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ONWARD Reports First Half 2022 Financial and Operating Results

Company also Provides Business Update and Reiterates 2022 Outlook

Conference call and webcast (in English) today, September 27, 2022, at 4:00 PM CEST
(3:00 PM BST/10:00 AM EDT)

EINDHOVEN, the Netherlands, LAUSANNE, Switzerland & BOSTON, MA USA — September 27, 2022, 7:30 CET– 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 first half 2022 financial and operating results.

The Company's financial and operating highlights include the following:

Clinical Development:

- In September 2022, ONWARD reported positive top-line results from its pivotal study evaluating the ability of ARC-EX to improve arm and hand function in people with spinal cord injury (SCI).
- In June 2022, enrollment completed in the LIFT Home study, evaluating ARC-EX in the home setting, with 17 participants at 5 leading research centers across the United States.
- In May 2022, the first patient was enrolled in the HemON feasibility study, a precursor to the upcoming planned pivotal trial with ARC-IM for blood pressure and trunk control. This was the first time that the Company's ARC-IM implantable pulse generator (IPG) was used in a human.

Financial:

- ONWARD reported an operating loss of EUR 15,1 million for the first six months of 2022 compared to EUR 9,3 million in the same period of 2021.
- The Company ended the six-month period with a positive cash balance of EUR 76,8 million (31 December 2021: EUR 89,4 million). The decrease in cash of EUR 12,6 million compared to 31 December 2021 is due to cash outflows mainly for operating activities.
- Management reiterated its guidance of a cash runway through the end of 2024.

Corporate:

- In March 2022, the Company was added to Euronext Brussels' BEL Small Index.
- In April, Bryan, Garnier & Co, a leading investment bank focused on growth companies, initiated research coverage on the Company with a buy rating and target price of EUR 17,00 per share.
- The Company hired Zouhir Mechta as Vice President Operations in May 2022 and Lara Smith Weber as Chief Financial Officer in June 2022.
- In June 2022, former Alcon and Medtronic executive, Kristina Dziekan, was appointed to the Board of Directors, bringing extensive experience in market access and reimbursement across global markets and specific industry experience in neuromodulation.

Science & Intellectual Property:

- From January to June 2022, the Company added 24 patents to its IP portfolio, now totaling over 330 issued and pending patents covering a broad range of technologies and activities.
- In February 2022, results of the STIMO study, which highlighted the use of ARC-IM Therapy to enable people with even the most severe forms of spinal cord injury to stand and walk again, were published in the journal Nature Medicine and highlighted in major media outlets around the globe.
- In March 2022, the Company reported that it had obtained rights to breakthrough innovations in brain-spine interface and Parkinson’s disease from the Swiss Federal Institute of Technology Lausanne (EPFL) and Lausanne University Hospital (CHUV).
- In April 2022, the New England Journal of Medicine highlighted the use of ONWARD’s innovative approach to treating orthostatic hypotension (low blood pressure) in a patient with MSA-P, a form of Parkinson’s disease that affects the sympathetic nervous system.
- In June 2022, research published in Nature Neuroscience showed the potential for ONWARD’s ARC-IM Therapy to restore movement and function in hands and arms after spinal cord injury.

“In the first half of 2022, we continued to execute against our strategy – advancing development of our technology, enlarging our IP portfolio, validating our therapies through clinical milestones, and strengthening our organizational capabilities,” said Dave Marver, CEO of ONWARD. “We are very pleased with the excellent results from the Up-LIFT study that we announced earlier this month and are now focusing on preparing regulatory submissions for ARC-EX. We are hopeful we can begin to positively impact the lives of people with spinal cord injury sometime during the second half of 2023.”

“We expect our current cash to propel operations through the end of 2024 and support our planned investments in product development, clinical trials, operational capabilities, and commercial launch in 2023,” commented Lara Smith Weber, CFO of ONWARD. “ONWARD is well prepared for its next chapter as a commercial organization, and we are ready to grow the Company in the years ahead for the benefit of our stakeholders.”

First Half 2022 Financial Summary:

<i>In EUR millions</i> <i>For the six-month period ended June 30,</i>	2022	2021
Total Revenues & Other Income	1,0	0,6
Total Operating Expenses	(16,1)	(9,8)
Operating Loss for the Period	(15,1)	(9,3)
Net Finance Expenses	(0,9)	(2,9)
Income Tax Expenses	(0,0)	(0,0)
Net Loss for the Period	(16,0)	(12,2)
Basic (and diluted) Earnings per Share (in EUR)	(0,53)	(3,14)
<i>At</i>	30 June 2022	31 Dec. 2021
Cash position at the end of the period	76,8	89,4
Interest Bearing Loans	(12,0)	(11,5)
Equity	68,9	82,7

Total Revenues & Other Income

Other Income during the first six months of 2022 increased to EUR 1,0 million (H1 2021: EUR 0,6 million), following a new grant from the European Innovation Council and SMEs Executive Agency (EISMEA) focusing on brain-spine interfaces to reverse upper- and lower-limb paralysis.

Total Operating Expenses

Total Operating Expenses increased during H1 2022 by EUR 6,3 million to EUR 16,1 million. The increase in operating expenses included EUR 2,9 million of additional Research & Development Expenses, driven by increased staff and outsourced development expenses associated with the Company's ARC Therapies. It also included clinical expenses of EUR 3,0 million, an increase of EUR 1,1 million compared to the same period in the prior year, as a result of the Up-LIFT and LIFT Home studies. Lastly, General & Administrative Expenses showed an increase of EUR 1,6 million compared to the same period in the prior year due to the costs associated with being a public company following the Euronext listing in October 2021.

Net Finance Expense

Net Finance Expense decreased during the first six months of 2022 by EUR 2 million compared to H1 2021. The costs in H1 2021 included interest on the Company's innovation loan from RVO NL (Dutch government), the convertible loan (CLA), and the accrued dividend for the preference A shares. Both the CLA and preference A shares converted in October 2021. The expense for H1 2022 relates to the innovation loan from RVO NL and bank interest paid on the positive cash balance.

Cash Position

The Company ended the six-month period with a positive cash balance of EUR 76,8 million on 30 June 2022 (31 December 2021: EUR 89,4 million). The decrease in cash of EUR 12,6 million compared to 31 December 2021 is due to cash outflows mainly for operating activities.

Interest-bearing Loans

Interest-bearing Loans increased from 31 December 2021 by EUR 0,5 million to EUR 12 million, due to the interest that accumulated on the innovation loan from RVO NL (Dutch government).

Equity

The Company's positive Equity position of EUR 82,7 million at year-end 2021 decreased to EUR 68,9 million on 30 June 2022. The decrease related to the operating loss for the period of EUR 16 million, mitigated by positive reserve items related to the share-based payment expense of EUR 0,8 million, the revaluation of defined benefit obligation through comprehensive income of EUR 0,7 million, and the foreign currency translation impact of U.S. operations of EUR 0,6 million.

Outlook

ONWARD's management expects to continue the steady and consistent execution of its strategy in the second half of 2022 and beyond.

Following positive top-line data from its first pivotal study, Up-LIFT, ONWARD announced plans to submit for regulatory approval in the US and EU late this year or in early 2023 to allow the Company to commercialize ARC-EX for the improvement of upper extremity strength and function in patients with SCI. These authorizations are expected in the second half of 2023.

In the second half of 2022, top-line data from the LIFT Home study are expected. The Company plans to discuss findings from LIFT Home with regulatory authorities to determine the requirements to gain clearance to market ARC-EX for home use, including the design and scope of a potential pivotal study for the home setting, should this be necessary.

Also in the second half of 2022, the Company expects to release combined top-line data from the STIMO-HEMO and HemON studies. Both studies are exploring the use of ARC-IM Therapy to normalize low blood pressure and provide enhanced trunk control 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 top-line data from current clinical feasibility studies for ARC-IM, providing important clinical validation of both of its major technology platforms.

The Company expects to continue building its team and capabilities in preparation for launch of its ARC-EX Therapy in the second half of 2023, both operationally and commercially. In late 2022 or early 2023, ONWARD plans to place even greater focus on recruiting for sales, marketing, and field service roles to cover the US and select European markets.

Organizational enhancements extend to the Company's Board of Directors, which this September added Vivian Riefberg, a highly accomplished expert in healthcare, government, and strategy. In 2020, Ms. Riefberg retired as a senior partner with McKinsey & Company, where she held a variety of senior positions, including leader of the Public Sector Practice for the Americas and co-leader of the U.S. Healthcare practice. She served on McKinsey & Company's global board of directors and on the committee evaluating and developing global partners. Ms. Riefberg is currently Professor of Practice at the University of Virginia Darden School of Business where she holds the David C. Walentas Jefferson Scholars Chair.

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 live webcast today at 4 pm CET / 10 am EDT. The webcast may be accessed on the News and Events page of the Company's website or by clicking [here](#). A replay of the webcast will be available on the ONWARD website.

The Half-Year Report 2022 is available on the Company's website in the Investors section (<https://ir.onwd.com>) and the website of the Netherlands Authority for the Financial Markets (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 three 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 at the High Tech Campus in Eindhoven, the Netherlands. It has substantial operations in Lausanne, Switzerland, and a growing U.S. presence in Boston, Massachusetts, USA. For additional information about the company, please visit ONWD.com. To access our 2022 Financial Calendar, please visit IR.ONWD.com.

For Company Enquiries:

info@onwd.com

For Media Enquiries:

MC Services AG

US: Laurie Doyle, P: +1 339 832 0752

Europe: Dr. Johanna Kobler, Katja Arnold, Kaja Skorka P: +49 89 210 228 0

media@onwd.com

For Investor Enquiries:

investors@onwd.com

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