

This announcement is relating to the intention of the Company (as defined below) to proceed with the Offering (as defined below) and the Admission (as defined below). This announcement does not constitute a prospectus. This announcement is for information purposes only and is not intended to constitute, and should not be construed as, an offer to sell or a solicitation of any offer to buy Shares (as defined below) in any jurisdiction, including the United States, Canada, Australia or Japan. If and when the Offering is launched, further details about the Offering and the Admission will be included in the Prospectus (as defined below). Once the Prospectus has been approved by the Netherlands Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*) (the "AFM"), the Prospectus will be published and made available at no cost at the start of the offer period through the corporate website of the Company ([ir.onwd.com](http://ir.onwd.com)), subject to securities law restrictions in certain jurisdictions. Furthermore, the prospectus will be made available on paper (free of charge) by the Underwriters upon request and on the websites of the Underwriters, subject to securities law restrictions. An offer to acquire Shares pursuant to the Offering will be made, and any potential investor should make their investment, solely on the basis of information that will be contained in the Prospectus and in particular the "Risk Factors" section. Potential investors should read the Prospectus (and notably the risk factors section) before making an investment decision in order to fully understand the potential risks and rewards associated with the decision to invest in the Shares. The approval of the Prospectus by the AFM should not be understood as an endorsement of the quality of the Shares and the Company (as defined below).

## **ONWARD Announces Intention to Launch an Initial Public Offering and Listing on Euronext Brussels and Amsterdam**

EINDHOVEN, the Netherlands & LAUSANNE, Switzerland--September 29, 2021--ONWARD Medical B.V. ("ONWARD" or the "Company") today announces its intention to raise new funds through an initial public offering (the "Offering") and to apply for admission to listing and trading of its ordinary shares (the "Shares") on Euronext in Brussels, a regulated market operated by Euronext Brussels SA/NV ("Euronext Brussels"), and a secondary listing on the regulated market of Euronext in Amsterdam (together with Euronext Brussels, "Euronext") (the "Admission"). The Company's largest current shareholders, LSP, INKEF Capital, Wellington Partners, and GIMV have confirmed their commitment to invest in the Offering. Additionally, new, long-term investors AXA, Belfius Insurance, and Ohman Fonder have confirmed their commitment to invest in the Offering. The Offering is expected to take place in the coming weeks, subject to market conditions and other relevant considerations.

### **Company highlights**

- ONWARD is a medical technology company developing and commercializing innovative therapies to enable functional recovery for people with spinal cord injury (SCI).
- The Company's innovative technology platform is based on ONWARD ARC™ Therapy ("ARC Therapy"), a targeted programmed electrical stimulation of the spinal cord to restore movement, independence, and health in people with spinal cord injury.
- ARC Therapy consists of two platforms, one implantable platform, named ARC<sup>IM</sup> and one external platform, named ARC<sup>EX</sup>, both targeting spinal cord injury and potentially other diseases/disorders, such as Parkinson's disease and stroke. ARC<sup>EX</sup> will initially target restoration of upper limb strength and function, while ARC<sup>IM</sup> will initially target restoration of normal blood pressure and trunk control, and mobility.
- The Company is headquartered in Eindhoven, the Netherlands, with subsidiaries in the United States and Switzerland, where it maintains an office in Lausanne.
- The future commercialization of both ARC Therapy platforms depends on receiving regulatory authorization in the regions where the Company intends to generate revenues in the coming years following approval granted by notified bodies, including the U.S. Food and Drug Administration ("FDA"). Both the ARC<sup>EX</sup> (upper extremities) and the ARC<sup>IM</sup> (mobility and blood pressure and trunk control) platforms have received Breakthrough Device Designation from the FDA in the U.S.

- Upon successful completion of a pivotal trial, a study intended to support submissions for regulatory clearances and approvals to market products for commercial sale, the Company expects to commercialize its initial product, the ARC<sup>EX</sup> platform, in the U.S. and European Union ("E.U.") in 2023. This pivotal trial (the "Up-LIFT trial"), commenced in January 2021 with plans to enroll 65 subjects at up to 15 centers worldwide.
- ONWARD then expects to commercialize the ARC<sup>IM</sup> platform, if approved, in the U.S. and E.U. in 2024 to restore normal blood pressure and trunk control. In 2025, it expects to pursue Humanitarian Device Exemption ("HDE") if approved by the FDA for the commercialization of ARC<sup>IM</sup> for mobility (walking) in the U.S. The E.U. authorization process for ARC<sup>IM</sup> for mobility is not yet determined.
- The Company is led by a strong and experienced team with a proven track record in the medical technology and neurostimulation industry and in bringing therapies to market.
- The Company is backed by investors that include international venture capital firms LSP, INKEF Capital, Wellington Partners and GIMV.

### *Company Strengths*

- The Company has a large, underserved patient population: there is no cure for SCI and the Company's therapies are among the first to offer the potential to help.
- The Company is developing and intends to market two proprietary, synergetic technology platforms (ARC<sup>EX</sup> and ARC<sup>IM</sup>): these two platforms may allow the Company to address a broad range of indications including SCI and potentially stroke and Parkinson's disease.
- The Company has already been granted three FDA Breakthrough Device Designation awards in the U.S.
- The Company's therapies can potentially be applied to multiple indications, supported by a robust research pipeline.
- The Company has a deep and comprehensive intellectual property portfolio, consisting of more than 290 issued or pending patents worldwide.
- The Company has a seasoned, international management team consisting of individuals with long-held experience in medical technology, extensive international experience, and backgrounds working at relevant companies, both private and public, large and small.
- The Company has strong validation from leading life science investors.
- The Company enjoys deep relationships with leading patient associations.
- The Company has the potential to generate significant news flow related to its therapies.

*"ONWARD has a vision to help people with SCI enjoy life in every way that matters to them. Spinal Cord Injury is a hugely underserved area for which too few therapies have been translated and commercialized,"* said Dave Marver, CEO of ONWARD. *"ONWARD is working with great determination to bring impactful new therapies to people with SCI. We are pleased to announce our intention to float on Euronext and our expectation to use new capital to bring significant value to our investors, employees and most importantly the spinal cord injury community."*

### **Impact of spinal cord injury**

Spinal cord injury results from damage to any part of the spinal cord. Depending on the severity of the injury, it becomes challenging or even impossible to transmit signals across the lesion and the injured person can lose muscle control and sensation.

While it is common to associate spinal cord injury with paralysis, people with spinal cord injury are impacted in many ways. They can experience difficulty breathing and swallowing; it can be difficult for them to modulate their temperature and blood pressure, and they frequently

experience incontinence and loss of sexual function. All of these impacts of spinal cord injury affect activities of daily life in profound ways and require expensive assistance and caregiver support.

There are approximately 650,000 people in the U.S. and E.U. living with SCI today.

Following a spinal cord injury, people undergo intensive physical therapy for three to six months. Despite the effort of dedicated rehabilitation professionals, progress often plateaus at that point.

### **The Company intends to use the expected net proceeds from the Offering as follows:**

- Fund product development and research and development activities, more specifically the development of the commercial ARC<sup>EX</sup> device and the ARC<sup>IM</sup> system including its associated lead portfolio;
- Conduct clinical trials in the U.S. and E.U. including but not limited to:
  - Feasibility and pivotal trials for the ARC<sup>IM</sup> blood pressure and trunk control indications;
  - Feasibility and pivotal trials for the ARC<sup>IM</sup> mobility indication; and,
  - Clinical trials in the U.S. and E.U. for the ARC<sup>EX</sup> upper limb indication, including evaluation of the therapy's effectiveness during use in the clinic and at home.
- Build the Company's commercial capabilities in both the U.S. and E.U. in order to begin marketing the Company's therapies. This is expected to include hiring and training of field-based sales and engineering staff, office-based customer service and technical support staff, marketing and market access staff, and the systems and infrastructure required to support those hires and to conduct commerce in the Company's target markets; and,
- General corporate purposes, including corporate staff, facilities, insurance, and other items.

### **Offer Highlights**

- ONWARD believes that the Admission and the Offering is a logical next step in its development and that its timing is appropriate, given ONWARD's current profile and level of maturity.
- The Admission will further provide ONWARD with access to capital markets, which it may use to support and develop further growth and to finance further research and/or strategic M&A transactions, as they become available.
- The Company further expects the Admission and the Offering to create a new long-term shareholder base as well as liquidity for the existing and future shareholders. It is the intention of the Company to create a meaningful free float in the Ordinary Shares on Admission.
- An application is expected to be made for the Admission of the Shares on Euronext Brussels and Euronext Amsterdam.
- The Offering is expected to consist of: (i) an initial public offering to retail and institutional investors in Belgium; (ii) a placement in the United States to persons that are reasonably believed to be qualified institutional buyers, as defined in Rule 144A under the U.S. Securities Act of 1933, as amended (the "U.S. Securities Act"); and (iii) placements to certain qualified and/or institutional investors outside Belgium and the United States. The

Offering outside the United States is expected to be made in compliance with Regulation S under the U.S. Securities Act.

- If and when the Offering is launched, further details about the Offering and the Admission will be included in the prospectus to be published by the Company in relation to the Offering and the Admission (the "Prospectus"). Once the Prospectus has been approved by the AFM, the Prospectus will (i) be notified to the Financial Services and Markets Authority in Belgium for passporting in accordance with article 25 of the Prospectus Regulation, (ii) made available on paper (free of charge) by the Underwriters upon request and on the websites of the Underwriters, and (iii) be published and made available at no cost at the start of the offering period through the corporate website of the Company (ir.onwd.com), subject to securities law restrictions in certain jurisdictions.
- At the date of the Prospectus, the Company will still be a private limited liability company (besloten vennootschap met beperkte aansprakelijkheid) named Onward Medical B.V. The Company is expected to be converted into a public company with limited liability (naamloze vennootschap) named Onward Medical N.V. ultimately on the first trading date.
- The Company has appointed Bank Degroof Petercam SA/NV and Belfius Bank NV/SA as joint global coordinators for the Offering (the "Joint Global Coordinators").

### **Prospectus and Risk Factors**

If and when the Offering is launched, further details about the Offering and the Admission will be included in the prospectus to be published by the Company in relation to the Offering and the Admission (the "Prospectus"). An investor should make its investment solely on the basis of information that will be contained in the Prospectus and in particular the "Risk Factors" section. The AFM's approval should not be considered as an endorsement of the Company or the quality of the securities that are the subject of the Prospectus.

Investing in the Shares involves certain risks. Before investing in the Shares, prospective investors should carefully consider the risks and uncertainties described in the Prospectus, together with the other information contained or incorporated by reference in the Prospectus. The following key risks relate to the Company's business, results of operations, financial condition and prospects. In selecting and ordering the risk factors, the Company has considered circumstances such as the probability of the risk materializing on the basis of the current state of affairs, the potential impact which the materialization of the risk could have on the Company's business, financial condition, results of operations and prospects, and the attention that management of the Company would on the basis of current expectations have to devote to these risks if they were to materialize.

- The Company is wholly dependent on the success of two investigational devices, the ARC<sup>IM</sup> and ARC<sup>EX</sup> platforms. Even if the Company is able to complete clinical development and obtain favorable clinical results for the initial indications it is pursuing, it may not be able to obtain regulatory clearance or approval for, or successfully commercialize, its ARC<sup>IM</sup> and ARC<sup>EX</sup> platforms;
- The Company has incurred significant operating losses since inception, and expects to incur operating losses in the future, and it may not be able to achieve or sustain profitability, which may adversely affect the market price of its Ordinary Shares and ability to raise capital and continue operations;
- The Company may require additional capital to finance its planned operations, which may not be available to it on acceptable terms or at all. This may adversely affect the Company's sales and marketing plan, its ongoing research and development efforts and have a material adverse effect on its business, financial condition, and result of operations;

- The Company may face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than it does;
- Enrollment and retention of patients in clinical trials, including its Up-LIFT pivotal clinical trial for ARC<sup>EX</sup>, is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside its control, which could cause significant delays in the completion of such trials or may cause it to abandon one or more clinical trials;
- The Company must obtain FDA clearance or approval before it can sell any of its products in the United States and CE Certification before it can sell any of its products in the European Union. Approval of similar regulatory authorities in countries outside the United States and the European Union is required before it can sell its products in countries that do not accept FDA clearance or approval or CE Certification. The Company may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of its products if such clearance or approval is denied or delayed;
- If the Company obtains clearance or approval for its products, their commercial success will depend in part upon the level of reimbursement it receives from third parties for the cost of its products to users;
- If its investigational devices are cleared or approved, the Company will need to receive access to hospital facilities and clinics, or its sales may be negatively impacted;
- The Company may not receive the necessary approvals, granted de novo classifications, or clearances for its ARC<sup>EX</sup> and ARC<sup>IM</sup> platforms or future devices and expanded indications, and failure to timely obtain these regulatory clearances or approvals would adversely affect its ability to grow its business;
- The clinical development process required to obtain regulatory clearances or approvals is lengthy and expensive with uncertain outcomes, and the data developed in those clinical trials is subject to interpretation by FDA and foreign regulatory authorities. If clinical trials of the current ARC<sup>EX</sup> platform and ARC<sup>IM</sup> platform and future products do not produce results necessary to support regulatory clearance or approval, a granted de novo classification or clearance in the United States or, with respect to the Company's current or future products, elsewhere, it will be unable to commercialize these products and may incur additional costs or experience delays in completing, or ultimately be unable to complete, the commercialization of those products;
- Breakthrough Device Designation by the FDA does not guarantee regulatory clearance or approval and may not actually lead to a faster development or regulatory review or clearance or approval process, which may impact the Company's ability to develop its investigational devices in a timely manner, or at all, and could have a material adverse effect on its business;
- Part of the Company's assets, including intellectual property is pledged to Rijksdienst voor Ondernemend Nederland (RvO part of Dutch ministry of Economic Affairs), and the enforcement of such pledge could substantially harm the future development and operations of the Company; and
- The Company licenses certain technology underlying the development of its investigational devices and the loss of the license would result in a material adverse effect on its business, financial position, and operating results and cause the market value of its Ordinary Shares to decline.
- The payment of any future dividends will depend on the Group's financial condition and results of operations, as well as on the Company's operating subsidiaries' distributions to the Company;

- The fact that no minimum amount is set for the Offering may affect the Company's investment plan and the liquidity of the Shares; and
- Certain significant shareholders of the Company after the Offering may have different interest from the Company and may be able to control the Company, including the outcome of shareholder votes.

Investors should read, understand and consider all risk factors which will be included in the Prospectus, which should be read in its entirety before making an investment decision to invest in the Shares. The occurrence of any of the events or circumstances described in the risk factors chapter in the Prospectus, individually or together with other circumstances, could have a material adverse effect on the Company's business, results of operations, financial condition and prospects. In that event, the value of the Shares could decline, and an investor might lose part or all of its investment.

### **About ONWARD**

ONWARD is a medical technology company creating innovative therapies to restore movement, independence, and health in people with spinal cord injury. 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<sup>IM</sup>) or external (ARC<sup>EX</sup>) systems, is designed to deliver targeted, programmed stimulation of the spinal cord 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 FDA encompassing both ARC<sup>IM</sup> and ARC<sup>EX</sup>. The company's first FDA pivotal trial, called Up-LIFT, commenced in January 2021 with plans to enroll 65 subjects at up to 15 centers worldwide.

ONWARD is headquartered at the High Tech Campus in Eindhoven, the Netherlands. It maintains an office at the EPFL Innovation Park in Lausanne, Switzerland and has a growing U.S. presence in Boston, Massachusetts, USA. For additional information about the company, please visit [ONWD.com](https://onwd.com).

## Disclaimer

*This announcement is not for release, distribution or publication, whether directly or indirectly and whether in whole or in part, in or into the United States, Canada, Australia, South Africa or Japan or any other jurisdiction where to do so would constitute a violation of the relevant laws of such jurisdiction.*

*This announcement is not an advertisement and for information purposes only, does not purport to be full or complete and is not intended to constitute, and should not be construed as, an offer to sell or a solicitation of any offer to buy the Securities in any jurisdiction, including the United States, Canada, Australia, South Africa or Japan. No reliance may be placed by any person for any purpose on the information contained in this announcement or its accuracy, fairness or completeness.*

*This announcement does not contain, constitute, or form part of, an offer to sell, or a solicitation of an offer to purchase, any Securities in the United States. The Securities have not been and will not be registered under the U.S. Securities Act of 1933, as amended (the "Securities Act"), and may not be offered or sold within the United States absent registration or pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the Securities Act. There is no intention to register the Securities in the United States or to make a public offering of the Securities in the United States. The Company has not authorised any offer to the public of Securities in any Member State of the European Economic Area, other than in Belgium. With respect to any Member State of the European Economic Area, other than Belgium (each a "Relevant State"), no action has been undertaken or will be undertaken to make an offer to the public of securities requiring publication of a prospectus in any Relevant State. As a result, the Securities may only be offered in Relevant States (i) to any legal entity which is a qualified investor as defined in the Prospectus Regulation (EU) No. 2017/1129, as amended (the "Prospectus Regulation"); or (ii) in any other circumstances falling within Article 1(4) of the Prospectus Regulation. For the purpose of this paragraph, the expression "offer of securities to the public" means the communication in any form and by any means of sufficient information on the terms of the offer and the Securities to be offered so as to enable the investor to decide to exercise, purchase or subscribe for the Securities. In Belgium, an offer to the public of securities may not be made except pursuant to a prospectus that has been passported in Belgium. This implies that the prospectus is passported by the AFM to the Belgian Financial Services and Markets Authority.*

*The Company has not authorised any offer to the public of Securities in the United Kingdom. With respect to the United Kingdom no action has been undertaken or will be undertaken to make an offer to the public of securities requiring publication of a prospectus in the United Kingdom. As a result, the Securities may only be offered in the United Kingdom (i) to any legal entity which is a qualified investor within the meaning of Article 2(e) of Regulation (EU) No. 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018 ("**UK Prospectus Regulation**"); or (ii) in any other circumstances falling within Article 1(4) of the UK Prospectus Regulation. For the purpose of this paragraph, the expression "offer of securities to the public" means the communication in any form and by any means of sufficient information on the terms of the offer and the Securities to be offered so as to enable the investor to decide to exercise, purchase or subscribe for the Securities.*

*This does not constitute a prospectus within the meaning of the Prospectus Regulation and does not constitute an offer to acquire securities. Any offer to acquire Securities will be made, and any investor should make his investment, solely on the basis of information that will be contained in*

*the Prospectus to be made generally available in Belgium in connection with the Offering. When made generally available, copies of the Prospectus may be obtained at no cost from the Company or through the website of the Company. The information in this announcement is subject to change.*

*In the United Kingdom, this announcement is only being distributed to, and is only directed at, and any investment or investment activity to which this announcement relates is available only to, and will be engaged in only with, "qualified investors" within the meaning of Article 2(e) of UK Prospectus Regulation who are also (i) persons having professional experience in matters relating to investments who fall within the definition of "investment professionals" in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "**Order**"); or (ii) persons who are high net worth entities falling within Article 49(2)(a) to (d) of the Order, or (iii) persons to whom it may otherwise be lawfully communicated (all such persons together being referred to as "relevant persons"). Persons who are not relevant persons in the United Kingdom should not take any action on the basis of this announcement and should not act or rely on it.*

*No action has been taken by the Company that would permit an offer of securities or the possession or distribution of this announcement or any other offering or publicity material relating to such Securities in any jurisdiction where action for that purpose is required.*

*The release, publication or distribution of this announcement in certain jurisdictions may be restricted by law and therefore persons in such jurisdictions into which they are released, published or distributed, should inform themselves about, and observe, such restrictions.*

*This announcement may include statements, including the Company's financial and operational medium-term objectives that are, or may be deemed to be, "forward-looking statements" within the meaning of the United States federal securities laws. These forward-looking statements may be identified by the use of forward-looking terminology, including the terms "believes", "estimates", "plans", "projects", "anticipates", "expects", "intends", "may", "will" or "should" or, in each case, their negative or other variations or comparable terminology, or by discussions of strategy, plans, objectives, goals, future events or intentions. Forward-looking statements may and often do differ materially from actual results. Any forward-looking statements reflect the Company's current view with respect to future events and are subject to risks relating to future events and other risks, uncertainties and assumptions relating to the Company's business, results of operations, financial position, liquidity, prospects, growth or strategies. Forward-looking statements speak only as of the date they are made. The Company and its affiliates expressly disclaims any obligation or undertaking to update, review or revise any forward looking statement contained in this announcement whether as a result of new information, future developments or otherwise, except to the extent required by applicable law.*

*None of the Underwriters or any of their respective subsidiary undertakings, affiliates or any of their respective directors, officers, employees, advisers, agents, alliance partners or any other entity or person accepts any responsibility or liability whatsoever for, or makes any representation, warranty or undertaking, express or implied, as to the truth, accuracy, completeness or fairness of the information or opinions in this announcement (or whether any information has been omitted from this announcement) or any other information relating to the group, its subsidiaries or associated companies, whether written, oral or in a visual or electronic form, and howsoever transmitted or made available or for any loss howsoever arising from any use of this announcement or its contents or otherwise arising in connection therewith. Accordingly, the Underwriters disclaim, to the fullest extent permitted by applicable law, all and any liability,*



*whether arising in tort or contract or that they might otherwise be found to have in respect of this announcement and/or any such statement.*

*In connection with the Offer, each of the Underwriters and any of their affiliates, may take up a portion of the Securities in the Offering as a principal position and, in that capacity, may retain, purchase, sell, offer to sell for its own account such Securities and other securities of the Company or related investments in connection with the Offering or otherwise. In addition, each of the Underwriters and any of their affiliates may enter into financing arrangements (including swaps or contracts for differences) with investors in connection with which each of the Underwriters and any of their affiliates may from time to time acquire, hold or dispose of Securities. None of the Underwriters or their affiliates intends to disclose the extent of any such investment or transactions otherwise than in accordance with any legal or regulatory obligations to do so.*

*For the avoidance of doubt, the contents of the Company's website are not incorporated by reference into, and do not form part of, this announcement.*