

A man in a red t-shirt is smiling broadly while shaking hands with another person whose hand is visible on the right. They are in a gym or fitness studio, with a person in a white shirt visible in the background. The scene is dimly lit with a focus on the man in the foreground. A large, stylized red graphic element, consisting of several parallel curved lines, is positioned on the right side of the image.

**ONWARD**<sup>TM</sup>

**2021**  
Annual Report

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# ONWARD at a Glance

- Founded in 2015
- 75+ employees
- HQ in Eindhoven, the Netherlands
- Science and Engineering Center in Lausanne, Switzerland
- Growing US presence in Boston, Massachusetts
- IPO 2021, Euronext Brussels and Amsterdam
- 320+ patents issued or pending
- 3 FDA Breakthrough Device Designations

- 2 proprietary technology platforms
- Almost EUR 8 million invested in R&D in 2021
- Almost EUR 5 million invested in Clinical and Regulatory activities in 2021
- Enrollment completed in the company's first pivotal trial, Up-LIFT
- Robust future therapy pipeline
- Experienced, international management team



## Message from the Chairman & CEO

Dear Shareholders, Colleagues, Partners, and Collaborators,

It is a privilege to lead this company and its many wonderful employees, research collaborators, and business partners. Our work is important and meaningful, and together with you, we are working hard to make a difference in the lives of people with spinal cord injury (SCI).

Nearly 7,000,000 people worldwide have spinal cord injury<sup>1</sup>. 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. The quality of life following spinal cord injury can be quite poor for those injured and their loved ones who provide care. SCI is also an expensive condition, the average lifetime cost of care exceeding EUR 2.2 million (USD 2.5 million) for someone with paraplegia and EUR 4.4 million (USD 5.0 million) for someone with tetraplegia<sup>2</sup>.

Conventional rehabilitation does not offer sufficient promise, with most people reaching a plateau in their progress after three to six months. Thereafter, many of those injured face decades of continuing challenges, declines in quality of life, and dependence on outside care. ONWARD seeks to fill this void, bringing forward therapies that can improve strength, function, and quality of life even for those injured many years ago. Indeed, our vision is to help people across the range of challenges faced after a spinal cord injury.

### Our Vision

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

Our team is pursuing this vision with urgency and determination, developing ONWARD ARC Therapy with the intent to commercialize and make our solutions broadly available from 2023 in the United States and Europe. We have two technology platforms, one external (called ARC<sup>EX</sup>) and the other implantable (called ARC<sup>IM</sup>).

The work to complete and commercialize these platforms is aided by three FDA Breakthrough Device Designation awards and protected by over 320 issued or pending

patents worldwide. While many of these innovations were created by ONWARD's innovative R&D team, others have been exclusively licensed from the top neuroscience research universities in the world, underscoring ONWARD's position as pioneer and leader in our space.

With the completion of our successful initial public offering on Euronext in late 2021, we are now well capitalized and focused on fulfilling our vision to help people with spinal cord injury in their activities of daily life. We pledge to be good stewards of this capital and hope our many new investors enjoy good returns, financial and otherwise, from the journey you have undertaken alongside us.

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

We are proud of our many achievements in 2021 and we have an ambitious set of goals for 2022 and beyond. Please sign up for updates on our website or follow ONWARD on social media so we can keep you well informed of our progress throughout the year.



Warm regards,

Jan Øhrstrøm & Dave Marver

<sup>1</sup>Kumar et al. 2018, "Traumatic Spinal Injury: Global Epidemiology and Worldwide Volume"; *World Neurosurg.*, vol. 113, pp. e345-e363, May 2018, doi: 10.1016/j.wneu.2018.02.033.

<sup>2</sup>2020 NSCISC Annual Report, US



# 2021 Achievements

We made strong progress in 2021 in several important areas:

In January, we initiated our first pivotal trial to generate the clinical evidence required to submit for regulatory authorization to commercialize our therapies in the US and Europe. The trial, called Up-LIFT, is designed to evaluate the ability of our transcutaneous ARC<sup>EX</sup> therapy to restore strength and function in the hands and arms after spinal cord injury. In December, we completed enrollment of Up-LIFT with 65 subjects at 14 centers in the US, Canada, the UK, and the Netherlands. In our view, completing enrollment ahead of schedule in a year plagued by COVID-19 and its many challenges signals the enthusiastic response of the SCI clinical community to our therapy. We are currently optimizing our ARC<sup>EX</sup> technology platform with the expectation that we will receive regulatory authorization and permission to commercialize our transcutaneous therapy, enabling us to realize our first revenue in 2023.

Also in January, our science partners at EPFL in Lausanne, Switzerland and the University of Calgary in Canada published a seminal paper outlining the use of spinal cord stimulation to restore normal blood pressure in people suffering from orthostatic hypotension, a very common side effect of SCI. This paper was published in Nature, one of the world's premiere scientific journals. Blood pressure regulation and trunk (torso) control are the initial planned indications for our ARC<sup>IM</sup> implantable technology platform, and we have exclusively licensed much of the associated intellectual property from EPFL. The January Nature publication offers a rigorous scientific understanding of the mechanism of action for our blood pressure indication, in addition to providing a strong reference we can use when commercializing this therapy in the future.

In early 2021, we also received our third Breakthrough Device Designation award from the US Food and Drug Administration (FDA). These awards recognize devices that the FDA considers as truly innovative and that address an unmet need. The Breakthrough Device Designation provides for more frequent contact with FDA, more flexible clinical trial design, and a streamlined approval process. ONWARD now has three such awards, underscoring the pioneering nature of our therapies.

Perhaps our most impactful achievements in 2021 were in fundraising. We raised a successful pre-IPO financing in the form of a EUR 30 million convertible note in early 2021, followed by a EUR 80 million initial public offering on Euronext Brussels and Amsterdam in late October. We expect these financings to provide the company with capital through the end of 2024, supporting our development activities, conduct of clinical trials, and preparation for commercialization.



# Overview

ONWARD's mission is to enable people with spinal cord injury to regain movement and other functions so they may enjoy life in every way that matters to them. We develop and plan to commercialize therapies that address major challenges faced by people with SCI, leveraging the Company's ARC<sup>IM</sup> and ARC<sup>EX</sup> platforms to deliver spinal cord stimulation for SCI patients across a broad spectrum of injury locations and impairment severities. While the Company's primary objective will be 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 strokes, or have Parkinson's disease or other neurodegenerative disorders. We also aim to reward those who invest their capital, time and ideas in our Company, while engaging in sustainable, equitable, and inclusive business practices.

## The Case for Innovative Neurostimulation Therapies

Seven million people worldwide have a spinal cord injury. The annual global incidence exceeds 768,000. In the US and Europe, there are approximately 650,000 people with SCI and the annual incidence is approximately 50,000, including 31,000 in Europe<sup>2</sup> and around 18,000 in the US<sup>3</sup>.

This results not only in disability and poor health for individuals, but also in significant costs for economies, due to lost productivity and high healthcare costs. The average lifetime cost to support a person with a severe spinal cord injury can exceed EUR 4.4 million.

Currently, the neuromodulation market is comprised primarily of revenues from spinal cord stimulation for pain management and deep brain stimulation for epilepsy and Parkinson's disease. Market revenues totaled USD 8.2 billion in 2019 and were projected to grow at more than 15% over the following five years.

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

<sup>2</sup>Kumar et al. 2018, "Traumatic Spinal Injury: Global Epidemiology and Worldwide Volume", *World Neurosurg.*, vol. 113, pp. e345-e363, May 2018, doi: 10.1016/j.wneu.2018.02.033.

<sup>3</sup>National Spinal Cord Injury Statistical Center, *Facts and Figures at a Glance*. Birmingham, AL: University of Alabama at Birmingham, 2019.



## The SCI market is large and underserved



## Market – A Large Unmet Medical Need



<sup>1</sup> 2020 NSCISC Annual Statistical Report Complete Public Version

<sup>2</sup> European prevalence calculated by annual incidence\* 25 years of additional lifetime expectancy

<sup>3</sup> Kumar et al. 2018, Traumatic Spinal Injury: Global Epidemiology and Worldwide Volume.

(traumatic spinal injury is broader than traumatic spinal cord injury).



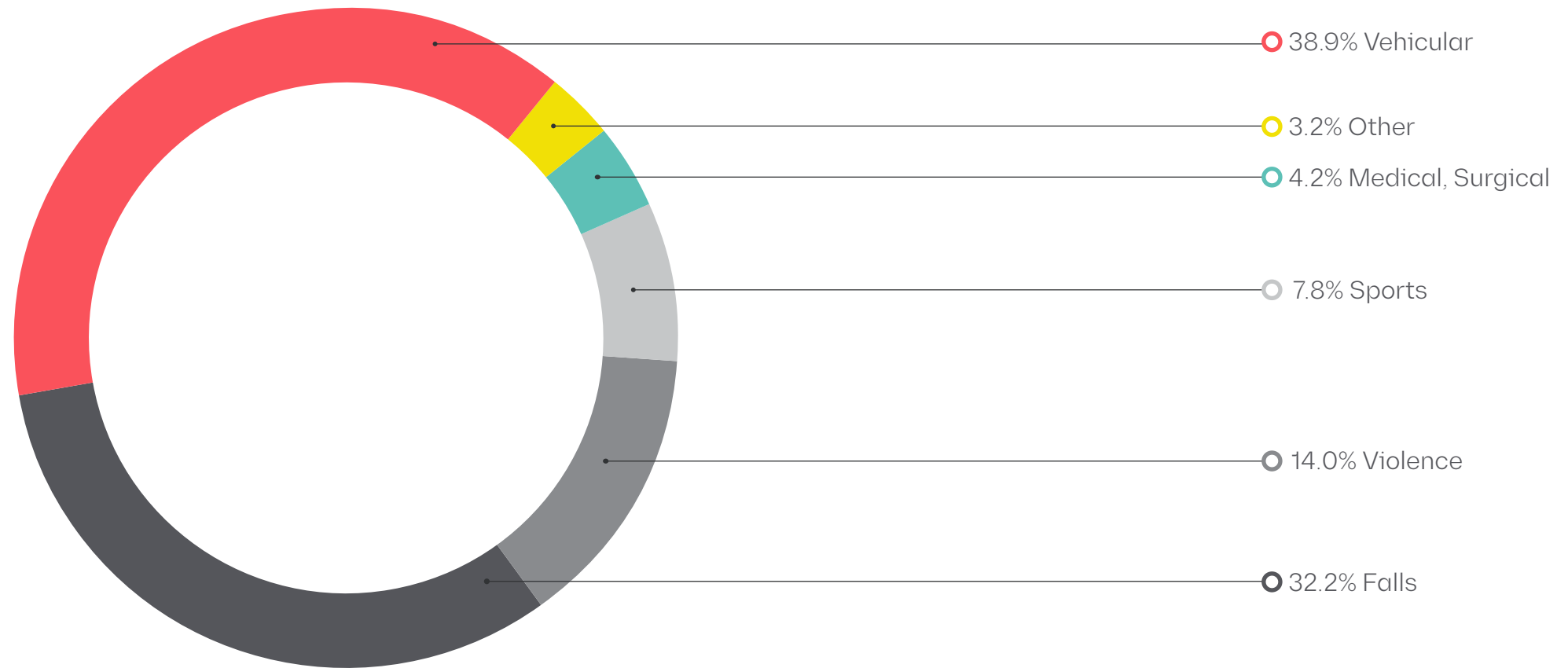
# Damage to the spinal cord resulting in loss of function

# SCI Causes & Patient Profile

## Profile of SCI Patient

- Nearly half of the injuries occur between the ages of 16 and 30 years<sup>1</sup>
- 78% of new SCI cases are male<sup>1</sup>

## SCI Causes



Source: (1) 2020 NSCISC Annual Statistical Report Complete Public Version





Overview

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

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

**\$8.2B** (2019)      **15.4% CAGR** (2020 - 2026)

Spinal cord stimulation and DBS are most well developed current applications

**\$2.9B** (2019)      **8.0% CAGR** (2020 - 2026)

**Growth Trends:**

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

Sources: Global Market Insights Neurostimulation Devices Market; Fortune Business Insights Spinal Cord Stimulation Market; Harmsen I, E, Hasanova D, Elias G, J, B, Boutet A, Neudorfer C, Loh A, Germann J, Lozano A, M: Trends in Clinical Trials for Spinal Cord Stimulation. Stereotact Funct Neurosurg 2021;99:123-134; Johnson RL, Wilson CG. A review of vagus nerve stimulation as a therapeutic intervention. J Inflamm Res. 2018;11:203-213. Mayo Clinic

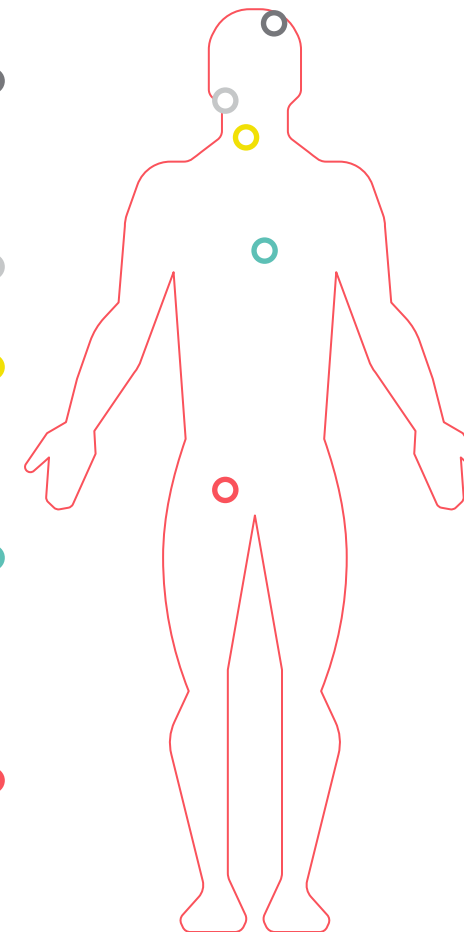
# Neurostimulation Market

**FDA Approved**

- Deep Brain Stimulation** ◯  
Dystonia, Epilepsy, Essential tremor, Obsessive-compulsive disorder, Depression, Parkinson's disease
- Hypoglossal Nerve Stimulation** ◯  
Sleep apnea
- Vagus Nerve Stimulation** ◯  
Depression, Epilepsy
- Spinal Cord Stimulation** ◯  
Pain management
- Sacral Nerve Stimulation** ◯  
Urinary incontinence, Fecal incontinence

**Emerging**

- Deep Brain Stimulation** ◯  
Addiction, Chronic pain, Cluster headache, Dementia, Depression (major), Huntington's disease, MS, Stroke, Tourette, Traumatic brain injury, Sleep disorder, Autism
- Vagus Nerve Stimulation** ◯  
Alzheimer's, Obesity, Lung injury, Cardiovascular disease, Stroke, Diabetes, Anxiety, Pain management
- Spinal Cord Stimulation** ◯  
Mobility, blood pressure control, bladder and bowel control, trunk control, upper limb function, sexual function, spasticity
- Sacral Nerve Stimulation** ◯  
Interstitial cystitis



# Our Strategy

Our strategy is to build an enduring, impactful, and successful medical device company that makes a meaningful difference in the lives of people with spinal cord injury and their loved ones.

1. Work with leading neuroscience researchers across the globe to identify breakthrough therapies for people with spinal cord injury and other movement-related challenges.
2. Leverage our R&D and regulatory capabilities to develop proprietary technologies that are well suited to deliver our breakthrough therapies at scale; protect these innovations via rigorous IP prosecution.
3. Commercialize these breakthrough therapies in our target markets using a direct channel into SCI clinics and hospitals with functional neurosurgery expertise.

The stages for the execution of our strategy are as follows:



# 1. Research & Preclinical Development

ONWARD has relationships with several leading academic research centers throughout the world. Examples include Caltech (USA), University of California at Los Angeles (USA), University of Louisville (USA), and University of British Columbia (Canada). The Company's primary research partnership is with .NeuroRestore, a joint research initiative involving École polytechnique fédérale de Lausanne ("EPFL") and Centre Hospitalier Universitaire Vaudois ("CHUV") in Lausanne, Switzerland, with whom the Company has an exclusive IP and commercialization license agreement.

NeuroRestore's range of research activities is extensive, extending across a continuum that encompasses basic research, preclinical research that includes rodents and non-human primates, and human proof-of-concept studies across its network of advanced research facilities in Switzerland. Several projects that could potentially be commercialized have shown sufficient promise to reach the human proof of concept stage. The Company will select the most promising of these projects to develop and commercialize, based primarily on clinical results and commercial viability. Each of the potential indications can leverage the existing ARC™ platform with minor software and firmware modifications.

The .NeuroRestore team has published extensively in some of the most prestigious scientific journals. In 2018, Professor Courtine and colleagues published clinical results in NATURE demonstrating for the first time in humans that motor control and the ability to walk continuously for at least 20 and up to 90 minutes could be restored even after complete paralysis. These results were obtained using an implantable platform consisting of an IPG and epidural lead. In January 2022, the latest results were published in NATURE MEDICINE. Three participants with complete sensorimotor spinal cord injury (AIS-A) who could neither contract their leg muscles nor take a single step were implanted with a new lead developed by ONWARD. On the first day following implant, all participants were able to take steps independently on a treadmill with body weight support. After 5 months of rehabilitation, participants were able to use their legs to stand, walk, swim, and/or cycle. They also regained control of their trunk muscles. This recovery of leg and trunk motor function also enabled participants to stand independently in community settings.

.NeuroRestore is led by Professor Grégoire Courtine and Neurosurgeon Jocelyne Bloch, who founded ONWARD's predecessor entity in 2014 alongside other researchers in neuroscience and neurosurgery at EPFL and CHUV. Professor Courtine also serves as ONWARD's Chief Science Officer.

Research & Preclinical Development

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



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



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

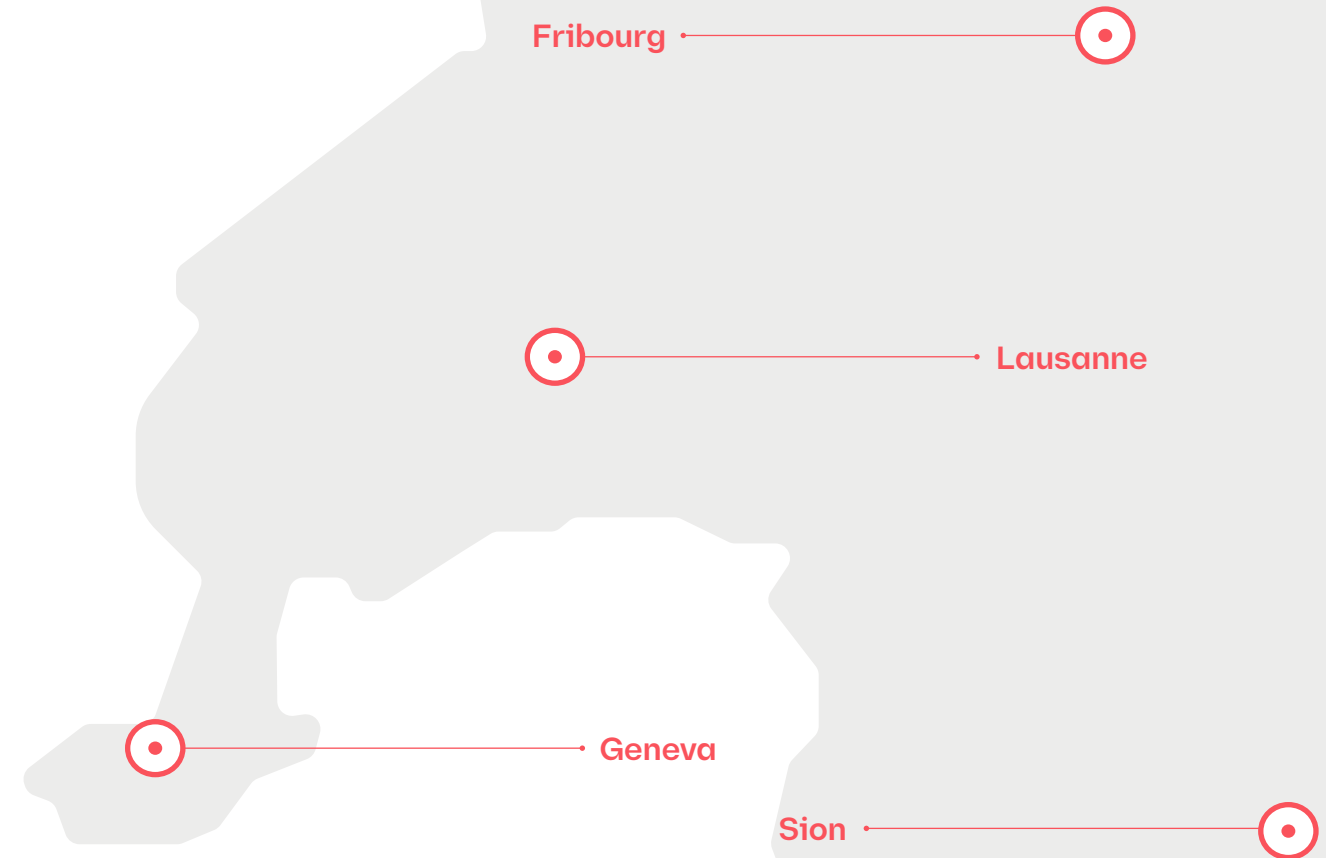


**Suva – Sion**  
Specialized Center for Acute Spinal Cord Injury



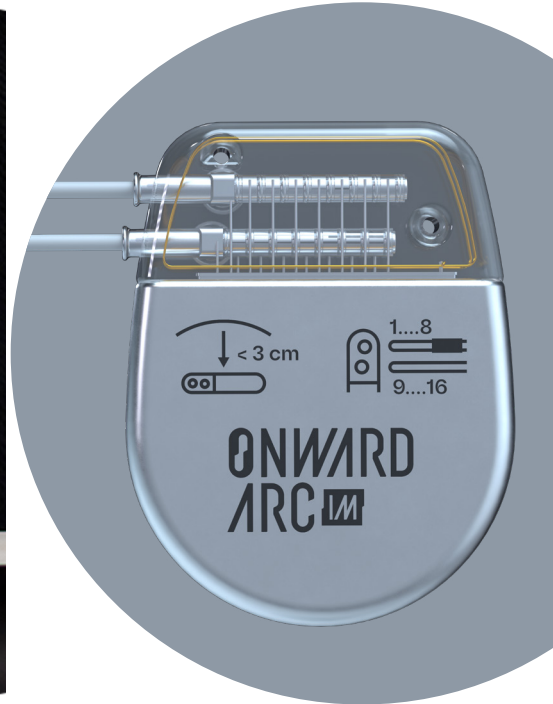
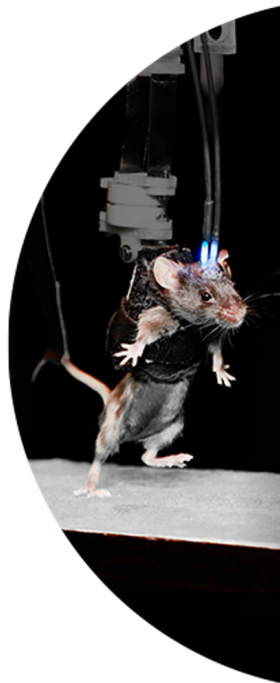
**UNIFR – Fribourg**  
University of Fribourg  
Pre-Clinical Center

# Network of Advanced Research Facilities





Research & Preclinical Development



**Basic**  
Mechanisms

**Preclinical**  
Therapy

**Translation**  
Scale Up

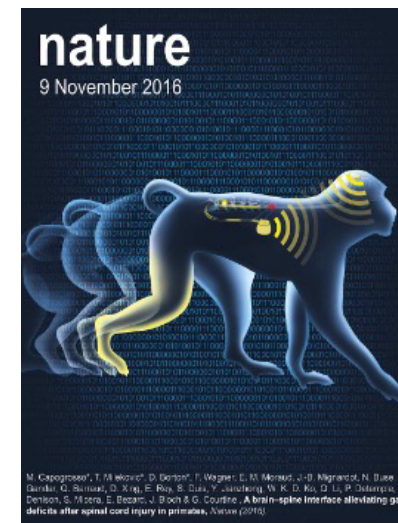
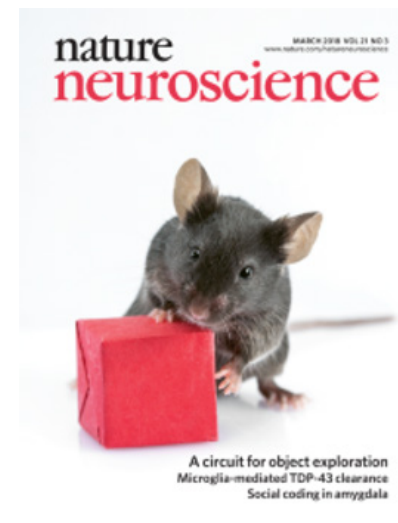
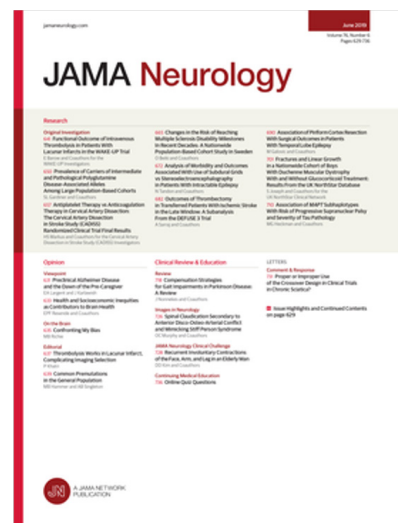
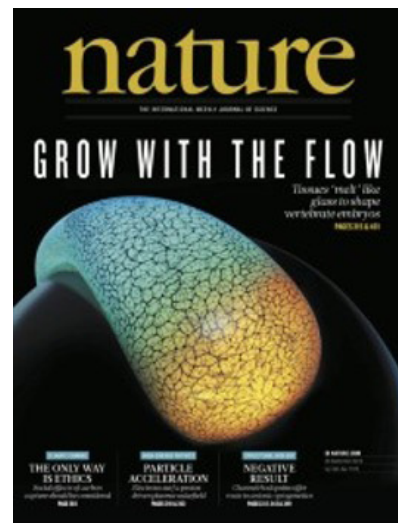
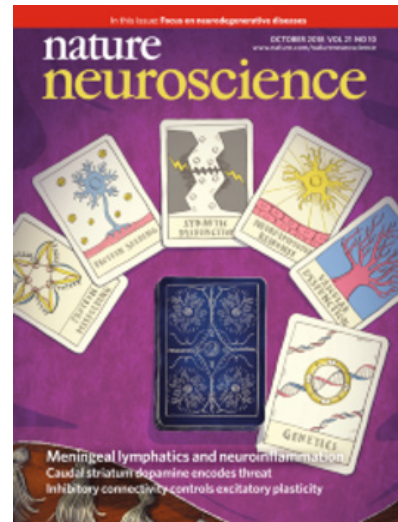
**Clinical**  
Proof of Concept

**Commercial Engine**  
Therapy



Research & Preclinical Development

High quality research underlies our therapies, validated by caliber of .NeuroRestore’s publications





## Research & Preclinical Development

### ARC Therapy: A Breakthrough in Neuromodulation Technology

ONWARD's ARC Therapy applies targeted, programmed stimulation of the spinal cord to restore movement, independence, and health in people with spinal cord injury. The stimulation can be delivered by an implantable platform, called ARC<sup>IM</sup>, or an external, transcutaneous platform, called ARC<sup>EX</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 – or both – in these areas. Functions and organs controlled by the autonomic nervous system may also be affected, leading to difficulty with breathing, swallowing, blood pressure regulation, sexual arousal, and bowel and bladder function. 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 spinal cord injury, some neural pathways in the spinal cord remain intact but inactive. At present, rehabilitation after SCI aims to mobilize these latent nerve connections and promote regeneration through intensive physiotherapy. Unfortunately, these activity-based therapies have few 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 or 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, higher-quality lives. This is where ONWARD's ARC Therapy has the potential to make a dramatic impact.

### ARC Therapy Activates Intact Nerve Fibers With Biomimetic Stimulation

By delivering precisely timed and calibrated 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 volition, this enables users to improve motor control in the arms, legs, or trunk, making daily activities, like moving in and out of a wheelchair, much easier. Moreover, programmed neurostimulation has the potential to improve the management of internal functions, chief among them blood pressure, and bowel and bladder control.

The technology developed by ONWARD is based on pioneering research carried out over the last two decades by Prof. Grégoire Courtine at the Ecole Polytechnique Fédérale de Lausanne (EPFL) and Dr. Jocelyne Bloch, Neurosurgeon at the Centre Hospitalier Universitaire Vaudois (CHUV), along with their colleagues at .NeuroRestore, ONWARD's research partner described in the above section.

Using advanced imaging technologies, Prof. Courtine, Dr. Bloch, and the .NeuroRestore team identified the exact location of the spinal cord neurons that are activated during locomotion. This enabled them to deliver targeted electrical impulses to trigger the contraction of specific muscles, in a programmed sequence corresponding to the desired movement.<sup>5</sup>

Most participants in clinical trials using ARC Therapy regain some degree of independent movement even when the stimulation is switched off. This remarkable result can be explained by the fact that 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 remarkable plasticity of the nervous system.

Using a similar approach, .NeuroRestore, identified the precise area in the lower thoracic spinal cord responsible for increasing vascular resistance and normalizing blood pressure in the event of orthostatic hypotension (a rapid fall in blood pressure that may occur when sitting upright, standing, or changing body position).<sup>6</sup> ONWARD is building on these insights to adapt its ARC<sup>IM</sup> system to address blood pressure regulation.



## Research & Preclinical Development

### Three Priority Indications to Improve Quality of Life After SCI

#### Upper Limb Mobility

Since 2015, 60% of new spinal cord injuries in the US have resulted in some form of tetraplegia<sup>7</sup>. Injuries at the level of the cervical section 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 living (tasks as simple as grooming and eating) are extremely challenging. Better arm and hand function is therefore an important rehabilitation goal for a majority of the SCI community, consistently ranked ahead of walking or sexual function.

In December 2021, we completed enrollment in our first pivotal trial, Up-LIFT, which aims to evaluate the ability of our transcutaneous ARCEX therapy to restore strength and function in the hands and arms for people living with chronic cervical spinal cord injury. Previous small-scale pilot studies using a clinical version of our device demonstrated performance gains in one or more of the various outcome measures. Functional gains were also noted, such as the ability to pick up and hold objects, manage the use of an object such as a pen or a utensil, or perform a new task.

#### Blood Pressure Regulation

The inability to regulate blood pressure following an SCI has profound consequences at both the acute and chronic stages, affecting nearly 75% of people with spinal cord injury.<sup>8</sup> Immediately after injury, blood rushes to the area of the lesion and causes swelling, which starves the nerve cells of oxygen, compounding the initial damage. The outcome for many patients may be vastly improved if clinicians could intervene immediately to prevent this process 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, chronic hypotension, and a life-threatening form of hypertension called autonomic dysreflexia. The chronic condition of hypotension affects a person's ability to perform everyday movements like sitting up or leaning over. It can also inhibit a person's ability to engage in activity-based rehabilitation.

The spinal implant, or lead, developed by ONWARD for this purpose has the potential not only to normalize blood pressure, but also, thanks to its placement in the thoracic area, to improve the tone and control of the trunk muscles for people with cervical injuries. Trunk control is essential to maintain stability when seated, making activities like eating or dressing much easier.





## Research & Preclinical Development

### Lower Limb Mobility

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

Starting in 2016, nine participants 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, more remarkably, to stand and walk at will even while the stimulation was inactive.

While walking may seem like an ambitious goal for many, even modest gains in lower limb function can make a big difference. Incorporating ARC™ 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 perform a variety of everyday movements such as standing briefly to place a wheelchair in a car.

<sup>4</sup>Wagner, F.B., Mignardot, J.B., Le Goff-Mignardot, C.G. et al. Targeted neurotechnology restores walking in humans with spinal cord injury. *Nature* 563, 65–71 (2018). doi: 10.1038/s41586-018-0649-2.

<sup>5</sup>Squair, J.W., Gautier, M., Mahe, L. et al. Neuroprosthetic baroreflex controls hemodynamics after spinal cord injury. *Nature* 590, 308–314 (2021). <https://doi.org/10.1038/s41586-020-03180-w>

<sup>6</sup>National Spinal Cord Injury Statistical Center (NSCISC), *Facts and Figures at a Glance, 2021* ([www.nscisc.uab.edu](http://www.nscisc.uab.edu))

<sup>7</sup>National Spinal Cord Injury Statistical Center (NSCISC), *Facts and Figures at a Glance, 2021* ([www.nscisc.uab.edu](http://www.nscisc.uab.edu))

<sup>8</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





## 2. Two Platforms, One System

ONWARD has developed two targeted, programmable neurostimulation platforms: an implantable system, ARC<sup>IM</sup>, and a non-invasive, transcutaneous system, ARC<sup>EX</sup>, both of which have been awarded FDA breakthrough device designation for a range of indications.

Both systems contain the same basic elements: an electrical impulse generator, electrodes placed in proximity to the spinal cord, either externally or internally, and a control system that enables clinicians to program the stimulation and users to set some therapy parameters.

The two ARC Therapy 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. We envision that both ARC<sup>IM</sup> and ARC<sup>EX</sup> may be used to treat someone with SCI, for example leveraging ARC<sup>IM</sup> for blood pressure regulation while using ARC<sup>EX</sup> for upper limb training.

ARC<sup>IM</sup> has four components (Fig 1 on next page<sup>9</sup>):

1. An **epidural lead** implanted next to the spinal cord in the area corresponding to the movement or function being targeted by the therapy. ONWARD is currently developing a family of leads that are optimized for placement in different areas of the spinal cord, both in terms of their shape and the placement of the electrodes.
2. An **implantable pulse generator** (IPG) implanted under the skin in the abdominal area and connected to the lead through a wire. When switched on, this pacemaker-like device delivers precisely timed and calibrated bursts of electricity to specific electrodes in the lead.
3. An **external control hub** that connects wirelessly to the IPG to turn therapy on or off, set the frequency and intensity of the impulses, and recharge the device through the skin. The hub is small enough to be worn around the neck or clipped to a belt.
4. A **digital interface** that doctors and physiotherapists can use to select a stimulation program and calibrate it using a tablet or computer connected wirelessly to the control hub. ONWARD expects to use mobile phone and smartwatch technology to enable users to turn the stimulation on or off and adjust certain parameters using voice commands.

<sup>9</sup>The smartwatch in the graphic may be a smartphone once development has been completed

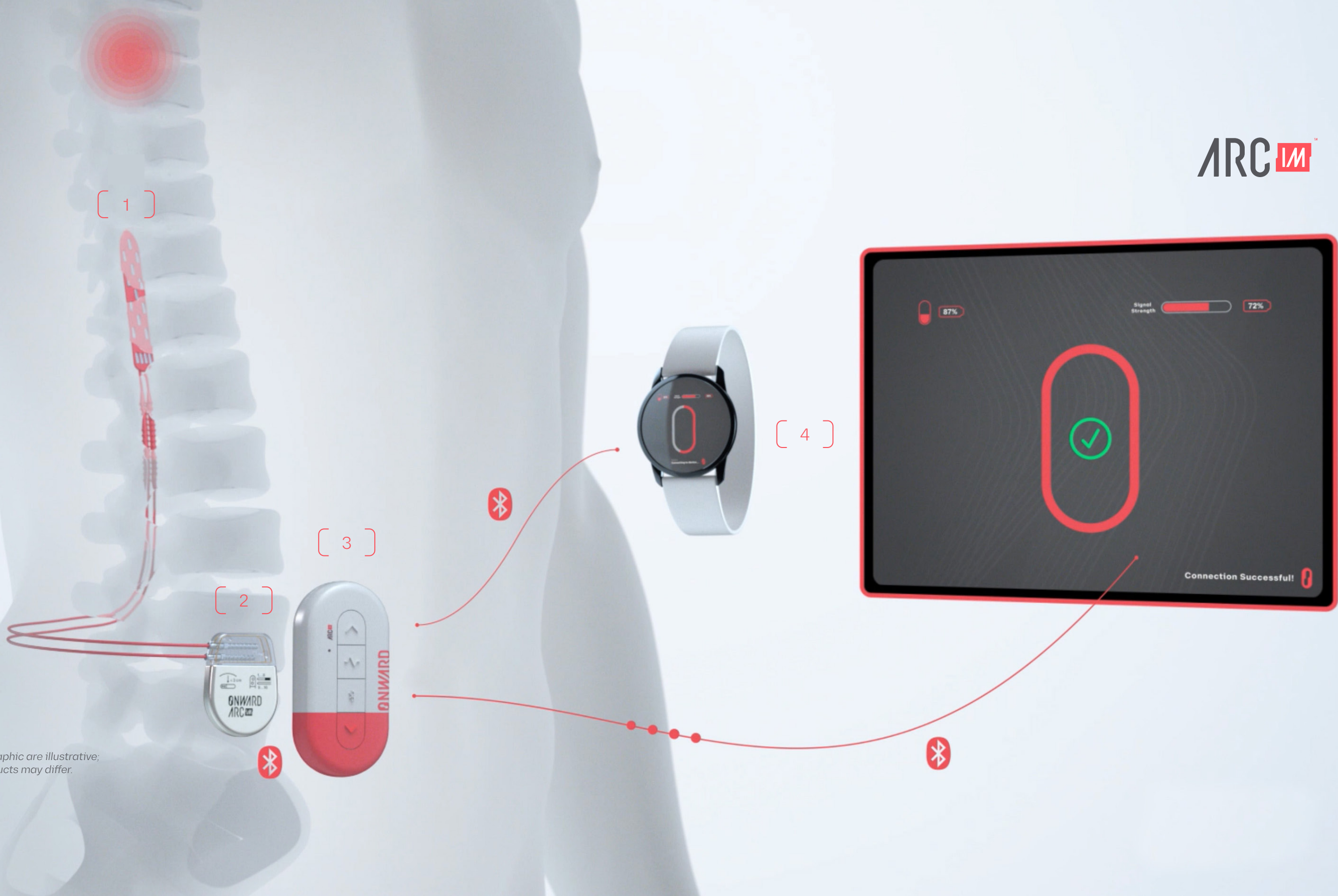
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Note:  
The renderings in the above graphic are illustrative;  
the design of commercial products may differ.

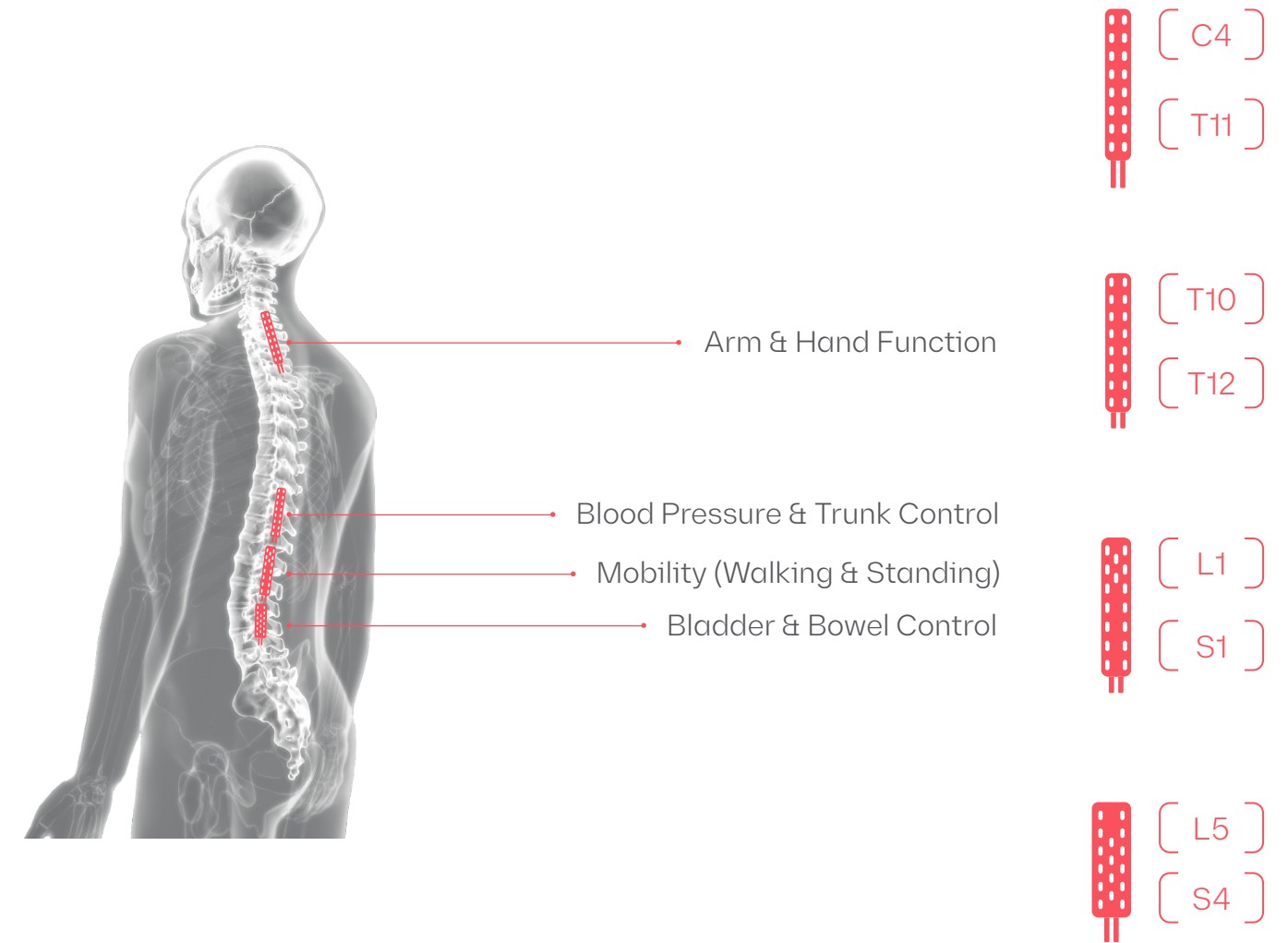


**ARC Therapy**



**ARC™ Leads**

ARC™ is currently targeted toward improving blood pressure regulation and trunk control and restoring the ability to stand and walk again. Other potential indications may be explored in the future, including spasticity reduction, improved sexual function, bladder control, and bowel control, each enabled by further development of ONWARD's proprietary lead portfolio.



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







**ARC<sup>EX</sup>** is targeted toward improving strength and function of the upper limbs. It is designed to be used periodically for 20 or 30 minutes in rehabilitation sessions in the clinic and, at a later stage, at home. In the future, ARC<sup>EX</sup> may be used to targeted additional indications, such as trunk control and mobility.

**ARC<sup>EX</sup>** has three components:

- **External patch electrodes** placed on the skin of the neck near the area of the spinal cord that controls movement in the arms and hands.
- A **stimulator** that delivers programmed electrical impulses directly to the electrodes through a lead.
- A **digital interface** with similarities to the interface found in the ARC<sup>IM</sup> system, which connects wirelessly to the stimulator to adjust its parameters.

### **ARC<sup>EX</sup> Non-Invasive Platform**

External system for transcutaneous stimulation of the spinal cord



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



## 3. Clinical Trials & Regulatory Approvals

The development, manufacture, and marketing of ONWARD ARC Therapy and associated technology is subject to government regulation in the United States, Europe and other countries. To apply for regulatory clearance or approval to market our devices in any of these jurisdictions, we must complete extensive human clinical trials that demonstrate their safety and efficacy. In the US, clinical trials are a requirement for Premarket Approval (PMA) and increasingly also for de novo clearance and 510(k) submission, all of which we expect to pursue for our various ARC Therapies. Similarly, under the European Medical Device Regulation (MDR) clinical investigations are required in view of completing conformity procedures to get a CE mark, a prerequisite for marketing the device in the EEA.

### FDA Regulatory Process

To obtain FDA approval for a medical device, companies must complete several steps:

1. Determine the device's classification (Class I, II or III)

In the US, ARC<sup>IM</sup> is a Class III<sup>10</sup> device that will require PMA approval, although for at least one indication it may pursue HDE approval. ARC<sup>EX</sup> is expected to be a Class II device.

2. Develop the prototype and conduct preclinical testing.
3. Conduct human clinical trials (early feasibility studies, followed by feasibility studies and then by pivotal studies) and improve the prototype along the way based on study results.

In the US, clinical trials of investigational devices must be conducted in accordance with the FDA's investigational device exemption (IDE) regulations, which govern labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting, and monitoring responsibilities of study sponsors and investigators.

If the device presents a "significant risk" to human health, as defined by the FDA<sup>11</sup>, the device sponsor must submit an IDE application, supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE and may pose additional requirements for the conduct of the study.

Once the IDE application is approved by the FDA and relevant IRBs, human clinical trials may begin at a specific number of sites and with a specific maximum number of patients.

If the device presents a non-significant risk to human health, the sponsor may begin the clinical trial after obtaining approval of one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements.

ONWARD will submit an IDE application for the ARC<sup>IM</sup> Blood Pressure and Mobility indications. For ARC<sup>EX</sup> Upper Limbs indication, ONWARD will follow abbreviated IDE requirements.



## Clinical Trials & Regulatory Approvals

During the study, ONWARD, as the study sponsor, is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, and ensuring IRB review and adverse event reporting. The clinical investigators we work with are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements.

4. Submit a pre-market notification or application, in case of a Class II or Class III device, which can be one of the following:
  - a. 510(k): a premarketing submission to demonstrate equivalence to existing device(s) to obtain clearance that the device to be marketed is safe and effective.
  - b. Premarket Approval (PMA), an application containing sufficient valid scientific evidence to provide reasonable assurance that the device is safe and effective for its intended use or uses.
  - c. Humanitarian Device Exemption (HDE), an approval pathway created by the FDA for humanitarian use device (HUD) intended to treat or diagnose a disease or condition that affects fewer not more than 8,000 individuals in the US per year. The HDE application is similar in both form and content to the PMA application, but is exempt from the PMA's effectiveness requirements.
  - d. De novo classification, also known as the Evaluation of Automatic Class III Designation. Created under the Food and Drug Administration Modernization Act of 1997 (FDAMA), this option provides an alternate pathway to classify novel devices that carry low to moderate risk. Devices classified through the de novo process may be marketed and used as predicates for future 510(k) submissions.
5. Wait for FDA review and approval. During this process FDA may request several clarifications to be provided by the manufacturer.
6. Maintain FDA compliance for the devices' lifespan.

## EU Regulatory Process

To be marketed in member countries of the European Economic Area (EEA), our products must comply with the essential requirements of the new Medical Devices Regulation (MDR) (2017/745), which became fully applicable on 26 May 2021. The regulation aims to ensure that the device is deemed acceptable across several dimensions, including its appropriateness for the intended use, safety, device performance, labeling and packaging, effects of transportation and storage, and showing a positive balance of risk versus benefit for the end user.

To obtain approval to market a device in the EEA companies must:

1. Determine the device's classification (Class I, IIa, IIb or III) according to the associated risks
 

In Europe, ARC<sup>IM</sup> is expected to be designated as Class III.<sup>12</sup> In Europe, ARC<sup>EX</sup> is expected to be designated as a Class IIa device.<sup>13</sup>
2. Establish a quality system (QMS) to manage the medical device. The QMS is audited annually by the Notified Body, resulting in the issuance of a certificate that established that the QMS is compliant to the ISO 13485 standard.
3. Produce a technical file to satisfy EU MDR General Safety and Performance Requirements that includes:
  - Product Description and Specifications
  - Manufacturing Information
  - Risk Management File
  - Design Verification and Validation Test Reports
  - Clinical Evaluation
  - Labeling



## Clinical Trials & Regulatory Approvals

For Class III devices, a Design Dossier needs to be compiled which contains the data of the technical file along with a description of the design process for the device

### 4. Undergo review by notified body to prove device conformity

The conformity assessment procedure varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), this conformity assessment is conducted by a notified body accredited by a member state of the EEA.

A successful assessment results in the issuance of the CE marking certificate for the medical device along with an ISO 13485 certificate that establishes that the device is compliant with the General Safety and Performance requirements and European standards.

### 5. Declare conformity of medical device

The Declaration of Conformity is a legally binding document issued by the company which declares that the device meets all of the General Safety and Performance requirements as laid out by EU MDR and any other applicable regulatory standards.

## Clinical Trials

In 2021, ONWARD completed enrollment in the Up-LIFT study, the first large-scale pivotal trial of non-invasive spinal cord stimulation technology. It has 65 subjects enrolled at 14 leading SCI research sites throughout the United States, Canada, the United Kingdom, and the Netherlands. The Up-LIFT Study is a prospective, single-arm study designed to evaluate the safety and effectiveness of non-invasive electrical spinal cord stimulation (ARC Therapy) to treat upper extremity functional deficits in people with chronic tetraplegia.

It is important to note that the results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for regulatory authorities to grant approval or clearance of a product. Additionally, after a trial begins, the clinical trial may be terminated at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits

<sup>10</sup>The FDA defines Class III devices as products that “usually sustain or support life, are implanted or present a potential unreasonable risk of illness or injury.”

<sup>11</sup>A significant risk device is one that presents a potential for serious risk to the health, safety, or welfare of a subject and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject.

<sup>12</sup>The EU MDR defines Class III as “strictly high-risk devices.”

<sup>13</sup>The EU MDR defines Class IIa as “devices that are installed within the body for only between 60 minutes and 30 days.”





## 4. Commercialization

ONWARD does not currently offer any products for commercial sale. We are working towards approval of the ARC<sup>™</sup> device for the blood pressure and trunk control indication with an aim to receive regulatory clearance and start commercialization in 2025. We believe that we will be able to get the necessary regulatory approvals in the US and Europe in order to commercialize ARC<sup>EX</sup> starting in 2023. However, our plans to commercialize our products are dependent on our ability to demonstrate their safety and effectiveness to regulatory authorities, as described in the previous section.

### Geographical Focus & Commercial Objectives

ONWARD plans to market our products in the United States and Europe, where most people with SCI are cared for by a limited number of trauma and rehabilitation centers. When people suffer a spinal cord injury, they typically undergo emergency surgery in a trauma center, after which they spend a week in intensive care. They then begin rehabilitation training, which is generally provided by specialized clinics with the necessary expertise and equipment. In most cases, this rehabilitation lasts three to six months, although in some markets it can extend to one year, after which ongoing therapy aims principally to maintain gains.

In the initial period following commercial launch, our focus will be on the US and four selected European markets: Germany, France, UK and the Netherlands. These markets were selected based on their attractive reimbursement environment for new medical technologies and sophisticated SCI rehabilitation infrastructure. We plan to deploy a direct sales and service organization, as the total number of facilities to be targeted, whether to market our therapies and to support surgical interventions, numbers in the mid hundreds. If FDA clearance or approval or CE certification permits us to pursue entry into other large markets, including in Asian markets such as Japan, we will likely do so via a distribution partner.



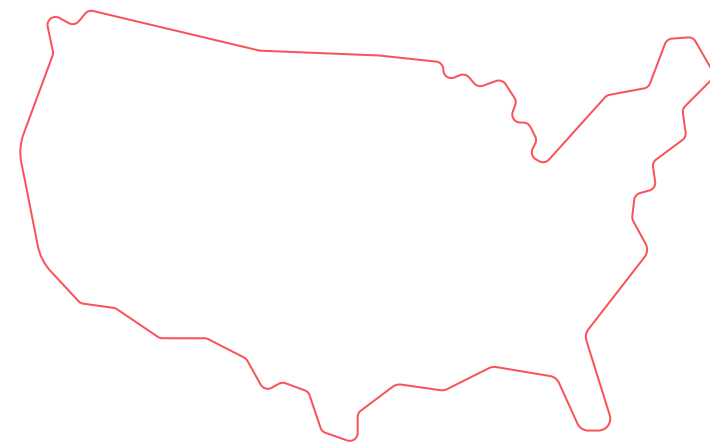
Patients are concentrated in specialized rehabilitation clinics

# Commercial Strategy

Call Points

**~200**  
(2019)

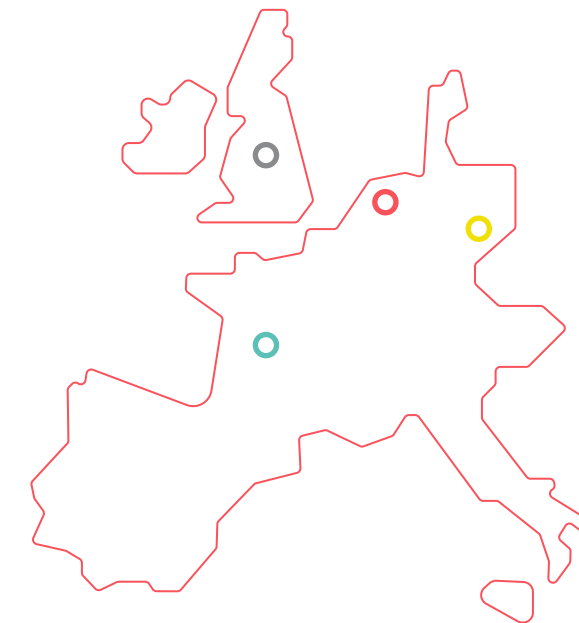
US



**105**

Specialized Rehabilitation Clinics

Europe



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

**83**

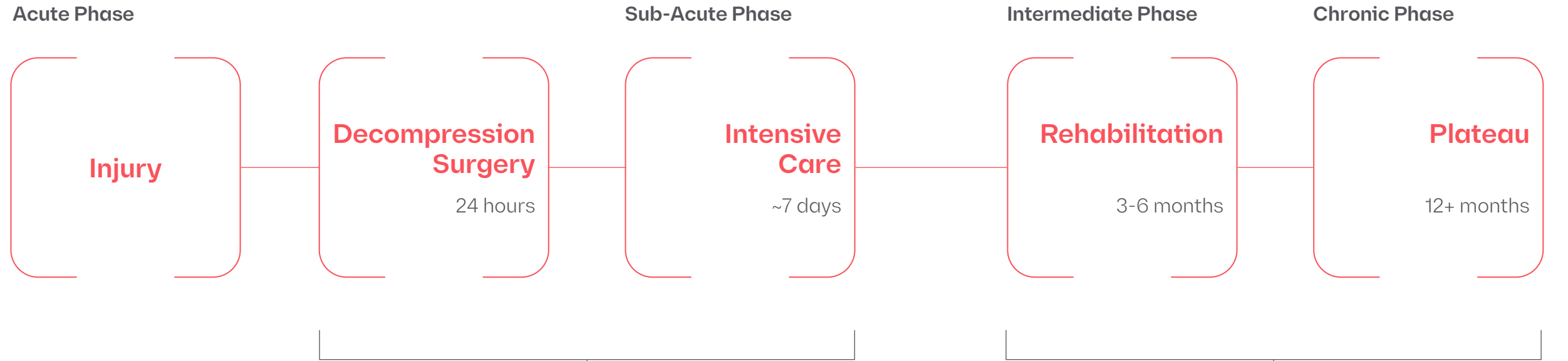
Specialized Rehabilitation Clinics



**Commercialization**

Specific customer targets at each stage in patient journey

# Clinician Customers in Patient Journey



**Trauma Centers**  
Trauma and functional neurosurgeons



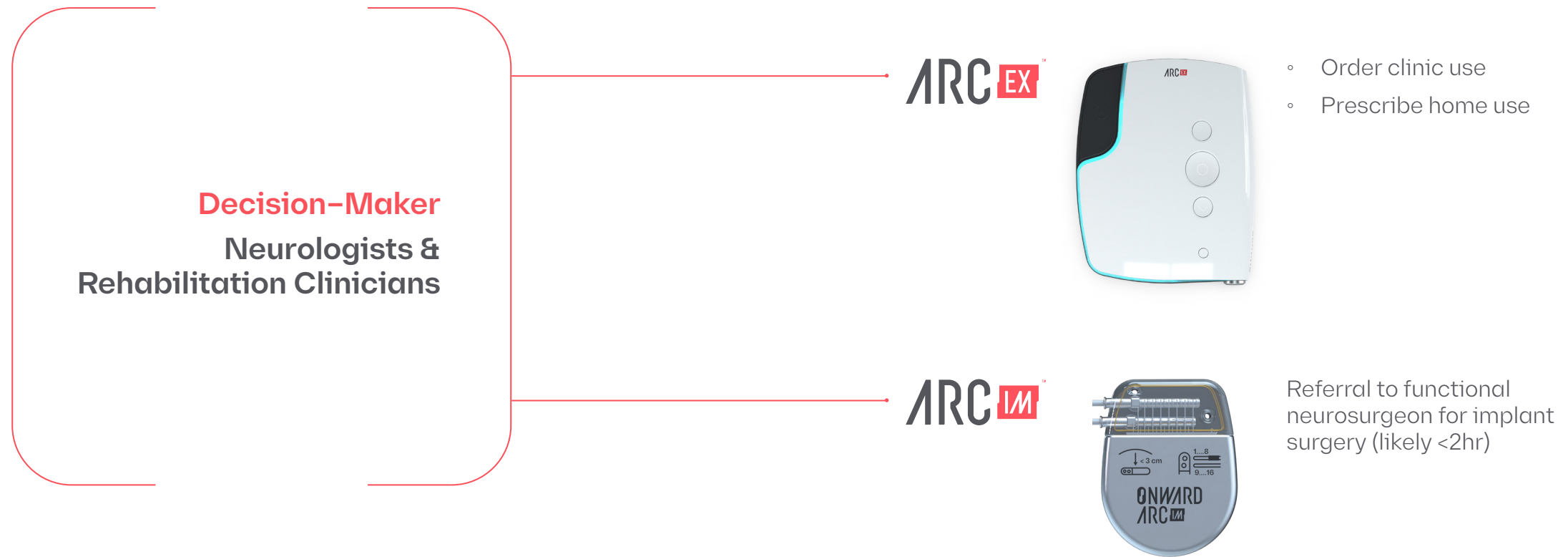
**SCI Rehabilitation Clinics**  
Neurologists, rehabilitation physicians and therapists  
Functional neurosurgeons  
Patients & caregivers



**Commercialization**

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

# Referral Pathway



**Commercialization****Rehabilitation Clinics**

Our marketing efforts will focus mainly on clinicians managing SCI patients in specialty rehabilitation clinics. These include neurologists, rehabilitation physicians, physical therapists, and occupational therapists providing rehabilitation training post-injury as well as ongoing support to those who are chronically injured. The latter constitute the largest pool of SCI patients globally.

We expect clinicians to use our therapies as follows:

- Apply ARC Therapy using ARCEX in the clinic
- Prescribe ARCEX for use in the home
- Refer patients to functional neurosurgeons for implantation of ARC<sup>IM</sup> and subsequent use of ARC Therapy in the clinic and home

There are a limited number of specialty rehabilitation clinics in the US and Europe. In the US, we expect to primarily target the 105 SCI rehabilitation clinics certified by the Commission of Accredited Rehabilitation Facilities (CARF). CARF certification demonstrates a clinic has a comprehensive integrated inpatient rehabilitation program, outpatient medical rehabilitation program, home and community services, residential rehabilitation, and vocational services.<sup>14</sup> These certified centers provide a robust referral base for the Company's products and will serve as focused and fertile marketing targets.

In the four selected European markets, there are a total of 83 SCI specialty rehabilitation centers: 27 in Germany,<sup>15</sup> 10 in the United Kingdom,<sup>16</sup> 8 in the Netherlands,<sup>17</sup> and 38 in France.

**Hospitals & Ambulatory Surgery Centers**

When patients are referred for an implant of ARC<sup>IM</sup>, surgery will typically be carried out in hospitals or ambulatory surgery centers by functional neurosurgeons who are already familiar with device therapy and neuromodulation, and commonly perform implants for deep brain stimulation and spinal cord stimulation for pain therapy. The implant procedure for ARC<sup>IM</sup> is substantially similar to that for spinal cord stimulation for pain, so we expect little resistance to adoption and a minimal training burden.

**Trauma Centers**

In addition to rehabilitation centers, we plan to target trauma centers to provide our therapies at the acute or subacute stage. Major trauma centers provide total care for all aspects of an injury, and prompt availability of relevant specialists such as neurosurgeons.<sup>18</sup> They are thus an access point to acute and subacute SCI patients, as well as neurosurgeons who can implant ARC<sup>IM</sup> devices. We envision that the blood pressure management indication may be well suited for acute management of SCI, by helping to stabilize blood pressure and promote spinal cord perfusion.

In the US, most SCI patients are treated at just 190 level 1 or major trauma centers.<sup>19</sup> In the four selected European markets, there are 152 major trauma centers: 27 in the UK,<sup>20</sup> 11 in the Netherlands,<sup>21</sup> 91 in Germany,<sup>22</sup> and 23 in France.<sup>23</sup>

<sup>14</sup>CARF International, provider search, United States (carf.org).

<sup>15</sup>Deutsche Behandlungszentren (dmgp.de).

<sup>16</sup>Medical Management Advice: Royal National Orthopaedic Hospital (rnoh.nhs.uk).

<sup>17</sup>PHM50279 93..95 (insci.network).

<sup>18</sup>American Trauma Society <https://www.amtrauma.org/page/TraumaLevels>, retrieved 09AUG2021.

<sup>19</sup>MacKenzie E.J., Hoyt D.B., Sacra J.C., et al. National Inventory of Hospital Trauma Centers. *JAMA*. 2003;289(12):1515–1522. doi:10.1001/jama.289.12.1515.

<sup>20</sup>National Health Services A4\_map (www.nhs.uk) Retrieved 09AUG2021.

<sup>21</sup>PHM50279 93..95 (insci.network).

<sup>22</sup>Orthopedic Trauma Association Development of trauma systems in Europe—reports from England: OTA International (lww.com) Retrieved 09 August 2021.

<sup>23</sup>France does not have official criteria for trauma center levels as the above countries, however Traumabase lists 23 top trauma hospitals in France. Traumabase Registry [https://www.traumabase.eu/en\\_US](https://www.traumabase.eu/en_US).





# People & Culture

We strive to create a positive culture, inspired by our ONWARD Code and our compelling vision. We also foster a culture of continuous learning, feedback, and development, providing the necessary tools and opportunities for our people to enhance their skills and grow in their capabilities and careers.

Our technology is highly innovative, and we seek talented people who bring boldness and creativity to our organization. We are diverse, with 20 nationalities currently represented on our team.

We differentiate ourselves as an employer of choice by fostering a purpose-driven culture with an entrepreneurial mindset. We offer competitive rewards, encourage learning and development, and build leadership and change-management expertise among our current and future leaders.

We have an employee-driven Culture Club that nurtures and reinforces our cultural norms, builds teamwork and common understanding, and supports SCI-focused charitable events such as the Wings4Life World Run and Christopher Reeve Foundation 5k Challenge.



# 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.

**People & Culture**

Our Code is communicated as part of our employee onboarding and reconfirmed in our monthly meetups. The Company believes it is important to cultivate an open and transparent culture that allows employees to express, in good faith, any concern they may have. Our employees are encouraged to raise concerns without fear of retaliation, knowing issues will be treated confidentially, seriously, fairly and promptly. During the financial year 2021 no concerns were reported.

**A Great Place to Work**

We strive to provide a positive employee experience, starting with the hiring process. We have a talent management system to help drive a culture of performance, accountability, and development. We use this system to track individual objectives, give feedback to colleagues, and capture employee development and performance. We frequently host speakers from the SCI community who help us stay connected to our vision and the meaning and urgency of our work. We participate in charitable events, most commonly supporting causes to help people with SCI.

**Competitive Hiring**

Software engineers and other technology-focused professionals account for approximately 65% of our recent new hires. As demand for technology talent outstrips supply, attracting the right people in this highly competitive landscape becomes essential. We endeavor to attract the best candidates: people who are motivated by our vision and the opportunity to work on true breakthroughs, rather than incremental gains.

During the COVID-19 pandemic, our pace of technology hiring remained brisk. By leveraging our professional networks and building partnerships with key academic institutions and other relevant organizations, we were able to attract great talent. Our employee referral program also incentivizes our employees to leverage the power of their networks to recruit people who are a good cultural and organizational fit.

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

**Employee Well-Being During COVID-19**

Safety, employee health and well-being have been the primary driver of our response during the pandemic.

Following the recommendations of the governments and health authorities of the countries in which we operate, we transitioned our employees to working from home, unless their work required access to specialized equipment and facilities found only in our offices, and as permitted by local measures. As a technology company our employees are used to collaborating across multiple locations and time zones with colleagues who are not in the same place. This, along with a dedicated communication channel during the pandemic, enabled us to continue to collaborate effectively and continue delivering on our strategic priorities. Our staff exhibited a high degree of adaptability and resilience, showing a strong sense of commitment towards each other and the organization.

We also realized that the pandemic took a toll on individuals' well-being and mental health. Hence, we launched a program early in 2022 to help our employees better manage their well-being. This consists in a series of workshops, webinars, and information on best practices from health and mindfulness experts.





# Corporate Responsibility

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

## ESG Principles

Our ESG strategy rests on four core principles:

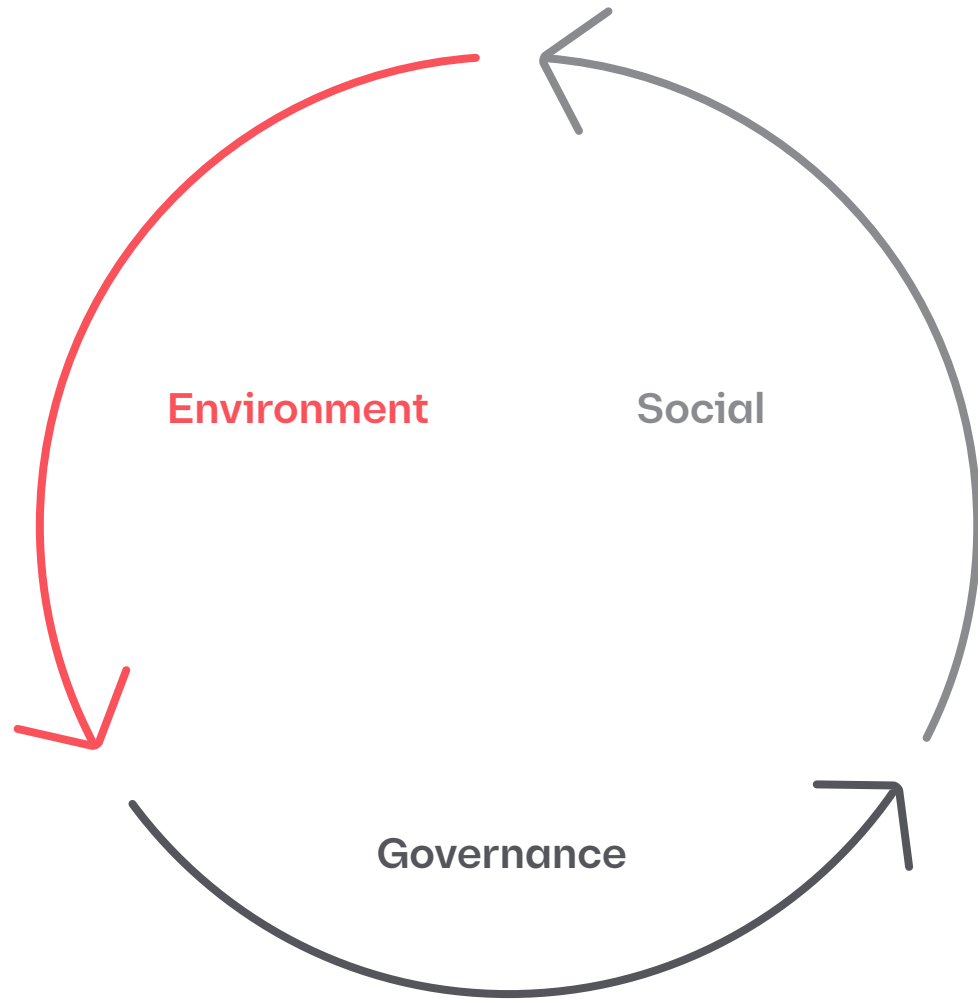
- **Innovating for the underserved:** There is no cure for SCI. Our therapies are among the first to offer the potential to help people with spinal cord injury regain movement and other functions, improving quality of life for a large, underserved group of people. Our products also have potential to benefit large populations of stroke sufferers and people with Parkinson's disease. We have already been granted three Breakthrough Device Designations (BDD) by the FDA for three different indications: restoration of upper extremity strength and function for ARC<sup>EX</sup>, blood pressure and trunk control and mobility for and restoration of walking for ARC<sup>IM</sup>. We continuously innovate and strive 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:** We enjoy excellent relationships with the world's leading patient advocacy groups for people with spinal cord injury. The Christopher and Dana Reeve Foundation, the world's largest such organization, is an investor in ONWARD. We also collaborate with Wings for Life in Europe, the Praxis Foundation in Canada and International Spinal Research Trust in the UK.

- **Attracting and retaining the best talent:** To deliver on our vision, we are committed to creating an unrivalled and inclusive environment for our employees. We care deeply about the well-being and continuous development of our staff as evidenced by the various programs we have put in place, such as our well-being program. Having a highly motivated and engaged workforce enables us to retain and attract top talent. We also engage with partners with spinal cord injury as consultants, who enable our workforce to have a better understanding of the challenges that they face.
- **Minimizing our environmental footprint:** In our operations, we strive to reduce our carbon footprint, for instance by replacing air travel with videoconferencing except for the most pressing business needs and by encouraging a hybrid workplace, thus reducing our employees' commute. We also work with our suppliers to minimize waste in the manufacturing process.
- **Maintain high ethical standards:** At ONWARD, we are open and act with integrity. We are committed to high ethical standards in dealing with our business partners as outlined in our Code of Conduct, which covers anti-bribery and anti-money laundering, government relations and political affairs and international business practices. Our Code of Conduct ensures our people across the organization understand what is expected of them when acting on behalf of the Company. We aim to comply with all applicable anti-bribery laws, including the US Foreign Corrupt Practices Act. We apply the highest quality and safety standards to everything that we do, and we ensure strong labor practices in our supply chain. We also work hard to secure key personal data and comply with GDPR (General Data Protection Regulations) and HIPAA. We uphold human rights and operate in geographies with a strong track record on this topic.



Our ESG Strategy includes four areas in support of nine UN Sustainable Development Goals<sup>1</sup>

# ESG Strategy



### Environment



#### Minimizing Our Environmental Footprint

We strive to reduce our carbon footprint and waste in our operations

### Social



#### Innovating for the Underserved

We innovate to help people with Spinal Cord Injury, empowered by movement, to enjoy life in every way that matters to them

### Governance



#### Maintaining High Ethical Standards

We act with integrity, respect human rights and apply the highest quality and safety standards



#### Attracting & Retaining Top Talent

We are committed to creating a positive, diverse and inclusive work environment for all our employees, underpinned by continuous development

Source: 1 <https://sdgs.un.org/goals>



# Privacy & Data Governance

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

We are subject to various regional, national and state laws that protect the confidentiality and security of patient health information, including patient medical records. We have chosen to apply 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 right to access or amend certain records containing protected health information, or to request that its use or disclosure be restricted.

We have strengthened our product compliance with cybersecurity and data protection requirements under GDPR and HIPAA. We plan to create traceability in accordance with relevant standards and provide evidence that we are compliant with the regulations. We are currently evaluating our process for compliance with GDPR and HIPAA requirements and expect to close any gaps in 2022. We are hardening our data management processes and we regularly train our staff on security and privacy issues.



# Operational Review

Although COVID introduced a unique set of challenges, ONWARD made considerable progress in 2021:

## Science & Intellectual Property

As the pioneer in our space, we have forged relationships and exclusively licensed important intellectual property from many of the world's leading neuroscience research laboratories such as Caltech (USA), University of California at Los Angeles (USA), University of Louisville (USA), and University of British Columbia (Canada).

Our primary research partnership is with .NeuroRestore, a joint research initiative of EPFL and CHUV in Lausanne, Switzerland, with whom we have an exclusive IP license agreement. In 2021 we signed a framework agreement with .NeuroRestore governing future research initiatives, as well as contracts covering existing and ongoing research. Additionally, we supported research on blood pressure and trunk control, mobility, and incontinence.

Benefitting from these research collaborations and in combination with our own innovations, ONWARD's IP portfolio grew to over 320 issued or pending patents in 2021 (a 26% annual increase). We also out-licensed certain ONWARD IP for the first time, an initiative we are likely to expand. We will continue to consolidate and grow our IP portfolio in 2022 and beyond, a key strength of the company.

## Research & Development

Our engineering team made considerable progress across several development initiatives in 2021:

- ARC<sup>EX</sup> System development: We completed software prototypes for the patient and clinician programmers (tablet, smartphone and smartwatch ), the stimulator hardware prototype, and initiated full development with selected key supplier partners.
- ARC<sup>IM</sup> Lead Platform: We used sophisticated modeling to complete designs and prototyped the Thoracic and Lumbar lead models
- Agile at Scale: We created a blueprint for Agile-at-Scale, which will be implemented in 2022 to improve our velocity and overall effectiveness.
- ARC<sup>IM</sup> Platform: We completed the full 1.0 system in preparation for regulatory submission for first-in-human trials, expected to begin in 2022. We also successfully completed deliverables for Phase I of the Defense Research Projects Agency (DARPA) project, as described below.

ONWARD is part of a research consortium including partners in the US, Canada and Switzerland that has been awarded a research funding by DARPA to advance innovative SCI therapies. In response to the DARPA "Bridging the Gap Plus" funding call, the consortium proposed the development of a new clinical intervention to modulate blood pressure and spinal cord perfusion and oxygenation in the hours following spinal cord injury. The intervention includes spinal cord stimulation using ARC<sup>IM</sup>, combined with implanted sensors for blood pressure and spinal cord perfusion, as well as stem cells and scaffolds to be implanted in the lesion site to promote neural regrowth across the injury.



**Operational Review**

The DARPA grant is a five-year project (October 2021 to September 2025) for a total of USD 36 million, of which ONWARD could potentially receive USD 6.3 million. To receive this funding in full, we must meet specific milestones at each stage:

**Phase 1:** System design, IPG software and firmware update for spinal cord stimulation for blood pressure control (already granted)

**Phase 2:** System development completion (to be granted), development of a dedicated lead (contingent), and clinical validation in ten chronic patients in Switzerland and Canada (contingent)

**Phase 3:** FDA IDE secured and clinical validation shown in five acute patients in Canada (to be granted)

We believe that our involvement in the DARPA consortium will contribute to our leadership and expertise in blood pressure management and pave the way for the introduction of next-generation systems that may follow the initial configuration of ARC<sup>IM</sup> we expect to launch for blood pressure.

**Clinical & Regulatory**

We expect to commercialize our first technology platform and therapy, ARC<sup>EX</sup> for the restoration of upper limb function, in 2023.

In 2021, we completed enrollment in our Up-LIFT pivotal trial in less than 12 months, ahead of schedule, despite COVID-related challenges. The Up-LIFT study is designed to evaluate the safety and effectiveness of non-invasive electrical spinal cord stimulation administered by a clinical version of ARC<sup>EX</sup> to treat upper extremity functional deficits in people with chronic tetraplegia. Study Principal Investigators are Edelle Field-Fote, PT, PhD, of the Shepherd Center, Atlanta, and Chet Moritz, PT, PhD, of the University of Washington, Seattle.<sup>24</sup>

The first planned indication for our ARC<sup>IM</sup> implantable platform is restoration of normal blood pressure and trunk control. The Breakthrough Device Designation awarded by the FDA for this indication in early 2021 is recognition of the truly innovative nature of this device and its potential to address an unmet need.

**Quality**

ONWARD has a robust quality system that is compliant with current applicable standards. In 2018, we obtained the ISO 13485 certification designed for organizations involved in the design, production, installation, and servicing of medical devices and related services.<sup>25</sup> The most recent audit was conducted and passed in late 2021 by TÜV SÜD, a well-respected notified body with global reach.

We also conducted audits of key suppliers and partners to ensure their compliance with appropriate regulatory standards and company requirements. We have continued to strengthen our Quality function by hiring additional qualified staff.





## Operational Review

### Commercial Operations

ONWARD does not currently offer any products for commercial sale. Following the expected successful completion of Up-LIFT, we plan to commercialize ARC<sup>EX</sup> in the US and Europe in 2023 for the improvement of strength and function of the upper extremities. In 2025, we expect to launch ARC<sup>IM</sup> commercially in the US and selected European markets to restore normal blood pressure and trunk control. In 2025, we expect to commercialize ARC<sup>IM</sup> in the US for mobility via HDE from the FDA (The European authorization process for ARC<sup>IM</sup> for the mobility indication is not yet determined.)

Given the modest number of centers and clinicians responsible for providing rehabilitation training, managing SCI patients, and performing accompanying surgeries (as detailed on p. 57), we plan to deploy our own direct sales and service organization in both the US and Europe, using distributor partners selectively where appropriate.

In 2021, ONWARD started building its commercial organization by recruiting Vice President of Marketing and Market Access, Andy Dolan (bio under Management Team).

### Financing

To support our R&D activities, conduct clinical trials, and prepare for commercialization, we successfully raised EUR 80 million through an initial public offering on Euronext Brussels and Amsterdam in late October 2021. This successful financing was preceded by a pre-IPO convertible note financing of EUR 30 million in April 2021.

<sup>24</sup>Details for the Up-LIFT study can be found on [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04697472), under identifier NCT04697472.

<sup>25</sup>ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes.



# 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	2021	2020
<b>Total Grant Income</b>	<b>1,4</b>	<b>0,8</b>
<b>Total Operating Expenses</b>	<b>(30,0)</b>	<b>(16,3)</b>
Science Expenses	(2,7)	(1,1)
Marketing & Market Access Expenses	(1,5)	(0,4)
Research & Development Expenses	(7,9)	(5,8)
Clinical & Regulatory Expenses	(4,8)	(2,8)
Patent Fees & Related Expenses	(1,4)	(1,2)
Quality Assurance Expenses	(1,0)	(0,4)
General & Administrative Expenses	(10,7)	(4,7)
<b>Operating Loss for the Period</b>	<b>(28,6)</b>	<b>(15,5)</b>
Net financial result	(5,7)	(4,5)
<b>Net loss for the period</b>	<b>(34,3)</b>	<b>(20,0)</b>
<b>Cash positions at end of year</b>	<b>89,4</b>	<b>6,4</b>
<b>Interest-bearing loans</b>	<b>(11,5)</b>	<b>(41,8)</b>
<b>Equity</b>	<b>82,7</b>	<b>(32,1)</b>

## Total Grant Income

Total Grant Income increased to EUR 1.4 million in 2021, compared to EUR 0.8 million in 2020. The increase mainly relates to the DARPA Phase I grant that was applicable for the full 12 months in 2021 as opposed to only 3 months in 2020.

## Science Expenses

The Company's science expenses consist primarily of the costs of sponsored research activities that are undertaken by universities with which it collaborates. Since its inception, the Company has had a close working relationship with two of the founders of the Company, Grégoire Courtine, Professor at EPFL and Jocelyne Bloch, Neurosurgeon at CHUV, Professor at Université de Lausanne.

The activities between the Company and EPFL are formalized in research agreements which govern the activities sponsored by the Company. In addition to these scientific research expenses also the consultancy expenses and related shared-based payment expenses for Grégoire Courtine and Jocelyne Bloch are included. Science expenses increased by 144% from EUR 1.1 million in 2020 to EUR 2.7 million in 2021, of this increase EUR 1.8 million relates to the share-based payment expense as a result of the Employee Investment Plan that vested on the date of the IPO. The increase is offset by a decrease in scientific research expenses of EUR 0.2 million due to research activities being limited to blood pressure and bladder and bowel indications in 2021.

## Financial Review

### Marketing & Market Access Expenses

Marketing and Market Access Expenses increased by 273% from EUR 0.4 million in 2020 to EUR 1.5 million in 2021 as a result of spending on the ONWARD rebranding, combined with market access investigative activities in Europe and the US, as well as the share-based payment expense as a result of the Employee Investment Plan that vested on the date of the IPO.

### Research & Development Expenses

Research and development expenses consist of product development, engineering to develop and support our products, testing, consulting services, and other costs associated with ARC therapies that do not meet the development capitalization criteria. These expenses primarily include employee compensation and outsourced development expenses. Research and development expenses increased by 37% from EUR 5.8 million in 2020 to EUR 7.9 million in 2021 due to progress in the development initiatives, as described above in the operational review, as well as the share-based payment expense as a result of the Employee Investment plan that vested on the date of the IPO.

### Clinical & Regulatory Expenses

Clinical expenses consist primarily of clinical studies related to the development of our ARCEX system, consulting services, and other costs associated with clinical activities. These expenses include employee compensation, clinical trial management and monitoring, payments to clinical investigators, data management, and travel expenses to our various clinical trial locations. Clinical expenses increased by 72% from EUR 2.8 million in 2020 to EUR 4.8 million in 2021. The increase was mainly due to an increase in staff and consulting to support the study, continuous recruitment for the Up-LIFT study in the US, and the share-based payment expense as a result of the Employee Investment Plan that vested on the date of the IPO.

### Patent Fees & Related Expenses

Patent Fees and Related Expenses consist primarily of costs required to maintain ONWARD's growing IP portfolio.

### Quality Assurance Expenses

Quality Assurance expenses include employee compensation, consulting, testing and travel expenses incurred to ensure the quality of our products. These costs increased by 175% from EUR 0.4 million in 2020 to EUR 1 million in 2021. The increase was due to the hiring of new staff, quality assurance activities, and the share-based payment expense as a result of the Employee Investment Plan that vested on the date of the IPO.

### General & Administrative Expenses

General and administrative expenses increased by 278% from EUR 4.7 million in 2020 to EUR 10.7 million in 2021. The increase is due to consulting expenses, staff and legal fees to support the Company growth as well as the costs incurred relating to the IPO. The increase also includes the share-based payment expense as a result of the Employee Investment Plan that vested on the date of the IPO.

### Net Financial Result

The net financial expense increased by 27% from EUR 4.5 million in 2020 to EUR 5.7 million in 2021. Costs in 2021 consists mainly of interest on the Company's sources of funding from the innovation loan from RVO NL (Dutch Government), the convertible loan (CLA), and the accrued dividend of the preference A shares.





## Financial Review

### Cash Position

The increase in ONWARD's cash position at the end of the year is primarily due to proceeds from the IPO in October 2021, as well as the proceeds from the convertible loan financing in April 2021.

The table below summarizes the cash flows of the Company for the year 2021.

EUR' Million	2021	2020
Net cash generated / (used) from operating activities	<b>(19,874)</b>	<b>(12,900)</b>
Net cash generated / (used) from investing activities	<b>(2,324)</b>	<b>(173)</b>
Net cash generated / (used) from financing activities	<b>105,361</b>	<b>4,367</b>
Effect of exchange rates on cash and cash equivalent	<b>(100)</b>	<b>(41)</b>

The increase in cash outflow from operating activities of EUR 12.9 million in 2020 to EUR 19.9 million in 2021 is due to higher losses due mainly from higher general and administrative expenses relating to the IPO as well as increases in the costs as explained above.

Cash flow from investing activities represented a net outflow of EUR 2.3 million, related to the acquisition of property, plant, and equipment and license fee payments to UCLA and Caltech.

The increase in cash inflow of EUR 101 million from financing activities is primarily due to proceeds from the IPO in October 2021 and the convertible loan financing in April 2021.

The increase in the effect of exchange rates is due to higher activity in the US relating to the Up-LIFT clinical trial.

### Interest-bearing Loans

Interest-bearing loans on 31 December 2021 decreased by EUR 30 million. This is mainly due to the conversion of the preference A shares into ordinary shares immediately preceding the IPO in October 2021. This resulted in a decrease in interest-bearing loans relating to the financial liability portion and accrued dividend.

### Equity

The Company has a positive equity position of EUR 82.7 million at year-end 2021 versus a negative position EUR 32.1 million at year-end 2020, an increase of EUR 114.8 million. The main drivers of this increase are the proceeds of a share offering of EUR 80.1 million, conversion of the CLA into ordinary shares of EUR 31 million, the conversion of the preference A shares into ordinary shares of EUR 34 million and the accelerated vesting of the employee investment plan of EUR 8.5 million. The increase is offset by the loss of EUR 34.3 million and the capitalization of costs relating to the issue of new shares during the IPO of EUR 4.9 million.



# 2022 Outlook

We expect to achieve several important milestones in 2022.

By mid-year, we expect to complete conduct of the Up-LIFT trial, at which time we expect to release top-line data showing the effectiveness of our transcutaneous therapy in restoring strength and function in the hands and arms of people with SCI. Late this year or in early 2023, we plan to file regulatory submissions for de novo clearance to commercialize in the US and CE marking to commercialize in Europe. These authorizations are expected in 2023.

During 2022, we expect to launch first-in-human use of our ARC<sup>™</sup> implantable platform for blood pressure regulation and trunk control in people with SCI.

In addition, we expect further publications in the world's leading scientific and medical journals this year, highlighting the promise of our therapies to help people with SCI and other movement-related disorders in new and critical areas.

Lastly, we expect to make progress across several fronts to prepare our business for commercial launch in 2023.

To achieve these important milestones, we will continue to invest in our product development, clinical trials, and robust quality assurance. We plan to hire additional staff in 2022, mainly within our Clinical and Development teams but also in Operations, beginning with a VP Operations. In late 2022 or early 2023, we will place a greater focus on recruiting for commercial roles to cover our target markets. We expect our current funding to be sufficient to support our ambitions through the end of 2024.



# Governance

## General

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

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

The Company and its subsidiaries act as one company, the subsidiaries are mainly established to follow local regulations.

ONWARD's corporate governance is guided by the rules and principles set out in the Dutch 2016 Corporate Governance Code (the CGC)<sup>26</sup>, by the Company's Articles of Association (available on the **Company's website**) and by Dutch law.<sup>27</sup>

## Governance Framework

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

- For the 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 (*uitvoerende bestuurders*) and one or more non-executive directors (*niet-uitvoerende 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 duties of the directors. Whereas, in the case of a two-tier governance structure, supervisory and management roles are divided between two corporate bodies, in a one-tier governance structure such as that adopted by ONWARD, non-executive directors and executive directors share responsibility for the management of the company for those tasks and duties that are not delegated to one or more other specific directors by virtue of Dutch law, the Articles of Association or any other arrangement catered for therein (e.g., the Rules of the Board). It is therefore important that the Board ensure sufficient independent supervision by non-executive directors.

In accordance with the CGC, the role of the Board is to provide leadership and supervision to the Company on matters of strategy, risk management and policies. It has overall responsibility 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 the directors must be guided by the best interests of the company as well as of its stakeholders, which include its 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** 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 proposal of the Board.

Dutch Law does not set a limit on the maximum number of consecutive terms that a director may serve. According to the CGC non-executive directors may be elected for a maximum of two consecutive four-year terms and, subsequently, for a maximum of two consecutive two-year terms.

The Board meets as often as any Director considers necessary or appropriate. Resolutions are passed by a simple majority of votes cast. In the case of a tie in the vote of the Board, the resolution is not passed. Any resolutions that concern a material change to the character or identity of the Company or its business must be submitted to the General Meeting for approval.<sup>28</sup>

### Composition of the Board of Directors

As of the date of this Annual Report, the Company has a one-tier Board consisting of nine members.

### Governance

Name	Year of Birth	Nationality	Gender	Position	Year Appointed	End of Term
<b>Jan Øhrstrøm</b>	1957	Danish	Male	Independent Non-Executive Director & Chairperson	2016	Annual General Meeting of 2024
<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 & CSO	2016	Annual General Meeting of 2023
<b>Ian Curtis</b>	1968	British	Male	Independent Non-Executive Director & Vice-Chair	2019	Annual General Meeting of 2025
<b>Fredericus Colen</b>	1952	Dutch	Male	Independent Non-Executive Director	2017	Annual General Meeting of 2025
<b>Regina Hodits</b>	1969	Austrian	Female	Non-Executive Director	2016	Annual General Meeting of 2023
<b>Roel Bulthuis</b>	1976	Dutch	Male	Non-Executive Director	2020	Annual General Meeting of 2022
<b>John de Koning</b>	1968	Dutch	Male	Non-Executive Director	2016	Annual General Meeting of 2024
<b>Patrick Van Beneden</b>	1962	Belgian	Male	Non-Executive Director	2016	Annual General Meeting of 2022





## Governance

### Biographies of the Board Members

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

**Dave Marver** (CEO) is an accomplished chief executive and director with more than 25 years of international experience in public, private, and emerging companies. Previously, Dave spent almost 15 years with Medtronic in 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 start-ups. He holds a BA from Duke University and an MBA from University of California Los Angeles.

**Grégoire Courtine** is a fulltime 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 several prestigious prizes, including the Rolex Award, the Schellenberg Research Prize, and the 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 member, Grégoire serves as a non-executive director in addition to his role as CSO.

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

**Fred Colen** has over 40 years of experience in the medical device industry, with a track record in building strong organizations to bring new technology to market. Fred is President and CEO of Neovasc Inc., a Canadian publicly traded company developing products for the cardiovascular marketplace. Previously, he held senior executive roles at Boston Scientific and St Jude Medical. He holds Master's degrees in Electrical Engineering and Medical Technology from RWTH Aachen University, Germany. Fred is a Member of the Audit Committee and of the Compensation Committee.

**Regina Hodits** has over 20 years of experience in venture capital and is a managing partner at Wellington Partners Life Science Venture Capital Consulting GmbH, where she focuses on early-stage and growth investments. Before joining Wellington, Regina led the European life sciences efforts of Boston-based Atlas Venture. She was a founding investor in Bicycle Therapeutics, F-star, and JenaValve, and currently serves on the boards of Carisma, Sidekick, SNIPR Biome, and Stipe. Regina holds PhD in Biochemistry from the Technical University of Vienna. Regina is a Member of the Nominating and Corporate Governance Committee.

**Roel Bulthuis** combines 20 years of experience across venture capital, pharma business development, and investment banking at M-Ventures, Merck Serono, and Fortis Bank. He is currently Managing Partner at INKEF capital and the head of its healthcare investment team. A graduate of the prestigious Kauffman Fellows program, he serves as a director of ten companies. He holds an MS in Biopharmaceutical Sciences from Leiden University and an MBA in Finance from the Helsinki School of Economics. Roel is a Member of the Compensation Committee.

**John de Koning** is a General Partner at LSP, one of the largest European investment firms providing financing for life sciences and health care companies. Since joining LSP 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 Nominating and Corporate Governance Committee.



## Governance

**Patrick Van Beneden** is an Associate Partner at Gimv N.V., a leading European private equity firm. As Partner of GIMV for 35 years, Patrick has established a stellar track record in early and late-stage investments in the life sciences, including Devgen, CropDesign, Plexxikon, and Endosense. He is a board member of FIRE1, Biotalys, and JenaValve Technology. He holds a Master's degree in Financial Sciences from VLEKHO Business School in Brussels. Patrick is a Member of the Audit Committee.

### Director Independence

In accordance with best practice provision 2.1.7 of the CGC, the majority of the non-executive directors must be independent and at most one non-executive director does not have to meet the independence criteria. A board member is considered "not independent" if they, a spouse, partner, or close family member (related by blood or marriage up to the second degree) meet any of the conditions listed below:

- a. 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.
- b. Receives personal financial compensation from the company, or an associated company, other than the compensation received for the work performed as a board member.
- c. Has had an important business relationship with the company or an associated company in the year prior to the appointment.
- d. 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.
- e. Has temporarily performed management duties during the previous twelve months in the absence or incapacity of a member of the management board.
- f. Has a shareholding in the company of at least 10%.
- g. 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 nine members, eight of which are non-executive directors. Five of these non-executive directors are deemed "not independent" based on meeting certain of the conditions above. This is a deviation from the requirement of best practice provision 2.1.7ii of the CGC. (Refer to 'Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code'.)

### 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 the 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 of the committees is summarized below.

### Audit Committee

The Audit Committee consists of three members: Ian Curtis (Chair), Patrick Van Beneden, and Fredericus Colen.

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

## Governance

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

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

### Compensation Committee

The Compensation Committee consist of three members: Jan Øhrstrøm (Chair), Roel Bulthuis and Fredericus Colen. In deviation from best practice provision 2.3.4/5.1.4 of the CGC, the Compensation Committee is led by the Jan Øhrstrøm, who is also Chairperson of the Board. (Refer to 'Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code'). The Board considers that the experience and continuity of Mr. Øhrstrøm being chair of the Compensation Committee outweighs the disadvantages of him holding both positions.

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

- a. Submitting proposals to the Board concerning changes to the Company's compensation policy.
- b. Submitting proposals to the Board concerning the compensation of individual directors, covering:
  - Compensation structure
  - Amount of the fixed and variable compensation components
  - Applicable performance criteria



**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 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).

The Management Team generally meets at least once a week.

		<b>Management Team</b>
<b>Name</b>	<b>Position</b>	<b>Member Since</b>
<b>Dave Marver</b>	Chief Executive Officer	2020
<b>Grégoire Courtine</b>	Chief Science Officer	2016
<b>John Murphy</b>	Chief Technology Officer	2020
<b>Marko Jansen</b>	Chief Financial Officer	2017
<b>Hendrik Lambert</b>	VP Clinical & Regulatory	2016
<b>David Harari</b>	Managing Director USA	2019
<b>Andy Dolan</b>	VP Marketing	2021
<b>Vincent Delattre</b>	VP Business Development	2016
<b>Rano Burkhanova</b>	Global HR Director	2020

- 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 & Corporate Governance Committee**

The Nomination and Corporate Governance Committee consists of three directors: Jan Øhrstrøm (chair), John de Koning and Regina Hodits. Jan Øhrstrøm serves as chairperson of the Nomination and Corporate Governance Committee. In deviation from the CGC more than half of the committee members are not “independent” within the meaning of the Code, namely John de Koning and Regina Hodits. (Refer to ‘Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code’). The Board considers that the experience and continuity of Mr. de Koning and Ms. Hodits outweigh the disadvantages of these deviations from the CGC.

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 a review 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





## Governance

### Biographies of the Management Team

**Dave Marver** (see biography above).

**Grégoire Courtine** (see biography above).

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

**Marko Jansen** has 25 years of experience in financial management across both multinational companies and innovative startups. Building on his extensive expertise in financial analysis and agile project management, Marko has served as the company's CFO since 2017. Prior to that, he held senior positions at Audionova International B.V., a hearing aid company, and nVent Erico, a global electrical equipment manufacturer. Marko began his career in public accounting with Arthur Andersen. He is a licensed CPA and holds a BA in Accounting and a PhD in Business Economics from the University of Tilburg.

**Hendrik Lambert** has over 20 years of experience in leading clinical and regulatory strategies for high-risk (Class III) medical devices in both Europe and the US, from initial design to market approval. Before joining ONWARD in 2015, Hendrik was Vice President for Clinical and Regulatory Affairs at Endosense, a Geneva-based Medtech company developing innovative products for the cardiology market, which was acquired by St. Jude Medical. He holds a PhD in Biomedical Engineering from the University of Ghent, Belgium.

**David Harari** is a talented scientific leader with 30 years of experience in the clinical and regulatory management of medical devices, from initial concept to commercialization. Before joining ONWARD in 2019 to lead its US affiliate, David held senior positions in clinical affairs with Guidant, Boston Scientific, Endosense, St Jude Medical, and Vytronus Inc. He holds a BS in Engineering Sciences and Biomedical Engineering from the University of Michigan.

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

**Vincent Delattre** co-founded ONWARD in 2014 and currently oversees the company's extensive IP portfolio and business development activities. Vincent combines expertise in science and business management: he has led pioneering research on electrical stimulation and neural circuit reorganization and has been recognized by several business prizes, including Hello Tomorrow, Venture Best Business Idea, and the Wellcome Trust Award. He previously served as the company's CEO and Chief Technology Officer. Vincent holds a PhD in Neurosciences from EPFL, Lausanne.

**Rano Burkhanova** is an accomplished talent development executive with 15 years of experience with multinational companies in the US and the Netherlands. Before joining ONWARD in 2020, Rano managed leadership development, gender diversity, and engagement programs for Danone Nutrition, Elsevier, and Medtronic. She holds an MA in Human Resources Management from Cornell University and an MBA from the Quantic School of Science and Technology.



## Governance

### Diversity

On 28 September 2021, a bill (*Wetsvoorstel inzake evenwichtige man vrouw verhouding in de top van het bedrijfsleven*) introducing stricter gender diversity measures was adopted by the Dutch Senate of the Dutch House of Representatives (*Eerste Kamer*). The bill entered into force on 1 January 2022. The new legislation requires Dutch listed companies to ensure that men and women each hold at least one third of the seats on their supervisory boards. In a one-tier board, this one-third quota is applicable to non-executive directors only. The quota will apply to new appointments; companies may thus reappoint a non-executive director without complying with the one-third quota, but only if the re-appointment occurs within eight years of the initial appointment. A new appointment that fails to comply with the quota will in principle be regarded as null and void (*nietig*). Companies will be required to report annually on their progress to achieve diversity.

The Board has adopted a diversity policy which became effective on the date of first trading. The policy defines concrete objectives to achieve a Board that comprises one-third of female members, while also ensuring a diversity in terms of background, skills, and age. This policy is available on our website.<sup>29</sup>

As of the date of this report, ONWARD's Board consists of 8 male directors and 1 female director. The Company has retained a leading medical technology search firm to assist in its efforts to recruit independent directors with backgrounds that would help it achieve its independence and diversity objectives by the end of 2023.

### Conflicts of Interest

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

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

As at 31 December 2021, the potential conflicts of interests between the duties to the Company of each of the directors and members of the Management and their private interests or other professional duties were as follows:

- a. Grégoire Courtine is the Chief Science Officer and a Non-Executive Director of the Company
- b. Roel Bulthuis is a director of INKEF Capital, a major Shareholder of the Company and Non-Executive Director of the Company.
- c. John de Koning represents LSP V Coöperatieve U.A., a major shareholder of the Company and Non-Executive Director of the Company.
- d. Regina Hodits represents Wellington Partners Life Science Venture Capital Consulting GmbH, a major Shareholder of the Company and Non-Executive Director of the Company.

No conflicts of interest were reported to the Board in 2021.



## Governance

### Related Party Transactions

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

The Dutch act to implement the EU Shareholder Rights Directive II (*Bevordering van de langetermijnbetrokkenheid van aandeelhouders*, “Dutch SRD Act”) which entered into force on 1 December 2019, added new rules on related party transactions to the DCC. These rules stipulate that “material transactions” with “related parties” that are not entered into within the ordinary course of business or not concluded on normal market terms must be approved by the Board and be publicly announced at the time of or before the transaction takes place. The Board is required to establish an internal procedure to periodically assess whether transactions with related parties are concluded in the ordinary course of business and on normal market terms.

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

No related party transactions were reported to the Board in 2021.

### 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 first Annual General Meeting is scheduled for 10 June 2022.

ONWARD’s authorized share capital (*maatschappelijk kapitaal*) amounts to EUR 12,225,000 divided into 50,937,500 Ordinary Shares and 50,937,500 Preferred Shares with a nominal value of EUR 0.12 each. All of the issued Ordinary Shares are fully paid-up and represent capital in the Company. No Shareholders have any voting rights different from any other Shareholder. At 31 December 2021, 30,184,388 Ordinary Shares represented all issued capital.



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

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

- **Best practice provision 2.1.7ii.** The CGC provides that the criteria referred to in best practice provision 2.1.8, when applicable, should account for less than half of the total number of non-executive directors. Five of the non-executive directors are deemed “not independent” in accordance with best practice provision 2.1.7ii.

Prof. Courtine, one of the Company’s founders, is considered “not independent” as he is the Chief Science Officer of the Company and receives personal compensation for this role. Regina Hodits, John de Koning, Roel Bulthuis, and Patrick Van Beneden are considered “not independent” as they are representatives of major shareholders holding at least 10% of the shares in the Company (Wellington, LSP, Inkef and GIMV). These shareholders have a long term interest in the Company and have made these senior partners or staff available in service to the Company as directors. The Board considers that Regina Hodits, John de Koning, Roel Bulthuis, and Patrick Van Beneden fit the intended profile of the Board and that their contributions outweigh any perceived disadvantage of non-independence. In addition, the Board believes that continuity in its membership is key to ensuring the Company’s successful transition from private to public company following its initial public offering on 21 October 2021. The Company has retained a leading medical technology search firm to assist in its efforts to recruit independent non-executive directors with backgrounds that would help it achieve its independence and diversity objectives by the end of 2023.

- **Best practice provision 2.2.6/2.2.7.** The CGC recommends that non-executive directors should evaluate their own functioning and the functioning of the executive directors. Since ONWARD became a listed company in October 2021, following its initial public offering, the Board has not yet formalized the policy and process for evaluation of its functioning. The Board intends to evaluate its functioning on the basis of a self-evaluation form distributed to, and completed by, the directors. As part of these evaluations, the Board will consider (i) substantive aspects, mutual interactions, and the interaction between the non-executive directors and the executive directors, (ii) events that occurred in practice from which lessons may be learned, and (iii) the desired profile, composition, competencies, and expertise of the Board. These evaluations will intend to facilitate an examination and discussion by the Board of its effectiveness and potential areas for improvement. Based on these evaluations, the Board will conclude whether it is functioning properly. The Board intends to formalize the policy and process for self-evaluation during 2022.
- **Best practice provision 2.3.4/5.1.4.** The CGC provides that the Compensation Committee should not be chaired by the Chairperson of the Board. In deviation from the CGC, the Compensation Committee is chaired by the Chairperson of the Board. The Board considered that the experience and continuity of Jan Øhrstrøm being chairperson of the Compensation Committee outweighs the disadvantages of him also being the Chairperson of the Board. For the reasons provided, the Company does not intend to fully comply with this best practice provision.
- **Best practice provision 2.3.4.** The CGC provides that more than half of the members of the Committees should be independent within the meaning of best practice provision 2.1.8. The Nomination and Corporate Governance Committee consists of three directors: Jan Øhrstrøm (chair), John de Koning, and Regina Hodits. In deviation from the CGC more than half of the committee members are not “independent” within the meaning of the Code, namely John de Koning and Regina Hodits. The Board considered that the experience and continuity of Mr. de Koning and Ms. Hodits outweigh the





## Governance

disadvantages of these deviations from the CGC. For the reasons provided, the Company does not intend to fully comply with this best practice provision.

- **Best practice provision 3.1.2v** recommends that variable remuneration should be linked to measurable performance criteria determined in advance. To align the employee's 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 in December 2021. There are no specific performance conditions associated to these options, only a service condition. However, considering that the value of the option is linked to the share price of ONWARD it includes an inherent performance criterion. Furthermore, the size of the stock option is linked to the position and job grade of the individual and is contingent on the performance of the individual. We will consider if more clear measurable performance criteria should be added to future grants.
- **Best practice provision 3.3.2.** The CGC recommends against providing equity awards as part of the compensation of a non-executive director. In recognition for his extraordinary contributions in 2021, the Chairman of the Board was granted a one-time option award of 38,000 shares concurrent with the executive equity grants. Our current non-executive director compensation policy does not include an ongoing equity award for the Board Chair and we do not intend to make supplemental equity awards to the Board Chair (or any non-executive directors) outside of the policy going forward.
- **Best practice provision 3.3.3.** The CGC recommends that shares held by a non-executive director in the company on whose board of directors they serve should be held as a long-term investment. The Company's Compensation Policy does not include such a requirement.

- **Best practice provision 3.4.1iii** The CGC recommends that scenario analyses be taken into consideration in determining the remuneration of the Executive Director. Since ONWARD became a listed company only in October 2021, following its initial public offering, no scenario analysis was taken into consideration in determining the remuneration of the Executive Director for 2021. The Remuneration Committee will consider performing scenario analyses in 2022.
- **Best practice provision 4.3.3.** The CGC recommends that the General Meeting should be capable of passing a resolution cancelling the binding nature of a nomination or dismissal by simple majority, representing no more than one-third of the issued share capital. Under the Articles of Association, directors can only be appointed or dismissed by the General Meeting by simple majority of votes cast, provided that the Board proposes the appointment or dismissal. In other cases, the General Meeting can only pass a resolution to appoint or dismiss a director by a two-thirds majority representing more than half of the issued share capital. The Company deems this appropriate considering the remaining shareholdings and involvement of the Company's current significant shareholders.

<sup>26</sup> Available on the [website of the Monitoring Commissie](#)

<sup>27</sup> Available on [ONWARD's website](#) under Investors/Governance

<sup>28</sup> See article 18 of the Articles of Association for more detailed information on Board decision-making.

<sup>29</sup> Available on [ONWARD's website](#) under Investors/Governance



# Risk Management & Control

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

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

As ONWARD has not established a separate internal audit function, the Board assesses annually whether adequate alternative measures have been taken. Based on the recommendations of the Audit Committee, the directors may consider whether it is necessary to establish an internal audit function. In 2021 no material failings in the internal risk management and control systems were discovered. It should be noted that these systems cannot provide absolute assurance that the Company will realize its targets, nor can they prevent all misstatements, errors and non-compliances with legislation, rules, and regulations.



## Risk Control Matters

Due to its size and history, the Company does not yet have a fully deployed and formalized risk detection, evaluation, and management system in place. The Board and Management Team continuously analyze the potential risks, evaluate their (financial) impact and likelihood, and determine appropriate measures to minimize these risks. The risk assessments are updated in line with changing internal and external circumstances. The Board and Management Team meet regularly to review developments, set targets and milestones, and evaluate progress towards realizing them. During these meetings, they also review ONWARD's financial position and present budgets/cashflow forecasts, which are followed up and regularly adjusted to changing prospects. The Management Team monitors risks as they arise and evolve, assesses their development, and implements the necessary countermeasures as required.

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

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

We use only highly specialized consultants and attorneys to secure and monitor our IP. In addition, the Management Team monitors ongoing patent protection and potential conflicts on a regular basis.

## Risk Management & Control

Our risk management and internal control system in relation to our financial reporting process is designed to provide reasonable assurance that the books and records accurately reflect transactions necessary to permit preparation of financial statements, that the financial reporting is consistent and in compliance with legal regulations and generally accepted accounting principles and that published financial data do not contain any material misstatements. The system also provides reasonable assurance that all receipts and expenditures are only made by people authorized to do so and that assets are safeguarded. As part of this system, we have adopted various internal rules and regulations, including standard operating procedures, the dual-control principle, spot checks, automated expenses reimbursement tooling, internal contract approval processes, and signatory rules.

### Risk Appetite

Our risk appetite is different for the various risk categories ONWARD is exposed to, namely:

**Risks related to our industry** may affect our strategic ambitions. We are prepared to take moderate to high strategic risks to achieve our ambitions and to create the right balance between risk and long-term reward.

**Risks related to the business and intellectual property** include adverse unexpected developments resulting from internal processes, people and systems, or from external events which are linked to the actual operation of the business. We aim to minimize these risks, only accepting a low level, to ensure that quality standards are unaffected and intellectual property is protected.

**Risks related to government regulation** relate to unanticipated failures to comply with applicable laws and regulations. We aim to minimize these risks by aiming to be fully compliant with these laws and regulations.



## Risk Management & Control

**Risks related to the 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 to maintain long terms solvency. We are committed to transparent and truthful accounting and reporting that allow users of the financial statements to take decisions considering these risks. We currently do not engage in any hedging activities. The 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

The following section describes the main risks and uncertainties that we consider as the major threats to achieve our objectives. Additional factors not listed here may also have an adverse effect on our business, financial condition, results of operations, and prospects, and could adversely affect our share price. All these risks are contingencies which may or may not occur.

### Risks Related to the Company's Industry

*If ONWARD obtains clearance or approval for its products, their commercial success will depend in part upon 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 health care 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 and 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 United States, are increasingly examining not only the safety and effectiveness of products but also their cost effectiveness when making coverage and payment decisions. It is uncertain whether the Company'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.

### Risks Related to the Company's Business

*ONWARD is wholly dependent on the success of two investigational devices, the ARC<sup>IM</sup> and ARC<sup>EX</sup> platforms. Even if the Company is able to complete clinical development and obtain 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>EX</sup> platforms.*

ONWARD currently has only two investigational devices in clinical development, the ARC<sup>IM</sup> and ARC<sup>EX</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 no products available for sale, generates no revenues from sales of any products, and may never be able to develop marketable products.

Our ARC<sup>IM</sup> and ARC<sup>EX</sup> platforms 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 PMA approval for our ARC<sup>IM</sup> platform, we must demonstrate, among other things, that the product is safe and effective for use in each target indication, a process that can take many years. If we opt to seek approval via the HDE pathway for the commercial sale of ARC<sup>IM</sup>, we must demonstrate through extensive preclinical testing and clinical trials that the product candidate does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, considering the probable risks and benefits of currently available devices or alternative forms of treatment. Of the substantial number of medical devices in development in the United States, only a small percentage successfully complete the regulatory clearance or approval process required by the FDA and are commercialized. Similarly, a substantial number of medical devices in development will eventually not obtain a certificate of conformity required for commercialization in the European Economic Area. Accordingly, even if we are able to obtain the requisite capital to continue to fund our development and clinical programs, we may be unable to successfully develop or commercialize our ARC<sup>IM</sup> and ARC<sup>EX</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 its control, which could cause significant delays in the completion of such trials or may cause it to abandon one or more clinical trials.*

ONWARD may encounter delays or difficulties in enrolling, or be unable to enroll, a sufficient number of patients to complete any of its clinical trials on its current timelines, or at all, and even once enrolled, it 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, the 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 its 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 its products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

Some of the indications that our investigational devices are intended to treat are limited, so it expects only a subset of patients with spinal cord injury 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 that participate in ongoing clinical trials for products that are competitive with our investigational devices are not eligible to participate in its 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 and market its investigational devices, if cleared or approved.

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

*The Company must obtain FDA clearance or approval before it can sell any of its products in the United States and CE Certification before it can sell any of its products in the European Union. Approval of similar regulatory authorities in countries outside the United States and the European Union 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.*

The development, manufacture, and commercialization of our products are subject to government regulation. In the United States, Europe and most other countries, ONWARD must complete rigorous preclinical testing and extensive human clinical trials that demonstrate the safety and efficacy 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.

To market our devices for use in clinics in the United States, we will need to obtain de novo classification for ARC<sup>EX</sup>. If this is granted, we intend to pursue additional clearances, including for use in the home. ARC<sup>IM</sup> is a Class III device that will require PMA approval to be marketed in the United States, while for at least one indication, it may pursue HDE approval. In Europe, under the Medical Device Regulation (MDR), ARC<sup>EX</sup> is expected to be classified as a Class IIa device and ARC<sup>IM</sup> as Class III.

Although we believe that our preclinical and clinical data will be sufficient to support regulatory clearance or approval, if the data we submit is not acceptable to the relevant regulatory authorities, clearance or approval may be delayed or may not be feasible, which could adversely impact our business and financial condition.



*The Company relies on a limited number of third-party suppliers and contract manufacturers for the manufacture and assembly of its products, and a loss or degradation in performance of these suppliers and contract manufacturers could have a material adverse effect on its business, financial condition, and results of operations.*

We rely on a limited number of third parties, some of which 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 interruptions to supply.

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. In that event, we are confident that we will be able to find alternative suppliers for all our needs. However, because of the relatively low volume of orders and 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 with 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.

*If there are quality issues, or if the performance of its products does not meet the expectations of physicians or patients, the Company may be subject to claims and liability, and its brand, reputation, and business could be adversely affected.*

In the course of conducting our business, ONWARD must adequately address quality issues that may arise with the ARC<sup>IM</sup> and ARC<sup>EX</sup> systems, including defects in third-party

## Risk Management & Control

components included in its 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 be sufficient to eliminate or mitigate occurrences of these issues and associated liabilities. In addition, even in the absence of quality issues, we may be subject to claims and liability if the performance of its products does not meet the expectations of physicians or patients.

*The Company relies on relationships with academic research centers to support its research and development activities, and it may not be able to enhance its product offerings through its research and development efforts.*

ONWARD's primary research partnership is with .NeuroRestore, a joint initiative of EPFL and CHUV in Lausanne, Switzerland, with whom we have an exclusive IP and commercialization license agreement. Additionally, we have relationships with several leading research universities around the world, including Caltech, the University of California at Los Angeles, the University of Louisville, and the University of British Columbia.

.NeuroRestore's conducts ground-breaking research ranging from basic research to preclinical research all the way to human proof-of-concept studies. ONWARD will select the most promising projects developed by .NeuroRestore to develop and commercialize, based primarily on clinical results and commercial viability. If our relationships with .NeuroRestore or our other academic partners were to be terminated or otherwise modified, it could adversely affect our ability to expand potential indications for our ARC Therapy in the future.

Grégoire Courtine, ONWARD's Chief Science Officer, is a professor at EPFL. If this potential conflict of interest is not prudently managed, it could adversely affect our ability to license intellectual property from EPFL and commercialize therapies that rely on that intellectual property.



ONWARD may also decide to invest in developing new partnerships and licensing agreements to provide us with new product offerings without significant research and development activities. However, these agreements may not give us exclusive rights to use the intellectual property for all relevant fields of use or territories where we wish to develop or commercialize our products. As a result, we may not be able to prevent other companies from developing and commercializing competing products. Moreover, if these licenses were terminated, competitors would have the freedom to develop products similar or identical to ours.

Despite thorough market research, our products may not incorporate all the features sought by consumers, their caregivers or healthcare providers. We may also experience delays in various phases of product development that cause customers to delay or forgo purchases of our devices. Even if we are able to successfully develop these products, they may not generate sales in excess of the costs of development. Lastly, they may be quickly rendered obsolete by changing consumer preferences or the arrival on the market of competing products with new technologies or features.

*Active implantable medical devices such as the ARC<sup>™</sup> platform carry risks associated with the surgical procedure for implant or removal of the device, use of the device, or the therapy delivered by the device.*

The ARC<sup>™</sup> system includes a component that is implanted in the patient through a surgical procedure. It is not possible to design and build electronic implantable medical devices that are 100% reliable, since all electronic devices carry a risk of failure. Furthermore, all surgical procedures carry risks, and the effectiveness of any medical therapy varies between patients. The consequences of a failure of the ARC<sup>™</sup> system may include complications arising from product use or the surgical procedure and could potentially range from minor to life-threatening effects and even death. Such adverse events could lead to product liability lawsuits, medical malpractice lawsuits, investigations by regulatory authorities, adverse publicity, or even criminal charges that may negatively impact our ability to conduct our business, obtain regulatory approval for the ARC<sup>™</sup> system, and commercialize it.

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*Interim, “topline,” and preliminary data from its clinical trials that the Company announces or publishes from time to time may change as more patient data become available and are subject to confirmation, regulatory audit, and verification procedures that could result in material changes in the final data.*

From time to time, ONWARD may publicly disclose preliminary or “topline” data from our preclinical studies and clinical trials, based on a preliminary analysis of the data available at the time. Preliminary results are subject to change and should be viewed with caution. They may differ from future results of the same studies, or they may be qualified with different conclusions or considerations once the final data has been fully evaluated. That is because clinical outcomes may materially change as continued patient enrolment and treatment makes more patient data available, or as clinical trial participants continue other treatments for their disease. Differences between preliminary or interim data and final data could significantly harm our business prospects. In addition, disclosure of interim data by ONWARD or our competitors could result in volatility in our share price.

If the interim, topline, or preliminary data that we report differ from actual results, or if third parties, including regulatory authorities, disagree with the conclusions reached, this could adversely affect our ability to obtain approval for and commercialize our investigational devices, and harm our business, operating results, prospects or financial condition.

*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 cyber-attack.*

Our information technology (IT) systems are essential to the successful operation of our business. We seek to allocate and manage the resources necessary 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 cyber-attacks 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, to date none has been material.



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 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 United States or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, could adversely affect its business.*

In 2021, the Company's business, financial condition and results of operations were negatively affected by COVID-19 pandemic as well as the various restrictions and measures imposed by national, state and local authorities in an effort to control the spread of the disease. Among others, research and development of our ARC<sup>IM</sup> System was impacted by work-from-home requirements, which limited our ability to test and debug hardware and software systems, as these processes require access to laboratories and equipment. We experienced delays in patient enrollment in our Up-LIFT Study from September 2020 to January 2021, as well as reduced productivity as a result of employee's inability to work due to illness.

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, among others, to inventory shortages or obsolescence; delays in approval of our devices by regulatory authorities; delays in decisions by insurance companies regarding coverage of our products; delays in clinical trials; delays in growing our sales organization; adjustments or disruptions to the business of third parties we work with, including suppliers, medical

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institutions and clinical investigators; decrease 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 the COVID-19 pandemic adversely affects our business and financial results, it may also heighten many of the other risks described in this section, including those relating to incurring future operating losses, advance of the ARC<sup>IM</sup> and ARC<sup>EX</sup> platforms through regulatory pathways, and if cleared or approved, successful commercialization, supply chain and distribution channels.

### Risks Related to Government Regulation

*The Company may not receive the necessary approvals, granted de novo classifications, or clearances for its ARC<sup>EX</sup> and ARC<sup>IM</sup> platforms or future devices and expanded indications, and failure to timely obtain these regulatory clearances or approvals would adversely affect its ability to grow its business.*

ONWARD is seeking de novo classification to market ARC<sup>EX</sup> for use in clinics in the United States. If this is granted, we intend to pursue additional regulatory clearances, including for use in the home. ARC<sup>IM</sup> is a Class III device that will require PMA approval in order to be marketed in the United States, while for at least one indication, it may pursue HDE approval. 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 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 demonstrate 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 preclinical studies and clinical trials
- Inability to demonstrate that the clinical and other benefits of the device outweigh the risk
- Manufacturing process or facilities used do not meet 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. Furthermore, 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 lengthier, more rigorous process than expected for future products, or for modifications to existing products, their introduction could be delayed or canceled, 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 in the EEA (Regulation (EU) 2017/745). The MDR, which became fully applicable on 26 May 2021, impose the same basic requirements as the EU Medical Devices Directive, but is generally more stringent, especially in terms of risk classes and the oversight provided by notified bodies that perform conformity assessments of devices.

## Risk Management & Control

Following its departure from the EU on 31 January 2020, the UK continued to follow the same regulations as the EU during a transition period which ended on 31 December 2020. From that point, all medical devices must be registered with the Medicines and Healthcare products Regulatory Agency (MHRA) before being placed on the UK market. European CE marks will continue to be recognized in UK until June 30, 2023, following which a UK Conformity Assessed (UKCA) mark will be required for a medical device to be marketed in the United Kingdom. The new Medical Devices Regulation will not automatically apply in the UK, so the regulation of medical devices in the UK may diverge from EU Regulations in future.

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

*The clinical development process required to obtain regulatory clearances or approvals is lengthy and expensive with uncertain outcomes, and the data developed in those clinical trials is subject to interpretation by EU Regulators, FDA and foreign regulatory authorities. If clinical trials of the current ARC<sup>EX</sup> platform and ARC<sup>IM</sup> platform and future products do not produce results necessary to support regulatory clearance or approval, a granted de novo classification or clearance in the United States or, with respect to the Company's current or future products, elsewhere, it will be unable to commercialize these products and may incur additional costs or experience delays in completing, or ultimately be unable to complete, the commercialization of 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 the trials. The following circumstances could harm our ability to complete development or commercialize our products:

- The FDA may reject our 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 partner 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, 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.

## Risk Management & Control

- We may be required to terminate clinical research for various reasons, including safety issues or noncompliance 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 our 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, clinical trials conducted in countries outside the United States 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 have an adverse effect on the Company's business, financial condition and results of operations.



We may from time to time publicly announce the date at which we expect to reach various clinical, regulatory, or product development milestones. These could include the submission to the FDA of an IDE application to commence 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.

*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.*

If we successfully secure FDA approval and clearance, our investigational devices will remain subject to oversight and regulation by the FDA throughout the manufacturing and commercialization processes. In particular, we and our suppliers or manufacturers will be required to comply with the FDA's Quality System Regulations (QSR), which cover the manner in which we conduct and document the design, testing, production, control, quality assurance, labelling, packaging, sterilization, storage, and shipping of our products.

The FDA audits compliance with the QSR and other regulatory requirements through periodic announced and unannounced inspections of manufacturing and other facilities. Failure to meet these QSR requirements could delay production and lead to fines, difficulties in obtaining regulatory clearances and approvals, withdrawal of PMAs that have already been granted, product recalls, and various enforcement actions or sanctions. Such compliance failures or sanctions could have a material adverse effect on our reputation, business, results of operations, and financial condition.

## Risk Management & Control

### Risks Related to the Company's Intellectual Property

*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.*

ONWARD 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 our 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, we may not be able to secure alternatives, negatively affecting our ability to develop our products.

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

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

Patents do not automatically provide a competitive advantage. Competitors may be able to design around our patents and develop products that provide comparable or superior outcomes. Any changes we make to our products, including design improvements that we



believe make them more marketable, may not be covered by previously licensed patents. We may be required to file new applications and/or seek other forms of protection covering these alterations.

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

We may in the future obtain certain intellectual property related to our technology from third parties. If that is the case, we cannot be certain that these third parties took the necessary actions to maintain the IP rights or that their transfer to us was proper and effective. As a result, we may be subject to claims challenging their ownership or enforceability, which would limit our ability to prevent competitors from making or selling duplicate or similar technologies for which, or in countries where, we have no patent protection.

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

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

In both the United States and Europe, the lifespan of a patent 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 from competitive

## Risk Management & Control

products. 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 might expire before or shortly after commercialization begins. As a result, our patent portfolio may not provide the Group with sufficient rights to exclude others from commercializing similar or identical products for a sufficient amount of time.

*If the Company is unable to protect the confidentiality of its trade secrets, its business or competitive position could be harmed.*

To protect our confidential and proprietary information, we rely upon non-patent protection such as trademark or trade secret protection and confidentiality agreements with employees, consultants, vendors, and third parties. We also implement commonly accepted physical and technological security measures to protect our confidential information. However, these various measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be expensive and time-consuming, and the outcome is unpredictable. The criteria for protection of trade secrets can vary among different jurisdictions. Moreover, trade secrets may be independently developed by others in a manner that could prevent legal recourse.

*If any of our confidential or proprietary information were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed.*

*The Company relies on licenses and sublicenses to certain patent rights with third parties. If the Company fails to comply with its obligations under its patent licenses with third parties, it could lose license rights that are important to its business. Additionally, the Company may not be able to control the prosecution or maintenance of such patent rights, which could adversely affect its business.*





ONWARD relies on licenses and sublicenses to certain patent rights and other intellectual property from third parties that are necessary to the development of our products, including the software modules that we expect to integrate into our ARC<sup>IM</sup> and ARC<sup>EX</sup> platforms. All the following circumstances related to licensing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects:

- Future licenses we enter into may not provide exclusive rights to use the related intellectual property for all the fields of use or territories in which we wish to develop or commercialize our products. We would therefore not be able to prevent other companies from developing and marketing competing products.
- As some of the underlying intellectual property rights related to a license would not belong to us, our rights would be subject to the continuation and compliance with the terms of the licensing agreement. If the agreement is terminated, competitors would have the freedom to develop and market products similar or identical to ours.
- If our licensor concludes that we have materially breached the license agreement and terminates it, we may have to cease developing, manufacturing or marketing any product covered by these agreements.
- A license agreement may not grant us the right to control the preparation, filing, prosecution or maintenance of patents and patent applications covering our products. If our licensing partner fails to adequately manage these rights, we may be unable to prevent competitors from developing or commercializing similar or identical products.
- Where we have the right to control the prosecution and maintenance of the relevant patents, we may still be adversely affected by actions that took place prior to the date upon which we assumed control.
- Where we are permitted to pursue the enforcement or defense of these patents, we cannot be certain that the licensors will provide us with the necessary cooperation, or that they will allocate sufficient resources to defend their interests. An adverse outcome from any legal action, even we are not a party to it, could harm our business by preventing us from continuing to license intellectual property we need to operate our business.

## Risk Management & Control

- If other third parties, in addition to the licensor, have ownership rights to these patents, they may be able to license them to our competitors. We may need to obtain additional rights from them or we could be prevented from developing and commercializing the related products.
- If we need to amend existing licenses, the licensor may impose terms that are more favorable to them, including terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the related intellectual property.

*The Company may be required to pay certain milestones and royalties and fulfil other obligations under its license agreements with third-party licensors.*

ONWARD may be required to pay milestones and royalties related to the development or commercialization of products using technologies that we may license or sublicense from third parties. These payments could adversely affect our profitability related to products that we may seek to develop or commercialize in the future. We may need to meet specified milestones or fulfill certain obligations to maintain these licensing agreements, such as devoting a certain quantity of resources to developing our products. Failure to satisfy such obligations could result in the termination of our rights under such agreements.

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

*The Company has incurred significant operating losses since inception, and expects to incur operating losses in the 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 invested substantially all of our efforts in the research and development of, and seeking regulatory clearance or approval for, our ARC<sup>IM</sup> and ARC<sup>EX</sup> platforms. We are not profitable and has 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 about future success, performance or viability may not be as accurate as they could be if the Company had a longer operating history or commercial revenues.



ONWARD has not yet derived sufficient revenues to support operations, as our activities have consisted of developing our technology and conducting preclinical studies and clinical trials. As of 31 December 2021, the loss brought forward amounted to EUR 34 million. These losses have resulted primarily from costs incurred in the development of the ARC<sup>IM</sup> and ARC<sup>EX</sup> platforms, and from general and administrative costs associated with operations.

The current or future clinical trials of any current or future investigational devices are, and the manufacturing and marketing of any such investigational devices will be, subject to extensive and rigorous review and regulation by the FDA and other government authorities in the United States 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 (i) continue research and development activities for our ARC<sup>IM</sup> and ARC<sup>EX</sup> technology platforms and related technologies; (ii) seek FDA regulatory clearances and approvals for the ARC<sup>IM</sup> and ARC<sup>EX</sup> platforms or other future investigational devices in the US, regulatory approvals in Europe, and potentially other regulatory approvals in other jurisdictions; (iii) build our commercial infrastructure; and (iv) incurs additional operational costs associated with being a public company. As a result, ONWARD expects to continue to incur operating losses for the foreseeable future. The expected future operating losses, combined with prior operating losses, may adversely affect the market price of our Ordinary Shares and ability to raise capital and continue operations.

We expect sales of our ARC<sup>IM</sup> and ARC<sup>EX</sup> platforms, if cleared or approved, to account for a majority of our future revenue. If the ARC<sup>IM</sup> and/or ARC<sup>EX</sup> platforms do not achieve regulatory clearance or approval, an adequate level of acceptance by physicians, healthcare payors, and patients or adequate reimbursement from third-party payors, the Company may not generate sufficient revenue and may not be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability in subsequent periods or on an ongoing basis. In such a 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 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.*

## Risk Management & Control

As of 31 December 2021, ONWARD had cash and cash equivalents of KEUR xxx. Based on cash flow forecasts for 2022 and 2023, we believe that this will be sufficient to meet our capital requirements and fund our operations for at least 12 months as of the date of this Annual Report. However, we have based these estimates on assumptions that may prove to be incorrect and we could spend our available financial resources much faster than currently expected.

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

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

- Continuing our research and development efforts, completing ongoing and planned clinical trials, and applying for (i) de novo classification granting marketing authorization for ARC<sup>EX</sup> for use in clinics, and thereafter 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>, though we expect to pursue approval to legally market at least one indication via HDE.
- 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 United States, 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 intellectual property portfolio, as well as any other action required in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other intellectual property 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 needs to implement additional internal systems and infrastructure, including financial and reporting systems, incidental to being a public company.

The Company may 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 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>IM</sup> and ARC<sup>EX</sup> platforms, technologies, future revenue streams, or research programs, or grant licenses on terms that may not be favorable to us. If we are unable to obtain adequate financing when needed and on terms that are acceptable to us, we may have to delay, reduce the scope of or suspend the implementation of our sales and marketing plan and our ongoing research and development efforts, which would have a material adverse effect on our business, financial condition, and results of operations.

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

## Risk Management & Control

ONWARD's revenue and results of operations 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>IM</sup> and ARC<sup>EX</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>IM</sup> and ARC<sup>EX</sup> platforms for cleared or approved indications, if any.
- Expenses incurred in manufacturing and selling our ARC<sup>IM</sup> and ARC<sup>EX</sup> platforms, if cleared or approved.
- Costs associated with scaling up and expanding our manufacturing capacity.
- Costs associated with building and expanding our sales and marketing efforts in the US, Europe, and internationally.
- Costs associated with conducting research and development efforts for future improvements to, or versions of, our ARC<sup>IM</sup> and ARC<sup>EX</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. And
- The severity, duration and impact of the Covid-19 pandemic, which may adversely impact our business and planned development and future commercialization of our ARC<sup>IM</sup> and ARC<sup>EX</sup> platforms.



Because of 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.

Any unanticipated change in revenues or operating results is likely to cause the price of our Ordinary Shares to fluctuate. New information may cause investors and analysts to revalue our business, which could cause a decline in the price of our Ordinary Shares.

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

In general, under Sections 382 and 383 of the 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 utilize 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 utilize 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 utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers, even if we attain profitability.





# Investor Relations

We engage and maintain open dialogue with investors and analysts through a variety of communication channels, including the General Meeting, roadshows, investor conferences, presentations, and webcasts.

Up-to-date financial information about ONWARD is published on our Investor Relations **website**. 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 2022

- 26 April: Annual Report and Q1 Business Update
- 10 June: Annual General Meeting
- 27 September: Interim Report
- 8 November: Q3 Business Update

During a closed period prior to the publication of the annual and half-year results, we do not engage in discussion with analysts, investors and financial journalists or make presentations at investor conferences.

Closed periods based on the 2022 financial calendar:

- 28 March–26 April 2022
- 29 August–27 September 2022

## Dividend Policy

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

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

## Capital Structure & Voting Rights

The authorized share capital of ONWARD comprises 50,937,500 Ordinary Shares and 50,937,500 Preferred Shares. All of the issued Ordinary Shares are fully paid-up and represent capital in the Company. There are no convertible securities, exchangeable securities or securities with warrants in the Company. No shareholders have any voting rights different from any other shareholder and no voting rights are limited in any manner. ONWARD is not aware of any agreements that might result in a limitation of the transferability of the 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 the 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 between 3% and 25% in the Company’s total issued share capital as at 31 December 2021:

- NRT Holdings LLC (12.30%, notification date 22 October 2021)
- Inkef Capital B.V. (12.26%, notification date 22 October 2021)
- LSP V Management B.V. (11.48%, notification date 22 October 2021)
- Wellington Partners Nominee Ltd. (10.94%, notification date 22 October 2021)
- GIMV NV (10.82%, notification date 22 October 2021)
- Stichting G-Therapeutics Participaties (8.94%<sup>a</sup>, notification date 22 October 2021)
- Staat der Nederlanden (Invest-NL Capital) (3.65%, notification date 22 October 2021)
- D.L. Marver (3.23%, notification date 22 October 2021)

<sup>a</sup>: The 8.94% interest includes 3.20% of D.L. Marver’s holding.

## Investor Relations

### Listing



The shares of ONWARD Medical N.V. trade on Euronext in Brussels (primary listing) and Euronext Amsterdam (secondary listing) under the symbol “ONWD” since the IPO on 21 October 2021.

### Share Price

#### Broker

Degroef Petercam

Kepler Cheuvreux

#### Analysts

David Seynnaeve, PhD and Laura Roba

Damien Choplain and Daan Vandenberg, CFA

### Analyst Coverage

ONWARD was covered by two brokers at the end of 2021.



# Report of the Non-Executive Directors

Provided below is the report of the Non-Executive Directors of the Company for the financial year 2021, as referred to in best practice provision 5.1.5 of the CGC.

## Supervision by the Non-Executive Directors

The Non-Executive Directors are in charge of supervising the policies implemented by the Executive Director and the management team, and the general affairs of the Company and its affiliated entities, including the deployment of the Company's strategy regarding long-term value creation.

With a view of maintaining supervision of the Company, the Non-Executive Directors regularly discussed strategic matters with the Executive Director and management team during meetings of the Board of Directors, such as the annual financial reports, financing transactions, yearly budget and long-term business plans.

Furthermore, the Non-Executive Directors have examined and monitored each and all stages of the domiciliation process and taken all relevant decisions.

The Board has allocated certain specific responsibilities to the Audit Committee, Compensation Committee and the 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.

## Audit Committee

The main topics discussed by the Committee in 2021 were:

- The operation of the internal risk management and control systems, including supervision of the enforcement of the relevant legislation and regulations and supervision of the operation of codes of conduct
- The provision of financial information by the company (including but not limited to the choice of accounting policies, application and assessment of the effects of new rules, information about the treatment of estimated items in the financial statements, forecasts and external auditors)
- Relations with the external auditor, including the audit plan and the external auditor's independence (also considering any non-audit services provided) and remuneration
- The financing of the company
- The need for an internal audit function
- Various updates on the application of information and communication technology, including cyber security matters

The Committee made recommendations and issued advice in relation to these topics to the entire Board for approval (if applicable). During 2021, since becoming a listed entity, the Audit Committee held one meeting (attendance details provided in the table below).



## Report of the Non-Executive Directors

### Compensation Committee

The main activities carried out by the Compensation Committee during 2021 were:

- Submitted proposals to the board concerning changes to the Company's compensation policy
- Submitted proposals to the board concerning the compensation of individual Directors and the management team that included the compensation structure, amount of fixed and variable compensation components, applicable performance criteria, scenario analyses and pay ratios within the group
- Approved the proposal to grant stock options for the management team
- Evaluated a preliminary proposal of the employee stock ownership plan (reserved to non-director employees)
- Prepared the compensation report

The Committee made recommendations and issued advice in relation to these topics were made by the Committee to the Board for approval (if applicable). During 2021, since becoming a listed entity, the Compensation Committee held one meeting (attendance details provided in the table below).

### Nomination & Corporate Governance Committee

The main activities carried out by the Nomination and Corporate Governance Committee during 2021 were:

- Established selection criteria and appointment procedures for directors
- Reviewed the size and composition of the Board and submitted proposals for the composition profile of the Board (when required)
- Reviewed the functioning of individual directors and reported on the results of the review to the Board

- Drafted a plan for the succession of directors
- Submitted proposals for (re)appointment of directors
- Supervised the policy of the Board regarding the selection criteria and appointment procedures for the Company's senior management and executive officers
- Examined the corporate governance report pursuant to applicable law

A search for new Directors to the Board was initiated prior to the IPO and the recruiter provided several potential candidates to the Committee. There has been considerable communication among Committee members (including the topics above as well as candidate screening and feedback, Chairman interactions with search firm etc.) but no formal Committee meeting was held in 2021 since the IPO in October 2021. The Committee made recommendations and issued advice in relation to these topics to the Board for approval (if applicable) based on these communications.

The Non-Executive Directors also examined the report prepared by the Compensation Committee then approved by the Board. The Non-Executive Directors were able to review and evaluate the performance of the Nomination and Corporate Governance Committee. There is no need to amend the size or composition of any of the committees.

### Evaluation

Each year the Non-Executive Directors should evaluate their own functioning, the functioning of the Board committees and the functioning of the Executive Directors. Since ONWARD became a listed company only in October 2021, following its initial public offering, the Board has not yet formalized the policy and process for evaluating its functioning. This is a deviation from the requirements of best practice provisions 2.1.7 and 2.1.8 of the CGC. Also refer to the section 'Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code' of the governance section for further information.

The Board believes that its committees have functioned well in carrying out their duties to the extent possible for the 2021 year.





**Report of the Non-Executive Directors****Internal Audit Function**

As per the recommendation of the Audit Committee, the Board concluded that due to the size of the Company it does not yet require an internal audit function to be created. The Board has assessed whether adequate alternative measures have been taken and will consider each year whether it is necessary to establish an internal audit department. In arriving at this conclusion, the Board took into consideration that the Company has provided for management to support the assessment and testing of our risk management and control systems.

**Independence of the Non-Executive Directors**

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

The Non-Executive Directors have determined that five of the eight Non-Executive Directors do not qualify as independent in accordance with best practice provisions 2.1.7 and 2.1.8 of the CGC. Prof. Courtine, one of the founders of ONWARD, is considered "not independent" as he is the Chief Science Officer of the Company and receives personal compensation for this role. Regina Hodits, John de Koning, Roel Bulthuis, and Patrick Van Beneden are considered "not independent" as they are representatives of major shareholders holding at least 10% of the shares in the Company (Wellington, LSP, Inkef and GIMV). These four shareholders have a long-term interest in the Company and were willing to back this up by making senior partners or staff with relevant knowledge and experience available to the Company. Also refer to the paragraph '*Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code*' of the governance section for further information.



21 October – 31 December 2021

# Meetings of the Board & Committees

Member & Principal Position	Independent According to CGC	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 and CSO	No	100%							
<b>Ian Curtis</b> Non-Executive Director and Vice-Chairperson	Yes	100%	X <sup>a</sup>	100%					
<b>Fredericus Colen</b> Non-Executive Director	Yes	100%	X	100%	X	100%			
<b>Regina Hodits</b> Non-Executive Director	No	100%						X	100%
<b>Roel Bulthuis</b> Non-Executive Director	No	100%				X	100%		
<b>John de Koning</b> Non-Executive Director	No	100%						X	100%
<b>Patrick Van Beneden</b> Non-Executive Director	No	100%	X	100%					
<b>Number of Meetings Held:</b>		<b>1</b>		<b>1</b>		<b>1</b>			<b>0<sup>b</sup></b>

a: Chairperson of the respective committee.

b: No formal Committee meeting was held in 2021 since the IPO in October 2021



# Board of Directors' Statements

The Report of the Board of Directors (the Report) (consisting of pages 4 up to and including 139) and such parts of the financial statements as referred to in the Report, comprise the Bestuursverslag, within the meaning of article 2:391 of the DCC.

The Board of Directors confirms, in accordance with best practice provision 1.4.3 of the Dutch Corporate Governance Code, and with reference to the risk management and control section on pages 107–134 and the financial review on pages 76–81, that to the best of its knowledge:

- The Report provides sufficient insights into any deficiencies in the effectiveness of the internal risk and control systems; no deficiencies in the effectiveness of the internal risk and control systems have been identified
- The Company's internal risk management and control systems provide reasonable assurance that financial reporting does not contain any material inaccuracies
- There is a reasonable expectation that the Company will be able to continue its operations and meet its liabilities for at least 12 months. Therefore, it is appropriate to adopt the going concern basis in preparing the financial reporting, as referred to in note 1.6 of the Consolidated Financial Statements
- There are no material risks or uncertainties that could reasonably be expected to have a material adverse effect on the continuity of the Company's operations in the coming twelve months

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

- The consolidated financial statements as at and for the year ended 31 December 2021, 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 Dutch Civil Code, 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, 25 April 2022 – **Board of Directors**

# Remuneration Report

This remuneration report gives an overview of the remuneration of the Board in 2021 and explains how this relates to the Company's policy with regard to the remuneration of its Non-Executive and Executive Directors (the Compensation Policy), which policy was adopted at the Company's general meeting on 11 October 2021. This Remuneration Report has been prepared in line with Section 2:135b of the Dutch Civil Code and best practice provision 3.4.1 of the CGC. This report will be submitted to the Annual General Meeting (AGM) for an advisory vote. The first AGM of the Company is scheduled for 10 June 2022.

Effective as of 21 October 2021, the Company completed its conversion into an N.V..

The Compensation Policy is available on the Company's website ([onwd.com](https://onwd.com)) under **Governance Documents**.





**Remuneration of the Executive Director**

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 achievement of individual 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, as well as typical compensation levels in the industry and in the market, especially in comparison with similar listed companies in the MedTech sector. The fixed remuneration is paid out as a monthly salary.

**Variable Remuneration**

The short-term variable remuneration consists of annual performance-based compensation (a bonus) defined on a yearly basis. The company takes into account both corporate and individual objectives. Corporate objectives are centered around strategic R&D deliverables, key regulatory milestones, financing goals. These corporate objectives are measured through a set of specific targets that help track progress towards their completion.

The long-term variable remuneration consists of periodic grants of stock options that vest monthly over a four-year vesting period. 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 10-year term of the options. 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 amongst our industry peer group in Europe and the US. Award sizes are determined at the point of grant in reference 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, amongst others, the applicable yearly exercise periods, they may be exercised after expiration of at least 10 years after their issuance
- In case of termination of the management agreement of an Executive Director (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
- The plan is not based on the achievement of specific performance related KPI's. However, the size of the stock option grant is linked to the job grade of the position and is contingent on the performance of the individual 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 leading to an increase in the share price

There are no specific performance conditions associated to this grant, only a service condition. This is a deviation from the requirements of best practice provision 3.1.2 v of the CGC. Also refer to the section 'Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code' of the governance section for further information.

**Remuneration Report**

An award letter was granted to the Executive Director in December 2021 to the varying degree contingent on the impact and scope of his role. The main conditions for exercise of 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: 0 Unvested: 188,000	EUR 9,70	15/12/2031

**Reduction or Clawback of Variable Remuneration**

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

- 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 were to be unacceptable according to the criteria of reasonableness and fairness
- Clawback: the Board has the authority under Dutch law to recover from an Executive Director any variable remuneration paid based on incorrect financial or other data

These rules do not apply to the variable remuneration granted to the Executive Director prior to the Conversion.

**Contribution to Long-Term Performance & Value Creation**

The 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, in order to attract both the required top talent to execute our long-term strategy and the necessary non-executive expertise to effectively supervise its execution, with the purpose of creating long-term value and sustainable growth in the best interest of the Company and all of our stakeholders.



## Remuneration Report

### Executive Director's Remuneration for 2021

A detailed breakdown of the remuneration of the Executive Director is presented in the table below.

EUR'000	Dave Marver CEO since 1 July 2020	
	2021	2020
Base Salary	340	207
Pension Benefits	28	5
Relocation & Other Benefits	228	-
<b>Total Fixed Compensation</b>	596	212
Annual Performance-Based Compensation	595	50
Share-Based Remuneration / Stock Options	2,140 <sup>a</sup>	746
<b>Total Variable Compensation</b>	2,735	796
<b>Total Compensation</b>	3,331	1,008

<sup>a</sup>: Share-based remuneration relates to the employee investment plan (EIP) that vested on the date of the IPO (EUR 2,118,495). The expense relating to the stock options granted 15 December 2021 amounted to EUR 21,289.

### Liability Insurance (D&O) & Indemnity

The Company maintains D&O insurance covering the Executive Director, with a reasonable retained amount. Pursuant to article 23 of the Articles of Association, the Executive Director is indemnified, held harmless, and reimbursed by the Company for all expenses, financial effects of judgements, fines, and amounts paid in settlement actually and reasonably incurred by him in connection with an action, suit, proceeding or investigation against him in his capacity as Executive Director.

### Scenario Analyses

Since ONWARD became a listed company only in October 2021, following its initial public offering, no scenario analysis was taken into consideration in determining the remuneration of the Executive Director for 2021. This is a deviation from the requirements of best practice provision 3.4.1iii of the CGC. Also refer to the section 'Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code' of the governance section for further information.

### Performance Assessment

The variable remuneration of the Executive Director is determined by the Board (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 judgement. The variable remuneration is linked to the performance against a set of financial and non-financial targets that is consistent with and supportive of the strategy and long-term interests of the Company. These targets include, among other topics, performance, business development, strategy, investor relations and general management. Risk alignment is also embedded in the target setting to promote sound and effective risk management. The variable remuneration is paid out according to how the Company's business develops, the scope of the Executive Director's achievement, as well as the realization of the Company's general objectives.



**Remuneration Report**

For our Executive Director, there was a set of both financial and non-financial KPIs as listed below:

- Complete enrollment in the Up-LIFT Study
- Complete development of ARC™ System
- Initiate enrollment in HEMO FiH Hybrid Study
- Establish ONWD as leading stakeholder in SCI community
- Create culture of performance, accountability, and meaning
- Raise capital to sustain operations through mid-2022

Name of Director, Position	Type of Performance Criteria	Relative Weighting	a. On Target Performance
			b. Corresponding Award
Dave Marver, CEO	Strategic Objectives	80%	a. 100% b. EUR 272,000
	Financial Objectives	20%	a. 100% b. EUR 68,000

For 2021 only the on-target performance and corresponding award was formalized. After conclusion of the financial year, the Board assesses to what extent the KPIs have been met and determines the bonus payout percentage for the Executive Director. Bonus compensation is at the discretion of the Remuneration Committee and ultimately the Board. On the recommendation of the Remuneration Committee, it was recognized by the Board that the company had an exceptional and very successful year that included two fundraising events in which the CEO played an integral part and the CEO was granted a 175% bonus payout relating to 2021.

**Remuneration of Non-Executive Directors**

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:

**Determination of Non-Executive Directors’ Remuneration**

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





## Remuneration Report

The remuneration of the Non-Executive Directors for 2021 amounted to:

Name	Board	Audit Committee	Compensation Committee	Nomination & Corporate Governance Committee	Total 2021 Compensation
<b>Jan Øhrstrøm</b>	Chair		Chair	Chair	533,577 <sup>a</sup>
<b>Gregoire Courtine</b>	Member				980,918 <sup>b</sup>
<b>Fred Colen</b>	Member	Member	Member		96,820 <sup>c</sup>

a: The compensation includes the vesting of the Employee Investment Plan on IPO, the 2021 expense for the one-off option award of 38,000 shares that was approved by the board and the reimbursement of travel expenses.

b: The compensation includes the remuneration paid in relation to his role as CSO (EUR 118,522), as well as the vesting of the Employee Investment Plan on IPO (EUR 807,161) and stock options granted in December 2021 under the new long term incentive plan (EUR 7,021).

c: The compensation includes the vesting of the Employee Investment Plan on IPO.

In recognition for his extraordinary contributions in 2021, the Chairman of the Board was granted a one-time option award of 38,000 shares concurrent with the executive equity grants. This was in addition to the fees as Chairman of the Board and his various Committee positions. This is in deviation from best practice provision 3.3.2 of the CGC, which recommends against providing equity awards as part of the compensation of a non-executive director. (Refer to *Deviations from the Best Practices Provisions of the Dutch Corporate Governance Code*.)

## Liability Insurance (D&O) & Indemnity

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

Pursuant to article 23 of the Articles of Association, Non-Executive Directors are indemnified, held harmless, and reimbursed by the Company for all expenses, financial effects of judgements, 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 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 2020 and 2021. The amounts mentioned in the table are gross amounts before the impact of social security or income tax deductions.

EUR'000	2021	2020	Change %
Net loss of the period	34,314	20,014	-71%
Executive Director	3,331	1,008	65% <sup>a</sup>
FTE employees	76.7	55	39%
Employee costs of FTE employees	15,519	8,534	82%
Cost per FTE	202	155	30%
Non-Executive Directors	1,616	959	69%

a: CEO was appointed on 1 July 2020. For comparability the change % was calculated by extrapolating the 2020 salary for 12 months (EUR 2,016 thousand).



## Pay Ratio

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

The entire workforce of the Company is included in the reference group expressed in the form of full-time equivalent employees (FTE). The full-time equivalence of each employee is calculated based on the number of hours worked by the employee in each period, compared to the maximum number of hours/period allowed, as per the local law prevalent in the country of operation. As of 31 December 2021, there were 76.7 FTEs.

The calculation of the pay ratios is based on the average of the remuneration received by the employees of the reference group. The remuneration taken into account is that 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 ended 31 December 2021.

The Company used both fixed and variable remuneration components when determining the pay ratio for a given year. The pay ratio disclosed by the Company reflects the last financial year. The average Executive Director to employee pay ratio stands at 16 in 2021 compared to 13 in 2020. 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).



# Financials

# Consolidated Statement of Profit & Loss

For the Year Ended 31 December

<i>All amounts in EUR '000</i>	Notes	2021	2020
Grants	2.1	1,399	800
<b>Total Revenues &amp; Other Income</b>		<b>1,399</b>	<b>800</b>
Science expenses	2.2,2.9	(2,686)	(1,123)
Research & Development expenses	2.3,2.9	(7,932)	(5,823)
Clinical & Regulatory expenses	2.4,2.9	(4,775)	(2,770)
Marketing & Market Access expenses	2.5,2.9	(1,516)	(394)
Patent & related expenses	2.6,2.9	(1,361)	(1,186)
Quality assurance expenses	2.7,2.9	(993)	(361)
General & administrative expenses	2.8,2.9	(10,667)	(4,655)
<b>Total Operating Expenses</b>		<b>(29,931)</b>	<b>(16,312)</b>
<b>Operating Loss for the Period</b>		<b>(28,532)</b>	<b>(15,512)</b>
Financial income		-	-
Financial expense	4.5	(5,713)	(4,482)





# Consolidated Statement of Comprehensive Income

For the Year Ended 31 December

<i>All amounts in EUR '000</i>	Notes	2021	2020
<b>Net Loss for the Period</b>		<b>(34,314)</b>	<b>(20,014)</b>
Remeasurement of post-employment benefits	5.0	(714)	35
<b>Other comprehensive income that will not be reclassified to profit or loss in subsequent periods (net of tax)</b>		<b>(714)</b>	<b>35</b>
Currency translation differences		249	(441)
<b>Other comprehensive income that will be reclassified to profit or loss in subsequent periods (net of tax)</b>		<b>249</b>	<b>(441)</b>
<b>Total Comprehensive Result for the Year, Net of Tax</b>		<b>(34,779)</b>	<b>(20,420)</b>
Attributable to:			
Equity holders of the parent		(34,779)	(20,420)
Non-controlling interests		-	-
		<b>(34,779)</b>	<b>(20,420)</b>

# Consolidated Statement of Financial Position

For the Year Ended 31 December

All amounts in EUR '000	Notes	2021	2020
<b>Assets</b>			
<b>Non-Current Assets</b>			
Intangible fixed assets	3.0	10,029	6,825
Property, plant and equipment	3.1	190	248
Right of use assets	3.2	2,190	149
		12,409	7,222
<b>Current Assets</b>			
Indirect tax receivables	3.3	339	93
Receivable from related parties		60	57
Other current assets	3.4	2,546	436
Cash and cash equivalents	3.5	89,443	6,382
		92,387	6,968
		<b>104,796</b>	<b>14,190</b>

**Consolidated Financial Statements**

**Equity & Liabilities**

**Equity & Reserves**

Issued capital	4.0	3,622	-
Share premium	4.0	155,248	3,083
Other reserves*	4.0	(214)	17,933
Retained earnings		(75,974)	(53,111)
<b>Total Equity Attributable to Shareholders</b>		<b>82,683</b>	<b>(32,095)</b>

**Non-Current Liabilities**

Interest-bearing loans	4.2	11,451	41,817
Deferred tax liability	2.11	1,991	1,343
Lease liability	3.2	1,741	61
Post-employment benefits	5.0	1,388	399
		<b>16,571</b>	<b>43,620</b>

**Current Liabilities**

Income tax liabilities		83	27
Lease liability	3.2	473	137
Trade payables	3.6	952	911
Other payables	3.7	4,034	1,590
		<b>5,542</b>	<b>2,665</b>
		<b>104,796</b>	<b>14,190</b>

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



## Consolidated Statement of Changes in Equity

<i>All amounts in EUR '000</i>	Notes	Issued Capital*	Share Premium	Other Reserves**	Retained Earnings	2020
<b>As at 1 January 2020</b>		-	3,083	15,127	(33,131)	(14,923)
Loss for the year 2020		-	-	-	(20,014)	(20,014)
Other comprehensive income		-	-	(441)	35	(406)
Total comprehensive result		-	-	(441)	(19,979)	(20,420)
Share based payments		-	-	2,700	-	2,700
Issue of share capital		-	-	548	-	548
<b>As at 31 December 2020</b>	<b>4.0</b>	-	3,083	17,933	(53,111)	(32,095)
<b>As at 1 January 2021</b>		-	3,083	17,933	(53,111)	(32,095)
Loss for the year 2021		-	-	-	(34,314)	(34,314)
Other comprehensive income		-	-	249	(714)	(465)
Total comprehensive result		-	-	249	(35,028)	(34,779)
Conversion of preference A-shares	4.0,4.1	-	49,467	(14,794)	-	34,673
Reversed stock-split	4.0	2,445	(2,445)	-	-	-
Share based payments: EIP	2.10	-	-	8,494	-	8,494
Share based payments: EIP accelerated vesting	2.10	-	-	(12,165)	12,165	-
Conversion of CLA	4.0,4.1	391	30,731	-	-	31,122
Issue of share capital: EPFL option	4.0	32	-	-	-	32
Issue of share capital: IPO	4.0	708	74,517	-	-	75,225
Issue of share capital: Over-allotment	4.0	46	4,835	-	-	4,881
Capitalization of costs related to IPO and issue of new shares	4.0	-	(4,939)	-	-	(4,939)
Share based payments: LTIP	2.10	-	-	69	-	69
<b>As at 31 December 2021</b>	<b>4.0</b>	<b>3,622</b>	<b>155,248</b>	<b>(214)</b>	<b>(75,974)</b>	<b>82,683</b>

\* share capital amounts to EUR 28.74 as at 31 December 2020

\*\* 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

<i>All amounts in EUR '000</i>	Notes	2021	2020
<b>Cash Flows from Operating Activities</b>			
<b>Loss for the Period Before Taxes</b>		<b>(34,245)</b>	<b>(19,994)</b>
Adjusted for:			
◦ Depreciation and impairment of property, plant and equipment and right-of-use assets	<b>3.1, 3.2</b>	329	271
◦ Share based payment transaction expense	<b>2.10</b>	8,564	2,700
◦ Post-employment benefits		246	(5)
◦ Net finance costs		5,713	4,482
◦ Net foreign exchange differences		(43)	
◦ Other non-cash items		(2)	(7)
Changes in working capital:			
Increase (-) Decrease (+) in Trade and other receivables		(2,358)	(221)
Increase (+) Decrease (-) in Trade and other payables		2,097	(48)



**Consolidated Financial Statements**

Interests received	4.5	-	-
Interests paid	4.5	(146)	(37)
Income tax paid		(14)	(31)
Bank Charges paid	4.5	(17)	(11)
<b>Net cash generated /(used) from operating activities</b>		<b>(19,874)</b>	<b>(12,901)</b>
<b>Cash flows from investing activities</b>			
Investments in fixed assets	3.1	(91)	(173)
Investments in intangible fixed assets	3.0	(2,233)	-
<b>Net cash generated/(used) from investing activities</b>		<b>(2,324)</b>	<b>(173)</b>
<b>Cash flows from financing activities</b>			
Proceeds from interest-bearing loans	4.2	30,000	3,946
Payment of principal portion of lease liabilities	3.2	(144)	(126)
Proceeds from issuance of shares		80,106	548
Transaction costs on issuance of shares	4.0	(4,601)	-
<b>Net cash generated/(used) from financing activities</b>		<b>105,361</b>	<b>4,368</b>
<b>Movement in cash and cash equivalents</b>			
Cash and cash equivalents at 1 January		6,382	15,129
Effect of exchange rates on cash and cash equivalents		(100)	(41)
Changes in cash and cash equivalents during the period		83,162	(8,706)
<b>Cash and cash equivalents at 31 December</b>		<b>89,443</b>	<b>6,382</b>



# Notes to the Consolidated Financial Statements

## 1. Section 1: General Information & Basis of Preparation

### 1.1 Corporate Information

#### General

ONWARD Medical B.V. was a Dutch private company with limited liability (besloten vennootschap met beperkte aansprakelijkheid), incorporated on 20 November 2015. On 21 October 2021 (the First Trading Date) the Company completed a corporate conversion, converting into a public limited company under Dutch law (naamloze vennootschap). The legal name changed to ONWARD Medical N.V. (“ONWARD”). The registered office is located at High Tech Campus 32, Eindhoven, the Netherlands. ONWARD Medical N.V. is registered in the Commercial Register of the Chamber of Commerce under number 64598748.

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

The financial statements have been prepared by the board of directors and were authorized for issue on 25 April 2022. The financial statements will be submitted for adoption to the General Meeting on 10 June 2022.

### 1.2 Group Information

#### Information about subsidiaries

The consolidated financial statements of the Group include:

- ONWARD Medical SA, Switzerland; principal activities: the development and commercialization of an Implantable Neuro Stimulation System (INS) medical device solution to improve the lives of Spinal Cord Injured people. Holding 100%.
- ONWARD Medical Inc, United States of America; principal activities: the development and commercialization of a non-invasive medical device solution to improve the lives of Spinal Cord Injured people. Holding 100%.

### 1.3 First-time adoption of IFRS

As stated in the special purpose consolidated financial statement of ONWARD Medical B.V., the financial statements, for the year ended 31 December 2020, were the first the Group had prepared in accordance with IFRS. Detailed disclosure relating to the first-time adoption is included in Note 6 of the special purpose consolidated financial statements that was made publicly available through the Prospectus issued in the lead up to the IPO that was completed on 21 October 2021.

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The statutory financial statements, filed with the Chamber of Commerce, for ONWARD Medical B.V. for the 2020 financial year, were not consolidated financial statements and were prepared in accordance with local generally accepted accounting principles (Local GAAP) in the Netherlands.

Below is a reconciliation of the equity and net loss as stated in the statutory financial statements, to the equity and net loss as stated in the 2020 special purpose consolidated financial statements:

	<b>2020</b>
Equity balance per statutory financial statements	240
IFRS adjustment: Cumulative preference A-shares	(31,407)
IFRS adjustment: IAS 19 Swiss pension plan valuation	(399)
IFRS adjustment: Foreign currency revaluation of the NRT acquisition, including deferred tax	(529)
<b>Equity balance per special purpose consolidated financial statements</b>	<b>(32,095)</b>

	<b>2020</b>
Net loss per statutory financial statements	(13,823)
IFRS adjustment: Cumulative preference A-shares	(3,537)
IFRS adjustment: IAS 19 Swiss pension plan valuation	4
IFRS adjustment: Share-based payment expense	(2,700)
IFRS adjustment: Lease	42
<b>Net loss per special purpose consolidated financial statements</b>	<b>(20,014)</b>

**1.4 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. Income and expenses are accounted for on an accrual basis. The Consolidated financial statements provide comparative information in respect of the previous period. Certain prior year amounts have been reclassified for consistency with the current year presentation. Refer to section 1.10 below.

The Consolidated financial statements are presented in euros and all values are rounded to the nearest thousand (€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.

**1.5 Basis of Consolidation**

The Consolidated financial statements comprise the financial statements of the Group and its subsidiaries as at 31 December 2021. 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 re-assesses 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. Assets, liabilities, income



and expenses of a subsidiary acquired or disposed of during the year are included in the statement of comprehensive income from the date the Group gains control until the date the Group ceases to control 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 and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. 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 intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

### 1.6 Going Concern

As at 31 December 2021 the Company had cash and cash equivalents of EUR 89 million. Based on cash flow forecasts for the years 2022 and 2023, which include significant expenses and cash outflows in relation to -among others- the ongoing clinical trials and the continuation of research and development projects, the Company believes that this cash position will be sufficient to meet the Company's capital requirements and fund its operations for at least 12 months as from the date of this Annual Report.

Inherent uncertainties in these forecasts may have an impact on the Company's cash position. To continue development and reach commercialization as planned, the Company may need to attract additional funding in future. Please note that the Company's long-term success is contingent on achieving FDA approval and CE mark of its products.

In view of the above, and notwithstanding a loss brought forward of EUR 76 million as of 31 December 2021 the application of the valuation rules in the assumption of a "going concern" is justified. As a result, the consolidated financial statements have been prepared on a going concern basis.

## 1.7 Summary of Other Significant Accounting Policies

### a) Business Combinations

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred, measured at acquisition date fair value and the amount of any non-controlling interest in the acquiree. For each business combination, the Group elects whether to measure the non-controlling interest in the acquiree at fair value or at the proportionate share of the acquirer's identifiable net assets. Acquisition-related costs are expensed as incurred and included in administrative expenses.

When the Group acquires a business, it assesses the financial assets and liabilities assumed for appropriate classification and designation in accordance with the contractual terms, economic circumstances and pertinent conditions as at the acquisition date. This includes the separation of embedded derivatives in host contracts by the acquiree.

If the business combination is achieved in stages, any previously held equity interest is re-measured at its acquisition date fair value and any resulting gain or loss is recognized in profit or loss. It is then considered in the determination of goodwill.

Any contingent consideration to be transferred by the acquirer will be recognized at fair value at the acquisition date. Contingent consideration classified as an asset or liability that is a financial instrument and within the scope of IFRS 9 Financial Instruments, is measured at fair value with changes in fair value recognized in the statement of profit or loss in accordance with IFRS 9. Other contingent consideration that is not within the scope of IFRS 9 is measured at fair value at each reporting date with changes in fair value recognized in profit and loss.

### b) 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:

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- 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.

**c) 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.

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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.





## 1.8 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 have a significant risk of causing a material adjustment 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 2.3)</b>
Share-based Payments	<b>(Note 2.10)</b>
Post-employment Benefits	<b>(Note 5.0)</b>
Taxes	<b>(Note 2.11)</b>

## 1.9 New Accounting Standards & Developments

### 1.9.1 New and Amended Standards and Interpretations

Several amendments apply for the first time in 2021, but do not have an impact on the consolidated financial statements of the Group. The Group has not early adopted any standards, interpretations or amendments that have been issued but are not yet effective.

The nature and the impact of each of the following new standards, amendments and/or interpretations are described below:

- Amendments to IFRS 4 Insurance Contracts – deferral of IFRS 9, effective 1 January 2021
- Amendments to IFRS 9 Financial Instruments, IFRS 7 Financial Instruments: Disclosures, IAS 39 Financial Instruments: Recognition and measurement, IFRS 4 Insurance contracts and IFRS 16 Leases- Interest Rate Benchmark Reform – Phase 2, effective 1 January 2021
- Amendments to IFRS 16 Leases – Covid-19 related rent concessions beyond 30 June 2021, effective 1 April 2021

#### Amendments to IFRS 4 Insurance Contracts – deferral of IFRS 9

The amendment to IFRS 4 provides a temporary exemption that permits, but does not require, the qualifying insurer to apply IAS 39 Financial Instruments: Recognition and Measurement rather than IFRS 9 for annual periods beginning before 1 January 2023.

This standard is not applicable to the Group.

#### Amendments to IFRS 9 Financial Instruments, IFRS 7 Financial Instruments: Disclosures, IAS 39 Financial Instruments: Recognition and measurement, IFRS 4 Insurance contracts and IFRS 16 Leases- Interest Rate Benchmark Reform – Phase 2, effective 1 January 2021



The amendments provide temporary reliefs which address the financial reporting effects when an interbank offered rate (IBOR) is replaced with an alternative nearly risk-free interest rate (RFR).

The amendments include the following practical expedients:

- A practical expedient to require contractual changes, or changes to cash flows that are directly required by the reform, to be treated as changes to a floating interest rate, equivalent to a movement in a market rate of interest
- Permit changes required by IBOR reform to be made to hedge designations and hedge documentation without the hedging relationship being discontinued
- Provide temporary relief to entities from having to meet the separately identifiable requirement when an RFR instrument is designated as a hedge of a risk component.

These amendments had no impact on the consolidated financial statements of the Group. The Group intends to use the practical expedients in future periods if they become applicable.

#### **Amendments to IFRS 16 Leases – Covid-19 related rent concessions beyond 30 June 2021, effective 1 April 2021**

The amendments provide relief to lessees from applying IFRS 16 guidance on lease modification accounting for rent concessions arising as a direct consequence of the Covid-19 pandemic. As a practical expedient, a lessee may elect not to assess whether a Covid-19 related rent concession from a lessor is a lease modification. A lessee that makes this election accounts for any change in lease payments resulting from the Covid-19 related rent concession the same way it would account for the change under IFRS 16, if the change were not a lease modification. This amendment has extended the relief by one year to cover rent concessions that reduce only lease payments due on or before 30 June 2022.

The amendment applies to annual reporting periods beginning on or after 1 April 2021.

These amendments had no impact on the consolidated financial statements of the Group.

#### **1.9.2 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 disclosed below. The Group intends to adopt these new and amended standards and interpretations, if applicable, when they become effective.

##### **IFRS 17 Insurance Contracts**

In May 2017, the IASB issued IFRS 17 Insurance Contracts (IFRS 17), a comprehensive new accounting standard for insurance contracts covering recognition and measurement, presentation and disclosure. Once effective, IFRS 17 will replace IFRS 4 Insurance Contracts (IFRS 4) that was issued in 2005. IFRS 17 applies to all types of insurance contracts (i.e., life, non-life, direct insurance and re-insurance), regardless of the type of entities that issue them, as well as to certain guarantees and financial instruments with discretionary participation features.

A few scope exceptions will apply. The overall objective of IFRS 17 is to provide an accounting model for insurance contracts that is more useful and consistent for insurers. In contrast to the requirements in IFRS 4, which are largely based on grandfathering previous local accounting policies, IFRS 17 provides a comprehensive model for insurance contracts, covering all relevant accounting aspects. The core of IFRS 17 is the general model, supplemented by:

- A specific adaptation for contracts with direct participation features (the variable fee approach)
- A simplified approach (the premium allocation approach) mainly for short-duration contracts

IFRS 17 is effective for reporting periods beginning on or after 1 January 2023, with comparative figures required. Early application is permitted, provided the entity also applies IFRS 9 and IFRS 15 on or before the date it first applies IFRS 17. This standard is not applicable to the Group.



### Amendments to IAS 1: Classification of Liabilities as Current or Non-current

In January 2020, the IASB issued amendments to paragraphs 69 to 76 of IAS 1 to specify the requirements for classifying liabilities as current or non-current. The amendments clarify:

- What is meant by a right to defer settlement
- That a right to defer must exist at the end of the reporting period
- That classification is unaffected by the likelihood that an entity will exercise its deferral right
- That only if an embedded derivative in a convertible liability is itself an equity instrument would the terms of a liability not impact its classification.

The amendments are effective for annual reporting periods beginning on or after 1 January 2023 and must be applied retrospectively. The Group is currently assessing the impact the amendments will have on current practice and whether existing loan agreements may require renegotiation.

### Amendments to IFRS 3: Reference to the Conceptual Framework

In May 2020, the IASB issued Amendments to IFRS 3 Business Combinations - Reference to the Conceptual Framework. The amendments are intended to replace a reference to the Framework for the Preparation and Presentation of Financial Statements, issued in 1989, with a reference to the Conceptual Framework for Financial Reporting issued in March 2018 without significantly changing its requirements. The amendments add an exception to the recognition principle of IFRS 3 to avoid the issue of potential 'day 2' gains or losses arising for liabilities and contingent liabilities that would be within the scope of IAS 37 or IFRIC 21 Levies, if incurred separately. At the same time, the amendments add a new paragraph to IFRS 3 to clarify that contingent assets do not qualify for recognition at the acquisition date. The amendments are effective for annual reporting periods beginning on or after 1 January 2022 and apply prospectively. The amendments are not expected to have a material impact on the Group.

### Amendments to IAS 16: Property, Plant and Equipment Proceeds before intended use

In May 2020, the IASB issued Property, Plant and Equipment – Proceeds before Intended Use, which prohibits entities deducting from the cost of an item of property, plant and equipment, any proceeds from selling items produced while bringing that asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Instead, an entity recognises the proceeds from selling such items, and the costs of producing those items, in profit or loss. The amendment is effective for annual reporting periods beginning on or after 1 January 2022 and must be applied retrospectively to items of property, plant and equipment made available for use on or after the beginning of the earliest period presented when the entity first applies the amendment. The amendments are not expected to have a material impact on the Group.

### Amendments to IAS 37: Onerous Contracts – Costs of Fulfilling a Contract

In May 2020, the IASB issued amendments to IAS 37 to specify which costs an entity needs to include when assessing whether a contract is onerous or loss-making. The amendments apply a “directly related cost approach”. The costs that relate directly to a contract to provide goods or services include both incremental costs and an allocation of costs directly related to contract activities. General and administrative costs do not relate directly to a contract and are excluded unless they are explicitly chargeable to the counterparty under the contract. The amendments are effective for annual reporting periods beginning on or after 1 January 2022. The Group will apply these amendments to contracts for which it has not yet fulfilled all its obligations at the beginning of the annual reporting period in which it first applies the amendments. The amendments are not expected to have a material impact on the Group.

### Disclosure of Accounting Policies - Amendments to IAS 1 and IFRS Practice Statement 2

In February 2021, the IASB issued amendments to IAS 1 and IFRS Practice Statement 2 Making Materiality Judgements, in which it provides guidance and examples to help entities apply materiality judgements to accounting policy disclosures. The amendments aim to help entities provide accounting policy disclosures that are more useful by replacing the requirement for entities to disclose their ‘significant’ accounting policies with a requirement



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to disclose their 'material' accounting policies and adding guidance on how entities apply the concept of materiality in making decisions about accounting policy disclosures.

The amendments to IAS 1 are applicable for annual periods beginning on or after 1 January 2023 with earlier application permitted. Since the amendments to the Practice Statement 2 provide non-mandatory guidance on the application of the definition of material to accounting policy information, an effective date for these amendments is not necessary.

The Group is currently assessing the impact of the amendments to determine the impact they will have on the Group's accounting policy disclosures.

**Definition of Accounting Estimates - Amendments to IAS 8**

In February 2021, the IASB issued amendments to IAS 8, in which it introduces a definition of 'accounting estimates'. The amendments clarify the distinction between changes in accounting estimates and changes in accounting policies and the correction of errors. Also, they clarify how entities use measurement techniques and inputs to develop accounting estimates.

The amendments are effective for annual reporting periods beginning on or after 1 January 2023 and apply to changes in accounting policies and changes in accounting estimates that occur on or after the start of that period. Earlier application is permitted as long as this fact is disclosed.

The amendments are not expected to have a material impact on the Group.

**Amendments to IAS 12 - Deferred Tax related to Assets and Liabilities arising from a Single Transaction**

In May 2021, the Board issued amendments to IAS 12, which narrow the scope of the initial recognition exception under IAS 12, so that it no longer applies to transactions that give rise to equal taxable and deductible temporary differences. The amendments clarify

that where payments that settle a liability are deductible for tax purposes, it is a matter of judgement (having considered the applicable tax law) whether such deductions are attributable for tax purposes to the liability recognized in the financial statements (and interest expense) or to the related asset component (and interest expense). This judgement is important in determining whether any temporary differences exist on initial recognition of the asset and liability. Under the amendments, the initial recognition exception does not apply to transactions that, on initial recognition, give rise to equal taxable and deductible temporary differences. It only applies if the recognition of a lease asset and lease liability (or decommissioning liability and decommissioning asset component) give rise to taxable and deductible temporary differences that are not equal. An entity should apply the amendments to transactions that occur on or after the beginning of the earliest comparative period presented. Effective for annual periods beginning on or after 1 January 2023.

**Amendments to IFRS 1: First-time Adoption of International Financial Reporting Standards – Subsidiary as a first-time adopter**

As part of its 2018-2020 annual improvements to IFRS standards process, the IASB issued an amendment to IFRS 1 First-time Adoption of International Financial Reporting Standards. The amendment permits a subsidiary that elects to apply paragraph D16(a) of IFRS 1 to measure cumulative translation differences using the amounts reported by the parent, based on the parent's date of transition to IFRS. This amendment is also applied to an associate or joint venture that elects to apply paragraph D16(a) of IFRS 1. The amendment is effective for annual reporting periods beginning on or after 1 January 2022 with earlier adoption permitted. The amendments are not expected to have a material impact on the Group.

**IFRS 9 Financial Instruments – Fees in the '10 per cent' test for derecognition of financial liabilities**

As part of its 2018-2020 annual improvements to IFRS standards process the IASB issued amendment to IFRS 9. The amendment clarifies the fees that an entity includes when assessing whether the terms of a new or modified financial liability are substantially different from the terms of the original financial liability. These fees include only those paid



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or received between the borrower and the lender, including fees paid or received by either the borrower or lender on the other's behalf. An entity applies the amendment to financial liabilities that are modified or exchanged on or after the beginning of the annual reporting period in which the entity first applies the amendment.

The amendment is effective for annual reporting periods beginning on or after 1 January 2022 with earlier adoption permitted. The Group will apply the amendments to financial liabilities that are modified or exchanged on or after the beginning of the annual reporting period in which the entity first applies the amendment. The amendments are not expected to have a material impact on the Group.

## 1.10 Changes in Accounting Policies & Disclosures

### 1.10.1 Change in Disclosure in the Consolidated Statement of Profit & Loss

The Group has reassessed the presentation of line items in the consolidated statement of profit and loss and decided to present the costs of Quality assurance as a separate line item as opposed to a component of General and administrative expenses. This presentation aligns with the internal budgeting and monitoring process. Quality assurance is a key function towards obtaining regulatory approval for commercialization. This presentation is also in line with companies within the industry and will therefore enhance comparability.

Also the following notes were restated:

	Reported: 2020	Restated: 2020	Change
Quality assurance expenses	–	361	361
General and administrative expenses	5,016	4,655	(361)

## 2. Section 2: Results of the Year

	Reported: 2020	Restated: 2020	Change
<i>2.7 Quality assurance expenses</i>			
Staff costs	–	318	318
Outsourced cost	–	43	43
	–	361	361

	Reported: 2020	Restated: 2020	Change
<i>2.8 General and administrative expenses</i>			
Staff costs	2,765	2,447	(318)
Outsourced cost	2,189	2,146	(43)
Depreciation	62	62	–
	5,016	4,655	(361)





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**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.

**2.1 Revenues & Other Income**

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

	<b>2021</b>	<b>2020</b>
Government subsidies (EU)	1,399	800
<b>Total revenues and other income</b>	<b>1,399</b>	<b>800</b>

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>Grants</b>	<b>Total Grant*</b>	<b>Recognized</b>	
		<b>2021</b>	<b>2020</b>
RESTORE	<b>370</b>	–	<b>37</b>
DISPERSE	<b>311</b>	–	<b>36</b>
WALKAGAIN	<b>500</b>	–	<b>185</b>
CONFIRM	<b>416</b>	<b>139</b>	<b>197</b>
BESTABLE	<b>99</b>	<b>16</b>	<b>25</b>
SWISS LOCAL (one -offs)	–	<b>41</b>	<b>24</b>
PREP2GO	<b>348</b>	<b>139</b>	<b>104</b>
DARPA	<b>1,152</b>	<b>981</b>	<b>192</b>
ZonMW	<b>250</b>	<b>83</b>	–
<b>Total</b>		<b>1,399</b>	<b>800</b>

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



**Terms & Conditions**

**CONFIRM**

This Eurostars funding agreement with the Swiss Innovation Agency Innosuisse for a total amount of EUR 416,293 started in May 2019 and ended in October 2021, with follow up reporting resulting in the additional 25.75% granting of the allocated amount. The remainder of the grant was received in 2021 after submission of the final report. In this project, ONWARD collaborated with Inomed A.G., Universitätsklinikum Heidelberg and EPFL to develop an intra-operative neuromonitoring system and algorithms facilitating the surgical implantation of ARC<sup>IM</sup>.

**BESTABLE**

This Eurobench funding agreement with PKF ATTEST INNCOME S.L. and the Spanish National Research Council CSIC for a total amount of EUR 100,000 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 will be paid after submission 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.

**PREP2GO**

This Eurostars funding agreement with the Netherlands enterprise agency RVO for a total amount of EUR 347,802 started in April 2020 and ends in September 2022. An amount equal to 90% of the grant is paid during the grant period in tranches in 2020, 2021 and 2022. The remaining 10% of the grant is being paid after submission of the final report. In this project, ONWARD is collaborating 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**

This US Department of Defense funding agreement for phase 1 for a total amount of EUR 1,152,000 (or USD 1,354,000) started in October 2020 and ends in March 2022. In October 2021 an amount of EUR 477,000 (or USD 560,000) was accelerated from phase 2 and made available for spending in phase 1. The grant amounts are being charged on a monthly basis over the 18 months period based on actual incurred costs. The agreement with the DOD provides for additional funding beyond March 2022. Phase 2 was approved in February 2022 for an amount of EUR 1,318,798 (or USD 1,500,000). In this project, ONWARD is collaborating with a large consortium of academic partners, companies, and consultants to develop a new clinical intervention to modulate blood pressure and spinal cord perfusion and oxygenation in the hours following SCI. This correspond to a roadmap development of ARC-IM to be used in the hours following SCI.

**ZonMW**

This Dutch funding agreement is with the Netherlands Organisation for Health Research and development for a total amount of EUR 250,000 that started in January 2021 and ends in January 2024. An amount equal to 80% of the grant is being paid during the grant period in three equal tranches in 2021, 2022 and 2023. The remaining 20% of the grant will be paid after submission of the final report. In this project, ONWARD is collaborating with the University of Bordeaux, CHUV and EPFL to develop a research interface for ARC<sup>IM</sup> and evaluating its use to alleviate locomotor deficits in Parkinson's disease.

**2.2 Science Expenses**

	<b>2021</b>	<b>2020</b>
Staff costs	2,555	779
Outsourced cost	131	344
	<b>2,686</b>	<b>1,123</b>



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The Company’s science expenses consist primarily of cost of sponsored research activities that are undertaken by universities with which it collaborates. Since its inception, the Company has had a close working relationship with two of the founders of the Company, Grégoire Courtine, Professor at EPFL and Jocelyne Bloch, Neurosurgeon at CHUV, Professor at Université de Lausanne.

The activities between the Company and EPFL are formalized in research agreements which govern the activities of Professor Courtine sponsored by the Company. The increase in 2021 is due to the share-based payment expense resulting from the Employee Investment plan that vested on the date of the IPO.

**2.3 Research & Development Expenses**

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

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

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

	<b>2021</b>	<b>2020</b>
Staff costs	5,218	3,538
Outsourced cost	2,715	2,068
Depreciation and amortization expense	–	199
	<b>7,932</b>	<b>5,823</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>™</sup> systems as well as the employee related expenses for research and development, including salaries and benefits. The increase in 2021 is due to the share-based payment expense resulting from the Employee Investment plan that vested on the date of the IPO.

**2.4 Clinical & Regulatory Expenses**

	<b>2021</b>	<b>2020</b>
Staff expenses	2,905	2,278
Outsourced expenses	1,871	482
Depreciation and amortization expense	–	11
	<b>4,775</b>	<b>2,770</b>

The Company’s clinical and regulatory expenses consist of the employee related expenses including salaries and benefits for employees working on clinical trials. The increase in 2021 is due to the share-based payment expense resulting from the Employee Investment plan that vested on the date of the IPO as well the ongoing Up-LIFT study.



**Consolidated Financial Statements****2.5 Marketing & Market Access Expenses**

	<b>2021</b>	<b>2020</b>
Staff expenses	916	209
Outsourced expenses	600	185
	<b>1,516</b>	<b>394</b>

The Company's marketing and market access expenses include rebranding activities relating to the introduction of the ONWARD brand as well as the investigating activities on the future therapy reimbursement performed by third party consultants. The increase in 2021 is due to the share-based payment expense resulting from the Employee Investment plan that vested on the date of the IPO.

**2.6 IP & License Agreement Expenses**

	<b>2021</b>	<b>2020</b>
Staff expenses	329	277
Outsourced expenses	1,032	908
	<b>1,361</b>	<b>1,185</b>

The Company's patents 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 as well as related employee expenses, including salary and benefits in the area of business development.

**2.7 Quality Assurance Expenses**

	<b>2021</b>	<b>2020</b>
Staff costs	960	318
Outsourced cost	33	43
	<b>993</b>	<b>361</b>

Quality assurance expenses consist primarily of quality control, quality assurance and regulatory expenses. These expenses include employee expenses, including salary benefits for personnel, consulting, testing and travel expenses. The increase in 2021 is due to the share-based payment expense resulting from the Employee Investment plan that vested on the date of the IPO.

**2.8 General & Administrative Expenses**

	<b>2021</b>	<b>2020</b>
Staff costs	5,968	2,447
Outsourced cost	4,370	2,146
Depreciation and amortization expense	329	62
	<b>10,667</b>	<b>4,655</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. The increase in 2021 is primarily due to the share-based payment expense resulting from the Employee Investment plan that vested on the date of the IPO as well as the costs incurred relating to the IPO not capitalized.



## 2.9 Employee Benefit Expenses

**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 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 statement of income. 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 recognised 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 recognised in profit or loss on the earlier of:

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

Net interest is calculated by applying the discount rate to the net defined benefit liability or asset. The Group recognises 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.

	2021	2020
Wages and salaries	7,203	6,037
Social security costs	908	615
Pension costs – defined benefit plan	445	51
Pension costs – other	101	154
Share based benefit expenses	8,564	2,700
Other labour costs	1,629	993
	<b>18,850</b>	<b>10,550</b>





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As at 31 December 2021, the ONWARD Group employed 76.9 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 2021 and 2020:

	<b>2021</b>	<b>2020</b>
Science	0.2	0.2
Research & Development	41.6	28.1
Clinical & Regulatory	15.7	14.0
Marketing & Market Access	2.0	1.0
Patent & Related Expenses	1.0	1.0
Quality Assurance	4.8	3
General & Administrative Expenses	11.6	7.7
	<b>76.9</b>	<b>55.0</b>

As of 31 December 2021, the Company had 35.5 full-time equivalents located in The Netherlands (2020: 35.5), 32.9 full-time equivalents located in Switzerland (2020: 14.4) and 8.5 (2020: 5.0) full-time equivalents located in the United States.

## 2.10 Share-Based Payments

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

### Equity-Settled Transactions

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

That cost is recognized, together with a corresponding increase in other reserves in equity, over the period in which the performance and/or service conditions are fulfilled in employee benefits expense. The cumulative expense recognized for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest. The statement of profit or loss expense or credit for a period represents the movement in cumulative expense recognized as at the beginning and end of that period and is recognized in operating expenses.

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

When the terms of an equity-settled award are modified, the minimum expense recognized is the expense had the terms had 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.



## Employee Investment Plan (EIP)

Under the Employee Investment Plan, eligible employees have the opportunity to subscribe for, indirectly via Stichting G-Therapeutics Participaties (“STAK”), an equity stake in ONWARD Medical N.V.. The Employee Investment Plan was set-up to align the Employee’s interest with the interests of the Shareholders and to participate in the long term growth of the Company.

Eligible employees were granted depository receipts (DR) via the STAK by means of a deed of issuance. At the time of the deed issuance, the eligible employee accepted the obligation to subscribe to (purchase) the DRs for a value of € 0,01 cent and payment was required within 10 days. The agreement did not provide the eligible employee with any options to be exercised at a future date. From this point the owners obtained all rights and obligations from indirect share ownership. One depository receipt at all times equaled one ordinary non-voting E share in the capital of The Company. In the event of the distribution of proceeds, the ordinary shares (also from the DRs) would rank equal to all other shares after settlement with preferred A shares. The DRs were not transferrable. The DRs had a one year cliff from grant date, after this one year cliff period 25% of the issue vests and the remaining 75% vested over the remaining 3 years. When employment ceased the non-vested part was forfeited except in the event of illness or death. The DRs issued to employees were considered to be shares in accordance with IFRS 2, that were issued under an equity settled shared based compensation plan. In article 3.2. of the Deed of issuance of the DRs it was determined that a trade sale of the Company or an IPO, of not less than EUR 50M at a price per share to the public not less than EUR 5,- per share, would trigger accelerated vesting of the DR’s. At each of these two events all Depository Receipts under the EIP plan were fully deemed vested.

The IPO on 21 October 2021 raised EUR 80M at a share price of EUR 12.75. Taking into account the reversed stock split that was contemplated just prior to the IPO the share price would have been € 5.10 per share on the outstanding shares prior to the reversed stock split. As both conditions of the IPO event were met, all DR’s were deemed fully vested at 21 October 2021. The vesting resulted in a share-based payment expense of EUR 8.5 million.

## Long-Term Incentive Plan (LTIP)

Following the IPO, and the vesting of the EIP, the Board has agreed upon a new LTIP plan to align the Employee’s interest with the interests of the Shareholders and to allow the employee to participate in the long-term growth of the Company. The LTIP is an omnibus plan with the flexibility to issue different type of equity incentives.

ONWARD has awarded options over its ordinary shares to participants (referred to as the “Award” or “Grant”) at Grant Date 15 December 2021. 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 3 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. This is a non-market vesting condition since the vesting condition is not linked to the share price of ONWARD. In total 612,000 options were granted to eleven participants. 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	Options Vested / Unvested	Exercise Price	Expiration Date	Fair Value
2021	15/12/2021	Stock Options	Vested: 0 Unvested: 612,000	EUR 9,70	15/12/2031	EUR 4,89

This fair value per option has been applied to the granted Awards on 15 December 2021 resulting in a share-based payment expense of EUR 69 thousand.

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:

	<b>2021</b>
<b>Fair value on date of measurement (EUR)</b>	<b>4.89</b>
Share price (EUR)	<b>9.20</b>
Exercise price (EUR)	<b>9.70</b>
Expected volatility	<b>58.90%</b>
Term of the option	<b>4<sup>a</sup></b>
Expected dividend	–
Risk-free interest rate	<b>-0.30%</b>
Time to expiration	<b>10</b>

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

## 2.11 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 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.

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- 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 2018. Considering the uncertainty and limited future profits, the Group will, consistent with the treatment in the Dutch entity, not recognize any deferred tax assets relating to any temporary differences for the Swiss entity.

All NOLs in the US entity prior to the business combination are not carried forward due to ownership change. Losses since the transaction can be carried forward for 20 years. These losses have not been recognized in the balance sheet to date.

	2021	2020
Current income tax	(69)	(20)
Deferred income tax	–	–
<b>Total corporate income tax in profit and loss</b>	<b>(69)</b>	<b>(20)</b>
Current Income Tax charge at tax rate of 25%	8,561	4,999
Net operating tax losses not recognized	(8,621)	(5,051)
Effect of Tax rate difference Switzerland and US	(9)	32
	<b>(69)</b>	<b>(20)</b>

The estimated unused Dutch operating tax losses for which no deferred tax asset is recognized amounts to EUR 59 million (2020: EUR 39 million). These losses may be carried forward indefinitely.

The unused US operating tax losses for which no deferred tax asset is recognized expire after 2038 (EUR 58k), 2039 (EUR 618k) and 2040 (EUR 697k).

The deferred tax liability arose on the acquisition of NeuroRecovery Technologies, Inc ('NRT') in 2019 (subsequently renamed to ONWARD Medical Inc.). In 2021 License fees paid were capitalized as an intangible asset that increased the deferred tax liability:

	2021	2020
Opening balance as at January 1	(1,343)	(1,448)
Foreign currency translation difference	(78)	105
Addition (License fees)	(570)	–
<b>Deferred tax liability as at December 31</b>	<b>(1,991)</b>	<b>(1,343)</b>

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**3. Section 3: Non-current Asset & Working Capital****3.0 Intangible Assets**

	2021	2020
Goodwill	1,702	1,607
In-Process R&D	6,109	5,218
License fees	2,218	–
<b>Net book value at December 31</b>	<b>10,029</b>	<b>6,825</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 re-assesses 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 re-assessment 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.

	2021	2020
Cost	1,607	1,732
Accumulated amortization	–	–
<b>Net book value at January 1</b>	<b>1,607</b>	<b>1,732</b>
Additions	–	–
Foreign currency translation difference	95	(125)
Depreciation for the year	–	–
Impairments	–	–
Net change	95	(125)
Cost	1,702	1,607
Accumulated amortization	–	–
<b>Net book value at December 31</b>	<b>1,702</b>	<b>1,607</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.

	2021	2020
Cost	5,370	5,777
Accumulated changes	(152)	(127)
<b>Net book value at January 1</b>	<b>5,218</b>	<b>5,650</b>
Foreign currency translation difference	321	(407)
Additions	570	-
Depreciation for the year	-	(25)
Impairments	-	-
Net change	891	(432)
Cost	6,261	5,370
Accumulated changes	(152)	(152)
<b>Net book value at December 31</b>	<b>6,109</b>	<b>5,218</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.

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Amortization is recorded in operating expenses. During the period of development, the asset is tested for impairment annually.

	2021	2020
Cost	-	-
Accumulated changes	-	-
<b>Net book value at January 1</b>	<b>-</b>	<b>-</b>
Additions	2,233	-
Foreign currency translation difference	(15)	-
Depreciation for the year	-	-
Impairments	-	-
Net change	2,218	-
Cost	2,218	-
Accumulated changes	-	-
<b>Net book value at December 31</b>	<b>2,218</b>	<b>-</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 success of the FDA approval of the NRT product. In terms of the NRT acquisition agreement ONWARD also received, and assumed responsibility for, the exclusive license agreements with the Regents of the University of California ("UCLA") and the California Institute of Technology ("Caltech").



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terms of these agreements, the occurrence of the IPO triggered the change in ownership clauses and resulted in additional payments to be made. These payments, as well as the annual license fee payments, are recognized as a separate class of intangible assets.

As per the accounting policies above goodwill, in-process R&D and license fees are tested for impairment annually. ONWARD performed its annual impairment test at year end (consistent with the prior year) based on the most recent budgets and forecast calculations. These budgets and forecast calculations cover a period of five years. A long-term growth rate is calculated and applied to project future cash flows after the fifth year.

**Significant Estimates:**

Key assumptions used in the impairment test was the growth rate, EBITDA and the rate for discounting the projected cash flows.

- Growth rate estimate: rate is based on published industry research.
- EBITDA: Revenue is expected only towards the end of 2023, starting with rehabilitation first. Home use following in later years. Based on management’s best estimate EBITDA will not be positive prior to 2026.
- Discount rate: Discount rates represent the current market assessment of the risks specific to ONWARD. The discount rate calculation is based on the specific circumstances of the Group and is derived from its weighted average cost of capital (WACC). The WACC takes into account both debt and equity. The cost of equity is derived from the expected return on investment by the Group’s investors. The cost of debt is based on the interest-bearing borrowings the Group is obliged to service.

The cash flow projections were determined using management’s internal forecasts that cover an initial period from 2022 to 2026, after which a terminal value was calculated. The values assigned to the key assumptions represent management’s assessment of future expectations and were based on historical data from both external and internal sources. ONWARD performed a sensitivity analysis and noted that a reasonable change in either the discount rate (to 20%) or terminal growth rate (to 0%), or both the discount rate (to 20%) and terminal growth rate (to 0%), would not cause the carrying amount to exceed its recoverable amount. Also, should the expected revenues towards the end of 2023 move out with one year to 2024, this would still not cause the carrying amount to exceed its recoverable amount.

	<b>2021</b>	<b>2020</b>
Discount rate	9.22%	14.45% <sup>a</sup>
Terminal value growth rate	1.70%	1.75%

*a: The 2020 discount rate did not consider the advancement of the studies in the US. Enrolment of the pivotal study has been completed and the study is progressing well, lowering the risk included in the 2020 assessment.*



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**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 cost 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.

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

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

- Office equipment – 3 years

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 de-recognition 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.

**Office Equipment**

	<b>2021</b>	<b>2020</b>
Cost	711	538
Accumulated depreciation	(463)	(323)
<b>Net book value at January 1</b>	<b>248</b>	<b>215</b>
Investments	91	173
Assets acquired from business combination	–	–
Depreciation for the year	(149)	(140)
Net change	(58)	33
Cost	802	711
Accumulated depreciation	(612)	(463)
<b>Net book value at December 31</b>	<b>190</b>	<b>248</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 recognises 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 impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, 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, as follows:

- Plant and machinery 3 to 15 years
- Motor vehicles and other equipment 3 to 5 years

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

- Lease Liabilities

At the commencement date of the lease, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and 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 (see Note 16).

- Short-term leases and leases of low-value assets

The Group applies the short-term lease recognition exemption to its short-term leases of machinery and equipment (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.

**Consolidated Financial Statements****Right-of-use Assets**

The Group leases the office building in Eindhoven. In November 2021 the Group also entered into a 5-year lease for offices in Lausanne, Switzerland. Both these leases are classified as right of use assets.

Key movements relating to this lease are presented below:

	<b>2021</b>	<b>2020</b>
<b>Net book value at January 1</b>	<b>149</b>	<b>254</b>
Additions	2,220	-
Depreciation for the year	(179)	(105)
<b>Net book value at December 31</b>	<b>2,190</b>	<b>149</b>

The office building is leased for office space. The lease includes an extension option exercisable up to one year before the end of the non-cancellable lease term. The option to renew the lease is for an additional period of the same duration after the end of the contract term and are at the option of the Group as lessee. The Group has elected not to exercise the option and no new lease agreement has been entered into as replacement yet.

**Lease Liabilities**

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

	<b>2021</b>	<b>2020</b>
Less than one year	473	137
One to five years	1,741	61
More than five years	-	-
<b>Net book value at December 31</b>	<b>2,214</b>	<b>198</b>

Movement of the lease liability:

	<b>2021</b>	<b>2020</b>
<b>Balance as at January 1</b>	<b>198</b>	<b>324</b>
Addition: Lausanne office	2,220	-
Repayments	(225)	(139)
<i>Of which relates to interest</i>	21	13
<b>Total lease liability</b>	<b>2,214</b>	<b>198</b>

The incremental borrowing rate applied is 6% for the Eindhoven office and 4% for the Lausanne office.

Additionally, the group leases a car with contract term of one year. This lease is a short-term lease. The expense recognised in profit and loss for the year is EUR 10k (2020: EUR 70k - this included the amounts paid in respect of the previous office in Lausanne). The Group has elected not to recognise a right-of-use asset and lease liability for this lease.





### 3.3 Indirect Tax Receivables

The tax receivables consist of refundable VAT and are collectable within 12 months.

### 3.4 Other Current Assets

At 31 December 2021, the Group had other current assets of EUR 2,546k (2020: EUR 436k) mainly related to prepayments of the D&O Insurance and suppliers, grant amounts receivable and prepaid pension and insurance premiums. The Group has pledged EUR 297k (2020: EUR 20k) of its cash at banks to fulfil collateral requirements relating to the EPFL and new Lausanne office rental agreement.

### 3.5 Cash & 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.

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>2021</b>	<b>2020</b>
Cash at bank	89,443	6,382
<b>Total cash and cash equivalents</b>	<b>89,443</b>	<b>6,382</b>

Short-term deposits comprise a liquidity management account that is used, depending on the immediate cash requirements of the Group, and earns interest at the respective short-term deposit interest rates.

At December 31, 2020, the Group had no bank overdrafts. All cash is freely at the disposal of the company.

### 3.6 Trade & Other Payables

Trade payables and accrued expenses are non-interest bearing and are normally settled on 30-90 day terms.

### 3.7 Other Payables

The other payables can be broken down as follows:

	<b>2021</b>	<b>2020</b>
Wage tax and social security	126	367
Government grants	–	101
Bonus	1,770	843
Invoices to be received	160	102
Other	1,978	177
	<b>4,034</b>	<b>1,590</b>

Other relates mainly to accrued expenses.

## 4. Section 4: Financing, Financial Risk Management & Financial Instruments

### 4.0 Issued Capital & Reserves

#### Evolution of Share Capital & Share Premium

As at 1 January 2021, the issued share capital of the Company comprises of 4,806,221 ordinary shares O and 8,501,172 non-voting ordinary shares E with a nominal value of EUR 0.000003 each and 37,666,666 preference shares A with a nominal value of EUR 0.000001 each.

As part of the Corporate Conversion:

- (i) all outstanding non-voting ordinary shares E, ordinary shares O and preference A shares were converted into Ordinary Shares on a 1:1 ratio,
- (ii) such Ordinary Shares were subject to a 5:2 Reverse Stock Split, and
- (iii) the nominal value of all Ordinary Shares were increased to EUR 0.12.

This was affected by a notarial deed executed on 21 October 2021 (first day of trading).

After the Corporate Conversion but prior to Settlement the Company issued shares to EPFL and to the Lenders under the Convertible Loan Agreement.

269,213 new shares in the Company with an aggregate value of EUR 32,306 was issued to EPFL.

The conversion of the convertible loan (CLA) (including interest) in shares (triggered by the IPO) resulted in an aggregate capital increase in the Company of EUR 31,121,902 (including share premium) in exchange for 3,254,578 new shares in the Company.

On 21 October 2021 (Settlement Date), the Company's **authorized** (maatschappelijk kapitaal) share capital amounts to EUR 12,225,000 divided into 50,937,500 Ordinary Shares and 50,937,500 Preferred Shares with a nominal value of EUR 0.12 each. All of the issued Ordinary Shares are fully paid-up and represent capital in the Company. There

are no convertible securities, exchangeable securities or securities with warrants in the Company at the date of conversion. No share or loan capital of any member of the Group is under option or agreed, conditionally or unconditionally, to be put under option. No Shareholders have any voting rights different from any other Shareholder.

The Initial Public Offering (IPO) and exercise of the over-allotment warrant resulted in an aggregate capital increase in the Company of EUR 79,397,585 (including share premium) in exchange for 6,282,791 new shares in the Company at the price of EUR 12.75 per share.

As part of the initial public offering, the Company incurred direct-attributable transaction costs of EUR 4,939,319 which have been deducted from the share premium. The costs capitalised relates to fees and commission paid to agents, advisors, auditors, brokers and dealers and levies by regulatory agencies and security exchanges.

#### Convertible Preference A Shares

**Accounting Policy:** Convertible preference shares are separated into liability and equity components based on the terms of the contract.

On issuance of the convertible preference shares, the fair value of the liability component is determined using a market rate for an equivalent non-convertible instrument. This amount is classified as a financial liability measured at amortized cost (net of transaction costs) until it is extinguished on conversion or redemption. Upon conversion, the liability is reclassified to equity and no gain or loss is recognized in the statement of profit and loss.

The remainder of the proceeds is allocated to the conversion option that is recognized and included in equity. Transaction costs are deducted from equity, net of associated income tax. The carrying amount of the conversion option is not remeasured in subsequent years.

Transaction costs are apportioned between the liability and equity components of the convertible preference shares, based on the allocation of proceeds to the liability and equity components when the instruments are initially recognized.

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The preference shares carry a dividend of 6% per annum. The dividend rights are cumulative. The preference shares rank ahead of the ordinary shares in the event of a liquidation. The preference A shares can be converted into Ordinary Shares of the company under different scenarios, where the rights and number of Ordinary Shares received differs. In the event of an IPO, conversion is mandatory at a fixed conversion rate of 1:1, subject to adjustments for any changes in the share capitalization of the Company.

The equity component of the issued convertible preference A shares was determined at each issue date. The preference shares were valued by discounting the future dividend payments to their present value. The value of the embedded conversion options is equal to the remaining difference between the transaction value of the Preference Shares and the fair value of the debt portion.

For the discounting of the expected future interest and principal payments, an appropriate discount rate is determined using the (historic) debt spreads as determined by Aswath Damodaran, a renowned valuation practitioner. The applied debt spreads are based on the issue dates of the Preference Shares, as well as an indicative credit rating to incorporate the implied credit risk of Onward as at the valuation date. Moody's rating methodology for pharmaceutical companies was used to estimate an indicative credit rating for Onward. This methodology not only considers financial metrics but also qualitative factors and the potential of Onward and its pipeline. Notching adjustments are included to incorporate the risk profile of the subordinate ranking of the preference shares.

For the valuation management assumed mandatory conversion upon IPO as the most likely scenario at a conversion rate of one ordinary share for one preference share. The liability component was included in Interest-bearing loans and borrowings. An assumed maturity period of 10 years from the first issuance date in 2016 was chosen. This was considered a best estimate for a normal go-to-market period for similar types of devices. This was kept consistent for all subsequent issues. Based on the result of the valuation management used the mid-range of the outcome for the recognition of the embedded conversion option.

As part of the corporate conversion (prior to IPO), all preference A shares were converted to Ordinary shares at a ratio of 1:1 based on the numbers of preference A shares. Consistent with the valuation the mandatory conversion upon IPO is viewed as the

maturity event for this instrument. The carrying value of the financial liability was therefore derecognised and recognised as equity (share premium reserve) The equity component of the conversion option (previously recognized in other reserves) was reclassified to share premium on conversion, before the reversed stock split was affected on all ordinary shares and the nominal value increased to EUR 0,12 per share. Refer to 'Other reserves' below and Note 4.3 Financial liabilities for further details.

**EPFL Options**

**Significant Estimate:** The rights provided to Ecole Polytechnique Fédérale de Lausanne (EPFL) have been evaluated. The Group accounts for these options as equity settled transactions as per IFRS 2.

The Ecole Polytechnique Fédérale de Lausanne (EPFL) has the right to acquire 493,778 Ordinary shares at nominal value set forth in the terms of the license agreement in respect of the use of EPFL's intellectual property rights (the "**EPFL Option 1**"). The EPFL Option 1 can be exercised by EPFL until an initial public offering ("IPO") or an exit transaction ("Exit"). An "Exit" shall mean: (i) the sale of all or substantially all of the Company's assets, or (ii) the sale of more than fifty per cent (50%) of the Company's issued and outstanding capital stock, to any company, entity or person, or (iii) the liquidation, dissolution or winding up of the Company including, without limitation, any merger or consolidation where the Company is not the surviving company.

In addition EPFL has the right to acquire 0.3% of the total Ordinary shares of the Company at zero consideration at the time of an IPO as set forth in the terms of the license agreement in respect of the use of EPFL's intellectual property rights (the "**EPFL Option 2**").

Under this agreement EPFL also has a right to receive the cash value equivalent to the number of shares representing 0.3% of the total capital stock of the Company existing, on a fully diluted basis, at the time of an Exit not being an IPO. An Exit, not being an IPO, is not considered to be the most probable outcome. The rights are non-cumulative and shall only apply once according to the earliest event. Cash settlement is therefore not probable.



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These rights were accounted for under IFRS 2 as equity settled share based payments. The fair value of the goods and services received on the respective grant dates were considered negligible mainly due to the lack of regulatory approvals.

Immediately before the IPO an agreement was reached with EPFL regarding the exercising of their options as described above. The total numbers of shares issued to EPFL under both options were 269,213 at the nominal amount of EUR 32,306. These shares were issued at zero consideration and as a cost to the Company.

*Convertible Loan Agreement*

On 20 April 2021 the Company entered into a Convertible Loan Agreement of EUR 30 million (EUR 27.1 million (the “Principal Amount”) furnished per 30 June 2021, with an additional EUR 2.9 million executed in July 2021). The outstanding portion of the Principal Amount shall bear interest at a rate of 8% per year. Under Convertible Loan, there are several situations that would trigger a conversion of the loan into shares:

- Upon closing of a qualified financing event
- Upon closing of a financing round not qualifying as a qualified financing event
- Upon entering into a liquidity event prior to conversion or repayment
- Upon a milestone event
- Upon election by the option holder

These conversion options are mutually exclusive.

**Accounting Policy:** For recognition as equity all conversion options should meet the fixed-for-fixed requirement of IAS 32. This is not the case for each of the conversion options. Generally, multiple embedded derivatives in a single hybrid contract are treated as a single compound embedded derivative. These conversion options are considered a single compound embedded derivative as a) they relate to the same underlying risk exposure (the valuation of the Company) and b) these conversion options are mutually exclusive and therefore not independent of each other. Based on the aforementioned, the option

is considered an embedded derivative which is bifurcated and classified as a financial liability through profit and loss (“FVPL”).

Initial and subsequent measurement will be in line with the accounting policy as included in Note 4.2 Financial liabilities at fair value through profit and loss (“FVPL”). Interest related to the financial liability is recognised in profit and loss. On conversion at maturity, the financial liability is reclassified to equity and no gain or loss is recognised.

The fair value of the embedded conversion options could not be measured reliably with reference to the terms and conditions as there is no active market. The fair value of the embedded conversion options is therefore equal to the difference between the fair value of the Convertible loan and the fair value of the debt portion.

At the Issue Date, the fair value of the debt portion and the fair value of the embedded derivatives together have a total fair value equal to the issue price of the Convertible Loan, given that the Convertible Loan was issued to market participants and therefore the total fair value should equal the transaction price. The expected cash flows are estimated per issue date based on the terms of the convertible loan agreement. This agreement specifies that an interest rate of 8.0% per annum is charged. The interest is accrued and repaid at maturity. As a result, there is one expected payment of principal and accrued interest at maturity date of the loan. For the discounting of the expected future interest and principal payments, an appropriate discount rate is determined using the (historic) debt spreads as determined by Aswath Damodaran, a renowned valuation practitioner. The applied debt spreads are based on the issue date of the Convertible Loan, as well as an indicative credit rating to incorporate the implied credit risk of Onward as at the valuation date.

Moody’s rating methodology for pharmaceutical companies was used to estimate an indicative credit rating for Onward. This methodology not only considers financial metrics but also qualitative factors and the potential of Onward and its pipeline. Notching adjustments are included to incorporate the risk profile of the unsecured nature of the convertible bonds. Based on the result of the valuation management used the mid-range of the outcome for the recognition of the embedded conversion option. The embedded conversion option recognised amounted to EUR 2,480,179 within Other financial liabilities.



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After the corporate conversion but immediately before the IPO the full loan amount, including contractual interest accrued converted into ordinary shares. The conversion option was revalued immediately prior to settlement and the difference was recognised in profit and loss. The numbers of shares issued varied as a result of the pricing mechanisms within the agreement. 3,254,578 shares were issued at a value of EUR 31,121,902 (including share premium), representing the carrying value of the loan at conversion. The shares issued represents full and final settlement of the convertible loan.

**Other Reserves**

	Currency Translation Differences	Stock Compensation Reserve	Conversion Option Preference Shares	Total Other Reserves
<b>Balance at January 1, 2020</b>	(91)	971	14,246	15,126
Series A Financing (jul'20)	-	-	337	337
Series A Financing (oct'20)	-	-	53	53
Series A Financing (nov'20)	-	-	158	158
Share based payment expense for the year	-	2,700	-	2,700
Currency translation differences	(441)	-	-	(441)
<b>Balance at December 31, 2020</b>	<b>(532)</b>	<b>3,671</b>	<b>14,794</b>	<b>17,933</b>
Conversion of preference share on IPO	-	-	(14,794)	(14,794)
Share based payment expense: EIP	-	8,494	-	8,494
Share based payments: EIP accelerated vesting	-	(12,165)	-	(12,165)
Share based payment expense: LTIP	-	69	-	69
Currency translation differences	249	-	-	249
<b>Balance at December 31, 2021</b>	<b>(283)</b>	<b>69</b>	<b>-</b>	<b>(214)</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 2021.





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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**

	2021	2020
Profit (loss) for the year, attributable to equity holders of the parent	<b>(34,314)</b>	<b>(20,014)</b>

**Weighted-average Number of Ordinary Shares**

	2021 Thousands	2020 Thousands
Weighted average number of ordinary shares for basic EPS	<b>9,485</b>	<b>9,002</b>
Weighted average number of ordinary shares for basic EPS (adjusted*)	<b>9,485</b>	<b>3,601</b>

\* Ordinary shares were subject to a 5:2 reverse stock split as part of the corporate conversion. The comparative weighted average number of ordinary shares (2020) was restated to include the effect of the reverse stock split.

**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.

Financial liabilities are classified as measured at amortized cost or at Fair Value through Profit or Loss (“FVPL”). 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, 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 (loans and borrowings)

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

Financial liabilities at fair value through profit or loss include financial liabilities held for trading and financial liabilities designated upon initial recognition as at fair value through profit or loss.

Financial liabilities are classified as held for trading if they are incurred for the purpose of repurchasing in the near term. This category also includes derivative financial instruments entered into by the Group that are not designated as hedging instruments in hedge relationships as defined by IFRS 9. Separated embedded derivatives are also classified as held for trading unless they are designated as effective hedging instruments.



Gains or losses on liabilities held for trading are recognized in the statement of profit or loss.

Financial liabilities designated upon initial recognition at fair value through profit or loss are designated at the initial date of recognition, and only if the criteria in IFRS 9 are satisfied. The Group has not designated any financial liability as at fair value through profit or loss.

**Financial Liabilities at Amortized Cost (Loans & Borrowings)**

This is the category most relevant to the Group. After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortized cost using the effective interest rate (“EIR”) method. Gains and losses are recognized in the profit or loss when the liabilities are derecognized as well as through the EIR amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the EIR. The EIR amortization is included as finance costs in the statement of profit or loss.

**Derecognition**

A financial liability is derecognised 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 recognised 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.

**Innovation Loan**

At February 5, 2016, the Group was granted a loan from RVO NL (Dutch Government) of EUR 10 million payable according a set payment scheme.

	2021	2020
<b>Loan as per January 1</b>	<b>10,410</b>	<b>7,561</b>
Loan amount received	-	1,994
Interest accrued during the year	1,041	855
<b>Net book value at December 31</b>	<b>11,451</b>	<b>10,410</b>

The loan carries interest at 10%.

The current redemption plan for the loan is as presented below:

Date	% of Loan Amount
1 January 2026	15.0
1 April 2026	15.0
1 July 2026	17.5
1 October 2026	17.5
1 January 2027	17.5
1 April 2027	17.5
1 July 2027	All due interest

Certain Intellectual Property (patents registered), have been pledged to the RVO NL in case of default of repayment of the loan. These patents have not been capitalized as at 31 December 2021.



**Consolidated Financial Statements****Convertible Preference A Shares**

On 31 December 2020, there were 37,666,666 convertible preference A shares in issue (2019: 35,583,332; 2018: 20,000,001). The preference shares carry a dividend of 6% per annum. The dividend rights are cumulative. The preference shares rank ahead of the ordinary shares in the event of a liquidation. The preference A shares can be converted into Ordinary Shares of the company under different scenarios, where the rights and number of Ordinary Shares received differs as summarized below:

<b>Conversion Option</b>	<b>Option Holder/ Lender/ Mandatory</b>	<b>Fixed or Variable Number of Shares</b>
Voluntary conversion	Option holder	Fixed, 1:1 conversion rate subject to adjustments for any changes in the share capitalization of the Company
Conversion upon IPO	Mandatory	
Conversion upon other Financing	Option holder	
SSA Defaulting Party of Issuer	Mandatory	Fixed, 10:1 conversion ratio

For the purpose of the valuation management assumed mandatory conversion upon IPO as the most likely scenario at a conversion rate of one ordinary share for one preference share.

Conversion occurred immediately preceding the IPO on 21 October 2021, refer to Note 4.1 for further details. The IPO is considered to be the maturity event.

	<b>2021</b>	<b>2020</b>
<b>Balance as at January 1</b>	<b>31,407</b>	<b>25,918</b>
Preference shares issued	-	1,952
Cumulative preference dividend (accrued)	3,266	3,537
Conversion to ordinary shares - IPO	(34,673)	-
<b>Balance as at December 31</b>	<b>-</b>	<b>31,407</b>

**Convertible Loan**

On 20 April 2021 the Company entered into a Convertible Loan Agreement of EUR 30 million (EUR 27.1 million (the "Principal Amount"), with an additional EUR 2.9 million executed in July 2021). The annual interest rate is 8%. The convertible loan was repayable within 36 months from date of signing the agreement. The repayment date was therefore 2024. The conversion option was considered an embedded derivative which is bifurcated and treated as a financial instrument at fair value through profit and loss. Based on the valuation performed this instrument was recognized at the amount of EUR 2,480,179 within other financial liabilities and the loan at the amount of EUR 27,519,821 was included in interest-bearing liabilities. Interest accrued for the period, also included in the conversion amounted to EUR 1,122,034. Refer to Note 4.1 for further details.

	<b>2021</b>
<b>Loan opening balance</b>	<b>-</b>
Loan amount received	30,000
Interest accrued during the period	1,122
Conversion to ordinary shares - IPO	(31,122)
<b>Closing net book value</b>	<b>-</b>



**Consolidated Financial Statements****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:

**Liquidity Risk**

The Company 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 Company mainly makes use of liquid investment in current accounts (in Euro) or short-term deposit accounts. The ability of the Company to maintain adequate cash reserves to support its activities in the medium term is highly dependent on the Company's ability to raise additional funds.

The following table details the undiscounted remaining contractual maturity for the Company's financial liabilities with agreed repayment periods, including both interest and principal cash flows:

As of 31 December 2021:

	<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	12,798	19,298
Lease liability	473	1,741	-	-	2,214
Trade & other payables	4,459	-	-	-	4,459
<b>Total</b>	<b>4,932</b>	<b>1,741</b>	<b>6,500</b>	<b>12,798</b>	<b>25,971</b>

As of 31 December 2020:

	<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	-	-	-	19,298	19,298
Convertible preference A shares	-	-	-	60,541	60,541
Lease liability	137	61	-	-	198
Trade & other payables	2,501	-	-	-	2,501
<b>Total</b>	<b>2,638</b>	<b>61</b>	<b>-</b>	<b>79,839</b>	<b>82,538</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 Company's activities may expose it to changes in foreign currency exchange rates and interest rates. The Company is not exposed to any equity price risk or commodity price risk as it does not invest in these classes of investments.

**Credit Risk**

Because of the absence of sales to third parties and therefore trade receivables, credit risk arises mainly from cash and cash equivalents and deposits with banks and financial institutions. The Company only works with international reputable commercial banks and financial institutions. The Company holds accounts with ING, Belfius, UBS and First American Bank.

**Currency Risk**

Currency risk is the risk that reported financial performance, or the fair value or future cash flows of a financial instrument, will fluctuate because of changes in foreign exchange rates. The Group is exposed to currency risk for the activities mainly in the US as the accounting is performed in US dollars whereas the functional currency of the Group is the euro. The risk is currently managed by replenishing the US bank account at regular intervals to account for both the positive and negative changes.



#### 4.4 Fair Value & Fair Value Hierarchy of the Financial Statements

**Accounting Policy:** All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorised 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:

	Carrying Amount	Estimated Fair Value
2021		
<b>Financial liabilities</b>		
Innovation credit loan (Level 2)	11,451	13,218
<b>Total financial liabilities</b>	<b>11,451</b>	<b>46,942</b>
2020		
<b>Financial liabilities</b>		
Innovation credit loan (Level 2)	10,410	11,393
Convertible preference A shares (Level 3)	31,407	35,549
<b>Total financial liabilities</b>	<b>41,817</b>	<b>46,942</b>

Management has assessed that the fair values of cash and cash equivalents, accounts payable, taxes and social securities and other payables approximate to their carrying amounts largely due to the short-term maturities of these instruments.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale. The following methods and assumptions were used to estimate the fair values:

The fair value of Innovation credit loan and due interest have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities.

During the period, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.



#### 4.5 Financial 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, trade receivable, 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.

	2021	2020
Interest on loans	(5,430)	(4,392)
Interest post-employment benefits	1	(1)
Interest banks	(146)	(23)
Interest on lease liabilities	(21)	(14)
Exchange losses	(100)	(41)
Bank charges	(17)	(11)
<b>Total Financial expense</b>	<b>(5,713)</b>	<b>(4,482)</b>

#### 5. Section 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 recognised 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 recognised in profit or loss on the earlier of:

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

Net interest is calculated by applying the discount rate to the net defined benefit liability or asset. The Group recognises 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.



**Consolidated Financial Statements**

	<b>2021</b>	<b>2020</b>
Plan assets	1,756	879
Obligation	(3,144)	(1,278)
<b>Net liability</b>	<b>1,388</b>	<b>399</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 62 (female) and 63 (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.



## Consolidated Financial Statements

## Movement of Net Defined-benefit Liability

	2021	2020
<b>Balance as at January 1</b>	<b>399</b>	<b>429</b>
Service costs	167	41
Admin costs	14	10
Past service costs	264	-
Employee benefit expenses	445	51
Net interest costs / (income)	(1)	1
<b>Included in statement of profit and loss</b>	<b>444</b>	<b>52</b>
Actuarial gains / (losses)		
- Financial assumptions	(94)	35
- Demographic assumptions	-	(72)
- Experience adjustment	727	(8)
- Return on assets excluding interest income	81	10
	714	(35)
Exchange rate differences	30	6
<b>Included in statement of comprehensive income</b>	<b>744</b>	<b>(29)</b>
<b>Contributions by employer</b>	<b>(199)</b>	<b>(53)</b>
<b>Balance as at December 31</b>	<b>1,388</b>	<b>399</b>

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

	2021	2020
Discount rate	0,30%	0,15%
Salary increase	2,50%	2,50%
Interest credit rate	0,60%	0,60%
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:

	2021	2020
Discount rate		
+ 25bps	(147)	(57)
- 25bps	159	62
Salary increase		
+ 25bps	102	4
- 25bps	(62)	(4)
Interest credit rate		
+ 25bps	30	24
- 25bps	(29)	(19)
Mortality base table		
Life expectancy + 1 year	35	26
Life expectancy - 1 year	(33)	(26)

The sensitivity analyses have been determined based on a method that extrapolates the impact on the defined benefit obligation as a result of reasonable changes in key assumptions occurring at the end of the reporting period. The sensitivity analyses are based on a change in a significant assumption, keeping all other assumptions constant. The sensitivity analyses may not be representative of an actual change in the defined benefit obligation as it is unlikely that changes in assumptions would occur in isolation from one another.



**Consolidated Financial Statements**

The following are the expected payments or contributions to the defined benefit plan in future years:

	<b>2021</b>	<b>2020</b>
Within the next 12 months	123	51
Between 2 and 5 years	640	205
Beyond 5 years	1,428	472
<b>Total expected payments</b>	<b>2,191</b>	<b>727</b>

The average duration of the defined benefit plan obligation at the end of the reporting period is 19 years (2020: 19 years).

**Plan Assets Allocation**

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

	<b>2021</b>	<b>2020</b>
Bonds	1,004	519
Equities	168	70
Loans	52	44
Mortgages	207	106
Real Estate	300	141
Cash, derivatives and funds	25	
	<b>1,756</b>	<b>879</b>

Plan assets in 2021 do not include property occupied by or financial instruments issued by ONWARD.

**5.1 Commitments & Contingencies****Legal Claim Contingencies**

As at December 31, 2021, the Group had no legal claim contingencies.

**Guarantees**

The Group has provided a guarantee to High Tech Campus for EUR 41k, to EPFL for EUR 24k and to Wincasa for EUR 273k as collateral for the lease of the office spaces.

**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.

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 fixed 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.

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 transcutaneous neuromodulation and a non-exclusive license of certain other intellectual property. Various revenue milestone payments, diligence obligations and fixed royalty payments are due under the license. These payments range from USD 20k to USD 75k payable upon FDA approval, CE Mark and/or first commercial sale.



**Consolidated Financial Statements****5.2 Related Party Transactions**

Note 1.2 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>2021</b>	<b>Salary, Bonuses &amp; Other (Short- term Employee Benefits)</b>	<b>Pension Premiums (Post- employment Benefits)</b>	<b>Share-based Payment</b>	<b>Total</b>
Management team, excluding CEO	2,073	78	2,164	4,315
CEO	1,163	28	2,140	3,331
Non-executive directors	431	-	1,180	1,611
	<b>3,667</b>	<b>106</b>	<b>5,484</b>	<b>9,256</b>

<b>2020</b>	<b>Salary, Bonuses &amp; Other (Short- term Employee Benefits)</b>	<b>Pension Premiums (Post- employment Benefits)</b>	<b>Share-based Payment</b>	<b>Total</b>
Management team, excluding CEO	1,385	33	840	2,258
CEO	427	5	746	1,178
Non-executive directors	340	-	619	959
	<b>2,152</b>	<b>38</b>	<b>2,205</b>	<b>4,395</b>

**5.3 Events After the Reporting Period**

No other events have taken place after the reporting period to date that need to be reported.





# Company Statement of Income

For the Year Ended 31 December

All amounts in EUR '000	Notes	2021	2020
<b>Grants</b>		<b>1,219</b>	<b>580</b>
<b>Total operating income</b>	<b>B</b>	<b>1,219</b>	<b>580</b>
General and administrative expenses		(27,254)	(13,862)
<b>Total operating expenses</b>	<b>C</b>	<b>(27,254)</b>	<b>(13,862)</b>
<b>Operating result for the period</b>		<b>(26,035)</b>	<b>(13,283)</b>
Financial expenses	<b>D</b>	(5,662)	(4,483)
<b>Result before tax</b>		<b>(31,697)</b>	<b>(17,766)</b>
Income tax expense		-	8
Share in result of participating interests	<b>E</b>	<b>(2,617)</b>	<b>(2,256)</b>
<b>Result after tax</b>		<b>(34,314)</b>	<b>(20,014)</b>

The notes on pages **266** to **275** 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	2021	2020
<b>Assets</b>			
<b>Non-current assets</b>			
Property, plant and equipment	F	197	365
Financial assets	G	2,459	3,102
		<b>2,656</b>	<b>3,467</b>
<b>Current assets</b>			
Trade and other receivables	H	7,846	2,948
Cash at bank and in hand	I	88,777	6,294
		<b>96,623</b>	<b>9,241</b>
		<b>99,279</b>	<b>12,708</b>



**Equity & Liabilities**

**Equity and reserves**

	<b>J</b>		
Issued capital		3,622	-
Share premium		155,248	3,083
Other reserves		69	18,465
Legal reserve: Currency translation differences		(283)	(532)
Retained earnings		(41,660)	(33,097)
Result for the year		(34,314)	(20,014)

<b>Total equity</b>		<b>82,683</b>	<b>(32,095)</b>
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<b>Provisions</b>	<b>K</b>	214	-
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<b>Non-current liabilities</b>	<b>L</b>	11,451	41,817
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<b>Current liabilities</b>	<b>M</b>	4,931	2,924
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		<b>99,279</b>	<b>12,708</b>
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The notes on pages **266** to **275** 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 N.V. (the company) and the company structure, as included in the notes to the consolidated financial statements, also applies to the company financial statements.

These separate financial statements have been prepared in accordance with Title 9, Book 2 of the Dutch Civil Code. For setting the principles for the recognition and measurement of assets and liabilities and determination of results for its separate financial statements, the Company makes use of the option provided in section 2:362(8) of the Dutch Civil Code. This means that the principles for the recognition and measurement of assets and liabilities and determination of the result (hereinafter referred to as principles for recognition and measurement) of the separate financial statements of the Company are the same as those applied for the consolidated EU-IFRS financial statements. These principles also include the classification and presentation of financial instruments, being equity instruments or financial liabilities. In case no other principles are mentioned, refer to the accounting principles as described in the consolidated financial statements. For an appropriate interpretation of these statutory financial statements, the separate financial statements should be read in conjunction with the consolidated financial statements.

Information on the use of financial instruments and on related risks for the group is provided in the notes to the consolidated financial statements of the group.

## B. Operating Income

Operating income relates to grant 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.

Grants	Total Grant*	Recognized	
		2021	2020
RESTORE	370	–	37
DISPERSE	311	–	36
WALKAGAIN	500	–	185
BESTABLE	99	16	25
PREP2GO	348	139	104
DARPA	1,152	981	192
ZonMW	250	83	–
<b>Total</b>		<b>1,219</b>	<b>580</b>

**C. Operating Expenses**

Operating expenses by nature are as follows:

	2021	2020
Employee benefits	12,122	2,629
Other operating expenses	14,909	10,976
Depreciation	223	257
	<b>27,254</b>	<b>13,862</b>

**D. Financial Income & Expenses**

	2021	2020
Interest on loans	(5,430)	(4,392)
Interest banks	(146)	(24)
Interest on lease liabilities	(7)	(14)
Exchange losses	(65)	(41)
Bank charges	(14)	(12)
<b>Total Finance expense</b>	<b>(5,662)</b>	<b>(4,483)</b>

**E. Share in Results from Participating Interests**

An amount of EUR 2.617 million (2020: EUR 2.256 million) of share in results from participating interests relates to group companies.

**F. Property, Plant & Equipment**

	2021	2020
Cost	1,116	950
Accumulated depreciation	(751)	(519)
<b>Net book value at 1 January</b>	<b>365</b>	<b>431</b>
Investments	55	166
Assets acquired from business combination	–	–
Depreciation for the year	(223)	(232)
Net change	(168)	(66)
Cost	1,171	1,116
Accumulated depreciation	(974)	(751)
<b>Net book value at 31 December</b>	<b>197</b>	<b>365</b>



**G. 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 recognised for the amount by which the asset's carrying amount exceeds its recoverable amount.

	2021	2020
Cost	3,102	5,765
Accumulated impairments	-	-
<b>Net book value at 1 January</b>	<b>3,102</b>	<b>5,765</b>
Revaluations through OCI	(714)	35
Exchange differences	255	(442)
Share in result of participating interests	(2,617)	(2,256)
Addition: License fees	2,219	-
Provision: negative participating interest	214	-
Net change	(643)	(2,663)
Cost	2,459	3,102
Accumulated impairments	-	-
<b>Net book value at 31 December</b>	<b>2,459</b>	<b>3,102</b>

The Company has the firm intention to support its subsidiary, ONWARD Medical SA, to meet its obligations to third parties. A provision has been recognised for the negative value of the investment to the amount of EUR 214k (2020: Nil).

**H. 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 recognize 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.

	2021	2020
Indirect tax receivable	290	72
Receivables from related parties	5,492	2,476
Other	820	400
Advance payments made	1,244	-
	<b>7,846</b>	<b>2,948</b>

## Company Financial Statements

**I. Cash & Cash Equivalents**

	2021	2020
Cash at bank	88,777	6,294
	<b>88,777</b>	<b>6,294</b>

Short-term deposits comprise a liquidity management account that is used, depending on the immediate cash requirements of the Company, and earns interest at the respective short-term deposit interest rates.

At December 31, 2021, the Company had no bank overdrafts. All cash is freely at the disposal of the company.

**J. Shareholders' Equity**

For the statement of changes in equity for the year ended 31 December 2021, 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.

**K. Provisions**

	2021	2020
Opening balance as at 1 January	-	-
Negative participating interest	214	-
<b>Balance as at 31 December</b>	<b>214</b>	<b>-</b>

**L. Non-Current Liabilities**

	2021	2020
<b>Balance as at 31 December</b>	<b>11,451</b>	<b>41,817</b>

	2021		
	Innovation Loan	Convertible Preference A Shares	Convertible Loan
<b>Loan as per 1 January</b>	<b>10,410</b>	<b>31,407</b>	-
Loan amount received / preference shares issued	-	-	30,000
Interest / cumulative dividend accrued during the year	1,041	3,266	1,122
Conversion to ordinary shares - IPO	-	(34,673)	(31,122)
<b>Net book value at 31 December</b>	<b>11,451</b>	<b>-</b>	<b>-</b>

	2020	
	Innovation Loan	Convertible Preference A Shares
<b>Loan as per 1 January</b>	<b>7,561</b>	<b>25,918</b>
Loan amount received / preference shares issued	1,994	1,952
Interest / cumulative dividend accrued during the year	855	3,537
<b>Net book value at 31 December</b>	<b>10,410</b>	<b>31,407</b>

**M. Current Liabilities**

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

	2021	2020
Trade payables	464	724
Payables from related parties	2,358	1,255
Other payables	2,109	1,006
	<b>4,931</b>	<b>2,985</b>

**N. 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 5.3 of the consolidated financial statements. Full details of the remuneration of the board (CEO and non-executives) are included in the Remuneration report.

**O. Fees for Audit & Other Services**

In accordance with article 382.a of Part 9, Book 2, of the Netherlands Civil Code, the total audit cost can be specified as follows:

	Ernst & Young Accountants LLP	
	2021	2020
Audit of financial statements	180	43
Audit of special purpose financial statements	679	-
Other assurance services	39	27
	<b>898</b>	<b>70</b>

**P. Subsequent Events**

No other events have taken place after the reporting period to date that need to be reported.

**Q. Proposed Appropriation of Result**

The Management Board proposes to add the net loss in full to the retained earnings.

# 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 2021 Included in the Annual Report

### Our Opinion

We have audited the financial statements 2021 of ONWARD Medical N.V. based in Amsterdam.

The financial statements comprise the consolidated and company financial statements.

In our opinion:

- The accompanying consolidated financial statements give a true and fair view of the financial position of ONWARD Medical N.V. as at 31 December 2021 and of its result and its cash flows for 2021 in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and with Part 9 of Book 2 of the Dutch Civil Code
- The accompanying company financial statements give a true and fair view of the financial position of ONWARD Medical N.V. as at 31 December 2021 and of its result for 2021 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 2021
- The following statements for 2021: the consolidated statement of profit and loss, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and cash flows
- The notes comprising a summary of the significant accounting policies and other explanatory information.

The company financial statements comprise:

- The company balance sheet as at 31 December 2021
- The company statement of income for 2021
- 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).

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

### Information in Support of Our Opinion

We designed our audit procedures in the context of our audit of the financial statements as a whole and in forming our opinion thereon. The following information in support of our opinion and any findings were addressed in this context, and we do not provide a separate opinion or conclusion on these matters.

### Our Understanding of the Business

ONWARD Medical N.V. and its subsidiaries (the “Group”) are developing both an Implantable Neuro-stimulation System (INS) and a non-invasive system for electrical stimulation of specific areas of the spinal cord. The group is structured in components and we tailored our group audit approach accordingly. In October 2021 the company obtained a primary listing on Euronext in Brussels. We paid specific attention in our audit to a number of areas driven by the operations of the group and our risk assessment.

We start by determining materiality and identifying and assessing 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. 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.

### Materiality

**Materiality** € 1,100,000

**Benchmark applied** 3% of the operating expenses

**Explanation** R&D companies such as ONWARD Medical N.V., which are in the start-up phase, report no or modest revenues. The stakeholders expect the entity to operate at a loss during the R&D phase. The value that owners or others generally attribute to these entities is primarily based on the promise of future success of the products. Based on these factors we deem operating expenses to be a suitable basis, as it is one of the most important measures of the company’s performance.

We have also taken into account misstatements and/or possible misstatements that in our opinion are material for the users of the financial statements for qualitative reasons.

We agreed with the board of directors that misstatements in excess of € 55,000, which are identified during the audit, would be reported to them, as well as smaller misstatements that in our view must be reported on qualitative grounds.



**Scope of the Group Audit**

ONWARD Medical N.V. is at the head of a group of entities. The financial information of this group is included in the consolidated financial statements.

Because we are ultimately responsible for the opinion, we are also responsible for directing, supervising and performing the group audit. In this respect we have determined the nature and extent of the audit procedures to be carried out for group entities. Decisive were the size and/or the risk profile of the group entities or operations. On this basis, we selected group entities for which an audit or review had to be carried out on the complete set of financial information or specific items.

Our group audit mainly focused on significant group entities. We selected ONWARD Medical N.V., ONWARD Medical S.A. and ONWARD Medical Inc. as significant entities based on their size and/or their risk profile and performed full scope procedures for these entities. We have performed audit procedures ourselves at these group entities as the accounting function is centralized for the group.

In total these procedures represent 100% of the group's total assets, 100% of profit/loss and 100% of gross revenues.

By performing the procedures mentioned above at components of the group, together with additional procedures at group level, we have been able to obtain sufficient and appropriate audit evidence about the group's financial information to provide an opinion about the consolidated financial statements.

**Teaming & Use of Specialists**

We ensured that the audit team included the appropriate skills and competences which are needed for the audit of a listed client in the medical technology industry. We included specialists in the areas of IT audit, forensics, share based payments, income tax and actuaries.

**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.

**Our Audit Response Related to Fraud Risks**

We identify and assess the risks of material misstatements of the financial statements due to fraud. During our audit we obtained an understanding of the ONWARD Medical N.V. and its environment and the components of the system of internal control, including the risk assessment process and management's process for responding to the risks of fraud and monitoring the system of internal control as well as the outcomes.

We refer to section 17 Risk Management and Control in the Annual Report for management's fraud risk assessment.

We evaluated the design and relevant aspects of the system of internal control and in particular the fraud risk assessment, as well as the code of conduct and whistle blower procedures. We evaluated the design and the implementation and, where considered appropriate, tested the operating effectiveness, 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 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.

As in all of our audits, we addressed the risks related to management override of controls. For the risk related to management override of controls we have performed procedures among others 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 1.8 to the financial statements. We have also used data analysis to identify and address high-risk journal entries.

We considered available information and made enquiries of relevant executives and directors.

The fraud risk we identified, enquires 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 & Regulations**

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 management board, reading minutes, and inspection of compliance reports, and performing substantive tests of details of classes of transactions, account balances or disclosures.

We also inspected legal expenses and 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 Audit Response Related to Going Concern**

Management has made a specific assessment of ONWARD Medical N.V.'s ability to continue as a going concern and to continue its operations for at least the next 12 months in note 1.6 to the financial statements.

We discussed and evaluated the specific assessment with management exercising professional judgment and maintaining professional skepticism.

We considered whether management's going concern assessment, based on our knowledge and understanding obtained through our audit of the financial statements or otherwise, contains all events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion.

Based on our procedures performed, we did not identify serious doubts on the entity's ability to continue as a going concern for the next 12 months.

We performed the following procedures in order to identify and assess the risks of going concern and to conclude on the appropriateness of management's use of the going concern basis of accounting. We discussed and evaluated the specific assessment with management exercising professional judgment and maintaining professional skepticism, and specifically focusing on, among others, the process followed by management to make the assessment and management bias that could represent a risk and the impact of current events and conditions on the company's operations.

We evaluated forecasted cash flows, with a focus on whether the company will have sufficient liquidity to continue to meet its financial obligations as they fall due.

Based on our procedures performed, we concluded that the degree of consideration of all available information in management's going concern assessment and related disclosures in the financial statements are appropriate in the circumstances and in accordance with the financial reporting framework mentioned.

Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company to cease to continue as a going concern.

## Our Key Audit Matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements. We have communicated the key audit matters to board of directors. The key audit matters are not a comprehensive reflection of all matters discussed.

### Risk

At year-end 2021, ONWARD Medical N.V. carried an intangible asset balance of € 10.0 million, consisting of goodwill (€ 1.7 million), capitalized in-process R&D expenses (€ 6.1 million) and capitalized license fees of € 2.2 million. The goodwill as well as the in-process R&D expenses relate to the acquisition of ONWARD Medical Inc in 2019 and subsequent license fees. In accordance with EU-IFRS, ONWARD Medical N.V. is required to perform impairment tests on an annual basis. These impairment tests are significant to our audit because the assessment process is complex, requires management judgment, and is based on assumptions that are affected by expected future market conditions. Furthermore, the occurrence of the IPO in October 2021 triggered the change in ownership clauses in certain license agreements, resulting in additional payments capitalized in 2021. For these reasons, we consider this a key audit matter.

## Our audit approach

As part of our audit procedures we focused on the assumptions and methodologies used by the company, and also on the robustness of the planning process to evaluate whether the company is able to prepare reliable estimates. The value of the in-process R&D is contingent on the success of the US Food and Drug Association (FDA) and other competent authorities' approval of the company's products. To this end, management prepared a "success scenario" and a "failure scenario" to address the challenges of achieving the necessary approvals.

The company uses assumptions with respect to growth rate in the US, based on a report issued by the Congressional Budget office in the US. In order to assess the reasonability of input data, the valuation model and the discount rate, we have, among other procedures, compared the data with external data such as expected inflation rates, external market growth expectations and by analyzing sensitivities in the company's impairment testing model. With regard to the sensitivities, we specifically focused on the risk of not achieving regulatory approval and whether a reasonable possible change in assumptions, such as the discount rate and the growth rate, could cause the carrying amount to exceed its recoverable amount. We also focused on the adequacy of the company's disclosures regarding assumptions and sensitivities as well as consistency between the going concern forecasts and the inputs in the company's impairment testing model.

**Key observations**

We consider 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 in 2021. We assessed that the disclosures in respect of intangible assets in the financial statements (note 3.0) are appropriate.

**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 for the management board 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.

Management is responsible for the preparation of the other information, including the management board 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. Management 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.

Management is responsible for preparing the annual report, including the financial statements, in accordance with the RTS on ESEF, whereby management 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.

Our procedures, taking into account Alert 43 of the NBA (the Netherlands Institute of Chartered Accountants), included amongst others:

- Obtaining an understanding of the ONWARD Medical N.V.'s financial reporting process, including the preparation of the reporting package

- 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 Management for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with EU-IFRS and Part 9 of Book 2 of the Dutch Civil Code. Furthermore, management is responsible for such internal control as management 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, management is responsible for assessing the company's ability to continue as a going concern. Based on the financial reporting frameworks mentioned, management should prepare the financial statements using the going concern basis of accounting unless management either intends to liquidate the company or to cease operations, or has no realistic alternative but to do so. Management 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 errors and fraud during our audit.

Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements. The materiality affects the nature, timing and extent of our audit procedures and the evaluation of the effect of identified misstatements on our opinion.

We have exercised professional judgment and have maintained professional skepticism throughout the audit, in accordance with Dutch Standards on Auditing, ethical requirements and independence requirements. The 'Information in support of our opinion' section above includes an informative summary of our responsibilities and the work performed as the basis for our opinion.

Our audit further included among others:

- Performing audit procedures responsive to the risks identified, and obtaining audit evidence that is sufficient and appropriate to provide a basis for our opinion
- Obtaining an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control
- Evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management
- 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 management board 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 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 and management board 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 and management board, 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.

The Hague, 25 April 2022

Ernst & Young Accountants LLP

A.A. Kuijpers

## 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 2021, 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.

## Forward Looking Information / Statements

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

Actual results may differ materially from those expressed in these forward-looking statements, and you should not place undue reliance on them. For a discussion of factors that could cause future results to differ from such forward-looking statements, see also the Risk management and control of this Annual Report.

## Definitions & Abbreviations

The following definitions are used in this report:

### 510(k)

Clearance under Section 510(k) of the FDCA

### AIS

ASIA impairment scale

### AIMD

Active Implantable Medical Device – Device relying on electrical energy and intended to be introduced (partially or totally) into the human body.

### ASIA

American Spinal Injury Association

### BDD

Breakthrough Device Designation - Designation given by the FDA to allow a timely access to devices providing a more effective treatment or diagnosis of life-threatening diseases by speeding-up their development, assessment and review

### Brain Spine Interface

Electrical signal produced by the brain is recorded and translated into a signal allowing the stimulation of the spine in a timely manner

### Caltech

California Institute for Technology

### Cardiovascular

Relating to the heart and blood vessels

### CARF

Commission of Accredited Rehabilitation Facilities

### CE

Conformité Européene

### Cervical

Relating to the neck or located around the neck area

### CGC

The Dutch corporate governance code issued on 8 December 2016

### Chairperson

The Chairperson of the Board

### CHUV

Centre Hospitalier Universitaire Vaudois

**CRO**  
Contract research organisations

**CSO**  
Chief Scientific Officer

**DARPA**  
The US Department of Defense Advanced Research Projects Agency

**EBITDA**  
Earnings before interest, tax, depreciation and amortization

**EEA**  
European Economic Area

**EPFL**  
École Polytechnique Fédérale de Lausanne

**Epidural**  
Placed or administered outside the dura mater

**Eurostar Grants**  
A grant from the Eurostars Programme of EUREKA together with the European Community, named Prep2Go

**FDA**  
U.S. Food and Drug Administration

**FDCA**  
U.S. Federal Food, Drug, and Cosmetic Act

**FTEs**  
Full time equivalent personnel

**GCP**  
Good Clinical Practice

**HDE**  
Humanitarian Device Exemption

**Hemodynamics**  
Forces involved in blood circulation in the body

**HIPAA**  
Health Insurance Portability and Accountability

**HUD**  
Humanitarian use device

**Hypertension**  
Higher blood pressure than normal range

**Hypotension**  
Lower blood pressure than normal range

**IPG**  
ONWARD implantable pulse generator

**Lesion**  
A damaged region in the body

**LTIP**  
Long-Term Incentive Plan

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

**MDR**  
Medical Device Regulation

**Medical Devices Regulation**  
Regulation (EU) 2017/745

**MHRA**  
Medicines and Healthcare products Regulatory Agency

**Neurodegenerative**  
Characterized by the degeneration of the nervous system

**Neuromodulation**  
Field of bioengineering implicating technologies impacting neural interfaces

**Neuroprosthetic**  
Device used to restore function in the body via the interface of electrodes and the nervous system.

**Neurostimulation**  
Application of an electrical stimulation inducing modulation or activation of the nervous system for a therapeutic effect

**Neurorehabilitation**  
Supervised program of training to restore function to patients who suffered from a neurological disorder.

**NHS**  
National Health Service – in the United Kingdom: refers to the publicly funded healthcare systems

**Orthostatic hypotension**  
Hypotension caused by transition to an upright position

**Paraplegic**  
Someone affected by paralysis (partial or complete) of the lower half of the body due to an injury or disease of the spinal cord.

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

**PMA**  
Pre-market approval



**QSR**

Quality System Regulations

**Reeve Foundation**

Christopher and Dana Reeve Foundation

**RVO**

Rijksdienst voor Ondernemend Nederland

**Scaffold (cellular)**

Scaffolds engineered to induce cellular interactions contributing to the formation of new functional tissues

**SCI**

Spinal Cord Injury – damage to the nerves in the spine that circulate signals from the brain to and from the body. It can be caused by a trauma or a disease. This damage can lead to temporary or permanent dysfunctions.

**Sensorimotor paralysis**

Condition that decreases the ability of a person to feel and move due to a nerve damage

**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**

Title of a pivotal trial using the Company’s ARC<sup>EX</sup> System

**Vascular**

Relating to blood vessels

**ZonMw grant**

A grant from ZonMw



**ONWARD**

Forward to  
**2022**