THIS PRESS RELEASE CONTAINS INSIDE INFORMATION WITHIN THE MEANING OF ARTICLE 7(1) OF THE EUROPEAN MARKET ABUSE REGULATION (596/2014)

ONWARD Reports Third Quarter 2022 Highlights and Provides Business Update

Two additional Breakthrough Device Designations granted by U.S. FDA for ARC Therapy

Strong financial position with €70 million in cash and cash equivalents as of September 30, 2022, expected to fund operations through year-end 2024

Conference call and webcast (in English) today, November 8th at 2:30 PM CET/8:30 AM ET

EINDHOVEN, the Netherlands, LAUSANNE, Switzerland & BOSTON, MA USA — November 8, 2022– ONWARD Medical N.V. (Euronext: ONWD), the medical technology company creating innovative therapies to restore movement, independence, and health in people with spinal cord injury (SCI), today discussed highlights from the third quarter of 2022 and provided a business update.

"We are highly encouraged to have received two additional FDA Breakthrough Device Designations, validating the pioneering nature of our work and providing a streamlined approval process for these important therapies," said Dave Marver, CEO of ONWARD. "We are looking forward to additional upcoming milestones, including the expected release of interim data from ongoing blood pressure feasibility studies."

Recent highlights:

R&D and operations

- Today, ONWARD announced that the Company has been granted Breakthrough Device Designation by the U.S. Food and Drug Administration (FDA) for two additional indications: (1) to its external system ARC-EX for improving or restoring lower extremity sensory and motor function in people with chronic neurological deficits resulting from SCI; and (2) to its implantable system ARC-IM for treating neurogenic bladder dysfunction in people with SCI. The Company now has a total of five Breakthrough Device Designations for ARC Therapy.

  Breakthrough Device Designation is an FDA program designed to help patients and their physicians receive timely access to technologies that have the potential to provide more effective treatment or diagnosis for debilitating conditions of great unmet need, such as SCI. As part of this designation, the FDA will provide ONWARD with priority review and the opportunity to interact with FDA experts throughout the premarket review phase as the technology moves toward commercialization.

- In September 2022, ONWARD reported positive top-line results from its Up-LIFT pivotal study evaluating transcutaneous stimulation with its external ARC Therapy. The study enrolled 65 people at 14 leading SCI centers in the U.S., Europe, and Canada, achieving its primary effectiveness endpoint of improvement in upper extremity strength and function in people with SCI.

- In October 2022, ONWARD reported topline results from the LIFT Home study, evaluating the safety and feasibility of ARC-EX Therapy when used at home. The study enrolled 17 participants at 5 leading research centers across the U.S. Participants performed training on activities of daily living involving arm and hand movement three times per week over a

one-month period. Approximately 97% of these sessions were completed without usability issues, supporting the feasibility of home-based treatment.

Corporate and Financial

- The Company reported cash and cash equivalents of EUR 70 million as of September 30, 2022 and reiterated its guidance of expected cash runway through the end of 2024.

- In September 2022, ONWARD appointed Vivian Riefberg, a highly accomplished expert in healthcare, government, and strategy, to the Board of Directors. In 2020, Ms. Riefberg retired as a senior partner with McKinsey & Company, where she led the Public Sector Practice for the Americas and co-led the U.S. Health Care practice. She previously served on the U.S. National Institutes of Health (NIH) Clinical Center Board of Governors and on the NIH Advisory Board for Clinical Research.

Outlook:

ONWARD's management expects to continue the steady and consistent execution of its strategy through the end of 2022 and beyond.

Following positive top-line data from the Up-LIFT pivotal study, ONWARD expects to submit for regulatory approval in the U.S. and EU during the first half of 2023 to allow the Company to commercialize ARC-EX for the improvement of upper extremity strength and function in patients with SCI. If all goes as planned, these authorizations are expected in the second half of 2023.

Additionally, ONWARD plans to discuss the findings from the LIFT Home study with regulatory authorities to define the appropriate approval pathway for home use, with a goal to facilitate access to ARC-EX Therapy at home without the burden of continued visits to a clinic.

Before year-end 2022, the Company expects to release interim data from the STIMO-HEMO and HemON studies. Both studies are exploring the use of ARC-IM Therapy to normalize low blood pressure in people with SCI, which is the first planned indication for ARC-IM. By year-end, ONWARD, therefore, expects to have released top-line data from its pivotal study for ARC-EX and interim data from current clinical feasibility studies for ARC-IM, providing important clinical validation of both of its major technology platforms.

The Company plans to continue building its team and capabilities in preparation for the expected launch of its ARC-EX Therapy in the second half of 2023, both operationally and commercially. Over the next several months, ONWARD plans to focus on recruiting for sales, marketing, and field service roles to cover the U.S. and select European markets.

With a strong balance sheet, the current cash position is expected to be sufficient to finance operations through the end of 2024 and support investments in product development, clinical trials, operational capabilities, and commercial launch. ONWARD continues to consider opportunities to further strengthen its cash position as equity capital markets improve in the U.S. and around the globe.

Conference Call & Webcast

ONWARD will host a conference call with a live webcast today, November 8, 2022, at 2:30 pm CET / 8:30 am 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.

About ONWARD Medical

ONWARD is a medical technology company creating innovative therapies to restore movement, independence, and health in people with spinal cord injuries. ONWARD's work builds on more than a decade of basic science and preclinical research conducted at the world's leading neuroscience laboratories. ONWARD's 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 five Breakthrough Device Designations from the U.S. FDA encompassing both ARC-IM and ARC-EX. ARC-EX is an external, non-invasive platform consisting of a wearable stimulator and wireless programmer. Positive top-line data were reported in September 2022 from the company's first pivotal study, called Up-LIFT, evaluating the ability of ARC-EX Therapy to improve upper extremity strength and function. The company is now preparing marketing approval submissions for the U.S. and Europe. ARC-IM consists of an implantable pulse generator and lead that is placed near the spinal cord. The company completed its first-in-human use of the ARC-IM neurostimulator in May 2022.

ONWARD is headquartered in Eindhoven, the Netherlands. It maintains an office in Lausanne, Switzerland, and has a growing U.S. presence in Boston, Massachusetts. The company has an academic partnership with NeuroRestore, a collaboration between the Swiss Federal Institute of Technology (EPFL) and Lausanne University Hospital (CHUV). For additional information about ONWARD, please visit ONWD.com. To access our 2022 Financial Calendar, please visit IR.ONWD.com.

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