

# ONWARD<sup>®</sup> Medical Reports Q1 2024 Update and Year-to-Date Highlights

*Nature Medicine published Up-LIFT pivotal trial results*

*Submitted FDA De Novo application for ARC-EX<sup>®</sup> System*

*Successfully raised EUR 20M in equity capital*

EINDHOVEN, the Netherlands — May 23, 2024 — ONWARD Medical N.V. (Euronext: ONWD), a medical technology company creating innovative spinal cord stimulation therapies to restore movement, function, and independence in people with spinal cord injury (SCI), today provided a Q1 2024 business update.

“This week’s publication of Up-LIFT pivotal trial results in *Nature Medicine* underscores the tremendous potential of ARC-EX Therapy to restore independence in daily activities for people with spinal cord injury,” said Dave Marver, CEO of ONWARD Medical. “We are working closely with the FDA toward clearance for the ARC-EX System and we are preparing to introduce this technology to the SCI Community in the US later this year.”

## **Q1 and Year-To-Date Highlights:**

### *Clinical and Development*

- In January 2024, the Company expanded its HemON clinical feasibility study to explore use of the ARC-IM System to improve blood pressure regulation after SCI with the addition of Sint Maartenskliniek in the Netherlands. This additional research site prepares the Company for expected Q4 2024 initiation of a global pivotal trial called Empower BP to assess the safety and efficacy of ARC-IM Therapy to improve blood pressure regulation.
- In February 2023, the Company announced it has been awarded Breakthrough Device Designation (BDD) by the US Food and Drug Administration (FDA) for the ARC-BCI<sup>™</sup> System, which uses brain-computer interface (BCI) technology in conjunction with its ARC-IM Therapy to restore thought-driven lower limb mobility after spinal cord injury (SCI). This is the Company’s tenth BDD.
- In March 2024, ONWARD Medical was only the second BCI company admitted into the FDA’s new Total Product Lifecycle Advisory Program (TAP).
- In April 2024, the Company announced it had submitted a De Novo application to the US FDA to obtain regulatory clearance to begin marketing its non-invasive ARC-EX System in the United States. Clearance is expected Q4 2024.
- In May 2024, the Company announced the publication of global Up-LIFT pivotal trial results in *Nature Medicine*. The study achieved all primary and secondary safety and effectiveness endpoints, and ARC-EX Therapy demonstrated significant improvements

in upper limb strength, function, and sensation among people with chronic tetraplegia due to cervical SCI.

### *Intellectual Property*

- The Company was issued 13 new patents during Q1 2024, bringing its total number of issued patents year-to-date to more than 265, further strengthening its first-mover advantage.

### *Corporate and Financial*

- In March 2024, the Company completed a EUR 20M equity financing that strengthened its cash position to support investments in product development, clinical trials, operational and commercial capabilities; this financing extended the Company's cash runway through mid-2025.
- The Company reported cash and cash equivalents of EUR 42 million as of March 31, 2024.

### **Outlook:**

ONWARD Medical expects steady and consistent execution to continue throughout 2024 with planned achievement of the following target milestones:

- The Company expects FDA clearance and first commercial sale in the US for its ARC-EX System sometime in Q4 2024. European regulatory approval and commercialization are expected sometime in 2025.
- The Company continues to prepare for its Empower BP global pivotal trial to evaluate the safety and effectiveness of its implantable ARC-IM System to address blood pressure instability after SCI. It expects IDE approval from FDA in Q4 2024 to commence this study. First participant enrollment could occur in late 2024 or early 2025. The Company also expects publication of interim results from clinical feasibility studies for this indication in a leading scientific journal sometime in 2H 2024.
- The Company expects to gain additional clinical data and experience with its implantable ARC-IM System in 2024, with several implants planned with support from the Michael J. Fox Foundation for Parkinson's Research as well as several more planned in combination with an investigational brain-computer interface (BCI) with support from the European Innovation Council.
- The Company reaffirmed its expected cash runway through mid-2025 and will opportunistically evaluate measures to further strengthen its balance sheet in the coming months.

### **Conference Call & Webcast**

ONWARD Medical will host a conference call with a live webcast today, May 23, 2024, at 2:30 pm CET / 8:30 am ET. The webcast, which includes a discussion of Up-LIFT pivotal trial results with a panel of company leaders, study principal investigators, and study participants, may be accessed on the [Financial Information](#) page of the Company's website. A replay of the webcast also will be available on the ONWARD Medical investor website.

To join the webcast via Zoom, please register using this [link](#).

*\*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.*

### **About ONWARD Medical**

ONWARD® Medical is a medical technology company creating therapies to restore movement, function, and independence in people with spinal cord injury (SCI) and movement disabilities. Building on more than a decade of scientific discovery, preclinical, and clinical research conducted at leading hospitals, rehabilitation clinics, and neuroscience laboratories, the Company has developed ARC Therapy™, which has been awarded ten Breakthrough Device Designations from the US Food and Drug Administration (FDA).

ONWARD ARC Therapy is targeted, programmed spinal cord stimulation designed to be delivered by the Company's external ARC-EX® or implantable ARC-IM® platforms. ARC Therapy can also be delivered by the Company's ARC-BCI™ platform, which pairs the ARC-IM System with brain-computer interface (BCI) technology to restore movement after SCI with thought-driven control.

Use of non-invasive ARC-EX Therapy significantly improved upper limb function after SCI in the global pivotal Up-LIFT trial, with results published by *Nature Medicine* in May 2024. The Company has submitted its regulatory application to the FDA for clearance of the ARC-EX System in the US and is preparing for regulatory submission in Europe. In parallel, the Company is conducting clinical studies with its ARC-IM Therapy, which demonstrated positive interim clinical outcomes for improved blood pressure regulation following SCI. Other ongoing clinical studies focus on using ARC-IM Therapy to address mobility after SCI and gait challenges in Parkinson's disease as well as using the ARC-BCI platform to restore thought-driven movement of both upper and lower limbs after SCI.

Headquartered in Eindhoven, the Netherlands, ONWARD Medical has a Science and Engineering Center in Lausanne, Switzerland and a US office in Boston, Massachusetts. The Company is listed on Euronext Brussels and Amsterdam (ticker: ONWD).

For more information, visit [ONWD.com](http://ONWD.com), and connect with us on LinkedIn and YouTube.

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