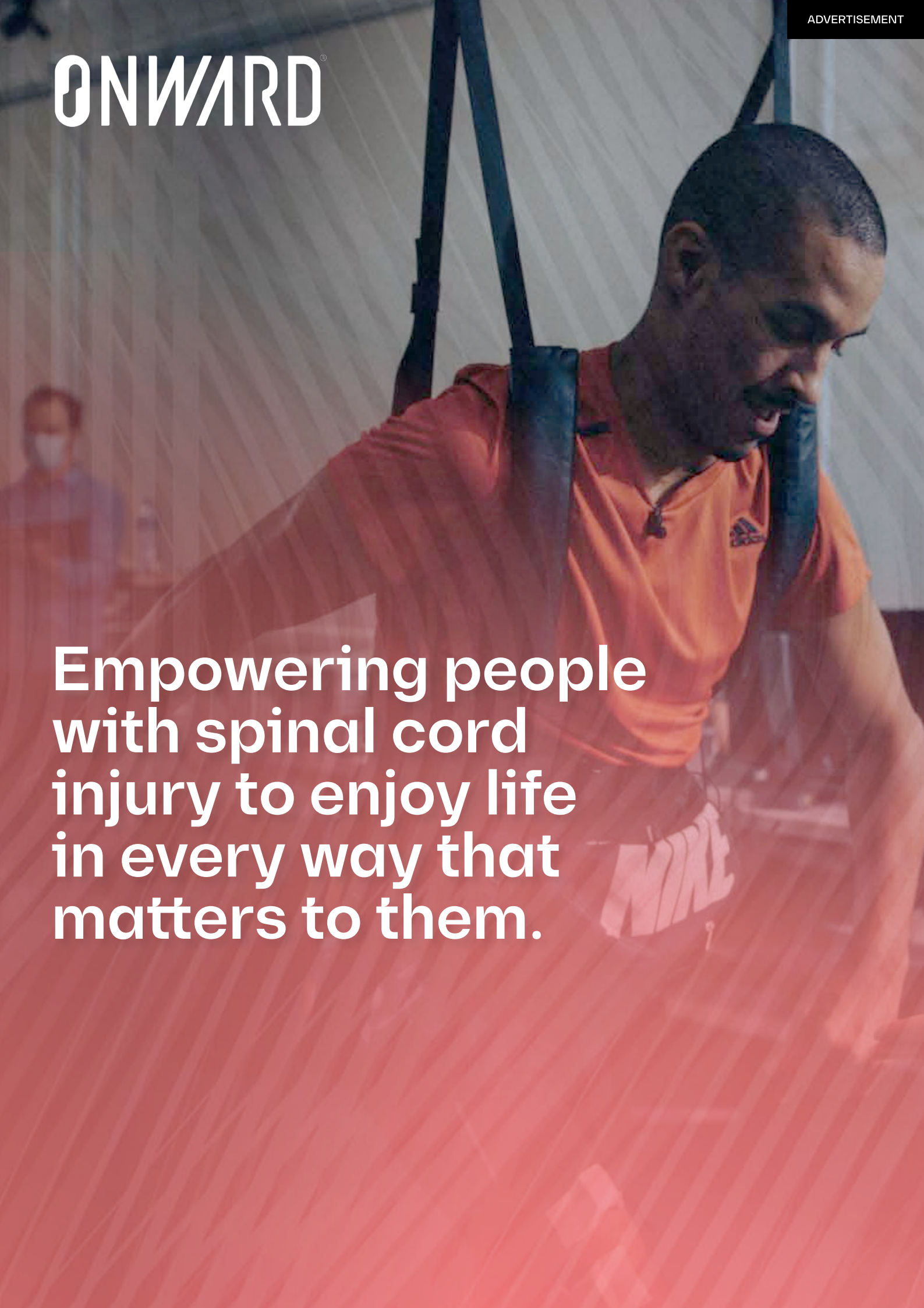

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# About ONWARD® Medical N.V.

ONWARD Medical N.V. (**ONWARD** or the **Company**) is a medical technology firm with a focused mission: to develop therapies specifically designed to aid individuals suffering from spinal cord injuries (SCI) in regaining movement and other bodily functions. To achieve this goal, the Company plans to harness the capabilities of its two distinct proprietary platforms – one implantable (ARC$^{IM®}$) and the other external (ARC$^{EX®}$). These experimental platforms are poised to introduce new therapies to the market that tackle the significant challenges encountered by SCI patients.

In safeguarding its technology and products, ONWARD has established a continuously expanding Intellectual Property (IP) rights portfolio. The Company has over 240 issued patents. These patents serve as protective measures, ensuring that the Company can continue its development efforts and provide effective therapies for individuals afflicted with SCI.

# How does ONWARD ARC Therapy™ work?

ARC Therapy uses targeted spinal cord stimulation to help people with SCI regain movement, function, and independence. This stimulation can be done through an implantable device (ARC$^{IM}$) or an external device (ARC$^{EX}$).

In 2022, ONWARD completed a pivotal trial with ARC$^{EX}$ Therapy for the upper limb. The device will be submitted to the FDA in the first half of 2024 and commercialisation is expected in the last quarter of 2024. Europe is expected to follow course in 2025. ARC$^{IM}$ Therapy will be used in a pivotal trial for blood pressure regulation that is expected to start in the second half of 2024 and commercialisation is expected in 2026. Both of these platforms have been awarded FDA Breakthrough Device Designation[1] for various uses. These platforms have three main components: a generator for electrical impulses, electrodes near the spinal cord, and a programmer for setting therapy parameters.

By sending precisely timed electrical signals to specific areas of the spinal cord, ARC Therapy mimics natural nerve signals from the brain. When combined with voluntary movements, this helps users improve control of their arms, legs, or torso, making tasks like getting in and out of a wheelchair a lot easier. Additionally, this therapy may improve the management of blood pressure and bowel and bladder control.

# The Case for Innovative Therapies

**c.7 million**

People are living with SCI.

**>768,000[2]**

New cases reported annually.

**650,000**

Individuals are currently affected by SCI in the US and Europe.

With yearly incidence standing at around **50,000**[3] cases.

**c.$5.0 million[4]**

Approximate cost to support someone with severe SCI throughout their lifetime.

SCI not only leads to disability, reduced quality of life, and health complications for individuals, but it also imposes significant economic burdens on societies due to high healthcare expenses.

[1]The FDA Breakthrough Devices Designation (BDD) is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

[2]2020 NSCISC Annual Statistical Report Complete Public Version.

[3]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 & National Spinal Cord Injury Statistical Center. Facts and Figures at a Glance. Birmingham, AL: University of Alabama at Birmingham, 2019.

[4]Kumar et al. 2018. Traumatic Spinal Injury: Global Epidemiology and Worldwide Volume (traumatic spinal injury may be broader than traumatic spinal cord injury.

# Expected Product Pipeline

## Short Term
2024

**Launch external platform (ARC$^{EX}$)**

**First indication:** Upper Limb

**Population:** SCI

## Medium Term
2026

**Launch implantable platform (ARC$^{IM}$)**

**First indication:** Blood Pressure

**Population:** SCI


## Long Term
2026+

**Expand labelling and platforms**

New indications and platforms to be assessed

**Populations:** SCI, Parkinson's, Stroke

# Promising Clinical Trial Results

## ARC$^{EX}$ Therapy

**About the Clinical Trial:** In 2022, the Company completed the Up-LIFT study, the first large-scale pivotal trial of non-invasive spinal cord stimulation technology. It enrolled 65 subjects at 14 leading SCI research centres throughout the USA, Canada, UK, and the Netherlands.

**Use Case:** The Up-LIFT study is a prospective, single-arm study[5] designed to evaluate the safety and effectiveness of non-invasive electrical spinal cord stimulation. This treatment is intended for individuals with chronic tetraplegia[6] who experience challenges in moving their arms and hands.

**Results: The trial achieved its primary objective endpoint, demonstrating statistically significant and clinically meaningful improvement in upper body strength and function.**

## ARC$^{IM}$ Therapy

**About the Clinical Trial:** In May 2023, the Company announced its ARC$^{IM}$ Therapy was paired with an investigational implanted wireless Brain-Computer Interface (BCI)[7] to restore upper body function after an SCI. The BCI developed by CEA - Clinatec in Grenoble is designed to initiate thought-driven movement when paired with ARC$^{IM}$ Therapy.

**Use Case:** The trial aims to investigate the safety and effectiveness of its investigational thought-initiated spinal cord stimulation device in patients with SCI.

**Results: This study achieved a positive result where the patient gained thought-driven, augmented control over when and how he moved his paralysed legs.**

Over the next 5 years, the Company seeks to gain regulatory approval to use ARC$^{IM}$ to restore the ability of people with SCI to walk and to normalise low and high blood pressure.

[5]A single-arm study is when a sample of individuals with the targeted medical condition are given the experimental therapy and then followed over time to observe their response.
[6]Tetraplegia also known as quadriplegia is a form of paralysis that impacts both arms and both legs. This describes the inability of voluntary movements of the upper and lower parts of the body.
[7]A brain-computer interface (BCI) is a technology that allows direct communication between the brain and an external device, such as a computer or prosthetic limb, without the need for conventional physical interfaces like keyboards or mouse devices. It enables the brain to send signals that can be interpreted by a computer, which can then perform actions based on those signals.

# Use of Proceeds

The Company aims to use the net proceeds from the Offering to extend its cash runway into mid-2025 in order to support future investments in product development, clinical trials, and operational and commercial capabilities. The Company intends to distribute the net proceeds from the Offering as follows: