ONWARD® MEDICAL

# Q1 Business Update and Up-LIFT *Nature Medicine* Panel

May 23, 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.*

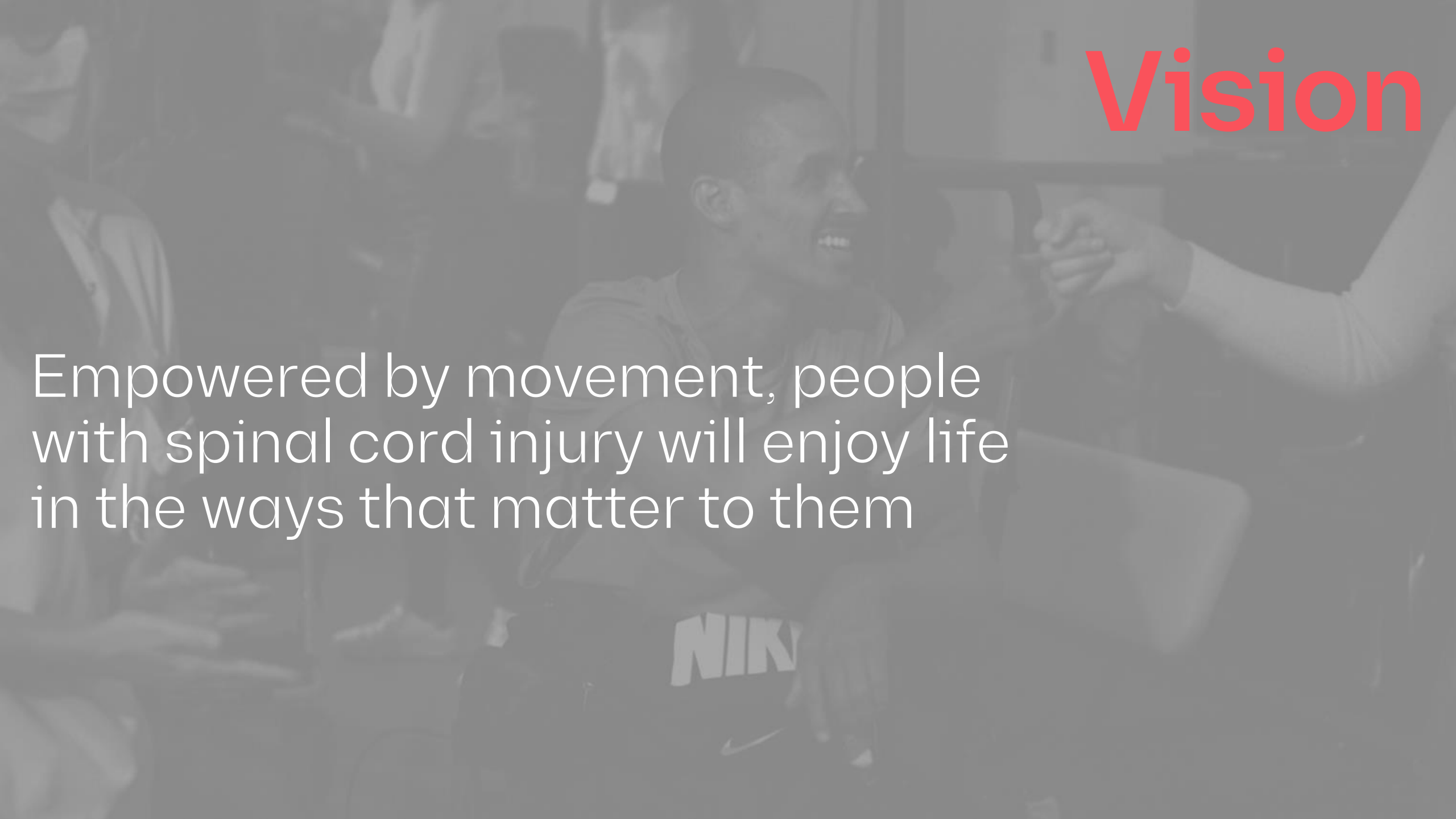
# ONWARD® Medical at a Glance

## Key Facts

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

- **Technology**: 3 purpose-built neuromodulation platforms
  - **ARC$^{EX}$®** delivers ARC Therapy™ externally through the skin
  - **ARC$^{IM}$®** delivers ARC Therapy via a fully implanted system
  - **ARC$^{BCI}$™** pairs ARC$^{IM}$ with an implanted brain-computer interface to restore thought-driven movement via a wireless DigitalBridge™
- **Innovation: 10 FDA Breakthrough Device Designations; 265+ issued patents**[1]
- **Clinical Success:**
  - **Safety and effectiveness of ARC$^{EX}$ Therapy** for upper limb mobility demonstrated in Up-LIFT clinical trial; results published in ***Nature Medicine*, May 2024**
  - **Positive interim results** for ARC$^{IM}$ Therapy to improve blood pressure regulation
- **Market Opportunity: $20B+ / €19B+ total addressable market** with **limited competition**
- **Commercialization:** First revenues expected 2H 2024 with **ARC$^{EX}$ launch**

*Note: 1 EUR = 1.1 USD; FTE figures as of end of Q4 2023; patent figures as of end of Q1 2024*
[1] *Includes EP country validations*



# Vision

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

# Our Technology

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


ARC EX®


ARC IM®


ARC BCI™

*Note: Investigational devices, not available for commercial use. The ARC$^{BCI}$ graphical representation includes ONWARD Medical's ARC$^{IM}$ with CEA Clinatec's WIMAGINE® brain-computer interface.*

# Company Focus

## Reach commercial stage by year-end, then expand

### Short Term
### 2024

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

First indication: Upper Limb

Population: SCI


### Medium Term
### 2026

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

First indication: Blood Pressure

Population: SCI


### Long Term
### 2026+

**Expand labeling and platforms**

New indications and platforms to be assessed such as BCI

Populations: SCI, Parkinson's, Stroke


*Note: Investigational devices, not available for commercial use; SCI = Spinal Cord Injury. The ARC$^{BCI}$ graphical representation includes ONWARD Medical's ARC$^{IM}$ with CEA Clinatec's WIMAGINE® brain-computer interface.*

# Q1 Business Update

## Important achievements disclosed in early 2024, including successful capital raise and regulatory clearance submission for ARC$^{EX}$

**January**

**Clinical**
Announced expansion of ARC$^{IM}$ clinical feasibility study for blood pressure regulation to the Netherlands

**February**

**Corporate**
KBC Securities research coverage initiated with Buy rating

**February**

**Clinical**
Awarded 10$^{th}$ FDA BDD[1] 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$^{EX}$ System

**April**

**Corporate**
Stifel research coverage initiated with Buy rating

**April**

**Science**
Published Up-LIFT pivotal study results in *Nature Medicine*

[1] *Breakthrough Device Designation*

# Introduction

**Amori Fraser** Finance Director

# Q1 Cash Update

## Expect current cash position to fuel operations through mid 2025

**Burn**
€6.8M used during Q1 2024

**Ending Balance[1]**
€42.0M net cash[2] as of 31 Mar 2024

[1] *Includes proceeds from the March 2024 capital raise*
[2] *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.*

## Several important catalysts expected in 2024

# Upcoming Milestones and News Flow

**ARC$^{EX}$**
**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

**ARC$^{IM}$**
**First participant enrollment**[1]
Early feasibility study
Parkinson's mobility

**ARC$^{IM}$**
**Interim results publication**
Blood pressure

**ARC$^{IM}$**
**IDE submission**
Empower BP pivotal study
Blood pressure

**ARC$^{IM}$**
**IDE approval**
Empower BP pivotal study
Blood pressure

**ARC$^{IM}$**
**First participant enrollment**
Empower BP pivotal study
Blood pressure

**ARC$^{IM}$**
**First-in-human**[2]
Bladder

**ARC$^{BCI}$**
**Additional implants**[3]
Upper limb and Mobility

*Note: All platforms and therapies are for investigational use only*
*[1] Funded by Michael J. Fox Foundation for Parkinson's Research grant*
*[2] Funded by Christopher & Dana Reeve Foundation grant*
*[3] Funded by European Innovation Council and Christopher & Dana Reeve Foundation grants*

# *Nature Medicine* Publishes ONWARD® ARC$^{EX}$® Therapy Results (Up-LIFT Pivotal Trial)

Moritz C, et al. "Non-invasive spinal cord stimulation for arm and hand function in chronic tetraplegia: a safety and efficacy trial." *Nature Medicine*. May 2024.

*All ONWARD® Medical devices and therapies, including but not limited to ARC$^{IM}$®, ARC$^{EX}$®, ARC$^{BCI}$™, and ARC Therapy™, alone or in combination with a brain-computer interface (BCI), are investigational and not available for commercial use.*

# Today's Panelists

**Chet Moritz, PhD**
Up-LIFT Co-lead Principal Investigator
Professor of Electrical & Computer Engineering, Rehabilitation Medicine and Physiology & Biophysics Departments, University of Washington

**Jessie Owen**
ARC$^{EX}$ Therapy Trial Participant

**Sherown Campbell**
Up-LIFT Trial Participant

**Dave Marver**
CEO, ONWARD Medical

**Candace Tefertiller, DPT, PhD**
Up-LIFT Principal Investigator
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**James Guest, MD, PhD, FAANS**
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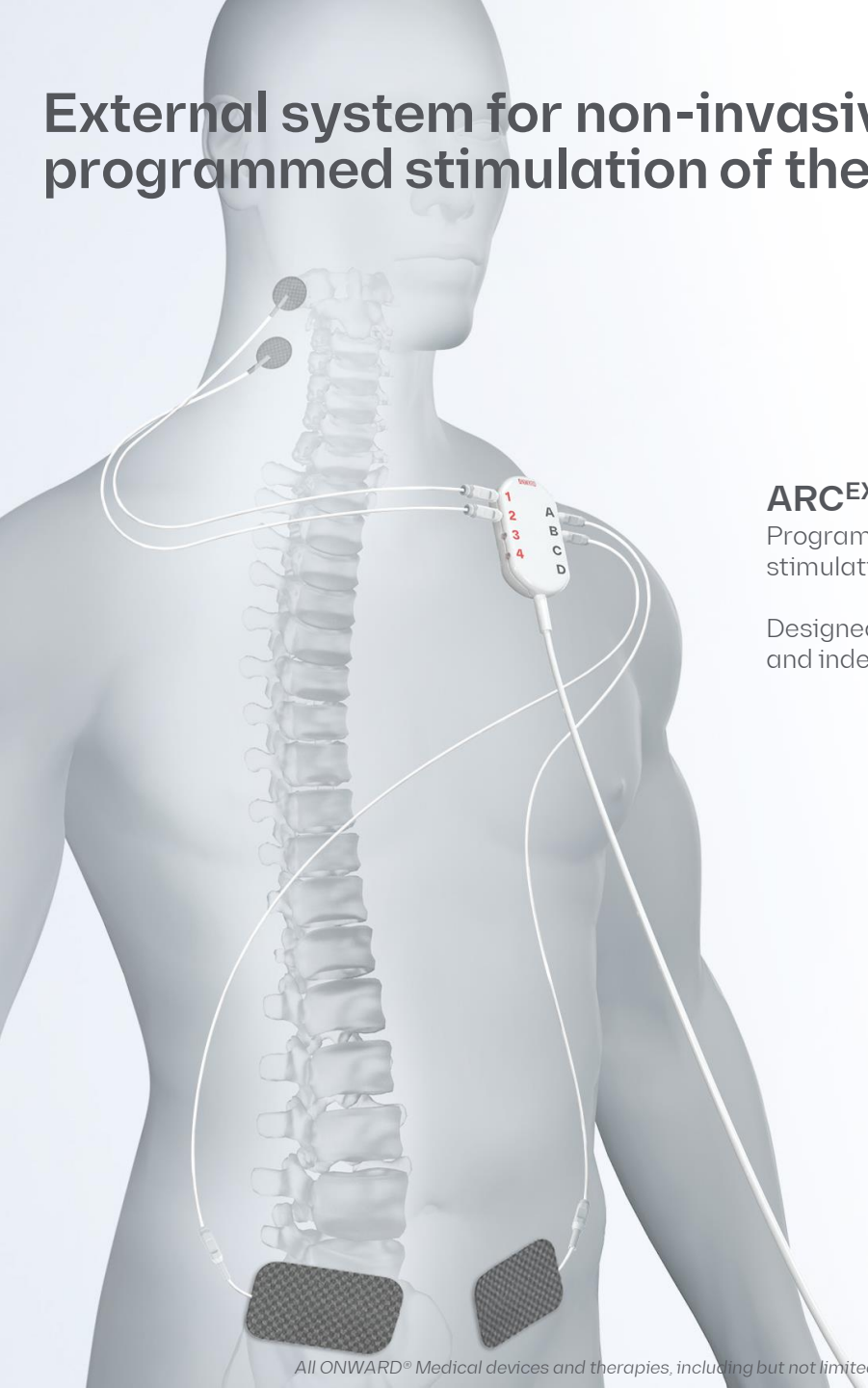
Professor of Neurological Surgery, the Miller School of Medicine & the Miami Project to Cure Paralysis

**Erika Ross Ellison, PhD**
VP, Clinical, Quality & Regulatory, ONWARD Medical

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

ARC EX

# System Overview

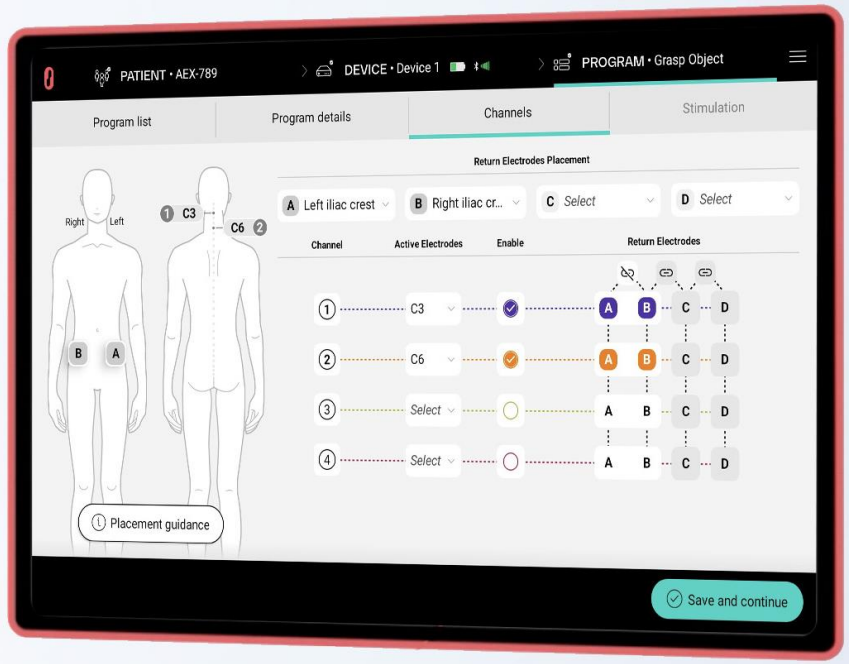



## ARC$^{EX®}$ Therapy

Programmed transcutaneous electrical stimulation to the spinal cord

Designed to restore movement, function, and independence in people with SCI


## ARC$^{EX®}$ Stimulator




## ARC$^{EX®}$ PRO & myARC$^{EX™}$ app

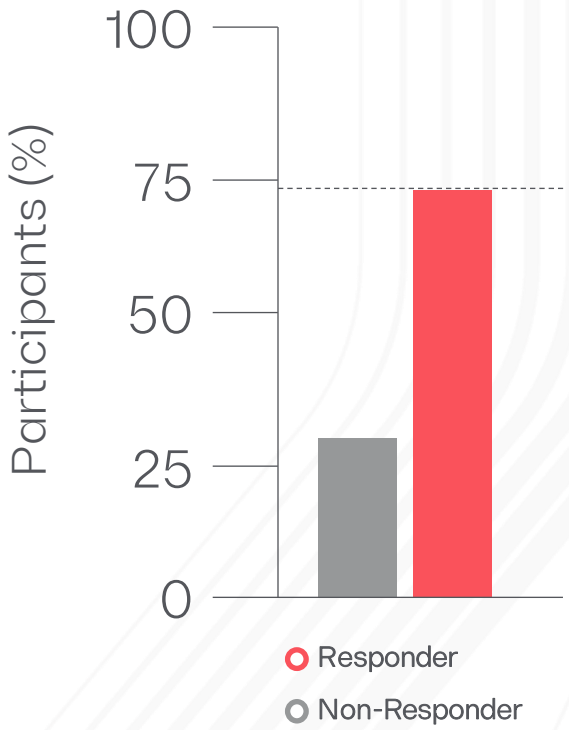
via ARC$^{EX}$ Programmer

## ARC$^{EX®}$ Therapy

Individual stimulation parameters can be optimized for each patient's unique needs

# Primary Endpoints

## Up-LIFT study met both primary safety and effectiveness endpoints




### Effectiveness:

**72%** responder rate

Endpoint defined as participants who met or exceeded minimally important difference criteria for ≥1 strength and ≥1 function metric

### Safety

No Serious Device-Related Adverse Events (SDAEs) were reported with ARC$^{EX}$ Therapy

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.

# First pivotal trial to study non-invasive spinal cord stimulation attracted world-class investigators

# Principal Investigators

## Global leaders in SCI research and care at 14 leading sites











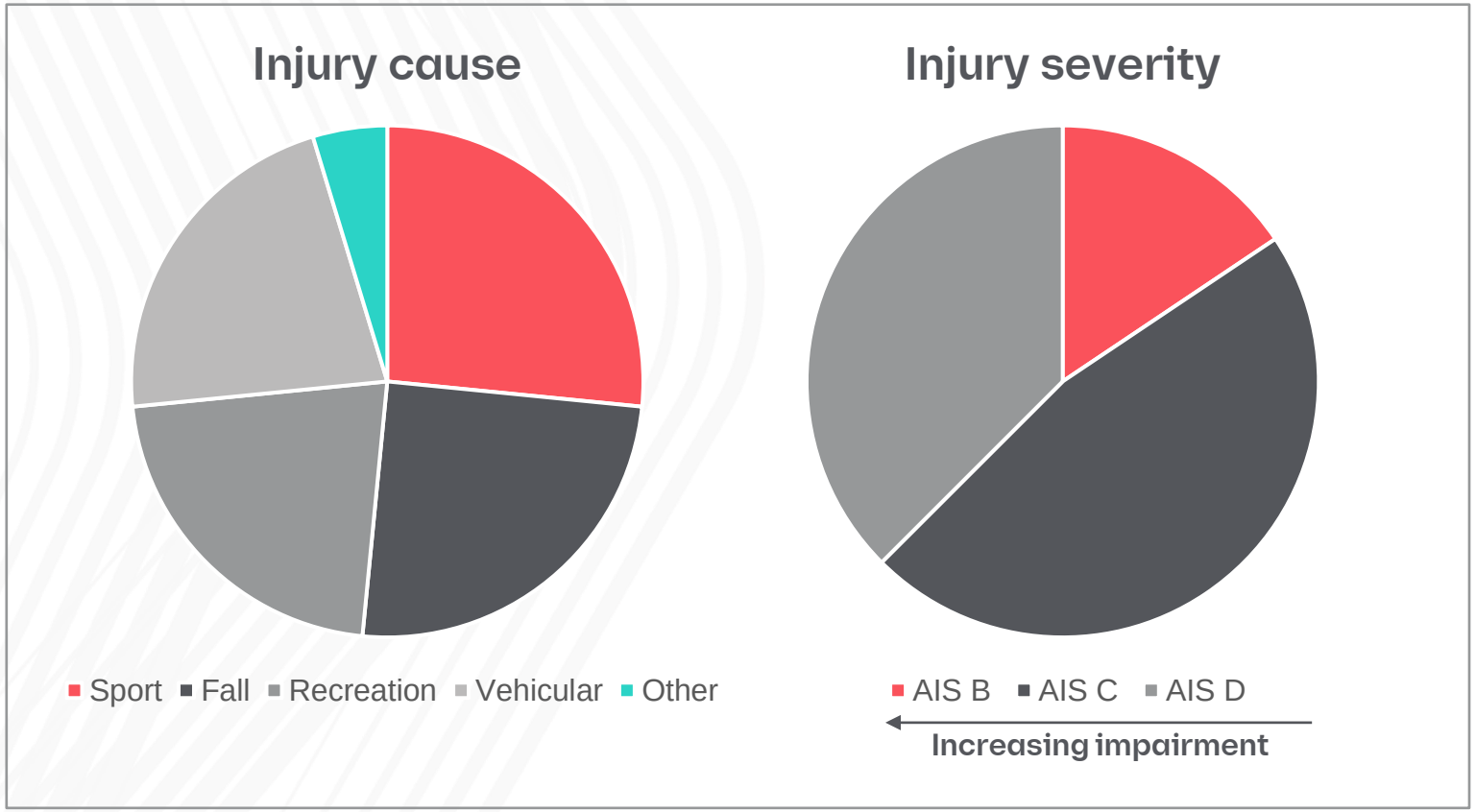



Moritz, Chet, et al. "Non-invasive spinal cord stimulation for arm and hand function in chronic tetraplegia: a safety and efficacy trial." *Nature Medicine*. 2024.

# Study Demographics

## People with chronic cervical spinal cord injuries across various severity levels were recruited (n=65)

- **Injury site:** Cervical vertebrae #2-8
- **Average age:** 47 years
- **Time since injury**
  - 1-5 years: 68%
  - 5-10 years: 18%
  - > 10 years: 13%
  - Average: 6 years
- **Sex**
  - Female: 17%, Male: 83%
- **Ethnicity**
  - Hispanic or Latino: 5%
  - Non-Hispanic or Latino: 95%
- **Study withdrawals were unrelated to ARC$^{EX}$ Therapy**




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.

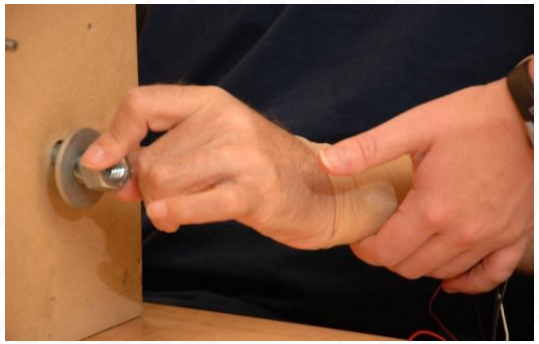
# Study Design

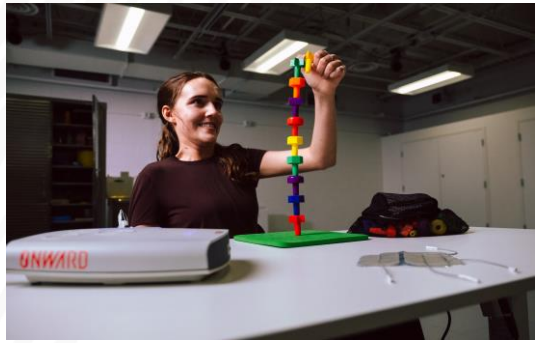
## Participants first received functional task practice (FTP) alone, followed by FTP plus non-invasive ARC$^{EX}$ Therapy

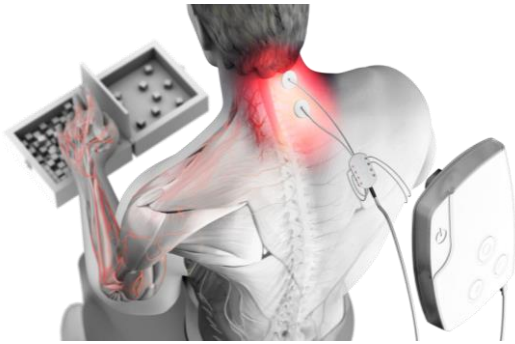
**FTP only** (2 months)
3 sessions per week
1 hour per session

**FTP + ARC$^{EX}$ Therapy** (2 months)
3 sessions per week
1 hour per session

Baseline assessment — Month 2 assessment — Month 4 assessment





Assessments for endpoint analyses

Note: Examples of FTP shown on next slide

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.

# Summary Results

## ARC$^{EX}$ Therapy met all primary and secondary endpoints, demonstrating safety and effectiveness in improving upper limb function after SCI

**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
- Examples of functional progress made by ARC$^{EX}$ Therapy users include lifting filled cups, pushing a button on a remote control, and picking up objects with a fork

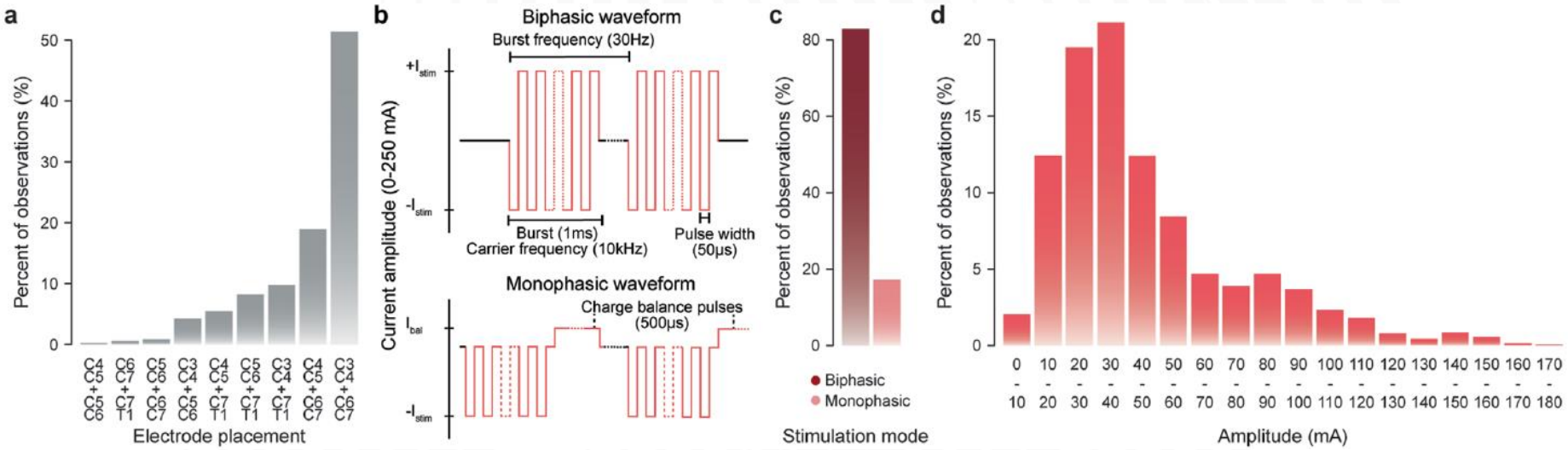
Moritz, Chet, et al. "Non-invasive spinal cord stimulation for arm and hand function in chronic tetraplegia: a safety and efficacy trial." *Nature Medicine*. 2024.
Smaby, Niels, et al. "Identification of key pinch forces required to complete functional tasks." *Journal of Rehabilitation Research and 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.

SCI = spinal cord injury

# ARC$^{EX}$ Therapy stimulation parameters can be personalized to optimize functional performance

# Optimizing Function

## Parameters adjusted to participants' individual goals




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.

# Therapeutic Changes

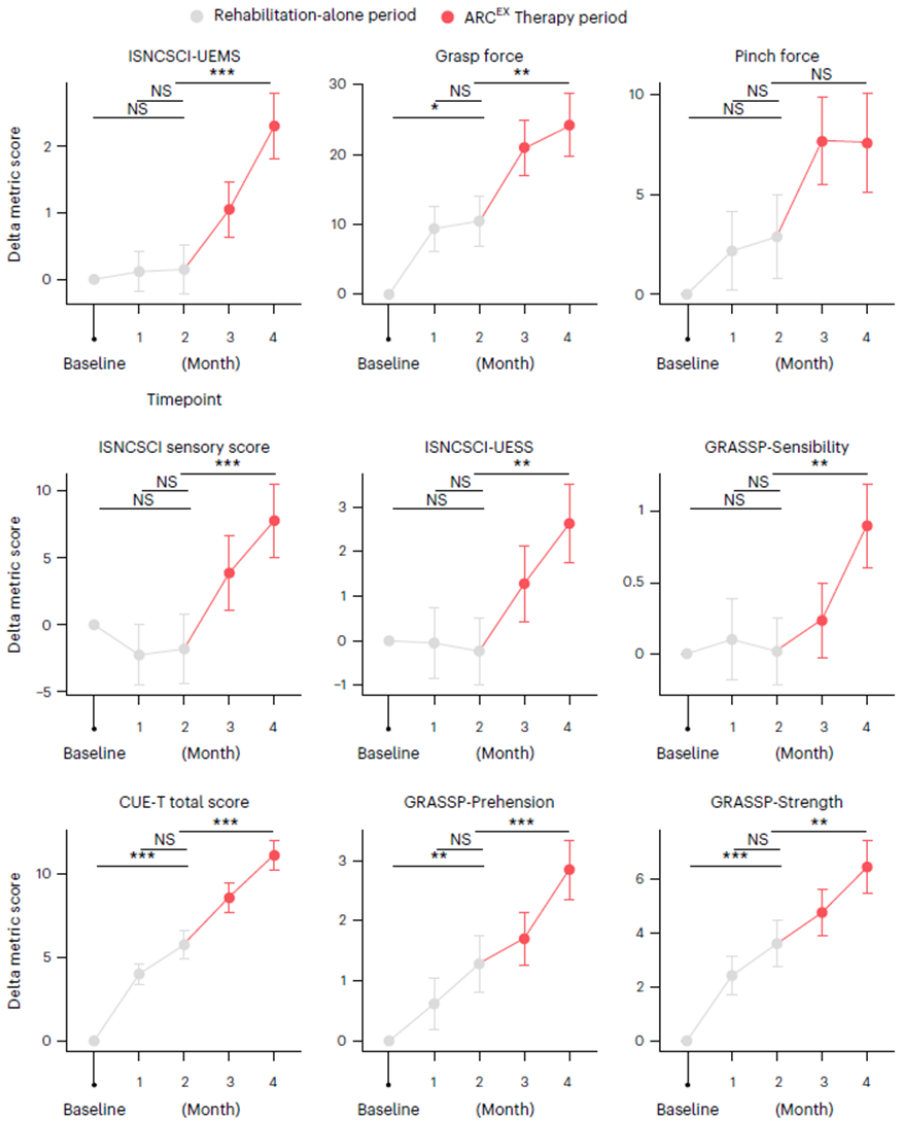



Fig. 3 | Effect of ARC$^{EX}$ Therapy on force, sensory and functional performance. Improvements in outcomes of strength and functional performance domains during the rehabilitation-alone period and during the ARC$^{EX}$ Therapy period. These results suggest that a longer period of ARC$^{EX}$ Therapy may promote additional benefits. Red color indicates the period of ARC$^{EX}$ Therapy. Statistics represent one-way repeated-measures ANOVA with Tukey's HSD post hoc testing. *p<0.05, **p<0.01, ***0<0.001. NS, not significant.

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.

- At the **end of the FTP only phase** (first 2 months), **recovery plateaued**
- **When ARC$^{EX}$ Therapy was introduced** (red lines at left), **improvements resumed** in arm and hand strength, function, and sensation
- This trend indicates the **demonstrated benefit** from ARC$^{EX}$ Therapy and the **potential for further improvements** with its continued use

# Summary & Market Expectations

## ARC$^{EX}$ Therapy demonstrated safety and effectiveness in the Up-LIFT trial and is expected to launch in H2 2024

### Demonstrated effectiveness in improving upper limb function after SCI

- 90% of participants had improvements in strength or function
- 87% reported improvement in overall quality of life
- Reduced spasm frequency, improved sleep, and improved sensation

### Application for ARC$^{EX}$ System market clearance submitted to US FDA

- US market launch is expected in the second half of this year; European application is on track to be submitted in the first half of 2025
- Opportunity for continued use at home

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.

# Comments from Study Participant

Sherown Campbell

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Jessie Owen

# Panel Q&A

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