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## ONWARD Reports 2022 Full Year Financial and Operating Results

***Company also Provides Business Update and Outlook for 2023***

*Conference Call and Webcast (in English) March 28, 2023, at 2:00 PM CEST/8:00 AM EDT*

EINDHOVEN, the Netherlands, LAUSANNE, Switzerland & BOSTON, MA USA — March 27, 2023 — 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, today announces its 2022 financial and operating results. The full Annual Report is available [here](#), on the Company's website in the Investors section (<https://ir.onwd.com>), and on the website of the Netherlands Authority for the Financial Markets ([www.afm.nl](http://www.afm.nl)).

"I am proud of the volume and significance of our team's achievements as we prepare for commercialization of our first therapy in late 2023 or early 2024," said Dave Marver, CEO of ONWARD. "We announced positive top-line results from our Up-LIFT pivotal study evaluating the use of our external ARC-EX Therapy to restore upper extremity function after spinal cord injury (SCI) and positive interim outcomes from our studies evaluating the use of our implantable ARC-IM Therapy to better regulate blood pressure after SCI. We also made progress in the development of the ARC-IM system to restore motor function, including the evaluation of our ARC-BCI platform, designed to augment ARC-IM Therapy to enable more natural movement. This first-of-its-kind system adds a brain-computer interface (BCI) that records a person's intention to move and directs our spinal cord stimulation platform to enable that movement with ARC-IM Therapy.

We added impactful talent to our Board of Directors and leadership team over the past 12 months. These new additions will help ONWARD scale and reach its vast potential. We are now implementing the operational and commercial capabilities required to successfully launch our first therapy.

We expect several important milestones in 2023, including the first-in-human use of the ARC-IM Lead, the commencement of mobility studies for both SCI and Parkinson's disease, the first-in-human use of the ARC-BCI platform to restore upper extremity function, the publication of detailed results from our Up-LIFT pivotal study, and regulatory clearance and first commercial sale of the ARC-EX device. It is an exciting time to be at ONWARD, and we are deeply motivated by the imperative to help people with SCI, their caregivers, and others with paralysis and movement disabilities."

The Company's financial and operating highlights for 2022 and early 2023 include the following:

### **Innovation and Clinical Development:**

- In May 2022, the first participant was enrolled in the HemON feasibility study, a precursor to the Company's planned pivotal trial, EMPOWER BP, evaluating ARC-IM Therapy to improve blood pressure regulation after SCI. This was also the first human use of the ARC-IM implantable pulse generator (IPG), a proprietary, purpose-built implantable neurostimulator.

- In September 2022, ONWARD reported positive top-line results from its pivotal study, Up-LIFT, evaluating ARC-EX Therapy to restore movement after SCI. The study achieved its primary effectiveness endpoint of clinically meaningful improvement in upper extremity strength and function.
- In October 2022, the Company released data from the LIFT Home observational study, which evaluated the usability of ARC-EX Therapy in the home setting. Approximately 97% of at-home sessions were completed without usability issues, supporting the feasibility of home-based therapy.
- In December 2022, the Company reported positive interim clinical outcomes from the first ten people treated to better regulate blood pressure with ARC-IM Therapy. The therapy improved blood pressure levels in all study participants, who also reported improved quality of life, increased energy and vitality, and reduced dizziness.
- During 2022 and early 2023, the Company added five more FDA Breakthrough Device Designation awards (BDD). ONWARD now has eight BDDs, underscoring the innovative nature of its work.

### Science and Intellectual Property (IP):

- During 2022, the Company added 24 patents to its IP portfolio, now totaling more than 330 issued and pending patents. ONWARD also obtained option rights to license IP from the Swiss Federal Institute of Technology Lausanne (EPFL) and Lausanne University Hospital (CHUV), allowing ONWARD to develop and commercialize a novel brain-computer interface (BCI) platform, called ARC-BCI, that captures brain signals and wirelessly transmits a person's intention to move to the Company's ARC-IM platform to enable more natural movement.
- In November 2022, ONWARD and research partners at EPFL and CEA-Clinattec were awarded a grant from the European Innovation Council (EIC) to further develop ARC-BCI to restore mobility and upper limb function in people with SCI.
- The Company was also the First Place Winner of the 2022 BCI Award, which was granted to ONWARD and its research partners for their submission, "Walking naturally after spinal cord injury using a brain-spine interface."
- Several important articles were published in major scientific journals during 2022. These included:
  - In February 2022, *Nature Medicine* published results of the STIMO study highlighting the use of ARC-IM Therapy to enable people with even the most severe forms of SCI to stand and walk again;
  - in April 2022, *New England Journal of Medicine* published the use of ONWARD's innovative approach to treating orthostatic hypotension (low blood pressure) in a patient with MSA-P, a severe form of Parkinson's disease;
  - in June 2022, *Nature Neuroscience* published pre-clinical research showing the potential for ONWARD ARC-IM Therapy to restore movement and function in hands and arms after SCI;
  - in November 2022, *Nature* published pioneering work from ONWARD's research partners at NeuroRestore identifying the precise neurons that restore walking after paralysis. This paper also detailed the results from nine participants in the STIMO trial, all of whom could stand and walk with the benefit of ARC-IM Therapy.

### Corporate:

- In March 2022, the Company was added to Euronext Brussels' Bel-Small Index.
- During 2022 and early 2023, several seasoned professionals joined ONWARD, each with the talent and experience to help the Company scale and reach its full potential:

- Kristina Dziekan and Vivian Riefberg were added to the Board of Directors. Kristina formerly led international reimbursement and market access for Medtronic Neuromodulation and served in a similar role at Alcon. Vivian was a senior partner with McKinsey & Company, where she co-led the US healthcare practice and led the US government practice; Vivian is currently the David C. Walentas Jefferson Scholars Chair Professor of Practice at the Darden School of Business at the University of Virginia.
- Lara Smith Weber joined as CFO and Zouhir Mechta as VP Operations. After spending nearly 20 years in various finance leadership roles in Europe, Lara led the Nasdaq IPO for MorphoSys. Zouhir brings expertise gained during a long career in operations leadership for Johnson & Johnson (J&J) and Dentsply Sirona.
- Erika Ross, VP Global Clinical & Regulatory and Sarah Moore, VP Global Marketing, joined ONWARD in early 2023. Erika was most recently at Abbott Neuromodulation, where she led clinical activities for their neuromodulation franchise, and was previously at Cala Health, where she managed the scientific research program that led to de novo clearance and launch of the company's neurostimulation technology. Sarah joined from Nevro, an implantable neuromodulation company, where she served as Head of Commercial Marketing; she previously held various leadership roles in global marketing across multiple J&J medical device franchises.

#### Financial:

- ONWARD reported an operating loss of EUR 32.0M in 2022, compared to EUR 28.6M in 2021.
- The Company ended the year with net cash of EUR 61.8M (2021: EUR 89.4M).
- Management reiterated its guidance of a cash runway through the end of 2024.

"We expect our current cash to propel operations through the end of 2024, providing us a sound financial base as we grow the Company and prepare for commercial operations in 2023," commented Lara Smith Weber, CFO of ONWARD.

#### Full Year Financial Summary:

<i>For the twelve-month period ended December 31</i>		
<i>In EUR millions, except for per-share data</i>	<b>2022</b>	<b>2021</b>
Total Revenues & Other Income	2.1	1.4
Total Operating Expenses	(34.2)	(30.0)
<b>Operating Loss for the Period</b>	<b>(32.0)</b>	<b>(28.6)</b>
Net Finance Expense	(1.5)	(5.7)
Income Tax Expense	0.8	(0.0)
<b>Net Loss for the Period</b>	<b>(32.8)</b>	<b>(34.3)</b>
<b>Basic (and diluted) Earnings per Share (in EUR)</b>	<b>(1.09)</b>	<b>(3.62)</b>

<i>At</i>	<b>31 Dec. 2022</b>	<b>31 Dec. 2021</b>
Net cash at the end of the period	61.8	89.4

### **Total Revenues & Other Income**

Other Income, mainly grant income, increased to EUR 2.1M (2021: EUR 1.4M) following an increase in US Defense Advanced Research Projects Agency (DARPA) funding and new grants received from the European Innovation Council (EIC) and SMEs Executive Agency (EISMEA) and Eurostars. The new grants support work on BCIs to reverse upper- and lower-limb paralysis as well as closed-loop control of blood pressure for people with SCI.

### **Total Operating Expenses**

Total Operating expenses increased during 2022 by EUR 4.2M to EUR 34.2M (2021: EUR 30.0M). As part of this, Research & Development expenses increased from EUR 10.6M in 2021 to EUR 13.1M in 2022, driven by advancements made with the ARC-EX and ARC-IM platforms. Additionally, Clinical expenses increased from EUR 4.8M in 2021 to EUR 5.7M in 2022, primarily due to the completion of the Up-LIFT and LIFT Home clinical trials. Marketing and Market Access expenses increased from EUR 1.5M in 2021 to EUR 2.0M in 2022 and include preparations for launch in the US and Europe, as well as attendance at key events to raise awareness of ARC Therapy among key customer groups. General and Administrative expenses were stable, decreasing slightly from EUR 10.7M in 2021 to EUR 10.6M in 2022.

### **Net Finance Expense**

Net Finance expense decreased from EUR 5.7M in 2021 to EUR 1.5M in 2022. The 2021 expense included the interest on the Company's sources of funding from our innovation loan from Rijksdienst voor Ondernemend (RVO, a Dutch government funding vehicle for entrepreneurial ventures), our convertible loan (CLA), and the accrued dividend of preference A shares. Both the CLA and preference A shares converted to ordinary shares in October 2021. The 2022 expense is related to the innovation loan from RVO NL plus bank interest paid on our positive cash balance.

### **Net Loss for the Period**

The Company realized a Net Loss for the period of EUR 32.8 million vs. EUR 34.3 million in 2021. The decrease is driven by a lower Net Finance expense (see above).

### **Net Cash Position**

The Company ended the year with a net cash position of EUR 61.8M (2021: EUR 89.4M), comprising of cash and cash equivalents of EUR 41.8M and fixed term deposits of EUR 20.0M. Cash outflow from operating activities increased from EUR 19.9M in 2021 to EUR 26.7M in 2022 due to higher operating costs, partially offset by a decrease in non-cash adjustments (relating to share-based compensation and net finance costs) and a positive change in working capital.

### **Outlook**

ONWARD expects to achieve several important milestones in 2023:

- The Company plans to submit a de novo application for FDA clearance of its ARC-EX system during 2023, which ONWARD anticipates will result in regulatory authorization

to commercialize that platform in the US in late 2023 or early 2024. The Company aims to obtain CE mark and European authorization in early 2024.

- The Company intends to publish detailed results from its Up-LIFT pivotal study for ARC-EX Therapy.
- ONWARD expects first-in-human use of its ARC-IM Lead, a purpose-designed lead that is optimized for placement along the spinal cord to stimulate the dorsal roots to restore mobility and autonomic function after SCI.
- The Company expects first-in-human use of ARC-BCI, its brain-computer interface platform. ONWARD is investigating ARC-BCI as its second-generation implantable platform to enable movement. The BCI platform harvests brain signals and wirelessly transmits a person's intention to move to the Company's ARC-IM system to enable more natural movement.
- ONWARD plans to continue to strengthen its organizational capabilities in preparation for the expected launch of ARC-EX in late 2023 or early 2024, recruiting field sales and service professionals and adding operational systems that will enable the Company to conduct commerce once FDA clearance and CE mark are received for the ARC-EX system. ONWARD will continue to recruit outstanding leaders with global experience and functional expertise who can help to scale effectively and realize the Company's significant potential as a business.
- In 2023, ONWARD plans to pursue opportunities to further strengthen its balance sheet and extend its cash runway to support future investments in product development, the conduct of clinical trials, and the addition of operational and commercial capabilities.

### Conference Call & Webcast

ONWARD will host a conference call with live webcast on March 28, 2023, at 2:00 PM CEST / 08:00 AM EDT. The webcast can be accessed on the News and Events page of the Company's website or by clicking [here](#). A webcast replay will be available after the call at the same location.

The Company's Annual Report 2022 is available [here](#), on the Company's website in the Investors section (<https://ir.onwd.com>), and on the website of the Netherlands Authority for the Financial Markets ([www.afm.nl](http://www.afm.nl)).

### 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 eight Breakthrough Device Designations from the US FDA encompassing both ARC-IM and ARC-EX. 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 US 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](https://onwd.com). To access our 2023 Financial Calendar, please visit [IR.ONWD.com](https://ir.onwd.com).

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