PRESS RELEASE

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ONWARD Medical Demonstrates Commercial Traction and Advances Pipeline in the First Half of 2025

Eindhoven, the Netherlands, September 2, 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 its results for the first half of 2025:

- **Commercial traction**: The Company met its objective of 30 ARC-EX® Systems sold to US clinics in H1 as part of the planned phased launch, demonstrating strong commercial traction for this groundbreaking external spinal stimulation system.

- **Regulatory milestones**: The Company submitted a 510(k) application to the US Food and Drug Administration (FDA) seeking clearance to expand the ARC-EX label to include home use. The Company also filed a CE Mark application to enable ARC-EX commercialization in Europe. Additionally, the 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 technology to address blood pressure instability after SCI.

- **Science & technology leadership:** The Pathfinder2 study found that sustained access to ARC-EX Therapy can continue to drive improvements after one year of treatment. The ARC-IM platform reached a new milestone with the first human implant of the investigational ARC-IM Lumbar Lead, designed to help restore mobility. Two additional individuals received the investigational ARC-BCI® Therapy, leveraging ONWARD's brain-computer interface (BCI) technology to restore thought-driven movement.

- **Financial highlights**: The Company ended the first half of the year with revenues, cash balance, and a financial profile in line with expectations.

"In the first half of 2025, we saw robust demand for our ARC-EX System in the US and continued to gain commercial traction," said Dave Marver, Chief Executive Officer of ONWARD Medical. "We also achieved a significant regulatory milestone with FDA IDE approval for the Empower BP study. With continued focus and capital efficiency, we look forward to successfully completing that study so we can bring the ARC-IM System to people with SCI challenged by blood pressure instability."

Commercial traction

The Company met its Q1 objectives for the limited initial phase of the ARC-EX System launch, deploying a US field organization, establishing a sales and service process, and building a roster of reference clinics. ONWARD further delivered a strong performance in Q2. In line with its H1 sales target, a total of 30 systems were sold to US clinics in the first half of the year. Positive feedback and strong demand from users reinforce confidence in the Company's outlook for the second half of the year.

Earlier in 2025, the Company secured access to prominent online US government procurement platforms, enabling Veterans Affairs (VA) and other US government buyers to purchase the ARC-EX System.

Regulatory milestones

ARC-EX System

ONWARD announced the submission of two major regulatory applications intended to offer improved and more convenient access to the ARC-EX System for people living with SCI in the US and EU. Following the successful initial phase of its US launch to clinics, the Company submitted a 510(k) application to the FDA seeking clearance to expand its label for home use. The Company also filed an application with the notified body for CE Mark certification in accordance with the European Union Medical Device Regulation (MDR) to enable commercialization of the ARC-EX System in the EU and other countries recognizing CE Marking.

ARC-IM System

ONWARD recently announced that the FDA has approved an investigational device exemption (IDE) for the ARC-IM System. This approval allows the initiation of Empower BP, a global pivotal study to assess the safety and efficacy of the implantable neurostimulation technology to address blood pressure instability after SCI.

Empower BP is a randomized, double-blind, sham-controlled study that is expected to involve approximately 20 leading neurorehabilitation and neurosurgical research centers across the US, Canada, and Europe. First patient enrollment is anticipated before the end of the year. The study will target participants with injuries at spinal cord levels C2-T6, injury severities of AIS A-D, and blood pressure instability characterized by chronic orthostatic hypotension (OH) and episodes of autonomic dysreflexia (AD).

Science & technology leadership

ARC-EX System

Earlier this year, positive results from the investigator-sponsored Pathfinder2 study were published in *Neuromodulation: Technology at the Neural Interface*. The study results further expanded the body of clinical evidence supporting the ARC-EX System. 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]

As the first and only FDA-cleared technology indicated to improve hand strength and sensation in people with SCI, the ARC-EX System was recognized as one of Fast Company's 2025 World Changing Ideas for its potential to transform lives.

ARC-IM System

The Company 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 also announced two 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 the fourth and fifth successful implants of its investigational ARC-BCI technology in two additional individuals, advancing ONWARD's leadership in BCI-enabled movement solutions for people with SCI. These latest implants are part of ongoing clinical feasibility studies using a brain-computer interface to investigate the use of thought-driven spinal cord stimulation after SCI.

Corporate governance

ONWARD announced the appointment of Professor Tim Denison, PhD, entrepreneur and neurotechnology thought leader, to its Board of Directors. Denison assumes the Board seat previously held by Professor Gregoire Courtine, PhD, who will continue to serve as Science Advisor. 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.

Financial highlights

Following the launch of the ARC-EX System in the US, the Company reported EUR 1.2 M in revenue.

In line with expectations, the Company reported an operating loss of EUR 20.0 M during the first six months of 2025. It ended the period with a positive cash balance of EUR 40.9 M.

In April 2025, 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.

Financial summary

In EUR millions *For the six-month period ended June 30*	**2025***	**2024**
Total Revenue & Other Income	**1.2**	**0.2**
Total Operating Expenses	**-21.0**	**-19.0**
Operating Loss for the Period	**-20.0**	**-18.7**
Net Finance Result	-1.0	0.2
Income Taxes	-0.2	0.3
Net Loss for the Period	**-21.2**	**-18.3**
At	*June 30, 2025*	*December 31, 2024*
Cash position	40.9	32.1
Interest Bearing Loans	-14.2	-16.0
Equity	27.7	18.3

* 2025 results are unaudited.

Outlook

Continued strong demand for the ARC-EX System and positive feedback from users across clinics suggest ONWARD is on track to meet its sales target for Q3 and deliver a strong 2025 in line with expectations. In addition, the Company anticipates FDA clearance to market the ARC-EX System for home use and CE Mark authorization for European commercialization by year end.

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 System and ARC-BCI to explore potential indications including mobility in SCI and Parkinson's disease.

Webcast details

ONWARD will hold a webcast today, September 2, 2025, at 2:00 PM CET / 8:00 AM 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 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. The Company is also developing an investigational implantable system called ARC-IM®, which can be paired with a brain-computer interface (BCI) 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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[1]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).

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