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ONWARD® Medical Reports Half Year 2024 Results and Provides a Business Update

Up-LIFT Study results published in Nature Medicine

De Novo application submitted to FDA to obtain clearance to market the investigational ARC-EX® System in the United States

Up to EUR 52.5M in growth financing obtained from US-based Runway Growth Capital

Several additional milestones achieved with the investigational ARC-BCI™ System, leveraging brain-computer interface (BCI) technology to restore thought-driven movement

EINDHOVEN, the Netherlands — September 10, 2024 — ONWARD Medical N.V. (Euronext: ONWD), the medical technology company creating innovative therapies to restore movement, function, and independence in people with spinal cord injury (SCI), today announces its Half Year 2024 Financial Results and provides a Business Update.

"We had an excellent first half of 2024, submitting a De Novo application for our ARC-EX System to the FDA, publishing the results of our Up-LIFT pivotal study in *Nature Medicine*, and obtaining up to EUR 52.5M in growth financing from Runway Growth Capital," said Dave Marver, CEO of ONWARD Medical. "We also extended our leadership in the brain-computer interface realm, adding an FDA Breakthrough Device Designation (our 10th) and gaining admittance into the FDA's new TAP program to streamline commercialization. We are leading the way in developing a BCI-enabled therapy to restore movement after SCI."

Half Year Operating and Financial Results

Clinical and Development

- In January, the Company expanded its HemON clinical feasibility study to explore use of its investigational ARC-IM® System to improve blood pressure regulation after SCI. The addition of Sint Maartenskliniek in the Netherlands prepares the Company for expected initiation in the coming months of its global pivotal trial, Empower BP, to assess the safety and efficacy of ARC-IM Therapy to improve blood pressure regulation after SCI.

- In February, the Company announced it was awarded Breakthrough Device Designation (BDD) by the US Food and Drug Administration (FDA) for the ARC-BCI System, which uses BCI technology combined with its ARC-IM Therapy to restore thought-driven lower limb mobility after SCI. This is the Company's 10th BDD.

- In March, ONWARD Medical was only the second BCI company admitted into the FDA's new Total Product Lifecycle Advisory Program (TAP), which is intended to streamline the commercialization of innovative new technologies.

- In April, the Company announced it submitted a De Novo application to the FDA to obtain regulatory clearance to market its non-invasive ARC-EX System in the US. Clearance is expected Q4 2024.

- In May, the Company announced 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.

Science and Intellectual Property

- The Company was issued 30 new patents in the first half of 2024, bringing its total number of issued patents to 270+ and strengthening its first-mover advantage.

Corporate

- In March, the Company completed a €20M equity financing round that strengthened its cash position to support investments in product development, clinical studies, and operational and commercial capabilities; this financing extended the Company's cash runway into spring 2025.

- The Company now has five banks providing equity research coverage. In April, the Company announced that Stifel, a US-based full-service investment bank, had initiated research coverage. In February, the Company announced that KBC Securities also initiated research coverage. The Company continues to be covered by equity research analysts at Bryan Garnier & Co, Degroof Petercam, and Kepler Cheuvreux.

- In June, the Company signed a debt financing agreement for up to €52.5 million with US-based lender Runway Growth Capital. The initial tranche of this loan was used to retire the Company's outstanding debt. Future tranches are subject to the Company reaching certain milestones and are expected to be used to fund the Company's upcoming commercial and clinical activities and to support working capital and general corporate purposes.

Financial

- The Company reported an operating loss of EUR 18.7 million for the first six months of 2024, in line with the EUR 18.8 million loss recorded in the first half of 2023. Increased spending on clinical, regulatory, and quality activities was balanced by reduced external spending on research and development.

- The Company ended the first half of 2024 with a positive cash balance of EUR 32.1 million. The balance at year-end 2023 was EUR 29.8 million. The increase of EUR 2.3 million results from proceeds from the March 2024 equity financing offset by the cash outflows for operating activities.

Half Year 2024 Financial Summary

In EUR millions *For the six-month period ended June 30*	**2024**	**2023**
Total Revenues & Other Income	**0.2**	**0.9**
Total Operating Expenses	**(19.0)**	**(19.7)**
Operating Loss for the Period	**(18.7)**	**(18.8)**
Net Finance Result	0.2	(0.5)
Income Taxes	0.3	(0.0)
Net Loss for the Period	**(18.3)**	**(19.3)**
At	**30 June 2024**	**31 December 2023**
Cash position at the end of the period	32.1	29.8
Interest Bearing Loans	(16.0)	(15.3)
Equity	18.3	17.9

Business Update: Outlook and Upcoming Milestones

ONWARD Medical expects to continue the steady and consistent execution of its strategy in the coming quarters, including preparing for commercialization of its first product.

- The Company expects to obtain FDA clearance to launch its ARC-EX System in the US in Q4 2024. The Company has commenced the hiring of a field sales and service organization and plans to provide more detail about its launch plans during today's Half Year 2024 Investor Webinar and Business Update.

- 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.

- The Company is preparing to initiate its Empower BP global pivotal trial for ARC-IM Therapy to address blood pressure instability after SCI. Major associated milestones expected to occur in late 2024 and early 2025 include FDA Investigational Device Exemption (IDE) submission, FDA IDE approval, and first participant enrollment.

- The Company plans to advance clinical and development activities for its ARC-BCI System, leveraging new grant funding from the Christopher & Dana Reeve Foundation, ongoing financial support from the European Innovation Council under the Reverse Paralysis project, the previously announced FDA Breakthrough Device Designation, and acceptance into the FDA's new TAP program. Several additional ARC-BCI System implants are expected in the second half of 2024 and first half of 2025 as part of the ongoing clinical feasibility study with its partners at .NeuroRestore and CEA-Clinatec.

Conference Call & Webcast

ONWARD Medical will host a conference call with a live webcast today, September 10, 2024, at 2:00 pm CET / 8:00 am EDT. The 2024 Half-Year Report and webcast may be accessed on the Financial Information page of the Company's website. To join the webcast via Zoom, please register using this link.

**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).

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