

# ONMRD MEDICAL

**Investor Webcast** 2024 Half-Year Results and **Business Update** September 10, 2024



















# Forward Looking Statements

This Presentation may include statements, including the Company's financial and operational medium-term objectives, that 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 concerning 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** 



**Amori Fraser**Finance Director

Sarah Moore
Sales & Marketing Leader



## ONWARD® Medical at a Glance

## **Key Facts**

- o Founded in 2015
- o ~100 FTEs
- HQ in the Netherlands
- Science and Engineering Center in Switzerland
- Growing US presence
- IPO 2021, Euronext Brussels and Amsterdam
- Research coverage from Stifel, Bryan, Garnier & Co, KBC Securities, Degroof Petercam and Kepler Cheuvreux

- **Technology**: 3 purpose-built neuromodulation platforms
  - o **ARC**<sup>EX®</sup> delivers ARC Therapy<sup>™</sup> externally through the skin
  - o **ARC**<sup>IM®</sup> delivers ARC Therapy via a fully implanted system
  - o **ARC**<sup>BCI™</sup> pairs ARC<sup>IM</sup> with an implanted brain-computer interface to restore thought-driven movement via a wireless DigitalBridge<sup>™</sup>
- Innovation: 10 FDA Breakthrough Device Designations; 270+ issued patents<sup>1</sup>
- **Clinical Success:** 
  - o **Safety and effectiveness of ARC**<sup>EX</sup> **Therapy** for upper limb mobility demonstrated in Up-LIFT clinical trial; results published in *Nature Medicine*, May 2024
  - o **Positive interim results** for ARC<sup>IM</sup> Therapy to improve blood pressure regulation
  - Market Opportunity: \$20B+ / €19B+ total addressable market with limited competition
- Commercialization: First revenues expected 2H 2024 with ARC<sup>EX</sup> launch after FDA clearance





# 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 labeling and platforms

# **Company Focus**

# Short Term 2024

Medium Term **2026/2027** 

Long Term **2026/2027+** 

### Commercialize external platform (ARCEX)

First indication: Upper Limb

Population: SCI

Generate revenue and develop market for ARCIM



### Commercialize implantable platform (ARCIM)

First indication: Blood Pressure

Population: SCI

Enter traditional medtech IPO/M&A window



### **Expand labeling and platforms**

New indications and platforms to be assessed such as BCI

Populations: SCI, Parkinson's, Stroke



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

Short and medium term focus

## **Current Pipeline**

Clinical Indication **Human PoC Platform** FDA BDD<sup>1</sup> Pre-clinical Pivotal Feasibility<sup>2</sup> ARCEX Upper Limb Study expected to ARCIM **Blood Pressure** start early 2025 Mobility / Second ARCIM Indication ARCEX Mobility ARCIM Parkinson's - Mobility Human PoC ARCIM Bladder expected in 2025<sup>3</sup> ARCBCI Mobility ARCBCI Upper Limb ARCDBS Mobility ✓ BDD¹ Granted O Current Roadmap Compared to the compared to 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 ARC<sup>EX</sup> Bladder, ARC<sup>EX</sup> Blood Pressure, ARC<sup>EX</sup> Spasticity and ARC<sup>IM</sup> Spasticity

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

<sup>3</sup> Funded by Christopher & Dana Reeve Foundation grant, conducted by EPFL

Funded primarily through grants and research partners

# 1H 2024 Update

# Important achievements disclosed in first half of 2024, including successful FDA De Novo submission for ARC<sup>EX</sup> System, capital raise and debt financing

## **1H Business Update**

### January

### Clinical

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**

### Clinical

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

#### 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

Details to follow

### April

### Corporate

Stifel research coverage initiated with Buy rating

### May

### **Science**

Published Up-LIFT pivotal study results in Nature Medicine

Details to follow

#### June

### Corporate

Obtained debt financing with up to €52.5M secured loan from Runway Growth Capital LLC

Details to follow



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

# ARC<sup>EX</sup> FDA De Novo Submission



- o ARCEX is an investigational **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 8-9 months
- ARCEX commercial launch expected in the US in Q4 2024

## Met all primary and secondary endpoints, demonstrating safety and effectiveness in improving upper limb function after SCI

# Pivotal Trial Results for ARC<sup>EX</sup> Therapy

(n=65, 14 trial sites globally)

90%

Improved in at least one primary strength or function assessment

87%

Reported improvement in overall

quality of life

**34** yrs

Improvements demonstrated up to 34 years post-injury

Improved hand function



Improved quality of life



- No serious device-related adverse events
- Study participants also reported reduced spasm frequency, improved sleep, and improved upper body sensation, including the sense of touch
- o Examples of functional progress made by ARC<sup>EX</sup> Therapy users include lifting filled cups, pushing a button on a remote control, and picking up objects with a fork

Moritz, Chet, et al. "Non-invasive spinal cord stimulation for arm and hand function in chronic tetraplegia: a safety and efficacy trial." *Nature Medicine*. 2024. Smaby, Niels, et al. "Identification of key pinch forces required to complete functional tasks." *Journal of Rehabilitation Research and Development*. 2004. Kirshblum, Steven C, et al. "International standards for neurological classification of spinal cord injury (revised 2011)." *The Journal of Spinal Cord Medicine*. 2011



## Strong shareholder base and access to capital

Country

## **Financial Profile**

	Sildrefloider		Country	78 Of Capital
(0)	inkef capital		Netherlands	11.5%
	EQT Life Sciences		Netherlands	10.8%
ers	Ğimv		Belgium	9.2%
필	wellingtonpartners		Germany	7.6%
Pre-IPO shareholders	INVESTAL		Netherlands	3.1%
교	ONASSIS FOUNDATION		Greece	Undisclosed
S	Christopher & Dana REEVE FOUNDATION		United States	Undisclosed
	S SCI Ventures		United States	Undisclosed
	WORLDWIDE ASSET MANAGEMENT		Denmark	1.5%
	Öhman		Sweden	1.4%
	AKA		France	1.7%1
	BNP PARIBAS ASSET MANAGEMENT	Belgium	Belgium	1.0%
	SEB		Sweden	0.7%
suc	FON DITA		Finland	0.4%
Institutions	BNP PARIBAS ASSET MANAGEMENT	France	France	0.3%
l ţi l	DNB		Norway	0.2%
lns	Belpointe Asset Management		United States	0.1%
	CAPFI DELEN		Belgium	0.1%
	CROSSINVEST		Italy	0.1%
	CLAY Asset Management		France	0.1%
	Belfius		Belgium	Undisclosed
			Germany	Undisclosed
Jer	Board member	ers/Management	-	8.4%
Other	Free float		-	41.9%

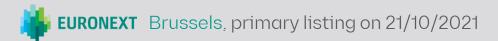
o Up to €52.5M / \$58M of tranched growth capital secured in June 2024

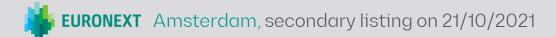
o Initial credit tranche of €16M drawn down RUNWAY



% of capital

## **Listing venue**





## **Analyst coverage**

Broker	Target Price	Recommendation
Bryan, Garnier & Co	€20.0	Buy
Degroof Petercam	€14.1	Buy
KBC	€9.3	Buy
STIFEL	€12.0	Buy
Kepler Cheuvreux	€12.3	Buy
Average	€13.5	Buy

Shareholder

# 2024 Half Year Results

## Half-Year 2024 Financial Review

EUR Million		
For the six-month period ended, 30 June	2024	2023
Total Revenues & Other Incomes	0.2	0.9
Research & Development Expenses Clinical & Regulatory Expenses Marketing & Market Access Expenses Patent Fees & Related Expenses Quality Assurance Expenses General & Administrative Expenses	(6.1) (2.7) (1.4) (0.5) (1.1) (7.1)	(7.6) (2.2) (1.6) (1.0) (0.8) (6.5)
Total Operating Expenses	(19.0)	(19.7)
Operating Loss for the Period Net Finance expenses Income Tax Expense	<b>(18.7)</b> 0.2 0.3	<b>(18.8)</b> (0.5) (0.0)
Net loss for the period	(18.3)	(19.3)
At	30 June 2024	31 December 2023
Net cash position at end of period Interest-bearing loans Equity	32.1 (16.0) 18.3	29.8 (15.3) 17.9

# Expect current cash position to fuel operations through spring 2025

# Half Year 2024 Cash Update

**H2 2023** €14.0M used

**Q1 2024** €6.8M used

Q2 2024 €9.9M used (including transaction and seasonal costs) Ending Balance €32.1M net cash<sup>1</sup> as of 30 Jun 2024

<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

# Year to date achievements since end of first half

## **YTD Business Update**

July

### Science

Announced publication highlighting evidence-based programming for ARC<sup>EX</sup> Therapy

July

## Corporate

Announced publication of annual sustainability summary for full year 2023

Details to follow

September

## Corporate

Awarded Christopher & Dana Reeve Foundation grant to further study Brain-Computer-Interface system

Details to follow

# Published annual sustainability summary for full year 2023

# **Sustainability Update**

## **Highlights**

 Rated in the top 40% in the industry for our sustainability performance by EcoVadis, the world's largest provider of business sustainability ratings



- New measures to strengthen sustainability approach and performance include:
  - **New policies** in stakeholder dialogue, environmental management and data privacy
  - **Codes of conduct** for marketing to healthcare professionals and for interactions with third parties, such as suppliers and contractors

Full sustainability summary available on company's website in the Investors section (link <u>here</u>)

### **Performance**

88%

of purchased electricity from renewable sources

45%

of supervisor and manager roles held by women<sup>2</sup>

50%

of top 20% of earners are women

# ONWARD Medical and partners awarded \$1.1M grant from Christopher & Dana Reeve Foundation Grant to further study ARC-BCI<sup>TM</sup> System

## Reeve Foundation BCI Grant



- ONWARD Medical, CEA-Clinatec, and .NeuroRestore awarded \$1.1M grant to support expansion of ongoing early clinical feasibility study to explore use of brain-computer interface (BCI) to restore thought-driven use of the hands and arms after SCI
- Ongoing early feasibility clinical study also supported by the European Innovation
   Council
- This grant *reflects our vision to facilitate rapid scientific advancement* to address the unmet needs of individuals living with SCI... We *look forward to working with ONWARD* Medical in learning more about the potential for BCI technology to meet those challenges.

- CSO of the Christopher & Dana Reeve Foundation



# Several important catalysts expected in the next 12 months

# Upcoming Milestones and News Flow

### ARCEX

Regulatory clearance submission

Upper limb

**COMPLETED** 

#### **ARC**EX

Up-LIFT pivotal study manuscript publication

Upper limb

**COMPLETED** 

### **ARC**EX

**FDA** clearance

Upper limb

#### **ARC**EX

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

#### **ARC**BCI

Additional implants<sup>3</sup>

Upper limb and Mobility

Note: All platforms and therapies are for investigational use only

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

<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

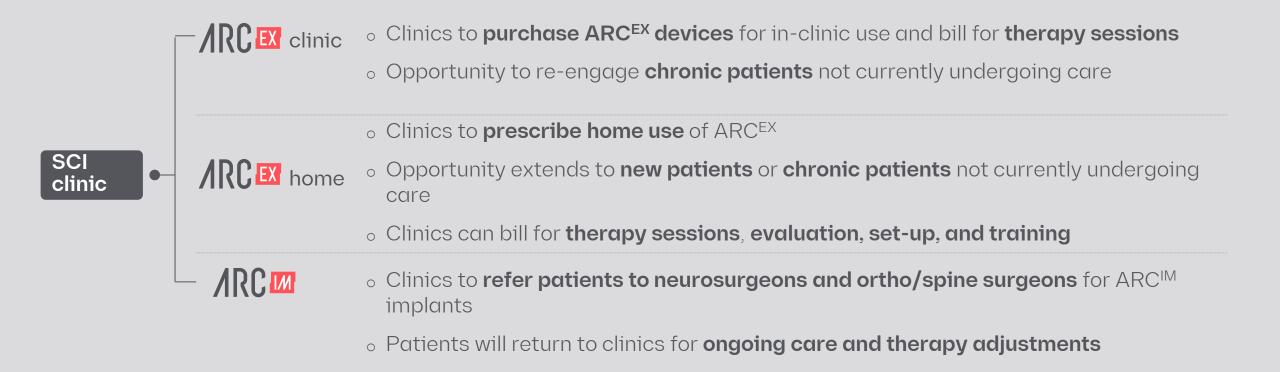
# ARCEX Commercial Plans

(to be initiated post-market clearance)

# Customer Targeting and Sales Deployment

# Following regulatory clearance, SCI rehabilitation clinics will be at the core of ONWARD's commercialization strategy

# Rehabilitation Clinic Importance



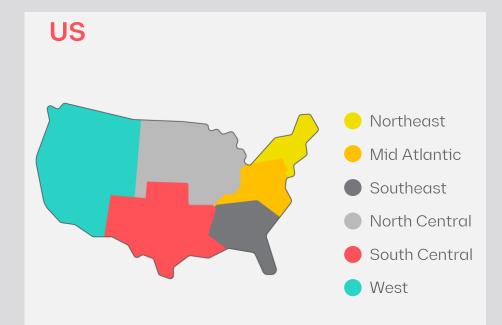
# Build enduring relationships with priority target customers; high customer concentration

### **Call Points**





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



~450

Specialist SCI and general rehab centers

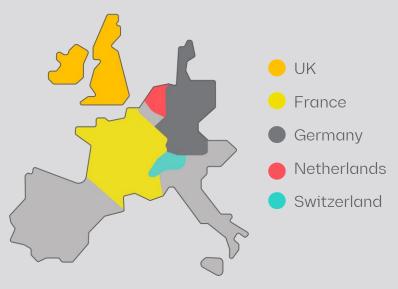
Initial focus: ~75 Tier 1 accounts including VA SCI hub centers, Up-LIFT investigational sites and other US flagship SCI clinics

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

Details in next slides

# Targeting and Channel Strategy

**Europe** 



 $\sim 80$ 

Specialist rehab centers

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

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

## Initial focus will be VA SCI hubs, Up-LIFT study sites, and other high volume, influential SCI clinics

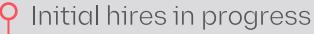
# US Clinic Targeting and Salesforce Ramp

L	o] nitial Focus	At Scale
Total accounts	~75	~375
Account types	<ul> <li>Up-Lift and KOL sites (~10-15)</li> <li>VA hubs (~25)</li> <li>Other SCI flagship centers (~35-40)</li> </ul>	<ul><li>VA spokes (~135)</li><li>Other rehabilitation centers (~240)</li></ul>
Accounts per sales rep <sup>1</sup>	10-15	20-25
Size of field organization <sup>1</sup>	6-10	20-25

<sup>&</sup>lt;sup>1</sup>Size of field organization and accounts per sales rep subject to change based on learnings from the field following commercial launch

# Initial hires on board, with additional hires in the queue

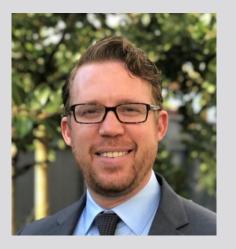
## Initial Sales Hiring Status



- Area VP (hired)
- Inside Sales & Customer Advocacy Director (hired)
- Sales Rep (expected by Oct 01)

Additional staff in the hiring queue

- 5 additional sales reps
- Customer service specialists and customer advocates
- Additional field sales



Blake Pokress
Area VP Sales



Sarah Montana
Director Sales &
Customer
Advocacy

## Forged partnership with US SDVOSB

# VA Commercial Partnership



## Service-Disabled Veteran-Owned Small Business will serve as our Veterans Administration (VA) contracting and logistics partner

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



Professional education program designed to initiate ARC-EX use at clinics efficiently and effectively, while building brand-affinity and engagement

# Training and New Clinic Customer Activation

## **Program components**

Digital starter kit	Includes video modules to accelerate start-up process
Hands-on training	3-4 hour in-person session delivered by ONWARD-certified trainer
Online resources	Checklists and information library (e.g., how-to-videos, exercises, stimulation optimization)

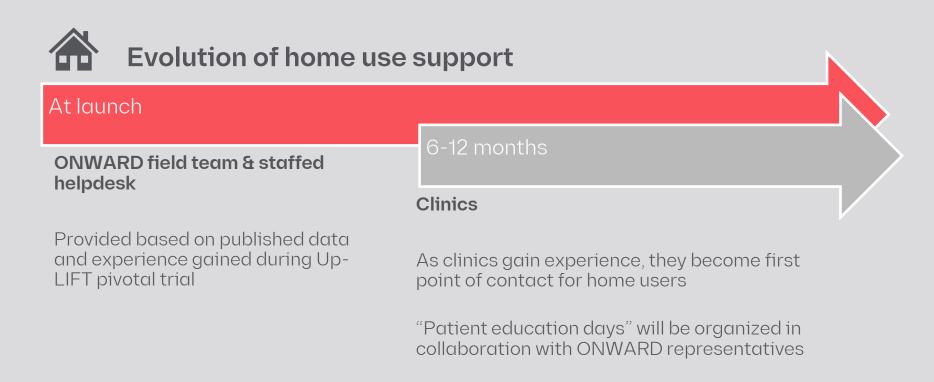
# Training for home use will be delivered by clinicians, with support from ONWARD as needed

# Home Use Activation and Support



### Clinicians play a key part

- o Prescription
- o Product training
- o Therapy adjustments



Home use support may evolve based on real-world experience and insights





## Competitive benchmarking vs. rehab devices widely available in the US and Western Europe

## **Positioning**

FES & other electrical stimulation devices

**Exoskeletons & FES bikes** 



<\$1k <\$5k \$10k **Basic electrical** 

**FES for gait** 

\$20k **Multichannel FES** 



\$45k **FES** bikes

\$60k **Upper extremity** robotics

\$120k

**Exoskeletons** 



stimulation













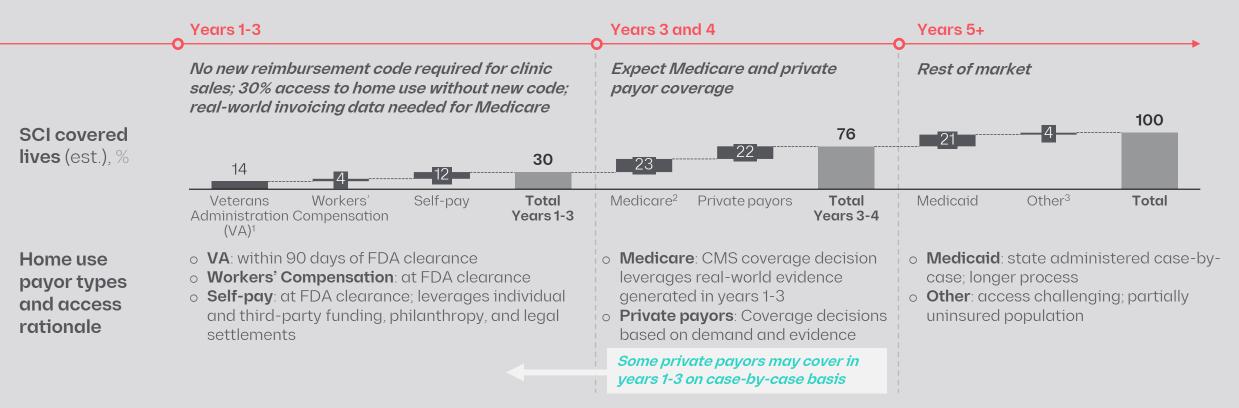






# Success in clinics will drive home use, which will generate data required for broad reimbursement; access to ~30% of market shortly after launch

# Home Market Access Landscape and Evolution



CMS = Centers for Medicare and Medicaid Services

Note: Assumes 300k people with SCI in the US, out of which 42k are potential VA patients; assumes primary payor breakdown as per NSCISC 2021 Annual Report 5 years post-injury for remaining 258k non-VA patients; assumes patients who can be accessed through self-pay represent 20% of "private payors" pool, 20% of "workers' compensation" pool, 15% of "Medicare" pool and 5% of "Medicare" pool and 5% of "Medicare" pool.



<sup>&</sup>lt;sup>1</sup> Includes veterans with SCI who are not currently seen at VA centers but who may be eligible for VA coverage

<sup>&</sup>lt;sup>2</sup> Medicare covered lives are split 50/50 between fee-for-service (CMS administered) and Medicare Advantage (private payor (MAC) administered). CMS decisions affect coverage for all, but private payors set payment for Medicare Advantage covered lives and are not required to follow CMS payment assignments.

<sup>&</sup>lt;sup>3</sup> Includes other government, no pay, private funds and other payor categories from NSCISC 2021 Annual Report (may include people uninsured or not covered) Source: Company estimates; VA; NIH National Center for Biotechnology Information (NCBI); NSCISC 2021 Annual Report





