



PRESS RELEASE

ONWARD Medical Provides Preliminary Q3 2025 Update Highlighting Accelerating ARC-EX Adoption in the United States

Eindhoven, the Netherlands, October 13, 2025 — ONWARD Medical N.V. (Euronext: ONWD – US ADR: ONWRY), the leading neurotechnology company pioneering therapies to restore movement, function, and independence in people with spinal cord injuries (SCI) and other movement disabilities, today announces the following key achievements in the third quarter of 2025:

- **Commercial traction:** 40 ARC-EX® Systems were sold in Q3, demonstrating continued strong commercial traction for the Company's groundbreaking external spinal cord stimulation technology. More than 50 clinics across the US are now equipped with the ARC-EX System.
- **Regulatory milestones:** The Company received CE Mark certification for the ARC-EX System, indicated to improve hand strength and sensation after SCI, both in the clinic and at home. Additionally, the US Food and Drug Administration (FDA) approved an investigational device exemption (IDE) for the ARC-IM® System, allowing the initiation of Empower BP, a global pivotal study designed to assess the safety and efficacy of the Company's implanted neuromodulation platform to address blood pressure instability after SCI.
- **Science & technology leadership:** The Company announced the simultaneous publications of two articles in *Nature* and *Nature Medicine*. They highlight advances in blood pressure regulation after SCI and add to the compelling body of scientific and clinical evidence supporting the ARC-IM System ahead of the initiation of the Empower BP global pivotal study.^{1,2}
- **Financial highlights:** For the first time, the Company exceeded the EUR 1 million mark in quarterly revenue.

"This is another quarter of strong execution marked by accelerating adoption of our ARC-EX System, which is now accessible in over 50 US clinics," said Dave Marver, CEO of ONWARD Medical. "We look forward to providing a more fulsome update on our Q3 and year-to-date achievements in November."

The Company will deliver a comprehensive business and financial update during its upcoming quarterly call on November 11, 2025.

About ONWARD Medical

ONWARD Medical is the leading neurotechnology company pioneering therapies to restore movement, function, and independence in people with spinal cord injuries and other movement disabilities. Building on decades of scientific discovery, preclinical research, and clinical studies conducted at leading hospitals, rehabilitation clinics, and neuroscience laboratories, the Company developed ARC Therapy. It has subsequently been awarded 10 Breakthrough Device Designations from the FDA. The Company's ARC-EX® System is cleared for commercial sale in the US and Europe. The Company is also developing an



investigational implantable system called ARC-IM®, designed to address several unmet needs including blood pressure instability after spinal cord injury. It can also be paired with a brain-computer interface (BCI) and artificial intelligence (AI) to restore thought-driven movement.

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, please visit [ONWD.com](https://onwd.com).

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

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References:

1. Phillips, A.A., Gandhi, A.P., Hankov, N. et al. An implantable system to restore hemodynamic stability after spinal cord injury. Nat Med 31, 2946–2957 (2025). <https://doi.org/10.1038/s41591-025-03614-w>
2. Soriano, J.E., Hudelle, R., Mahe, L. et al. A neuronal architecture underlying autonomic dysreflexia. Nature (2025). <https://doi.org/10.1038/s41586-025-09487-w>

Forward-Looking Statements

Certain statements, beliefs, and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company directors' current expectations and projections about future events. By their nature, forward-looking statements involve several risks, uncertainties, and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, delays in regulatory approvals, changes in demand, competition, and technology, can cause actual events, performance, or results to differ significantly from any anticipated development. Forward-looking statements contained in this press release regarding past trends or activities should not be taken as a representation that such trends or activities will continue in the future. As a result, the Company expressly disclaims any obligation or undertaking to release any update or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions, or circumstances on which these forward-looking statements are based. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking



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ARC-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, nonprogressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive).

ARC-EX Indication for Use (EU): The ARC-EX System is intended to deliver programmed, transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic and with take-home exercises in the home to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic (>1 year post-injury), 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.