ONWARD Reports Q1 Business Update and Year-To-Date Highlights

First-in-Human Use of the ARC-IM™ Lead

New Breakthrough Device Designation Awarded by the U.S. FDA for ARC Therapy™, Bringing Total to 9

10 Additional Patents Issued, Bringing Total Pending and Issued Patents to More than 340 and Strengthening First-Mover Advantage

EINDHOVEN, the Netherlands — May 16, 2023 — 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 provided a first quarter 2023 business update.

"Our team continued to execute at a high level in Q1, achieving milestones and adding strength across our range of activities," said Dave Marver, CEO of ONWARD. "We were especially pleased to announce that the Up-LIFT pivotal study met all primary endpoints including a 72% responder rate. We expect to achieve several important milestones in the months ahead, including FDA submission of our de novo application for ARC-EX® Therapy and initiation of a groundbreaking clinical feasibility study that includes first-in-human use of a brain-computer interface in combination with ARC-IM™ Therapy to restore hand and arm function."

Q1 and Year-To-Date Highlights:

Clinical and Development

- The Company has been issued 10 new patents during Q1 2023, bringing the total number of issued or pending patents to more than 340 and strengthening its first-mover advantage.
- In April 2023 at the American Academy of Neurology Annual Meeting, Dr. James Guest, Professor of Neurological Surgery at the University of Miami and the Miami Project to Cure Paralysis, shared detailed results from the Up-LIFT pivotal study that investigated non-invasive neuromodulation for improving upper extremity strength and function after SCI. In addition to meeting all primary safety and effectiveness endpoints, the study demonstrated that 72% of participants responded[1] to ARC-EX Therapy.
- The Company has been awarded Breakthrough Device Designation (BDD) for ARC-IM Therapy for spasticity in people with SCI. Breakthrough Device Designation is an FDA program aimed at helping patients and their clinicians receive timely access to new treatments. The Company now has a total of 9 BDDs, which affords it priority FDA review and the opportunity to interact with FDA experts throughout the pre-market review phase as the technology moves toward commercialization.
- First-in-human use of the Company's ARC-IM Lead, which was used with the investigational implantable ARC-IM system as part of the ongoing HemON study to evaluate use of ARC-IM Therapy to better regulate blood pressure after SCI. ONWARD is developing a portfolio of ARC-IM Leads in a range of sizes, shapes, and electrode arrays for the many indications the Company is developing or exploring, such as improved blood pressure management, mobility, upper extremity function, and bladder control. The ARC-IM Lead was specifically designed to stimulate the spinal cord anatomy to restore movement and function in people with SCI.

Corporate and Financial

- The Company reported cash and cash equivalents of EUR 53 million as of March 31, 2023 and reiterated its guidance of expected cash runway through the end of 2024.
- In Q1 2023, ONWARD strengthened its leadership team, appointing Erika Ross Ellison as Vice President, Global Clinical & Regulatory, and Sarah Moore as Vice President, Global Marketing. Erika comes to ONWARD from Abbott Neuromodulation, where she was Director, Global Clinical & Applied Research. She also served as Deputy Director, Medical Device Innovation Accelerator, Department of Surgery and Assistant Professor, Department of Neurologic Surgery at Mayo Clinic. Sarah comes to ONWARD from Nevro, an implantable neuromodulation company, and has more than 20 years of experience in new product development and commercial marketing in medical devices, including at Johnson & Johnson.

Outlook:

ONWARD expects to continue steady and consistent execution of its strategy in 2023 and beyond with the achievement of the following milestones:

- The Company plans to submit a de novo application for FDA clearance for the ARC-EX system this year and aims to submit an application for European authorization in the same period.
- The Company also plans to begin its pivotal clinical study in the next year to evaluate the safety and effectiveness of the implantable ARC-IM system to better regulate blood pressure after SCI.
- The Company plans to begin clinical feasibility studies to investigate the ability for a brain-computer interface (BCI) to communicate with the ARC-IM system to enable a person with SCI to more naturally control when and how they move. This program is supported by a grant from the European Innovation Council.
- The Company plans to continue to build organizational capabilities in preparation for expected launch of ARC-EX later this year or early next year, recruiting field sales and service professionals and adding operational systems that will enable it to conduct commerce once it receives FDA clearance and CE mark.
- The Company anticipates its current cash position will fuel operations through the end of 2024. In 2023, it plans to pursue opportunities to further strengthen cash position to support future investments in product development, clinical trials, and operational and commercial capabilities.

Conference Call & Webcast

ONWARD will host a conference call with a live webcast today, May 16, 2023, at 2:00 pm CET / 8:00am ET. The webcast may be accessed on the Financial Information page of the Company's website. A replay of the webcast also will be available on the ONWARD website.

To join the webcast via Zoom, please register using this link.

All ONWARD devices and therapies referenced here, including but not limited to ARC-IM, ARC-EX, and ARC Therapy, are investigational and not available for commercial use.

[1]Responder was defined as a participant who met or exceeded the minimally important difference criteria for at least one outcome of the strength domain and at least one outcome of the functional performance domain.

About ONWARD® Medical

ONWARD is a medical technology company creating innovative therapies to restore movement, function, and independence in people with spinal cord injuries. The Company's work builds on more than a decade of basic science and preclinical research conducted at the world's leading neuroscience laboratories. ONWARD ARC Therapy™, which can be delivered by implantable (ARC-IM™) or external (ARC-EX®) systems, is designed to deliver targeted, programmed spinal cord stimulation to restore movement and other functions in people with spinal cord injury, ultimately improving their quality of life.

ONWARD has received nine Breakthrough Device Designations from the U.S. FDA. ARC-EX is an external, non-invasive platform consisting of a stimulator and wireless programmer. Positive top-line data were reported in 2022 from the Company's first pivotal study, called Up-LIFT, evaluating the ability of transcutaneous ARC Therapy to improve upper extremity strength and function. The Company is now preparing marketing approval submissions for the US and Europe. ARC-IM consists of an implantable pulse generator and lead placed near the spinal cord. The Company completed the first-in-human use of the ARC-IM neurostimulator and reported positive interim clinical outcomes for ARC-IM Therapy for improved blood pressure regulation following SCI in 2022.

ONWARD is headquartered in Eindhoven, the Netherlands. It maintains a Science and Engineering Center in Lausanne, Switzerland, and has a growing U.S. presence in Boston, Massachusetts. The Company has an academic partnership with .NeuroRestore, a collaboration between EPFL, the Swiss Federal Institute of Technology in Lausanne, and Lausanne University Hospital (CHUV). For additional information about the Company, please visit ONWD.com. To access our 2023 Financial Calendar, please visit IR.ONWD.com.

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