

# ONWARD® Reports Q3 Business Update and Year-To-Date Highlights

*Completing activities required for ARC-EX® FDA submission*

*Expanded HemON Study as precursor to ARC-IM® Empower BP pivotal study*

*First-in-human use of ARC-IM BCI for upper limbs*

*Potential for ARC Therapy™ to improve mobility after Parkinson's disease published in Nature Medicine*

EINDHOVEN, the Netherlands — November 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 third quarter 2023 business update.

“We remain focused on completing activities required to submit an FDA *de novo* application for clearance of our ARC-EX System in the first half of 2024,” said Dave Marver, CEO of ONWARD. “In the meantime we achieved several additional milestones in Q3, including the first-in-human implant of our ARC-IM Neurostimulator paired with a brain-computer interface (BCI) to restore thought-driven movement in the fingers, hands, and arms and the expansion of our HemON clinical feasibility study. HemON will investigate use of the ARC-IM System to provide hemodynamic stability after SCI and is a precursor to our planned global pivotal study called Empower BP, which we expect to commence in the second half of next year. A recent *Nature Medicine* publication revealed the exciting potential to expand ARC-IM Therapy into the large, adjacent Parkinson’s disease market.”

## **Q3 and Year-To-Date Highlights:**

### *Clinical and Development*

- In August 2023, the Company marked the first-in-human implant of its ARC-IM Neurostimulator to restore upper extremity function after SCI. The study participant also received a wireless brain-computer interface (BCI), designed to initiate thought-driven movement when paired with ARC-IM. ONWARD ARC-IM delivers targeted, programmed ARC-IM Therapy to the spinal cord to restore movement and other functions after SCI. To date, ARC-IM Therapy has been applied across multiple clinical feasibility studies to restore mobility or stabilize blood pressure after SCI.
- In September, the Company expanded its HemON clinical feasibility study to assess the safety and effectiveness of the ARC-IM System to improve blood pressure regulation after SCI with the addition of Sint Maartenskliniek in Nijmegen, the Netherlands as a study site. The first participant at this site was implanted in September 2023. Expanding this clinical feasibility study prepares the company for expected 2H 2024 initiation of a global pivotal trial, called Empower BP, which is being designed to provide the evidence

necessary to submit a pre-market approval (PMA) application to the US Food and Drug Administration (FDA) and other global regulatory bodies.

- In November, the Company announced a publication in *Nature Medicine* highlighting the potential for ONWARD ARC Therapy to address gait challenges related to Parkinson's disease. The study participant described in the publication has been living with Parkinson's disease for nearly three decades. He has a severe gait disorder that has not responded to conventional therapies. After the introduction of ARC Therapy and benefitting from several weeks of rehabilitation, the participant was able to walk without previously noticeable gait interruptions.
- Also in November, ONWARD research partner .NeuroRestore was awarded a \$1 million grant from The Michael J. Fox Foundation for Parkinson's Research (MJFF) to implant the Company's ARC-IM System and investigate the effect of ARC Therapy in six additional participants with Parkinson's disease. This study will assist ONWARD in determining whether to conduct additional clinical trials and potentially commercialize ARC Therapy in the future for those living with Parkinson's disease.
- The Company was issued 33 new patents during Q3 2023, bringing its total number of issued patents to more than 230 and issued or pending patents to more than 390, further strengthening its first-mover advantage.

#### *Commercial*

- In September, the Company announced a partnership with Lovell Government Services (Lovell), a Service-Disabled Veteran-Owned Small Business (SDVOSB). Lovell is a government vendor and third-party logistics provider partnering with more than one hundred US healthcare providers. The two-year distribution agreement provides ONWARD access to the United States Veterans Health Administration, the world's largest healthcare system providing spinal cord injury care, and the US Department of Defense Military Health System, the world's largest military healthcare provider.

#### *Corporate and Financial*

- The Company reported cash and cash equivalents of EUR 36.8 million as of September 30, 2023, and reiterated its guidance of expected cash runway through the end of 2024.

#### **Outlook:**

ONWARD expects to continue steady and consistent execution of its strategy in through 2024 with the achievement of the following milestones:

- The Company plans to submit a *de novo* application for FDA clearance of the ARC-EX System in 2024, with US launch expected in the second half of next year. This would be the Company's first commercial offering.
- Based on positive feedback from potential customers on the value of the ARC-EX System, expected to be the first-ever external spinal cord stimulation therapy to restore

hand and arm function after SCI, the Company anticipates a list price of USD 30,000. In addition, the Company expects to supplement revenue by offering tiered service packages.

The Company also continues to prepare for its global pivotal clinical study, called Empower BP, to evaluate the safety and effectiveness of its implantable ARC-IM System to address blood pressure instability after SCI. This study is expected to begin enrollment in the second half of 2024.

- Concurrent with publication in a peer-reviewed journal, the Company expects to announce more detailed results from its Up-LIFT pivotal study in 2024. The Company has already announced that the study met both primary safety and effectiveness endpoints and that 72% of participants responded to ARC-EX. A responder was defined as meeting or exceeding the minimally important difference criteria for at least one strength outcome and at least one functional performance outcome.
- The Company expects to gain additional clinical data and experience with its implantable ARC-IM System in 2024, with several implants planned with support from the Michael J. Fox Foundation for Parkinson's Research and several implants planned in combination with an implanted brain-computer interface (BCI) with support from the European Innovation Council.
- The Company reaffirmed its expected cash runway through the end of 2024 and will look for efficient ways to further strengthen its balance sheet in the coming months.

### **Conference Call & Webcast**

ONWARD will host a conference call with a live webcast today, November 16, 2023, at 2:00 pm CET / 8:00 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](#).

*\*All ONWARD devices and therapies, including but not limited to ARC-IM, ARC-EX, and ARC Therapy, alone or in combination with BCI, are investigational and not available for commercial use.*

### **About ONWARD Medical**

ONWARD 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 science and preclinical research conducted at leading neuroscience laboratories, the Company has received nine Breakthrough Device Designations from the US Food and Drug Administration for its ARC Therapy™ platform.

ONWARD® ARC Therapy, which can be delivered by external ARC-EX® or implantable ARC-IM® systems, is designed to deliver targeted, programmed spinal cord stimulation. Positive results were presented in 2023 from the Company's pivotal study, called Up-LIFT, evaluating the ability for transcutaneous ARC Therapy to improve upper extremity strength and function. The

Company is now preparing regulatory approval submissions for ARC-EX for the US and Europe. In parallel, the Company is conducting studies with its implantable ARC-IM platform, which demonstrated positive interim clinical outcomes for improved blood pressure regulation, a component of hemodynamic stability following SCI. Other ongoing studies include combination use of ARC-IM with a brain-computer interface (BCI).

Headquartered in Eindhoven, the Netherlands, ONWARD has a Science and Engineering Center in Lausanne, Switzerland and a US office in Boston, Massachusetts. The Company also has an academic partnership with .NeuroRestore, a collaboration between the Swiss Federal Institute of Technology (EPFL), and Lausanne University Hospital (CHUV).

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

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