



**Investor Webcast 2023 Full Year Results** April 25, 2024



















# **Forward Looking Statements**

This Presentation may include statements, including the Company's financial and operational medium term objectives that are, or may be deemed to be "forward looking statements". These forward looking statements may be identified by the use of forward looking terminology, including the terms "believes"," aims"," forecasts"," continues"," estimates"," plans"," projects"," anticipates"," expects"," intends"," may"," or "or, in each case, their negative or other variations or comparable terminology, or by discussions of strategy, plans, objectives, goals, future events or intentions. Forward looking statements may and often do differ materially from actual results. Any forward looking statements reflect the Company's current view with respect to future events and are subject to risks relating to future events and other risks, uncertainties and assumptions relating to the Company's business, results of operations, financial position, liquidity, prospects, growth or strategies. Forward looking statements speak only as of the date they are made.

# Speaking Today



**Dave Marver CEO** 



Khaled Bahi Interim CFO



#### **ONWARD®** at a Glance

#### **Key Facts**

- o Founded in 2015
- o ~100 FTEs
- o HQ in Eindhoven, the Netherlands
- Science and Engineering Center in Lausanne, Switzerland
- US office in Boston, Massachusetts
- IPO 2021, Euronext Brussels and Amsterdam
- Followed by Stifel, Bryan, Garnier & Co, Degroof Petercam, Kepler Cheuvreux and KBC Securities

Technology - 2 purpose-built neuromodulation platforms that stimulate the spinal cord via implantable (ARCIM®) or external (ARCEX®) technologies

Innovation - 10 FDA Breakthrough Device Designations and 240+ issued patents<sup>1</sup>

Clinical Success - One pivotal study completed with positive top line results reported for ARC<sup>EX</sup>; positive interim results also reported for ARC<sup>IM</sup> blood pressure indication

Market Opportunity - Large total addressable market (\$20B+ / €19B) with limited competition

Commercialization - ONWARD expects to launch its first product and realize its first revenues in 2H 2024

Note: 1 EUR = 1.1 USD; FTE and patent figures as of end of Q4 2023  $^{\rm 1}$  Includes EP country validations

# Vision

Empowered by movement, people with spinal cord injury will enjoy life in ways that matter to them





#### Targeted, programmed electrical stimulation of the spinal cord to restore movement, function, and independence in people with spinal cord injury

## **Our Technology**









# Reach commercial stage by year-end, then expand

### **Company Focus**

#### Short Term 2024

# Medium Term 2026

Long Term 2026+

Commercialize external platform (ARCEX)

First indication: Upper Limb

Population: SCI

Commercialize implantable platform (ARCIM)

First indication: Blood Pressure

Population: SCI

Expand labeling and platforms

New indications and platforms to be assessed

such as BCI

Populations: SCI, Parkinson's, Stroke





## 2024 comprises key value inflection points for ONWARD

## **2024 Strategic Priorities**

2024



ARCEX commercial launch (upper limb)

- FDA De Novo request submission (COMPLETED)
- FDA clearance
- o First commercial sale



ARCIM pivotal study first participant enrollment (blood pressure)

- IDE submission
- IDE approval
- o First participant enrollment



Continue clinical studies<sup>1</sup> and strengthen unique position in BCI field (upper limb and mobility)

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

### **Current Pipeline**

Short and medium term focus Funded primarily through grants and research partners Clinical Platform Indication FDA BDD<sup>1</sup> Pre-clinical Human PoC Pivotal Feasibility<sup>2</sup> **ARCEX Upper Limb ARCIM Blood Pressure ARCIM** Mobility / Second Indication ARCEX Mobility **ARCIM** Parkinson's - Mobility **ARCIM** Bladder Human PoC expected in **ARC**BCI Mobility **ARC**BCI **Upper Limb** ARCDBS Mobility ✓ BDD¹ Granted O Current Roadmap Label Expansion O Platform Expansion

Note: The company may modify the pipeline based on clinical progress and marketplace considerations

<sup>1</sup> BDD = FDA Breakthrough Device Designation. ONWARD has been granted four additional BDDs for ARCEX Bladder, ARCEX Blood Pressure, ARCEX Spasticity and ARCIM Spasticity

<sup>&</sup>lt;sup>2</sup> Includes both early feasibility (typically before device design finalized) and feasibility (near-final or final device design) studies

<sup>&</sup>lt;sup>3</sup> Funded by Christopher & Dana Reeve Foundation grant

# 2023 Business Update

# Major achievements, including BCI publication and FIH, new commercial partnership and Parkinson's grant

# 2023 Publicly Disclosed Achievements

April January – April January May May Mav Corporate Clinical Clinical Clinical Science Corporate Awarded FDA BDD<sup>1</sup> for Shared additional Appointed two new First-in-human use of Nature publication **Bryan Garnier** ARCIM Lead results from Up-LIFT Leadership Team three additional showing that wireless reinitiated with buy members indications pivotal study BCI can use thought to rating modulate ARC Therapy Details to follow

Clinica

August

First-in-human use of ARC<sup>BCI</sup> platform to restore arm, hand, and finger movement after SCI

Details to follow

September

Commercial

Agreement with US 3PL<sup>2</sup> (a SDVOSB<sup>3</sup>), providing rapid US government contract access post FDA clearance

Details to follow

September

Clinical Began early feasibility clinical study for ARC<sup>IM</sup> mobility indication

mobility indicatior

November

Science
Nature Medicine
publication detailing use
of ARC<sup>IM</sup> Therapy for
Parkinson's disease

November

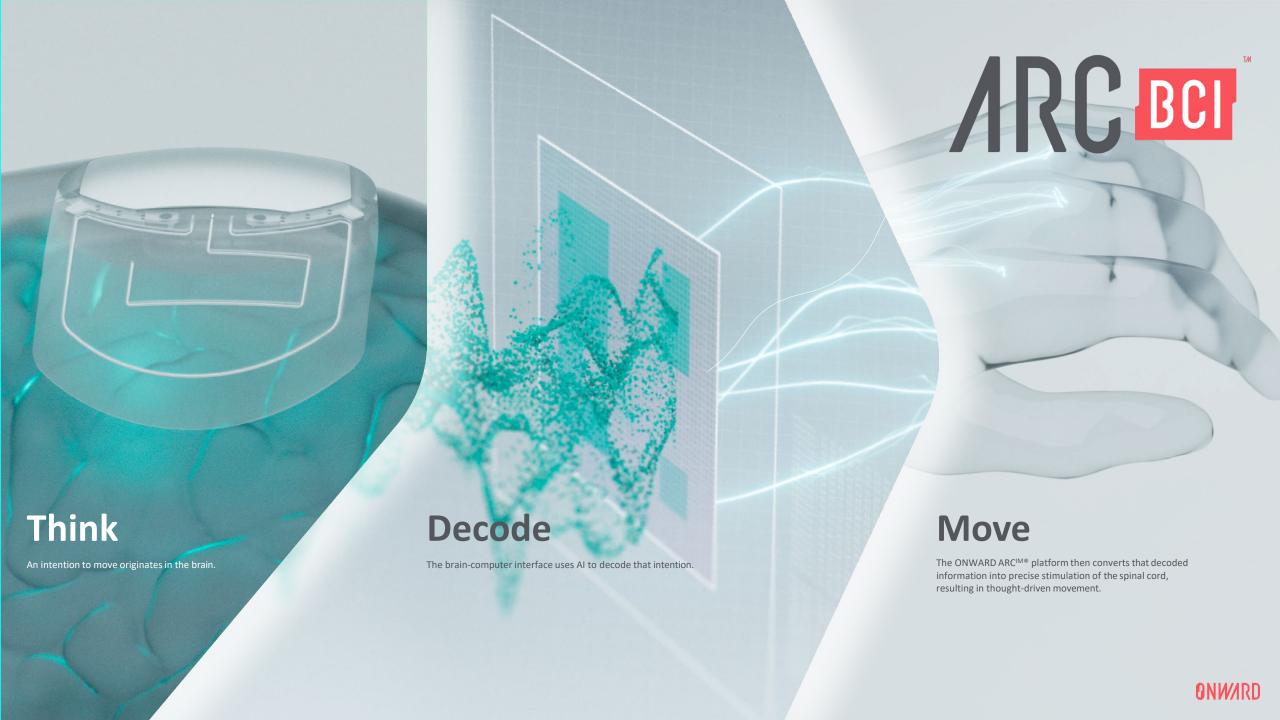
Clinical
Announced grant from
The Michael J. Fox
Foundation for
Parkinson's Research

Details to follow

December

Awarded 50+ new patents<sup>4</sup>

<sup>&</sup>lt;sup>1</sup> Breakthrough Device Designation, <sup>2</sup> 3PL = Third-party logistics, <sup>3</sup> Service-Disabled Veteran-Owned Small Business, <sup>4</sup> Patents added to the ONWARD portfolio in 2023 (between January and December), including EP country validations





#### ONWARD is strategically well positioned to benefit from advances in BCI technology

## **Brain Computer** Interface (BCI)

#### BCI landscape

- Multiple companies racing to develop implanted brain recording devices
- All these companies are focused on recording brain signals to establish the capability to control computers with thought









#### ONWARD differentiation

- Advancing BCI technology to restore movement of the human body using our ARC<sup>IM</sup> spinal cord stimulation therapy
- ARCIM platform is "BCI-ready" (i.e. designed to receive wireless signals from a BCI)
- Unique capabilities and flexible technology platform means ONWARD could eventually partner with other BCI companies or develop its own BCI using in-licensed technology

Note: For investigational use only

# Global media coverage for *Nature* publication detailing *thought-driven* ARC Therapy

## **Major BCI Publications**





Artificial intelligence used in medical procedure to help paralyzed man walk





Brain and spine implants enabled a paralyzed man to climb stairs and walk on rough terrain, study shows

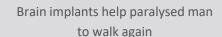




BBC

Paralyzed man able to walk again with brain and spine implants

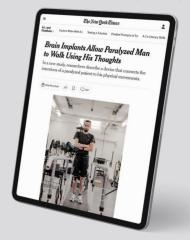






The Washington Post

A Paralyzed Man Walks with Brain and Spine Implants



The New Hork Times

Brain Implants Allow Paralyzed Man to
Walk Using His Thoughts



Note: For investigational use only

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# Forged agreement with US logistics and fulfillment partner in September 2023

# New Commercial Partnership



Service-Disabled Veteran-Owned Small Business (SDVOSB) will serve as our Veterans Administration (VA) sales partner

- ONWARD promotes therapy and maintains customer relationship (sales and training)
- 3PL partner manages logistics and fulfilment to federal government <u>and</u> commercial customers in the US
- Relationship gives ONWARD access to US government purchasing vehicles shortly after FDA clearance

# Potential expansion into large, adjacent population with same technology platform and therapy

## Parkinson's Disease Opportunity



A spinal cord neuroprosthesis for locomotor deficits due to Parkinson's disease, *Nature Medicine*, Nov 2023

Proof of concept published in *Nature Medicine*, to be followed by early feasibility study

- Supported by \$1M grant\* from Michael J.

  Fox Foundation for Parkinson's research

  FOR PARKINSON'S RESEARCH

  FOR PARKINSON'S RESEARCH
- Six participants to be implanted with ONWARD ARC<sup>IM</sup> System in 2024
- One year follow-up; study expected to be completed by end of 2025

<sup>\*</sup>Awarded to .NeuroRestore; ONWARD will provide investigational ARC<sup>IM</sup> systems and regulatory support

# 2023 Full Year Results

#### **FY 2023 Financial Review**

EUR Million		
For the year ended, 31 December	2023	2022
Total Revenues & Other Income	0.5	2.1
R&D Expenses (incl. Clinical & Regulatory)	(18.8)	(18.9)
Marketing & Market Access Expenses	(2.9)	(2.0)
Patent Fees & Related Expenses	(1.5)	(1.5)
Quality Assurance Expenses	(1.5)	(1.2)
General & Administrative Expenses	(11.3)	(10.6)
Total Operating Expenses	(36.0)	(34.2)
Operating loss for the period	(35.5)	(32.0)
Net Finance expenses	(0.6)	(1.5)
Income Tax Expense	(0.1)	0.8
Net loss for the period	(36.2)	(32.8)
At	31 December 2023	31 December 2022
Net cash position at end of period	29.8	61.8
Interest-bearing loans	(15.3)	(12.7)
Equity	17.9	52.5

# Expect current cash position to fuel operations through mid 2025

## FY 2023 Cash Update



With gross proceeds from capital raise, pro-forma ending balance is €49.8M

<sup>&</sup>lt;sup>1</sup> Net cash is defined as the sum of cash and cash equivalents and fixed term deposits included in the current assets as included in consolidated statement of financial position in the Financial Statements.

# 2024 YTD Business Update

# Important achievements disclosed in early 2024, including 10th FDA BDD¹ for BCI

#### **2024 YTD Achievements**

January

Announced expansion of ARC<sup>IM</sup> clinical feasibility study for blood pressure regulation to the Netherlands

February

Corporate KBC Securities research coverage initiated with buy rating **February** 

Awarded 10<sup>th</sup> FDA BDD<sup>1</sup> for Brain Computer Interface (BCI)

March

Clinical
Accepted to New US FDA TAP
Program
for development of BCI system

Details to follow

March

#### Corporate

Raised €20M in capital increase by way of accelerated bookbuild offering and public offering in France

April

#### Clinical

Submitted De Novo application to FDA for ARC<sup>EX</sup>
System

April

Corporate Stifel research coverage initiated with buy rating

Details to follow

Details to follow

<sup>&</sup>lt;sup>1</sup> Breakthrough Device Designation

## Successful €20M capital raise despite challenging market conditions

## **Capital Raise**

#### Key takeaways

- Fully subscribed upsize option
- Separate public offering with retail investors in France
- Net proceeds expected to extend current cash runway into mid-2025

#### Expected use of net proceeds

- Fund research & development activities
- Establish commercial organization in preparation for expected US launch of ARC<sup>EX</sup>
- Build quality, operations, and other infrastructure capabilities
- Fund working capital requirements

# Regulatory submission to allow marketing of ARC<sup>EX</sup> in the US for upper limb indication

## ARCEX FDA De Novo Submission



- ARC<sup>EX</sup> is a breakthrough therapy
  - First spinal cord stimulation therapy to restore hand and arm function after SCI
  - First commercial product for ONWARD Medical
- Submitted De Novo application to FDA to allow marketing of ARC<sup>EX</sup> system to improve or restore hand and arm function after spinal cord injury in the US
- FDA review expected to take 6-9 months
- O ARCEX commercial launch expected in the US in Q4 2024

# 2024 Outlook April 2024 Webcast 26

# Several important catalysts expected in 2024

# Upcoming Milestones and News Flow

#### **ARC**EX

Regulatory clearance submission
Upper limb
COMPLETED

#### ARCEX

Up-LIFT pivotal study manuscript publication
Upper limb

#### **ARC**EX

FDA clearance Upper limb

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

First commercial sale (US) Upper limb

#### **ARCIM**

First participant enrollment<sup>1</sup> Early feasibility study
Parkinson's mobility

#### **ARCIM**

Interim results publication Blood pressure

#### **ARCIM**

IDE submission Empower BP pivotal study Blood pressure

#### **ARCIM**

IDE approval Empower BP pivotal study Blood pressure

#### **ARCIM**

First participant enrollment Empower BP pivotal study Blood pressure

#### **ARCIM**

First-in-human<sup>2</sup> Bladder

#### ARCIM BCI

Additional implants<sup>3</sup>
Upper limb and Mobility

Note: All platforms and therapies are for investigational use only

<sup>&</sup>lt;sup>1</sup> Funded by Michael J. Fox Foundation for Parkinson's Research grant

<sup>&</sup>lt;sup>2</sup> Funded by Christopher & Dana Reeve Foundation grant

<sup>&</sup>lt;sup>3</sup> Funded by European Innovation Council and Christopher & Dana Reeve Foundation grants





