



PRESS RELEASE

ONWARD Medical Builds Commercial Momentum for the ARC-EX System and Reinforces its Brain-Computer Interface Leadership in Q1 2025

EINDHOVEN, the Netherlands, June 17, 2025 — ONWARD Medical N.V. (Euronext: ONWD and US OTCQX: ONWRY), the leading neurotechnology company pioneering therapies to restore movement, function, and independence in people with spinal cord injury (SCI) and other movement disabilities, today announces its Q1 2025 business update and year-to-date highlights:

- **Commercial traction:** Following FDA market authorization, the Company met its Q1 objective for the limited initial phase of its US launch of the ARC-EX[®] System, hiring, training and deploying a field organization, establishing a sales and service process, building a roster of reference clinics, and selling ten systems.
- **Technology advancement:** The Company's investigational ARC-IM[®] and ARC-BCI[®] platforms reached new milestones with the 4th and 5th successful BCI implants to restore thought-driven movement, and the first human implant of its investigational ARC-IM Lumbar Lead, which is designed to help restore mobility.
- **Scientific leadership:** Further expanding the body of clinical evidence supporting the ARC-EX System, Pathfinder2 study results published in *Neuromodulation: Technology at Neural Interface* showed that sustained access to ARC-EX Therapy can continue to drive functional improvements. Participants continued to make gains after one year of treatment.
- **Financial highlights:** The Company established a sponsored Level 1 American Depositary Receipt ("ADR") program to facilitate US investor trading and participation in its growth.

"Our Q1 achievements reflect ONWARD's successful transition to a commercial organization that delivers breakthrough therapies to people with spinal cord injuries," said Dave Marver, Chief Executive Officer of ONWARD Medical. "The initial demand for our ARC-EX System and strong positive feedback we've received from users gives us confidence we can deliver against expectations in 2025."



Commercial traction

ONWARD met its Q1 objective for the limited initial phase of its US launch of the ARC-EX System, hiring, training and deploying a field organization, establishing a sales and service process, building a roster of reference clinics, and selling ten systems.

Strong early demand and positive feedback from users suggest the Company expects to meet its 1H sales target of approximately 30 systems and deliver a strong 2025.

The Company also secured access to prominent US government online procurement platforms, enabling Veterans Affairs (VA) and other US government buyers to purchase the ARC-EX System.

Technology advancement

ARC-IM System

In the first quarter, ONWARD announced the first human implant of its ARC-IM Lumbar Lead. The new lead is designed for placement in the lumbar region of the spinal cord, the optimal location for therapies targeting restoration of standing, stepping, and lower limb mobility. The Company's ARC-IM Thoracic Lead has been used in humans since early 2023.

The Company also announced two new grants to support early clinical feasibility studies using its ARC-IM System to help people with Parkinson's disease. The Michael J. Fox Foundation for Parkinson's Research (MJFF) awarded the Company's research partner .NeuroRestore a USD 1M grant to explore how the ARC-IM System can address mobility challenges in Parkinson's disease. The US Department of Defense awarded a USD 1.5M grant to ONWARD and .NeuroRestore to support a clinical feasibility study to explore how the ARC-IM System can address blood pressure instability in Parkinson's disease.

The Company continues to prepare for the initiation of Empower BP, a global pivotal study to assess the safety and efficacy of the ARC-IM System to address blood pressure instability after SCI. Commencement of the study is pending Investigational Device Exemption (IDE) approval from the US Food and Drug Administration (FDA).

ARC-BCI System

In June, ONWARD announced the 4th and 5th successful implants of its ARC-BCI technology in two additional individuals. These achievements further reinforce ONWARD's leadership in developing BCI-enabled movement solutions for people with SCI. Both procedures were performed at Centre Hospitalier Universitaire Vaudois (CHUV) in Lausanne, Switzerland, under the direction of Jocelyne Bloch, MD, Chief of Neurosurgery.

The Company's innovations with BCI technology were featured on CBS 60 Minutes with Anderson Cooper, one of the most respected and longest-running US news programs. The segment highlighted the experience of study participants who received this breakthrough therapy. A companion segment, 60 Minutes Overtime, highlighted the Company's other advancements in SCI and Parkinson's disease.



Scientific leadership

In the first quarter, ONWARD announced the publication of positive results from the investigator-sponsored Pathfinder2 Study in *Neuromodulation: Technology at Neural Interface*. This peer-reviewed publication details findings from a one-year trial demonstrating that ARC-EX Therapy combined with activity-based rehabilitation delivered significant functional improvements when administered to people with SCI in community-based rehabilitation centers. Participants experienced gains in upper body strength, trunk control, and balance at one year of treatment, indicating no plateau in therapeutic benefit¹.

Financial highlights

As part of the phased launch of the ARC-EX System in the US, the Company reported EUR 0.4M in revenue. The quarter ended with net cash of EUR 50.5M, in line with expectations.

Facilitating greater access for US investors, in April the Company established a sponsored Level 1 American Depository Receipt ("ADR") program through the Bank of New York Mellon ("BNY"). The ADRs trade on the OTCQX[®] Best Market under the symbol: ONWRY.

Outlook

Strong early demand for the ARC-EX System and positive feedback from initial users suggest ONWARD expects to meet its 1H sales target of approximately 30 systems and deliver a strong 2025 in line with expectations.

The Company anticipates FDA clearance to market the ARC-EX System for home use. It also anticipates CE Mark authorization so it can begin marketing the device in Europe. The Company further expects to commence its Empower BP global pivotal study for the ARC-IM System. It also plans additional implants of its ARC-IM System and ARC-BCI to explore additional indications in SCI and Parkinson's disease.

Webcast details

ONWARD will hold a webcast today at 2:00PM CET / 08:00AM EST, hosted by CEO Dave Marver. To join the session, please register using [this link](#).

About ONWARD Medical

ONWARD Medical is the leading neurotechnology company pioneering therapies to restore movement, function and independence in people with spinal cord injury (SCI) and other movement disabilities. Building on more than a decade of scientific discovery, preclinical research, and clinical studies 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). The Company's ARC-EX System is cleared for commercial sale in the US. In addition, the Company is developing an investigational implantable system called ARC-IM with and without an implanted brain-computer interface (BCI).

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) and its US ADRs can be traded on OTCQX (ticker: ONWRY).

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



To be kept informed about the Company's technologies, research studies, and the availability of therapies in your area, please [complete this webform](#).

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¹ARC-EX Indication for Use (US): The ARC-EX System is intended to deliver programmed, transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive).

Other Investigational Products: All other ONWARD Medical devices and therapies including ARC-IM and ARC-BCI are investigational and not available for commercial use.