PRESS RELEASE

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ONWARD Medical Reports Full Year 2025 Financial and Operating Results, Highlighting Strong US Commercial Performance and Major Pipeline Milestones

Eindhoven, the Netherlands, March 31, 2026 — 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 its financial and operating results for the full year 2025:

- **Commercial traction:** The Company initiated the commercialization of its first technology platform and sold 117 ARC-EX® Systems, demonstrating strong commercial traction for its groundbreaking external spinal stimulation system. ARC-EX was sold to more than 80 US rehabilitation clinics by the end of the year.

- **Regulatory milestones:** The Company received CE Mark certification for the ARC-EX System for use in both clinics and homes. In November, the US Food and Drug Administration (FDA) granted 510(k) clearance to expand the ARC-EX System indication for home use in the US. Additionally, the FDA approved an investigational device exemption (IDE) for the ARC-IM® System, allowing the initiation of the Empower BP global pivotal study.

- **Science & technology leadership:** The Company announced the simultaneous publications of two articles in *Nature* and *Nature Medicine*, further expanding the body of scientific and clinical evidence supporting ARC-IM Therapy. Additional publications in *Neuromodulation: Technology at the Neural Interface* and *Neurology: Clinical Practice* added to the body of clinical evidence supporting ARC-EX. Four additional individuals received the investigational ARC-BCI® Therapy, advancing ONWARD's leadership in the field of brain-computer interface (BCI) technology to restore thought-driven movement.

- **Financial results:** The Company reported EUR 5.4M in revenue and successfully raised EUR 50.8M in equity capital in October. It ended the year with a net cash position of EUR 68.1M.

"In 2025, we established a US commercial organization that drove rapid adoption of our groundbreaking ARC-EX System in US rehabilitation clinics. The FDA 510(k) for home use of ARC-EX further expands the US market opportunity and helps fulfill our mission to provide the SCI community with broad and convenient access to our therapies," said Dave Marver, CEO of ONWARD Medical. "We achieved several scientific, regulatory, and clinical milestones including the initiation of Empower BP, our second global pivotal study.

With focus, discipline, and determination, we are poised to accelerate the development and commercialization of the ARC-EX and ARC-IM Systems, addressing the most pressing needs of people living with spinal cord injuries and other movement disabilities."

Commercial traction

The Company launched the ARC-EX System in the US, deploying a US field organization, and establishing a sales and service process. The Company sold 117 ARC-EX Systems in 2025. Positive feedback and continued strong demand drove commercial traction for ONWARD's groundbreaking external spinal cord stimulation technology, which was recognized as one of Fast Company's 2025 World Changing Ideas for its potential to transform lives after SCI. Demonstrating rapid US adoption, the Company sold ARC-EX Systems to more than 80 US clinics by the end of 2025, representing a market penetration of approximately 25% of specialized rehabilitation clinics in the US.

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

In the last quarter of the year, the Company initiated the phased launch of ARC-EX in Europe. The Company delivered the first systems to clinics in the Netherlands, Switzerland, Germany, and the UK.

Regulatory milestones

ARC-EX System

In September, the Company received CE Mark certification for the ARC-EX System, allowing commercialization for both clinic and home use in the European Union and facilitating a streamlined regulatory pathway in other countries. As part of the CE Mark application process, the Company achieved its first certification in accordance with the European Medical Device Regulation (MDR), meeting European standards and requirements relating to patient safety, clinical performance, risk management, and post-market surveillance.

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 ARC-EX System also received UL Mark certification, a globally recognized symbol of product safety and quality.

ARC-IM System

The US FDA 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 breakthrough technology to manage blood pressure instability in people with SCI. Empower BP is the first global pivotal study to evaluate the Company's implantable spinal cord stimulation system. The randomized, double-blinded, sham-controlled study is expected to involve participants across approximately 20 leading neurorehabilitation and neurosurgical research centers in the US, Canada, France, Germany, Spain, and the UK. The first

participant enrollment and implant occurred in the first quarter of 2026 at Craig Hospital in Denver, Colorado. 10 clinical sites have been activated and are actively recruiting for Empower BP in the US.

Science & technology leadership

ARC-EX System

Positive results from the investigator-sponsored Pathfinder2 study were published in *Neuromodulation: Technology at the Neural Interface*. The one-year trial found that ARC-EX Therapy, combined with activity-based rehabilitation, delivered significant functional improvements and continued gains in upper body strength, trunk control, and balance after one year of treatment, with no plateau in therapeutic benefit.[1,5]

Additionally, 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.[2]

ARC-IM System

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 multi-year clinical feasibility studies show that participants who received ARC-IM Therapy saw immediate and robust increases in blood pressure, as well as reduced frequency and severity of hypotensive symptoms. The enhanced hemodynamic stability resulted in improved quality of life and greater engagement in rehabilitation and daily life activities.[3,4]

The Company also announced the first human implant of its ARC-IM Lumbar Lead. The new proprietary 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 received new grants to support early clinical feasibility studies using its ARC-IM System to help people with Parkinson's disease. These grants were awarded by The Michael J. Fox Foundation for Parkinson’s Research (MJFF) and the US Department of Defense.

ARC-BCI System

The Company announced that four additional individuals living with spinal cord injuries have received ARC-BCI Therapy, advancing ONWARD’s leadership in BCI-enabled movement solutions for people with SCI. ARC-BCI is the world’s first and most advanced purpose-designed platform pairing a brain-computer interface with an implantable spinal cord stimulation system. In total, seven study participants have now received ARC-BCI Therapy to restore movement of their own paralyzed limbs.

In May, ARC-BCI Therapy was featured on CBS’s 60 Minutes with Anderson Cooper, one of the most respected and longest-running US news programs.

Corporate governance

The Company announced the appointment of Professor Tim Denison, PhD, entrepreneur and neurotechnology thought leader, to its Board of Directors. The Company also announced the appointment of Lucas Buchanan to its Board of Directors. Buchanan is a well-respected medtech operations and finance leader with NASDAQ-listed company experience.

In January 2026, the Company announced the appointment of Ali Kiboro as Chief Financial Officer, joining ONWARD from AliveDx (formerly Quotient Limited, a NASDAQ-listed company).

Financial results

The Company reported EUR 5.4M in total revenue. Revenue from the sale of ARC-EX Systems grew from EUR 0.08M in 2024 to EUR 3.7M in 2025. Other income, mainly grant income, remained consistent year over year at EUR 1.7M.

In line with expectations, the Company reported an operating loss of EUR 40.9M. Operating expenses in 2025 reflect the Company's transition towards commercialization, with anticipated shifts in spending to reflect evolving priorities. Research & Development (R&D) expenses decreased by approximately 11% to EUR 12.3M due to lower external development costs. Clinical & Regulatory expenses increased by 21% to EUR 5.7M, primarily driven by regulatory activities supporting ARC-EX and continued preparations for the Empower BP study. Marketing and market access expenses increased by 142% to EUR 8.1M, primarily reflecting investments in personnel to establish the commercial infrastructure required to support ARC-EX commercialization in the US and other key geographies. Quality assurance expenses increased by 17% to EUR 2.4M in support of ongoing regulatory initiatives, manufacturing readiness, and commercial activities. General and administrative expenses increased by 33% to EUR 16.8M, reflecting the continued scaling and maturation of the Company's operating infrastructure as it advances its commercial activities.

The Company ended the year 2025 with a net cash position of EUR 68.1M (2024: EUR 60.0M). Cash outflow from operating activities increased to EUR 39.1M in 2025, reflecting continued investment in personnel and infrastructure to support the commercialization of ARC-EX and the scaling of the Company's operational capabilities.

Financial summary

In EUR millions *For the twelve-month period ended December 31*	**2025**	**2024**
Total Revenue & Other Income	**5.4**	**1.7**
Gross Profit	**4.4**	**1.7**
Total Operating Expenses	**(45.3)**	**(36.6)**
Operating Loss for the Period	**(40.9)**	**(34.9)**

Net Finance Expense	(0.6)	(0.9)
Income Taxes	(0.3)	0.0
Net Loss for the Period	**(41.8)**	**(35.7)**
At	*December 31, 2025*	*December 31, 2024*
Cash position	68.1	60.0
Interest Bearing Loans	(13.1)	(14.0)
Equity	55.3	48.1

Other financial highlights

In April, the Company established a sponsored Level 1 American Depositary Receipt (ADR) program through the Bank of New York Mellon (BNY). The ADRs trade on the OTCQX® Best Market under the symbol: ONWRY.

In October, the Company successfully raised over EUR 50M 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 drawdown of the Company's debt facility from Runway Growth.

Also in October, BNP Paribas' broker Portzamparc initiated coverage with a Buy rating, expanding the Company's equity research coverage to five leading banks.

The Company has filed an F-1 registration statement with the SEC for a potential NASDAQ IPO within the next 12 to 18 months, subject to favorable market conditions and other factors.

Outlook

Building on its 2025 success, the Company expects to deliver steady and consistent execution of its commercial and innovation strategy.

Newly received regulatory approvals and robust demand for the ARC-EX System position the Company to deliver strong commercial results in 2026, supported by two new growth drivers: (1) Sales of the ARC-EX System for use in the home setting and (2) commercialization in Europe and other key geographies.

The Company plans to execute the Empower BP global pivotal study, assessing the safety and effectiveness of ARC-IM Therapy to address blood pressure instability after SCI. The Company also expects to announce further advancements across its ARC Therapy pipeline, including the initiation of the first clinical feasibility study involving first-in-human use of the ARC-IM System to explore its potential to restore bladder function after SCI, as well as additional ARC-IM and ARC-BCI implants to explore additional indications in SCI, Parkinson's disease, and stroke.

Webcast details

ONWARD Medical will hold a webcast today, March 31, 2026, 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.

Annual reporting

The Company today announces that its Annual Report for the fiscal year ended December 31, 2025 has been filed with the Dutch Authority for the Financial Markets (AFM). The Company has also released its 2025 Sustainability Report. Both reports are available on the Company's investor website.

About ONWARD Medical

ONWARD Medical is the leading neurotechnology company pioneering therapies to restore movement, function, and independence in people with spinal cord injuries (SCI) 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

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 nor 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 statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.

[5]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.