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## ONWARD® Reports 2023 Half Year Results and Business Update

*US commercialization of ARC-EX™ expected 2H 2024 with USD 30,000 anticipated price*

*Clinical study initiated pairing ARC Therapy™ with a brain-computer interface to restore use of legs and upper extremities*

EINDHOVEN, the Netherlands — September 19, 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 announced its first 2023 half results and provided a Business Update.

“During the first half of 2023 we delivered several significant milestones, including revealing additional positive data from our Up-LIFT pivotal study and initiating a groundbreaking clinical feasibility study that includes first-in-human use of an investigational implanted brain-computer interface (BCI) in combination with our ARC-IM™ Therapy to restore thought-driven movement after SCI,” said Dave Marver, CEO of ONWARD. “We have also taken the difficult but correct decision to update the ARC-EX system circuit board assembly. While we share the disappointment of the SCI community that this decision will impact launch timing, now expected in 2H 2024, our cash guidance remains unchanged. We are also increasingly well prepared for launch after recent agreements with a third-party logistics partner that provides rapid access to US government procurement vehicles.”

### 1H Operating and Financial Results

#### *Clinical and Development*

- 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 additional results from the Up-LIFT pivotal study that investigated ARC-EX Therapy 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 to ARC-EX Therapy<sup>1</sup>, showing improvement in both strength and function.
- In May, the Company announced its ARC Therapy was paired with an investigational implanted wireless BCI, resulting in an individual gaining thought-driven augmented control over when and how he moved his paralyzed legs. This breakthrough was published in the journal *Nature* and highlighted in major media outlets around the globe.
- Also in May, the Company announced the successful first-in-human use of its investigational ARC-IM Lead to deliver targeted electrical pulses to the spinal cord. The ARC-IM Lead is a key component of the ONWARD ARC-IM system, engineered to address multiple indications by precisely delivering ARC Therapy. The ARC-IM Lead is designed to be used with the ARC-IM Neurostimulator (IPG) and is purpose-built for placement along the spinal cord to restore movement and function in people with SCI.

- The Company announced four new Breakthrough Device Designations (BDD) from the US Food and Drug Administration (FDA) in the first half of 2023. These include BDDs for the use of its ARC-EX platform for bladder control (awarded late 2022), alleviation of spasticity, and blood pressure regulation in people with SCI. In addition, the Company received an additional BDD for its ARC-IM platform for spasticity in people with SCI. The Company now has a total of nine 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.

#### *Science and Intellectual Property*

- The Company was issued 39 new patents in H1, bringing its total number of pending or issued patents to more than 360. Of these, more than 200 are issued patents, further reinforcing the Company's first-mover advantage.

#### *Corporate*

- In January, the Company strengthened its leadership team, appointing Erika Ross Ellison as Vice President, Global Clinical, Regulatory, and Quality and Sarah Moore as Vice President, Global Marketing. Erika came to ONWARD from Abbott Neuromodulation, where she was Director, Global Clinical & Applied Research. Previously, Erika was Neuroscience Director at Cala Health, a non-invasive neuromodulation company. She also served as Deputy Director, Medical Device Innovation Accelerator, Department of Surgery and Assistant Professor, Department of Neurologic Surgery at the Mayo Clinic. Sarah came to ONWARD from Nevro, an implantable neuromodulation company, and has more than 20 years of experience in new product development and commercial marketing in the medical device industry, including at Johnson & Johnson.
- In May, Bryan, Garnier & Co, a leading investment bank focused on growth companies, reinitiated research coverage on the Company with a Buy rating. The Company is also covered by equity research at Degroof Petercam and Kepler Cheuvreux.

#### *Financial*

- ONWARD reported an operating loss of EUR 18.8 million for the first six months of 2023 compared to EUR 15.1 million in the same period of 2022.
- The Company ended the six-month period with a positive cash balance of EUR 43.8 million (31 December 2022: EUR 61.8 million). The decrease in cash of EUR 18 million compared to 31 December 2021 is due to cash outflows for operating activities.

#### **First Half 2023 Financial Summary**

<i>In EUR millions</i> <i>For the six-month period ended June 30</i>	<b>2023</b>	<b>2022</b>
<b>Total Revenues &amp; Other Income</b>	<b>0.9</b>	<b>1.0</b>
<b>Total Operating Expenses</b>	<b>(19.7)</b>	<b>(16.1)</b>
<b>Operating Loss for the Period</b>	<b>(18.8)</b>	<b>(15.1)</b>

Net Finance Expenses	(0.4)	(0.9)
Income Tax Expenses	(0.0)	(0.0)
<b>Net Loss for the Period</b>	<b>(19.2)</b>	<b>(16.0)</b>
<i>at</i>	<b>30 June 2023</b>	<b>31 December 2022</b>
Cash position at the end of the period	43.8	61.8
Interest Bearing Loans	(14.3)	(12.7)
Equity	34.3	52.6

## Business Update: 2H Outlook and Upcoming Milestones

ONWARD expects to continue strong execution of its strategy in the second half of 2023 and beyond.

### *Clinical and Development*

- In August, ONWARD marked the successful first-in-human use of an investigational implanted wireless BCI to help a person with SCI recover use of paralyzed arms and hands with thought-driven movement. The implant was part of a clinical feasibility study with partners at CEA-Clinattec, CHUV, and EPFL that is supported by a grant from the European Innovation Council. BCI-augmented ARC-IM implants will continue throughout 2024 as part of this study.
- ONWARD now expects to launch ARC-EX in the US in the second half of 2024. The new date is driven by our decision to redesign the device's printed circuit board assembly (PCBA). Once the PCBA redesign and associated testing are completed, the Company plans to submit a *de novo* application for FDA clearance for the ARC-EX system, which would be the Company's first commercial offering. The Company does not expect the postponement to negatively impact its cash runway.
- The Company also continues to prepare for its 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.

### *Commercial Update*

- ONWARD continues to make robust progress in preparing for launch. In September, it forged an agreement with a US third-party logistics (3PL) provider to manage fulfillment to civilian customers and an agreement with a US Service-Disabled Veteran-Owned Small Business (SDVOSB) to manage fulfillment to the US Veterans Affairs (VA) Health Administration. The latter agreement will provide ONWARD with rapid access to US government purchasing vehicles after FDA clearance.
- 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 is anticipating a list price of USD 30,000. In addition, the Company expects to offer tiered service packages.

### *Corporate*

- CFO Lara Smith Weber will step down as Chief Financial Officer at the end of September to pursue a new opportunity in the Boston area. Khaled Bahi will join ONWARD as Interim CFO. Prior to joining ONWARD, Khaled served as CFO of Lausanne-based Symetis, acquired by Boston Scientific in 2017 for USD 435 million, and Paris-based Stilla Technologies. He was also a finance leader with Fresenius Medical Care in Europe, Latin America, Middle East, and Africa. Khaled brings more than 20 years of finance experience in the medtech industry. Early in his career, he was a corporate and investment banker with Crédit Lyonnais and the Industrial Bank of Japan.
- The Company continues to expect its current cash position to fuel operations through the end of 2024. ONWARD plans to explore opportunities to further strengthen its 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, September 19, 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. The Half Year Report 2023 is available on the Company's website in the Investors section. 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.*

<sup>1</sup>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 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 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](https://ONWD.com), and connect with us on [LinkedIn](#) and [YouTube](#).

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