

ONWARD[®] Medical Reaffirms 2024 Strategic Priorities and Releases Unaudited Q2 Financial Highlights

Company expects to commercialize the investigational ARC-EX[®] System in Q4 2024 and has commenced launch preparations

Company preparing to initiate global pivotal trial for investigational ARC-IM[®] Therapy to address blood pressure instability after spinal cord injury

Company expects to advance clinical and development activities for its unique ARC-BCI[™] brain-computer interface therapy

EINDHOVEN, the Netherlands — August 5, 2024 — 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), today reaffirms its 2024 strategic priorities and releases its unaudited Q2 financial highlights.

2024 Strategic Priorities

ARC-EX commercial launch. The Company expects to launch its ARC-EX Therapy for people with SCI in the US in Q4 2024, pending FDA clearance. Accordingly, the Company has accelerated launch preparations and continues to hire and develop its field sales and service organization. More detail about its launch plans will be provided during the 1H 2024 Investor Webinar on 10 September 2024.

ARC-EX System pricing. Based on the strength of the Up-LIFT pivotal study data published in [Nature Medicine](#) in June 2024, the Company plans to price the ARC-EX System at \$40,000.

ARC-IM interim data publication. The Company expects a peer-reviewed publication in a top-tier medical journal detailing the results of the first 10+ patients implanted with investigational ARC-IM Therapy to address blood pressure instability after SCI.

ARC-IM pivotal study commencement. The Company prepares to launch its global pivotal study, called Empower BP, for ARC-IM Therapy to address blood pressure instability after SCI. Major associated milestones expected to occur in Q4 2024 and Q1 2025 include FDA IDE submission, FDA IDE approval, and first participant enrollment.

ARC-BCI therapy advancement. The Company plans to advance clinical and development activities for its investigational ARC-BCI System, leveraging grant funding, previously announced FDA Breakthrough Device Designation, and acceptance into the new FDA new Total Product Life Cycle Advisory Program (TAP). Several additional ARC-BCI System implants are expected in 2H 2024 and 1H 2025 as part of the ongoing clinical feasibility study with partners at .NeuroRestore and CEA-Clinattec.

Q2 Unaudited Financial Highlights

- The net cash balance on June 30, 2024 was EUR 32.1 million.

- Company plans to publish its Half Year 2024 financial statements and host an investor webinar focused on commercial launch plans for the ARC-EX System on September 10, 2024.

“We are preparing to launch the ARC-EX System in Q4 in the US. The strength of the Up-LIFT pivotal trial data published in *Nature Medicine* supports a system price of \$40,000,” said Dave Marver, CEO of ONWARD Medical. “In addition to this important first commercial launch, the coming quarters promise many significant milestones and developments, including major publications, study initiations, and clinical advancements.”

To learn more about ONWARD Medical’s commitment to partnering with the SCI Community to develop innovative solutions for restoring movement, function, and independence after spinal cord injury, please visit [ONWD.com](https://onwd.com).

**All ONWARD® Medical devices and therapies, including but not limited to ARC-IM®, ARC-EX®, ARC-BCI™, and ARC Therapy™, alone or in combination with a brain-computer interface (BCI), are investigational and not available for commercial use.*

About ONWARD Medical

ONWARD® Medical is a medical technology company creating therapies to restore movement, function, and independence in people with spinal cord injury (SCI) and movement disabilities. Building on more than a decade of scientific discovery, preclinical, and clinical research 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).

ONWARD ARC Therapy is targeted, programmed spinal cord stimulation designed to be delivered by the Company’s external ARC-EX® or implantable ARC-IM® platforms. ARC Therapy can also be delivered by the Company’s ARC-BCI™ platform, which pairs the ARC-IM System with brain-computer interface (BCI) technology to restore movement after SCI with thought-driven control.

Use of non-invasive ARC-EX Therapy significantly improved upper limb function after SCI in the global pivotal Up-LIFT trial, with results published by *Nature Medicine* in May 2024. The Company has submitted its regulatory application to the FDA for clearance of the ARC-EX System in the US and is preparing for regulatory submission in Europe. In parallel, the Company is conducting clinical studies with its ARC-IM Therapy, which demonstrated positive interim clinical outcomes for improved blood pressure regulation following SCI. Other ongoing clinical studies focus on using ARC-IM Therapy to address mobility after SCI and gait challenges in Parkinson’s disease as well as using the ARC-BCI platform to restore thought-driven movement of both upper and lower limbs after SCI.

Headquartered in Eindhoven, the Netherlands, ONWARD Medical has a Science and Engineering Center in Lausanne, Switzerland and a US office in Boston, Massachusetts. The Company is listed on Euronext Brussels and Amsterdam (ticker: ONWD).

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

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