PRESS RELEASE

ONWARD Medical Drives Strong US ARC-EX Adoption and Achieves Important Scientific and Regulatory Milestones in Q3 2025

Eindhoven, the Netherlands, November 24, 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 announced its results for the third quarter of 2025 and provides a comprehensive business update:

- **Commercial traction:** The Company met its objective of 40 ARC-EX® Systems sold in Q3.

- **Regulatory milestones:** The US Food and Drug Administration (FDA) approved an investigational device exemption (IDE) for the ARC-IM® System, allowing the initiation of the Empower BP global pivotal study. The Company received CE Mark certification for the ARC-EX System. In November, the FDA also cleared the ARC-EX System for home use in the US.

- **Science & technology leadership:** Key publications in *Nature*, *Nature Medicine*, and *Neurology: Clinical Practice* added to the strong body of clinical evidence supporting the Company's innovative therapies.

- **Financial highlights:** The Company reported EUR 1.7 million in revenue in Q3 and successfully raised over EUR 50 million in equity capital in October, extending runway into Q1 2027.

Dave Marver, CEO of ONWARD Medical, said: "We continued to deliver strong commercial execution in Q3, and we achieved several meaningful scientific and regulatory milestones across our technology platforms. Home-based ARC-EX Therapy greatly enlarges the US market opportunity and helps fulfill our mission to provide the SCI community with broad and convenient access to innovative therapies. We are also well positioned to initiate Empower BP, our second global pivotal study and the first to evaluate the ARC-IM implanted neuromodulation platform to address blood pressure instability after SCI. The recent well-supported financing allows us to further advance our strategic priorities with focus, discipline and determination."

Commercial traction

The Company met its objective of 40 ARC-EX Systems sold in Q3, demonstrating continued strong commercial traction for its groundbreaking external spinal cord stimulation technology.

ARC-EX Therapy is now available in over 60 clinics across the US.

Regulatory milestones

The Company received CE Mark certification for the ARC-EX System, allowing commercialization for both clinic and home use in the European Union. The CE Mark facilitates a streamlined regulatory pathway in other countries, including the UK and Switzerland. First commercial sales of the ARC-EX System in Europe are expected in Q4.

In November, the Company received 510(k) clearance to expand the ARC-EX System indication for home use in the US. ARC-EX is the first and only FDA-cleared technology demonstrated to improve hand strength and sensation in people with SCI.

The US FDA also approved an IDE for the ARC-IM System, allowing the initiation of the Empower BP global pivotal study designed to assess the safety and effectiveness of this novel technology designed to manage blood pressure instability in people with SCI. The first patient enrollment in Empower BP is anticipated before the end of the year.

Science & technology leadership

The Company announced the simultaneous publication of two landmark articles in *Nature* and *Nature Medicine*. They highlighted advances in blood pressure regulation after SCI and added to the compelling body of scientific and clinical evidence supporting the ARC-IM System ahead of the initiation of Empower BP. Detailed results from clinical feasibility studies show immediate improvement in blood pressure stability and durable reduction of hypotensive symptoms, resulting in improved quality of life.

The results of the LIFT Home Study, published in *Neurology: Clinical Practice*, showed that continued use of ARC-EX Therapy at home is effective in maintaining and extending gains achieved in the clinic.

Financial highlights

The Company reported EUR 1.7 million in revenue in Q3, exceeding the EUR 1 million mark in quarterly revenue for the first time.

In October, the Company successfully raised over EUR 50 million in equity capital. The transaction was supported by strong demand from existing and new high-quality, long-only, and sector specialist investors. The net proceeds from the transaction are expected to provide the Company with cash runway into Q1 2027, assuming no draw down of the Company's debt facility. As of October 31, 2025, the cash balance was EUR 77.7 million.

BNP Paribas' broker Portzamparc initiated coverage with a Buy rating and Target Price of EUR 10.20, expanding the Company's equity research coverage to five leading banks, each with Buy ratings.

Outlook

Continued demand for the ARC-EX System and positive feedback from users suggest the Company is on track to deliver a strong first year as a commercial organization. The CE Mark certification and FDA clearance to market the ARC-EX System for home use put the Company in a strong position to accelerate growth in 2026.

The Company anticipates first patient enrollment in the Empower BP pivotal study before the end of the year. It also plans additional implants of its ARC-IM and ARC-BCI® Systems to explore potential future indications, including mobility in SCI and Parkinson's disease.

Webcast details

ONWARD Medical will hold a webcast today, November 24, 2025, at 2:00 p.m. CET / 8:00 a.m. ET, 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 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.

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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Forward-Looking Statements

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ARC-EX Indication for Use: 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, nonprogressive neurological deficits resulting from an incomplete spinal cord injury (C2-C8 inclusive). The ARC-EX System is intended to be operated in medical centers by rehabilitation professionals and at home by patients and persons providing assistance to patients, as needed.

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