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ADMISSION TO LISTING AND TRADING OF 11,300,000 NEW SHARES IN ONWARD MEDICAL N.V. ON THE REGULATED MARKETS OF EURONEXT BRUSSELS, EURONEXT AMSTERDAM AND EURONEXT PARIS

This information document (the "**Information Document**"), dated October 24, 2025 is made available pursuant to Article 1(5)(ba) and Annex IX of Regulation (EU) 2017/1129, as amended (the "**Prospectus Regulation**") in connection with the admission to trading on (i) the regulated market of Euronext Brussels ("**Euronext Brussels**"), (ii) the regulated market of Euronext Amsterdam ("**Euronext Amsterdam**") and (iii) the regulated market of Euronext Paris ("**Euronext Paris**") of new shares to be issued by ONWARD Medical N.V. (the "**Company**," and together with its consolidated subsidiaries, the "**Group**") in connection with a share capital increase without pre-emption rights for a gross amount of € 50,850,000 consisting of the issuance of 11,300,000 new ordinary shares of the Company with a par value of €0.12 per share (the "**New Shares**") which were placed with qualified investors in a private placement outside the United States in reliance on Regulation S under the US Securities Act of 1933, as amended, (the "**Securities Act**") and in the United States to "qualified institutional buyers" as defined in Rule 144A under the Securities Act in transactions exempt from, or not otherwise subject to, the registration requirements of the Securities Act in reliance on Section 4(a)(2) of the Securities Act.

An investment in the Company's shares involves substantial risks and uncertainties and investors could lose all or part of their investment. Prospective investors must be able to bear the economic risk of an investment in the Company's shares and should be able to sustain a total or partial loss of their investment. Prospective investors should carefully consider the information contained in this Information Document (and the documents referred to therein) and, in particular Section 8 (Risk Factors) below, before investing in the Company's shares.

1. INFORMATION ABOUT THE COMPANY

The Company is a Dutch public company with limited liability (*naamloze vennootschap*), incorporated under the laws of the Netherlands, whose registered office is located at Schimmelt 2, 5611 ZX Eindhoven, the Netherlands, registered with the Dutch Chamber of Commerce under number 64598748 and whose Legal Entity Identifier (LEI) number is 9845007A2CC4C8BFSB80. The website of the Company is: www.onwd.com. The Company is a commercial stage medical technology company developing innovative therapies to enable functional recovery for people with spinal cord injury.

2. BOARD OF DIRECTORS' RESPONSIBILITY STATEMENT

The Company, represented by its board of directors (the "**Board of Directors**"), is solely responsible for the content of the Information Document. To the best of the Company's knowledge, represented by its Board of Directors, the information provided herein is in accordance with the facts and the Information Document makes no omission likely to affect its import.

3. COMPETENT AUTHORITY

The competent authority in the Netherlands pursuant to Article 20 of the Prospectus Regulation is the Dutch Authority for the Financial Markets ("**AFM**") (Vijzelgracht 50, 1017 HS AMSTERDAM, the Netherlands).

The Information Document does not constitute a prospectus within the meaning of the Prospectus Regulation and has not been subject to scrutiny and approval by the AFM.

4. STATEMENT ON REPORTING OBLIGATIONS

In conformity with applicable reporting and disclosure obligations throughout the period in which the Company's shares have been admitted to listing and trading on Euronext Brussel, Euronext Amsterdam and Euronext Paris, including under Directive 2004/109/EC of the European Parliament and of the Council of December 15, 2004 on the harmonization of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market and amending Directive 2001/34/EC, as amended, Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014 on market abuse and repealing Directive 2003/6/EC of the European Parliament and of the Council and Commission Directives 2003/124/EC, 2003/125/EC and 2004/72/EC, as amended ("**MAR**"), and Commission Delegated Regulation (EU) 2017/565 of 25 April 2016 supplementing Directive 2014/65/EU of the European Parliament and of the Council as regards organizational requirements and operating conditions for investment firms and defined terms for the purposes of that Directive, as amended (MiFID II Delegated Regulation 565), in each case as far as applicable, the Company has published via press releases available on its website <https://ir.onwd.com/news-events> and the website of the AFM on www.afm.nl all "inside information" as defined under the MAR, as well as required periodic financial statements (available at <https://ir.onwd.com/financial-information>).

5. AVAILABLE INFORMATION

Each investor is encouraged to make their own assessment regarding the suitability of investing in the Company. The regulated information published by the Company pursuant to its ongoing disclosure obligations is available on its website (<https://ir.onwd.com/news-events>), including the most recent prospectus of the Company prepared in accordance with the Prospectus Regulation, dated October 24, 2024 which is available via <https://ir.onwd.com/static-files/cfb66402-d0ec-4c2d-ab60-bd74e916588c> and on the website of the AFM (www.afm.nl).

6. STATEMENT ON DISCLOSURE OF INSIDE INFORMATION

Not applicable, as no public offering for the New Shares has been made.

7. REASON FOR THE ISSUANCE AND USE OF PROCEEDS

On October 23, 2025, the Company's pricing committee on behalf of the Board of Directors resolved to issue the New Shares without pre-emption rights for the Company's existing shareholders. The resolution was based on an authorization granted to the Board of Directors by the Company's general meeting on June 11, 2025.

The Company will raise gross proceeds of € 50,850,000 through the issuance of the New Shares. The net proceeds from the issue of the New Shares are expected to be together with the existing cash balance as follows:

- Fund development initiatives, including but not limited to product development, clinical studies and regulatory activities for the investigational ARC-IM System to address blood pressure instability in people with spinal cord injury (40%);
- Expand sales and operations to support commercialization of the ARC-EX System in the United States, Europe and select other geographies (30%);
- Support and scale quality and administrative activities (20%);
- Fund working capital and other general corporate purposes (5%); and
- Cover financing costs including existing debt obligation (5%).

8. RISK FACTORS

The Company operates in a fast-changing environment involving numerous risks, some of which are beyond its control. Before purchasing shares in the Company, investors are invited to examine all the information contained in the risks described in this Section 8. These risks are those that the Company considers likely to have a material adverse effect on the Company, its business, prospects, financial situation, results and development, and which it considers important in making an investment decision. Investors' attention is however drawn to the fact that the list of risks presented in this Section 8 is not exhaustive. The occurrence of any of the events or circumstances described in these risk factors, individually or together with other circumstances, could have a material adverse effect on the Group's (as defined above) business, results of operations, financial condition and prospects. In that

event, the value of your investment could decline, and an investor might lose part or all of its investment. In selecting the risk factors, the Group 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 Group's business, financial condition, results of operations and prospects, and the attention that management of the Group would, on the basis of current expectations, have to devote to these risks if they were to materialize. Although the Group believes that the risks and uncertainties described below are the material risks and uncertainties concerning the Group's business and the shares, they are not the only risks and uncertainties relating to the Group and the shares. Other risks, facts or circumstances not presently known to the Group, or that the Group currently deems to be immaterial, could, individually or cumulatively, prove to be important and could have a material adverse effect on the Group's business, results of operations, financial condition and prospects. The value of the Company's shares could decline as a result of the occurrence of any such risks, facts or circumstances, or as a result of the events or circumstances described in these risk factors, and investors could lose part or all of their investment.

These risks include, among others, the following:

8.1 Risks related to the Company's Financial Position and need for Additional Capital

- The Company is not profitable and has incurred significant operating losses each year since beginning its operations in 2014, which is due to a lack of a meaningful commercial operating history upon which to evaluate its business and prospects. Consequently, any predictions about its future success, performance or viability may not be as accurate as they could be if it had a longer operating history or commercial revenues.
- Despite receiving de novo classification by the US Food and Drug Administration (the "FDA") to commercialize its first product (ARC^{EX} for clinic use), deriving sufficient revenues to support operations are not imminent, as the Company's activities continue to consist of developing its technology, conducting pre-clinical studies and clinical trials, and investing in activities relating to commercialization, leading to a net loss for the six months period ended June 30, 2025 of EUR 21.2 million and EUR 35.7 million for the fiscal year ended December 31, 2024. To date, the Company has financed its operations primarily through equity financings, grant funding and interest-bearing loans.
- The current or future clinical trials of any of its current or future investigational devices are, and the manufacturing and marketing of any such investigational devices will be, subject to extensive and rigorous review and regulation by the FDA and other government authorities in the United States and in other countries where the Company intends to test and, if cleared or approved, market such investigational devices. The Company expects that its operating expenses will continue to increase as it continues research and development activities, seeks FDA regulatory clearances and approvals in the United States, regulatory approvals in Europe, and potentially other regulatory approvals in other jurisdictions, builds its commercial infrastructure and incurs additional operational costs associated with being a public company.
- Even if it does achieve profitability, it may not be able to sustain or increase profitability in subsequent periods or on an ongoing basis. If the Company does not achieve or sustain profitability, it will be more difficult for it to finance its business and accomplish its strategic objectives, either of which would have a material and adverse effect on its business, financial condition and results of operations.
- The Company may need to raise additional capital, and if it raises additional capital through public or private equity offerings, the ownership interest of its existing shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect its existing shareholders' rights. If the Company raises additional capital through debt financing, it may be subject to covenants limiting or restricting its ability to take specific actions, such as incurring additional debt or liens, making capital expenditures or declaring dividends. If the Company raises additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, it may have to relinquish certain valuable rights to its products, technologies, future revenue streams or research programs, or grant licenses on terms that may not be favorable to the Company.
- If the Company is unable to obtain adequate financing when needed and on terms that are acceptable to it, it may have to delay, reduce the scope of or suspend the implementation of its sales and marketing plans and its ongoing research and development efforts, which would have a material adverse effect on its business, financial condition, and results of operations and could significantly impair the Company's ability to continue its operations as a going concern.
- The Company's ability to raise additional funds may also be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United

States and worldwide resulting from geopolitical tensions, such as the ongoing war in Ukraine, the Israel and Palestine conflict, government actions implemented as a result of either of the foregoing, as well as inflation, interest rates, and liquidity concerns at, and failures of, banks and other financial institutions. The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in economic growth, increases in inflation rates, higher interest rates and uncertainty about economic stability. In addition, actions by the U.S. government, including changes in policies, regulations, or priorities relating to trade, tariffs, taxation, healthcare funding, and research grants, may create further uncertainty. For example, potential reductions in or reallocations of funding by agencies such as the National Institutes of Health (NIH) could limit the availability of non-dilutive financing opportunities for the Company or its collaborators, while shifts in trade policy, including the imposition of tariffs or other trade restrictions, could increase costs or disrupt supply chains. If the equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Market volatility may further adversely impact the Company's ability to access capital as and when needed.

- If the Company or one of the Company's subsidiaries breaches an obligation under the Group's existing EUR 52.5 million loan agreement with Runway Growth Finance Corp, the Group may be required to repay the loan before it would ordinarily become due and the administrative and collateral agent under the loan agreement may dispose of the significant collateral, which substantially covers all of the Group's assets, the Group furnished to secure the loan. It cannot be guaranteed, that the Company will generate the necessary liquidity to be able to pay the interest due under the loan agreement in addition to the investments required to develop its operating business. There can be no assurance that a breach of the covenants under the loan agreement will not occur in the future, particularly in the context of evolving business conditions, financial performance, or changes in the regulatory environment or as the amendment under which covenant compliance has been temporarily waived may not be extended beyond 2025 or renewed in the future.
- The Company's operating results may vary significantly from period to period, which may negatively impact the price of its ordinary shares in the future. Factors which may cause the price of the Company's shares to fluctuate include, for example, revenues from already approved devices, the cost of obtaining and maintaining marketing authorization for the Company's products, expenses the Company incurs in connection with manufacturing and selling its products, costs associated with scaling up and expanding its manufacturing, sales and marketing organization, costs associated with conducting research and development, compliance costs, tariffs, duties and other trade barriers, as well as costs associated with capital expenditures and costs associated with any future litigation.
- The Company's results may be impacted by changes in foreign currency exchange rates. The Company's operating currency is the Euro. Since the de novo classification of ARC^{EX} by the FDA for use in clinics, the Company commenced commercial operations and entered, and will continue to enter, into a number of transactions denominated in US Dollars (initially) but also expanding to various currencies, which can expose it to changes in currency exchange rates.

8.2 Risks related to the Company's Business

- Company is partially dependent on the success of two investigational devices in clinical development, the ARC^{IM} and ARC^{BCI} Systems. 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 marketing authorization for, or successfully commercialize, its ARC^{IM} and ARC^{BCI} Systems. The Company's ARC^{IM} and ARC^{BCI} Systems will require substantial additional clinical development, testing, manufacturing process development, and regulatory clearance or approval before it is permitted to commence their commercialization. Of the large number of medical devices in development in the United States, only a small percentage successfully complete the marketing authorization process required by the FDA and are commercialized. Similarly, a substantial percentage of medical devices in development will never obtain CE certification required for commercialization in the EU. Accordingly, even if the Group will be able to obtain the requisite capital to continue to fund its development and clinical programs, the Group may be unable to successfully develop or commercialize its ARC^{IM} and ARC^{BCI} Systems or any other product candidate.
- The Company has limited experience manufacturing its products. Failure of the Company and its supplier partners to successfully and consistently manufacture its products in high-quality commercial quantities to meet demand will limit the Company's growth and could have a material adverse effect on its ability to continue its business. As the Company continues the commercial production of its products and increases its manufacturing capacity, it may encounter quality issues that could result in product defects, errors or recalls. Manufacturing delays related to its suppliers or quality control could have a significant negative impact on

the Company's ability to bring its products to market, severely harm the Company's reputation and decrease its revenue. Any defects, errors or recalls could be expensive and generate negative publicity, which could impair the Company's ability to market or sell its products, and adversely affect its results of operations. If the Company fails to adequately meet commercial requirements while also maintain product quality standards, the Company may fail to maintain its regulatory clearance and efficiently manage costs, and the Company's sales and operating margins could be negatively impacted, which would have an adverse impact on the Company's financial condition and its operating results.

- The Company currently has a limited marketing and sales organization and has limited experience as a commercial-stage company marketing devices. If the Company is unable to successfully expand its marketing, sales and reimbursement capabilities or enter into additional agreements with third parties to market and sell devices, it may not be able to generate product revenue which would have a significant adverse effect on the Company's business. As the Company competes with other medical technology companies it will have to expend additional capital in order to recruit, hire, train and retain additional marketing and sales personnel. In addition, if the Company's efforts to expand do not generate a corresponding increase in revenue, the Company's financial results will be adversely impacted.
- The Company may face substantial competition which may result in others discovering, developing, or commercializing products before or more successfully than it does. In general, the medical device industry is subject to intense competition and rapid and significant technological change. The Company has many potential competitors, including specialized medical and biotechnology firms, academic institutions, government agencies, and private and public research institutions. While ARC^{IM} and ARC^{BCI} do not have any direct commercial competitors, there are several large medical technology companies marketing spinal cord stimulation platforms for different indications, such as pain management. ARC^{EX} also faces competition from companies which are pursuing similar indications with technology similar to ARC^{EX}. Though the Company believes its IP rights would prevent such companies from being able to commercialize similar devices utilizing the Company's IP-protected waveform, there can be no guarantee that the Company will be able to enforce its IP rights, and third parties may attempt to invalidate the Company's IP.
- Enrollment and retention of patients in clinical trials 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 may encounter delays or difficulties in enrolling, or be unable to enroll, a sufficient number of patients to complete any of its clinical trials on its current timelines, or at all, and even once enrolled, it may be unable to retain a sufficient number of patients to complete any of its trials. Slow enrollment in the Company's clinical trials may lead to delays in its development timelines.
- The Company must obtain FDA marketing authorization 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. Authorization and certification from 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 marketing authorization 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 marketing authorization is denied or delayed.
- The ARC^{EX} System and, if authorized and certified for marketing, the ARC^{IM} and ARC^{BCI} Systems, will require market acceptance to be successful. Failure to gain market acceptance would impact the Company's revenues and may materially impair its ability to continue its business. Even after receiving certification and marketing authorization (like the de novo classification received from the FDA for ARC^{EX} in the clinic setting to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive)), the commercial success of the Company's products will depend on, among other things, their acceptance by physicians, physical therapists, occupational therapists, neurologists, and physiatrists who work in the rehabilitation clinic setting, functional neurosurgeons, patients, third-party payors such as health insurance companies, and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments, including therapeutic options offered by rehabilitation centers for people with spinal cord injury. Physicians, physical therapists, hospitals, and rehabilitation clinics will need to establish care pathways that utilize the Company's technology, and there can be no assurance that these parties will adopt the use of these devices or develop sufficient training and procedures to properly utilize them. Market acceptance of, and demand for, any product that the Company may develop and commercialize will depend on many factors, both within and outside of its control.
- The Company's success depends on its ability to retain its management, consultants and other key personnel. The loss of any members of senior management or key scientific personnel could harm its business and

significantly delay or prevent the achievement of research, development, or business objectives. Competition for qualified employees and consultants is intense among medical device companies, and the loss of qualified employees or consultants, or an inability to attract, retain, and motivate additional highly skilled employees or consultants could hinder its ability to successfully develop marketable products. The Company's future success also depends on its ability to identify, attract, hire, train, retain, and motivate other highly skilled scientific, technical, marketing, managerial, and financial personnel, as well as sales personnel once commercialization may begin in additional territories.

- The Company relies on a limited number of third-party suppliers and contract manufacturers for the manufacturing and assembly of its products, and a loss or degradation in performance of these suppliers and contract manufacturers could have a material adverse effect on its business, financial condition, and results of operations. Reliance on a limited number of third-party suppliers and in some cases single-source suppliers, makes the Company vulnerable to supply shortages and problems and price fluctuations, which could further harm the Company's business. The suppliers that provide certain materials and components are sole suppliers. These sole suppliers, and any of the Company's other suppliers or its third-party contract manufacturers, may be unwilling or unable to supply the necessary materials and components or manufacture and assemble its products reliably and at the levels the Company anticipates or that are required by the market. The Company's ability to supply its products for clinical trials and, if cleared or approved, commercially, and to develop any future products depends, in part, on its ability to obtain these materials, components, and products in accordance with regulatory requirements and in sufficient quantities for clinical testing and potential commercialization. While its suppliers and contract manufacturers have generally met the Company's demand for their products and services on a timely basis in the past, the Company cannot guarantee that they will in the future be able to meet its demand for their products, which could be adversely affected.
- If there are quality issues, or if the performance of its products does not meet the expectations of physicians or patients, the Company may be subject to claims and liability, and its brand, reputation, and business could be adversely affected. In the course of conducting its business, the Company must adequately address quality issues that have arisen, and may in the future continue to arise, with its products, including defects in third-party components included in its products. Additionally, even if free of quality issues, its products may not meet the expectations of physicians or patients with respect to achieving desired results. Even after FDA approval, the Company's products will remain subject to ongoing regulatory review. Notwithstanding any clinical trial studies which may lead to the products' initial clearance, the FDA may require the Company to conduct additional post-marketing studies, update labelling with new warnings or restrictions, limit approved indications, impose distribution controls, or even withdraw approval if new safety or efficacy concerns arise or if the product's risk-benefit profile is reassessed unfavorably. Any such actions could limit the Company's commercial prospects and materially harm its business and results of operations.
- The internal procedures designed to minimize risks that may arise from quality issues may not be sufficient to eliminate or mitigate occurrences of these issues and associated liabilities. In addition, even in the absence of quality issues, the Company may be subject to claims and liability if the performance of its products does not meet the expectations of physicians or patients.
- The Company will need to increase the size of its organization and it may be unable to manage its growth effectively. In terms of work force as well as organizational expertise, the Company has increased the number of its employees in recent periods and has a relatively short history of operations. Any failure by the Company to manage its growth effectively could have an adverse effect on its ability to achieve its development and commercialization goals. Having received its first marketing authorizations, the Company may experience difficulties with manufacturing yields, quality control, component supply and shortages of qualified personnel, among other problems. These problems could result in delays in product availability and increases in expenses. Future growth will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on the Company's administrative and operational infrastructure. In order to manage its operations and growth the Company will need to continue to improve its operational, compliance and management controls, reporting and information technology systems and financial internal control procedures. In addition, as a public company, the Company will need to support managerial, operational, financial and other resources to manage its operations, commercialize its products and continue its research and development activities. The Company's management and personnel, systems and facilities currently in place may not be adequate to support this future growth, and this growth may place significant strain on the Company as it grows. Successful growth will also be dependent upon its ability to implement appropriate financial and management controls. Due to the limited experience in managing a company with substantial growth, the Company's management may not be able to effectively manage the expansion of the Company's operations or recruit and train additional qualified personnel.

- The Company relies on relationships with academic research centers to support its research and development activities, and it may not be able to enhance its product offerings through its research and development efforts. If its relationships with partners were to be terminated or otherwise modified, it could adversely affect its ability to expand potential indications for its products in the future. Should a conflict of interest arise in such a relationship that is not prudently managed, the relationship and the Company's ability to license intellectual property from that partner and commercialize therapies that rely on that intellectual property may be negatively impacted. Licenses granted to the Company may not provide exclusive rights to use such intellectual property in all relevant fields of use and in all territories in which the Company may wish to develop or commercialize its products.
- The Company's business involves the use of hazardous materials such as lithium batteries and the Company and its third-party manufacturers must comply with environmental laws and regulations, which may be expensive and restrict how it does business.
- If its facilities are damaged or become inoperable, the Company will be unable to continue to research and develop its products and, as a result, there will be an adverse effect on its business until it is able to secure a new facility and rebuild its inventory.
- Interruption or distress in the supply chain due to geopolitical, climate-related, and other uncertainties beyond the Company's control could adversely affect the Company's business.
- International trade policies, including tariffs, sanctions and trade barriers may adversely affect the Company's business, financial condition, results of operations and prospects.
- Failures by third parties may lead to higher development costs, delays in obtaining regulatory approvals or certifications, and setbacks or obstacles in commercialization.
- The Company's results of operations could be materially harmed if it is unable to accurately forecast customer demand for its products and manage its inventory.
- Dependence on suppliers for ARCEX System components and services poses operational and financial risks.
- Active implantable medical devices such as the ARC^{IM} System carry risks associated with the surgical procedure for implant or removal of the device, use of the device, or the therapy delivered by the device.
- Interim, "topline," and preliminary data from its clinical trials that the Company announces or publishes from time to time may change as more patient data becomes available and are subject to confirmation, regulatory audit, and verification procedures that could result in material changes in the final data.
- The Company's operations and reputation may be impaired if its information technology systems fail to perform adequately or if it is the subject of a data breach or cyber-attack.

8.3 Risks related to the Company's Industry

- Despite the Company obtaining marketing authorization and certification for certain of its products, the commercial success will depend in part upon the level of reimbursement it receives from third parties for the cost of its products to users. In both US and non-US markets, the Company's ability to successfully commercialize and achieve market acceptance of its products that are approved and cleared for commercialization, depends, in significant part, on the availability of adequate financial coverage and reimbursement from third-party payors, including governmental payors (such as the Medicare and Medicaid programs in the United States), managed care organizations and private health insurers. Third-party payors decide which treatments they will cover and establish reimbursement rates for those treatments.
- If its investigational devices receive marketing authorization and certification, the Company will need to receive access to hospital facilities, clinics, and direct distribution channels, or its sales may be negatively impacted.
- Healthcare reform initiatives and other administrative and legislative proposals in the United States may adversely affect the Company's business, financial condition, results of operations and cash flows in one of its key markets. There have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control or manage the increased costs of healthcare and, more generally, to reform the US healthcare system. Certain of these proposals could limit the prices the Company is able to charge for its products, or the coverage and reimbursement available for its products and could limit the acceptance and availability of its product candidates. Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services, and could have a material adverse effect on the Company's business, financial condition and results of operations. On the

European Union level there are currently no concrete legislative proposals in this regard, but the cost-effectiveness of healthcare is part of the EU agenda on effective, accessible and resilient health systems. This does not exclude that legislation on maximum pricing for medical devices can be applicable or developed on national levels.

- A pandemic, epidemic or outbreak of an infectious disease in Europe, the United States or worldwide, similar to COVID-19, could adversely affect the Company's business.

8.4 Risks related to Government Regulation

- The Company may not receive the necessary approvals, be granted de novo classifications, or clearances and certifications for its products 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. As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. If the Company fails to remain in compliance with applicable European laws and regulations, it would be unable to continue to affix the CE mark to its products, which would prevent the Company from selling them within the EEA.
- The clinical development process required to obtain marketing authorizations and certifications is lengthy and expensive with uncertain outcomes, and the data developed in those clinical trials is subject to interpretation by EU regulators, FDA and foreign regulatory authorities, even if the clinical trials and endpoints are oftentimes aligned and authorized in advance by EU regulators and or the FDA. If clinical trials of the current ARC^{IM} System 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. Conducting clinical trials is a complex and expensive process, can take many years, and outcomes are inherently uncertain. The Company incurs substantial expense for, and devotes significant time to, clinical trials but cannot be certain that the trials will ever result in commercial revenue. The Company may experience significant setbacks in clinical trials, even after earlier clinical trials showed promising results, and failure can occur at any time during the clinical development process. The Company may experience a number of events during the conduct of its clinical trials that could adversely affect the costs, timing or successful completion.
- Breakthrough device designation ("BDD") by the FDA or acceptance into certain FDA programs do not guarantee marketing authorization and may not actually lead to a faster development or regulatory review or marketing authorization process. Further, even though the Company has received BDD for ARC^{EX}, ARC^{BCI} and ARC^{IM}, it may not experience faster development, review or clearance or approval process compared to conventional FDA procedures, and it may not receive regulatory clearance or approval at all. BDD does not change the statutory standards for approval, de novo classification, or clearance. The FDA may withdraw BDD if the FDA believes that the device is no longer eligible for the designation, such as if the FDA believes the designation is no longer supported by data from its clinical development program.
- Failure to comply with post-marketing regulatory requirements could subject the Company to enforcement actions, including substantial penalties, and might require the Company to recall or withdraw a product from the market. The regulations to which the Company is subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on its ability to continue or expand its operations, higher than anticipated costs, or lower than anticipated sales. Even after the Company has obtained the proper regulatory authorization to market a device, the Company has ongoing responsibilities under FDA and EU regulations and applicable laws and regulations of other countries. The FDA, state and foreign regulatory authorities have broad enforcement powers.
- If the Company or its suppliers fail to comply with FDA regulatory requirements, or if it experiences unanticipated problems with any authorized and certified products, these products could be subject to restrictions or withdrawal from the market. Any product for which the Company obtains regulatory clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data, and promotional activities for such product, will be subject to continued regulatory review and oversight by the FDA. In particular, the Company and its third-party suppliers will be required to comply with the FDA's

quality system regulations. These FDA regulations cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage, and shipping of products.

- The Company may be subject to enforcement action if it engages in improper marketing or promotion of its products. As recently illustrated by the FDA's September 2025 directive expanding enforcement of direct-to-consumer pharmaceuticals advertising and proposing to tighten risk-disclosure rules, the US Government's interpretation of what is permissible in promotional communications is in flux, increasing unpredictability in compliance.
- Disruptions at the FDA and other government agencies caused by, funding shortages, staffing limitations and reassignments, or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent new or modified products from being developed, review, approved or commercialized in a timely manner or at all, which could negatively impact the Company's business.
- The Company is subject to certain federal and state fraud and abuse laws and transparency laws that could subject it to substantial penalties or other adverse consequences. Additionally, any challenge to or investigation into its practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm the Company's business.
- Any actual or perceived failure to comply with new or existing laws, regulations and other requirements relating to the privacy, security and processing of personal information could adversely affect the Company's business, results of operations, or financial condition.
- In the event that the Company receives clearance or approval by regulatory authorities, it will be subject to the FDA's medical device reporting regulations and similar foreign regulations, which require it to report to the FDA when it receives or become aware of information that reasonably suggests that its products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The FDA and foreign regulatory authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that its products could cause serious injury or death. The Company may also choose to voluntarily recall its products if any material deficiency is found. A government-mandated or voluntary recall by the Company could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. The Company may initiate voluntary withdrawals or corrections for its products in the future that it may determine do not require notification of the FDA. If the FDA disagrees with its determinations, it could require the Company to report those actions as recalls and the Company may be subject to enforcement action. A future recall announcement could harm its reputation with customers, potentially lead to product liability claims against the Company and negatively affect its sales.

8.5 Risks related to the Company's Intellectual Property

- Substantially all of the Group's assets, including intellectual property, are pledged to Runway Growth Finance Corp, the Company's main creditor, and the enforcement of such pledge could substantially harm the future development and operations of the Company.
- 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.
- If the Company is unable to obtain and maintain sufficient intellectual property protection for its technology and products and product candidates it may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, its competitors or other third parties could develop and commercialize products similar or identical to the Company's, and its ability to successfully develop and, if approved, commercialize its products may be adversely affected.
- Patent terms may be inadequate to protect its competitive position on its future products for an adequate amount of time and the Company might be unable to obtain relevant patents in the future.
- The Company may enjoy only limited geographical protection with respect to certain patents and it may not be able to protect its intellectual property rights throughout the world.
- The Company may in the future become, involved in lawsuits to defend itself against intellectual property disputes, which could be expensive and time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, and hinder its ability to commercialize its existing or future products.

- If the Company is unable to protect the confidentiality of its trade secrets, or fail to execute invention assignment agreements with its employees and contractors involved in the development of intellectual property, its business or competitive position could be harmed.
- Third parties may assert ownership or commercial rights to inventions the Company develops.
- The Company relies on licenses and sublicenses to certain intellectual property rights with third parties. If the Company fails to comply with its obligations under its intellectual property licenses with third parties, it could lose license rights that are important to its business. Additionally, the Company may not be able to control the prosecution or maintenance of in-licensed patent rights, which could adversely affect its business.
- The Company will be required to pay certain milestones and royalties, subject to milestone achievements and sales covered by the license, and fulfill other obligations under its license agreements with third-party licensors.
- The Company's use of open source software could impose limitations on its ability to commercialize its products.
- Intellectual property rights do not address all potential threats to the Company's competitive advantage.

8.6 Risks related to Taxation

- The Company's ability to use its net operating losses, tax loss carryforwards and other tax attributes to offset future taxable income is conditioned on the Group's attaining profitability and generating taxable income and, may, additionally, be subject to certain United States Federal income tax and Dutch tax limitations.
- Future changes to tax laws could materially and adversely affect the Company and reduce net returns to its shareholders.
- If the Company is a passive foreign investment company, there could be adverse US federal income tax consequences to US holders.

9. CHARACTERISTICS OF THE SHARES

9.1 Type, class and ISIN code of shares to be admitted to trading

The New Shares will be ordinary shares and of the same class as the Company's existing shares and will have a nominal value of €0.12 each. The New Shares will be fully paid-up and will rank *pari passu* in all respects with all other existing shares of the Company. The New Shares will be trading under the symbol "ONWD" and bear the same international securities identification number (ISIN) as the Company's existing shares, namely NL0015000HT4.

9.2 Form and method of registration of the shares

The New Shares are registered shares which will be included in a collective deposit and book-entry deposit on the basis of the Netherlands' Securities Giro and Transfer Act (*Wet giraal effectenverkeer*). The New Shares will be delivered in book-entry form through the facilities of Nederlands Centraal Instituut voor Giraal Effectenverkeer B.V. ("**Euroclear Netherlands**"). Application has been made for the New Shares to be accepted for clearance through the book-entry facilities of Euroclear Netherlands. Euroclear Netherlands has its offices at Herengracht 459-469, 1017 BS Amsterdam, the Netherlands. In accordance with the Articles of the Netherlands' Securities Giro and Transfer Act, title to the New Shares shall be evidenced by book-entries in the books of the Company or, as the case may be, an authorized intermediary and the transfer of the securities may only be effected through registration of the transfer in such books. The New Shares will be in registered dematerialized form.

9.3 Rights attached to the shares

The New Shares will have the same rights, including voting, dividend and pre-emption rights, as the Company's existing shares. The New Shares will be freely tradeable. There are no restrictions in the articles of association of the Company restricting free trading in the Company's shares or under Dutch law, that limit the right of shareholders to hold New Shares. The transfer of New Shares to persons who are located or resident in or who are citizens of or have a registered address in jurisdictions other than the Netherlands may, however, be subject to specific regulations or restrictions according to their securities laws.

10. DILUTION AND SHAREHOLDING AFTER THE ISSUANCE

Through the capital increase, the Company's share capital will increase to 56,008,526 shares through the issuance of 11,300,000 New Shares. The shareholdings of the current shareholders of the Company will be diluted as a result of the issuance of the New Shares. The dilution for the current shareholders from the capital increase will be approximately 25.3% on the basis of the issuance of 11,300,000 New Shares.

11. TERMS AND CONDITIONS OF THE OFFER

Not applicable as no public offering for the New Shares has been made.

12. INFORMATION ON THE ADMISSION TO LISTING OF THE NEW SHARES

The Company's existing shares are already admitted to trading on Euronext Brussels, Euronext Amsterdam and Euronext Paris. ING Bank N.V. is the Company's listing agent with respect to the admission to listing and trading of the New Shares on Euronext Brussels, Euronext Amsterdam and Euronext Paris. An application will be made for the admission to trading for the New Shares and the admission and commencement of trading in the New Shares is expected to occur on or about October 28, 2025.