

ONWARD Medical Reports Full Year 2024 Financial and Operating Results and Shares 2025 Year-to-Date Highlights

Received FDA authorization and recorded first commercial sales of ARC-EX System
Secured strategic investment from Ottobock and extended cash runway for two years
Gained exclusive rights to premier brain-computer interface technology

EINDHOVEN, the Netherlands — April 1, 2025 — ONWARD Medical N.V. (Euronext: ONWD), the medical technology company creating innovative spinal cord stimulation therapies to restore movement, function, and independence in people with spinal cord injury (SCI) and other movement disabilities, today announces its Full Year 2024 Financial and Operating Results.

"2024 was a transformative year for ONWARD®, highlighted by our FDA De Novo authorization and first commercial sales of the ARC-EX® System," said Dave Marver, CEO of ONWARD Medical. "We strengthened our balance sheet, welcomed Ottobock as a strategic investor and partner, and advanced our technology portfolio by gaining exclusive rights to a premier brain-computer interface (BCI) technology. Our US commercial launch is underway, marking the next chapter in our mission to deliver life-changing therapies to people with spinal cord injuries."

Full Year 2024 and Year-to-Date 2025 Highlights

Clinical and Development

- In January 2024, the Company announced the expansion of its HemON clinical feasibility study with the addition of Sint Maartenskliniek in the Netherlands. This additional site prepares the Company for the expected 1H 2025 initiation of a global pivotal trial called Empower BP to assess the safety and efficacy of ARC-IM® Therapy to improve blood pressure stability.
- In February 2024, the Company announced it has been awarded Breakthrough Device Designation (BDD) by the US Food and Drug Administration (FDA) for the investigational ARC-BCI® System, which uses brain-computer interface (BCI) technology in conjunction with its investigational ARC-IM Therapy to restore thought-driven lower limb mobility after SCI, creating the ONWARD DigitalBridge™. This is the Company's tenth BDD.
- In March 2024, ONWARD was accepted into the US FDA's new Total Product Lifecycle Advisory Program (TAP) for the development of its ARC-BCI System, becoming only the second BCI company to join the program.
- In April 2024, the Company announced it had submitted a De Novo application to the US FDA to obtain regulatory authorization to begin marketing its non-invasive ARC-EX System in the United States. Authorization was awarded in Q4 2024.

- In May 2024, the Company announced the publication of its Up-LIFT pivotal trial results in [Nature Medicine](#). The study achieved all primary and secondary safety and effectiveness endpoints, and ARC-EX Therapy demonstrated significant improvements in upper limb strength, function, and sensation among people with chronic tetraplegia due to cervical SCI*.
- In July 2024, the Company announced a publication in [Neuromodulation: Technology at the Neural Interface](#), summarizing effective stimulation parameters informed by the Up-LIFT and LIFT Home studies, and a decision-making framework for clinical implementation of ARC-EX Therapy.
- In September 2024, renowned neurosurgeon Dr. Jocelyne Bloch performed another successful implant of the ARC-BCI System at Centre Hospitalier Universitaire Vaudois (CHUV) in Lausanne, Switzerland.
- Also in September 2024, the Company announced a USD 1.1M grant from the [Christopher & Dana Reeve Foundation](#) to expand an ongoing clinical feasibility study exploring the use of ARC-BCI Therapy to restore thought-driven use of the hands and arms after SCI. The grant will support four additional study participants to be implanted with the ARC-BCI System.
- In October 2024, ONWARD signed an exclusive license with the French Alternative Energies and Atomic Energy Commission (CEA) to develop and commercialize the investigational WIMAGINE® BCI as part of the Company's ARC-BCI System. This exclusive license positions the Company to be first to market with a BCI-enabled system to restore thought-driven movement after paralysis.
- In November 2024, the Company announced a grant from the European Innovation Council (EIC) to study the use of ARC-BCI Therapy to restore upper limb movement after stroke.
- In December 2024, the Company's De Novo application was granted by the US Food and Drug Administration (FDA) and the Company received market authorization for its ARC-EX System.
- In February 2025, results from the investigator-sponsored Pathfinder2 Study were published in [Neuromodulation: Technology at Neural Interface](#), highlighting the benefits of sustained access (at least one year) to ARC-EX Therapy.
- In March 2025, the Company announced two new grants to support studies using its ONWARD ARC-IM System to help people with Parkinson's disease: A USD 1M grant from The Michael J. Fox Foundation for Parkinson's Research to address mobility challenges and a US Department of Defense grant of ~USD 1.5M to address blood pressure instability.

- Also in March 2025, the Company announced the first-in-human use of its investigational ARC-IM Lumbar Lead, designed to be used as part of the ARC-IM System to restore standing, stepping, and lower limb mobility.

Intellectual Property

In 2024, ONWARD added 20 patents to its IP portfolio. It now has more than 150 issued patents, excluding EP country validations. Including EP country validations, the Company exited 2024 with more than 290 issued patents, strengthening the Company's first-mover advantage.

Commercial Developments and Industry Recognition

- In October, the Company's ARC-EX System was named one of TIME Magazine's Best Inventions of 2024.
- In December 2024, the Company earned the first commercial sales of its ARC-EX System to UW Medicine (University of Washington) and Next Steps Chicago, a community-based rehabilitation clinic.
- In January 2025, the Company's ARC-EX System was added to US Veterans Affairs (VA) online procurement platforms, allowing the VA and other government agencies to purchase the breakthrough technology. This is the first major benefit resulting from the Company's partnership with Lovell Government Services, a Service-Disabled Veteran-Owned Small Business (SDVOSB).

Corporate

- In February 2024, the Company announced that KBC Securities initiated research coverage with a Buy rating.
- In March 2024, the Company completed a EUR 20M equity financing that strengthened its balance sheet to support investments in product development, clinical studies, and operational and commercial capabilities.
- In April 2024, the Company announced that Stifel, a US-based full-service investment bank, had initiated research coverage with a Buy rating. The Company now has five banks providing equity research coverage, each with Buy ratings.
- In June 2024, the Company signed a debt financing agreement for up to EUR 52.5M with US-based lender Runway Growth Capital.
- In July 2024, the Company published its 2023 Annual Sustainability Summary, underscoring its commitment to integrating responsible and sustainable practices into all aspects of its business.

- In September 2024, the Company added a Euronext Paris listing, highlighting the Company's strong French roots and significant ties to France, including its close partnership with CEA (see Clinical and Development section above).
- In October 2024, the Company announced medtech leader Rob ten Hoedt, former Medtronic President and Executive Committee member and longtime Chairman of MedTech Europe, joined its Board of Directors as incoming Chairman (he was elevated to Chairman in December 2024).
- Also in October 2024, the Company successfully raised EUR 50M including a cornerstone investment from Ottobock SE & Co., a global leader in prosthetics, orthotics, and exoskeleton technology. Ottobock acquired c.10% of ONWARD Medical N.V.'s share capital, initiating a strategic relationship to support the Company's commercialization of the ARC-EX System and other important development, clinical, and commercial activities.
- In December 2024, the Company was awarded a silver medal by EcoVadis, the world's largest provider of business sustainability ratings. The award placed ONWARD in the top 15% of companies assessed by EcoVadis that year.

Financial

- The Company ended the year with net cash of EUR 60.0M compared to EUR 29.8M at year end 2023.
- For 2024, the Company reported an operating loss of EUR 34.9M compared to EUR 35.5M in 2023.

<i>In EUR millions</i>		
<i>For the twelve-month period ended December 31</i>	2024¹	2023
Total Revenues & Other Income	1.7	0.5
Total Operating Expenses	(36.6)	(36.0)
Operating Loss for the Period	(34.9)	(35.5)
Net Finance Expenses	(0.9)	(0.6)
Income Tax Expenses	0.0	(0.1)
Net Loss for the Period	(35.7)	(36.2)
<i>At</i>	31 Dec 2024¹	31 Dec 2023
Cash position at the end of the period	60.0	29.8
Interest Bearing Loans	(14.0)	(15.3)
Equity	48.1	17.9

¹ 2024 results are unaudited

Total Revenues & Other Income

- Other Income, mainly grant income, increased to EUR 1.7M (2023: EUR 0.5M). In 2024, the Company successfully negotiated an amendment with the European Innovation Council and was able to secure replacement funding from the Swiss State Agency (SERI) for activities conducted in Switzerland. As a result, grant income has been recognized in 2024 to reflect progress on the grant-funded Reverse Paralysis program from inception through the end of 2024. This recognition represents ~EUR 1M of the 2024 income. After FDA clearance on 19 December 2024 the Company realized the sale of 2 ARC-EX Systems, generating EUR 77K in revenue.

Total Operating Expenses

- Operating Expenses in 2024 reflect the Company's transition towards commercialization, with anticipated shifts in spending to reflect evolving activities. Research & Development (R&D) expenses decreased by 10% to EUR 12.4M due to lower external costs. Clinical & Regulatory expenses remained relatively stable, decreasing by 3% to EUR 4.8M, and were comprised of costs related to the FDA submission for the ARC-EX System and preparations for the ARC-IM System Empower BP global pivotal study. Marketing & Market Access expenses increased by 14% to EUR 3.4M, reflecting expanded sales and marketing efforts in anticipation of US commercialization. Quality Assurance expenses saw a 38% increase to EUR 2.0M to support regulatory compliance and manufacturing activities for the ARC-EX System. General & Administrative expenses rose by 11% to EUR 12.6M due to investments in manufacturing, supply chain, and operational infrastructure, along with one-time bonus compensation to reward fundraising successes. Patent fees remained stable, comprising costs to maintain the Company's intellectual property portfolio and including costs to secure exclusive rights to Clinatec's BCI technology.

Net Finance Expenses

- Net Finance expense increased from EUR 0.6M in 2023 to EUR 0.9M in 2024. Interest expense is divided between the innovation loan from the RVO NL that was repaid in July 2024 and replaced with the first tranche of the growth debt facility from Runway Growth. The Company continued to invest excess cash in short-term deposits with stable and reputable banks yielding interest income.

Net Loss for the Period

- The Company realized a Net Loss for the period of EUR 35.7M versus EUR 36.2M in 2023, driven by higher grant income and lower operating expenses.

Net Cash Position

- The Company ended the year 2024 with a net cash position of EUR 60.0M (2023: EUR 29.8M). Cash outflow from operating activities decreased from EUR 32.2M in 2023 to EUR 31.0M in 2024, driven by higher grant income and changes in working capital. Cash flow from financing activities reflects the two rounds of equity financing net of transaction costs. As mentioned above, the Company also repaid the Innovation loan from RVO NL and replaced it with the first tranche of the growth debt facility from Runway Growth.

2025 Outlook

We expect to achieve several important milestones in 2025:

Engineering, Clinical, and Regulatory Developments

- The Company has a robust pipeline of indications that can be pursued using one or more of its technology platforms. These indications primarily target spinal cord injury, but several also show promise in potentially addressing movement or functional challenges resulting from Parkinson's disease, stroke, and other movement disabilities. The Company expects to announce major advancements in this pipeline, including first-in-human use of its technology for new indications and/or populations.
- In 1H 2025, the Company plans to submit a 510(k) application to the US FDA to expand the ARC-EX System label to include use in the home setting, building on the current authorization for use in the clinic setting.
- In 1H 2025, the Company expects to publish detailed results from ongoing clinical feasibility studies exploring the use of the ARC-IM System to stabilize blood pressure after spinal cord injury.
- In 1H 2025, the Company anticipates receiving an Investigational Device Exemption (IDE) from FDA so it can begin its global pivotal trial for the ARC-IM System, called Empower BP.
- In 1H 2025, the Company expects to submit an application for CE Mark certification so it can begin commercializing the ARC-EX System in Europe and other CE Mark countries in 2H 2025 and 2026.
- In 2025, the Company expects to initiate a clinical feasibility study involving first-in-human use of the ARC-IM System to explore the potential to restore bladder function in people with SCI.
- In 2025, the Company expects to advance its research pipeline with additional ARC-IM System implants with financial support from the Michael J. Fox Foundation for Parkinson's Research and US Department of Defense, and additional ARC-BCI implants financially supported by the European Innovation Council and the Christopher & Dana Reeve Foundation.

Commercial Developments

- In 2H 2025 pending FDA authorization, the Company anticipates it will begin marketing the ARC-EX System for use in the home setting, an expansion that would significantly broaden access and treatment options for people with SCI.
- In 2H 2025 and 2026 pending CE Mark certification, the Company plans to expand marketing of the ARC-EX System to Europe and other select geographies.
- In 2025, the Company plans to expand its US field organization. It also plans to establish direct and indirect sales channels outside the US.

Conference Call & Webcast

ONWARD Medical will host a conference call with a live webcast today, April 1, 2025, at 2:00 pm CET / 8:00 am EDT. The 2024 Full Year Report and webcast will be accessible on the Financial Information page of the Company's website. To join the webcast via Zoom, please register using this [link](#).

About ONWARD Medical

ONWARD Medical is a medical technology company creating therapies to restore movement, function, and independence in people with 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 now 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).

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

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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**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, 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.