

# ONWARD Medical Provides Q3 2024 Update and Year-to-Date Highlights

*Raised EUR 50 million in new capital with cornerstone investment from Ottobock, now the Company's top investor*

*Signed exclusive license with CEA to develop and commercialize WIMAGINE Brain-Computer Interface (BCI) as part of the Company's investigational ARC-BCI System*

*Rob ten Hoedt, former Medtronic President and Executive Committee member, joined Board of Directors as incoming Chairman*

EINDHOVEN, the Netherlands — November 26, 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 Q3 2024 Business Update.

“We secured EUR 50 million in additional capital, added Ottobock as a strategic investor and partner, and gained exclusive rights to develop and commercialize a superb BCI technology,” said Dave Marver, CEO of ONWARD Medical. “This was an historic quarter for the Company and our commitment to develop breakthrough therapies for people with spinal cord injury.”

## **Q3 2024 and Year-To-Date Highlights:**

### *Clinical and Development*

- In July, the Company announced publication in *Neuromodulation: Technology at the Neural Interface*, summarizing effective stimulation parameters informed by the Up-LIFT and LIFT Home studies, and a decision-making framework for clinical implementation of investigational ARC-EX Therapy.
- In September, renowned neurosurgeon Dr. Jocelyne Bloch performed another successful implant of the ARC-BCI System at [Centre Hospitalier Universitaire Vaudois \(CHUV\)](#) in Lausanne, Switzerland.
- Also in September, the Company announced a \$1.1 million grant from the [Christopher & Dana Reeve Foundation](#) to expand an ongoing clinical feasibility study exploring the use of ARC-BCI Therapy to restore thought-driven use of the hands and arms after SCI. The grant will support four additional study participants to be implanted with the ARC-BCI System.
- In October, ONWARD Medical signed an exclusive license with [Commissariat à l'énergie Atomique et aux Énergies Alternatives \(CEA\)](#) to develop and commercialize the WIMAGINE® BCI as part of the Company's ARC-BCI System. This exclusive license positions the Company to be first to market with a BCI-enabled system to restore thought-driven movement after paralysis.

- Also in October, the Company's ARC-EX System was named one of TIME Magazine's Best Inventions of 2024. The selection process involved nominations from TIME editors and correspondents around the world, with special attention paid to growing fields, including healthcare, artificial intelligence, and green energy. The 200 winners were evaluated based on originality, efficacy, ambition, and impact.
- In November, the Company announced a grant from the European Innovation Council (EIC) to study the use of ARC-BCI Therapy to restore upper limb movement after stroke. The grant will support the exploration of ARC-BCI Therapy as a viable treatment to restore hand and arm function following subcortical stroke.

### *Intellectual Property*

- The Company was issued five new patents during Q3 2024, bringing its total number of issued patents to 279, and further strengthening its first-mover advantage.

### *Corporate and Financial*

- In July, the Company published its 2023 Annual Sustainability Summary, underscoring its commitment to integrating responsible and sustainable practices into all aspects of its business.
- In September, the Company began listing its shares on the Euronext Paris Exchange, in addition to its listings on Euronext Brussels and Amsterdam. The new listing highlights the Company's strong French roots and significant ties to France, including its close partnership with CEA (*see Clinical and Development section above*).
- In October, the Company announced changes to its Board of Directors. Medtech leader Rob ten Hoedt, former Medtronic President and Executive Committee member and Chairman of MedTech Europe, joined as incoming Chairman. Rob's appointment coincides with the planned retirement of Jan Ohrstrom after eight years of service as Chairman. Rahma Samow also joined the Board of Directors. She is currently President and CEO of ClearChoice Dental Implant Centers, a fast-growing US-based leader in dental implant therapy and tooth replacement services with more than 2,000 employees. Fred Colen also announced his retirement as Director after eight years of service.
- Also in October, the Company successfully raised EUR 50 million in an upsized capital increase that included a cornerstone investment from Ottobock SE & Co., a global leader in prosthetics, orthotics, and exoskeleton technology. Ottobock acquired c.10% of ONWARD Medical N.V.'s share capital, initiating an important strategic relationship to support the Company's expected commercialization of the ARC-EX System and other important development, clinical, and commercial activities.

- The Company reported cash and cash equivalents of EUR 23.2 million as of September 30, 2024.

### **Business Update: Outlook and Upcoming Milestones**

ONWARD Medical expects to continue the steady and consistent execution of its strategy in the coming quarters, including preparing for commercialization of its first product.

- The Company anticipates US FDA clearance of its ARC-EX System in Q4 2024. European regulatory submission is expected to follow in 1H 2025 with expected CE mark in 2H 2025.
- The Company continues to prepare for its Empower BP global pivotal trial to evaluate the safety and effectiveness of its investigational ARC-IM System to address blood pressure instability after SCI. Major associated milestones expected in 1H 2025 include FDA IDE submission, FDA IDE approval, and first participant enrollment.
- The Company expects results from its ARC-IM System clinical feasibility studies to address blood pressure instability after SCI to be published in a top-tier medical journal.
- The Company plans multiple additional implants of its ARC-IM System in clinical feasibility studies, including exploring potential benefit to Parkinson's patients in research supported by the Michael J. Fox Foundation.

### **Conference Call & Webcast**

ONWARD Medical will host a conference call with a live webcast today, November 26, 2024, at 2:00 pm CET / 8:00 am ET. To join the webcast via Zoom, please register using this [link](#). A recording of the presentation will also be available on the ONWARD Medical [investor website](#) after the presentation.

*Note: 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. ONWARD, ARC-EX, ARC-IM, ARC-BCI, and the stylized O-Logo are proprietary and registered trademarks of ONWARD Medical. WIMAGINE is a proprietary and registered trademark of CEA. Unauthorized use is strictly prohibited.*

### **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 the Netherlands, the Company has a Science and Engineering Center in Switzerland and a US office in Boston, Massachusetts. The Company is listed on Euronext Paris, Brussels, and Amsterdam (ticker: ONWD).

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

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