical stimulation of the spinal cord designed to restore movement, independence, and health in people with SCI.

The financial statements for the year ended 31 December 2024 have been prepared by the Board of Directors and were authorized for issue on 28 April 2025. The financial statements will be submitted for adoption to the General Meeting on 11 June 2025.

## 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 2024. 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 preparing the financial statements for the year ended 31 December 2024, Management assessed the Company's ability to continue as a going concern, evaluating projected cash flows over the next 12 months. This forecast includes significant expenditures related to the Empower BP pivotal trial, ongoing research and development initiatives, the FDA submission for home-use clearance of the ARC<sup>EX</sup> System, and CE mark certification for the ARC<sup>EX</sup> System in Europe. As of 31 December 2024, the Company held €60 million in cash and cash equivalents, which, based on current forecasts, is expected to be sufficient to fund operations and meet capital requirements for at least 12 months from the date of this Annual Report.

While the Company believes it has the necessary resources to fund operations for the foreseeable future, the heightened uncertainty surrounding revenue projections and financing obligations, as explained below, indicate the existence of material uncertainties, which may also cast doubt about the Company's ability to continue as a going concern.



The Company recently launched ARCEX, a novel product with no directly comparable market data to substantiate sales projections. While Management has developed revenue forecasts based on market research and initial customer interest, the absence of historical sales data introduces a degree of uncertainty regarding revenue generation. The Company's sales projections include both clinic and home-use applications, but only the clinic setting received FDA clearance in December 2024. The Company plans to submit a 510(k) application for home-use authorization, with expectations for FDA clearance later in 2025. Given these factors, actual sales may deviate from projections, affecting the Company's cash flows and liquidity position.

The uncertainty in cash flow forecasts is further compounded by the Company's financing obligations. While the Company has remained in compliance with its loan covenants, future financial performance may impact continued compliance. While the Company has demonstrated strong cost management capabilities, further reductions in spending to maintain compliance may require operational trade-offs, including potential project delays and a slower pace of clinical development.

To address potential risks, the Company is proactively engaging with investors to explore additional fundraising options. Additionally, the Company maintains a strong working relationship with its lender, which has demonstrated flexibility in modifying loan terms in response to changing conditions. Management remains confident in its ability to successfully navigate these challenges through a combination of disciplined cost management, strategic financing, and ongoing engagement with stakeholders. The Board of Directors believes that a combination of one or more of the foregoing measures—including cost management, additional equity and/or debt financing, and renegotiation or refinancing of existing debt facilities—will support the Company's liquidity and funding structure. Efforts to secure additional financing from existing and new investors are ongoing.

Based on these considerations, and despite a cumulative loss of €181.8 million as of 31 December 2024, they deem the preparation of the Consolidated Financial Statements on a going concern basis to be appropriate.

## 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 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	<b>Note 2.2</b>
Share-Based Payments	<b>Note 2.9</b>
Impairment of Intangible Assets	<b>Note 3.0</b>
Post-Employment Benefits	<b>Note 5.0</b>
Taxes	<b>Note 2.10</b>



**1.7 New Accounting Standards & Developments**

**1.7.1 New and Amended Standards and Interpretations**

Several amendments applied for the first time in 2024:

- 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

None of these had a material impact on the consolidated financial statements of the Group in 2024.

**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.

- Lack of exchangeability – Amendments to IAS 21, effective 1 January 2025
- Classification and Measurement of Financial Instruments - Amendments to IFRS 9 and IFRS 7, effective 1 January 2026
- IFRS 18 – Presentation and Disclosure in Financial Statements, effective date 1 January 2027
- IFRS 19 - Subsidiaries without Public Accountability: Disclosures, effective date 1 January 2027

- 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.

With the exception of IFRS 18 which will require further assessment, based on the nature and impact of the remaining new standards, amendments and/or interpretations, the Group expects no material impact considering the circumstances as at the date of 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.

	<b>2024</b>	<b>2023</b>
Non-current assets		
Netherlands	105	118
Switzerland	2,077	2,273
United States of America	10,336	9,815
<b>Non-current assets</b>	<b>12,518</b>	<b>12,206</b>



Notes to the Consolidated Financial Statements

2.1 Revenues & Other Income

**Accounting Policy:** The Company has started commercialization of its ARC<sup>EX</sup> system in the US, targeting customers, primarily comprised of clinics. Revenue recognition aligns with the satisfaction of performance obligations under contractual agreements, with contracts having a single, short-term performance obligation. Performance obligation is deemed fulfilled at a specific point in time when the customer gains control of the ARC<sup>EX</sup> system, upon product delivery, per the terms outlined in contractual agreements. The ARC<sup>EX</sup> full system, delivered as a kit of items simultaneously, is treated as a singular performance obligation.

Warranty obligations: The Company provides a three-year warranty on the ARC<sup>EX</sup> system for general repairs of defects that existed at the time of sale. The assurance-type warranties are accounted for as warranty provisions which is currently not material.

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.

	2024	2023
Revenue from sale of devices	77	-
Government subsidies (EU)	1,510	464
Other income	152	68
<b>Total revenues and other income</b>	<b>1,739</b>	<b>532</b>

All the revenue from the sale of devices occurred in the United States of America.

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 2024	Recognized as Grant Income 2023	Recognized as Grant Income cumulative before 2023	Grant received in advance as per 31-12-2024
BESTABLE	100	(16)	-	100	-
SWISS LOCAL (one-offs)**	-	22	-	150	-
PREP2GO	362	-	15	347	-
DARPA	3,004	-	419	2,585	-
ZonMW	250	-	83	166	-
EISMEA – ReverseParalysis***	292	232	(237)	273	-
SERI-Reverse Paralysis	997	970	-	-	-
EISMEA - NEMO BMI***	144	-	(85)	85	(108)
Eurostars Impulse	500	150	160	14	-
Rewire	360	50	56	-	(112)
SH-ARC	500	-	53	-	(210)
MJFF SPARKL	91	91	-	-	-
PD-HemoN project	224	11	-	-	(11)
Other	-	-	-	(12)	-
<b>Total</b>		<b>1,510</b>	<b>464</b>	<b>3,708</b>	<b>(441)</b>

\* 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**

**BESTABLE**

This Eurobench funding agreement with PKF ATTEST INNCOME S.L. and the Spanish National Research Council CSIC for a total amount of EUR 100k started in September 2019 and ended in December 2021. An amount equal to 85% of the grant is paid during the grant period in tranches in 2019, 2020 and 2021. The remaining 15% of the total grant amount is payable after evaluation of the final report. In this project, ONWARD is collaborating with the Technical University of Delft and the University Rehabilitation Institute to develop a benchmarking system for assessment of balance performance. The final 15% was not received by the end of 2024 and the amount previously recognized was reversed.

**PREP2GO**

This Eurostars funding agreement was 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 was paid 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 was a five-year project that started in October 2020. The award was 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). ONWARD collaborated 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. 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). Phase3 of the DARPA project was cancelled late 2023.

**ZonMW**

This was a Dutch funding agreement with the Netherlands Organisation for Health Research and Development for a total amount of EUR 250k that started in January 2021 and ended in January 2024. An amount equal to 80% of the grant was paid during the grant period in three equal tranches in 2021, 2022, and 2023. The remaining 20% of the grant was paid after submission of the final report. In this project, ONWARD collaborated with the University of Bordeaux, CHUV, and EPFL to develop a research interface for ARC™ and evaluate its use to alleviate locomotor deficits in Parkinson’s disease.

**Reverse Paralysis**

The European Innovation Council and SMEs Executive Agency (EISMEA) awarded a EUR 3.6 million grant to support the development of innovative Brain-Spine Interface technology aimed at restoring mobility and upper limb function. ONWARD, along with research partners EPFL, CEA-Cinatec, and Sint Maartenskliniek, is participating in this project, with ONWARD allocated €1.3 million.

The project commenced on 1 May 2022, and is scheduled to conclude on 30 April 2025. ONWARD has received 75% of its grant funding as pre-financing, with an additional 15% payable 90 days after the first periodic reporting, and the final payment due 90 days after the second periodic reporting.

Due to changes in ONWARD’s research footprint, a portion of the work originally planned in the Netherlands has shifted to Switzerland, affecting the eligibility of certain costs under the EISMEA framework. To address this, ONWARD successfully negotiated an amendment with EISMEA to transfer activities and secured replacement funding from the Swiss State Secretariat for Education, Research, and Innovation (SERI) to cover activities performed in Switzerland.

**EISMEA - NEMO BMI**

The EISMEA also awarded a €3.8 million grant for the development of Motor Brain-Machine Interfaces (BMIs). These interfaces translate brain neural signals into commands for external



effectors, with the NEMO BMI project focusing on assistance-free, portable neuroprosthetics, including a wireless neuronal activity recorder, a real-time neuronal decoder, and a spinal cord stimulator.

The project, involving ONWARD and partners EPFL, CEA, and IICT, began on 1 October 2022, and is expected to conclude on 30 September 2025. ONWARD's share of the grant is EUR 1 million, with 75% received as pre-financing, 15% payable 90 days after the first periodic reporting, and the final installment due 90 days after the second periodic reporting.

Following the relocation of certain R&D activities to Switzerland, ONWARD has submitted an amendment request to EISMEA to reflect these changes in project execution. This amendment remains under review.

**EISMEA pending and approved amendment**

ONWARD was awarded two grants from EISMEA—Reverse Paralysis and NEMO BMI—to advance brain-computer interface technology for individuals with spinal cord injury. At the time of application, ONWARD's R&D activities were primarily conducted in the Netherlands. However, the Company has since relocated certain research functions to Switzerland to be closer to its key clinical partner, EPFL.

- As Switzerland is not an EU member and is no longer associated with the Horizon Europe framework, ONWARD Medical SA (eFor Reverse Paralysis, ONWARD has secured replacement funding from SERI, covering the Swiss-based research efforts.
- For NEMO BMI, the amendment submitted to EISMEA remains under review, and ONWARD is engaging with SERI to explore potential Swiss funding once the amendment is approved.

ONWARD continues to collaborate with both EISMEA and SERI to ensure funding continuity and compliance while advancing its groundbreaking research initiatives.

**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.

**PD-HemON**

ONWARD Medical and its research partner, NeuroRestore, have received approximately EUR 1.5M from the US Department of Defense (DoD), Parkinson's Research Program (PRP) Investigator-Initiated Research Award (IIRA). This funding will support a clinical feasibility study with 5 participants to explore the ability of the ONWARD ARC™ System to address blood pressure instability in Parkinson's disease. The project started on 30 September 2024 and will continue until 29 September 2027.

**MJFF - SPARKL**

ONWARD Medical and its partner NeuroRestore have received approximately EUR 900k from the Michael J. Fox Foundation for Parkinson's Research. This grant will support a clinical feasibility study with 6 participants to explore the ability of the ONWARD ARC™ System to address mobility challenges in Parkinson's disease. The study commenced on 01 January 2023, with the first participant implanted in late 2024, and the project will end 13 December 2025.



**Notes to the Consolidated Financial Statements**

**2.2 Research & Development Expenses**

**Accounting Policy:** Research costs are expensed as incurred. Development expenditure 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.

	<b>2024</b>	<b>2023</b>
Staff expenses	9,260	9,200
Operating expenses	3,182	4,641
	<b>12,442</b>	<b>13,841</b>

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<sup>EX</sup> and ARC<sup>IM</sup> systems, as well as employee-related expenses including salaries and benefits. The decrease in 2024 is driven by advancements made on our ARC<sup>EX</sup> and ARC<sup>IM</sup> platforms and preparing for FDA submission of ARC<sup>EX</sup> in 2024.

**2.3 Clinical & Regulatory Expenses**

	<b>2024</b>	<b>2023</b>
Staff expenses	3,011	3,472
Operating expenses	1,743	1,439
	<b>4,754</b>	<b>4,911</b>

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 2024 primarily relate to the preparation of ARC<sup>EX</sup> for FDA submission and related consulting work.

**2.4 Marketing & Market Access Expenses**

	<b>2024</b>	<b>2023</b>
Staff expenses	2,101	1,830
Operating expenses	1,249	1,113
	<b>3,350</b>	<b>2,943</b>

The Company's marketing and market access expenses include the ARC<sup>EX</sup> launch preparation and activities towards awareness and engagement around ONWARD ARC Therapies in the SCI community.

**2.5 Patent fees & Related Expenses**

	<b>2024</b>	<b>2023</b>
Staff expenses	-	373
Operating expenses	1,441	1,136
	<b>1,441</b>	<b>1,509</b>

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, Employee expenses, including salary and benefits in this area are borne by a different department in 2024.

**2.6 Quality Assurance Expenses**

	<b>2024</b>	<b>2023</b>
Staff expenses	1,693	1,204
Operating expenses	323	260
	<b>2,016</b>	<b>1,464</b>

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**

	<b>2024</b>	<b>2023</b>
Staff expenses	7,249	5,419
Depreciation and amortization	898	726
Other operating expenses	4,429	5,182
	<b>12,576</b>	<b>11,327</b>

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.



**Notes to the Consolidated Financial Statements**

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.

	<b>2024</b>	<b>2023</b>
Wages and salaries	17,330	15,356
Social security costs	1,507	1,512
Pension costs – defined benefit plan	771	720
Pension costs – other	64	69
Share-based benefit expenses	2,720	2,564
Other labor costs	923	1,277
	<b>23,315</b>	<b>21,498</b>

The increase in wages and salaries is driven by the composition of new hires versus leavers. This shift in expertise aligns with the Company’s strategic goals. As at 31 December 2024, the Group employed 102.6 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 2024 and 2023:

	<b>2024</b>	<b>2023</b>
Research & Development	40.0	50.0
Clinical & Regulatory	14.0	14.6
Marketing & Market Access	14.0	5.0
Patent Fees & related	–	1.0
Quality Assurance	8.6	8.8
General & Administrative	26.0	19.8
	<b>102.6</b>	<b>99.2</b>

As at 31 December 2024, the Company had 12.4 full-time equivalents located in the Netherlands (2023: 11.9), 76.15 full-time equivalents located in Switzerland (2023: 75.3), and 14 (2023: 12) 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.



**Notes to the Consolidated Financial Statements**

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 types 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 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 9.70	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
2024	15/1/2024	Stock Options	710,975	EUR 2.94	15/1/2034	EUR 1.60
2024	1/7/2024	Stock Options	460,688	EUR 5.08	1/7/2034	EUR 2.85
2024	5/12/2024	Stock Options	704,625	EUR 4.77	4/12/2034	EUR 2.68

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

	2024	2023
Share-based payment expense	2,720	2,564
	<b>2,720</b>	<b>2,564</b>



Notes to the Consolidated Financial Statements

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

	2024 Number	2024 WAEP	2023 Number	2023 WAEP
Outstanding at 1 January	1,828,650	EUR 6.85	873,125	EUR 7.41
Granted during the year	1,876,288	EUR 4.15	1,418,225	EUR 5.81
Forfeited during the year	(151,332)	EUR 6.65	(462,700)	EUR 6.90
Exercised during the year	-	-	-	-
<b>Outstanding at 31 December</b>	<b>3,553,606</b>	<b>EUR 5.43</b>	<b>1,828,650</b>	<b>EUR 6.85</b>

	Number	WAEP
Exercisable at 31 December 2024	950,137	EUR 7.22
Exercisable at 31 December 2023	298,961	EUR 9.10

The weighted average remaining contractual life for the share options outstanding at 31 December 2024 was 8.69 years (2023: 8.79 years).

The weighted average fair value of options granted during the year was EUR 2.31 (2023: EUR 3.20).

The range of exercise prices for options outstanding at the end of the year was EUR 2.94 to EUR 9.70 (2023: EUR 4.95 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:

	2024-12	2024-07	2024-01	2023-07	2023-02	2023-01
Fair value on date of measurement (EUR)	2.68	2.85	1.60	2.85	2.73	3.37
Share price (EUR)	4.77	5.08	2.94	5.18	4.97	6.12
Exercise price (EUR)	4.77	5.08	2.94	5.18	4.95	6.12
Expected volatility	61.4%	59.1%	57.0%	56.10%	57.20%	57.80%
Term of the option	4 <sup>a</sup>					
Expected dividend	-	-	-	-	-	-
Risk-free interest rate	2.11%	2.61%	2.23%	2.44%	2.65%	2.38%
Time to expiration	10	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 liability arises from the initial recognition of goodwill or 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 taxable temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future

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 2022. 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 and on the capitalized license fee. The Company recognized a deferred tax asset in the US entity that offsets the deferred tax liability as allowed under IAS 12, with no impact on previously reported results.



**Notes to the Consolidated Financial Statements**

	<b>2024</b>	<b>2023</b>
Current income tax	(294)	(148)
Adjustments of current income tax of previous year	(45)	–
Deferred income tax	379	41
<b>Total corporate income tax in profit and loss</b>	<b>40</b>	<b>(107)</b>
Current income Tax charge at tax rate of 25.8%	9,227	9,307
Tax rate differences in foreign jurisdictions	(156)	152
Adjustments of current income tax of previous year	(45)	–
Non-deductible expenses	(553)	(662)
Non-recognized deferred tax asset on temporary differences	–	66
Non-recognized deferred tax asset on permanent differences	–	(203)
Net operating losses not recognized	(8,960)	(8,709)
Recognition of prior year deferred tax adjustments	575	–
Other	(48)	(58)
	<b>40</b>	<b>(107)</b>

The effective tax rate was 0.4% in 2024 (2023: -0.3%), which is lower than the statutory income tax rate of 25.8% (2023: 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 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**

<b>2024</b>	<b>Assets</b>	<b>Liabilities</b>	<b>Net</b>
Intangible assets, including Goodwill	–	(1,786)	(1,786)
Right of use assets	–	(148)	(148)
Lease liability	156	–	156
Post-employment benefits	560	–	560
Losses available for offset against future	–	–	–
Taxable income	1,483	–	1,483
Set-off of deferred tax	(1,631)	1,631	–
<b>Net deferred tax asset / (liability)</b>	<b>568</b>	<b>(303)</b>	<b>265</b>

<b>2023</b>	<b>Assets</b>	<b>Liabilities</b>	<b>Net</b>
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	–
<b>Net deferred tax asset / (liability)</b>	<b>310</b>	<b>(631)</b>	<b>(321)</b>

	<b>2024</b>	<b>2023</b>
Opening balance at January 1	(321)	(507)
Recognized in profit & loss	379	41
Remeasurement (gain)/loss on actuarial gains and losses in OCI	255	125
Foreign currency translation difference	(48)	20
<b>Net deferred tax asset /(liability) at December 31</b>	<b>265</b>	<b>(321)</b>



**Notes to the Consolidated Financial Statements**

Of the estimated amount of tax losses carried forward and available as at 31 December 2024, a deferred tax asset of EUR 1,483k has been recognized to offset the reversal of temporary differences in the US. For the remaining unused operating losses in the Netherlands of EUR 148M (2023: EUR 120M) and in the US of EUR 27M (2023: EUR 28.5M) no deferred tax is recognized. These losses can be carried forward indefinitely subject to local tax rules, except for approximately EUR 3.2M of losses in the US, which can be carried forward for 20 years (ultimately by 2037).

No deferred tax liability has been recorded for the Swiss subsidiary due to the applicable tax treaty between Switzerland and the Netherlands, which eliminates potential tax consequences on undistributed earnings. Similarly, no deferred tax liability has been recognized for the U.S. subsidiary, as it has negative retained earnings, and there are no undistributed profits that could result in taxable temporary differences.

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.

**3. Non-Current Asset & Working Capital**

**3.0 Intangible Assets**

	<b>2024</b>	<b>2023</b>
Goodwill	1,962	1,845
In-Process R&D	6,059	5,698
License fees	2,404	2,261
<b>Net book value at 31 December</b>	<b>10,425</b>	<b>9,804</b>

**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 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.

	<b>2024</b>	<b>2023</b>
Cost	1,845	1,902
Accumulated changes	-	-
<b>Net book value at 1 January</b>	<b>1,845</b>	<b>1,902</b>
Additions	-	-
Foreign currency translation difference	117	(57)
Impairments	-	-
Net change	117	(57)
Cost	1,962	1,845
Accumulated changes	-	-
<b>Net book value at 31 December</b>	<b>1,962</b>	<b>1,845</b>



**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.

	<b>2024</b>	<b>2023</b>
Cost	5,850	6,025
Accumulated changes	(152)	(152)
<b>Net book value at 1 January</b>	<b>5,698</b>	<b>5,873</b>
Foreign currency translation difference	361	(175)
Additions	-	-
Reclassification	-	-
Amortization for the year	-	-
Impairments	-	-
Net change	361	(175)
Cost	6,211	5,850
Accumulated changes	(152)	(152)
<b>Net book value at 31 December</b>	<b>6,059</b>	<b>5,698</b>

**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. 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.

	<b>2024</b>	<b>2023</b>
Cost	2,261	2,383
Accumulated changes	-	-
<b>Net book value at 1 January</b>	<b>2,261</b>	<b>2,383</b>
Additions	-	-
Foreign currency translation difference	143	(72)
Reversals	-	(50)
Amortization for the year	-	-
Impairments	-	-
Net change	143	(122)
Cost	2,404	2,261
Accumulated changes	-	-
<b>Net book value at 31 December</b>	<b>2,404</b>	<b>2,261</b>

**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 successful development and regulatory approvals of the Group's technologies across various platforms. 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.



**Notes to the Consolidated Financial Statements**

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 flow projections: Cash flow forecasts are based on the expectation of regulatory approvals in key markets. Revenue generation is anticipated to commence following market clearance, with initial sales focusing on specific target segments, followed by broader market expansion. FDA clearance of the first device (ARCEX) for use in the clinic setting was obtained in December 2024. The forecasts includes the Group’s best estimate of future revenues. Operating costs are expected to increase to support commercial activities, ongoing product development, and clinical research. Based on current estimates, EBITDA is not projected to be positive in the near term.
- Cash generating unit: The Group has developed multiple neurostimulation platforms that share key technological components, a unified development framework, and an aligned user experience. These platforms incorporate common elements such as stimulation generators, electrodes, and programming interfaces, reflecting a high degree of integration in both design and functionality. While the Group has recently entered its commercial phase, the business continues to operate with a significant shared cost structure across research, development, and commercialization efforts. Given these interdependencies, the Group is assessed as a single CGU. The ability to track revenue and cost of goods sold (COGS) separately does not, in isolation, indicate the existence of distinct CGUs, as substantial operational and financial integration remains across the organization. Regulatory approvals and commercialization strategies vary across platforms, but these factors do not alter the overall assessment of a single CGU at this stage.
- Growth rate estimate: The applied growth rate is derived from industry benchmarks and external market research.
- Discount rate: The discount rate reflects the current market assessment of risks specific to the Group. It is determined based on the weighted average cost of capital (WACC), which accounts for expected returns required by both debt and equity investors, weighted according to their respective contributions to the Group’s capital structure.

The cash flow projections were determined using management’s internal forecasts that cover an initial period from 2025 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 (increasing with 5%) or terminal growth rate (to 0%), or both the discount rate (increasing with 5%) and terminal growth rate (to 0%), would not cause the carrying amount to exceed its recoverable amount.

	2024	2023
Discount rate	11.9%	13.4%
Terminal value growth rate	1.71%	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 includes 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.

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.



**Notes to the Consolidated Financial Statements**

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**

	<b>Office Equipment</b>	<b>Leasehold Improvements</b>	<b>Total</b>
At 1 January 2023	923	265	1,188
Additions	352	70	422
<b>At 31 December 2023</b>	<b>1,275</b>	<b>335</b>	<b>1,610</b>
Additions	153	–	153
Disposals	–	–	–
Foreign currency translation difference	39	14	53
<b>At 31 December 2024</b>	<b>1,467</b>	<b>349</b>	<b>1,816</b>

**Accumulated Depreciation**

	<b>Office Equipment</b>	<b>Leasehold Improvements</b>	<b>Total</b>
At 1 January 2023	(747)	(26)	(773)
Depreciation for the year	(141)	(87)	(228)
<b>At 31 December 2023</b>	<b>(888)</b>	<b>(113)</b>	<b>(1,001)</b>
Depreciation for the year	(214)	(129)	(343)
<b>At 31 December 2024</b>	<b>(1,102)</b>	<b>(242)</b>	<b>(1,344)</b>

**Net Book Value**

	<b>Office Equipment</b>	<b>Leasehold Improvements</b>	<b>Total</b>
At 31 December 2023	387	222	609
<b>At 31 December 2024</b>	<b>365</b>	<b>106</b>	<b>471</b>

**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.



**Notes to the Consolidated Financial Statements**

**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 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 was extended in November 2024 for a period of one year (ending October 2025).

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

	<b>2024</b>	<b>2023</b>
<b>Net book value at 1 January</b>	<b>1,483</b>	<b>1,681</b>
Additions	82	299
Depreciation for the year	(560)	(497)
Foreign currency translation impact	49	-
<b>Net book value at 31 December</b>	<b>1,054</b>	<b>1,483</b>

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. The additions represent the annual increase in lease payments under the lease contracts and the additional one year extension.

**Lease Liabilities**

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

	<b>2024</b>	<b>2023</b>
Less than one year	597	568
One to five years	518	1,051
More than five years	-	-
<b>Total lease liability</b>	<b>1,115</b>	<b>1,619</b>



**Notes to the Consolidated Financial Statements**

Movement of the lease liability:

	<b>2024</b>	<b>2023</b>
<b>Balance as at 1 January</b>	<b>1,619</b>	<b>1,721</b>
Additions	82	299
Interest accretion	56	69
Repayments	(616)	(548)
Foreign currency impact	(26)	78
<b>Total lease liability</b>	<b>1,115</b>	<b>1,619</b>

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

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

**3.3 Inventories**

**Accounting Policy:** Inventories consist of raw materials, work-in-progress and finished goods of the ARC<sup>EX</sup> System. Inventories are valued at the lower of cost and net realizable value. Costs incurred in bringing each product to its present location and condition are accounted for as follows: cost of direct materials and labor and a proportion of manufacturing overheads based on the normal operating capacity, excluding borrowing costs. The cost is assigned using the FIFO (“first-in-first-out”) method. Net realizable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale.

	<b>2024</b>	<b>2023</b>
Raw Materials	102	-
	<b>102</b>	<b>-</b>

As at 31 December 2024, the Group had inventory of Raw materials amounting to EUR 102k. The increase in stock of raw materials is directly attributable to start of production of ARC<sup>EX</sup> devices in 2024.

**3.4 Indirect Tax Receivables**

The tax receivables consist of refundable VAT amounting to EUR 125k (2023: EUR 117k) and are collectable within 12 months. The increase in the receivable is a direct result of increase in expenses during the year. The VAT returns are filed on a quarterly basis and claims received throughout the year.

**3.5 Other Current Assets**

	<b>2024</b>	<b>2023</b>
Advance payments	2,137	936
Grants and other receivables	714	260
Rental guarantee	302	305
Trade receivables	160	-
	<b>3,313</b>	<b>1,501</b>

The Group provided a guarantee of EUR 302k (2023: EUR 305k) 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 and advance paid to suppliers for production and components.

Trade receivables represent amounts due from customers, are non-interest bearing, and are generally due for settlement within 30 days in accordance with the agreed credit terms.

**3.6 Cash and Cash Equivalents**

**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.



**Notes to the Consolidated Financial Statements**

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.

	<b>2024</b>	<b>2023</b>
Cash at bank	12,043	3,568
Short-term deposits	48,000	26,200
<b>Cash and cash equivalents</b>	<b>60,043</b>	<b>29,768</b>
<b>Cash and cash equivalents</b>	<b>60,043</b>	<b>29,768</b>

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.

As part of the loan agreement with Runway Growth Capital LLC, the Group has pledged the majority of the bank and deposit accounts as collateral to secure its outstanding debt obligations. This serves as security for compliance with the loan covenants outlined in the agreement. In the event of a breach of these covenants, the lender may have the right to enforce its security interest over these assets. Management actively monitors compliance with all covenants to mitigate the risk of default.

As at 31 December 2024, there were no fixed term deposits for periods exceeding three months.

At 31 December 2024, the Group had no bank overdrafts. All cash is freely at the disposal of the company.

**3.7 Trade Payables**

Trade payables and accrued expenses are non-interest bearing and are normally settled on 30-90 day terms. The decrease in trade payables to EUR 1,269k (2023: EUR 1,369k) is a direct result of ARC<sup>EX</sup> launch related activities and the timing of settlement.

**3.8 Other Payables**

The other payables can be broken down as follows:

	<b>2024</b>	<b>2023</b>
Wage tax and social security	144	485
Grants received in advance	441	473
Bonus	3,095	1,243
Invoices to be received	1,194	538
Other	555	425
Grant-related payables	1,359	1,358
	<b>6,788</b>	<b>4,522</b>

The increase in Other Payables is due to increase in the bonus accrual and amounts that were due to subcontractors (on grants). 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 18,000,000 (2023: EUR 12,225,000) divided into 75,000,000 (2023: 50,937,500) Ordinary Shares and 75,000,000 (2023: 50,937,500) Preferred Shares with a nominal value of EUR 0.12 each.



**Notes to the Consolidated Financial Statements**

In March 2024, the Company raised EUR 20 million (gross proceeds) by way of an accelerated bookbuild offering and a public offering in France. A total of 4,444,444 new ordinary shares were issued at the price of EUR 4.50 per share. Transaction costs of EUR 2,05 million was recognised in Equity decreasing share premium.

In October 2024, the Company raised EUR 50 million (gross proceeds) in as part of a capital raise. A total of 10,000,000 new ordinary shares were issued at the price of EUR 5 per share. Transaction costs of EUR 3,69 million was recognised in Equity decreasing share premium.

At 31 December 2024, 44,628,834 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
<b>Balance at 1 January 2023</b>	<b>319</b>	<b>1,760</b>	<b>2,079</b>
Share-based payment expense: LTIP	-	2,564	2,564
Currency translation differences	(155)	-	(155)
<b>Balance at 31 December 2023</b>	<b>164</b>	<b>4,324</b>	<b>4,488</b>
Share-based payment expense: LTIP	-	2,720	2,720
Reclassification of the fair value of forfeited options	-	(873)	(873)
Currency translation differences	434	-	434
<b>Balance at 31 December 2024</b>	<b>598</b>	<b>6,171</b>	<b>6,770</b>

**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 2024. 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 2024.

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**

	2024	2023
Profit (loss) for the year, attributable to equity holders of the parent	(35,725)	(36,181)

**Weighted-Average Number of Ordinary Shares**

	2024 Thousands	2023 Thousands
Weighted average number of ordinary shares for basic EPS	44,629	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**

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.



**Notes to the Consolidated Financial Statements**

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.

	<b>2024</b>	<b>2023</b>
<b>Current financial liabilities</b>	<b>437</b>	<b>-</b>
Warrants issued to Runway Growth	437	-
<b>Non-current financial liabilities</b>	<b>13,972</b>	<b>15,255</b>
Innovation loan	-	15,255
Runway Growth loan	13,972	-
<b>Total financial liabilities</b>	<b>14,409</b>	<b>15,255</b>

**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. This loan was repaid in 2024 .

	<b>2024</b>	<b>2023</b>
<b>Loan as per January 1</b>	<b>15,255</b>	<b>12,656</b>
Loan amount received	-	1,292
Interest accrued during the year	767	1,307
Loan amount repaid during the year	(16,022)	-
<b>Net book value at December 31</b>	<b>-</b>	<b>15,255</b>

The loan carried interest at 10%.

**Runway Growth Loan**

On 28 June 2024 the Company and its subsidiaries, ONWARD Medical, Inc. and ONWARD Medical S.A., signed a loan agreement in the amount of up to EUR 52.5 million (the “Loan Agreement”) with U.S.-based lender Runway Growth Capital LLC (the “Lender”). The loan was used to (i) repay all of the Company’s outstanding debt, (ii) fund the Company’s upcoming commercial and clinical activities, and (iii) support for working capital and general corporate purposes. The facility is divided into five individual credit tranches. The first initial credit tranche of EUR 16.0 million was available upon signing of the Loan Agreement and was drawn down immediately. Three subsequent credit tranches of EUR 14.0 million, up to EUR 5.0 million and up to EUR 7.5 million will be available to be drawn by the Company until 31 March 2025 and 31 July 2026 respectively, in each case subject to the Company’s achievement of certain milestones under the Loan Agreement. The fifth credit tranche of up to EUR 10.0 million is uncommitted and available in the first quarter of 2027 upon the sole discretion of the Lender. The loan bears interest at a rate equal to Term Secured Overnight Financing Rate (SOFR) for a three-month interest period (currently at 6.00% and subject to a 4.25% floor), plus a margin of 6.50%. The loans advanced under the Loan Agreement is secured by a security interest in substantially all of the assets of the ONWARD Medical, N.V. and its subsidiaries.

The loan documents provide for a number of affirmative and negative covenants by the Company customary for financings of this type, including financial covenants relating to revenue, earnings before interest taxes, depreciation and amortization (EBITDA) and minimum liquidity targets. In December 2024, an amendment was agreed upon stipulating that, for 2025,



**Notes to the Consolidated Financial Statements**

compliance with other covenants would not be required, provided the company maintains the specified minimum cash-to-debt ratio.

As of the reporting date, the Company was in compliance with all covenants. Management actively monitors covenant compliance to ensure ongoing adherence. The loan is classified as non-current since earliest maturity date is 15 June 2028, provided that if the Extension Milestone is satisfied, the maturity date shall automatically be extended to 15 June 2029.

The funds required for the repayment of the existing (RVO) loan, representing the first tranche, were received on 2 July 2024, at which point the conditions for the recognition of the new loan were satisfied. The RVO loan was also repaid on 2 July 2024. Certain Intellectual Property (patents registered) have been pledged to Runway Growth in case of default of repayment of the loan. These patents have not been capitalized as at 31 December 2024.

	<b>2024</b>
<b>Loan opening balance</b>	–
Loan amount received	14,116
Tx cost amortisation	212
Interest accrued during the period	944
Interest paid	(861)
Warrants issued to Runway growth	(439)
<b>Closing balance</b>	<b>13,972</b>

**Warrants issued to Runway Growth**

On 28 June 2024 the Company and its subsidiaries, ONWARD Medical, Inc. and ONWARD Medical S.A., signed a loan agreement in the amount of up to EUR 52.5 million (the “Loan Agreement”) with U.S.-based lender Runway Growth Capital LLC (the “Lender”). In addition, upon the signing of the debt financing the Company will issue to the Lender warrants which will entitle the Lender to purchase ordinary shares in the capital of the Company at an exercise price per newly issued share calculated on the basis of the lowest 30-day volume weighted average price (VWAP) between 9 April 2024 and the signing of the debt financing. The number of shares subject to the warrants are five percent (5.00%) of the drawn down principal amount initially and upon each subsequent loan advance, divided by the exercise price of EUR 4.83.

Warrants may be exercised either by the warrant holder paying the total warrant price in cash to the Company for the shares being purchased, or on a cashless basis, in which case the Company will issue a number of shares based on the fair value of the warrants. The exercise period is set at a period of ten (10) years from (and including) the date of expiry of the waiting period, which is ninety (90) calendar days after the closing date. As the warrants can be exercised 90 days after closing, the company does not have the right to defer the settlement of the liability for at least twelve months after the reporting date. The Lender warrants is therefore classified as current.

Financial Year	Issue Date	Type of Security	Number of Warrants	Exercise Price	Expiration Date
<b>2024</b>	2/7/2024	Lender Warrants	165,631	EUR 4.83	2/7/2034

The fair value of the awarded options was determined by applying a Binomial Option Pricing Model that allows for exercising of the Lender Warrants before the end of the exercise period. The Hull-White binomial formula 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.

The following parameters were used in the option model for the calculation of the fair value of the warrants:

	<b>2 Jul 2024</b>	<b>31 Dec 2024</b>
<b>Fair value on date of measurement (EUR)</b>	<b>2.65</b>	<b>2.64</b>
Share price (EUR)	5.12	5.18
Exercise price (EUR)	4.83	4.83
Expected volatility	59.1%	61.2%
Vesting period in years	0.24	0.00
Expected dividend	–	–
Risk-free interest rate	2.60%	2.40%
Time to expiration	10	9.7



	<b>2024</b>
Lender warrants issued	439
Fair value adjustment recognised in profit and loss	(2)
<b>Closing balance</b>	<b>437</b>

### 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:

As at 31 December 2024:

	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>3-5 Years</b>	<b>More than 5 Years</b>	<b>Total</b>
Runway Growth loan	1,972	3,944	18,820	-	24,736
Lease liability	633	527	-	-	1,160
Warrants issued to Runway Growth	437	-	-	-	437
Trade payable	1,269	-	-	-	1,269
<b>Total</b>	<b>4,311</b>	<b>4,471</b>	<b>18,820</b>	<b>-</b>	<b>27,602</b>

As at 31 December 2023:

	<b>Less than 1 Year</b>	<b>1-3 Years</b>	<b>3-5 Years</b>	<b>More than 5 Years</b>	<b>Total</b>
Innovation loan	-	6,500	14,295	-	20,795
Lease liability	615	1,084	-	-	1,699
Trade payables	1,369	-	-	-	1,369
<b>Total</b>	<b>1,984</b>	<b>7,584</b>	<b>14,295</b>	<b>-</b>	<b>23,863</b>

#### 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.



**Notes to the Consolidated Financial Statements**

**Credit Risk**

Since the Company has only recorded two sales to date, trade receivables remain limited and are not yet considered a significant risk. As a result, credit risk for the current year primarily relates to cash, cash equivalents, and deposits held 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, Banque Cantonale Vaudoise (BCV) and JP Morgan Chase. 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**

The Group is exposed to currency risk for the activities in the US (accounting in US dollars) and Switzerland (accounting in Swiss francs), whereas the functional currency of the Group is the Euro. The risk is currently managed by replenishing the US and Swiss bank accounts at regular intervals to account for both the positive and negative changes. The Company does not hedge currently its operational FX risk and its risk on outstanding balances denominated in another currency than its functional currency.

**Interest Rate Risk**

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Group’s exposure to the risk of changes in market interest rates relates primarily to the Runway Growth long-term debt obligation that bears interest at a rate equal to Term Secured Overnight Financing Rate (SOFR) for a three-month interest period (currently at 6.00% and subject to a 4.25% floor), plus a margin of 6.50%.

**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:

<b>2024</b>	<b>Carrying Amount</b>	<b>Estimated Fair Value</b>
<b>Financial liabilities</b>		
Runway Growth loan (Level 2)	13,972	16,818
Lender Warrants (Level 3)	437	437
<b>Total financial liabilities</b>	<b>14,409</b>	<b>17,255</b>
<b>2023</b>	<b>Carrying Amount</b>	<b>Estimated Fair Value</b>
<b>Financial liabilities</b>		
Innovation credit loan (Level 2)	15,255	15,460
<b>Total financial liabilities</b>	<b>15,255</b>	<b>15,460</b>

Management has assessed that the fair values of cash and cash equivalents, accounts receivable and accounts payable 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



**Notes to the Consolidated Financial Statements**

in a forced or liquidation sale. The following methods and assumptions were used to estimate the fair values:

The fair value of the Runway Growth loan (2023: 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 any levels for either financial assets or financial liabilities. The Lender Warrants issued in 2024 are considered to be level 3 in the fair value hierarchy.

The significant unobservable inputs used in the fair value measurement of the Lender Warrants, categorized within level 3, together with a quantitative sensitivity analysis at 31 December 2024 is shown below. Any movement in the fair value of the Lender Warrants will be recognized in profit and loss. Please refer to Note 4.2 for the detailed description of the methodology applied for the fair value measurement of the Lender Warrants.

Please refer to Note 4.2 for the detailed description of the methodology applied for the fair value measurement of the Lender Warrants

For the sensitivity analysis the exercise multiple is adjusted by steps of 0.2, and for the volatility sensitivity we applied a range of 50.0% to 68.4%. The impact in profit and loss can vary from a gain of EUR 44k to a loss of EUR 35k.

Exercise Multiple	Volatility		
	50.0%	61.2%	68.4%
2.0	393	418	429
2.2	421	437*	451
2.4	443	470	472

\* This is the fair value of the Lender Warrants as recognized at 31 December 2024.

**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.

	2024	2023
Interest income from deposits	791	972
Interest on loans	(1,923)	(1,307)
Interest post-employment benefits	(18)	-
Interest banks	-	-
Interest on lease liabilities	(56)	(69)
Exchange losses	372	(190)
Bank charges	(20)	(17)
Fair value adjustment of Lender Warrants	2	-
Transaction costs on lender warrants	(51)	-
<b>Net Finance expense</b>	<b>(903)</b>	<b>(611)</b>

**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.

	<b>2024</b>	<b>2023</b>
Plan assets	7,017	4,289
Obligation	(11,016)	(6,370)
<b>Net liability</b>	<b>3,999</b>	<b>2,081</b>

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**

	<b>2024</b>	<b>2023</b>
<b>Balance as at 1 January</b>	<b>2,081</b>	<b>1,121</b>
Service costs	760	652
Admin costs	47	45
Past service costs	(38)	23
Employee benefit expenses	769	720
Net interest costs/(income)	18	15
<b>Included in statement of profit and loss</b>	<b>787</b>	<b>735</b>
Actuarial gains/(losses)		
– Financial assumptions	1,104	932
– Demographic assumptions	–	–
– Experience adjustment	441	(449)
– Return on assets excluding interest income	274	321
	1,819	804
Exchange rate differences	(28)	80
<b>Included in statement of comprehensive income*</b>	<b>1,792</b>	<b>884</b>
<b>Contributions by employer</b>	<b>(661)</b>	<b>(659)</b>
<b>Balance as at 31 December</b>	<b>3,999</b>	<b>2,081</b>

\*Excluding tax impact

The principal assumptions used in determining post-employment (pension) benefit obligations for the plan are shown below:

	<b>2024</b>	<b>2023</b>
Discount rate	0.95%	1.35%
Salary increase	3.00%	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:

	<b>2024</b>	<b>2023</b>
Discount rate		
+ 25bps	(605)	(271)
- 25bps	407	292
Salary increase		
+ 25bps	89	119
- 25bps	(314)	(113)
Interest credit rate		
+ 25bps	61	101
- 25bps	(293)	(98)
Mortality base table		
Life expectancy + 1 year	(19)	44
Life expectancy - 1 year	(216)	(42)

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:

	<b>2024</b>	<b>2023</b>
Within the next 12 months	627	350
Between 2 and 5 years	2,476	1,702
Between 6 and 10 years	3,503	3,172
<b>Total expected payments</b>	<b>6,606</b>	<b>5,224</b>

The average duration of the defined benefit plan obligation at the end of the reporting period is 18 years (2023: 18 years).

#### Plan Assets Allocation

The asset allocation in the Swiss pension plan at 31 December was as follows:

	<b>2024</b>	<b>2023</b>
Bonds	4,553	2,709
Equities	-	-
Loans	149	93
Mortgages	766	507
Real Estate	1,441	922
Cash, derivatives and funds	108	58
	<b>7,017</b>	<b>4,289</b>

Plan assets in 2024 and 2023 do not include property occupied by or financial instruments issued by ONWARD.

## 5.1 Commitments & Contingencies

### Legal Claim Contingencies

As at 31 December 2024, the Group had no legal claim contingencies

### Guarantees

The Group has provided a guarantee to Wincasa for EUR 302k 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. For the milestones triggered by the FDA clearance received on 19 December 2024, accruals are included in Note 3.8 Other Payables (Invoices to be received) for an amount of EUR 18k.

On 8 October 2019, Neurorecovery Technologies Inc. (now ONWARD Medical 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



**Notes to the Consolidated Financial Statements**

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 certification, and/or first commercial sale. For the milestones triggered by the FDA clearance received on 19 December 2024, accruals are included in Note 3.8 Other Payables (Invoices to be received) for an amount of EUR 185k.

**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.

	<b>Salary, bonuses and other (short-term employee benefits)</b>	<b>Pension premiums (post-employment benefits)</b>	<b>Share-based payment</b>	<b>Total</b>
<b>2024</b>				
Management Team, excluding CEO	2,311	77	618	3,006
CEO	1,211	72	757	2,040
Non-Executive Directors	691	-	352	1,043
	<b>4,213</b>	<b>149</b>	<b>1,727</b>	<b>6,089</b>

	<b>Salary, Bonuses &amp; Other (Short-Term Employee Benefits)</b>	<b>Pension Premiums (Post-Employment Eenefits)</b>	<b>Share-Based Payment</b>	<b>Total</b>
<b>2023</b>				
Management Team, excluding CEO	2,827	98	643	3,568
CEO	703	64	916	1,683
Non-Executive Directors	445	-	441	886
	<b>3,975</b>	<b>162</b>	<b>2,000</b>	<b>6,137</b>

**5.3 Events After the Reporting Period**

There were no significant events after the reporting period.



ONWARD<sup>®</sup>



# Company Financial Statements

# Company Statement of Income

For the Year Ended 31 December

All amounts in EUR '000	Notes	2024	2023
Revenue	B	48	-
Less: Cost of goods sold		(10)	-
<b>Gross profit</b>		<b>38</b>	-
Grants and other income	B	658	532
Operating expenses	C	(40,164)	(29,679)
<b>Operating result for the period</b>		<b>(39,468)</b>	<b>(29,147)</b>
Net finance expense	D	(1,916)	(392)
<b>Result after tax</b>		<b>(41,384)</b>	<b>(29,539)</b>

The notes on pages **309** to **319** 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	2024	2023
<b>Assets</b>			
<b>Non-current assets</b>			
Tangible fixed assets	G	105	118
Financial fixed assets	H	2,372	807
		<b>2,477</b>	<b>925</b>
<b>Current assets</b>			
Trade and other receivables	I	6,392	26,748
Cash at bank and in hand	J	56,989	13,854
		<b>63,381</b>	<b>40,602</b>
		<b>65,858</b>	<b>41,527</b>



**Company Financial Statements**

**Equity & Liabilities**

**Equity and reserves**

	<b>K</b>		
Issued capital		5,355	3,622
Share premium		217,774	155,248
Other reserves		3,820	4,199
Legal reserve: Currency translation differences		625	165
Retained earnings		(143,795)	(109,122)
Result for the year		(35,725)	(36,181)

<b>Total equity</b>		<b>48,054</b>	<b>17,931</b>
---------------------	--	---------------	---------------

<b>Provisions</b>	<b>L</b>	-	5,233
-------------------	----------	---	-------

<b>Non-current liabilities</b>	<b>M</b>	14,016	15,297
--------------------------------	----------	--------	--------

<b>Current liabilities</b>	<b>N</b>	3,788	3,066
----------------------------	----------	-------	-------

		<b>65,858</b>	<b>41,527</b>
--	--	---------------	---------------

The notes on pages **309** to **319** 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. Revenue & Other 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.

	<b>2024</b>	<b>2023</b>
Revenue (net of cost of goods sold)	38	–
Government subsidies (EU)	507	464
Other income	151	68
<b>Total revenues and other income</b>	<b>696</b>	<b>532</b>



**Company Financial Statements**

(In EUR 000)

Grants	Total Grant*	Recognized as Grant Income 2024	Recognized as Grant Income 2023	Recognized as Grant Income cumulative before 2023	Grant received in advance as per 31-12-2024
BESTABLE	100	(16)	-	100	-
PREP2GO	362	-	15	347	-
DARPA	3,004	-	419	2,585	-
ZonMW	250	-	83	166	-
EISMEA - ReverseParalysis***	292	232	(237)	273	-
EISMEA - NEMO BMI***	144	-	(85)	85	(108)
Eurostars Impulse	500	150	160	14	-
Rewire	360	50	56	-	(112)
SH-ARC	500	-	53	-	(210)
MJFF SPARKL	91	91	-	-	-
Other	-	-	-	(12)	-
<b>Total</b>		<b>507</b>	<b>464</b>	<b>3,558</b>	<b>(430)</b>

**C. Operating Expenses**

Operating expenses by nature are as follows:

	2024	2023
Wages and salaries	(1,212)	(1,242)
Social security costs (includes WBSO benefit)	(58)	54
Pension costs – other	(64)	(69)
Share-based benefit expenses	(370)	(148)
Other labor costs	(617)	(724)
Other operating expenses	(37,773)	(27,492)
Depreciation and amortization	(70)	(58)
	<b>(40,164)</b>	<b>(29,679)</b>

The increase in Other operating expenses is driven by Research and Development expenses due to advancements made on our ARC<sup>EX</sup> and ARC<sup>IM</sup> platforms (mainly in Switzerland) which increased the charge from Switzerland to the Netherlands under the existing agreement.

As at 31 December 2024, the Company had 12.4 full-time equivalents located in the Netherlands (2023: 11.9), 76.15 full-time equivalents located in Switzerland (2023: 75.3), and 14 (2023: 12) full-time equivalents located in the United States.

**D. Net Finance Expense**

	2024	2023
Interest income	550	891
Interest on loans	(1,710)	(1,307)
Interest banks	-	-
Interest on lease liabilities	(6)	(5)
Amortisation of transaction costs on loan	(212)	-
Exchange losses	(523)	35
Bank charges	(15)	(6)
<b>Net Finance expense</b>	<b>(1,916)</b>	<b>(392)</b>

The increase is the result of interest expense on Runway Growth loan and corresponding transaction cost.



**E. Income Tax Expense**

	2024	2023
Current income tax	-	-
Deferred income tax	-	-
<b>Total corporate income tax in profit and loss</b>	<b>-</b>	<b>-</b>
Current income tax charge at tax rate of 25.8%	10,624	7,621
Non-deductible expenses	(1,664)	(38)
Permanent difference: Prior year adjustment	-	66
Non-recognized deferred tax asset on permanent differences	-	(203)
Net operating losses not recognized	(8,960)	(7,446)
	-	-

The effective tax rate was 0% in 2024 (2023: 0%), which is lower than the statutory income tax rate of 25.8% (2023: 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. In 2024, the correction of intercompany charges with the U.S. subsidiary relating to 2023, gives rise to the permanent difference. 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 5.45M (2023: EUR 6.64M) 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 2023	716	-	716
Additions	18	97	114
Disposal	-	-	-
<b>At 31 December 2023</b>	<b>734</b>	<b>97</b>	<b>830</b>
Additions	4	51	55
Disposal	-	-	-
<b>At 31 December 2024</b>	<b>738</b>	<b>148</b>	<b>885</b>

**Accumulated Depreciation**

	Office Equipment	Right-of-use-asset	Total
At 1 January 2023	(655)	-	(655)
Depreciation for the year	(49)	(9)	(58)
Disposal	-	-	-
<b>At 31 December 2023</b>	<b>(704)</b>	<b>(9)</b>	<b>(713)</b>
Depreciation for the year	(21)	(49)	(70)
Disposal	-	-	-
<b>At 31 December 2022</b>	<b>(725)</b>	<b>(58)</b>	<b>(783)</b>

**Net Book Value**

	Office Equipment	Right-of-use-asset	Total
At 31 December 2023	30	88	118
<b>At 31 December 2024</b>	<b>14</b>	<b>91</b>	<b>105</b>



**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.

	2024	2023
Cost	807	1,139
Accumulated impairments	-	-
<b>Net book value at 1 January</b>	<b>807</b>	<b>1,139</b>
Revaluations through OCI	(1,820)	(928)
Exchange differences	609	(155)
Group share-based payment scheme	2,350	2,416
Share in result of participating interests	5,659	(6,642)
Addition: license fees paid on behalf of subsidiary	-	-
Provision: negative participating interest	(5,233)	4,977
Net change	1,362	(332)
Cost	2,372	807
Accumulated impairments	-	-
<b>Net book value at 31 December</b>	<b>2,372</b>	<b>807</b>

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 recognizes 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.

	2024	2023
Indirect tax receivable	80	76
Receivables from related parties – group companies	5,124	25,596
Receivables from related parties – other	36	37
Other	362	239
Advance payments made	790	800
	<b>6,392</b>	<b>26,748</b>

The Company funds subsidiary operations, and the decrease in the receivable reflects the appropriation of cost allocations relating to the U.S. operations.

**J. Cash at Bank, in Hand & Fixed Term Deposits**

	2024	2023
Cash at bank	8,989	2,654
Short-term deposits	48,000	11,200
Cash at bank and in hand	<b>56,989</b>	<b>13,854</b>
Cash at bank, in hand, and fixed term deposits	<b>56,989</b>	<b>13,854</b>

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



**Company Financial Statements**

deposit rates. At 31 December 2024, the Group had no fixed term deposits or 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 2024, please refer to 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**

	<b>2024</b>	<b>2023</b>
Opening balance as at 1 January	5,233	256
Negative participating interest	-	4,977
Reversal of provision for negative participating interest	(5,233)	-
<b>Balance as at 31 December</b>	<b>-</b>	<b>5,233</b>

The prior year provision of EUR 5,233k relating to the negative participating interest was reversed in the current year due to correction of intercompany recharge with the U.S. subsidiary.

**M. Non-Current Liabilities**

	<b>2024</b>	<b>2023</b>
<b>Balance as at 31 December</b>	<b>14,015</b>	<b>15,297</b>
	<b>2024 Others</b>	<b>2024 Runway Growth</b>
<b>Loan as at 1 January</b>		<b>2024 Innovation Loan</b>
Loan amount received		-
Interest/cumulative dividend accrued during the year		15,255
Transaction cost amortization		-
Loan amount repaid during the year		-
Interest paid during the year		14,116
Warrants issued to lender		944
Long term lease liability and others	43	212
<b>Net book value as 31 December</b>	<b>43</b>	<b>13,972</b>

**N. Current Liabilities**

Amounts due to Group companies recognized as financial liabilities at amortized cost as per the policy in the consolidated financial statements.

	<b>2024</b>	<b>2023</b>
Trade payables	471	734
Tax liabilities	31	4
Payables from related parties	-	-
Other payables	2,419	970
Grant-related payables	430	1,358
Warrants issued to lender	437	-
	<b>3,788</b>	<b>3,066</b>



**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:

**EY Accountants B.V**

	<b>2024</b>	<b>2023</b>
Audit of financial statements	362	259
Other assurance services	10	-
	<b>372</b>	<b>259</b>

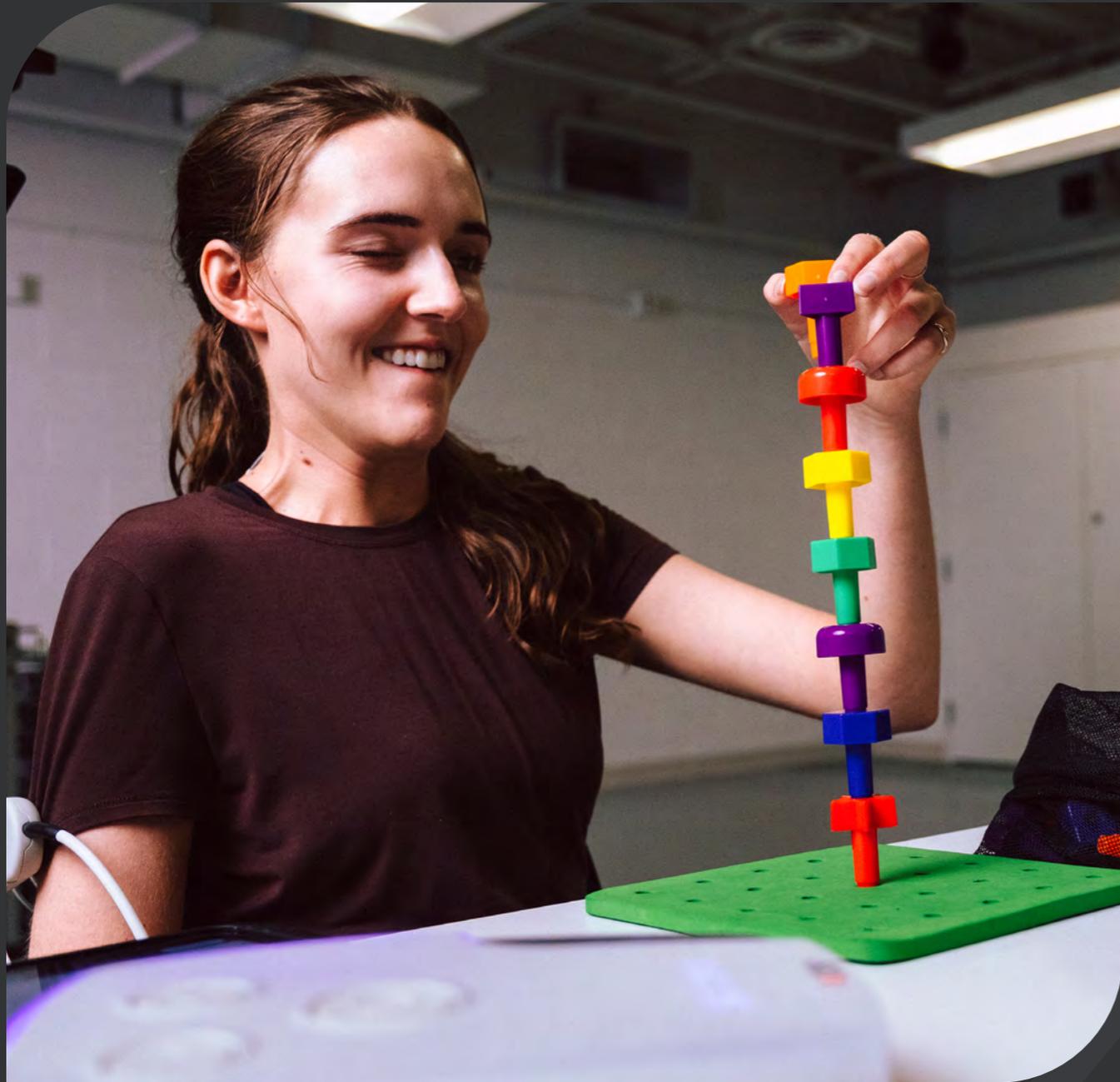
**Q. Subsequent Events**

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<sup>®</sup>

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 2024 included in the annual report

### Our opinion

We have audited the accompanying financial statements for the financial year ended 31 December 2024 of ONWARD Medical N.V. based in Amsterdam, the Netherlands.

The financial statements comprise the consolidated financial statements and the company financial statements.

In our opinion:

- The consolidated financial statements give a true and fair view of the financial position of ONWARD Medical N.V. as at 31 December 2024 and of its result and its cash flows for 2024 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 company financial statements give a true and fair view of the financial position of ONWARD Medical N.V. as at 31 December 2024 and of its result for 2024 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 2024
- The following statements for the year ended 31 December 2024: the consolidated statements of profit and loss, comprehensive income, changes in equity and cash flows
- The notes comprising material accounting policy information and other explanatory information

The company financial statements comprise:

- The company balance sheet as at 31 December 2024
- The company statement of income for the year ended 31 December 2024
- 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. 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 for professional accountants).

We believe the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

**Material uncertainty related to going concern**

We draw attention to the Going concern paragraph in the notes in section 1.4 of the financial statements which indicates that while ONWARD Medical N.V. believes it has the necessary resources to fund operations for the foreseeable future, there is heightened uncertainty surrounding its revenue projections and financial obligations. These conditions indicate the existence of a material uncertainty which may cast significant doubt about the company’s ability to continue as a going concern. We refer to the section Our audit response related to going concern that describes how the going concern assumption and the relevant events and conditions that may cast significant doubt on the company’s ability to continue as a going concern were addressed in our audit. Our opinion is not modified in respect of this matter.

**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. (“the company” and, together with its consolidated subsidiaries, the “group”) is developing and commercializing innovative therapies to enable functional recovery for people with spinal cord injury. We paid specific attention in our audit to a number of areas driven by the operations of the group and our risk assessment.

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**

<b>Materiality</b>	€1.1 million (2023: € 1.1 million)
<b>Benchmark applied</b>	3% of operating expenses for the year ended 31 December 2024 (2023: 3%)
<b>Explanation</b>	R&D companies such as ONWARD Medical N.V. which are in the start-up phase, report no or modest revenues and the stakeholders expect the company to operate at a loss. The value that owners or others generally attribute to these companies is primarily based on the promise of future success of the products. Based on these factors we deem operating expenses to be a suitable benchmark, as it is one of the most important measures for the level of cash used in operating activities to support the advancement of the development and commercialization of the company’s products.

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 €52,500, 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 that consists of the headquarters in the Netherlands, ONWARD Medical S.A., the science and engineering center in Switzerland and ONWARD Medical Inc., the US-based field clinical and sales organization. The financial information of this group is included in the financial statements.

We are responsible for planning and performing the group audit to obtain sufficient appropriate audit evidence regarding the financial information of the entities or business units within the group as a basis for forming an opinion on the financial statements. We are also responsible for the direction, supervision, review and evaluation of the audit work performed for purposes of the group audit. We bear the full responsibility for the auditor’s report.

Based on our understanding of the group and its environment, the applicable financial framework and the group’s system of internal control, we identified and assessed risks of material misstatement of the financial statements and the significant accounts and disclosures. Based on this risk assessment, we determined the nature, timing and extent of audit work performed, including the entities or business units within the group (components) at which to perform audit work. For this determination we considered the nature of the relevant events and conditions underlying the identified risks of material misstatements for the financial statements, the association of these risks to components and the materiality or financial size of the components relative to the group.

As the processes of the group are highly centralized and all transactions are initiated, recorded, processed and reported on central level, we performed the audit work centrally ourselves for all three components of the group.

This resulted in a coverage of 100% of the net loss for the period, 100% of total operating expenses and 100% of total assets.

By performing the audit work mentioned above for the entities or business units within the group, together with additional work 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 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 turnaround and restructuring specialists, actuaries and specialists in the areas of IT audit, forensics, share based payments, valuation of intangible assets and derivatives and income tax.

**Our audit response related to going concern**

We refer to the section ‘Material uncertainty related to going concern’ above. Based on our procedures performed, we concluded that a material uncertainty exists which may cast significant doubt about the company’s ability to continue as a 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.

The board of directors evaluated the expected cash flows and 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 ‘Going Concern’ to the consolidated financial statements, the forecast includes significant expenditures relating to the development and commercialization of the company’s products. The board notes heightened uncertainty surrounding it’s revenue projections and finance obligations, which may impact continued compliance with loan covenants. This indicates the existence of material uncertainties about the company’s ability to continue as a going concern. The company explores additional fundraising options.

We further refer to Section ‘Risk-Management and Control’ of the annual report that includes the detailed description of the ‘Risks related to the Company’s financial position, need for additional capital and taxation’. 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 involved our Turnaround and Restructuring Specialists and specifically focused on, among other things, the impact of the events and conditions that are relevant for the company’s ability to continue as a going concern and mitigating factors, significant assumptions, the process followed by the board



of directors to make the specific assessment and management bias that could represent a risk of material misstatement.

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. Furthermore, we evaluated the forecasted cash flows and the substantiation for significant assumptions, with a focus on whether the company will have sufficient liquidity to continue to meet its obligations as they fall due and will continue to comply with loan covenants in the next twelve months and the foreseeable future. We have specifically assessed the potential impact of non-compliance on the cashflow forecast. Furthermore, we have performed sensitivity analyses on revenue projections to assess the impact on the cashflow forecasts and continued compliance with loan covenants. Finally, we evaluated relevant disclosures and considered whether relevant events and conditions, mitigating factors and significant assumptions related to going concern have been disclosed and particularly whether these disclosures adequately convey the degree of uncertainty.

**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 the board of directors’ process for responding to the risks of fraud and monitoring the system of internal control, as well as the outcomes.

We refer to Section ‘Risk-Management and Control’ of the annual report for the board of directors’ risk assessment after consideration of potential fraud risks.

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, whistle blower procedures and incident registration. 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 organizations. For these risks we have among other things performed procedures 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 “Significant Accounting Judgments, Estimates and Assumptions” to the consolidated financial statements, including research & development, share-based payments, impairment of intangible assets, post-employment benefits and 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 did not identify a risk of fraud in revenue recognition, other than the risks related to management override of controls.



We considered available information and made enquiries of relevant executives, directors, legal, and human resources.

The fraud risk 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 received a confirmation that there were no legal cases. We inspected the correspondence with regulatory authorities and 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 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 matters to the board of directors. The key audit matters are not a comprehensive reflection of all matters discussed.

In addition to the matters described in the ‘Material uncertainty related to going concern’ section, we identified the following key audit matter. 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 2024, ONWARD Medical N.V. carried an intangible assets balance of € 10.4 million, consisting of goodwill (€ 2 million), in-process R&D (€ 6.1 million) and license fees (€ 2.4 million). The goodwill as well as the in-process R&D and license fees relate to the acquisition of ONWARD Medical Inc. in 2019.

As disclosed in Note 3.0 ‘Intangible Assets’ to the consolidated financial statements, pursuant to IAS 36 ‘Impairment of Assets’, the company 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. Key assumptions used in the impairment test are the cashflow forecast based on the expectation of regulatory approvals of the company’s products, the growth rate and discount rate.

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.

Moreover, as discussed in Section ‘Risk-Management and Control’ of the annual report, sub-section ‘Risks related to the Company’s financial position, need for additional capital and taxation’, substantially all of the assets of the company are pledged to Runway Growth LLC. Should the Company default on the loan covenants, Runway could enforce its pledge on these assets.

For these reasons, we consider this a key audit matter.



**Our audit approach**

We evaluated the appropriateness of the company’s accounting policies relating to the valuation and impairment testing of intangible assets in accordance with IAS 36 and whether the methods for making estimates are appropriate and have been applied consistently or whether changes, if any, are appropriate in the circumstances.

As part of our audit procedures, we audited the assumptions and methodologies used by the company to prepare the cashflow forecast, as well as the robustness of the company’s forecasts. We specifically focused on the risk of not achieving regulatory approvals and whether a reasonable possible change in the assumptions could trigger an impairment.

In order to assess the reasonability of the valuation model and input data, including the growth rate and discount rate, we have among others performed the following procedures with assistance of specialists:

- 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 also evaluated the adequacy of the company’s disclosure, including disclosures regarding assumptions and sensitivities as well as consistency between the going concern forecasts as disclosed in Note 1.4 to the consolidated financial statements 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 as at 31 December 2024.

**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 management 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 management 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 of directors 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.



**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 misstatements, whether due to fraud or error 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, 28 April 2025**

**EY Accountants B.V.**

**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 2024, 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: Amounts in EUR ‘000

	<b>2024</b>	<b>2023</b>
Cash at bank	60,043	3,568
Short-term deposits	-	26,200
<b>Cash and cash equivalents</b>	<b>60,043</b>	<b>29,768</b>
Fixed term deposits	-	-
	-	-
<b>Net cash</b>	<b>60,043</b>	<b>29,768</b>



**Definitions and Abbreviations**

The following definitions are used in this report:

<p><b>510(k)</b> Clearance under Section 510(k) of the FDCA (US)</p> <p><b>AGM</b> Annual General Meeting</p> <p><b>ASC</b> Ambulatory surgery centers</p> <p><b>BG</b> Berufsgenossenschaft</p> <p><b>BDD</b> 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</p> <p><b>Brain – Computer Interface (BCI)</b> 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</p>	<p><b>Caltech</b> California Institute for Technology</p> <p><b>Cardiovascular</b> Relating to the heart and blood vessels</p> <p><b>CARF</b> Commission of Accredited Rehabilitation Facilities</p> <p><b>CE</b> Conformité Européene (European medical device certification)</p> <p><b>Cervical</b> Relating to the neck or located around the neck area</p> <p><b>CEO</b> Chief Executive Officer</p> <p><b>DCGC</b> The Dutch corporate governance code issued on 8 December 2016</p> <p><b>Chairperson</b> The Chairperson of the Board</p>	<p><b>CHUV</b> Centre Hospitalier Universitaire Vaudois</p> <p><b>CRO</b> Contract research organizations</p> <p><b>DAPA</b> Distribution and Pricing Agreement</p> <p><b>DARPA</b> The US Department of Defense Advanced Research Projects Agency</p> <p><b>DCC</b> Dutch Civil Code</p> <p><b>DoD</b> U.S. Department of Defense</p> <p><b>DME</b> Durable Medical Equipment</p> <p><b>EBITDA</b> Earnings before interest, tax, depreciation and amortization</p> <p><b>ECAT</b> Electronic Catalog Contract</p>	<p><b>EEA</b> European Economic Area</p> <p><b>EPFL</b> École Polytechnique Fédérale de Lausanne</p> <p><b>Epidural</b> Placed or administered outside the dura mater</p> <p><b>ESEF</b> European Single Electronic Reporting Format</p> <p><b>EU</b> European Union</p> <p><b>FDA</b> U.S. Food and Drug Administration</p> <p><b>FDCA</b> U.S. Federal Food, Drug, and Cosmetic Act</p> <p><b>FSS</b> U.S. Federal Supply Schedule</p> <p><b>FTE</b> Full time equivalent personnel</p>
--	--	---	---



**GCP**  
Good Clinical Practice

**GDPR**  
General Data Protection Regulation

**GKV**  
Gesetzliche Krankenversicherung or GKV System (Public System)

**GSA**  
General Services Administration

**HCPCS**  
Healthcare Common Procedures Coding System

**HDE**  
Hilfsmittelverzeichnis

**HIPAA**  
Health Insurance Portability and Accountability Act

**HMV**  
Humanitarian Device Exemption

**hr**  
Hours

**Hypertension**  
Higher blood pressure than normal range

**Hypotension**  
Lower blood pressure than normal range

**IAS**  
International Accounting Standards

**ICD**  
International Classification of Diseases

**IFRS**  
International Financial Reporting Standards

**IFRIC**  
IFRS Interpretations Committee

**IPG**  
Implantable pulse generator

**k**  
Thousands

**KPI**  
Key performance indicator

**Lesion**  
A damaged region in the body

**LTIP**  
Long-Term Incentive Plan

**Lumbar**  
Relating to the lumbar region of the back

**M**  
Millions

**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**  
Training to restore function after an injury or neurological disorder

**NHS**  
National Health Service (UK)

**OPS**  
Procedure codes

**Orthostatic hypotension**  
Hypotension tied to posture or postural changes

**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

**PBS**  
Public Broadcasting System (U.S.)

**Perfusion**  
Passage of a fluid (blood, water) through blood vessels, tissue or organ

**PMA**  
U.S. FDA 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

**SCS**

Spinal cord stimulation

**SDVOSB**

Service-disabled veteran-owned small business

**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<sup>EX</sup> Therapy

**US**

United States

**USD**

US Dollar

**Vascular**

Relating to blood vessels



**ONWARD<sup>®</sup> MEDICAL**

Forward to **2025**

EMPOWERING  
MOVEMENT™

[onwd.com](http://onwd.com)

