



(ONWARD Medical N.V., a public company with limited liability (naamloze vennootschap), incorporated under the laws of the Netherlands, with its statutory seat (statutaire zetel) in Amsterdam, the Netherlands)

Admission to listing and trading of the new ordinary shares on Euronext Brussels, Euronext Amsterdam and Euronext Paris

This prospectus (this "**Prospectus**") has been prepared in connection with the admission to listing and trading of 10,000,000 ordinary shares in the issued share capital of ONWARD Medical N.V. (the "**Company**") with a nominal value of EUR 0.12 each (the "**New Ordinary Shares**") with a primary listing on Euronext in Brussels, a regulated market operated by Euronext Brussels SA/NV ("**Euronext Brussels**"), a secondary listing on Euronext in Amsterdam, a regulated market operated by Euronext Amsterdam N.V. ("**Euronext Amsterdam**"), and a secondary listing on Euronext in Paris (the "**Listing**"), a regulated market operated by Euronext Paris S.A. ("**Euronext Paris**" and together with Euronext Amsterdam and Euronext Brussels, "**Euronext**").

On 28 October 2024, the Company will issue in total 10,000,000 New Ordinary Shares to certain qualified investors as defined in Article 2 of Regulation (EU) 2017/1129 (as amended, the "**Prospectus Regulation**") (the "**Qualified Investors**") and to certain qualified investors as defined in the Prospectus Regulation as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018 (the "**UK Prospectus Regulation**") in the United Kingdom who are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the "**Financial Promotion Order**"), (ii) high net worth entities or other persons falling within Article 49(2)(a) to (d) of the Financial Promotion Order or (iii) persons to whom an invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 (as amended, the "**FSMA 2000**") in connection with the issue or sale of any New Ordinary Shares may otherwise lawfully be communicated or caused to be communicated (all such persons being referred to as "**Relevant Persons**") following a private placement of the New Ordinary Shares to Qualified Investors in the European Economic Area, to Relevant Persons in the United Kingdom and to institutional investors in certain other jurisdictions (the "**Private Placement**").

The existing ordinary shares in the share capital of the Company, each with a nominal value of EUR 0.12, are admitted to trading on Euronext under the symbol "ONWD" (the "**Ordinary Shares**"). Application has been made to admit the New Ordinary Shares to listing and trading on Euronext under the symbol "ONWD". Trading of the New Ordinary Shares on Euronext is expected to commence at 9:00 am Central European Time on or around 28 October 2024 (the "**Listing Date**"). Prior to the Listing Date, all Ordinary Shares other than the New Ordinary Shares were already admitted to listing and trading on Euronext.

The New Ordinary Shares will be delivered in book-entry form through the book-entry systems of the Netherlands Central Institute for Giro Securities Transactions (*Nederlands Centraal Instituut voor Giraal Effectenverkeer B.V.*) ("**Euroclear Nederland**"). Delivery of the New Ordinary Shares is expected to take place on the Listing Date.

The Prospectus serves as a listing prospectus only. The Prospectus does not constitute an offer to sell, or a solicitation of any offer to buy any of the New Ordinary Shares or any other securities issued by the Company.

The distribution of this Prospectus may be restricted by law in certain jurisdictions. Accordingly, neither this Prospectus nor any advertisement may be distributed or published in any jurisdiction, except under circumstances that will result in compliance with applicable laws and regulations. Persons in possession of this Prospectus are required by the Company to inform themselves about and to observe any such restrictions. Failure to comply with these laws and regulations may constitute a violation of the securities laws of any such jurisdictions. The Ordinary Shares and the New Ordinary Shares have not been and will not be registered under the US Securities Act of 1933, as amended (the "**US Securities Act**"), or with any securities regulatory authority of any state or other jurisdiction in the United States.

This Prospectus constitutes a prospectus for the purposes of, and has been prepared in accordance with, the Prospectus Regulation. This Prospectus has been approved as a prospectus for the purposes of the Prospectus Regulation by, and filed with, the Dutch Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*, the "**AFM**"), as the competent authority under the Prospectus Regulation. This Prospectus has, following its approval thereof by the AFM been notified to the Financial Services and Markets Authority in

Belgium (*Autorité des Services et Marchés Financiers*; the "**FSMA**") and to the French Authority of the Financial Markets (*Autorité des Marchés Financiers*, the "**AMF**") for passporting in accordance with Article 25 of the Prospectus Regulation. The AFM only approves this Prospectus as meeting the standards of completeness, comprehensibility and consistency imposed by the Prospectus Regulation. Such approval should not be considered as an endorsement of the issuer or the quality of the securities that are the subject of this Prospectus. This Prospectus has been drawn up as part of a simplified prospectus in accordance with Article 14 of the Prospectus Regulation. Investors should make their own assessments as to the suitability of investing in the New Ordinary Shares.

The validity of this Prospectus will expire on the earlier of (i) the Listing Date and (ii) 12 months from the date of this Prospectus. The obligation to supplement a prospectus in the event of significant new factors, material mistakes or material inaccuracies shall cease to apply when this Prospectus is no longer valid (see "*Important Information – Supplements*").

INVESTING IN THE NEW ORDINARY SHARES INVOLVES RISKS. SEE "*RISK FACTORS*" BEGINNING ON PAGE 15 OF THIS PROSPECTUS FOR A DESCRIPTION OF THE MATERIAL RISK FACTORS THAT SHOULD BE CAREFULLY CONSIDERED BEFORE INVESTING IN THE ORDINARY SHARES.

Listing Agent

ING BANK N.V.

This Prospectus is dated 24 October 2024

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SUMMARY

Section A – Introduction and Warnings

This summary should be read as an introduction to this prospectus (this "**Prospectus**") prepared in connection with the listing of 10,000,000 ordinary shares in the issued share capital of ONWARD Medical N.V. (the "**Company**") with a nominal value of EUR 0.12 per share (the "**New Ordinary Shares**") with a primary listing on Euronext in Brussels, a regulated market operated by Euronext Brussels SA/NV ("**Euronext Brussels**"), a secondary listing on Euronext in Amsterdam, a regulated market operated by Euronext Amsterdam N.V. ("**Euronext Amsterdam**"), and a secondary listing on Euronext in Paris (the "**Listing**"), a regulated market operated by Euronext Paris S.A. ("**Euronext Paris**", and together with Euronext Brussels and Euronext Amsterdam, "**Euronext**"). The ordinary shares in the share capital of the Company, each with a nominal value of EUR 0.12, are admitted to trading on Euronext under the symbol "ONWD" (the "**Ordinary Shares**").

The Company's statutory seat (*statutaire zetel*) is in Amsterdam, the Netherlands, and its registered office is at Schimmelt 2, 5611 ZX Eindhoven, the Netherlands. The Company's telephone number is + 31 40 288 2830 and its website is (www.onwd.com). The Company is registered in the Commercial Register of the Chamber of Commerce (*Handelsregister van de Kamer van Koophandel*) under number 64598748 and its legal entity identifier ("**LEI**") is 9845007A2CC4C8BFSB80. The international securities identification number ("**ISIN**") of the Ordinary Shares is NL0015000HT4.

This Prospectus was approved on 24 October 2024 as a prospectus for the purposes of Article 3 of Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 (including any relevant delegated regulations) (the "**Prospectus Regulation**") by the Dutch Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*, the "**AFM**"), as competent authority under the Prospectus Regulation. This Prospectus has, following its approval thereof by the AFM, been notified to the Financial Services and Markets Authority in Belgium (the "**FSMA**") and to the French Authority of the Financial Markets (*Autorité des Marchés Financiers*, the "**AMF**") for passporting in accordance with article 25 of the Prospectus Regulation. The AFM's address is Vijzelgracht 50, 1017 HS Amsterdam, the Netherlands. Its telephone number is +31 (0)20 797 2000 and its website is www.afm.nl.

Any decision to invest in the Ordinary Shares should be based on a consideration of this Prospectus as a whole by the investor. An investor could lose all or part of the invested capital, and where the investor's liability is not limited to the amount of the investment, the investor could lose more than the invested capital. Where a claim relating to the information contained, or incorporated by reference into, this Prospectus is brought before a court, the plaintiff investor might, under the relevant national legislation, have to bear the costs of translating this Prospectus before the legal proceedings can be initiated. Civil liability attaches only to those persons who have tabled the summary including any translation thereof, but only where the summary is misleading, inaccurate or inconsistent, when read together with the other parts of this Prospectus, or where it does not provide, when read together with the other parts of this Prospectus, key information in order to aid investors when considering whether to invest in the Ordinary Shares.

Section B – Key Information on the Issuer

Who is the issuer of the securities?

The issuer of the Ordinary Shares is the Company. The Company is incorporated as a public company with limited liability (*naamloze vennootschap*) with its statutory seat (*statutaire zetel*) in Amsterdam, the Netherlands and operating under the laws of the Netherlands. The Company's LEI is 9845007A2CC4C8BFSB80 and its trade register number is 64598748. The Company together with its subsidiaries is a group within the meaning of article 2:24b of the Dutch Civil Code (*Burgerlijk Wetboek*) ("**DCC**") (the "**Group Companies**", each a "**Group Company**", and together with the Company, the "**Group**"). The Company is a medical technology company developing and commercializing innovative therapies to enable functional recovery for people with Spinal Cord Injury ("**SCI**"). The Company's technology platforms are based on ONWARD ARC™ Therapy ("**ARC Therapy**"), targeted, programmed electrical stimulation of the spinal cord designed to restore movement, independence, and health in people with SCI. ARC Therapy consists of two investigational proprietary platforms, one implantable platform ("**ARC^{IM}**") and one external platform ("**ARC^{EX}**"), both designed to improve mobility and quality of life by addressing a wide range of challenges confronting people with SCI and potentially other diseases/disorders, such as Parkinson's disease and Stroke. Since its inception, the Company has not yet generated any revenues or net cash flows from sales of its products. ARC^{EX} and ARC^{IM}, the Company's most advanced products and its only products in clinical development, have not yet been approved for marketing.

As of the date of this Prospectus, the Company's authorized share capital comprises Ordinary Shares, which are admitted to listing and trading on Euronext, and preferred shares having a nominal value of EUR 0.12 (the "**Preferred Shares**"; the Preferred Shares, the Ordinary Shares and the New Ordinary Shares are together referred to as the "**Shares**"). As an anti-takeover measure, the Company's general meeting of shareholders has

authorized the Board (as defined below) to grant a call option to an independent foundation under Dutch law (if and when incorporated, the "**Protective Foundation**"), to acquire Preferred Shares pursuant to a call option agreement which may be entered into between the Company and the Protective Foundation if then existing. In addition, on 28 October 2024 the Company will issue the New Ordinary Shares. As of the date of the Prospectus, the Company's share capital comprises Ordinary Shares and New Ordinary Shares. Upon the Listing, all of the Company's Ordinary Shares, Preferred Shares and New Ordinary Shares, each with a nominal Value of EUR 0.12 will be listed.

The Company's major shareholders and their respective shareholdings are listed in the following table. These shareholders hold a direct or indirect capital or voting interest of 3% or more in the Company's total issued share capital (a substantial holding within the meaning of Chapter 5.3 of the Dutch Financial Supervision Act (*Wet op het financieel toezicht*) as of the date of this Prospectus.

Shareholders	Ordinary Shares as of the Date of this Prospectus*		
	Amount	Share capital	Voting rights
Ottobock SE & Co. KGaA	4,500,000	540,000.00	10.1%
INKEF Capital B.V.	3,987,754	475,530.48	8.9%
LSP Advisory B.V.	3,883,368	466,004.16	8.7%
Gimv (Private Equity)	3,201,689	384,202.68	7.2%
Wellington Partners GmbH	2,638,936	316,672.32	5.9%

* Takes into account the effect of 10,000,000 New Ordinary Shares sold in the Private Placement and to be issued on the Listing Date.

The Company has a one-tier board consisting of one or more executive directors (*uitvoerend bestuurders*) and one or more non-executive directors (*niet-uitvoerend bestuurders*) (together the "**Board**" and each a "**Director**"). Dave Marver is the Executive Director, and Jan Øhrstrøm, Fredericus Colen, Grégoire Courtine, Ian Curtis, John de Koning, Kristina Dziekan, Vivian Riefberg, Rahma Samow and Rob ten Hoedt are the Non-Executive Directors. The Company's independent auditor is EY Accountants B.V. ("**EY**").

What is the key financial information regarding the issuer?

Interim Condensed Consolidated Financial Statements for the six-months-period ended 30 June 2024 and the Consolidated Financial Statements as of and for the Year ended 31 December 2023

The following tables set out information from the Company's interim condensed consolidated financial statements as of and for the six-month-period ended 30 June 2024 (the "**Interim Condensed Consolidated Financial Statements**"), which have been prepared in accordance with IAS 34, "Interim Financial Reporting" as adopted by the European Union and which have not been audited or reviewed and the consolidated financial statements as of and for the year ended 31 December 2023, which have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union ("**IFRS**") and Part 9 of Book 2 of the Dutch Civil Code (the "**Consolidated Financial Statements**"). Ernst & Young Accountants LLP has audited the Consolidated Financial Statements and has issued an unqualified independent auditor's report thereon.

Condensed Consolidated Statement of Profit and Loss

<i>In EUR thousand</i>	Audited		Unaudited	
	For the year ended 31 December		For the six-month-period ended 30 June	
	2023	2022	2024	2023
Total Revenues and Other Income	532	2,148	208	928
Operating Loss for the Period	(35,463)	(32,028)	(18,749)	(18,780)
Net Loss for the Period	(36,181)	(32,772)	(18,252)	(19,282)
Earnings Per Share (EUR):				
Basic earnings per ordinary share attributable to shareholders:	(1.20)	(1.09)	(0.53)	(0.64)

Diluted earnings per ordinary share attributable to shareholders:	(1.20)	(1.09)	(0.53)	(0.64)
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Condensed Consolidated Statement of Financial Position

In EUR thousand	Audited		Unaudited	
	As of 31 December		As of 30 June	
	2023	2022	2024	
Total assets	43,629	76,593	46,854	
Total equity attributable to shareholders	17,931	52,631	18,348	

Condensed Consolidated Statement of Cash Flows

In EUR thousand	Audited		Unaudited	
	For the year ended 31 December		For the six-month-period ended 30 June	
	2023	2022	2024	2023
Net cash generated / (used) from operating activities	(32,270)	(26,685)	(14,805)	(18,391)
Net cash generated / (used) from investing activities	19,578	(20,417)	(7,524)	(5,303)
Net cash generated / (used) from financing activities	813	(557)	17,642 ⁽¹⁾	775

(1) This does not include any proceeds under the Runway Loan (as defined below).

No pro forma financial information has been included in this Prospectus.

Working Capital Statement

On the date of this Prospectus, the Group is of the opinion that it does have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months following the date of this Prospectus.

What are the key risks that are specific to the issuer?

The following key risks relate to the Group's business, results of operations, financial condition and prospects. In selecting and ordering 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. Investors should read, understand and consider all risk factors, which are material and should be read in their entirety, as set out under "Risk Factors" beginning on page 15 of this Prospectus before making a decision to invest in the Ordinary Shares.

- The Company is wholly dependent on the success of two investigational devices, the ARC^{IM} and ARC^{EX} 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^{IM} and ARC^{EX} 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 will 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;
- On 28 June 2024, the Company, ONWARD Medical S.A. and ONWARD Medical Inc. signed a loan and security agreement in the amount of up to EUR 52.5 million with U.S.-based lender Runway Growth Finance Corp. ("Runway") (the "Runway Loan"). The Runway Loan is divided into five individual credit tranches, with the availability of the second, third and fourth credit tranche being subject to the Company's

achievement of certain milestones. It bears an interest rate equal to Term Secured Overnight Financing Rate (SOFR) for a three-month interest period (currently at 6.00% and subject to a 4.25% floor), plus margin of 6.50%. It cannot be guaranteed, that the Company will generate the necessary liquidity to be able to pay the interest due under the Runway Loan in addition to the investments required to develop its operating business. If the Company or a Group Company breaches an obligation under the Runway Loan (including, but not limited to, failure to comply with covenants or a payment default), they may be required to repay the loan before it would ordinarily become due and Runway may dispose of the significant collateral the Company and the Group Companies have furnished to secure the loan. This may have a material adverse effect on the Company's net assets and its financial condition;

- 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 is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside the Company's 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 solve technical and engineering challenges prior to being able to offer a commercialized product to the SCI patient population. In addition, 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^{EX} and ARC^{IM} 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^{EX} platform and ARC^{IM} 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;
- Substantially all of the Group's assets, including intellectual property, are pledged to Runway, 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.

Section C – Key Information on the Securities

What are the main features of the securities?

The Ordinary Shares constitute the issued share capital of the Company, which consists of 34,628,832 ordinary shares in the issued share capital of the Company with a nominal value of EUR 0.12 per share. The Ordinary Shares are denominated in and trade in euro on Euronext. The ISIN of the Ordinary Shares is NL0015000HT4.

The Ordinary Shares (including the New Ordinary Shares) rank *pari passu* with each other and Shareholders are entitled to dividends and other distributions declared after the adoption of the annual accounts that show that such distribution is allowed and paid on them. The Board may also resolve to make interim distributions in accordance with the articles of association of the Company (the "**Articles of Association**"). Each Ordinary Share carries distribution rights and entitles its holder to the right to attend and cast one vote at the general meeting of the Company, being the corporate body, or where the context so requires, the physical meeting of Shareholders (*algemene vergadering*) (the "**General Meeting**"). There are no restrictions on voting rights attaching to the Ordinary Shares.

Upon the issue of Ordinary Shares or grant of rights to subscribe for Ordinary Shares, subject to exceptions (i.e. in case of an issue of Ordinary Shares to employees of the Company or a Group Company, against a contribution other than in cash or pursuant to the exercise of a previously acquired right to subscribe for Ordinary Shares), each Shareholder shall have a pre-emptive right in proportion to the number of Ordinary Shares already held by it. No pre-emption rights are attached to Preferred Shares and no pre-emption rights apply in the event of an issue of Preferred Shares. Pre-emptive rights have been limited or excluded by a resolution of the General Meeting authorizing the Board to issue Ordinary Shares or grant rights to subscribe for Ordinary Shares for a period of 18 months following 13 June 2024 and to limit or exclude the pre-emptive rights pertaining to such Ordinary Shares and rights in connection therewith in order to satisfy obligations under employee incentive plans and for other purposes without the expense of calling an extraordinary general meeting of Shareholders. This authorization of the Board is limited to up to a maximum of 10% of the Company's issued share capital, provided that the above-mentioned percentage shall be calculated by reference to the Company's issued share capital determined as at the close of business on 13 June 2024. In addition, the General Meeting authorized the Board for a period of 18 months following 13 June 2024 to issue Ordinary Shares and grant rights to subscribe for Ordinary Shares for up to a maximum of 50% of the Ordinary Shares issued and outstanding at the close of business on 13 June 2024 and to limit or exclude the pre-emptive rights in connection with one or more potential capital raises or for other strategic purposes. The Board exercised the authorization to exclude the pre-emptive rights pertaining to such Ordinary Shares and rights in connection with the issuance of the New Ordinary Shares on 28 October 2024.

In the event of insolvency proceedings, any claims of Shareholders are subordinated to those of the creditors of the Company. This means that an investor could potentially lose all or part of its invested capital. If and to the extent that Preferred Shares are outstanding, such Preferred Shares shall have a relative preference over the Ordinary Shares in making dividend distributions or in connection with a distribution being made upon liquidation of the Company.

There are no restrictions on the transferability of the Ordinary Shares in the Articles of Association. However, the offering to persons located or resident in, or who are citizens of, or who have a registered address in countries other than the Netherlands, Belgium and France and the transfer of Ordinary Shares into jurisdictions other than the Netherlands, Belgium and France may be subject to specific regulations or restrictions.

The Company has never paid or declared any cash dividends in the past and does not anticipate paying any cash dividends in the foreseeable future. The Company intends to retain all available funds and any future earnings to fund the further development and expansion of the Company's business.

Where will the securities be traded?

Application has been made to list all New Ordinary Shares under the symbol "ONWD" on Euronext Brussels (primary listing), Euronext Amsterdam (secondary listing) and Euronext Paris (secondary listing). Trading in the New Ordinary Shares on Euronext is expected to commence, on an "as-if-when-issued-and/or-delivered" basis, on or about 28 October 2024 (the "**Listing Date**"). Prior to the Listing Date, all Ordinary Shares other than the New Ordinary Shares were already admitted to listing and trading on Euronext.

What are the key risks that are specific to the securities?

The following key risks relate to the Ordinary Shares, results of operations, financial condition and prospects. In selecting and ordering 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. Investors should read, understand and consider all risk factors, which are material and should be read in their entirety, as set out under "Risk Factors" beginning on page 15 of this Prospectus before making a decision to invest in the Ordinary Shares:

- 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; and
- Certain significant shareholders of the Company after the Listing may have different interest from the Company and may be able to control the Company, including the outcome of shareholder votes.

Section D – Key Information on the Listing

Under which conditions and timetable can I invest in the securities?

The Listing. The Listing is expected to occur on the Listing Date.

Admission to trading. Prior to the Listing Date, all Ordinary Shares other than the New Ordinary Shares were already admitted to listing and trading on Euronext. Application has been made to admit the New Ordinary

Shares to listing and trading on Euronext Brussels (primary listing), Euronext Amsterdam (secondary listing) and Euronext Paris (secondary listing) under the symbol "ONWD" with ISIN NL0015000HT4. Trading in the New Ordinary Shares on Euronext Brussels (primary listing), Euronext Amsterdam (secondary listing) and Euronext Paris (secondary listing) is expected to commence on the Listing Date.

Listing Agent: ING BANK N.V. is the listing agent with respect to the Listing.

Dilution. The private placement of the New Ordinary Shares to certain qualified investors as defined in Article 2 of the Prospectus Regulation (the "**Qualified Investors**") in the European Economic Area, to certain qualified investors as defined in the Prospectus Regulation as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018 (the "**UK Prospectus Regulation**") in the United Kingdom who are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the "**Financial Promotion Order**"), (ii) high net worth entities or other persons falling within Article 49(2)(a) to (d) of the Financial Promotion Order or (iii) persons to whom an invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 (as amended, the "**FSMA 2000**")) in connection with the issue or sale of any New Ordinary Shares may otherwise lawfully be communicated or caused to be communicated (all such persons being referred to as "**Relevant Persons**") and to institutional investors in certain other jurisdictions (the "**Private Placement**") will result in dilution of voting interests of the shareholders of the Company holding shares in the Company prior to the Private Placement.. The New Ordinary Shares, subscribed for by the investors who participated in the Private Placement, have already been allocated to the investors in the Private Placement on 24 October 2024. The dilutive effect following the consummation of the Private Placement is summarized in the table below:

	<u>Prior to the Private Placement</u>	<u>Subsequent of the Private Placement</u>
Number of ordinary shares each with a nominal value of EUR 0.12	34,628,832	44,628,832
% dilution		22.4

Estimated expenses. The expenses and taxes related to the Private Placement and the Listing payable by the Company are estimated at approximately EUR 3.4 million.

Who is the issuer and/or the person asking for the Listing?

The Company is listing the New Ordinary Shares. The Company is incorporated as a public company with limited liability (*naamloze vennootschap*) with its statutory seat (*statutaire zetel*) in Amsterdam, the Netherlands and operating under the laws of the Netherlands. The Company's LEI is 9845007A2CC4C8BFSB80 and its trade register number is 64598748.

Why is this prospectus being produced?

Reasons Listing and use of proceeds. The Listing will create liquidity for the holders of the New Ordinary Shares. The Company intends to distribute the net proceeds from the Private Placement as follows: (i) approximately 40% to fund research and development initiatives, including continued product development, clinical studies and regulatory activities for the investigational ARC^{EX} system to restore hand and arm function, the investigational ARC^{IM} system for improved blood pressure regulation and other exploratory indications, and the investigational system, that uses brain-computer interface ("**BCI**") technology in conjunction with ARC^{IM} Therapy ("**ARC^{BCI}**") to restore thought-driven movement of the human body after SCI, (ii) approximately 30% to support the expected commercial launch of the ARC^{EX} system in the United States of America in the second half of 2024, including hiring a field sales organization and conducting selling activities, producing training and education materials and conducting training events, attending congresses, developing customer support capabilities and conducting customer support activities, and conducting market access and reimbursement activities, (iii) approximately 20% for building quality, operations and administrative capabilities, (iv) approximately 5% for working capital requirements and potential strategic opportunities, aimed at establishing, maintaining, or strengthening competitive advantage through license arrangements, acquisitions whether by assets or shares, or other arrangements (partnering or otherwise) and (v) approximately 5% of the funds will be allocated to cover financing costs associated with existing obligations under current and anticipated debt funding. The Company may be required to raise additional capital in the future in order to meet its funding requirements.

Most material conflicts of interest. There are no material conflicts of interest pertaining to the Listing.

RÉSUMÉ

Section A – Introduction et Avertissements

Ce résumé doit être lu comme une introduction au prospectus (le "**Prospectus**") préparé dans le cadre de l'admission à la cotation et à la négociation de 10.000.000 actions ordinaires du capital social de ONWARD Medical N.V. (la "**Société**") d'une valeur nominale de EUR 0,12 par action (les "**Actions Ordinaires Nouvelles**") avec une cotation primaire sur Euronext à Bruxelles, un marché réglementé géré par Euronext Bruxelles S.A./N.V. ("**Euronext Bruxelles**"), une cotation secondaire sur Euronext à Amsterdam, un marché réglementé géré par Euronext Amsterdam N.V. ("**Euronext Amsterdam**"), et une cotation secondaire sur Euronext à Paris (l' "**Admission**"), un marché réglementé géré par Euronext Paris S.A ("**Euronext Paris**", et ensemble avec Euronext Bruxelles et Euronext Amsterdam, "**Euronext**"). Les actions ordinaires du capital social de la Société, d'une valeur nominale de EUR 0,12 chacune, sont admises aux négociations sur Euronext sous le symbole "ONWD" (les "**Actions Ordinaires**").

Le siège statutaire de la Société (*statutaire zetel*) est situé à Amsterdam, aux Pays-Bas, et son siège social est situé à Schimmelt 2, 5611 ZX Eindhoven, aux Pays-Bas. Le numéro de téléphone de la Société est le +31 40 288 2830 et son site internet est (www.onwd.com). La Société est enregistrée au Registre du commerce de la Chambre de commerce (*Handelsregister van de Kamer van Koophandel*) sous le numéro 64598748 et son identifiant d'entité juridique ("**LEI**") est 9845007A2CC4C8BFSB80. Le numéro international d'identification ("**ISIN**") des Actions Ordinaires est NL0015000HT4.

Le Prospectus a été approuvé le 24 octobre 2024 en tant que prospectus aux fins de l'Article 3 du Règlement (UE) 2017/1129 du Parlement européen et du Conseil du 14 juin 2017 (y compris tout règlement délégué pertinent) (le "**Règlement Prospectus**") par l'Autorité néerlandaise des Marchés Financiers (*Stichting Autoriteit Financiële Markten*, l' "**AFM**"), en tant qu'autorité compétente en vertu du Règlement Prospectus. La version française du résumé de ce Prospectus n'a pas été examinée ou approuvée par l'AFM. Ce Prospectus a, suite à son approbation par l'AFM, été notifié à l'Autorité des Services et Marchés Financiers en Belgique (la "**FSMA**") et à l'Autorité française des Marchés Financiers (l' "**AMF**") aux fins de bénéficier du régime de passeport conformément à l'Article 25 du Règlement Prospectus. L'adresse de l'AFM est Vijzelgracht 50, 1017 HS, Amsterdam, Pays-Bas. Son numéro de téléphone est le +31 (0)20 797 2000 et son site Internet est www.afm.nl.

Toute décision d'investir dans les Actions Ordinaires doit être basée sur l'examen du Prospectus dans son ensemble par l'investisseur. Un investisseur pourrait perdre tout ou partie du capital investi, et lorsque la responsabilité de l'investisseur n'est pas limitée au montant de l'investissement, l'investisseur pourrait perdre plus que le capital investi. Lorsqu'une plainte relative aux informations contenues ou incorporées par référence dans le Prospectus est déposée devant un tribunal, l'investisseur plaignant pourrait, en vertu de la législation nationale pertinente, devoir supporter les coûts de traduction du Prospectus avant que la procédure judiciaire ne puisse être engagée. La responsabilité civile n'est engagée qu'à l'égard des personnes qui ont déposé le résumé, y compris toute traduction de celui-ci, mais uniquement lorsque le résumé est trompeur, inexact ou incohérent, lorsqu'il est lu conjointement avec les autres parties du Prospectus, ou lorsqu'il ne fournit pas, lorsqu'il est lu conjointement avec les autres parties du Prospectus, des informations clés afin d'aider les investisseurs lorsqu'ils envisagent d'investir dans les Actions Ordinaires.

Section B – Informations clés sur l'Émetteur

Qui est l'émetteur des valeurs mobilières ?

L'émetteur des Actions Ordinaires est la Société. La Société est une société anonyme (*naamloze vennootschap*) ayant son siège statutaire (*statutaire zetel*) à Amsterdam, aux Pays-Bas et exerçant ses activités en vertu du droit néerlandais. Le LEI de la Société est 9845007A2CC4C8BFSB80 et son numéro d'immatriculation au registre du commerce est 64598748. La Société et ses filiales constituent un groupe au sens de l'article 2:24b du Code civil néerlandais (*Burgerlijk Wetboek*) ("**DCC**") (les "**Sociétés du Groupe**", chacune étant une "**Société du Groupe**", et ensemble avec la Société, le "**Groupe**"). La Société est une société de technologie médicale qui développe et commercialise des thérapies innovantes pour permettre la récupération fonctionnelle chez les personnes souffrant de Lésions de la Moelle Epinière ("**LME**"). Les plateformes technologiques de la Société sont basées sur la Thérapie ONWARD ARC™ ("**Thérapie ARC**"), une stimulation électrique programmée et ciblée de la moelle épinière conçue pour restaurer le mouvement, l'indépendance et la santé des personnes atteintes de LME. La Thérapie ARC se compose de deux plateformes expérimentales brevetées, une plateforme implantable ("**ARC^{IM}**") et une plateforme externe ("**ARC^{EX}**"), qui sont toutes deux conçues pour améliorer la mobilité et la qualité de vie en relevant un large éventail de défis auxquels sont confrontés les personnes atteintes de LME et potentiellement d'autres maladies/troubles, comme la maladie de Parkinson et les accidents vasculaires cérébraux. Depuis sa création, la Société n'a pas encore généré de revenus ou de flux de trésorerie nets provenant de la vente de ses produits. ARC^{EX} et ARC^{IM}, les

produits les plus avancés de la Société et ses seuls produits en développement clinique, n'ont pas encore été approuvés pour la commercialisation.

À la date du Prospectus, le capital de la Société comprendra des Actions Ordinaires, qui sont admises à la cotation et à la négociation sur Euronext, et des actions privilégiées d'une valeur nominale de EUR 0,12 (les "**Actions Privilégiées**"; les Actions Privilégiées, les Actions Ordinaires et les Actions Ordinaires Nouvelles sont collectivement désignées les "**Actions**"). En tant que mesure anti-OPA, l'assemblée générale des actionnaires de la Société a autorisé le Conseil (tel que défini ci-dessous) à octroyer une option d'achat à une fondation indépendante de droit néerlandais (si et quand elle sera constituée, la "**Fondation Protectrice**"), pour acquérir des Actions Privilégiées conformément à une convention d'option d'achat qui peut être conclue entre la Société et la Fondation Protectrice si elle a été constituée. En outre, la Société émettra les Actions Ordinaires Nouvelles le 28 octobre 2024. À la date du Prospectus, le capital social de la Société est composé d'Actions Ordinaires et d'Actions Ordinaires Nouvelles. Lors de l'Admission, toutes les Actions Ordinaires, les Actions Privilégiées et les Actions Ordinaires Nouvelles de la Société, chacune d'une Valeur nominale de EUR 0,12 seront cotées.

Les principaux actionnaires de la Société et leurs participations respectives sont énumérés dans le tableau suivant. Ces actionnaires détiennent directement ou indirectement une participation de 3% ou plus du capital social émis ou des droits de vote dans la Société (une participation substantielle (*substantiële deelneming*) au sens du Chapitre 5.3 de la loi néerlandaise sur la supervision financière (*Wet op het financieel toezicht*), à la date du Prospectus.

Actionnaires	Actions Ordinaires à la date du Prospectus*		
	Montant	Capital social	Droits de vote
Ottobock SE & Co. KGaA	4.500.000	540.000,00	10,1%
INKEF Capital B.V.	3.987.754	475.530,48	8,9%
LSP Advisory B.V.	3.883.368	466.004,16	8,7%
Gimv (Private Equity)	3.201.689	384.202,68	7,2%
Wellington Partners GmbH	2.638.936	316.672,32	5,9%

* Tient compte de l'effet des 10.000.000 Actions Ordinaires Nouvelles cédées dans le cadre du Placement Privé et devant être émises à la Date d'Admission.

La Société dispose d'un conseil d'administration moniste composé d'un ou plusieurs administrateurs exécutifs (*uitvoerend bestuurders*) et d'un ou plusieurs administrateurs non exécutifs (*niet-uitvoerend bestuurders*) (ensemble le "**Conseil**" et chacun un "**Administrateur**"). Dave Marver est l'Administrateur Exécutif, et Jan Øhrstrøm, Fredericus Colen, Grégoire Courtine, Ian Curtis, John de Koning, Kristina Dziekan, Vivian Riefberg, Rahma Samow et Rob ten Hoedt sont les Administrateurs Non Exécutifs. Le commissaire aux comptes indépendant de la Société est EY Accountants B.V. ("**EY**").

Quelles sont les informations financières clés concernant l'émetteur ?

États Financiers Consolidés Intermédiaires Condensés pour la période de six mois close le 30 juin 2024 et États Financiers Consolidés pour l'exercice clos le 31 décembre 2023

Les tableaux suivants présentent les informations des états financiers consolidés intermédiaires condensés de la Société au 30 juin 2024 et pour la période de six mois close à cette date (les "**États Financiers Consolidés Intermédiaires Condensés**"), qui ont été préparés conformément à la norme IAS 34, « Information Financière Intermédiaire » telle qu'adoptée par l'Union européenne et qui n'ont pas été audités ou examinés, et les états financiers consolidés à la date et pour l'exercice clos le 31 décembre 2023, qui ont été préparés conformément aux Normes Internationales d'Information Financière telles qu'adoptées par l'Union européenne ("**IFRS**") et à la Partie 9 du Livre 2 du Code civil néerlandais (les "**États Financiers Consolidés**"). Ernst and Young Accountants LLP a audité les États Financiers Consolidés et a émis un rapport de commissaire aux comptes indépendant sans réserve les concernant.

Compte de résultat consolidé condensé

En milliers d'euros	Audité		Non audité	
	Pour l'exercice clos le 31 décembre		Pour la période de six mois close le 30 juin	
	2023	2022	2024	2023
Total des recettes et autres revenus	532	2.148	208	928

Perte d'exploitation de la période	(35.463)	(32.028)	(18.749)	(18.780)
Perte nette de la période	(36.181)	(32.772)	(18.252)	(19.282)
Bénéfice par action (EUR) :				
Résultat de base par action ordinaire attribuable aux actionnaires :	(1,20)	(1,09)	(0,53)	(0,64)
Résultat dilué par action ordinaire attribuable aux actionnaires :	(1,20)	(1,09)	(0,53)	(0,64)

État consolidé condensé de la situation financière

En milliers d'euros	Audité		Non audité	
	Au 31 décembre		Au 30 juin	
	2023	2022	2024	
Total des actifs	43.629	76.593	46.854	
Total des capitaux propres attribuables aux actionnaires	17.931	52.631	18.348	

État consolidé condensé des flux de trésorerie

En milliers d'euros	Audité		Non audité	
	Pour l'exercice clos le 31 décembre		Pour la période de six mois close le 30 juin	
	2023	2022	2024	2023
Trésorerie nette générée / (utilisée) provenant des activités d'exploitation	(32.270)	(26.685)	(14.805)	(18.391)
Trésorerie nette générée / (utilisée) par les activités d'investissement	19.578	(20.417)	(7.524)	(5.303)
Trésorerie nette générée / (utilisée) par les activités de financement	813	(557)	17.642 ⁽¹⁾	775

(1) Ce montant ne comprend pas le produit du Prêt Runway (tel que défini ci-dessous).

Aucune information financière pro forma n'a été incluse dans ce Prospectus.

Déclaration sur le fonds de roulement

À la date du présent Prospectus, le Groupe est d'avis qu'il dispose d'un fonds de roulement suffisant pour faire face à ses exigences actuelles et couvrir les besoins en fonds de roulement pendant une période d'au moins 12 mois à compter de la date du présent Prospectus.

Quels sont les principaux risques spécifiques à l'émetteur ?

Les risques clés suivants concernent l'activité, les résultats d'exploitation, la situation financière et les perspectives du Groupe. En sélectionnant et en classant les facteurs de risque, le Groupe a tenu compte de circonstances telles que la probabilité que le risque se matérialise sur la base de l'état actuel des choses, l'impact potentiel que la matérialisation du risque pourrait avoir sur l'activité, la situation financière, les résultats d'exploitation et les perspectives du Groupe, et l'attention que la direction du Groupe devrait, sur la base des attentes actuelles, consacrer à ces risques s'ils devaient se matérialiser. Les investisseurs devraient lire, comprendre et prendre en considération tous les facteurs de risque, qui sont importants et doivent être lus dans leur intégralité, comme indiqué à la rubrique "Facteurs de Risques" commençant à la page 15 du Prospectus avant de prendre la décision d'investir dans les Actions Ordinaires.

- La Société est entièrement dépendante du succès de deux dispositifs expérimentaux, les plateformes ARC^{IM} et ARC^{EX}. Même si la Société est en mesure d'achever le développement clinique et d'obtenir des résultats cliniques favorables pour les indications initiales qu'elle poursuit, elle pourrait ne pas être en mesure d'obtenir l'autorisation ou l'approbation réglementaire pour, ou commercialiser avec succès, ses plateformes ARC^{IM} et ARC^{EX};
- La Société a subi d'importantes pertes d'exploitation depuis sa création, et s'attend à subir des pertes d'exploitation à l'avenir, et elle pourrait ne pas être en mesure d'atteindre ou de maintenir la rentabilité, ce

qui pourrait avoir un impact négatif sur le prix du marché de ses Actions Ordinaires et sur sa capacité à lever des capitaux et à poursuivre ses activités ;

- La Société peut avoir besoin de capitaux supplémentaires pour financer ses opérations prévues, qui peuvent ne pas être disponibles à des conditions acceptables ou ne pas l'être du tout. Cela peut avoir un impact négatif sur le plan de vente et de marketing de la Société, sur ses efforts de recherche et de développement en cours et avoir un impact négatif important sur ses activités, sa situation financière et son résultat d'exploitation;
- Le 28 juin 2024, la Société, ONWARD Medical S.A. et ONWARD Medical Inc. ont signé un contrat de prêt et de garantie d'un montant maximal de EUR 52,5 millions avec le prêteur basé aux Etats-Unis Runway Growth Finance Corp. ("**Runway**") (le "**Prêt Runway**"). Le Prêt Runway est divisé en cinq tranches de crédit individuelles, la mise à disposition de la deuxième, troisième et quatrième tranche de crédit étant subordonnée à la réalisation de certaines étapes clés par la Société. Il porte un taux d'intérêt égal au Taux de Financement Garanti au Jour le Jour (*Term Secured Overnight Financing Rate*, SOFR) pour une période d'intérêt de trois mois (actuellement au taux de 6,00 % et soumis à un plancher de 4,25 %), plus une marge de 6,5 %. Il ne peut être garanti que la Société générera la liquidité nécessaire pour être en mesure de payer les intérêts dus au titre du Prêt Runway ainsi que les investissements nécessaires au développement de son activité d'exploitation. Si la Société ou une Société du Groupe viole une obligation au titre du Prêt Runway (y compris, mais sans s'y limiter, le non-respect des engagements ou un défaut de paiement), elle peut être tenue de rembourser le prêt avant qu'il ne devienne normalement exigible et Runway peut disposer des garanties importantes que la Société et les Sociétés du Groupe ont fournies pour garantir le prêt. Cela pourrait avoir un effet défavorable significatif sur les actifs nets de la Société et sa situation financière;
- La Société peut être confrontée à une concurrence importante, qui peut se traduire par le fait que d'autres découvrent, développent ou commercialisent des produits avant elle ou avec plus de succès qu'elle;
- Le recrutement et la rétention des patients dans les essais cliniques est un processus coûteux et long et pourrait être rendu plus difficile ou impossible par de multiples facteurs hors de son contrôle, ce qui pourrait entraîner des retards importants dans la réalisation de ces essais ou pourrait l'amener à abandonner un ou plusieurs essais cliniques;
- La Société doit résoudre des défis techniques et d'ingénierie avant de pouvoir commercialiser un produit aux personnes souffrant de LME. En outre, la Société doit obtenir l'autorisation ou l'approbation de la FDA avant de pouvoir vendre l'un de ses produits aux États-Unis et la certification CE avant de pouvoir vendre l'un de ses produits dans l'Union européenne. L'approbation d'autorités réglementaires similaires dans des pays autres que les États-Unis et l'Union européenne est requise avant de pouvoir vendre ses produits dans des pays qui n'acceptent pas l'autorisation ou l'approbation de la FDA ou la certification CE. La Société peut encourir des coûts supplémentaires ou des retards dans l'achèvement, ou finalement ne pas être en mesure d'achever le développement et la commercialisation de ses produits si cette autorisation ou approbation est refusée ou retardée;
- Si la Société obtient une autorisation ou une approbation pour ses produits, leur succès commercial dépendra en partie du niveau de remboursement qu'elle recevra de tiers pour le coût de ses produits pour les utilisateurs;
- Si ses dispositifs expérimentaux sont autorisés ou approuvés, la Société devra obtenir l'accès aux installations hospitalières et aux cliniques, ou ses ventes pourraient être affectées négativement;
- La Société peut ne pas obtenir les approbations nécessaires, se voir accorder les classifications de novo ou les autorisations pour ses plateformes ARC^{IM} et ARC^{EX} ou les dispositifs futurs et les indications élargies, et l'incapacité à obtenir en temps voulu ces autorisations ou approbations réglementaires aurait un impact négatif sur sa capacité à développer son activité;
- Le processus de développement clinique requis pour obtenir les autorisations ou les approbations réglementaires est long et coûteux, avec des résultats incertains, et les données développées dans ces essais cliniques sont sujettes à interprétation par la FDA et des autorités réglementaires étrangères. Si les essais cliniques de la plateforme ARC^{EX} et de la plateforme ARC^{IM} actuelles et les produits futurs ne produisent pas les résultats nécessaires à l'obtention d'une autorisation ou d'une approbation réglementaire, d'une classification ou d'une autorisation de novo octroyée aux États-Unis ou, en ce qui concerne les produits actuels ou futurs de la Société, ailleurs, celle-ci sera incapable de commercialiser ces produits et peut encourir des coûts supplémentaires ou subir des retards dans la réalisation, ou finalement être incapable de réaliser la commercialisation de ces produits;
- La quasi-totalité des actifs du Groupe, y compris la propriété intellectuelle, est nantie en faveur de Runway, et la réalisation de ce nantissement pourrait nuire substantiellement au développement et aux opérations de la Société à l'avenir; et

- La Société accorde une licence pour certaines technologies sous-jacentes au développement de ses dispositifs expérimentaux et la perte de cette licence aurait un impact négatif significatif sur ses activités, sa situation financière et ses résultats d'exploitation et entraînerait une baisse de la valeur de marché de ses Actions Ordinaires.

Section C – Informations clés sur les Valeurs Mobilières

Quelles sont les principales caractéristiques des valeurs mobilières ?

Les Actions Ordinaires sont des actions ordinaires représentatives du capital émis de la Société, qui consiste en 34.628.832 actions ordinaires du capital social émis de la Société d'une valeur nominale de EUR 0,12 chacune. Les Actions Ordinaires sont exprimées et seront négociées en euros sur Euronext. L'ISIN des Actions Ordinaires est NL0015000HT4.

Les Actions Ordinaires (y compris les Actions Ordinaires Nouvelles) seront de rang égal entre elles (*pari passu*) et les Actionnaires auront droit aux dividendes et autres distributions déclarées après l'adoption des comptes annuels qui montrent que cette distribution est autorisée et payée sur celles-ci. Le Conseil peut également décider de procéder à des distributions intermédiaires conformément aux statuts de la Société (les "**Statuts**"). Chaque Action Ordinaire est assortie de droits de distribution et octroie à son détenteur le droit d'assister et d'exprimer une voix à l'assemblée générale de la Société, étant l'organe de société, ou lorsque le contexte l'exige, l'assemblée physique des Actionnaires (*algemene vergadering*) (l' "**Assemblée Générale**"). Aucune restriction sur les droits de vote n'est attachée aux Actions Ordinaires.

Lors de l'émission d'Actions Ordinaires ou de l'octroi de droits de souscription d'Actions Ordinaires, sous réserve des exceptions (i.e., en cas d'émission d'Actions Ordinaires au profit de salariés de la Société ou d'une Société du Groupe, en contrepartie d'un apport autrement qu'en numéraire ou en vertu de l'exercice d'un droit de souscription d'Actions Ordinaires précédemment acquis), chaque Actionnaire disposera d'un droit de préemption proportionnel au nombre d'Actions Ordinaires qu'il détient déjà. Aucun droit de préemption n'est attaché aux Actions Privilégiées et aucun droit de préemption ne s'applique en cas d'émission d'Actions Privilégiées. Les droits de préemption ont été limités ou exclus par une résolution de l'Assemblée Générale autorisant le Conseil à émettre des Actions Ordinaires ou à accorder des droits de souscription d'Actions Ordinaires pendant une période de 18 mois à compter du 13 juin 2024 et à limiter ou exclure les droits de préemption relatifs à ces Actions Ordinaires et les droits y afférents afin de satisfaire aux obligations découlant des plans d'intéressement des salariés et à d'autres fins sans frais de convocation d'une assemblée générale extraordinaire des Actionnaires. La présente autorisation du Conseil est limitée à un maximum de 10 % du capital social émis de la Société, étant entendu que le pourcentage susmentionné sera calculé par référence au capital social émis de la Société déterminé à la fermeture des bureaux le 13 juin 2024. En outre, l'Assemblée Générale a autorisé le Conseil, pour une période de 18 mois à compter du 13 juin 2024 à émettre des Actions Ordinaires et à octroyer des droits de souscription d'Actions Ordinaires dans la limite de 50 % des Actions Ordinaires émises et en circulation à la fermeture des bureaux le 13 juin 2024 et à limiter ou exclure les droits de préemption dans le cadre d'une ou plusieurs augmentations de capital potentielles ou à d'autres fins stratégiques. Le Conseil a exercé l'autorisation d'exclure les droits de préemption relatifs à ces Actions Ordinaires et droits dans le cadre de l'émission des Actions Ordinaires Nouvelles le 28 octobre 2024.

En cas de procédure d'insolvabilité, les créances des actionnaires sont subordonnées à celles des créanciers de la Société. Cela signifie qu'un investisseur peut potentiellement perdre tout ou partie de son capital investi. Si et dans la mesure où des Actions Privilégiées sont en circulation, ces Actions Privilégiées primeront sur les Actions Ordinaires dans la distribution de dividendes ou dans le cadre d'une distribution effectuée lors de la liquidation de la Société.

Il n'y a pas de restrictions sur la transférabilité des Actions Ordinaires dans les Statuts. Toutefois, l'Offre à des personnes situées ou résidant dans des pays autres que les Pays-Bas, la Belgique et la France, ou qui sont citoyens de ces pays, ou qui ont un siège dans ces pays, et le transfert des Actions Offertes dans des juridictions autres que les Pays-Bas, la Belgique et la France peuvent être soumis à des réglementations ou restrictions spécifiques.

La Société n'a jamais payé ou déclaré de dividendes en espèces dans le passé et ne prévoit pas de payer de dividendes en espèces dans un avenir prévisible. La Société a l'intention de conserver tous les fonds disponibles et tous les bénéfices futurs pour financer la poursuite du développement et de l'expansion des activités de la Société.

Où les valeurs mobilières seront-elles négociées ?

Il a été demandé l'admission de toutes les Actions Ordinaires Nouvelles sous le symbole "ONWD" sur Euronext Bruxelles (cotation primaire), Euronext Amsterdam (cotation secondaire) et Euronext Paris (cotation secondaire). Les négociations des Actions Ordinaires Nouvelles sur Euronext devraient commencer, sur une base "*as-if-when-issued-and/or-delivered*", vers le 28 octobre 2024 (la "**Date d'Admission**"). Avant la Date

d'Admission, toutes les Actions Ordinaires autres que les Actions Ordinaires Nouvelles étaient déjà admises à la cotation et à la négociation sur Euronext.

Quels sont les principaux risques spécifiques aux valeurs mobilières ?

Les risques clés suivants concernent les Actions Ordinaires, les résultats d'exploitation, la situation financière et les perspectives. En sélectionnant et en classant les facteurs de risque, le Groupe a tenu compte de circonstances telles que la probabilité que le risque se matérialise sur la base de l'état actuel des choses, l'impact potentiel que la matérialisation du risque pourrait avoir sur l'activité, la situation financière, les résultats d'exploitation et les perspectives du Groupe, et l'attention que la direction du Groupe devrait, sur la base des attentes actuelles, consacrer à ces risques s'ils devaient se matérialiser. Les investisseurs devraient lire, comprendre et prendre en considération tous les facteurs de risque, qui sont importants et doivent être lus dans leur intégralité, comme indiqué à la rubrique "Facteurs de Risques" commençant à la page 15 du présent Prospectus avant de prendre la décision d'investir dans les Actions Ordinaires :

- Le versement de tout dividende futur dépendra de la situation financière et des résultats d'exploitation du Groupe, ainsi que des distributions des filiales opérationnelles de la Société à la Société ; et
- Certains actionnaires importants de la Société après l'Admission peuvent avoir des intérêts différents de ceux de la Société et peuvent être en mesure de contrôler la Société, y compris le résultat des votes des actionnaires.

Section D – Informations clés sur l'Admission

A quelles conditions et selon quel calendrier puis-je investir dans les valeurs mobilières ?

L'Admission. L'Admission devrait avoir lieu à la Date d'Admission.

Admission à la négociation. Avant la Date d'Admission, toutes les Actions Ordinaires autres que les Actions Ordinaires Nouvelles étaient déjà admises à la cotation et à la négociation sur Euronext. Il a été demandé d'admettre les Actions Ordinaires Nouvelles à la cotation et à la négociation sur Euronext Bruxelles (cotation primaire), Euronext Amsterdam (cotation secondaire) et Euronext Paris (cotation secondaire) sous le symbole "ONWD" avec le numéro ISIN NL0015000HT4. Il est prévu que la négociation des Actions Ordinaires Nouvelles sur Euronext Bruxelles (cotation primaire), Euronext Amsterdam (cotation secondaire) et Euronext Paris (cotation secondaire) puisse commencer à la Date d'Admission.

Agent Introduceur : ING BANK N.V. est l'agent introduceur dans le cadre de l'Admission.

Dilution. Le placement privé des Actions Ordinaires Nouvelles auprès de certains investisseurs qualifiés tels que définis à l'Article 2 du Règlement Prospectus (les "**Investisseurs Qualifiés**") dans l'Espace Économique Européen, auprès de certains investisseurs qualifiés tels que définis par le Règlement Prospectus qui fait partie du droit interne en vertu de la loi de 2018 de (retrait de) l'Union européenne (le "**Règlement Prospectus U.K.**") au Royaume-Uni qui sont également (i) des personnes ayant une expérience professionnelle en matière d'investissements relevant de l'Article 19(5) du Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (tel que modifié, l' "**Ordonnance**"), (ii) des entités à valeur nette élevée et d'autres personnes relevant de l'Article 49(2)(a) à (d) de l'Ordonnance ou (iii) les personnes à qui une invitation ou une incitation à s'engager dans une activité d'investissement (au sens de la section 21 du Financial Services and Markets Act 2000 (tel que modifié, le "**FSMA 2000**") en rapport avec l'émission ou la vente de toute Action Ordinaire Nouvelle peut légalement être communiquée ou faire l'objet d'une communication (toutes ces personnes étant désignées sous le nom de "**Personnes Concernées**") et auprès d'investisseurs institutionnels dans certaines autres juridictions (le "**Placement Privé**") entraînera une dilution des droits de vote des actionnaires de la Société détenant des actions de la Société avant le Placement Privé. Les Actions Ordinaires Nouvelles, souscrites par les investisseurs qui ont participé au Placement Privé, ont déjà été attribuées aux investisseurs dans le cadre du Placement Privé le 24 octobre 2024. L'effet dilutif consécutif à la réalisation du Placement Privé est résumé dans le tableau ci-dessous:

	Préalablement au Placement Privé	Suite au Placement Privé
Nombre d'actions ordinaires d'une valeur nominale de 0,12 EUR chacune	34.628.832	44.628.832
% de dilution.....		22,4

Frais estimés. Les frais et taxes liés au Placement Privé et à l'Admission à la charge de la Société sont estimés à environ EUR 3,4 millions.

Qui est l'émetteur et/ou la personne qui demande l'Admission ?

La Société procède à l'admission des Actions Ordinaires Nouvelles. La Société est constituée sous la forme d'une société anonyme (*naamloze vennootschap*) ayant son siège statutaire (*statutaire zetel*) à Amsterdam, aux Pays-Bas et exerçant ses activités en vertu du droit néerlandais. Le LEI de la Société est 9845007A2CC4C8BFSB80 et son numéro d'immatriculation au registre du commerce est 64598748.

Pourquoi le présent prospectus est-il produit ?

Motifs de l'Admission et utilisation des produits. L'Admission créera des liquidités pour les détenteurs des Actions Ordinaires Nouvelles. La Société a l'intention de distribuer le produit net du Placement Privé comme suit : (i) environ 40 % pour financer les activités de recherche et développement, incluant le développement de produits, les essais cliniques et les activités réglementaires pour le système ARC^{EX} expérimental visant à rétablir la fonction des mains et des bras, le système ARC^{IM} expérimental visant à améliorer la régulation de la pression artérielle et d'autres indications exploratoires, et le système expérimental, qui utilise la technologie de l'interface cerveau-ordinateur ("**BCI**") en conjonction avec la thérapie ARC^{IM} ("**ARC^{BCI}**") pour restaurer le mouvement réfléchi du corps humain après une LME, (ii) environ 30 % pour soutenir le lancement commerciale prévu du système ARC^{EX} aux États-Unis au cours du second semestre de 2024, incluant le recrutement d'une organisation commerciale sur le terrain et mener des activités de vente, la production de matériel de formation et d'éducation et l'organisation d'événements de formation, la participation à des congrès, le développement des capacités d'assistance à la clientèle et mener des activités d'assistance à la clientèle, et la conduite des activités d'accès au marché et de remboursement, (iii) environ 20 % pour le développement de la qualité, les capacités opérationnelles et administratives, (iv) environ 5 % pour les besoins en fonds de roulement et les opportunités stratégiques potentielles, visant à établir, maintenir ou renforcer un avantage concurrentiel par le biais d'accords de licence, d'acquisitions d'actifs ou d'actions, ou d'autres accords (de partenariat ou autres) et (v) environ 5 % des fonds seront alloués à la couverture des coûts de financement associés aux obligations existantes dans le cadre du financement actuel et anticipé de la dette. La Société pourrait être amenée à lever des capitaux supplémentaires à l'avenir afin de répondre à ses besoins de financement.

Conflits d'intérêts les plus importants. Il n'existe aucun conflit d'intérêts important concernant l'Admission

RISK FACTORS

Before investing in the Ordinary Shares, prospective investors should carefully consider the material risks described below, together with the other information contained and/or incorporated by reference in this Prospectus. 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 below) business, results of operations, financial condition and prospects. In that event, the value of the Ordinary Shares could decline, and an investor might lose part or all of its investment.

All of these risk factors and events are contingencies, which may or may not occur. The Company together with its subsidiaries within the meaning of article 2:24b of the Dutch Civil Code (Burgerlijk Wetboek) ("DCC") (the "Group Companies", each a "Group Company", and together with the Company, the "Group") may face a number of these risks described below simultaneously. In accordance with article 16 of the Prospectus Regulation, the most material risk factors have to be presented first in each category. The order of categories in which risks are presented and order of subsequent risk factors in each category is not necessarily an indication of the likelihood of the risks actually materializing, of the potential significance of the risks to the Group, or of the scope of any potential harm to the business, results of operations, financial condition and prospects of the Group.

In selecting and ordering 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 described below are the material risks concerning the Group's business and the Ordinary Shares, they are not the only risks relating to the Group and the Ordinary 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 Ordinary 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.

Prospective investors should carefully read the entire Prospectus and should reach their own views before making an investment decision with respect to any Ordinary Shares. Furthermore, before making an investment decision with respect to any Ordinary Shares, prospective investors should consult their own stockbroker, bank manager, lawyer, auditor or other financial, legal and tax advisers, and carefully review the risks associated with an investment in the Ordinary Shares and consider such an investment decision in light of their personal circumstances.

Risks related to the Company

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

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.

The Company is a medical technology company with no commercial operating history. To date, the Company has invested substantially all of its efforts in the research and development of, and seeking regulatory clearance or approval for, its ARC^{IM} and ARC^{EX} platforms. The Company is not profitable and has incurred losses each year since beginning its operations in 2014. The Company has no 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.

The Company has not yet derived sufficient revenues to support its operations, as its prior activities have consisted of developing its technology and conducting preclinical studies and clinical trials. As

a result, the Company has recorded net losses of EUR 36.2 million and EUR 32.7 million for the years ended 31 December 2023 and 2022, respectively and EUR 18.3 million for the six-months period ended 30 June 2024 (totaling EUR 87.2 million over this aggregate period). As of 30 June 2024, the Company's retained earnings balance amounts to negative EUR 163.5 million. 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 US Food and Drug Administration ("FDA") and other government authorities in the United States of America (the "United States" or "US") 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 (i) continues research and development activities for its ARC^{IM} and ARC^{EX} technology platforms and related technologies, (ii) seeks FDA regulatory clearances and approvals (i.e. de novo classification, premarket notification ("510(k)") clearance under Section 510(k) of the US Federal Food, Drug, and Cosmetic Act ("FDCA"), Humanitarian Device Exemption ("HDE") approval, and premarket approval ("PMA") application approval) for its ARC^{IM} and ARC^{EX} platforms or other future investigational devices in the United States, regulatory approvals in Europe, and potentially other regulatory approvals in other jurisdictions, (iii) builds its commercial infrastructure and (iv) incurs additional operational costs associated with being a public company. As a result, the Company expects to continue to incur operating losses for the foreseeable future. The Company's expected future operating losses, combined with its prior operating losses, may adversely affect the market price of its Ordinary Shares and ability to raise capital and continue operations.

The Company expects that sales of its ARC^{IM} and ARC^{EX} platforms, if cleared or approved, will account for a majority of its future revenue. If the ARC^{IM} and/or ARC^{EX} platform(s) do(es) not achieve regulatory clearance or approval, or do(es) not achieve an adequate level of acceptance by physicians, healthcare payors, and patients and do(es) not receive adequate reimbursement from third-party payors, the Company may not generate sufficient revenue and may not be able to achieve profitability. 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 and cause the market price of its Ordinary Shares to decline. For further discussion related to the impact of the Company's investigational devices on its ability to generate revenues, see the interrelated risk factors: "*The Company is wholly dependent on the success of two investigational devices, the ARC^{IM} and ARC^{EX} 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^{IM} and ARC^{EX} platforms*" and "*If cleared or approved, the ARC^{IM} and ARC^{EX} 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.*"

The Company will require additional capital to finance its planned operations, which may not be available to it on acceptable terms or at all.

The net cash used from Company's operating and investing activities in 2023 and the six-month-period ended 30 June 2024 amounts to EUR 54.6 million, primarily due to its research and development activities and conducting clinical trials for its investigational devices. To maximize returns on cash available the Company implemented a cash and asset management policy to invest the cash with reputable financial institutions. The term of these short-term investments vary from 1 week up to 9 months to ensure sufficient liquidity. The Company's expenses will increase substantially in connection with any potential commercialization of its products in the United States and Europe, including hiring qualified personnel and building a sales team. Additional expenditures also will include costs associated with manufacturing and supply, sales and marketing costs, cost (including for the set-up of the sales and marketing organization) and expenses related to the deployment of a direct

sales and service organization and general operations. In addition, other unanticipated costs may arise.

As of 30 June 2024, the Company had net cash of EUR 32.1 million, and interest-bearing loans in the aggregate of EUR 16.0 million¹. "Net cash" is defined as the sum of cash and cash equivalents (EUR 24.6 million) and fixed term deposits (EUR 7.5 million) included in the current assets as included in the consolidated statement of financial position in the Interim Condensed Consolidated Financial Statements.

The Company's present and future funding requirements will depend on many factors, including:

- continuing its research and development efforts, completing its ongoing and planned clinical trials, receiving the de novo classification granting marketing authorization for ARC^{EX} for use in clinics, which the Company applied for in April 2024 and expects to receive in the fourth quarter of 2024, and subsequent to such de novo classification, 510(k) clearance is expected for ARC^{EX} for use in the home and applying for PMA approval, which will be required for ARC^{IM}, though the Company expects to pursue approval to legally market at least one indication via HDE;
- conducting additional clinical trials of its ARC^{EX} and ARC^{IM} platforms for future indications;
- its ability to retain and compensate the highly qualified personnel necessary to execute its plans;
- if cleared or approved, the costs associated with manufacturing, selling, and marketing its products in Europe and the United States, as well as other foreign jurisdictions, including the cost and timing of implementing its sales and marketing plan and expanding its manufacturing capabilities;
- its ability to effectively market and sell, and achieve sufficient market acceptance and market share for, its products;
- the costs to maintain, expand, and defend the scope of its intellectual property portfolio, as well as any other action required in connection with licensing, preparing, filing, prosecuting, defending, and enforcing any patents or other intellectual property rights;
- the emergence of competing technologies and other adverse market developments, and its need to enhance its products and/or develop new products to maintain market share in response to such competing technologies or market developments;
- its ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements; and
- its need to implement additional internal systems and infrastructure, including financial and reporting systems, incidental to being a public company.

The Company's present and future funding requirements will also depend on the Company's ability to combat increasing inflation, if the European Central Bank and the US Federal Reserve are unable to bring inflation back to targeted levels. The Company accounts for inflation in each cost category in its financial projections, based on historical trends. If the Company experiences significantly higher inflation than accounted for in its financial projections, in particular employee and supplier costs for the Company would increase and shorten the Company's cash runway.

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 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 ARC^{IM} and ARC^{EX} platforms, technologies, future revenue streams or research programs, or grant licenses

¹ This does not include the Runway Loan (as defined below).

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 plan and its ongoing research and development efforts, which would have a material adverse effect on its business, financial condition, and results of operations.

If the Company or a Group Company breaches an obligation under the Group's existing loan agreement, 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 the Group furnished to secure the loan.

On 28 June 2024, the Company, ONWARD Medical S.A. and ONWARD Medical Inc. signed a loan and security agreement in the amount of up to EUR 52.5 million with U.S.-based lender Runway Growth Finance Corp (“Runway”) (the “Runway Loan”). The Runway Loan is divided into five individual credit tranches, with the availability of the second, third and fourth credit tranche being subject to the Company's achievement of certain milestones. It bears an interest rate equal to Term Secured Overnight Financing Rate (SOFR) for a three-month interest period (currently at 6.00% and subject to a 4.25% floor), plus margin of 6.50% and provides for a number of affirmative and negative covenants by the Group, including financial covenants relating to minimum revenue, EBITDA (earnings before interest taxes depreciation and amortization) and liquidity requirements. The negative covenants restrict the Company and the Group Companies with regard to certain disposals of assets and the entering into certain financial indebtedness, among other things. To secure the Runway Loan the Company and the Group Companies have granted a security interest in substantially all of their assets.

It cannot be guaranteed, that the Company will generate the necessary liquidity to be able to pay the interest due under the Runway Loan in addition to the investments required to develop its operating business.

If the Company or any Group Company is unable to fulfill its obligations under the Runway Loan (including, but not limited to, failure to comply with covenants or a payment default) and is not in a position to cure such failure, Runway may be entitled to, inter alia, declare obligations of the Company and the Group Companies under the Runway Loan immediately due and payable or to dispose of the collateral, including cash, deposit accounts, financial assets, contract rights or rights to payment of money and intellectual property, without further negotiations. Please see also the interrelated risk factor “*Substantially all of the Group's assets, including intellectual property, are pledged to Runway, and the enforcement of such pledge could substantially harm the future development and operations of the Company*”.

The occurrence of these risks may have a material adverse effect on the net assets, the financial condition and the operations of the Company.

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.

The Company's revenue and results of operations may fluctuate from period to period due to, among others, the following reasons:

- the cost of obtaining and maintaining FDA and any other regulatory clearances or approvals for its ARC^{IM} and ARC^{EX} platforms, as well as any other future indication the Company may seek to develop its investigational devices to address;
- potential revenue generated by sales of its ARC^{IM} and ARC^{EX} platforms for cleared or approved indications, if any;
- expenses it incurs in manufacturing and selling its ARC^{IM} and ARC^{EX} platforms, if cleared or approved;
- costs associated with scaling up and expanding its manufacturing capacity;

- costs associated with building and expanding its sales and marketing efforts in the United States, Europe and internationally;
- costs associated with conducting research and development efforts for future improvements to, or versions of, its ARC^{IM} and ARC^{EX} platforms;
- the cost of complying with regulatory requirements;
- costs associated with capital expenditures;
- costs associated with any future litigation;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing its intellectual property rights and defending any intellectual property-related claims; and
- the severity, duration and impact of a global pandemic such as Covid-19, which may adversely impact its business and planned development and future commercialization of its ARC^{IM} and ARC^{EX} platforms.

Because of these and other factors, it is likely that in some future period its operating results will not meet investor expectations or those of public market analysts.

Any unanticipated change in revenues or operating results is likely to cause the price of its Ordinary Shares to fluctuate. New information may cause investors and analysts to revalue its business, which could cause a decline in the price of its Ordinary Shares.

The Company's results may be impacted by changes in foreign currency exchange rates.

If the Company's investigational devices are cleared or approved and it commences commercial operations, it may enter into a number of transactions denominated in various currencies, which could expose it to changes in currency exchange rates. The Company does not currently engage in any hedging transactions. If the Company is unable to address these risks and challenges effectively, its international operations may not be successful and its business could be harmed.

Risks related to the Company's Business

The Company is wholly dependent on the success of two investigational devices, the ARC^{IM} and ARC^{EX} 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^{IM} and ARC^{EX} platforms.

The Company currently has only two investigational devices in clinical development, the ARC^{IM} and ARC^{EX} platforms, and its business depends almost entirely on the successful clinical development, regulatory clearance or approval, and commercialization of these investigational devices, which may never occur. The Company currently has no products available for sale, generates no revenues from sales of any products, and it may never be able to develop marketable products. The Company's ARC^{IM} and ARC^{EX} platforms will require substantial additional clinical development, testing, manufacturing process development, and regulatory clearance or approval before it is permitted to commence its commercialization. For example, before obtaining the PMA approval for its ARC^{IM} platform, the Company must demonstrate, among other things, that the product is safe and effective for use in each target indication. This process can take many years. If the Company were to seek approval via the HDE pathway for the commercial sale of ARC^{IM}, the Company must demonstrate through extensive preclinical testing and clinical trials that the product candidate does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Of the large number of medical devices in development in the United States, only a small percentage successfully complete the regulatory clearance or approval process required by the FDA and are commercialized. Similarly, a substantial amount of medical devices in development will eventually not obtain a certificate of conformity required for commercialization in the European Economic Area. Accordingly, even if the Company is able to obtain the requisite capital to continue to fund its development and clinical programs, it may

be unable to successfully develop or commercialize its ARC^{IM} and ARC^{EX} platforms or any other product candidate.

The Company may face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than it does.

Currently, ARC^{IM} does not have any direct commercial competitors, however several large medical technology companies market spinal cord stimulation platforms for different indications, such as pain management. ARC^{EX} also faces competition from other companies with similar technology, each of which is pursuing similar indications to the Company and with similar technologies to ARC^{EX}. The outcome of any potential IP dispute or settlement to protect the Company's rights is hard to predict, and an adverse result could negatively impact the Company's position in the competitive landscape of Spinal Cord Injury ("**SCI**") therapies. For a discussion of how the Company's ability to protect its intellectual property portfolio may affect its ability to effectively compete, see "*Risks related to the Company's Intellectual Property*", especially the following interrelated risk factors: "*It is difficult and costly to protect its intellectual property and its proprietary technologies, and the Company may not be able to ensure their protection*", "*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*".

Current therapeutic options and technological approaches for people with SCI include exoskeletons, Functional Electrical Stimulation ("**FES**"), Epidural Electrical Stimulation ("**EES**"), Peripheral Nerve Stimulation ("**PNS**"), scaffolds and stem cells. Additionally, there are numerous pharmacological treatments available for people with SCI, to address symptoms of associated comorbidities such as spasticity, blood pressure, and mood disorders.

In general, the medical device industry is subject to intense competition and rapid and significant technological change. The Company has potential competitors, including specialized biotechnology firms, academic institutions, government agencies, and private and public research institutions. These competitors may have significantly greater financial and technical resources than the Company, and superior experience and expertise in research and development, preclinical testing, design and implementation of clinical trials, regulatory processes and approval for products, production and manufacturing, and sales and marketing of approved products. Smaller or early-stage companies and research institutions may prove to be significant competitors, particularly if they have collaborative arrangements with larger and more established medical device companies. The Company may also face competition from these parties and larger medtech companies in recruiting and retaining qualified scientific and management personnel (*see risk factor below – "The Company's success depends on its ability to retain its management, consultants and other key personnel"*), establishing clinical trial sites, and registering subjects for clinical trials.

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 the Company's 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 its clinical trials may lead to delays in its development timelines. For further discussion related to the impact of COVID-19 on enrollment and retention of patients for clinical trials, see the following interrelated risk factor: "*A pandemic, epidemic or outbreak of an infectious disease in Europe, the United States or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, could adversely affect its business.*"

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in

relation to other available therapies, including any new treatments that may be cleared or approved for the indications the Company is investigating. For example, patients may be discouraged from enrolling in its clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product candidate. In addition, patients participating in the Company's clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to its products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

Some of the indications that the Company's investigational devices are intended to treat are limited, so it expects only a subset of patients with spinal cord injury to be eligible for its clinical trials. For example, the initial targeted indication for ARC^{EX} is improvement in hand and arm strength and function for people with a cervical spinal lesion (C2-C8) with severity AIS B to D. Because the ARC^{EX} and ARC^{IM} platforms target specific patient populations, the Company must be able to identify patients in order to complete its development programs, secure regulatory clearance or approval and commercialize the ARC^{EX} and ARC^{IM} platforms successfully.

In addition, the protocols for the Company's clinical trials generally mandate that a patient cannot be involved in more than one clinical trial for the same indication. Therefore, subjects that participate in ongoing clinical trials for products that are competitive with the Company's investigational devices are not eligible to participate in its clinical trials. The Company cannot guarantee that any of its programs will identify a sufficient number of patients to complete clinical development, pursue regulatory clearance or approval and market its investigational devices, if cleared or approved. The combined number of patients in the US, Japan and Europe and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with either of the ARC^{EX} and ARC^{IM} platforms, or new patients may become increasingly difficult to identify, all of which would adversely affect its results of operations and its business. In addition, the Company relies on clinical trial sites to ensure timely conduct of its clinical trials and, while the Company has entered into agreements governing their services, the Company is limited in its ability to compel their actual performance.

An inability to recruit and enroll a sufficient number of patients for any of its current or future clinical trials would result in significant delays or may require the Company to abandon one or more clinical trials altogether, which could impact its ability to develop its investigational devices and may have a material adverse effect on its business, results of operations and financial condition.

The Company must solve technical and engineering challenges prior to being able to offer commercialized products to the SCI patient population. In addition, 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.

While the Company had anticipated to be able to launch ARC^{EX} in the second half of 2023, due to a high voltage isolation concern in the ARC^{EX} device the Company took the decision in September 2023 to redesign the device's printed circuit board assembly ("PCBA") and now continues to believe, underpinned by a positive testing report from a medical equipment testing laboratory confirming that the ARC^{EX} device conforms to prevailing electrical standards, it is on target to launch the ARC^{EX} device in the fourth quarter of 2024, subject to the FDA's regulatory review. This demonstrates the technical and engineering challenges which the Company has to solve in order to be able to offer a commercialized product to the SCI patient population. While the Company does not expect the postponement of the launch of the ARC^{EX} device to negatively impact its cash runway, there is a direct adverse impact from the delayed commercialization of ARC^{EX} on the timing of the Company's ability

to commence revenue generation through the sale of its medical devices and a negative impact on the perceived momentum of the Company's ability to execute on its commercialization strategy.

The development, manufacture, and marketing of the Company's products are also subject to government regulation in the United States, Europe and other countries. In the United States, Europe and most other countries, the Company must complete rigorous preclinical testing and extensive human clinical trials that demonstrate the safety and efficacy of a product in order to apply for regulatory clearance or approval to market the product. If the FDA or a notified body grants regulatory clearance or approval of a product, the clearance or approval may be limited to specific indications or limited with respect to its distribution. Expanded or additional indications for cleared or approved devices may not be cleared or approved, which could limit its potential revenues. Regulatory authorities from other countries may apply similar or additional limitations or may refuse to grant any approval. Consequently, even if the Company believes that preclinical and clinical data are sufficient to support regulatory clearance or approval for its products, the FDA or a notified body and regulatory authorities from other countries may not ultimately grant regulatory clearance or approval for commercial sale in any jurisdiction. If its investigational devices are not cleared or approved, its ability to generate revenues will be limited and its business will be adversely affected. For further discussion related to the Company's financial position prior to obtaining regulatory approval for its products, see the following interrelated risk factor: *"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."*

In order to market ARC^{EX} for use in clinics in the United States, the Company will need to obtain de novo classification granting marketing authorization for the device, which the Company applied for in April 2024 and expects to receive in the fourth quarter of 2024. Subsequent to obtaining such de novo classification, the Company may pursue additional regulatory clearances for ARC^{EX}. ARC^{IM} is a Class III device that will require PMA approval in order to be lawfully marketed in the United States, although, for at least one indication, it may pursue HDE approval. In Europe, under the Medical Device Regulation ("**MDR**"), ARC^{EX} will be classified as a Class IIa device and ARC^{IM} will be designated as Class III.

Once its clinical trials are completed, in the event its clinical data is not acceptable to the FDA or other comparable regulatory authorities from other countries, its ability to obtain clearance or approval under the various regulatory pathways may be delayed or may not be feasible. If the FDA, a notified body, or other comparable regulatory authorities from other countries do not approve its investigational devices in a timely fashion, or at all, its business and financial condition will be adversely affected. For further discussion related to the Company's financial position prior to obtaining regulatory approval for its products, see the following interrelated risk factor: *"The Company is wholly dependent on the success of two investigational devices, the ARC^{IM} and ARC^{EX} 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^{IM} and ARC^{EX} platforms."*

If cleared or approved, the Company may not be able to successfully commercialize its ARC^{IM} and ARC^{EX} platforms. Failure to gain market acceptance would impact the Company's revenues and may materially impair its ability to continue its business.

Even if the Company receives regulatory clearances or approvals for the commercial sale of its investigational devices, the commercial success of its products will depend on, among other things, their acceptance as a therapeutic and cost-effective alternative to competing products and treatments for people with SCI, by medical professionals working in the rehabilitation clinic setting, such as physicians, physical therapists, occupational therapists, neurologists, and physiatrists, as well as by functional neurosurgeons, patients, third-party payors such as health insurance companies, and other members of the medical community. There can be no assurance that medical professionals, hospitals, and rehabilitation clinics will adopt the use of ARC^{IM} and ARC^{EX} and establish training and procedures to implement 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. Payors may view new products or products that have only recently been launched or with limited clinical data

available, as investigational, unproven, or experimental, and on that basis may deny coverage of procedures involving use of these products. Payers may require additional clinical trials and data before providing coverage. If these investigational devices fail to gain market acceptance, the Company may be unable to earn sufficient revenue to continue its business.

For further discussion related to the Company's financial position prior to obtaining regulatory approval for its products, see the following interrelated risk factor: *"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."*

The Company's success depends on its ability to retain its management, consultants and other key personnel.

The Company depends on its senior management as well as key scientific personnel. In 2020, the Company appointed Dave Marver as Chief Executive Officer ("CEO"). The Company's Chief Scientific ("CSO") Officer, Professor Courtine, has been on its team since its inception in 2014 and currently serves as a consultant to the Company. The position of the Chief Financial Officer is filled by the Company's finance director on an interim basis (see "Management and Corporate Governance" – Management Team"). 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 and market access personnel once commercialization may begin. Although the Company will seek to hire and retain qualified personnel with experience and abilities commensurate with its needs, there is no assurance that it will succeed despite its collective efforts. The loss of the services of any of its senior management or other key personnel could hinder its ability to fulfill its business plan and further develop and commercialize its products and services. Competition for personnel in the medical technology industry is intense, and any failure to attract and retain the necessary technical, marketing, managerial, and financial personnel would have a material adverse effect on its business, prospects, financial condition, and results of operations.

The Company relies on a limited number of third-party suppliers and contract manufacturers for the manufacture 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 Company relies on third-party suppliers and contract manufacturers. 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 its 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 due to, for example, natural and man-made disasters, public health emergencies, pandemics such as COVID-19, other catastrophic events, the nature of its agreements with its contract manufacturers, its relative importance to such manufacturers as a customer or a contract manufacturer's decision to

discontinue or reduce the level of business they conduct with the Company. If the Company is required to change contract manufacturers due to any change in or termination of its relationships with these third parties, or if its manufacturers are unable to obtain the materials they need to produce its products at consistent prices or at all, it may lose sales, experience manufacturing or other delays, incur increased costs or otherwise experience impairment to its customer relationships. The Company cannot guarantee that it will be able to establish alternative relationships on similar terms, without delay or at all. For further discussion on the impact of COVID-19 on the Company's manufacturing and supply chain, see the following interrelated risk factor: "*A pandemic, epidemic or outbreak of an infectious disease in Europe, the United States or worldwide, including the outbreak of the novel strain of coronavirus disease, COVID-19, could adversely affect its business.*"

While the Company believes replacement suppliers and manufacturers exist for all materials, components, and services necessary to manufacture its ARC^{IM} and ARC^{EX} platforms, in light of the relatively low volume of orders and bespoke nature of the Company's requirements, establishing additional or replacement suppliers for any of these materials, components or services, if required, could be time-consuming and expensive, may result in interruptions in its operations and product delivery, may affect the performance specifications of its ARC^{IM} and ARC^{EX} platforms or could require that the Company modifies their designs. Even if the Company is able to find replacement suppliers or third-party contract manufacturers, it will be required to verify that the new supplier or third-party manufacturer maintains facilities, procedures, and operations that comply with its quality expectations and applicable regulatory requirements. Furthermore, its contract manufacturers could require the Company to move to another one of their production facilities or use alternative materials or components. Any of these events could require that the Company obtains a new regulatory authority approval before it implements the change, which could result in further delay and which may not be obtained at all. While the Company seeks to maintain sufficient levels of inventory as discussed above, those inventories may not fully protect it from supply interruptions.

For example, the Company uses microchip technology in its ARC^{IM} and ARC^{EX} platforms. In 2021, there has been a global shortage of microchips which may continue for an indeterminable amount of time in the future. If its third-party suppliers fail to deliver the required clinical, or if one or more of its investigational devices is approved, commercial quantities of materials, such as microchips, on a timely basis and at commercially reasonable prices, and the Company is unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, its clinical trials, potential commercialization and development of any future products will be delayed, limited or prevented, which could have a material adverse effect on its business, financial condition, and results of operations.

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 may arise with the ARC^{IM} and ARC^{EX} systems, 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. For example, the Company's current preclinical and clinical data supports the conclusion that its therapy does not increase episodes of high blood pressure when treating orthostatic hypotension. If this conclusion changes in the future, it is possible that physicians or patients will be less likely to use the Company's products, which could have an adverse effect on its business.

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 its number of employees in recent periods and has a relatively short history of operations. As of the date of this Prospectus, the Company has 98.35 full-time equivalents employed that includes both employees and contractors, including 12.3 working out of its headquarters location in Eindhoven, the Netherlands, 76.05 in Switzerland working out of its Lausanne office, and 10 in the United States. 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.

If the Company successfully achieves regulatory clearance or approval for either of its investigational devices, it 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. Any such delay or increased expense could adversely affect its ability to generate revenue and its operating results. For further discussion related to the managing growth upon obtaining regulatory approval for the Company's products, see in the interrelated risk factor "*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.*"

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 its administrative and operational infrastructure. In order to manage its operations and growth it will need to continue to improve its operational, compliance and management controls, reporting and information technology systems and financial internal control procedures. If the Company is unable to manage its growth effectively, it may be difficult for it to execute its business strategy and its operating results and business could suffer.

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 its limited experience in managing a company with substantial growth, it may not be able to effectively manage the expansion of its operations or recruit and train additional qualified personnel. The expansion of its operations may lead to significant costs and may divert the attention of its management and business development resources. If the Company fails to manage these challenges effectively, there may be an adverse effect on its business, financial condition and results of operations.

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.

The Company has relationships with several leading academic research centers throughout the world. Examples include the California Institute for Technology ("**Caltech**") (USA), University of California at Los Angeles (USA), University of Louisville (USA), and University of British Columbia (Canada). The Company's primary research partnership is with NeuroRestore, a joint research initiative involving École polytechnique fédérale de Lausanne ("**EPFL**") and Centre Hospitalier Universitaire Vaudois ("**CHUV**") in Lausanne, Switzerland, with whom the Company has an exclusive IP and commercialization license agreement. NeuroRestore's range of research activities is extensive, extending across a continuum that encompasses basic research, preclinical research that includes rodents and non-human primates, and human proof-of-concept studies. Several projects that could potentially be commercialized have shown sufficient promise to reach the human proof of concept stage. The Company will select the most promising of these projects to develop and commercialize, based primarily on clinic results and commercial viability. Each of the potential indications can leverage the existing ARC[™] platform with minor software and firmware modifications. If its relationships with NeuroRestore or other partners were to be terminated or otherwise modified, it could adversely affect its ability to expand potential indications for its ARC Therapy platforms in the future.

The Company's Chief Science Officer is a professor at EPFL. If the Company and its CSO do not prudently manage conflicts of interest, it could adversely affect the Company's relationship with EPFL and negatively impact the Company's ability to license intellectual property from EPFL and commercialize therapies that rely on that intellectual property.

This and other licenses 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 ARC^{IM} and ARC^{EX} platforms. As a result, the Company may not be able to prevent competitors from developing and commercializing competitive products in the markets that the Company hopes to address. Moreover, the Company would not own at least some of the underlying intellectual property rights, and as a result its rights would be subject to the continuation and compliance with the terms of those agreements. If such in-licenses were terminated, competitors would have the freedom to develop, seek regulatory approval of, and to market, products similar or identical to the Company's.

The Company may decide to invest its business development resources in additional partnerships, licensing agreements and other ways that will provide it with new product offerings without significant research and development activities. In addition, notwithstanding its market research efforts, its future products may not be accepted by people with SCI, their caregivers, healthcare providers or third-party payors who reimburse consumers for its products. The success of any proposed product offerings will depend on numerous factors, including its ability to:

- identify the product features that people with paralysis, their caregivers, and healthcare providers are seeking in a medical device that restores mobility and/or function and successfully incorporate those features into its products;
- identify the product features that people with stroke, Parkinson's or other similar indications require while the products are used at home as well as what items are valuable to the clinics that provide them rehabilitation;
- develop and introduce proposed products in sufficient quantities and in a timely manner;
- adequately protect its intellectual property and avoid infringing upon the intellectual property rights of third parties; and
- obtain the necessary regulatory clearance or approvals for proposed products.

If the Company fails to generate demand by developing products that incorporate features desired by consumers, their caregivers or healthcare providers, or if it does not obtain regulatory clearance or approval for proposed products in time to meet market demand, it may fail to generate sales sufficient to achieve or maintain profitability. The Company has in the past experienced, and it may in the future experience, delays in various phases of product development, including during research and development, manufacturing, limited release testing, marketing, and customer education efforts. Such delays could cause customers to delay or forgo purchases of its products, or to purchase its competitors' products. Even if the Company is able to successfully develop proposed products when anticipated, these products may not produce sales in excess of the costs of development, and they may be quickly rendered obsolete by changing consumer preferences or the introduction by its competitors of products embodying new technologies or features.

For further discussion related to the Company's ability to enhance its product offerings, see the interrelated risk factor "*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.*"

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.

The Company's activities and those of its third-party manufacturers' activities may involve the controlled storage, use and disposal of hazardous materials. For example, the Company's ARC^{IM} and ARC^{EX} investigational devices use lithium batteries. The Company and its third-party manufacturers are subject to federal, state, local and foreign laws and regulations governing the use, generation,

manufacture, storage, handling and disposal of these hazardous materials. The Company currently carries no insurance specifically covering environmental claims relating to the use of hazardous materials. Despite the safety procedures put in place by the Company and its manufacturers for handling and disposing of these materials and waste, the Company cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, state or federal or other competent authorities may curtail the Company or its manufacturers' use of these materials and interrupt their business operations, which could adversely affect the Company's 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.

The Company performs substantially all of its research and development and back office activity and maintains a substantial portion of its inventory for its ARC^{IM} and ARC^{EX} platforms in Eindhoven, the Netherlands and Lausanne, Switzerland. The Company's facilities, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. The Company's facilities, and those of its contractors, may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, tornadoes, flooding, fire and power outages, which may render it difficult or impossible for it to perform its research, development and commercialization activities for some period of time. The inability to perform those activities, combined with the time it may take to rebuild its inventory of finished product, may result in the loss of customers or harm to its reputation. The insurance taken out by the Company for damage to its property and the disruption of its business, may not be sufficient to cover all of its potential losses and this insurance may not continue to be available to it on acceptable terms, or at all.

Interruption or distress in the supply chain due to geopolitical uncertainties beyond the Company's control

Geopolitical uncertainties such as the threat of, realization, and escalation of adverse events associated with wars and conflicts, terrorism, and any tensions among states and political actors that affect the peaceful course of international relations such as for instance between Russia and Ukraine or in the Middle East (which for instance lead to general supply chain issues related to safety issues during the passage of the Red Sea) could damage or disrupt the Company's operations and those of its suppliers, partners or collaborators. Interruptions to the Company's operations could adversely affect the anticipated timing, completion and/or results of its clinical trials, and adversely affect potential future commercialization efforts. Geopolitical tensions could lead to sharply rising energy prices, which would have a negative impact on the costs for the raw materials used in the manufacturing of our products. Uncertainty in global markets may have a wide impact on the availability and price of various materials and services and might also sustainably affect global financial markets. Cost inflation may negatively impact the Company's ability to execute on its strategy in line with its business plan, while capital markets disruptions may adversely affect its future financing possibilities. All these changes may materially affect the Company economically and negatively affect its liquidity and financial position.

Active implantable medical devices such as the ARC^{IM} platform 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.

The ARC^{IM} system is a medical device with complex electronic circuits and software and includes a component that is implanted in the patient through a surgical procedure. It is not possible to design and build electronic implantable medical devices that are 100% reliable, since all electronic devices carry a risk of failure. Furthermore, all surgical procedures carry risks and the effectiveness of any medical therapy varies between patients. The consequences of failure of the ARC^{IM} system include complications arising from product use and associated surgical procedures and could potentially range from minor to life-threatening effects and even death. Adverse events associated with these risks may lead some patients to blame the Company, physicians or other parties for such occurrences. This may result in product liability lawsuits, medical malpractice lawsuits, investigations by regulatory authorities, adverse publicity, criminal charges or other harmful circumstances for the Company. Any

of those circumstances may have a material adverse effect on the Company's ability to conduct its business, obtain regulatory approval for the ARC^{IM} system, or ultimately commercialize the ARC^{IM} system, if approved.

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 become available and are subject to confirmation, regulatory audit, and verification procedures that could result in material changes in the final data.

From time to time, the Company may publicly disclose preliminary or topline data from its preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. The Company also make assumptions, estimations, calculations, and conclusions as part of its analyses of data, and it may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that the Company reports may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data it previously published. As a result, topline data should be viewed with caution until the final data is available. From time to time, it may also disclose interim data from its clinical trials. Interim or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment and treatment continues and more patient data become available or as patients from its clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm its business prospects. Further, disclosure of interim data by the Company or by its competitors could result in volatility in the price of its Ordinary Shares.

Further, others, including regulatory authorities, may not accept or agree with its assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing approval, grant, clearance or commercialization of the particular product candidate, any marketed product, and the Company in general. In addition, the information the Company chooses to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and the investors or others may not agree with what the Company determined was material or otherwise appropriate information to include in its disclosure.

If the interim, topline, or preliminary data that the Company reports differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, its ability to obtain approval for, and commercialize, its investigational devices may be harmed, which could harm its business, operating results, prospects or financial condition.

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.

The Company's information technology systems are important to operating its business. The Company relies on its information technology systems, some of which are or may be managed or hosted by or outsourced to third-party service providers, to manage its business data and other business processes. If the Company does not allocate and effectively manage the resources necessary to build, sustain, and protect appropriate information technology systems and infrastructure, or it does not effectively implement system upgrades or oversee third-party service providers, its business or financial results could be negatively impacted. The failure of the Company's information technology systems to perform as it anticipates could disrupt its business and could result in transaction or reporting errors and processing inefficiencies causing its business and results of operations to suffer.

Furthermore, its information technology systems may be vulnerable to cyber-attacks or other security incidents, service disruptions, or other system or process failures. Such incidents could result in unauthorized access to information including vendor, consumer or other company confidential data

as well as disruptions to operations. The Company has experienced in the past, and expects to continue to experience, cybersecurity threats and incidents, although to date none have been material. To address the risks to its information technology systems and data, the Company maintains an information security program that includes updating technology, developing security policies and procedures, implementing and assessing the effectiveness of controls, conducting risk assessments of third-party service providers and designing business processes to mitigate the risk of such breaches. There can be no assurance that these measures will prevent or limit the impact of a future incident. Moreover, the development and maintenance of these measures requires continuous monitoring as technologies change and efforts to overcome security measures evolve. If the Company is unable to prevent or adequately respond to and resolve an incident, it may have a material, negative impact on its operations or business reputation, and it may experience other adverse consequences such as loss of assets, remediation costs, litigation, regulatory investigations, and the failure by the Company to retain or attract customers following such an event. Additionally, the Company relies on services provided by third-party vendors for certain information technology processes and functions, which makes its operations vulnerable to a failure by any one of these vendors to perform adequately or maintain effective internal controls.

Risks related to the Company's Industry

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.

In both US and non-US markets, the Company's ability to successfully commercialize and achieve market acceptance of its ARC^{EX} and ARC^{IM} systems, if approved, 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. The Company's products are purchased by hospitals and other providers who will then seek reimbursement from third-party payors for the procedures performed using the Company's products. Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In certain markets, a product must be approved for reimbursement before it can be approved for sale in that country. Furthermore, many markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets there are private insurance systems as well as government-managed systems.

While third-party payors currently cover and provide reimbursement for procedures using the Company's currently cleared or approved products, there is no assurance that these third-party payors will continue to provide coverage and adequate reimbursement for the procedures using its products, to permit hospitals and doctors to offer procedures using its products to patients requiring treatment, or that current reimbursement levels for procedures using its products will continue. If sufficient coverage and reimbursement is not available for the procedures using the Company's products, in either the United States or in other countries, the demand for its products and its revenue will be adversely affected. Failure by hospitals and other users of the Company's products to obtain and maintain coverage and adequate reimbursement for the procedures using its products would materially adversely affect its business, financial condition and results of operations. For further discussion related to the Company's financial position prior to obtaining regulatory approval for its products, see the following interrelated risk factor: "*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.*"

In general, third-party payors, in particular in the United States, are also increasingly examining the cost effectiveness of products, in addition to their safety and efficacy, when making coverage and payment decisions. Third-party payors have also instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre-

approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. The imposition of higher deductibles tends to inhibit individuals from seeking the same level of medical treatments as they might seek if the costs were lower, particularly in the medical diagnostic portion of the Company's business. Third-party payors have also increased utilization controls related to the use of the Company's products and services by healthcare providers. Additionally, no uniform policy for coverage and reimbursement exists, and coverage and reimbursement can differ significantly from payor to payor. The Company cannot be sure that third-party payors in the countries in which its products are sold will reimburse its customers for procedures using its products at a level that will enable the Company to achieve or maintain adequate sales and price levels. Without adequate support from third-party payors, the market for the Company's products may be limited and adversely impacted. In the United States, third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations.

In Europe, reimbursement coverage and amounts are determined by country. Certain countries offer opportunities for accelerated or enhanced reimbursement for new technologies, such as NUB in Germany. However, reimbursement in Europe can generally be time-consuming, unpredictable, and require substantial, high-quality clinical evidence.

It is uncertain whether the Company's current products or any planned or future products will be viewed as sufficiently cost effective to warrant coverage and adequate reimbursement levels for procedures using such products in any given jurisdiction.

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.

In the United States, in order for physicians or clinicians to use the Company's products, the Company expects that the hospital facilities or clinics where these physicians or clinicians treat patients may require it to enter into purchasing contracts. This process can be lengthy and time-consuming and require extensive negotiations and management time. In Europe, certain institutions may require the Company to engage in a contract bidding process in the event that such institutions are considering making purchase commitments that exceed specified cost thresholds, which vary by jurisdiction. These processes are only open at certain periods of time, and the Company may not be successful in the bidding process. If the Company does not receive access to hospital facilities or clinics via these contracting processes or otherwise, or if it is unable to secure contracts or tender successful bids, its sales may be negatively impacted and its operating results may be harmed. Furthermore, it may expend significant effort in these time-consuming processes and still may not obtain a purchase contract from such hospitals or clinics.

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 if its ARC^{EX} or ARC^{IM} systems are approved, or the coverage and reimbursement available for its products and could limit the acceptance and availability of its product candidates. The adoption of proposals to control costs, such as the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, (collectively, the "**Affordable Care Act**"), could have a material adverse effect on the Company's business, financial condition and results of operations. There is no certainty that the Affordable Care Act, as currently enacted or as amended in the future, will not harm its business and financial results, and it is not possible to predict how future federal or state legislative or administrative changes relating to healthcare reform will affect its business.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. It is not possible to predict the initiatives that

may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- the Company's ability to set a price that it believes is fair for its products;
- the Company's ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several US Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit the Company's ability to generate revenue and attain profitability.

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 (e.g. in the framework of the reimbursement thereof) can be applicable or developed on national levels.

A pandemic, epidemic or outbreak of an infectious disease in Europe, the United States or worldwide, including the outbreak of the novel strain of coronavirus disease (COVID-19) could adversely affect its business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in Europe, the United States or worldwide, the Company's business may be adversely affected. Disruptions or potential disruptions include restrictions on the ability of its future sales representatives, clinical specialists and other personnel to travel and access customers for training and case support; inability of its suppliers to manufacture components and parts and to deliver these to the Company on a timely basis, or at all; disruptions in its production schedule and ability to manufacture and assemble products; inventory shortages or obsolescence; delays in actions of regulatory authorities; delays in operations at insurance agencies, which may impact timelines for the issuance of insurance coverage policies and local coverage determinations; delays in clinical trials; diversion of or limitations on employee resources that would otherwise be focused on the operations of its business, including because of sickness of employees or their families or the desire of employees to avoid contact with groups of people; delays in growing or reductions in its sales organization, including through delays in hiring, lay-offs, furloughs or other losses of sales representatives or salary and compensation reductions; restrictions in its ability to ship its products to customers; business adjustments or disruptions of certain third parties, including suppliers, medical institutions and clinical investigators with whom the Company conducts business; increase in bad debts due to an adverse impact of the pandemic on its clients' cash flows and resulting decrease in collectability of its account receivables; and additional government requirements or other incremental mitigation efforts that may further impact its or its suppliers' capacity to advance its investigational devices through clinical trials.

In 2021, the Company's business, financial condition, and results of operations were negatively affected by COVID-19 pandemic and the various restrictions and measures imposed by national, state, and local authorities in an effort to control the spread of the disease. Among others, research and development of the Company's ARC[™] system was impacted by work-from-home requirements, limiting the Company's ability to test and debug hardware and software systems, as these processes require access to laboratories and equipment. The Company experienced delays in patient enrollment in its Up-LIFT Study from September 2020 to January 2021, and reduced productivity as a result of employees' inability to work due to illness.

A future wide-scale outbreak of infectious disease similar to COVID-19 could negatively affect the Company's business in numerous ways. The Company's sales representatives, clinical specialists, and other personnel may be unable to travel and access customers for training and case support. The Company's production schedule may be affected if suppliers cannot manufacture or deliver parts and components on time. Pandemic-related restrictions could lead to, among others, inventory shortages or obsolescence; delays in approval of the Company's devices by regulatory authorities; delays in decisions by insurance companies regarding coverage of its products; delays in clinical trials; delays in growing its sales organization; adjustments or disruptions to the business of third parties we work with, including suppliers, medical institutions, and clinical investigators; decrease in collectability of its account receivables due to the adverse impact of the pandemic on its clients' cash flows; and reduced capacity of its suppliers to advance its investigational devices through clinical trials. While it is difficult to predict the potential economic impact and duration of a future outbreak, the current pandemic has resulted in significant disruption of global financial markets, reducing the Company's ability to access capital, which could in the future negatively affect its liquidity. In addition, a recession or market correction could have an adverse effect on the Company's long-term business as hospitals reduce capital spending.

To the extent a pandemic (like COVID-19) adversely affects the Company's business and financial results, it may also have the effect of heightening many of the other risks described herein, including those relating to incurring future operating losses, advance of the ARC^{IM} and ARC^{EX} platforms through regulatory pathways, and if cleared or approved, successful commercialization, supply chain and distribution channels.

See also discussion about the impact of COVID-19 in the following interrelated risk factors: "*The Company relies on a limited number of third-party suppliers and contract manufacturers for the manufacture 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.*", "*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.*", "*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.*", and "*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 trial.*"

Risks related to Government Regulation

The Company may not receive the necessary approvals, granted de novo classifications, or clearances for its ARC^{EX} and ARC^{IM} 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.

In order to market ARC^{EX} for use in clinics in the United States, the Company will need to obtain de novo classification granting marketing authorization for the device, which the Company applied for in April 2024 and expects to receive in the fourth quarter of 2024. Subsequent to obtaining such de novo classification, it intends to pursue additional regulatory clearances for ARC^{EX}, including use at home. ARC^{IM} is a Class III device that will require PMA approval in order to be lawfully marketed in the United States, although for at least one indication, it may pursue HDE approval. In Europe, under the MDR, ARC^{EX} is expected to be designated as a Class IIa device and ARC^{IM} is expected to be designated as Class III.

The PMA approval, de novo classification, and the 510(k) clearance processes can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process, which may require a clinical trial, usually takes from three to seven months, but can last longer, while the de novo classification process is usually longer and often requires a clinical trial. The process of obtaining a PMA is much more costly and uncertain than the de novo or 510(k) clearance processes and generally takes one year, or even

longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials.

The FDA can delay, limit or deny approval, grant of a de novo classification or clearance of a device for many reasons, including:

- its inability to demonstrate to the satisfaction of the FDA or the applicable regulatory authority that its products are safe or effective for their intended uses or, for a 510(k) device, that they are substantially equivalent to the predicate;
- the disagreement of the FDA or the applicable foreign regulatory authority with the design or implementation of its clinical trials or the interpretation of data from preclinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in its clinical trials;
- the data from its preclinical studies and clinical trials may be insufficient to support approval, de novo classification or clearance where required;
- its inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities the Company uses may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory authorities to change significantly in a manner that increases the costs of compliance or that renders its clinical data or regulatory filings insufficient for regulatory clearance or approval.
- Despite the time, effort and cost, a device may not be approved, granted a de novo classification, or cleared by the FDA. Any delay or failure to obtain necessary regulatory authorizations could harm its business. Furthermore, even if the Company is granted clearances, de novo classification requests or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.
- In the United States, the Company intends to seek approval of its ARC^{IM} platform through the PMA pathway and grant of a de novo classification for the ARC^{EX} platform. Many types of modifications to the ARC^{IM} platform not previously approved may require the Company to submit a new PMA or PMA supplement and obtain FDA approval prior to implementing the change. Similarly, modifications to the ARC^{EX} platform following de novo classification or subsequent 510(k) clearance may require the Company to submit a new 510(k), or could require a new de novo classification request or even a new PMA. The FDA may not agree with the Company's decisions regarding whether a new submission is necessary. If the FDA requires the Company to go through a lengthier, more rigorous process for future products or modifications to existing products than it had expected, product introductions or modifications could be delayed or canceled, which could adversely affect its ability to grow its business.

In order to sell its products in member countries of the European Economic Area ("**EEA**") its products currently must comply with the essential requirements of the Council Directive 93/42/EEC ("**EU Medical Devices Directive**"). Compliance with these requirements is a prerequisite to be able to affix the Conformité Européene ("**CE**"), mark to its products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements the Company must perform a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a member state of the EEA to conduct conformity assessments, or a notified body. Depending on the relevant conformity assessment procedure, the notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of its devices. The notified body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their

conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity. The EU Medical Devices Directive is being replaced by a new Medical Devices Regulation in the EEA. The Regulation (EU) 2017/745 (the new "**Medical Devices Regulation**") entered into force on 25 May 2017, and is subject to a transition period during which manufacturers of medical devices must update their technical information and processes in line with the new Medical Devices Regulation. Under European law, a Regulation differs from a Directive since it, as a Regulation, is directly effective in each Member State, without the need for implementing legislation (which is required for a Directive). The new Medical Devices Regulation has become fully applicable on 26 May 2021, following which all manufacturers of medical devices sold in the EEA will have to be compliant with the new Medical Devices Regulation. The new Medical Devices Regulation has the same basic requirements as the EU Medical Devices Directive, but is generally more stringent, especially in terms of risk classes and the oversight provided by notified bodies. There is also more emphasis on vigilance and post-market surveillance.

Following the UK's departure from the EU on 31 January 2020, the UK (which comprises England, Scotland, Wales and Northern Ireland) continued to follow the same regulations as the EU during a transition period which ended on 31 December 2020. Now that this transition period has ended, all medical devices must be registered with the Medicines and Healthcare products Regulatory Agency ("**MHRA**") before being placed on the UK market. European CE marks have been continued to be recognized in UK until 30 June 2023. Since then, a UK Conformity Assessed ("**UKCA**") mark is required for a medical device to be marketed in the United Kingdom. The new Medical Devices Regulation will not automatically apply in the UK, so the regulation of medical devices in the UK may diverge from EU Regulations in future. The EU regulatory framework on medical devices will, however, continue to apply in Northern Ireland under the Northern Irish Protocol and medical devices in Northern Ireland may either carry a European CE mark or a CE UK Northern Ireland ("**UKNI**") mark (although devices bearing the CE UKNI marking will not be accepted on the EU market).

On 28 November 2022, the Swiss Parliament reached a key decision by instructing the Swiss Federal Council to adapt national laws to enable Switzerland to accept medical devices with FDA approval.

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 regulatory clearances or approvals 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. If clinical trials of the current ARC^{EX} platform and ARC^{IM} 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.

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, including:

- the Company is required to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials, and FDA may reject the Company's IDE application and notify it that it may not begin investigational trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of its clinical trials;
- regulators and/or institutional review boards ("**IRBs**") or other reviewing bodies may not authorize the Company or its investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- the Company may not reach agreement on acceptable terms with prospective contract research organizations ("**CRO**"), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials may produce negative or inconclusive results, or the Company may not agree with regulatory authorities on the interpretation of its clinical trial results, and it may decide, or regulators may require it, to conduct additional clinical trials or abandon product development programs;
- the number of subjects or patients required for clinical trials may be larger than the Company anticipates, enrollment in these clinical trials may be insufficient or slower than it anticipates, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than anticipated;
- its third-party contractors, may fail to comply with regulatory requirements or meet their contractual obligations to the Company's in a timely manner, or at all;
- the Company might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- the Company may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which it may be required to submit to an IRB and/or regulatory authorities for re-examination;
- regulators, IRBs, or other parties may require or recommend that the Company or its investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials may be greater than the Company anticipates;
- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;
- the Company may be unable to recruit a sufficient number of clinical trial sites or trial subjects;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with the Company's manufacturing processes for clinical supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or it may experience interruptions in supply;
- approval policies or regulations of FDA or applicable foreign regulatory authorities may change in a manner rendering its clinical data insufficient for approval; and
- its current or future products may have undesirable side effects or other unexpected characteristics.

Furthermore, the Company relies on clinical trial sites to ensure the proper and timely conduct of its clinical trials and while the Company has agreements governing their committed activities, the Company has limited influence over their actual performance. The Company depends on its CROs to support the conduct of its clinical trials in compliance with good clinical practice ("**GCP**"), requirements. To the extent its CROs fail to help oversee the conduct of the study in compliance with

GCP standards or are delayed for a significant time in the execution of the trial, including achieving full enrollment, it may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States and Europe may subject the Company to further delays and expenses as a result of increased shipment costs, additional regulatory requirements, as well as expose the Company to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care. Any of these occurrences could have an adverse effect on the Company's business, financial condition and results of operations.

Successful results of preclinical studies are not necessarily indicative of future clinical trial results, and predecessor clinical trial results may not be replicated in subsequent clinical trials. Moreover, interim results or topline results may be subject to change upon full review of the data from a clinical trial. Additionally, the FDA's approval of an IDE application permits initiation of the clinical trial described in the IDE application but does not mean that the FDA agrees that the study design is appropriate or that the results of the study will be sufficient to obtain marketing regulatory clearance or approval. The FDA may disagree with the Company's interpretation of the data from its preclinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to demonstrate safety or effectiveness, and may require the Company to pursue additional preclinical studies or clinical trials, which could further delay the clearance, de novo classification, or approval of its products. The data the Company collects from its preclinical studies and clinical trials may not be sufficient to support FDA approval, a request for de novo classification, or clearance, and if the Company is unable to demonstrate the safety and effectiveness of its future products in its clinical trials, it will be unable to obtain regulatory approval, a granted de novo classification, or clearance to market its products.

In addition, the Company may estimate and publicly announce the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals, which are often referred to as milestones. These milestones could include the submission to the FDA of an IDE application to commence a clinical trial for a new product candidate; the enrollment of patients in clinical trials; the release of data from clinical trials; and other clinical and regulatory events; and the obtainment of the right to affix the CE mark in the European Union. The actual timing of these milestones could vary dramatically compared to its estimates, in some cases for reasons beyond its control. The Company cannot assure that it will meet its projected milestones and if it does not meet these milestones as publicly announced, the commercialization of its products may be delayed and, as a result, the price of its Ordinary Shares may decline.

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.

In 2017, the FDA granted a Breakthrough Device Designation for the ARC^{EX} platform for hand/arm function, and in May 2020, granted a Breakthrough Device Designation for the ARC^{IM} platform for recovery of leg motor functions and neurological controls. In June 2021, the FDA additionally granted a Breakthrough Device Designation for the ARC^{IM} platform for blood pressure and support of trunk stability. In September 2022, the FDA granted Breakthrough Device Designations for the ARC^{EX} platform for improving or restoring lower extremity sensory and motor function in people with chronic neurological deficits resulting from SCI and for the ARC^{IM} platform for treating neurogenic bladder dysfunction in people with SCI. In November 2022, the FDA granted Breakthrough Device Designations for the ARC^{EX} platform for treating neurogenic bladder dysfunction in people with SCI. In January 2023, the FDA granted Breakthrough Device Designations for the ARC^{EX} platform for treating episodic orthostatic hypotension adjunctive to standard of care treatment in adults with chronic SCI and in February 2023, the FDA granted further Breakthrough Device Designations for the ARC^{EX} platform for alleviating spasticity symptoms adjunctive to standard of care therapy in adults with chronic SCI. In May 2023, the FDA granted a Breakthrough Device Designation for the ARC^{IM} platform for spasticity in people with SCI. In February 2024, the FDA granted a Breakthrough Device Designation for the system, that uses brain-computer interface ("**BCI**") technology in conjunction with the ARC^{IM} Therapy ("**ARC^{BCI}**") to restore thought-driven lower limb mobility after SCI.

The goal of the FDA's Breakthrough Devices Program is to provide patients and healthcare providers with timely access to devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions by speeding up their development, assessment and review. There is no assurance the Company will receive similar designations for any of its future investigational devices. Further, even though the Company has received Breakthrough Device Designation for ARC^{EX}, ARC^{IM} and the ARC^{BCI} system, it may not experience a faster development, review or clearance or approval process compared to conventional FDA procedures, and it may not receive regulatory clearance or approval at all. Breakthrough Device Designation does not change the statutory standards for approval, de novo classification, or clearance. The FDA may withdraw Breakthrough Device Designation 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.

There is no assurance that the Company will be able to obtain Humanitarian Device Exemption approval or even if it obtains Humanitarian Device Exemption approval, that it will be able to recoup its expenses from selling such Humanitarian Device Exemption approved product.

The Company may seek approval for at least one indication for the ARC^{IM} platform through the FDA's HDE pathway. Prior to submission of an HDE application, the Company must first obtain a Humanitarian Use Device ("HUD") designation from FDA's Office of Orphan Products Development. If the Company does not receive HUD designation to product candidates for which it seeks such designation, it could limit its ability to obtain approval for such product candidate on a timely basis, if at all. Without such designation, the Company would be required to demonstrate efficacy rather than the reduced HUD standard of demonstrating that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Along with the extended review time that would be required without HUD designation, a delay in PMA submission in the event the HUD designation is not received could result in a delay of 12 months or longer before the Company can commercialize such product. As such, if the Company is unable to obtain HDE approval for a product candidate such as the ARC^{IM} platform, its business and financial condition will be adversely affected.

Even if the Company is able to obtain HDE approval, the Company does not expect to be able to sell the HDE approved product for profit. HUDs marketed under HDE approvals generally cannot be sold for an amount that exceeds the costs of research and development, fabrication and distribution of the device, except in limited circumstances. If the FDA determines that the HDE product does not meet the eligibility criteria to sell such product for profit, which are generally limited to devices targeting pediatric populations, the Company will be unable to do so. Should the FDA determine that it is eligible to sell its HDE approved product for profit, the number of products that the Company may sell for profit will be limited to a quantity determined by the FDA and known as the Annual Distribution Number ("ADN"), which is the number of devices reasonably necessary to treat or diagnose an individual per year multiplied by 8,000. If the number of devices distributed in a year exceeds the ADN, it may continue to sell the device but cannot earn a profit for the remainder of the year.

Should the Company obtain HDE approval, it will be subject to a number of post-approval requirements, such as the submission of periodic reports. Should the FDA determine that the HUD designation no longer applies to the device, for example based on information contained in its HDE periodic reports, the FDA may seek to revoke the HUD designation and/or withdraw the HDE approval. If the Company is unable to maintain HUD designation and HDE approval for a product candidate, the commercial prospects of that product candidate may be significantly diminished.

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.

If the Company receives regulatory clearance or approval for its investigational devices, it will be subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, labeling, packaging, advertising, medical device reporting, sale, promotion,

registration, storage, distribution and listing of devices. For example, the Company must submit periodic reports to the FDA as a condition of PMA approval. These reports include safety and effectiveness information about the device after its approval. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

In addition, the PMA approval for its ARC^{IM} platform may be subject to several conditions of approval, including a post-market extended follow-up of the premarket study cohort. Any failure to comply with the conditions of approval could result in the withdrawal of PMA approval and the inability to continue to market the device. Adverse outcomes in these studies could also be grounds for withdrawal of approval of the PMA.

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 regulations and applicable laws and regulations of other countries. The FDA, state and foreign regulatory authorities have broad enforcement powers. The Company's failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions:

- untitled letters, which the FDA issues for violations that may not meet the threshold of regulatory significance for a warning letter. Untitled letters give companies an opportunity to take voluntary and prompt action to correct violations before the FDA initiates enforcement action;
- warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of its products;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant its requests for future PMA approvals or foreign regulatory approvals of new products, new intended uses, or modifications to existing products;
- withdrawals or suspensions of its current PMA or foreign regulatory approvals, resulting in prohibitions on sales of its products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on its reputation, business, financial condition and results of operations.

Failure to comply with applicable EU regulations could also result in EU or national regulatory authorities taking various actions, including:

- levying fines and other civil or criminal penalties;
- imposing consent decrees or injunctions;
- requiring the Company to suspend or put on hold one or more of the Company's clinical studies;
- suspending or withdrawing regulatory approvals;
- delaying or refusing to approve pending applications or supplements to approved applications;
- requiring the Company to suspend manufacturing activities, sales, imports or exports of the ARC^{EX} or ARC^{IM} system;

- requiring the Company to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, and other issues involving the Company;
- mandating product recalls or seizing products;
- imposing operating restrictions; and
- seeking criminal prosecutions.

Any of the foregoing actions could be detrimental to the Company's reputation or result in significant costs or loss of revenues for the Company.

If the Company or its suppliers fail to comply with FDA regulatory requirements, or if it experiences unanticipated problems with any cleared or approved 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 ("**QSR**"). These FDA regulations cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage, and shipping of products. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. If the Company, or its manufacturers, fail to adhere to QSR requirements, this could delay production of its products and lead to fines, difficulties in obtaining regulatory clearances and approvals, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on its financial condition and results of operations.

In addition, the Company and its suppliers are required to comply with Good Manufacturing Practices for the manufacture of its products, and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage, and shipping of any product for which it obtains clearance or approval.

The FDA audits compliance with the QSR and other similar regulatory requirements through periodic announced and unannounced inspections of manufacturing and other facilities. The failure by the Company or one of its suppliers to comply with applicable statutes and regulations administered by the FDA, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in any of the following enforcement actions:

- untitled letters, warning letters, fines, injunctions, consent decrees, and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention, or seizure of its products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying its requests for premarket approval of new products or modified products;
- withdrawing PMAs that have already been granted;
- refusal to grant export approval for its products; or
- criminal prosecution.

Any of these sanctions could have a material adverse effect on its reputation, business, results of operations, and financial condition.

If the Company obtains approval for its products, it may be subject to enforcement action if it engages in improper marketing or promotion of its products.

The Company is not permitted to promote or market its ARC^{IM} and ARC^{EX} systems so long as they remain investigational products. If approved, its promotional materials and training methods must

comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label, use. Surgeons may use its products off-label, as the FDA does not restrict or regulate a surgeon's choice of treatment within the practice of medicine. However, if the FDA determines that the Company's promotional materials or training constitutes promotion of an off-label use, it could request that the Company modify its training or promotional materials or subject the Company to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal, state, or foreign enforcement authorities might take action if they consider its promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, its reputation could be damaged and adoption of the products could be impaired. In addition, the off-label use of its products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert its management's attention, result in substantial damage awards against the Company, and harm its reputation.

Even if cleared or approved by regulatory authorities, its products may cause or contribute to adverse medical events or be subject to failures or malfunctions that the Company is required to report to the FDA, and if it fails to do so, it would be subject to sanctions that could harm its reputation, business, financial condition and results of operations. The discovery of serious safety issues with its products, or a recall of its products, either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on the Company.

If the Company's products are cleared or approved 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 timing of the Company's obligation to report is triggered by the date it becomes aware of the adverse event as well as the nature of the event. The Company may inadvertently fail to report adverse events of which it becomes aware within the prescribed timeframe. The Company may also fail to recognize that the Company has become aware of a reportable adverse event, especially if it is not reported to the Company as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If the Company fails to comply with its reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of device approvals, seizure of its products or delay in clearance or approval of modifications to its products.

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. Defects or other errors in its products may occur in the future. Depending on the corrective action it takes to redress deficiencies or defects, the FDA may require, or the Company may decide, that it will need to obtain new approvals for its products before it may market or distribute the corrected device. Seeking such approvals may delay its ability to replace the recalled devices in a timely manner. Moreover, if the Company does not adequately address problems associated with its products, it may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. 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. Any corrective action, whether voluntary or involuntary, as well as defending itself in a lawsuit, will require the dedication of its time and capital, distract management from operating its business and may harm its reputation and financial results.

Additionally, if the Company or others identify undesirable side effects, or other previously unknown problems, caused by its products, a number of potentially negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require a recall of the product or the Company may voluntarily recall a product;
- regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or issuance of field alerts to physicians and pharmacies;
- regulatory authorities may require the Company to create a guide outlining the risks of such side effects for distribution to patients;
- the Company may be subject to limitations as to how it promotes the product;
- the Company may be required to change the way the product is administered or modify the product in some other way;
- regulatory authorities may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- sales of the product may decrease significantly;
- the Company could be sued and held liable for harm caused to patients; and
- its brand and reputation may suffer.

Any of the above events could prevent the Company from achieving or maintaining market acceptance of its products and could substantially increase the costs of commercializing its products. The demand for its products could also be negatively impacted by any adverse effects of a competitor's product or treatment.

Risks related to the Company's Intellectual Property

Substantially all of the Group's assets, including intellectual property, are pledged to Runway, and the enforcement of such pledge could substantially harm the future development and operations of the Company.

The Runway Loan is secured by a pledge on substantially all material and immaterial assets of the Group, including intellectual property.

The first repayment under the Runway Loan is not due before 15 June 2027 at the earliest and the loan and the accrued and unpaid interest and any other outstanding obligations under the Runway Loan need to be fully repaid by latest 15 June 2029.

If the Company or any Group Company is unable to fulfill its obligations under the Runway Loan (including, but not limited to, failure to comply with financial covenants or a payment default) Runway could enforce its pledge on these assets, which 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.

The Company licenses technology from EPFL, UCLA, Caltech, University of Louisville, University of Minnesota, University of Calgary and University of British Columbia that is integrated into its company portfolio under five licenses, each exclusive in the Company's Field of Uses. Under the different license agreements, the Company has agreed to milestone payments and/or to meet certain reporting obligations. In the event that the Company were to breach any of the obligations under the agreement and fail to cure timely, EPFL, UCLA, Caltech, would have the right to terminate the agreement upon notice. In addition, EPFL, UCLA and Caltech have the right to terminate its license upon the bankruptcy or receivership of the Company. If the Company is unable to continue to use or license this technology on reasonable terms, or if this technology fails to operate properly, it may not be able to secure alternatives in a timely manner and its ability to develop its products could be harmed.

It is difficult and costly to protect its intellectual property and its proprietary technologies, and the Company may not be able to ensure their protection.

The Company relies upon a combination of patents and trade secrets to protect the intellectual property related to its proprietary technologies. The Company's success depends significantly on its ability to obtain and maintain intellectual property protection with respect to its technology and products. Patents and other proprietary rights provide uncertain protections, and the Company may be unable to protect its intellectual property for reasons including those that result from complex factual and legal issues such as those that create uncertainty as to the validity, scope and enforceability of any particular patent that the Company holds or for which it has applied. As a result, it may be unsuccessful in defending its patents and other proprietary rights against third-party challenges, which could have a material adverse effect on its business.

Although the Company is attempting to obtain patent coverage for its technology where available and where it believes appropriate, there are aspects of the technology for which patent coverage may never be sought or received. Prior to its merger with NeuroRecovery Technologies, Inc. ("**NRT**"), the Company performed due diligence on its then existing intellectual property and did not discover any existing or potential third-party challenges. Investors have performed due diligence on its intellectual property prior to entering into financing agreements, and similarly did not find any existing or potential third party challenges to its then existing intellectual property. However, such due diligence is not an absolute guarantee that no third-party challenges exist with respect to its then existing intellectual property. Additionally, the Company may in the future obtain certain intellectual property related to its technology from third-parties, and it cannot be certain that such third parties took the necessary actions to maintain such rights or that the transfer of such rights to the Company was proper and effective. The Company may, as a result, be subject to claims challenging the ownership or enforceability of such rights. Furthermore, it may not possess the resources to, or for other reasons may not choose to, pursue patent protection on every invention or in any or every country where it may eventually decide to sell its future products. The Company's ability to prevent others from making or selling duplicate or similar technologies will be impaired for those technologies with respect to which, and in those countries where, it has no patent protection. In addition, there is no assurance that all potentially relevant prior art relating to its patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or later invalidate or narrow the scope of an issued patent. Even if patents do successfully issue and even if such patents cover its technology, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to the Company could deprive the Company of rights necessary for the successful commercialization of its technology.

In addition, for patents that are granted and issued based on the Company's applications or any future applications, any such issued patents may not provide the Company with any competitive advantages. Competitors may be able to design around its patents and develop products that provide outcomes comparable or superior to the Company's. Any changes the Company makes to its product or any

future products, including designs that may be required for commercialization or that cause them to have what the Company views as more advantageous properties, may not be covered by patents and patent applications it has licensed or owns, and the Company may be required to file new applications and/or seek other forms of protection for any such altered products if any such protection is available. In addition, the patent prosecution process is expensive, time-consuming and complicated, and the Company and its current or future licensors, licensees or collaborators may not be able to prepare, file, prosecute and maintain all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner. It is also possible that the Company or its current or future licensors, licensees or collaborators will fail to identify patentable aspects of inventions before it is too late to obtain patent protection for them. In addition, if the Company chooses to and is able to secure patent protection in countries outside the US and Europe where it has not already obtained patent protection, the laws of some foreign countries may not protect its intellectual property rights to the same extent as do the laws of the United States and/or Europe. For instance, the legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for the Company to stop the infringement of its patents or the misappropriation of its other intellectual property rights.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If the Company or any of its licensors is forced to grant a license to third parties with respect to any patents relevant to its business, its competitive position may be impaired.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish the Company's ability to protect its inventions and enforce its intellectual property rights, and more generally could affect the value of its intellectual property. The Company's efforts to seek patent protection for its technology could be negatively impacted by any such changes, which could have a material adverse effect on its existing patent rights and its ability to protect and enforce its intellectual property in the future. In particular, its ability to stop third parties from making, using, selling, offering to sell or importing products that infringe its intellectual property will depend in part on its success in obtaining and enforcing patent claims that cover its technology, inventions and improvements.

The Company may come to believe that third parties are infringing on, or otherwise violating, its patents or other proprietary rights. To prevent infringement or unauthorized use, it may need to file infringement and/or misappropriation suits, which are very expensive and time-consuming, could result in meritorious counterclaims against the Company and would distract management's attention. For further discussion related to the Company's ability to protect its intellectual property portfolio, see the interrelated risk factor "*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.*" Also, in an infringement or misappropriation proceeding, a court may decide that one or more of its patents is invalid, unenforceable, or both, in which case third parties may be able to use its technology without paying license fees or royalties. Even if the validity of its patents is upheld, a court may refuse to stop the other party from using the technology at issue on the grounds that the other party's activities are not covered by its patents.

The Company may in future obtain certain IP related to its technology from third parties. If that is the case, the Company cannot be certain that these third parties took the necessary actions to maintain the IP rights or that their transfer to it was proper and effective. As a result, the Company may be subject to claims challenging the ownership or enforceability, which would limit its ability to prevent competitors from making or selling duplicate or similar technologies for which, or in countries where, the Company has no patent protection.

In addition to patents, the Company relies on trade secrets to protect its technology; however, the policies it uses to protect its trade secrets may not be effective in preventing misappropriation of its trade secrets by others. In addition, confidentiality agreements executed by its employees, consultants and advisers may not be enforceable or may not provide meaningful protection for its

trade secrets or other proprietary information in the event of unauthorized use or disclosure. Litigating a trade secret claim is expensive and time consuming, and the outcome may be unexpected. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, its competitors may independently develop knowledge, methods and know-how that allow them to create substantially similar products or services without misappropriating the Company's trade secrets. If the Company is unable to protect its trade secrets, it may be unable to prevent competitors from using its own inventions and intellectual property to compete against the Company, and its business may be harmed. For further discussion related to the Company's ability to protect its intellectual property portfolio, see the interrelated risk factor "*If the Company is unable to protect the confidentiality of its trade secrets, its business or competitive position could be harmed.*"

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.

Patents have a limited lifespan. In the United States and Europe, if all maintenance fees are timely paid, the natural expiration of a patent is generally (i) 20 years from its earliest US non-provisional filing date and (ii) 20 years from its earliest European filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering the Company's future products are obtained, once the patent life has expired, it may be open to competition from competitive products. Medical devices such as the ARC^{EX} and ARC^{IM} platforms are covered by multiple patents which protect the system or platform as a whole and its individual parts. Patents also protect the system's or platform's intended use(s), and therefore, no single patent individually determines materiality of the entire system or platform protection.

The Company's current patent portfolio will begin to naturally expire in 2031. For example, the Company has continuously filed patent applications for the protection of its ARC^{EX} platform since 2011. The ARC^{EX} patent protection period currently extends to 2036 and has the potential to be afforded additional protection by way of pending patent applications. The patent protection for the ARC^{IM} platform currently extends to 2041 based on the most recent application granted. The Company may not be able to extend the relevant patents for the ARC^{EX} and ARC^{IM} platforms or to obtain relevant patents in the future. Given the amount of time required for the development, testing and regulatory review of new products, patents protecting potential future products beyond the current near-term roadmap might expire before or shortly after the Company or its future partners commercialize those products. As a result, its owned and licensed patent portfolio may not provide the Group with sufficient rights to exclude others from commercializing products similar or identical to the Company's for a sufficient amount of time, and, as a result, it may not be able to obtain adequate protection from its patent portfolio against competition, in spite of the time and effort invested in the commercialization of its future products.

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.

The Company's success depends in part on not infringing the patents or violating the other proprietary rights of others. Intellectual property disputes can be costly to defend and may cause its business, operating results and financial condition to suffer. Significant litigation regarding patent rights occurs in the medical industry. Whether merited or not, it is possible that US and foreign patents and pending patent applications controlled by third parties may be alleged to cover its products. The Company may also face allegations that its employees have misappropriated the intellectual property rights of their former employers or other third parties. For example, it may have inventorship or ownership disputes arising from conflicting obligations of employees, consultants or others who are involved in developing its technology or its products. The Company also may be required to participate in interference, derivation or opposition proceedings that concern disputes regarding priority of inventions disclosed in its patents. Determining whether a product infringes a patent, as well as priority of inventions and other patent-related disputes, involves complex legal and factual issues and the outcome is often uncertain. While the Company has conducted a significant search of patents issued to third parties,

this is not a guarantee that it will not face intellectual property suits in relation to its patent portfolio. Additionally, third-party patents containing claims covering its technology or methods that predate its patents may exist. Because of the number of patents issued and patent applications filed in its technical areas or fields, its competitors or other third parties may assert that its technology and the methods the Company employs in the use of products incorporating its technology are covered by European patents, United States patents or other foreign patents held by them. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which the Company is unaware, and which may result in issued patents that its technology or other future products would infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that the Company infringes.

As the number of competitors in the market for medical devices increases, and as the number of patents issued in this area grows, the possibility of patent infringement claims against the Company increases. Some of its competitors may be able to sustain the costs of complex patent litigation more effectively than it can, including if they have substantially greater resources. Defending against such litigation is costly and time consuming, and would distract its management from its business. In addition, any implications resulting from the initiation and continuation of any litigation could have a material adverse effect on its ability to raise the funds necessary to continue its operations.

In the event that the Company becomes subject to a patent infringement or other intellectual property lawsuit and if the relevant patents or other intellectual property were upheld as valid and enforceable and the Company was found to infringe or violate those rights or the terms of a license to which it is a party, it could be prevented from selling any infringing products of the Company unless it could obtain a license or were able to redesign the product to avoid infringement. If the Company were unable to obtain a license or successfully redesign, it might be prevented from selling its technology or other future products. If the Company is able to redesign, it may need to invest substantial resources in the redesign process. If there is an allegation or determination that it has infringed the intellectual property rights of a competitor or other person, it may be required to pay damages, or a settlement or ongoing royalties, or it may be required to enter into cross-licenses with its competitors. In any of these circumstances, it may be unable to sell its products at competitive prices or at all, and its business, financial condition, results of operations and prospects could be harmed.

The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved and the uncertainty of litigation significantly increase the risks related to any patent litigation. Any potential intellectual property litigation also could force the Company to do one or more of the following:

- stop selling, making, using, or exporting products that use the disputed intellectual property;
- obtain a license from the intellectual property owner to continue selling, making, exporting, or using products, which license may require substantial royalty payments and may not be available on reasonable terms;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights it may be found to be infringing, potentially including treble damages if the court finds that the infringement was willful;
- if a license is available from a third party, it may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for its products and services;
- pay the attorney fees and costs of litigation to the party whose intellectual property rights the Company may be found to infringe;
- find non-infringing substitute products, which could be costly and create significant delay due to the need for prior FDA authorization;

- find alternative supplies for infringing products or processes, which could be costly and create significant delay due to the need for FDA regulatory clearance or approval; and/or
- redesign those products or processes that infringe any third-party intellectual property, which could be costly, disruptive, and/or infeasible.

If any of the foregoing occurs, it may have to withdraw existing products from the market or may be unable to commercialize one or more of its products, all of which could have a material adverse effect on its business, results of operations and financial condition as the Company is currently only pursuing regulatory approval in certain indications for two investigational devices, its ARC^{EX} and ARC^{IM} systems. Any litigation or claim against the Company, even those without merit, may cause the Company to incur substantial costs, and could place a significant strain on its financial resources, divert the attention of management from its core business and harm its reputation. Further, as the number of participants in the neuromodulation industry grows, the possibility of intellectual property infringement claims against the Company increases.

In addition, it may be required to indemnify its customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to its products. Third parties may assert infringement claims against its customers or distributors. These claims may require the Company to initiate or defend protracted and costly litigation on behalf of its customers or distributors, regardless of the merits of these claims. If any of these claims succeed, it may be forced to pay damages on behalf of its customers or distributors, or may be required to obtain licenses for the products or services they use. If the Company cannot obtain all necessary licenses on commercially reasonable terms, its distributors may be forced to stop distributing its products or services, and its customers may be forced to stop using its products or services.

Similarly, interference or derivation proceedings provoked by third parties or brought by the United States Patent and Trademark Office or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to the Company's patents or patent applications. An unfavorable outcome in these or any other such proceedings could require it to cease using the related technology or to attempt to license rights to it from the prevailing party. The Company's business could be harmed if the prevailing party does not offer the Company a license on commercially reasonable terms, if any license is offered at all.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of its confidential information could be compromised by disclosure during discovery. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a material adverse effect on the price of the Ordinary Shares. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of the Ordinary Shares.

If the Company is unable to protect the confidentiality of its trade secrets, its business or competitive position could be harmed.

In addition to patent protection, the Company also relies upon other non-patent protection, such as: trademark, or, trade secret protection, as well as confidentiality agreements with its employees, consultants, vendors, and third parties, to protect its confidential and proprietary information. Despite the existence of such confidentiality agreements, or other contractual restrictions, it may not be able to prevent the unauthorized disclosure or use of its confidential proprietary information or trade secrets by employees, consultants, vendors, and third parties. In addition to contractual measures, the Company tries to protect the confidential nature of its proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for its proprietary information. The Company's security measures may not prevent an employee or consultant from misappropriating its trade secrets and providing them to a competitor, and, recourse it takes against such misconduct may not provide an adequate remedy to fully protect its interests. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of its products that it considers proprietary. Enforcing a claim that a party illegally disclosed, or misappropriated a trade secret, can be difficult, expensive and time-consuming, and, the outcome

is unpredictable. Even though the Company uses commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. Furthermore, the laws of foreign countries may not protect its trade secrets effectively or to the same extent as the laws of the United States. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by the Company. If any of its confidential or proprietary information, such as its trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, the Company's business and competitive position could be harmed.

Third parties may assert ownership or commercial rights to inventions the Company develops.

Many of the Company's employees, consultants and advisers, including its senior management, were previously employed at other companies that may have proprietary rights related to its business. Some of these employees, consultants and advisers, including members of its senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although the Company tries to ensure that such individuals do not use the proprietary information or know-how of others in their work for the Company, it may be subject to claims that it or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. The Company is not aware of any such disclosures, or threatened or pending claims related to these matters, but in the future, litigation may be necessary to defend against such claims. If the Company fails in defending any such claims, it may lose valuable intellectual property rights or personnel, in addition to possibly paying monetary damages and being enjoined from conducting its business as contemplated. Even if it is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. For further discussion on risks related to third parties with which the company has relationships, see the following interrelated risk factor: "*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.*"

Additionally, a licensor, collaborator, employee, consultant, adviser or other third party may dispute the Company's or its licensor's ownership of certain intellectual property rights. The Company seeks to address these concerns in its contractual agreements; however, it may not have contractual arrangements with the party in question and/or such provisions may not be effective. If these provisions prove to be ineffective, it may not be able to achieve its business objectives. If the Company or its licensors fail in defending any such claims, it may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact its business, financial condition and results of operations. See also discussion in the following interrelated risk factor: "*It is difficult and costly to protect its intellectual property and its proprietary technologies, and the Company may not be able to ensure their protection.*"

The Company relies on licenses and sublicenses to certain patent rights with third parties. If the Company fails to comply with its obligations under its patent 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 such patent rights, which could adversely affect its business.

The Company relies on licenses and sublicenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development of its products, including the software modules that it expects to integrate into its ARC[™] and ARC^{EX} platforms. Other licenses the Group may enter into in the future 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 and the underlying patents may fail to provide the intended exclusivity for the Company's products. As a result, it may not be able to prevent competitors from developing and commercializing competitive products in the markets that it hopes to address. Moreover, it would not own at least some of the underlying intellectual property rights related to these products, and as a result its rights would be subject to the continuation and compliance with the terms of those

agreements. If such in-licenses were terminated, competitors would have the freedom to develop, seek regulatory clearance or approval of, and to market, products similar or identical to ours.

In addition, these license agreements may not grant the Company the right to control the preparation, filing, prosecution or maintenance of patents and patent applications covering its products. Therefore, the Company cannot be certain that these patents and patent applications will be prepared, filed, prosecuted or maintained in a manner consistent with the best interests of its business. If its current or future licensing partners fail to file, prosecute or maintain such patents, including the payment of applicable fees, or otherwise lose rights to those patents or patent applications, the intellectual property it has licensed or exclusivity it has been granted may be reduced or eliminated, and its right to develop and commercialize any of its future products that are subject of such licensed rights, and its ability to prevent competitors from developing or commercializing such products, could be adversely affected. In addition, even where it has the right to control patent prosecution and maintenance of patents and patent applications it has licensed from third parties, it may still be adversely affected or prejudiced by actions or inactions of its licensees, its licensors and their counsel that took place prior to the date upon which it assumed control over patent prosecution.

Pursuant to the terms of such license agreements, the licensors may also have the right to control enforcement of its licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents. Even if the Company is permitted to pursue the enforcement or defense of its licensed patents, it may require the cooperation of its (present and/or future) licensors or collaboration partners and any other applicable patent owners and it cannot be certain that such cooperation will be provided to the Company. The Company also cannot be certain that its licensors will allocate sufficient resources or prioritize their or its enforcement of such patents or defense of such claims to protect its interests in the licensed patents. Even if the Company is not a party to these legal actions, an adverse outcome could harm its business because it might prevent the Company from continuing to license intellectual property that it may need to operate its business. If the Company loses any of its licensed intellectual property, its right to develop and commercialize any of its products that are subject of such licensed rights could be adversely affected.

In addition, its (present and/or future) licensors may rely on third-party consultants or collaborators or on funds from third parties such that its licensors are not the sole and exclusive owners of the patents the Company in-licenses. If other third parties have ownership rights to its in-licensed patents, they may be able to license such patents to its competitors, and its competitors could market competing products and technologies. In addition, if its licensors have not obtained adequate rights from these third parties, it may need to obtain additional rights from these third parties or it could be prevented from developing and commercializing the related products. This could have a material adverse effect on its competitive position, business, financial conditions, results of operations and prospects.

In spite of its best efforts, its licensors might conclude that the Company has materially breached its license agreements and might therefore terminate the license agreements, in which event the Company may have to cease developing, manufacturing or marketing any product covered by these agreements and it may face other additional penalties or be required to grant its licensors additional rights. In addition, it may seek to obtain additional licenses from its licensors and, in connection with obtaining such licenses, it may agree to amend its existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including its competitors) to receive licenses to a portion of the intellectual property that is subject to its existing licenses. Any of these events could have a material adverse effect on its competitive position, business, financial conditions, results of operations and prospects.

The Company may be required to pay certain milestones and royalties and fulfill other obligations under its license agreements with third-party licensors.

The Company may be required to pay milestones and royalties related to its development or commercialization activities of its products utilizing the technologies licensed or sublicensed from third parties under license agreements it may enter into with them. These payments could adversely affect its overall profitability related to any future products that it may seek to develop or commercialize. In order to maintain its license rights under its license agreements, it may need to meet certain specified

milestones or fulfill certain obligations, including to devote a certain amount of resources, in the development of its products. Failure to satisfy such obligations could result in the termination of its rights under such agreements.

Risks related to the Ordinary Shares

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.

Subject to the limitations described under "*Dividend Policy—Dividend Policy*", the Company does not intend to pay any dividends in the near future as will likely not be in the capacity to pay dividends until it starts to report positive retained earnings.

The ability and intention of the Company to declare and pay dividends in the future: (i) will mainly depend on its financial position, results of operations, capital requirements, investment prospects, the existence of distributable reserves and available liquidity and such other factors as the Company's Board of Directors (the "**Board**") may deem relevant; and (ii) are subject to factors that are beyond the Company's control.

If the Company does decide to pay dividends in the future, a distribution of dividends may only take place (i) after the adoption of the annual accounts referred to in article 2:391 DCC (the "**Annual Accounts**") pursuant to a resolution of the general meeting (*algemene vergadering*) of the Company, being the corporate body, or where the context so requires, the physical meeting of the Company's shareholders (each a "**Shareholder**") (the "**General Meeting**"), or (ii) in the case of an interim dividend after the Board has signed an interim statement of assets and liabilities, from which it appears that the distribution is allowed. The Company may only make distributions to its Shareholders insofar as the Company's equity exceeds the sum of the paid-up and called-up share capital increased by the reserves as required to be maintained by Dutch law or by the articles of association of the Company (the "**Articles of Association**"). The Board determines whether the Company is able to make the distributions. Because the Company is the parent company, the principal assets of the Company are the equity interests it directly or indirectly holds in its operating subsidiaries. As a result, the Company's ability to pay dividends will depend directly on distributions and other payments from such subsidiaries to the Company. The Company's subsidiaries may, on the basis of country specific legal restrictions, not be able to, or may not be permitted to, make distributions to enable the Company to make payments in respect of its indebtedness. Any such distributions may be materially and adversely impacted if the Company's operating subsidiaries' profitability suffers. The amount and timing of such distributions will furthermore depend on the laws of such subsidiaries' respective jurisdictions. Any of these factors, individually or in combination, could restrict the Company's ability to pay dividends and therefore could negatively impact the market price of the Ordinary Shares.

Future sales of a substantial number of Ordinary Shares by the Shareholders, or the perception thereof, may adversely affect the market price of the Ordinary Shares.

The market price of the Ordinary Shares could decline if a substantial number of Ordinary Shares are sold by the Shareholders, in the public market or if there is a perception that such sales could occur.

Furthermore, a sale of Ordinary Shares by any of the Directors, Managers or the current Shareholders could be perceived as a lack of confidence in the performance and prospects of the Group and could cause the market price of the Ordinary Shares to decline. In addition, any such sales could make it more difficult for the Company to raise capital through the issuance of equity securities in the future.

Ottobock SE & Co. KGaA, who entered into a cornerstone investor agreement with the Company on 22 October 2024 in connection with the Private Placement (the "**Cornerstone Investor Agreement**") (the "**Cornerstone Investor**"), agreed in the Cornerstone Investor Agreement that, without the prior written consent of the Company (such consent not to be unreasonably withheld or delayed) and subject to certain customary exceptions, it will not, and will not announce any intention to, during the period commencing on 28 October 2024 and continuing to and including the close of trading on the

date that is 180 days thereafter: (i) offer, pledge, sell, offer to sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, cause the Company to issue, or otherwise transfer or dispose of, directly or indirectly, any Ordinary Shares; or (ii) enter into a transaction or perform any action economically similar to those described in (i), in particular enter into any swap or other arrangement that transfers to another, in whole or in part, the economic risk of ownership of Ordinary Shares, whether any such transaction is to be settled by delivery of Ordinary Shares, in cash or otherwise (see "*Important Information—Lock-up arrangements*"). For more information on the Cornerstone Investor Agreement see "*The Listing—Cornerstone Investment*".

On 22 October 2024, the Directors, except for John de Koning, Rahma Samow and Rob ten Hoedt, (together, the "**Restricted Shareholders**"), entered into a lock-up arrangement with the Joint Global Coordinators (as defined below) in respect of their Ordinary Shares held in the Company. Pursuant to the lock-up arrangement, the Restricted Shareholders will not do or announce any intention to do, any of the following for a period of 180 days following 22 October 2024 (the "**Lock-up Period**") without the prior written consent (such consent not to be unreasonably withheld or delayed) of each of the Joint Global Coordinators (as defined below): (i) offer, pledge, sell, offer to sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, cause the Company to issue, or otherwise transfer or dispose of, directly or indirectly, any Ordinary Shares or any securities convertible into or exercisable or exchangeable for Ordinary Shares or any other similar instrument that would give an equity-like economic interest in the Company to its holders (the "**Related Securities**") owned either of record or beneficially (as defined in Rule 13d-3 under the U.S. Securities Exchange Act of 1934, as amended), by a Restricted Shareholder or a family member as of or following the commencement of the Lock-up Period; or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of Ordinary Shares or Related Securities, whether settled by delivery of Ordinary Shares or Related Securities, in cash or otherwise, subject to customary exemptions (see "*Important Information—Lock-up arrangements*"). The Joint Global Coordinators (as defined below) may jointly waive the above lock-up undertakings of the Restricted Shareholders during the Lock-up Period in full or in part in their absolute discretion.

Future offerings of debt or equity securities by the Company, or the perception thereof, may adversely affect the market price of the Ordinary Shares and any future issuances of Shares may dilute investors' shareholdings.

The Company may in the future seek to raise capital through public or private debt or equity financings by issuing additional Ordinary Shares, debt or equity securities convertible into Ordinary Shares or rights to acquire these securities and exclude the pre-emptive rights pertaining to the then outstanding Ordinary Shares. In addition, the Company may in the future seek to issue additional Ordinary Shares as dividends or as consideration for or otherwise in connection with the acquisition of new businesses. Furthermore, the Company may issue new Ordinary Shares or grant rights to subscribe for Ordinary Shares in connection with the establishment of employee share participation or share option plans.

In connection with the Runway Loan in the amount of up to EUR 52.5 million, on 28 June 2024 the Company issued warrants to Runway which entitle it to purchase Ordinary Shares in the capital of the Company at an exercise price per newly issued Ordinary Share of EUR 4.83. The number of Ordinary Shares subject to the warrants are 5.00% of the drawn down principal amount initially and upon each subsequent loan advance, divided by the exercise price. Upon exercise of the warrants the Company will have to issue the corresponding number of Ordinary Shares to Runway. The warrants may be exercised within a period of 10 years as from (and including) 26 September 2024.

On 22 October 2024, the Company and UBS AG London Branch, Bryan, Garnier & Co. Limited, Bryan Garnier Securities SAS and Bank Degroof Petercam SA/NV (collectively, the "**Placement Agents**", and UBS AG London Branch, together with Bryan, Garnier & Co. Limited and Bryan Garnier Securities SAS, the "**Joint Global Coordinators**") in the private placement (the "**Private Placement**") of the New Ordinary Shares to qualified investors in the European Economic Area, to relevant persons in the United Kingdom and to institutional investors in certain other jurisdictions, entered into a placement agents agreement, pursuant to which the Company agreed, during the period beginning

from 22 October 2024 and continuing to and including the date 180 days after the closing of the Private Placement, not to issue, offer, sell, pledge, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of, directly or indirectly, any Ordinary Shares or other securities that are substantially similar to the Ordinary Shares, or any securities that are convertible or redeemable into or exchangeable for, or that represent the right to receive, Ordinary Shares or any such substantially similar securities, or enter into any derivative or other transaction having substantially similar economic effect with respect to its Ordinary Shares or any such securities or announce its intention to perform one of the aforementioned transactions, in each case without the prior written consent of the Joint Global Coordinators and subject to customary exemptions (see "*Important Information—Lock-up arrangements*"). The Joint Global Coordinators may jointly waive the above lock-up undertakings of the Company during the respective period in full or in part in their absolute discretion.

Additionally, the Company agreed to a substantially similar lock-up agreement with the Cornerstone Investor (see "*Important Information—Lock-up arrangements*").

Any future offering or issuance of Ordinary Shares or equity securities by the Company, or the perception that an offering or issuance may occur, could have a negative impact on the market price of the Ordinary Shares and could increase the volatility in the market price of the Ordinary Shares.

In addition, the issuance of any additional Ordinary Shares may dilute an investor's shareholding interest in the Company.

Finally, any additional debt or equity financing the Company may need may not be available on terms favorable to the Company or at all, which could materially adversely affect its future plans and the market price of the Ordinary Shares.

Shareholders outside the Netherlands may not be able to exercise pre-emptive rights in future offerings.

In the event of an increase in the Company's issued share capital, Shareholders are generally entitled to full pre-emptive rights unless these rights are limited or excluded either by virtue of Dutch law, by a resolution of the General Meeting or by a resolution of the Board (if the Board has been designated by the General Meeting or the Articles of Association for this purpose). The Board has been designated by the General Meeting for a period of 18 months from 13 June 2024 to limit or exclude pre-emptive rights subject to limits as set out in this Prospectus. However, even if Shareholders' pre-emptive rights are not limited or excluded, certain Shareholders outside the Netherlands may not be able to exercise pre-emptive rights, and therefore could suffer dilution, unless local securities laws have been complied with.

In particular, Shareholders in certain other countries, including the United States, may not be able to exercise their pre-emptive rights or participate in a rights offer, as the case may be, unless the Company complies with local requirements, or in the case of the United States, unless a registration statement under the US Securities Act is effective with respect to such rights and the Ordinary Shares or an exemption from the registration requirements is available. The Company will evaluate at the time of any issue of Ordinary Shares subject to pre-emptive rights or in a rights offer, as the case may be, the costs and potential liabilities associated with compliance with any such local laws or any such registration statement, as well as the indirect benefits to it of enabling the exercise of such holders of their pre-emptive rights to Ordinary Shares or participation in a rights offer, as the case may be, and any other factors considered appropriate at the time and then to make a decision as to whether to comply with such local laws or file a registration statement. The Company cannot assure investors that any steps will be taken to enable the exercise of such holders' pre-emptive rights or participation in a rights offer.

In cases where Shareholders are not able to exercise their pre-emptive rights, and in situations where pre-emptive rights are limited or excluded, Shareholders may experience a dilution of their holding of Ordinary Shares, possibly without such dilution being offset by any compensation received in exchange for subscription rights.

The rights and responsibilities of a Shareholder are governed by Dutch law and will differ in some respects from the rights and obligations of Shareholders under the laws of other jurisdictions and the shareholder rights under Dutch law differ from the rights of a shareholder under the laws of other jurisdictions.

The Company is incorporated and exists under the laws of the Netherlands. Accordingly, the Company's corporate structure as well as the rights and obligations of the Shareholders may be different from the rights and obligations of shareholders of companies incorporated or organized under the laws of other jurisdictions. For example, resolutions of the General Meeting may be taken with majorities different from the majorities required for adoption of equivalent resolutions in companies organized under the laws of other jurisdictions. Additionally, in fulfilling their responsibilities, the Directors must act in the interest of the Company and give specific attention to the relevant interests of all of the Company's stakeholders, which, in addition to Shareholders, include clients, employees, lenders and suppliers. Under the DCC, any action to nullify (*vernietigen*) or declare void (*nietig*) any of the resolutions passed by the Company's corporate bodies must be filed with, and will be reviewed by, a Dutch court, in accordance with Dutch law. As such, the exercise of certain shareholders' rights by Shareholders outside the Netherlands may be more costly than the exercise of rights in a company organized under the laws of other jurisdictions.

Certain significant shareholders of the Company after the Listing may have different interest from the Company and may be able to control the Company, including the outcome of shareholder votes.

As of the date of this Prospectus, the Company has a number of significant shareholders. For an overview of the Company's current significant shareholders (see also "*Shareholder Structure and Related Party Transactions*"). They could, alone or together, have the ability to elect or dismiss directors, and, depending on how broadly the Company's other Shares are held, take certain other shareholders' decisions that require at least 66% of the votes of the shareholders that are present or represented at general shareholders' meetings where such items are submitted to voting by the shareholders. Alternatively, to the extent that these shareholders have insufficient votes to impose certain shareholders' decisions, they could still have the ability to block proposed shareholders' resolutions that require at least 66% of the votes of the shareholders that are present or represented at General Meetings where such decisions are submitted to voting by the shareholders. Any such voting by the Shareholders may not be in accordance with the interests of the Company or the other shareholders of the Company.

If securities or industry analysts do not publish research or reports about the Company's business or industry, or if such analysts (if any) change their recommendations regarding the Ordinary Shares adversely, the market price and trading volumes of the Ordinary Shares could decline.

The trading market for the Ordinary Shares will be influenced by the research and reports that securities or industry analysts publish about the Group's business or industry. If securities or industry analysts do not publish or cease to publish research or reports about the Group's business or industry, the Group could lose visibility in the financial markets, which could cause the market price or trading volume of the Ordinary Shares to decline. Also, if one or more of the analysts covering the Group's business or industry recommends selling Ordinary Shares, or if negative research is published on the industry or geographic markets the Group serves, the market price of the Ordinary Shares could decline.

The market price of the Ordinary Shares may be volatile and may be affected by a number of factors, some of which are beyond the Company's control.

The market price of the Ordinary Shares could fluctuate substantially due to factors, such as the risks described in "*Risks related to the Company's Business*" some of which could be specific to the Company and its operations and some of which could be related to the industry in which the Company operates or equity markets generally. As a result of these and other factors mentioned in this "*Risk Factors*" section, the Ordinary Shares may trade at significantly lower prices. The Company cannot

guarantee that the market price of the Ordinary Shares will not decline, regardless of the Company's actual performance.

Risks related to Taxation

The tax laws and regulations in the jurisdictions in which the Group operates may be subject to change.

The tax laws and regulations in the jurisdictions in which the Group operates may be subject to change. New tax laws or regulations may be introduced by competent authorities with or without retrospective effect and there may be changes in the interpretation and enforcement of such tax laws or regulations. As a result, we may face increases in taxes payable, for example, if tax rates increase, if tax laws or regulations are modified in an adverse manner, or if new tax laws or regulations are introduced by the competent authorities, with or without retrospective effect.

In this respect, on 20 December 2021, the Organization for Economic Cooperation and Development published the Global Anti-Base Erosion Model Rules (the "**GloBE Rules**"), also known as Pillar II. The GloBE Rules aim to impose a global minimum tax of 15% on multinational enterprises with a revenue in excess of EUR 750 million. On 22 December 2021, the European Commission published a legislative proposal for Pillar II (the "**EU Pillar II Directive**"). The EU Pillar II Directive is largely aligned with the GloBE Rules. Some deviations were introduced to ensure compliance with EU treaties.

On 15 December 2022, the Council of the European Union formally adopted the EU Pillar II Directive. The EU Pillar II Directive aims at consistently implementing among all 27 member states the GloBE Rules. EU Member States had to transpose the EU Pillar II Directive into their national laws and have to apply the Pillar II measures in respect of the fiscal years beginning on or after 31 December 2023. The Netherlands have transposed the EU Pillar II Directive into its national legislation with effect from 31 December 2023, pursuant to the Dutch Minimum Tax Act 2024 (*Wet minimumbelasting 2024*). The Group does not yet meet the revenue threshold for Pillar II but should this threshold be reduced, or the Group's revenue increases, then the application of Pillar II could have a material adverse effect on the Group's business, financial position and results of operations.

In addition, tax authorities in the relevant jurisdictions may periodically examine the Company's tax position. Tax audits for periods not yet reviewed may consequently lead to higher tax assessments (plus accrued interest and penalties). Any additional taxes or other sums that become due may have a material adverse effect on the Group's business, results of operations, financial condition and prospects.

The Company's ability to use its net operating losses, research and development credit carryforwards, tax loss carryforwards and other tax attributes to offset future taxable income may be subject to certain United States Federal income tax and Dutch tax limitations.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended ("**Internal Revenue Code**"), a corporation that undergoes an "ownership change," generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses ("**NOLs**") and its research and development credit carryforwards to offset future taxable income. The Company's existing NOLs and research and development credit carryforwards for U.S. federal income tax purposes may be subject to limitations arising from previous ownership changes, and if it undergoes an ownership change, its ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Internal Revenue Code. In addition, its ability to deduct net interest expense may be limited if the Company has insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. Future changes in its share ownership, some of which might be beyond its control, could result in an ownership change under Section 382 of the Internal Revenue Code. For these reasons, in the event the Company experiences a change of control, it may not be able to utilize a material portion of the NOLs, research and development credit

carryforwards or disallowed interest expense carryovers for U.S. federal income tax purposes, even if it attains profitability.

For Dutch tax purposes, the Company's ability to utilize its tax losses and tax loss carry-forwards and other tax attributes, including carry-forward non-deductible interest expenses under the Dutch earnings stripping rule, following the Listing is conditioned upon the Group's attaining profitability and generating taxable income.

Additionally, the Company's ability to utilize tax losses and tax loss carry-forwards and other tax attributes to offset future taxable income may be subject to certain limitations.

In this respect, pursuant to Article 20a of the Dutch Corporate Income Tax Act 1969, the tax loss carry-forwards of the Company can no longer be offset against future taxable profits if the ultimate ownership in the Company has substantially changed (>30%), unless certain counter evidence rules are met.

Furthermore, as of 1 January 2022, tax losses can be carried back one year and carried forward indefinitely in the Netherlands. However, both the carry back and carry forward tax loss relief is limited to 50% of the taxable profit to the extent it exceeds EUR 1 million, calculated per financial year. As a result of transitional law, tax losses incurred in the financial years that started on or after 1 January 2023 and that are still available for carry forward as of 1 January 2022 also fall under the new scheme that entered into effect on 1 January 2022 and will therefore be indefinite. For this reason, in the event the Company would attain profitability in the future, the Company may not be able to use tax losses available for carryforward to fully offset taxable income for Dutch tax purposes, which may result in Dutch income tax becoming due by the Company, even if it has tax loss carryforwards.

If the Company is a passive foreign investment company, there could be adverse US federal income tax consequences to US Holders.

The Company does not believe that it was classified as a passive foreign investment company (a "PFIC") for US federal income tax purposes for its most recent taxable year ending 31 December 2023 and, based on all information available to the Company, the composition of the Company's current gross assets and income (including the income and assets of the Group) and the manner in which the Company expects the Group to operate its business, the Company believes that it should not be classified as a PFIC for US federal income tax purposes for the Company's current taxable year. However, there can be no assurance that the Company will not be considered a PFIC in the current year or for any future taxable year. Under the Internal Revenue Code, a non-US company will be considered a PFIC for any taxable year in which (1) 75% or more of its gross income consists of passive income or (2) 50% or more of the average quarterly value of its assets consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-US corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation. If the Company is a PFIC for any taxable year during which a US Holder (a "US Holder" being a beneficial owner of Ordinary Shares that is, for US federal income tax purposes: (i) a citizen or individual resident of the United States; (ii) a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state thereof or the District of Columbia; (iii) an estate the income of which is subject to US federal income taxation regardless of its source; or (iv) a trust if a United States court can exercise primary supervision over the trust's administration and one or more United States persons are authorized to control all substantial decisions of the trust, or the trust has validly elected to be treated as a domestic trust for US federal income tax purposes) holds the Ordinary Shares, the Company will continue to be treated as a PFIC with respect to such US Holder in all succeeding years during which the US Holder owns the Ordinary Shares, regardless of whether the Company continues to meet the PFIC test described above, unless the US Holder makes a specified election once the Company ceases to be a PFIC. If the Company is classified as a PFIC for any taxable year during which a US Holder holds its Ordinary Shares, the US Holder may be subject to adverse tax consequences regardless of whether the Company continues to qualify as a PFIC, including ineligibility for any preferred tax rates

on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements.

IMPORTANT INFORMATION

General

This Prospectus was approved as a prospectus for the purposes of the Prospectus Regulation by, and filed with, the AFM, as competent authority under the Prospectus Regulation, on 24 October 2024. This Prospectus has, following the approval thereof by the AFM, been notified to the FSMA in Belgium and to the AMF in France for passporting in accordance with article 25 of the Prospectus Regulation.

This Prospectus has been prepared in English. The summary of this Prospectus is translated into French. The French version of the summary of this Prospectus has not been scrutinized or approved by the AFM. The Company is responsible for the consistency between the English and the French version of the summary of this Prospectus. Without prejudice to the responsibility of the Company for inconsistencies between the two different language versions of the summary of this Prospectus, in the case of discrepancies between the two different versions thereof, the English version will prevail.

The AFM has only approved this Prospectus as meeting the standard of completeness, comprehensibility and consistency imposed by the Prospectus Regulation. Such approval should not be considered as an endorsement of the issuer or the quality of the securities that are the subject of this Prospectus and the Company. This Prospectus has been drawn up as part of a simplified prospectus in accordance with Article 14 of the Prospectus Regulation. Investors should make their own assessment as to the suitability of investing in the Ordinary Shares.

The content of this Prospectus is not to be considered or interpreted as legal, financial or tax advice. It should not be considered as a recommendation by any of the Company, the members of its Board, ING BANK N.V. (the "**Listing Agent**") or any of their respective representatives that any recipient of this Prospectus should subscribe for or purchase any Ordinary Shares. Prior to making any decision whether to purchase the Ordinary Shares, prospective investors should read this Prospectus. Investors should ensure that they read the whole of this Prospectus and not just rely on key information or information summarized within it. Each prospective investor should consult his or her own stockbroker, bank manager, lawyer, auditor or other financial, legal or tax advisers before making any investment decision with regard to the Ordinary Shares, to consider, among other things, such investment decision in light of his or her personal circumstances and in order to determine whether or not such prospective investor is eligible to subscribe for the Ordinary Shares. In making an investment decision, prospective investors must rely on their own examination and analysis of the Company, the Ordinary Shares, including the merits and risks involved.

Prospective investors should rely only on the information contained in this Prospectus and any supplement to this Prospectus within the meaning of Article 23 of the Prospectus Regulation. The Company does not undertake to update this Prospectus, unless required pursuant to Article 23 of the Prospectus Regulation, and therefore potential investors should not assume that the information in this Prospectus is accurate as of any date other than the date of this Prospectus. No person is or has been authorized to give any information or to make any representation in connection with the Listing, other than as contained in this Prospectus, and, if given or made, any other such information or representations must not be relied upon as having been authorized by the Company, the members of the Board, the Listing Agent or any of their respective affiliates or representatives. The delivery of this Prospectus at any time after the date hereof will not, under any circumstances, create any implication that there has been no change in the Group's affairs since the date hereof or that the information set forth in this Prospectus is correct as of any time since its date.

Prospective investors are expressly advised that an investment in Ordinary Shares entails risks and that they should therefore carefully read and review the entire Prospectus. Prospective investors should not just rely on key information or information summarized within this Prospectus. Prospective investors should, in particular, read the section entitled "*Risk Factors*" when considering an investment in the Ordinary Shares. A prospective investor should not invest in Ordinary Shares unless it has the expertise (either alone or with a financial adviser) to evaluate how the Ordinary Shares will perform under changing conditions, the resulting effects on the value of the Ordinary Shares and the impact

this investment will have on the prospective investor's overall investment portfolio. Prospective investors should also consult their own tax advisers as to the tax consequences of the purchase, subscription, ownership and disposal of the Ordinary Shares.

No representation or warranty, express or implied, is made or given by the Listing Agent or any of its affiliates or any of its respective directors, officers or employees or any other person, as to the accuracy, completeness or fairness of the information or opinions contained in this Prospectus, or incorporated by reference herein, and nothing in this Prospectus, or incorporated by reference herein, is, or shall be relied upon as, a promise or representation by the Listing Agent or any of its respective affiliates or representatives as to the past or future. Neither the Listing Agent nor any of its affiliates or any of its respective directors, officers or employees accepts any responsibility whatsoever for the contents of this Prospectus or for any other statements made or purported to be made by either itself or on its behalf in connection with the Company, the Group, the Listing or the Ordinary Shares. Accordingly, the Listing Agent and any of its affiliates and any of its respective directors, officers or employees disclaim, to the fullest extent permitted by applicable law, all and any liability, whether arising in tort or contract or which they might otherwise be found to have in respect of this Prospectus and/or any such statement.

The Listing Agent is acting exclusively for the Company and for no one else and will not regard any other person (whether or not a recipient of this Prospectus) as its client in relation to the Listing and will not be responsible to anyone other than to the Company for giving advice in relation to the Listing and/or any other transaction or arrangement referred to in this Prospectus.

The distribution of this Prospectus may, in certain jurisdictions, be restricted by law, and this Prospectus may not be used for the purpose of, or in connection with, any offer or solicitation by anyone in any jurisdiction in which such offer or solicitation is not authorized or to any person to whom it is unlawful to make such offer or solicitation. This Prospectus does not constitute an offer of, or an invitation to, purchase any Ordinary Shares in any jurisdiction in which such offer or invitation would be unlawful. The Company and the Listing Agent require persons into whose possession this Prospectus comes to inform themselves of and observe all such restrictions. None of the Company, the Listing Agent or any of their respective affiliates or representatives accepts any legal responsibility for any violation by any person, whether or not a prospective purchaser of Ordinary Shares, of any such restrictions. The Company and the Listing Agent reserve the right in their own absolute discretion to reject any offer to purchase Ordinary Shares that the Company, the Listing Agent or their respective agents believe may give rise to a breach or violation of any laws, rules or regulations.

Responsibility Statement

This Prospectus is made available by the Company. The Company accepts responsibility for the information contained in this Prospectus. The Company declares that the information contained in this Prospectus is, to the best of its knowledge, in accordance with the facts and that this Prospectus makes no omission likely to affect its import.

Presentation of financial and other information

The consolidated financial statements of ONWARD Medical N.V., as of and for the year ended 31 December 2023 have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union ("**IFRS**") and Part 9 of Book 2 of the Dutch Civil Code (the "**Consolidated Financial Statements**").

The company financial statements of ONWARD Medical N.V. as of and for the year ended 31 December 2023 have been prepared in accordance with Part 9 of Book 2 of the Dutch Civil Code (the "**Company Financial Statements**" and, together with the Consolidated Financial Statements, the "**Financial Statements**").

Ernst & Young Accountants LLP, independent auditor, has audited the Consolidated Financial Statements and the Company Financial Statements and has issued an unqualified independent auditor's report thereon. Ernst & Young Accountants LLP changed its legal form from LLP to B.V. as from 29 June 2024.

The Company's interim condensed consolidated financial statements as of and for the six-month-period ended 30 June 2024 (the "**Interim Condensed Consolidated Financial Statements**"), which have been prepared in accordance with IAS 34, "Interim Financial Reporting" as adopted by the European Union.

The Interim Condensed Consolidated Financial Statements have not been audited or reviewed.

Alternative performance measures

Certain parts of this Prospectus contain non-IFRS financial measures and other related ratios, which are not recognized measures of financial performance or liquidity under IFRS and which are considered to be "alternative performance measures" as defined by the "ESMA Guidelines on Alternative Performance Measures" issued by the European Securities and Markets Authority on 5 October 2015 ("**APMs**" and each an "**APM**"). The Company has included net cash as an APM in this Prospectus.

The APM net cash presented is not a measure of financial performance under IFRS, but a measure used by management to monitor the underlying performance of the Group's business and operations and, accordingly, it has not been audited or reviewed. Further, it may not be indicative of the Group's historical operating results, nor is such measure meant to be predictive of the Group's future results. The APM net cash has not been audited or reviewed by the independent auditor.

The Company has included net cash as an APM in this Prospectus because it represents a key measure used by management to evaluate the Group's operating performance and the Group's need for future financing. Further, management believes that the presentation of net cash as an APM is helpful to prospective investors because this and other similar measures and related ratios are widely used by investors, securities analysts and other interested parties as supplemental measures of performance and liquidity. Management also believes that the APM net cash facilitates operating performance comparisons on a period-to-period basis to exclude the impact of items, which management does not consider to be indicative of the Group's core operating performance.

However, net cash as an APM has limitations as an analytical tool and not all companies calculate APMs in the same manner or on a consistent basis and other companies may use such measures for different purposes than the Company does. As a result, this measure may not be comparable to measures used by other companies under the same or similar names.

Prospective investors should not consider the APM net cash in isolation, as alternatives to revenue, profit before tax or cash flows from operations calculated in accordance with IFRS, as indications of operating performance or as measures of the Group's profitability or liquidity. Accordingly, undue reliance should not be placed on the APM contained in this Prospectus and it should not be considered as a substitute for operating profit, profit for the period, cash flow or other financial measures computed in accordance with IFRS.

"Net cash" is defined as the sum of cash and cash equivalents and fixed term deposits included in the current assets as included in consolidated statement of financial position in the Consolidated Financial Statements.

<i>(In EUR 000)</i>	As at 30 June 2024	As at 30 June 2023	As at 31 December	
			2023	2022
Cash and cash equivalents	24,553 ⁽¹⁾	18,788 ⁽¹⁾	29,768 ⁽²⁾	41,760 ⁽²⁾
Fixed term deposits	7,500 ⁽¹⁾	25,000 ⁽¹⁾	–	20,000 ⁽²⁾
Net cash	32,053⁽¹⁾	43,788⁽¹⁾	29,768⁽¹⁾	61,760⁽¹⁾

(1) Unaudited.

(2) Audited.

Other financial information

No pro forma financial information is provided in this Prospectus.

Rounding and negative amounts

Certain figures in this Prospectus, including financial data, have been rounded. Accordingly, figures shown for the same category presented in different tables may vary slightly and figures shown as totals in certain tables may not be an exact arithmetic aggregation of the figures which precede them.

In preparing the Financial Statements, most numerical figures are presented in thousands of euros. For the convenience of the reader of this Prospectus, certain numerical figures in this Prospectus are rounded to the nearest one hundred thousand. As a result of this rounding, certain numerical figures presented herein may vary slightly from the corresponding numerical figures presented in the Financial Statements.

The percentages (as a percentage of revenues or costs and period-on-period percentage changes) presented in the textual financial disclosure in this Prospectus are derived directly from the financial information contained in the Financial Statements. Such percentages may be computed using the numerical figures expressed in thousands of euros in the Financial Statements. Therefore, such percentages are not calculated on the basis of the financial information in the textual disclosure that has been subjected to rounding adjustments in this Prospectus.

In tables, negative amounts are shown between brackets. Otherwise, negative amounts may also be shown by "-" or "negative" before the amount.

Currency

All references in this Prospectus to "euro", "EUR" or "€" are to the single currency introduced at the start of the third stage of the European Economic and Monetary Union pursuant to the Treaty on the functioning of the European Community, as amended from time to time. All references to "US dollars", "US\$", "USD" or "\$" are to the lawful currency of the United States.

Exchange rates

The Group publishes its historical consolidated financial statements in euros. The table below sets forth, for the periods and dates indicated, period average (the average of the exchange rates on the last business day of each month for annual averages and the average of the exchange rates on each business day during the relevant period for monthly averages), high, low and period end exchange rates between the euro and the US dollar as published by the European Central Bank. This exchange rate information is solely provided for convenience purposes. The exchange rate of the euro on 23 October 2024 (the latest practicable date before publication of this Prospectus) was USD 1.0767 = EUR 1.00.

Year	Euro	US dollar (High)	US dollar (Low)	US dollar (Average)	US dollar (Period end)
2023	1	1.1255	1.0469	1.0813	1.1050
2022	1	1.1464	0.9565	1.0530	1.0666
2021	1	1.2338	1.1206	1.1827	1.1326
2020	1	1.2281	1.0707	1.1422	1.2271
2019	1	1.1535	1.0889	1.1195	1.1234
2018	1	1.2493	1.1261	1.1810	1.1450

Month	Euro	US dollar (High)	US dollar (Low)	US dollar (Average)	US dollar (Period end)
September 24	1	1.1196	1.1016	1.1106	1.1196
August 24	1	1.1163	1.0789	1.1012	1.1087

July 24	1	1.0934	1.0729	1.0844	1.0828
June 24	1	1.0898	1.0686	1.0759	1.0705
May 24	1	1.0882	1.0698	1.0812	1.0852
April 24	1	1.0867	1.0632	1.0728	1.0718
March 24	1	1.0939	1.0811	1.0872	1.0811
February 24	1	1.0883	1.0713	1.0795	1.0826
January 24	1	1.0987	1.0823	1.0905	1.0837
December 23	1	1.1114	1.0757	1.0903	1.1050
November 23	1	1.0985	1.0537	1.0808	1.0931
October 23	1	1.0632	1.0469	1.0563	1.0619

Market and Industry Information

All references to market share, market data, industry statistics and industry forecasts in this Prospectus consist of estimates compiled by industry professionals, competitors, organizations or analysts, of publicly available information or of the Group's own assessment of its sales and markets. Statements based on the Company's own proprietary information, insights, opinions or estimates contain words such as "the Group believes", "the Group expects", "the Group sees", "the Group considers", "the Group aims", "the Group estimates" and as such do not purport to cite, refer to or summarize any third-party or independent source and should not be so read.

Industry publications generally state that their information is obtained from sources believed to be reliable but that the accuracy and completeness of such information is not guaranteed and that the projections they contain are based on a number of significant assumptions. Where third-party information has been sourced in this Prospectus, the source of such information has been identified.

The market data have primarily been derived and extrapolated from reports provided by (i) Global Market Insights Neurostimulation Devices Market, (ii) Fortune Business Insights Spinal Cord Stimulation Market, (iii) Harmsen I, E, Hasanova D, Elias G, J, B, Boutet A, Neudorfer C, Loh A, Germann J, Lozano A, M: Trends in Clinical Trials for Spinal Cord Stimulation. *Stereotact Funct Neurosurg* 2021;99:123-134, and (iv) NSCISC Annual Report, and (v) Kumar et al. 2018, Traumatic Spinal Injury: Global Epidemiology and Worldwide Volume.

The information in this Prospectus that has been sourced from third parties has been accurately reproduced, as far as the Group is aware and is able to ascertain from the information published by that third party, no facts have been omitted that would render the reproduced information inaccurate or misleading. A reference to these sources has been added in the relevant paragraphs.

In this Prospectus, the Group makes certain statements regarding the characteristics of the SCI industry as well as its competitive and market position. The Group believes these statements to be true, based on market data and industry statistics, but the Group has not independently verified the information. The Group cannot guarantee that a third party using different methods to assemble, analyze or compute market data or public disclosure from competitors would obtain or generate the same results. In addition, the Group's competitors may define their markets and their own relative positions in these markets differently than the Group does and may also define various components of their business and operating results in a manner which makes such figures non-comparable with the Group's.

Supplements

If a significant new factor, material mistake or material inaccuracy relating to the information included in this Prospectus which may affect the assessment of the Ordinary Shares, arises or is noted between the date of this Prospectus and the expiry of the validity of this prospectus (see "*Validity*"), a supplement to this Prospectus is required. Such a supplement will be subject to approval by the AFM in accordance with article 23 of the Prospectus Regulation and will be made public in accordance with the relevant provisions under the Prospectus Regulation. The summary shall also be supplemented, if necessary to take into account the new information included in the supplement.

Statements contained in any such supplement (or contained in any document incorporated by reference therein) shall, to the extent applicable, be deemed to modify or supersede statements contained in this Prospectus or in a document which is incorporated by reference in this Prospectus. Any statement so modified or superseded shall, except as so modified or superseded, no longer constitute a part of this Prospectus.

Notice to Investors

The distribution of this Prospectus and the offer, acceptance, delivery, transfer, exercise, purchase of, subscription for, or trade in the New Ordinary Shares may be restricted by law. Persons in possession of this Prospectus are required to inform themselves about, and to observe, any such restrictions. Any failure to comply with such restrictions may constitute a violation of the securities laws of any such jurisdiction. This Prospectus may not be used for, or in connection with, and does not constitute, an offer to sell, or an invitation to purchase, any of the New Ordinary Shares in any jurisdiction in which such offer or invitation is not authorized or would be unlawful. Neither this Prospectus, nor any related materials, may be distributed or transmitted to, or published in any jurisdiction except under circumstances that will result in compliance with any applicable laws or regulations.

None of the Company, the members of the Board, the Listing Agent or any of their respective affiliates or representatives, is making any representation to any offeree, purchaser or subscribers of the New Ordinary Shares regarding the legality of an investment in the New Ordinary Shares by such offeree, purchaser or subscriber under the laws applicable to such offeree, purchaser or subscriber.

Investors who purchase New Ordinary Shares will be deemed to have acknowledged that: (i) they have not relied on the Listing Agent or any person affiliated with it in connection with any investigation of the accuracy of any information contained in this Prospectus or their investment decision; and (ii) they have relied only on the information contained in this Prospectus, and that no person has been authorized to give any information or to make any representation concerning the Company or its subsidiaries or the New Ordinary Shares (other than as contained in this Prospectus) and, that if given or made, any such other information or representation has not been relied upon as having been authorized by the Company or the Listing Agent.

This Prospectus does not constitute or form part of any offer or invitation to sell, or any solicitation of any offer to acquire, New Ordinary Shares in any jurisdiction in which such an offer or solicitation is unlawful or would result in the Company becoming subject to public company reporting obligations outside the Netherlands.

The distribution of this Prospectus, and the offer or sale of New Ordinary Shares, is restricted by law in certain jurisdictions. Persons who obtain this Prospectus must inform themselves about and observe all such restrictions. Neither the Company nor the Listing Agent accept any legal responsibility for any violation by any person, whether or not a prospective purchaser or subscriber of New Ordinary Shares, of any such restrictions.

No action has been or will be taken to permit a public offer or sale of New Ordinary Shares. Accordingly, neither this Prospectus nor any advertisement or any other related material may be distributed or published in any jurisdiction except under circumstances that will result in compliance with any applicable laws and regulations. Subject to certain exceptions, this Prospectus should not be forwarded or transmitted in or into the United States, Australia, Canada South-Africa or Japan.

Notice to prospective investors in the United States

The New Ordinary Shares have not been and will not be registered under the US Securities Act or with any securities regulatory authority of any state of the United States and may not be offered or sold within the United States absent registration under the US Securities Act, except pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act and in compliance with any applicable securities laws of any state or other jurisdiction of the United States. In the United States, the New Ordinary Shares will be sold only to persons reasonably believed to be QIBs as defined in, and pursuant to, Rule 144A ("**Rule 144A**") under the

US Securities Act or pursuant to another exemption from, or in a transaction not subject to, the registration requirement under the US Securities Act and applicable state securities laws. Prospective purchasers are hereby notified that the Company may be relying on the exemption from the provisions of Section 5 of the US Securities Act provided by Rule 144A or on Regulation S ("**Regulation S**") under the US Securities Act. All offers and sales of the New Ordinary Shares outside the United States have been made in "offshore transactions" as defined in, and in compliance with Regulation S and in accordance with applicable law. The distribution of this Prospectus and the offer and sale of the New Ordinary Shares in certain jurisdictions may be restricted by law. Persons in possession of this Prospectus are required to inform themselves about and to observe any such restrictions.

THE NEW ORDINARY SHARES HAVE NOT BEEN RECOMMENDED BY ANY US FEDERAL OR STATE SECURITIES COMMISSION OR REGULATORY AUTHORITY. FURTHERMORE, THE FOREGOING AUTHORITIES HAVE NOT CONFIRMED THE ACCURACY OR DETERMINED THE ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE IN THE UNITED STATES.

Notice to prospective investors in the EEA

In relation to each member state of the European Economic Area (each a "**Relevant Member State**"), the New Ordinary Shares which are the subject of the Listing contemplated by this Prospectus have not and will not be offered to the public except that the New Ordinary Shares may be offered to the public in that Relevant Member State at any time:

- (a) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation); or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation.

No such offer of New Ordinary Shares shall require the Company or the Listing Agent to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person who initially acquires New Ordinary Shares or to whom any offer is made will be deemed to have represented, warranted and agreed to the Company, that it is a Qualified Investor.

For the purposes of this provision, the expression an "offer to the public" in relation to the New Ordinary Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the Listing and the New Ordinary Shares so as to enable an investor to decide to purchase the New Ordinary Shares.

In the case of any New Ordinary Shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, such financial intermediary will also be deemed to have represented, acknowledged and agreed that the New Ordinary Shares acquired by it in the Private Placement have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to persons in circumstances which may give rise to an offer of any New Ordinary Shares to the public other than their offer or resale in a Relevant Member State to Qualified Investors. The Company, the Listing Agent and their affiliates and others, will rely upon the truth and accuracy of the foregoing representation, acknowledgement and agreement.

Notice to prospective investors in the United Kingdom

No New Ordinary Shares which are the subject of the Listing contemplated by this Prospectus have been offered to or will be offered to the public in the United Kingdom prior to the publication of a prospectus in relation to the New Ordinary Shares that either (i) has been approved by the Financial Conduct Authority or (ii) is to be treated as if it had been approved by the Financial Conduct Authority in accordance with the transitional provisions in Regulation 74 of the Prospectus (Amendment etc.)

(EU Exit) Regulations 2019, except that offers of New Ordinary Shares may be made to the public in the United Kingdom at any time:

- (a) to any legal entity which is a qualified investor as defined in Article 2 of Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018 (the "**UK Prospectus Regulation**");
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined in Article 2 of the UK Prospectus Regulation (subject to obtaining the prior consent of the Group) for any such offer; or
- (c) in any other circumstances falling within section 86 of the Financial Services and Markets Act 2000,

provided that no such offer of New Ordinary Shares shall require the Group or the Listing Agent to publish a prospectus pursuant to section 85 of the Financial Services and Markets Act 2000 or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

For the purposes of this provision, the expression "an offer of New Ordinary Shares to the public" in relation to any New Ordinary Shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the Listing and the New Ordinary Shares to be offered so as to enable an investor to decide to purchase or subscribe for the New Ordinary Shares.

In addition, in the United Kingdom, this document is for distribution only to, and is only directed at persons who (i) are investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the "**Financial Promotion Order**"), (ii) are high net worth entities or other persons falling within Article 49(2)(a) to (d) of the Financial Promotion Order or (iii) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 (as amended, the "**FSMA 2000**")) in connection with the issue or sale of any New Ordinary Shares may otherwise lawfully be communicated or caused to be communicated (all such persons being referred to as "relevant persons"). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

Notice to prospective investors in Switzerland

In Switzerland, the New Ordinary Shares may only be offered to "professional clients" within the meaning of the FinSA by way of a private placement. The New Ordinary Shares may not be publicly offered, directly or indirectly, in Switzerland within the meaning of the FinSA and no application has been or will be made to admit the New Ordinary Shares to trading on any trading venue (exchange or multilateral trading facility) in Switzerland. Neither this Prospectus nor any other offering or marketing material relating to the New Ordinary Shares constitutes a prospectus pursuant to the FinSA, and neither this Prospectus nor any other offering or marketing material relating to the New Ordinary Shares may be publicly distributed or otherwise made publicly available in Switzerland.

Enforcement of Civil Liabilities

The Company is incorporated under the laws of the Netherlands and has its registered seat (*statutaire zetel*) in Amsterdam, the Netherlands. As such, under Dutch private international law the rights and obligations of its shareholders vis-à-vis the Company originating from Dutch corporate law and the Articles of Association, as well as the civil liability of its officers (*functionarissen*) (including its Directors and its executive officers) are governed in certain respects by the laws of the Netherlands. The ability of Shareholders in certain countries other than the Netherlands, in particular in the United States, to bring an action against the Company, the Directors and its executive officers, may be limited under law.

The Company is not a resident of the United States and its officers may also not all be residents of the United States. As a result, depending on the subject matter of the action brought against the Company and/or its officers, United States courts may not have jurisdiction. If a Dutch court has jurisdiction with respect to such action, that court will apply Dutch procedural law and Dutch private international law to determine the law applicable to that action. Depending on the subject matter of the relevant action, a competent Dutch court may apply another law than the laws of the United States.

Also, service of process against non-residents of the United States can in principle (absent, for example, a valid choice of domicile) not be effected in the United States.

In addition, substantially all of the Company's assets are located outside the United States. As of the date of this Prospectus, (i) there is no treaty in force between the United States and the Netherlands for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters and (ii) both the Hague Convention on Choice of Court Agreements (2005) and the Hague Judgments Convention (2019) have entered into force for the Netherlands, but have not entered into force for the United States. Consequently, a judgment rendered by a court in the United States will not automatically be recognized and enforced by the competent Dutch courts. However, if a person has obtained a final judgment without appeal in such a matter rendered by a court in the United States which is enforceable in the United States and files its claim with the competent Dutch court, the Dutch court will in principle give binding effect to such foreign judgment insofar as it finds that (i) the jurisdiction of the court involved was based on a ground of jurisdiction that is generally acceptable according to international standards, (ii) the judgment by such court was rendered in legal proceedings that comply with the Dutch standards of proper administration of justice including sufficient safeguards (*behoorlijke rechtspleging*), (iii) binding effect of such judgment does not contravene Dutch public policy (*openbare orde*), and (iv) the judgment is not incompatible with a decision rendered between the same parties by a Dutch court or with an earlier judgment given between the same parties by a foreign court in a dispute concerning the same subject and is based on the same cause, provided that such previous decision qualifies for recognition in the Netherlands. However, even if such foreign judgment is given binding effect, a claim based thereon may still be rejected if the foreign judgment is not or no longer formally enforceable in the country of origin. The Company cannot provide assurance that all conditions precedent required for enforcement of foreign judgments in the Netherlands will be satisfied, or that a particular judgment will be enforced in the Netherlands. In addition, there can be no assurance that civil liabilities predicated upon federal or state securities laws of the United States will be enforceable in the Netherlands or any other jurisdiction. Moreover, if the foreign judgment is not final (for instance when appeal is possible or pending) a competent Dutch court may postpone recognition until the foreign judgment will have become final, refuse recognition under the understanding that recognition can be asked again once the foreign judgment will have become final, or impose as a condition for recognition that security is posted. Furthermore, a Dutch court may deny the recognition and enforcement of a judgment by the United States court in accordance with applicable anti-boycott laws.

A competent Dutch court may deny the recognition and enforcement of punitive damages or other awards. Moreover, a competent Dutch court may reduce the amount of damages granted by a United States court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Thus, United States investors may not be able, or experience difficulty, to enforce a judgment obtained in a United States court against the Company or its officers.

Forward-Looking Statements

This Prospectus contains forward-looking statements that reflect the Group's intentions, beliefs or current expectations and projections about the Group's future results of operations, financial condition, liquidity, performance, prospects, anticipated growth, strategies and opportunities and the markets in which the Group operates. Forward-looking statements involve all matters that are not historical facts. The Group has tried to identify forward-looking statements by using words as "may", "will", "would", "should", "expects", "intends", "estimates", "anticipates", "projects", "believes", "could", "hopes", "seeks", "plans", "aims", "aspires", "objective", "potential", "goal", "strategy", "target", "continue", "annualized" and similar expressions or negatives thereof or other variations thereof or comparable terminology, or by discussions of strategy that involve risks and uncertainties. Forward-looking

statements may be found principally in sections in this Prospectus entitled "*Risk Factors*", "*Dividend Policy*", "*Business*" and also elsewhere.

The forward-looking statements are based on the Group's beliefs, assumptions and expectations regarding future events and trends that affect the Group's future performance, taking into account all information currently available to the Group, and are not guarantees of future performance. These beliefs, assumptions and expectations can change as a result of possible events or factors, not all of which are known to the Group or are within the Group's control. If a change occurs, the Group's business, financial condition, liquidity, results of operations, anticipated growth, strategies or opportunities may vary materially from those expressed in, or suggested by, these forward-looking statements. In addition, the forward-looking estimates and forecasts reproduced in this Prospectus from third-party reports could prove to be inaccurate. A number of important factors could cause actual results or outcomes to differ materially from those expressed in any forward-looking statement as a result of risks and uncertainties facing the Company and its Group Companies. Such risks, uncertainties and other important factors include, but are not limited to those listed in the section entitled "*Risk Factors*". Other factors could also adversely affect the Group's results or accuracy of forward-looking statements in this Prospectus, and you should not consider the factors discussed under "*Risk Factors*" to be a complete set of all potential risks and uncertainties.

Investors or potential investors should not place undue reliance on the forward-looking statements in this Prospectus. The Group urges investors to read the sections of this Prospectus entitled "*Risk Factors*" and "*Business*" for a more complete discussion of the factors that could affect the Group's future performance and the markets in which the Group operates. In light of the possible changes to the Group's beliefs, assumptions and expectations, the forward-looking events described in this Prospectus may not occur. Additional risks currently not known to the Group or that the Group has not considered material as of the date of this Prospectus could also cause the forward-looking events discussed in this Prospectus not to occur. Forward-looking statements involve inherent risks and uncertainties and speak only as of the date they are made. The Group undertakes no duty to and will not necessarily update any of the forward-looking statements in light of new information or future events, except to the extent required by applicable law.

Definitions

Definitions used in this Prospectus are defined in "*Definitions*".

Available Information

Subject to any applicable securities laws, copies of the following documents will be available and can be obtained free of charge from the Company's website (<https://ir.onwd.com/>) from the date of this Prospectus until at least 12 months following the date of this Prospectus:

- this Prospectus;
- the Articles of Association (in Dutch, and an unofficial English translation);
- the Board Rules;
- the charter of the Compensation Committee;
- the charter of the Audit Committee; and
- the charter of the Nomination Committee.

Validity

This Prospectus has been approved by the AFM, as competent authority under the Prospectus Regulation and will be notified to the FSMA in Belgium and to the AMF in France for passporting in accordance with Article 25 of the Prospectus Regulation. The AFM only approves this Prospectus as meeting the standards of completeness, comprehensibility and consistency imposed by Prospectus Regulation. Such approval should not be considered as an endorsement of the issuer or the quality

of the securities that are the subject of this Prospectus. This Prospectus has been drawn up as part of a simplified prospectus in accordance with Article 14 of the Prospectus Regulation. Investors should make their own assessment as to the suitability of investing in the securities.

The validity of this Prospectus shall expire on the Listing Date or 12 months after its approval by the AFM, whichever occurs earlier. The obligation to supplement this Prospectus in the event of significant new factors, material mistakes or material inaccuracies shall cease to apply upon the expiry of the validity period of this Prospectus.

Documents Incorporated by Reference

The Articles of Association are incorporated in this Prospectus by reference and, as such, form part of this Prospectus. The Articles of Association (or copies thereof, in Dutch, and an unofficial English translation) may be obtained in electronic form free of charge from the Company's website at <https://ir.onwd.com/corporate-governance/documents/articles-of-association>. Any documents themselves incorporated by reference in the documents incorporated by reference in this Prospectus shall not form part of this Prospectus.

No Incorporation of Website

Unless expressly specified, the contents of any website referenced in this Prospectus, including any websites accessible from hyperlinks on the Company's website, do not form part of and are not incorporated by reference in this Prospectus, and have not been scrutinized or approved by the AFM.

Regulatory Disclosures

At the date of this Prospectus, the following information which has been disclosed under Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse, and the regulations promulgated thereunder (the "**Market Abuse Regulation**") over the last 12 months is still relevant as at the date of the Prospectus.

Disclosure of Company and Financial Information

- On 16 November 2023, the Company reported cash and cash equivalents of EUR 36.8 million as of 30 September 2023 and the Company's management confirmed its guidance of a cash runway through the end of 2024.
- On 15 March 2024, the Company reported cash and cash equivalents of EUR 29.8 million as of 31 December 2023 and the Company's management confirmed its guidance of a cash runway through the end of 2024.
- On 18 March 2024, the Company reported that it received a positive testing report from a medical equipment testing laboratory confirming that the ARC^{EX} device conforms to prevailing electrical standards. With the positive testing report, the Company moves closer to meeting regulatory obligations for the market launch of ARC^{EX}.
- On 20 March 2024, the Company announced the launch of a capital increase by way of an accelerated bookbuilding offering through a private placement with institutional investors and certain founders, management and members of the Board and a separate public offering via the PrimaryBid platform with retail investors in France of ordinary shares with a nominal value of EUR 0.12 each in the Company's issued share capital.
- On 21 March 2024, the Company reported, that it raised an amount of EUR 20.0 million in gross proceeds by way of an accelerated bookbuild offering through a private placement with institutional investors, certain founders, and certain management and members of the Board of 4,307,641 new ordinary shares and a separate public offering via the PrimaryBid platform with retail investors in France of 136,803 new ordinary shares, representing a total of 4,444,444 new ordinary shares. The new ordinary shares were offered at an issue price of EUR 4.50 per share. The Company also published a prospectus for the admission to listing

and trading of these new ordinary shares on Euronext Brussels and Euronext Amsterdam, which was approved by the AFM on the same day.

The Company issued the expectation, that the net proceeds from this offering extend the cash runway of the Company into mid-2025.

- On 25 March 2024, the Company announced the closing of its previously announced private placement with institutional investors, certain founders, certain members of management, and certain members of the Board and of its separate public offering via the PrimaryBid platform with retail investors in France. On the same day, the new ordinary shares were admitted to listing and trading on Euronext Brussels and Euronext Amsterdam.
- On 25 April 2024, the Company reported an operating loss of EUR 35.5 million in 2023, compared to EUR 32.0 million in 2022. The company ended the year 2023 with net cash of EUR 29.8 million (2022: EUR 61.8 million). The Company's management reiterated its guidance of a cash runway through mid-2025.

The Company also reported, that the FDA's authorization to commercialize the ARC^{EX} system in the US is anticipated for the second half of 2024 and the Company aims to apply for CE Mark and European authorization in 2025.

The Company further reported, that based on positive feedback from potential customers on the value of the ARC^{EX} system, the Company anticipated an approximate list price of USD 30,000. In addition, the Company expected to supplement revenue by offering tiered service packages.

The Company planned to apply for FDA IDE approval and to begin its global pivotal trial for the ARC^{IM} system, called Empower BP, in the second half of 2024 to provide the evidence necessary to ultimately submit a PMA application to the FDA and other global regulatory bodies.

The Company intended to gain additional clinical data and experience with its implantable ARC^{IM} system in 2024, with several implants planned with support from the Michael J. Fox Foundation for Parkinson's Research and several ARC^{IM} system implants planned in combination with an implanted brain-computer interface ("BCI") with support from the European Innovation Council.

- On 2 May 2024, the Company has convened the 2024 annual general meeting of shareholders, including the resolutions to be submitted for adoption at the 2024 annual general meeting, which was held in Amsterdam, the Netherlands, on 13 June 2024.
- On 23 May 2024, the Company reported cash and cash equivalents of EUR 42.0 million as of 31 March 2024.

The Company also reported, that it expects FDA clearance and first commercial sale in the US for its ARC^{EX} system sometime in the fourth quarter of 2024. European and regulatory approval and commercialization were expected sometime in 2025.

The Company continued to prepare for its Empower BP global pivotal trial to evaluate the safety and effectiveness of its implantable ARC^{IM} system to address blood pressure instability after SCI. It expected IDE approval from FDA in the fourth quarter of 2024 to commence this study. First participant enrollment could occur in late 2024 or early 2025. The Company also expected publication of interim results from clinical feasibility studies for this indication in a leading scientific journal sometime in the second half of 2024.

The Company also expected to gain additional clinical data and experience with its implantable ARC^{IM} system in 2024, with several implants planned with support from the Michael J. Fox

Foundation for Parkinson's Research as well as several more planned in combination with an investigational BCI with support from the European Innovation Council.

The Company's management reiterated its guidance of a cash runway through mid-2025. This expectation on 23 May 2024 did not take into account the effects of the net proceeds from the Private Placement on the working capital of the Company as the Private Placement took place on 22 and 23 October 2024. Please refer to "Reasons for the Listing and Use of Proceeds—*Working capital statement*" for the Company's assessment of its working capital taking into account the net proceeds from the Private Placement on the working capital of the Company.

- On 13 June 2024, the Company announced the results of the 2024 annual general meeting of shareholders, which was held on the same day in Amsterdam, the Netherlands. All proposed resolutions were duly passed.
- On 28 June 2024, the Company, ONWARD Medical S.A. and ONWARD Medical Inc. signed a loan and security agreement in the amount of up to EUR 52.5 million with U.S.-based lender Runway Growth Finance Corp ("**Runway**") (the "**Runway Loan**"). The Runway Loan bears an interest rate equal to Term Secured Overnight Financing Rate (SOFR) for a three-month interest period (currently at 6.00% and subject to a 4.25% floor), plus margin of 6.50%. The loans under the Runway Loan are secured by a security interest in substantially all of the Group's assets. In addition, upon signing of the Runway Loan the Company issued warrants to Runway which entitle it to purchase Ordinary Shares in the capital of the Company at an exercise price per newly issued share of EUR 4.83. The number of shares subject to the warrants are 5.00% of the drawn down principal amount initially and upon each subsequent loan advance, divided by the exercise price.
- On 5 August 2024, the Company reaffirmed its 2024 strategic priorities and released its unaudited financial highlights for the second quarter of 2024. The Company expected to launch its ARC^{EX} Therapy for people with SCI in the US in the fourth quarter of 2024, once it has received FDA clearance. The Company has accelerated launch presentations and continued to hire and develop its field sales and service organization. The Company planned to price the ARC^{EX} system at USD 40,000 based on the strength of the Up-LIFT pivotal study data published in *Nature Medicine* in June 2024. The Company expected a peer-reviewed publication in a top-tier medical journal detailing the results of the first 10+ patients implanted with the investigational ARC^{IM} Therapy to address blood pressure instability after SCI. The Company also reported that it prepares to launch its global pivotal trial study, called Empower BP, for ARC^{IM} Therapy to address blood pressure instability after SCI and that it expects major associated milestones to occur in the fourth quarter of 2024 and the first quarter of 2025, including FDA IDE submission, FDA IDE approval, and first participant enrollment. In addition, the Company stated that it plans to advance clinical and development activities for its investigational system, that uses BCI technology in conjunction with the ARC^{IM} Therapy ("**ARC^{BCI}**"), leveraging grant funding, previously announced FDA Breakthrough Device Designation, and acceptance into FDA's new Total Product Lifecycle Advisory Program. Several additional ARC^{BCI} system implants are expected in the second half of 2024 and in the first half of 2025 as part of the ongoing clinical feasibility study with partners at .NeuroRestore and CEA-Clinatec.

The Company reported a net cash balance of EUR 32.1 million on 30 June 2024 and the plan to publish the financial statements for the first half of 2024 on 10 September 2024.

- On 3 September 2024, the Company announced that the Christopher & Dana Reeve Foundation has awarded the Company and its partners CEA-Clinatec and .NeuroRestore a USD 1.1 million grant to support expansion of an ongoing early feasibility clinical study to explore the use of the investigational ARC^{BCI} system to restore thought-driven use of the hands

and arms after SCI. The grant enables up to four additional participants to be implanted with the ARC^{BCI} system.

- On 10 September 2024, the Company announced its results for the first half of 2024 and provided a business update. The Company provided, inter alia, updates on its clinical and corporate development in the six-month period ended 30 June 2024. The Company further reported an operating loss for the six-month period ended 30 June 2024 of EUR 18.7 million compared to EUR 18.8 million in the six-month period ended 30 June 2023 and updated its guidance for its cash runway to spring 2025. Such guidance did not take into account the effects of the net proceeds from the Private Placement on the working capital of the Company as the Private Placement took place on 22 and 23 October 2024. Please refer to "Reasons for the Listing and Use of Proceeds—*Working capital statement*" for the Company's assessment of its working capital taking into account the net proceeds from the Private Placement on the working capital of the Company.
- On 20 September 2024, the Company announced that its existing Ordinary Shares will be listed on Euronext Paris from 24 September 2024.
- On 15 October 2024, the Company announced that it has signed an exclusive license with the Commissariat à l'Energie Atomique et aux Energies Alternatives (CEA) to develop and commercialize the investigational WIMAGINE BCI designed by CEA-Clinatec as part of the Company's investigational ARC^{BCI} system to restore thought-driven movement and function of the human body after paralysis.
- On 21 October 2024, the Company announced that Rob ten Hoedt and Rahma Samow are joining the Company's Board in October 2024 as non-executive directors. The Company expects their appointments to be formally ratified by votes of the Company's shareholders at the 2025 annual general meeting. The current chairman of the Board Jahn Øhrstrøm and non-executive director Fredericus Colen will retire from the Board at year-end after eight years of service. Rob ten Hoedt is expected to assume the role of chairman in December 2024 upon the planned retirement of Jan Øhrstrøm. For more information on Rob ten Hoedt and Rahma Samow, please see "Management and Corporate Governance—Directors".

Disclosure related to Clinical Studies

- In November 2023, the Company announced a publication in *Nature Medicine* highlighting the potential for ONWARD ARC Therapy to address gait challenges related to Parkinson's disease. The study participant described in the publication has been living with Parkinson's disease for nearly three decades. He has a severe gait disorder that has not responded to conventional therapies. After the introduction of ARC Therapy and benefitting from several weeks of rehabilitation, the participant was able to walk without previously noticeable gait interruptions. Also in November, ONWARD research partner .NeuroRestore was awarded a USD 1.0 million grant from The Michael J. Fox Foundation for Parkinson's Research (MJFF) to implant the Company's ARC^{IM} system and investigate the effect of ARC Therapy in six additional participants with Parkinson's disease. This study will assist the Company in determining whether to conduct additional clinical trials and potentially commercialize ARC Therapy in the future for those living with Parkinson's disease.
- On 14 January 2024, the Company announced the start of the HemON NL clinical study. Building on the previously announced Swiss HemON clinical feasibility study, the HemON NL clinical study prepares the Company for a global pivotal trial, called Empower BP, which is designed to provide the evidence to necessary to submit a pre-market approval (PMA) to the FDA and other global regulatory authorities. The study aims to assess the safety and effectiveness of ARC Therapy based on ARC^{IM} to address hemodynamic instability after SCI.
- On 29 February 2024, the Company announced it has been awarded Breakthrough Device Designation (BDD) by the FDA for ARC^{BCI} to restore thought-driven lower limb mobility after SCI. This BDD is supported by clinical data from two feasibility studies. This is the tenth FDA

BDD awarded to ONWARD Medical. The designation is reserved for novel, cutting-edge therapies addressing an unmet need and provides many potential regulatory and reimbursement advantages. This latest award gives ONWARD Medical priority FDA review, the opportunity to interact with FDA experts throughout the pre-market regulatory review phase, and the potential to seek additional reimbursement for its ARC^{BCI} system.

- On 11 March 2024, the Company announced that it has been accepted into the FDA's new Total Product Lifecycle Advisory Program for its ARC^{BCI} system. The Company was only the second BCI company to be accepted into the program. The program provides the Company with early and frequent strategic engagement from the FDA, patients, providers, and payers to facilitate more rapid development and widespread patient access to safe, effective, high-quality medical devices of public health importance. The Company benefits from more timely premarket interactions, earlier identification and mitigation of device development risk, and more efficient premarket review process
- On 2 April 2024, the Company submitted its de novo application to the FDA to allow marketing of its ARC^{EX} system to restore function of the upper extremities after SCI. Once cleared by the FDA, ARC^{EX} would be the first-ever spinal cord stimulation therapy to restore hand and arm function after SCI and the first commercial product for the Company. The de novo application followed the Company's global pivotal study Up-LIFT, the first large-scale pivotal study of transcutaneous spinal cord stimulation.
- On 20 May 2024, the Company announced the publication of global Up-LIFT pivotal trial results in *Nature Medicine*. The study achieved all primary safety and effectiveness endpoints, and ARC^{EX} Therapy demonstrated significant improvements in upper limb strength, function, and sensation among people with chronic tetraplegia due to cervical SCI. At the end of the trial, 72% of trial participants were considered responders to non-invasive ARC^{EX} Therapy based on a conservative definition requiring responders to meet improvement criteria in both strength and functional domains vs. standard of care rehabilitation alone. The number of responders increased to 90% when the definition included participants with improvements in at least one strength or functional outcome. Study participants also reported reduced spasm frequency, improved sleep, and improved upper body sensation, including the sense of touch. 87% of participants reported that ARC^{EX} Therapy delivered improvements in overall quality of life. Self-care, a key component of independence after SCI, also improved significantly. The Up-LIFT study was a prospective, single-arm pivotal study designed to evaluate the safety and effectiveness of the ARC^{EX} system to treat upper extremity functional deficits in people with chronic tetraplegia. The global study was conducted with 65 participants at 14 leading SCI centers in the United States, Europe, and Canada.
- On 23 May 2024, the Company reported that it was issued 13 new patents during the first quarter of 2024, bringing its total number of issued patents year-to-date to more than 265, further strengthening its first-mover advantage.
- On 9 July 2024, the Company announced a publication in *Neuromodulation: Technology at the Neural Interface*, providing an evidenced-based framework to determine stimulation parameters for ARC^{EX} Therapy based on analysis of device parameters, usage data, and clinician and participant feedback from the Up-LIFT pivotal trial and follow-on LIFT home study.
- On 19 September 2024, the Company reported another successful implant of its investigational ARC^{BCI} system to restore lower limb mobility after SCI. The implant procedure was performed by a neurosurgeon at Centre Hospitalier Universitaire Vaudois ("**CHUV**") in Lausanne, Switzerland. This implant is part of an ongoing early feasibility clinical study supported by a grant from the European Innovation Council under the Reverse Paralysis

project and coordinated by .NeuroRestore. It marks the third human implant of the ARC^{BCI} system to restore thought-enabled movement after SCI and the second for lower limb mobility.

Disclosure of Managers' Transactions

The Company has made a number of disclosures in accordance with Article 19 of the Market Abuse Regulation in relation to transactions carried out by certain of the Company's persons discharging managerial responsibilities as well as persons closely associated with them.

Lock-up arrangements

On 22 October 2024, the Company and UBS AG London Branch, Bryan, Garnier & Co. Limited, Bryan Garnier Securities SAS and Bank Degroof Petercam SA/NV (collectively, the "**Placement Agents**", and UBS AG London Branch, together with Bryan, Garnier & Co. Limited and Bryan Garnier Securities SAS, the "**Joint Global Coordinators**"), entered into a placement agents agreement, pursuant to which the Company agreed, during the period beginning from 22 October 2024 and continuing to and including the date 180 days after the closing of the Private Placement, not to issue, offer, sell, pledge, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of, directly or indirectly, any Ordinary Shares or other securities that are substantially similar to the Ordinary Shares, or any securities that are convertible or redeemable into or exchangeable for, or that represent the right to receive, Ordinary Shares or any such substantially similar securities, or enter into any derivative or other transaction having substantially similar economic effect with respect to its Ordinary Shares or any such securities or announce its intention to perform one of the aforementioned transactions, in each case without the prior written consent of the Joint Global Coordinators.

The following actions are excluded from this restriction: (i) the issue of the New Ordinary Shares; (ii) the granting of stock options or free shares pursuant to any employee stock option or free shares plans or granted pursuant to an authorisation of the General Meeting in force on 22 October 2024; and (iii) the issuance of Ordinary Shares pursuant to the exercise of (A) warrants outstanding on 22 October 2024, (B) stock options or free shares outstanding on 22 October 2024 or on any subsequent date further to a grant of such options or free shares pursuant to an employee stock option or free shares plans referred to in (ii) above or (C) convertible bonds outstanding on 22 October 2024.

The Joint Global Coordinators may jointly waive the above lock-up undertakings of the Company during the respective period in full or in part in their absolute discretion.

In addition, the Directors, except for John de Koning, Rahma Samow and Rob ten Hoedt, (together, the "**Restricted Shareholders**"), entered into a lock-up arrangement with the Joint Global Coordinators in respect of their Ordinary Shares held in the Company.

Pursuant to the lock-up arrangement, the Restricted Shareholders will not do or announce any intention to do, any of the following for a period of 180 days following 22 October 2024 (the "**Lock-up Period**") without the prior written consent (such consent not to be unreasonably withheld or delayed) of each of the Joint Global Coordinators: (i) offer, pledge, sell, offer to sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, cause the Company to issue, or otherwise transfer or dispose of, directly or indirectly, any Ordinary Shares or any securities convertible into or exercisable or exchangeable for Ordinary Shares or any other similar instrument that would give an equity-like economic interest in the Company to its holders (the "**Related Securities**") owned either of record or beneficially (as defined in Rule 13d-3 under the U.S. Securities Exchange Act of 1934, as amended (the "**US Exchange Act**")) by a Restricted Shareholder or a Family Member (as defined below) as of or following the commencement of the Lock-up Period; or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of Ordinary Shares or Related Securities, whether settled by delivery of Ordinary Shares or Related Securities, in cash or otherwise.

For the purposes of this section, "**Family Member**" shall mean the spouse of a Restricted Shareholder, an immediate family member (in the meaning set forth in Rule 16a-1(e) under the Exchange Act) of a Restricted Shareholder or an immediate family member of the relevant Restricted Shareholder's spouse, in each case living in the Restricted Shareholder's household or whose principal residence is the Restricted Shareholder's household (regardless of whether such spouse or family member may at the time be living elsewhere due to educational activities, health care treatment, military service, temporary internship or employment or other-wise).

The restrictions do not prohibit the holders of Related Securities from: (i) accepting a public takeover or tender offer on all of the Ordinary Shares or Related Securities of the Company, giving an irrevocable commitment to accept such an offer, or disposing of Ordinary Shares or Related Securities to an offeror or potential offeror during the period of such an offer or pursuant to a squeeze-out; (ii) proceeding with any transfer required by law, regulation or a court of competent jurisdiction; (iii) transferring Ordinary Shares or Related Securities to legal successors upon (A) the death of such holder (in the event the holder is a natural person) or (B) the merger, liquidation, concursus, demerger, transfer of a division or transfer of a business as a whole of such holder (in the event the holder is a legal person), provided that each such transferee shall continue to be bound by the restrictions for the remaining period of the restrictions; (iv) the offer and sale of any Ordinary Shares or Related Securities acquired after the Private Placement in open market transactions; or (v) transfers of any Ordinary Shares or Related Securities by a Restricted Shareholder in favor of any entity within such Restricted Shareholder's control or under common control with such Restricted Shareholder or to one or more persons, whether natural or legal, who are the ultimate beneficial owners of such Restricted Shareholder, provided such transferee provides undertakings to the Joint Global Coordinators equivalent to those agreed by such Restricted Shareholder.

The Joint Global Coordinators may jointly waive the above lock-up undertakings of the Restricted Shareholders during the Lock-up Period in full or in part in their absolute discretion.

Ottobock SE & Co. KGaA, who entered into a cornerstone investor agreement with the Company on 22 October 2024 in connection with the Private Placement (the "**Cornerstone Investor Agreement**") (the "**Cornerstone Investor**"), agreed in the Cornerstone Investor Agreement that, without the prior written consent of the Company (such consent not to be unreasonably withheld or delayed), it will not, and will not announce any intention to, during the period commencing on 28 October 2024 and continuing to and including the close of trading on the date that is 180 days thereafter: (i) offer, pledge, sell, offer to sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, cause the Company to issue, or otherwise transfer or dispose of, directly or indirectly, any Ordinary Shares; or (ii) enter into a transaction or perform any action economically similar to those described in (i), in particular enter into any swap or other arrangement that transfers to another, in whole or in part, the economic risk of ownership of Ordinary Shares, whether any such transaction is to be settled by delivery of Ordinary Shares, in cash or otherwise.

The following actions are excluded from this restriction: (i) accepting a public takeover or tender offer on all of the Ordinary Shares of the Company, giving an irrevocable commitment to accept such an offer, or disposing of any Ordinary Shares to an offeror or potential offeror during the period of such an offer or pursuant to a squeeze-out; (ii) any disposal of Ordinary Shares pursuant to any offer by the Company to purchase its own securities which is made on identical terms to all holders of Ordinary Shares in the Company; (iii) any disposal of Ordinary Shares (a) which have been acquired by the Cornerstone Investor from a third party and not pursuant to the subscription contemplated under the Cornerstone Investor Agreement; (b) which are allotted or issued to the Cornerstone Investor pursuant to any capital reorganization (including, for the avoidance of doubt, by way of capitalization of profits, share premium account or any capital or reserve account of the Company) after the Private Placement; (iv) the disposal of Ordinary Shares if required by law or competent court or regulatory authority; (v) any disposal of Ordinary Shares by the Cornerstone Investor to an affiliate of the Cornerstone Investor, provided that such affiliate has agreed to be bound by the terms of the Cornerstone Investor Agreement as if it were the Cornerstone Investor; and (vi) any disposal of rights

granted in connection with a rights issue by the Company to the extent necessary to fund the subscription of the balance of the rights available for subscription by the Cornerstone Investor.

For more information on the Cornerstone Investor Agreement see "*The Listing—Cornerstone Investment*".

The Company agreed in the Cornerstone Investor Agreement that, without the prior written consent of the Cornerstone Investor (such consent not to be unreasonably withheld or delayed), for a period of 180 days following 28 October 2024, the Company shall not issue, offer or sell any Ordinary Shares (or options relating to Ordinary Shares) or enter into any contract to issue, sell, grant any option or right or warrant to acquire or otherwise transfer or dispose of, directly or indirectly, any Ordinary Shares or other securities that are substantially similar to Ordinary Shares or any securities that are convertible or redeemable into or exchangeable for Ordinary Shares, at a price which would be at an effective issue, sales or exercise price per Ordinary Share which is less than EUR 5.00.

The following actions are excluded from this restriction: (i) the issue of the New Ordinary Shares; (ii) the granting of stock options or free shares pursuant to any employee stock option or free shares plans existing on 22 October 2024 and disclosed to the public or granted pursuant to an authorization at the annual general meeting and in force on 22 October 2024; (iii) the potential one-off issuance of Ordinary Shares to a strategic investor for an aggregate purchase price of up to EUR 15,000,000.00 post the Private Placement, it being acknowledged and agreed by the Company that this strategic investor is not participating in the Private Placement; and (iv) the issuance of Ordinary Shares pursuant to the exercise of (A) warrants outstanding on 22 October 2024, (B) stock options or free shares outstanding on 22 October 2024 or on any subsequent date further to a grant of such options or free shares pursuant to an employee stock option or free shares plans referred to in (ii) above or (C) convertible bonds outstanding on 22 October 2024.

REASONS FOR THE LISTING AND USE OF PROCEEDS

The Company is contractually required to facilitate the Listing of the New Ordinary Shares placed in the Private Placement in accordance with the terms and conditions of the subscription agreements entered into by and among the Company and the investors who subscribed for the New Ordinary Shares in the Private Placement.

The Company intends to distribute the net proceeds from the Private Placement as follows: (i) approximately 40% to fund research and development initiatives, including continued product development, clinical studies, and regulatory activities for the investigational ARC^{EX} system to restore hand and arm function, the investigational ARC^{IM} system for improved blood pressure regulation and other exploratory indications, and the investigational ARC^{BCI} system to restore thought-driven movement of the human body after SCI, (ii) approximately 30% to support the expected commercial launch of the ARC^{EX} system in the United States of America in the second half of 2024, including hiring a field sales organization and conducting selling activities, producing training and education materials and conducting training events, attending congresses, developing customer support capabilities and conducting customer support activities, and conducting market access and reimbursement activities, (iii) approximately 20% for building quality, operations and administrative capabilities, (iv) approximately 5% for working capital requirements and potential strategic opportunities, aimed at establishing, maintaining, or strengthening competitive advantage through license arrangements, acquisitions whether by assets or shares, or other arrangements (partnering or otherwise) and (v) approximately 5% of the funds will be allocated to cover financing costs associated with existing obligations under current and anticipated debt funding. The Company may be required to raise additional capital in the future in order to meet its funding requirements.

The net proceeds from the Private Placement are, together with the Company's existing cash balance, including the funds received by the Company under the first credit tranche of the Runway Loan, and, assuming that the Company will achieve the respective milestones, the funds under the second, third and fourth credit tranche of the Runway Loan, expected to extend the Company's cash runway, meaning the point in time until which the Company has sufficient funding to carry out its business in line with its current business plan, to two years or more, thereby allowing the Company to (i) receive anticipated FDA clearance and commercialize the Company's external neuromodulation system ARC^{EX}, (ii) fund the Company's implanted neuromodulation system ARC^{IM} through the pivotal trial, PMA approval process, and post-approval commercialization of its first indication, blood pressure management, alone or in combination with potential future grant funding, currently under submission and review by the US National Institutes of Health (NIH), (iii) in combination with potential grant funding, pursue and potentially receive ARC^{IM} PMA approval for Mobility under an HDE, and (iv) fund general corporate purposes and the addition of operational capabilities in anticipation of commercialization, in support of the foregoing.

DIVIDEND POLICY

General

Under Dutch law, the Company may only make distributions, whether a distribution of profits or freely distributable reserves, to its Shareholders to the extent as the Company's shareholders' equity (*eigen vermogen*) exceeds the sum of the paid-in and called-up share capital plus the reserves that must be maintained under Dutch law or the Articles of Association and (if it concerns a distribution of profits) after adoption of the Annual Accounts by the General Meeting from which it appears that such dividend distribution is allowed. Subject to those restrictions, any future determination to pay dividends or other distributions from the Company's reserves will be at the discretion of the Board and will depend upon a number of factors, including the results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors the Board deems relevant.

Under the Articles of Association, if any preferred shares in the Company's share capital, with a nominal value of EUR 0.12 each, if and when issued (the "**Preferred Shares**") are or have been outstanding, a dividend is first paid out of the Company's profits, if available for distribution, to the holders or former holders, as applicable, of those Preferred Shares to the extent they are entitled to such distribution under the Articles of Association, which is referred to as preferred dividend. Thereafter, the Board may decide that all or part of the remaining profits shown in the Company's adopted Annual Accounts will be added to the Company's reserves. After reservation of any such profits, any remaining profits will be at the disposal of the General Meeting at the proposal of the Board for distribution on the Ordinary Shares, subject to applicable restrictions of Dutch law. The Board is permitted, subject to certain requirements and applicable restrictions of Dutch law, to declare interim dividends without the approval of the General Meeting. Dividends and other distributions shall be made payable no later than a date determined by the Company. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable will lapse and any such amounts will be considered to have been forfeited to the Company (*verjaring*).

The Board is permitted, subject to certain requirements and applicable restrictions of Dutch law, to declare interim dividends without the approval of the General Meeting. For this purpose the Board must prepare an interim statement of assets and liabilities evidencing sufficient distributable equity.

Furthermore, under the Articles of Association, the General Meeting may, at the proposal of the Board and subject to the applicable restrictions of Dutch law, decide that a distribution shall be made in the form of Ordinary Shares or in the form of the Company's assets, instead of cash.

Dividends and other distributions shall be due and payable on such date and, if it concerns a distribution in cash, in such currency or currencies as determined by the Board.

Dividend Policy

The Company has never paid or declared any cash dividends in the past and does not anticipate paying any cash dividends in the foreseeable future. The Company intends to retain all available funds and any future earnings to fund the further development and expansion of the Company's business. As a consequence of all of these factors, there can be no assurance as to whether dividends or similar payments will be paid out in the future nor, if they are paid, as to their amount.

Under the Runway Loan the Company is generally not allowed to pay dividends, with the exception, that it may pay dividends in form of equity interests (e.g. Ordinary Shares) of the Company.

The ability and intention of the Company to declare and pay dividends in the future: (i) will mainly depend on its financial position, results of operations, capital requirements, investment prospects, the existence of distributable reserves and available liquidity and such other factors as the Board may deem relevant; and (ii) are subject to factors that are beyond the Company's control. See also "*Risk Factors—Risks related to the Ordinary Shares—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." for the risks associated with the Company's ability to pay dividends.

Manner and Time of Dividend Payments

Payment of any dividend in cash will in principle be made in euro. According to the Articles of Association, the Board may determine that distributions on Ordinary Shares will be made payable either in euro or in another currency. Any dividends that are paid to Shareholders through Euroclear Nederland, will be automatically credited to the relevant Shareholders' accounts without the need for the Shareholders to present documentation proving their ownership of the Shares. Payment of dividends on the Shares in registered form (not held through Euroclear Nederland, but directly) will be made directly to the relevant Shareholder using the information contained in the Company's Shareholders' Register (as defined below) and records.

Uncollected Dividends

A claim for any dividends and other distributions lapses five years after the date those dividends or distributions became payable. Any dividend or distribution that is not collected within this period will be considered to have been forfeited to the Company (*verjaring*).

Taxation on Dividends

The tax legislation of the Shareholders' member states or other relevant jurisdictions and of the Company's country of incorporation may have an impact on the income received from the Ordinary Shares.

Dividend payments are generally subject to withholding tax in the Netherlands. See "*Taxation—Material Dutch Tax Considerations*".

For Belgian income tax purposes, the gross amount of all benefits paid on or attributed to the Ordinary Shares is generally treated as a dividend distribution. Belgian withholding tax at the current rate of 30% is normally levied on dividends by any intermediary established in Belgium that is in any way involved in the processing of the payment of non-Belgian sourced dividends (e.g. a Belgian financial institution). The Belgian withholding tax is calculated on the dividend amount after deduction of any non-Belgian dividend withholding tax. This withholding tax rate is however subject to such relief as may be available under applicable domestic or tax treaty provisions (See, section on "*Taxation—Material Belgian Tax Considerations*").

In France, dividend payments paid to French resident corporates are generally taxable as ordinary income and subject to corporate income tax at the standard rate. Dividend payments paid to French resident individuals are generally subject to a flat rate tax set at 30%, including income tax at 12.8% and social security contributions at 17.2%. See "*Taxation—Material French Tax Considerations*".

See "*Taxation*" for an overview of the material Dutch, Belgian and French tax consequences of the acquisition, holding and disposal of Ordinary Shares.

CAPITALIZATION AND INDEBTEDNESS

The tables below set forth the Group's consolidated capitalization and indebtedness (i) as of 31 July 2024, (ii) the effects of the Private Placement and the placement capital increase, and (iii) total numbers as adjusted for these effects. The adjustments are based on the assumption that these developments had been completed on 31 July 2024 and had no tax effects. These tables should be read in conjunction with the Consolidated Financial Statements included elsewhere in this Prospectus. See "*Description of Share Capital*" for information concerning the Company's share capital.

Capitalization

	As at 31 July 2024 ^(*)	Adjustments for the effects of the Private Placement and the connected capital increase ⁽¹⁾ <i>(unaudited)</i> <i>(in EUR 000)</i>	As adjusted
Total current debt (including current portion of non-current debt).....	1,912.70	–	1,912.70
Guaranteed	–	–	–
Secured.....	554.13 ⁽²⁾	–	554.13
Unguaranteed/unsecured	1,358.57 ⁽³⁾	–	1,358.57
Total non-current debt (excluding current portion of non-current debt).....	18,820.54	–	18,820.54
Guaranteed	–	–	–
Secured.....	16,794.12 ⁽⁴⁾	–	16,794.12
Unguaranteed/unsecured	2,026.43 ⁽⁵⁾	–	2,026.43
Shareholder's equity	15,372.41	46,600.00	61,972.41
Share capital	4,155.46	1,200.00	5,355.46
Share premium.....	172,662.08	48,800.00	221,462.08
Other reserves	5,437.33 ⁽⁶⁾	–	5,437.33
Retained earnings	(166,882.47) ⁽⁷⁾	(3,400.00)	(170,282.47)
Total	36,105.65	46,600.00	82,705.65

(*) Unaudited.

- (1) The adjustment reflects the increase of the Company's share capital by EUR 1,200,000 from EUR 4,155,459.84 to EUR 5,355,459.84 against cash contributions, and the resulting net proceeds from the Private Placement in connection with the capital increase, attributable to the Company of EUR 46.6 million (based on the issuance of 10,000,000 New Ordinary Shares at a placement price of EUR 5.00 per share and costs of the Private Placement and Listing of approximately EUR 3.4 million). The gross proceeds from the Private Placement amount to EUR 50.0 million.
- (2) The secured portion of the total current debt from the Group's unaudited management accounts as at 31 July 2024 comprises the short-term portion of lease liabilities and represents amounts payable to the landlord of the office building in the Switzerland and the Netherlands.
- (3) The unguaranteed/unsecured portion of the total current debt from the Group's unaudited management accounts as at 31 July 2024 consists of the amount repayable under the EISMEA grant.
- (4) The secured portion of the total non-current debt from the Group's unaudited management accounts as at 31 July 2024, represents amounts payable to Runway relating to the Runway Loan and the long-term portion of lease liabilities. Substantially all of the Group's assets have been pledged to Runway to secure the Runway Loan.
- (5) The unguaranteed/unsecured portion of the total non-current debt from the Group's unaudited management accounts as at 31 July 2024 consists of the post-employment benefits from the Swiss Pension Plan.
- (6) Other reserves as at 31 July 2024 consist of reserves for share-based payments and other comprehensive income relating to foreign currency translation differences.
- (7) Retained earnings includes the result for the seven-month period ended 31 July 2024 as derived from the unaudited management accounts.

Indebtedness

	As at 31 July 2024 ^(*)	Adjustments for the effects of the Private Placement and the connected capital increase ⁽¹⁾	Total
		<i>(unaudited)</i> <i>(in EUR 000)</i>	
A Cash	20,590.97 ⁽²⁾	46,600.00	67,190.97
B Cash equivalents	–	–	–
C Other current financial assets	7,797.38 ⁽³⁾	–	7,797.38
D Liquidity (A + B + C)	28,388.35	46,600.00	74,988.35
E Current financial debt (including debt instruments, but excluding current portion of non-current financial debt)	1,912.70 ⁽⁴⁾	–	1,912.70
F Current portion of non-current financial debt	–	–	–
G Current financial indebtedness (E + F)	1,912.70	–	1,912.70
H Net current financial indebtedness (G – D)	(26,475.65)	–	(73,075.65)
I Non-current financial debt (excluding current portion and debt instruments)	18,820.54 ⁽⁵⁾	–	18,820.54
J Debt instruments	–	–	–
K Non-current trade and other payables	–	–	–
L Non-current financial indebtedness (I + J + K)	18,820.54	–	18,820.54
M Total financial indebtedness (H + L)	(7,655.10)	–	(54,255.10)

(*) Unaudited.

- (1) The adjustment reflects the increase of the Company's share capital by EUR 1,200,000 from EUR 4,155,459.84 to EUR 5,355,459.84 against cash contributions, and the resulting net proceeds from the Private Placement in connection with the capital increase, attributable to the Company of EUR 46.6 million (based on the issuance of 10,000,000 New Ordinary Shares at a placement price of EUR 5.00 per share and costs of the Private Placement and Listing of approximately EUR 3.4 million). The gross proceeds from the Private Placement amount to EUR 50.0 million.
- (2) Cash and short-term deposits with a term to maturity of 3 months or less from inception from the Group's unaudited management accounts as at 31 July 2024.
- (3) Other current financial assets consists of short-term deposits with a term to maturity of more than 3 months from inception from the Group's unaudited management accounts as at 31 July 2024 and a cash deposit in the amount of EUR 297 thousand at free disposal to the Company that serves as a bank guarantee for the lease of the office in Switzerland, as derived from the Group's unaudited management accounts as at 31 July 2024.
- (4) The current financial debt from the Group's unaudited management accounts as at 31 July 2024 comprises the short-term portion of lease liabilities and represents amounts payable to the landlord of the office building in the Switzerland and the Netherlands as well as EUR 1,359 thousand repayable under the EISMEA grant.
- (5) The non-current financial debt from the Group's unaudited management accounts as at 31 July 2024 represents amounts payable to Runway relating to the Runway Loan, the long-term portion of lease liabilities and the post-employment benefits from the Swiss Pension Plan. Substantially all of the Group's assets have been pledged to Runway to secure the Runway Loan.

As of 31 July 2024, the Company has no indirect indebtedness.

As of 31 July 2024, the Company has the following contingent indebtedness:

Guarantees

The Group has provided a guarantee to Wincasa for EUR 297 thousand and EUR 8 thousand to SPACES as collateral for the lease of the office spaces.

Royalties

The Group has entered into 3 license agreements with EPFL (École polytechnique fédérale de Lausanne) which include certain payment obligations in the form of royalties or milestone payments in case the Company is able to generate revenues or achieve certain milestone events in the future

for products directly linked to these licenses. The royalty scheme with EPFL is based on net sales. To date no royalties have been paid as there is no product generating revenue.

On 27 September 2019 Neurorecovery Technologies Inc. (now ONWARD Medical Inc.) entered into a license agreement with the Regents of the University of California acting through Technology Development Group UCLA campus granting an exclusive license on certain patents in certain fields of neuromodulation and spinal cord stimulation and a non-exclusive license on certain other patent rights. Various revenue milestone payments are due under the exclusive license and fixed royalty payments are due under the nonexclusive license. The agreement contains various milestone and diligence obligations ranging from USD 10 thousand to USD 50 thousand payable upon entering a phase III clinical trial, regulatory approval and/or first commercial sale. To date, one milestone has occurred (UP-LIFT clinical trial) and a corresponding payment of USD 10 thousand was made in 2023.

On 8 October 2019 Neurorecovery Technologies Inc. (now ONWARD Medical Inc.) entered into a license agreement with Caltech (California Institute of Technology), the latter on behalf of various intellectual property owners, including UCLA (University of California), University of Louisville, DEI and USC, granting an exclusive license on certain technology in certain fields of epidural and transcutaneous neuromodulation and a non-exclusive license of certain other intellectual property. Various revenue milestone payments, diligence obligations and fixed royalty payments are due under the license. These payments range from USD 20 thousand to USD 75 thousand payable upon FDA approval, CE Mark and/or first commercial sale. To date no payments are due as none of the requirements have been met.

Please also refer to "*License Agreements with EPFL, NeuroRestore and other Parties*".

Working capital statement

On the date of this Prospectus, the Group is of the opinion that it has sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months following the date of this Prospectus.

SELECTED FINANCIAL INFORMATION

This Selected Financial Information is based on the Interim Condensed Consolidated Financial Statements and the Consolidated Financial Statements. For a discussion of the presentation of the Group's historical financial information included in this Prospectus, see "Important Information—Presentation of financial and other Information".

The Group's future results could differ materially from those discussed below. Factors that could cause or contribute to such differences include, without limitation, those discussed in particular in the sections entitled "Risk Factors" and "Business" and elsewhere in this Prospectus. See "Important Information—Forward-Looking Statements" for a discussion of the risks and uncertainties related to those statements.

Consolidated Statement of Profit and Loss

(In EUR 000)	Unaudited		Audited	
	For the six-month-period ended 30 June		For the year ended 31 December	
	2024	2023	2023	2022
Grants and Other Income	208	928	532	2,148
Total Revenues & Other Income	208	928	532	2,148
Research & Development Expenses	(6,134)	(7,638)	(13,841)	(13,138)
Clinical & Regulatory Expenses	(2,689)	(2,177)	(4,911)	(5,747)
Marketing & Market Access Expenses	(1,387)	(1,568)	(2,943)	(1,951)
Patent fees & Related Expenses	(547)	(950)	(1,509)	(1,549)
Quality Assurance Expenses	(1,052)	(799)	(1,464)	(1,228)
General & Administrative Expenses	(7,148)	(6,576)	(11,327)	(10,563)
Total Operating Expenses	(18,957)	(19,708)	(35,995)	(34,176)
Operating Loss for the Period	(18,749)	(18,780)	(35,463)	(32,028)
Financial income	–	–	972	62
Financial expense	179	(457)	(1,583)	(1,572)
Net Finance Expense	179	(457)	(611)	(1,510)
Loss for the Period before Taxes	(18,570)	(19,237)	(36,074)	(33,538)
Income Tax expense	318	(45)	(107)	766
Net Loss for the Period	(18,252)	(19,282)	(36,181)	(32,772)
Attributable to:				
Equity holders of the parent	(18,252)	(19,282)	(36,181)	(32,772)
Non-controlling interests	–	–	–	–
	(18,252)	(19,282)	(36,181)	(32,772)
Earnings Per Share (EUR):				
Basic earnings per ordinary share attributable to shareholders:	(0.53)	(0.64)	(1.20)	(1.09)
Diluted earnings per ordinary share attributable to shareholders:	(0.53)	(0.64)	(1.20)	(1.09)

Consolidated Statement of Comprehensive Income

(In EUR 000)	Unaudited		Audited	
	For the six-month-period ended 30 June		For the year ended 31 December	
	2024	2023	2023	2022
Net Loss for the Period	(18,252)	(19,282)	(36,181)	(32,772)
Remeasurement of post-employment benefits			(928)	427
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods (net of tax)	–	–	(928)	427
Currency translation differences	(606)	(250)	(155)	602
Other comprehensive income that will be reclassified to profit or loss in subsequent periods (net of tax)	(606)	(250)	(155)	602
Total Comprehensive Result for the Year, Net of Tax	(18,858)	(19,532)	(37,264)	(31,743)
Attributable to:				
Equity holders of the parent	(18,858)	(19,532)	(37,264)	(31,743)
Non-controlling interests	–	–	–	–
	(18,858)	(19,532)	(37,264)	(31,743)

Consolidated Statement of Financial Position

(In EUR 000)	Unaudited	Audited	
	As at 30 June	As at 31 December	
	2024	2023	2022
ASSETS			
Non-Current Assets			
Intangible assets	10,130	9,804	10,158
Property, plant & equipment	470	609	415
Right of use assets	1,162	1,483	1,681
Deferred tax assets	310	310	163
	12,072	12,206	12,417
Current Assets			
Indirect tax receivables	101	117	709
Receivable from related parties	34	37	251
Other current assets	2,594	1,501	1,456
Fixed term deposits	7,500	–	20,000
Cash and cash equivalents	24,553	29,768	41,760
	34,782	31,423	64,176
	46,854	43,629	76,593
EQUITY AND LIABILITIES			

Equity and Reserves			
Issued capital	4,155	3,622	3,622
Share premium	172,662	155,249	155,249
Other reserves *	4,616	4,488	2,079
Retained earnings	(163,085)	(145,428)	(108,319)
Total equity attributable to shareholders	18,348	17,931	52,631
Non-Current Liabilities			
Interest-bearing loans	16,022 ⁽²⁾	15,255	12,656
Deferred tax liability	195	631	670
Lease liability ⁽¹⁾	743	1,051	1,294
Post-employment benefits	2,006	2,081	1,121
	18,966	19,018	15,741
Current Liabilities			
Income tax liabilities	157	221	219
Lease liability ⁽¹⁾	549	568	427
Trade payables	3,312	1,369	1,909
Other payables	5,522	4,522	5,666
	9,540	6,680	8,221
	46,854	43,629	76,593

* Other reserves include the foreign currency translation reserve that qualifies as a legal reserve under Dutch Law.

- (1) The incremental borrowing rate applied is 4% for the Lausanne office and is 7.4% for the Eindhoven office. On 1 November 2022 the Group entered into a short-term office lease for 12 months for which the Group has elected not to recognize a right-of-use asset and lease liability. Amount recognized in relation to this short-term lease amounted to EUR 8.8 thousand.
- (2) This does not include the Runway Loan as the conditions precedent for the recognition of the Runway Loan included the repayment of the existing Innovation Loan from the RVO which did not occur in the six-month period ended 30 June 2024. The existing securities and pledges were contingent upon this repayment, and their release was necessary to secure and pledge assets to the new lender. The funds required for the repayment of the existing (RVO) loan, representing the first tranche, were received on 2 July 2024, at which point the conditions for the recognition of the Runway Loan were satisfied. The RVO loan was repaid on 2 July 2024.

Consolidated Statement of Changes in Equity

	Audited				
	Issued capital	Share premium	Other reserves*	Retained earnings	Total equity
<i>(In EUR 000)</i>					
At 1 January 2022	3,622	155,249	(214)	(75,974)	82,683
Loss for the year 2022	–	–	–	(32,772)	(32,772)
Other comprehensive income	–	–	602	427	1,029
<i>Total comprehensive result</i>	–	–	602	(32,345)	(31,743)
Share based payments: LTIP	–	–	1,691	–	1,691
At 31 December 2022	3,622	155,249	2,079	(108,319)	52,631

* Other reserves include the foreign currency translation reserve that qualifies as a legal reserve under Dutch Law.

	Audited				
	Issued capital	Share premium	Other reserves*	Retained earnings	Total equity
<i>(In EUR 000)</i>					
At 1 January 2023	3,622	155,249	2,079	(108,319)	52,631
Loss for the year 2023	–	–	–	(36,181)	(36,181)
Other comprehensive income	–	–	(155)	(928)	(1,083)

<i>Total comprehensive result</i>	–	–	(155)	(37,109)	(37,264)
Share based payments: LTIP	–	–	2,564	–	2,564
At 31 December 2023	3,622	155,249	4,488	(145,428)	17,931

* Other reserves include the foreign currency translation reserve that qualifies as a legal reserve under Dutch Law.

<i>(In EUR 000)</i>	Unaudited				
	Issued capital	Share premium	Other reserves*	Retained earnings	Total equity
At 1 January 2023	3,622	155,249	2,079	(108,319)	52,631
Loss for the period	–	–	–	(19,282)	(19,282)
Other comprehensive income	–	–	(250)	–	(250)
<i>Total comprehensive result</i>	–	–	(250)	(19,282)	(19,532)
Share based payments: LTIP	–	–	1,171	–	1,171
At 30 June 2023	3,622	155,249	3,000	(127,601)	34,270

* Other reserves include the foreign currency translation reserve that qualifies as a legal reserve under Dutch Law.

<i>(In EUR 000)</i>	Unaudited				
	Issued capital	Share premium	Other reserves*	Retained earnings	Total equity
At 1 January 2024	3,622	155,249	4,488	(145,428)	17,931
Loss for the period	–	–	–	(18,252)	(18,252)
Other comprehensive income	–	–	(606)	–	(606)
<i>Total comprehensive result</i>	–	–	(606)	(18,252)	(18,858)
Issue of shares	533	19,467	–	–	20,000
Issue of shares – closing costs	–	(2,054)	–	–	(2,054)
Share based payments: LTIP	–	–	734	595	1,329
At 30 June 2024	4,155	172,662	4,616	(163,085)	18,348

* Other reserves include the foreign currency translation reserve that qualifies as a legal reserve under Dutch Law.

Consolidated Statement of Cash Flows

<i>(In EUR 000)</i>	Unaudited		Audited	
	For the six-month-period ended 30 June		For the year ended 31 December	
	2024	2023	2023	2022
Cash flows from operating activities				
Loss for the period before taxes	(18,570)	(19,237)	(36,074)	(33,538)
Adjusted for:				
Depreciation and impairment of property, plant and equipment and right-of-use assets	434	329	726	735
Share based payment transaction expense	1,329	1,171	2,564	1,691

Post-employment benefits	–	22	76	154
Net finance costs	(179)	404	611	1,510
Net foreign exchange differences	–	–	–	–
Other non-cash items	(54)	61	197	106
Changes in working capital:				
Increase (-) Decrease (+) in Trade and other receivables	(828)	(566)	491	140
Increase (+) Decrease (-) in Trade and other payables	3,104	(713)	(1,654)	2,813
Interests received	194	237	916	15
Interests paid	–	–	–	(229)
Income tax paid	(225)	(91)	(106)	(49)
Bank Charges paid	(10)	(9)	(17)	(33)
Net cash generated/(used) from operating activities	(14,805)	(18,391)	(32,270)	(26,685)
Cash flows from investing activities				
Investments in fixed assets	(24)	(287)	(422)	(386)
Investments in intangible fixed assets	–	(16)	–	(31)
Investment in fixed term deposits	(7,500)	(5,000)	–	(20,000)
Withdrawal of term deposits	–	–	20,000	–
Net cash generated/(used) from investing activities	(7,524)	(5,303)	19,578	(20,417)
Cash flows from financing activities				
Proceeds from interest-bearing loans	– ⁽¹⁾	1,037	1,292	–
Payment of principal portion of lease liabilities	(304)	(263)	(479)	(557)
Proceeds from issuance of shares	20,000	–	–	–
Transaction costs on issuance of shares	(2,054)	–	–	–
Net cash generated/(used) from financing activities	17,642	775	813	(557)
Movement in cash and cash equivalents				
Cash and cash equivalents at 1 January	29,768	41,760	41,760	89,443
Effect of exchange rates on cash and cash equivalents	(528)	52	(113)	(24)
Changes in cash and cash equivalents during the period	(4,687)	(22,920)	(11,879)	(47,659)
Cash and cash equivalents at end of period	24,553	18,788	29,768	41,760

(1) This does not include any proceeds under the Runway Loan.

BUSINESS

Overview

The Company is a medical technology company developing innovative therapies to enable people with spinal cord injury ("SCI") to regain movement and other bodily functions. The Company develops and plans to commercialize therapies that address major challenges faced by people with SCI, leveraging the Company's two proprietary implantable ("ARC^{IM}") and external ("ARC^{EX}") platforms to address a broad spectrum of challenges that result from movement disabilities.

The Company's technology and products are protected by a strong and growing portfolio of intellectual property rights. In the course of the first three quarters of 2024, the Company added several new patents, bringing the Company's total number of issued patents to 278 as of the date of this Prospectus (including EP validations) .

The Case for Innovative Therapies

Seven million people worldwide have an SCI, and the annual global incidence of new injuries exceeds 768,000.² In the US and Europe alone, approximately 654,000 people live with SCI (prevalence), and the annual number of new cases (incidence) is about 50,000 (31,800 in Europe³ and 18,000 in the US⁴).

SCI results not only in disability, decreased quality of life and poor health for individuals, but also in significant costs for economies due to lost productivity and high healthcare costs. The average lifetime cost to support a person with a severe SCI can exceed USD 5.0 million⁵. Injuries to the spinal cord occur primarily as a result of automobile accidents and falls, and disproportionately affect young men.



² 2020 NSCISC Annual Statistical Report Complete Public Version

³ Kumar et al. 2018, "Traumatic Spinal Injury: Global Epidemiology and Worldwide Volume", World Neurosurg., vol. 113, pp. e345-e363, May 2018, doi: 10.1016/j.wneu.2018.02.033.

⁴ National Spinal Cord Injury Statistical Center, Facts and Figures at a Glance. Birmingham, AL: University of Alabama at Birmingham, 2019.

⁵ Kumar et al. 2018. Traumatic Spinal Injury: Global Epidemiology and Worldwide Volume (traumatic spinal injury may be broader than traumatic spinal cord injury).

Damage to the spinal cord resulting in loss of function

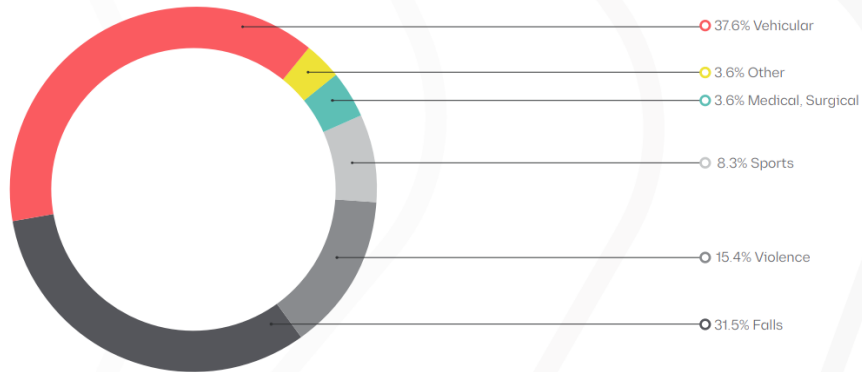
SCI Causes & Patient Profile

Profile of SCI Patient

- Nearly half of the injuries occur between the ages of 16 and 30 years¹
- 79% of new SCI cases are male²

Currently, the neuromodulation market is comprised primarily of revenues from spinal cord stimulation for pain management and deep brain stimulation for Parkinson's disease, essential tremor, dystonia, and epilepsy. The market is forecast to reach USD 14.8B by 2030 and is expected to grow to exhibit a CAGR of 12.2% over the same period³.

SCI Causes



¹2022 NSCISC Annual Statistical Report Complete Public Version
²NSCISC Traumatic Spinal Cord Injury Facts and Figures at a Glance (2023 SCI Data Sheet)
³Global News Wire - Vantage Market Research (November 2023)

Current pipeline indications and potential pipeline opportunities

Total Addressable Market

	Indication	Injury severity / level	US & EU eligible population ¹	Total addressable market ²
Current roadmap				
	Upper Limb	AIS B-D / lesion C2 - C8	199,000* 34% of SCI cases ³	\$6.0B
	Blood Pressure	AIS A-D / lesion C3 - T6	215,000 37% of SCI cases ³	\$7.3B
	Walking & Standing	AIS B-D / lesion C3 - T10	222,000 38% of SCI cases ³	\$7.6B
Potential future indications				
		Potential future indications ³	~3,845,000** Prevalence	~\$120B
			>4,000,000**	>\$140B

* Primarily driven by home use opportunity (vs. clinic use)
² Patients may benefit from more than one therapy (e.g. Blood Pressure and Upper Limb function)
³ Company data, epidemiology data from 2022 NSCISC Annual Statistical Report Complete Public Version
⁴ Assumes pricing in alignment with value in comparison to existing rehabilitation therapies
⁵ Includes a selection of potential future indications for ARC^{EX} (Bladder, Stroke Mobility and Stroke Upper Limb), ARC^{LM} (Bladder, Cervical and Parkinson's Mobility) and ARC^{BCI} (Mobility and Cervical)

Currently, the neuromodulation market is comprised primarily of revenues from spinal cord stimulation for pain management and deep brain stimulation for Parkinson's disease, essential tremor, dystonia and epilepsy. The market is forecast to reach USD 14.8 billion by 2030 and is expected to grow to exhibit a CAGR of 12.2% from 2023 to 2030.⁶

The Company is pioneering a new segment within neuromodulation, by stimulating the spinal cord to restore mobility and autonomic functions in people with SCI and also those with Parkinson's disease.

The Company's Strategy

The Company's objective is to build an enduring, impactful, and successful medical device company that creates sustainable long-term value and makes a meaningful difference in the lives of people with SCI, and their loved ones.

The Company is focusing on the following priorities as it pursues this objective:

⁶ Vantage Market Research, "Neuromodulation Market Size, Share & Trends Analysis Report by 2030".

- Short term (2024): Commercially launch the external platform (ARC^{EX}), starting with strength and function of the hands and arms as its first indication in the US and begin its Empower BP pivotal trial to evaluate implantable ARC^{IM} Therapy for regulating blood pressure after SCI
- Medium term (2026): Commercially launch the implantable platform (ARC^{IM}), starting with improved blood pressure regulation as its first indication
- Long term (2026+): Further expand labeling (new indications and populations) and platforms

To execute on its strategy:

- The Company works with leading neuroscience researchers across the globe to identify breakthrough therapies for people with SCI and other movement-related disorders, for which its therapies have shown promise.
- The Company leverages on its R&D, clinical and regulatory capabilities to develop proprietary technologies that are well suited to deliver breakthrough therapies at scale, and it protects these innovations via rigorous IP prosecution.
- The Company plans to commercialize these breakthrough therapies in its target markets, using a direct channel to SCI clinics with rehabilitation programs and hospitals with neurosurgery expertise.

ONWARD ARC Therapy

ARC Therapy applies targeted, programmed stimulation of the spinal cord to restore movement, independence, and health in people with SCI. The stimulation can be delivered by an implantable platform, ARC^{IM}, or an external, transcutaneous platform, ARC^{EX}. Both platforms have been awarded FDA Breakthrough Device Designation for a range of indications and both platforms contain the same basic elements: an electrical impulse generator, electrodes placed in proximity to the spinal cord, and a programmer that enables clinicians to set stimulation therapy parameters and users to control therapy.

By delivering precisely timed and calibrated electrical impulses to specific areas of the spinal cord, ARC Therapy mimics the natural pattern of nerve signals sent by the brain. When combined with voluntary efforts to move, this enables users to improve motor control in the arms, legs, or trunk, making daily activities, like moving in and out of a wheelchair, much easier. Moreover, programmed neurostimulation has the potential to improve the management of internal functions, chiefly regulation of blood pressure and bowel and bladder control.

ARC^{IM} platform

ARC^{IM} has four components (Fig 1 below):⁷

- A **Lead** implanted near the spinal cord in the area corresponding to the movement or function being targeted by the therapy. ONWARD is currently developing a family of leads that are optimized for precise placement in different areas of the spinal cord, both in terms of their shape and the configuration of the electrodes.
- A **Neurostimulator** implanted under the skin and connected to the lead through a wire. When switched on, this device delivers precisely sequenced and calibrated bursts of electricity to specific electrodes in the lead.
- An **external Hub** that connects wirelessly to the IPG to turn therapy on or off, set or update the frequency and intensity of the impulses, recharge the device, and integrate external sensors via wireless connections and sensor-specific algorithms. The hub is worn on a belt around the waist.

⁷ The smartwatch in the graphic may be a smartphone once development has been completed

- **Dedicated apps for efficiency and ease of use:** Apps are available for both clinicians and users of ARC Therapy. Clinicians use the professional app to create and adjust stimulation programs using a tablet connected wirelessly to the Hub and the user employs the personal app to control their therapy within clinician-prescribed programming parameters. The personal app is expected to be deployed on a mobile phone or smartwatch and enabled by voice commands as well.



Note: The renderings in the above graphic are illustrative; the design of commercial products may differ.

ARC IM is currently targeted toward improving lower limb mobility and regulating blood pressure after SCI. Other potential indications may be explored in the future, including SCI-related bladder control, spasticity reduction, improved sexual function, and upper limb mobility, each enabled by further development of the ONWARD proprietary lead portfolio.

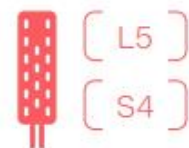
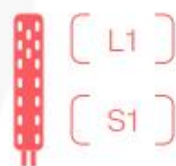
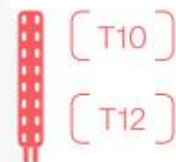
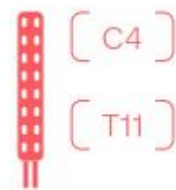


Arm & Hand Function

Blood Pressure & Trunk Control

Mobility (Walking & Standing)

Bladder & Bowel Control,
Sexual Function



ARC^{EX} is designed to improve strength and function of the upper limbs. It is built for use both during typical chronic phase SCI rehabilitation in the clinic and at home. In the future, ARC^{EX} may be used to target additional indications, such as bowel control and lower limb strength and function.

ARC^{EX} has three main components:

- A **Stimulator** that delivers programmed electrical impulses through the skin to the spinal cord.
- **Electrodes** placed externally on the skin of the neck near the area of the spinal cord that controls movement in the arms and hands.
- **Dedicated apps for efficiency and ease of use: ARC^{EX} PRO app**, which connects wirelessly to the Stimulator to program the therapy and adjust parameters and the **myARC^{EX} app** for users to easily control the stimulation during personal use in the home setting.

External system for non-invasive, programmed stimulation of the spinal cord

ARC^{EX} Therapy
 Programmed transcutaneous electrical stimulation to the spinal cord
 Designed to restore movement, function, and independence in people with SCI

ARC^{EX} Stimulator

ARC^{EX} External Platform

ARC^{EX} PRO & myARC^{EX} app
 via ARC^{EX} Programmer

ARC^{EX} Therapy
 Individual stimulation parameters can be optimized for each patient's unique needs

Research and Development

The Company's engineering team made advancements across several development initiatives in 2023 and the first half of 2024:

- ARC^{EX} system development: Design and all testing activities have been completed and de novo application for the product has been submitted to the FDA for marketing clearance in the US. Work continued to transfer the design to manufacturing, with all materials for first production now secured. Low rate initial, pilot production of the stimulator portion of the system has begun and the processes for customer fulfillment are under construction.
- ARC^{IM} lead development: The ARC^{IM} thoracic lead development, design verification, and validation have all been completed. The lead has been in the field for more than one year and there have been no additional risk elements identified. With manufacturing phases concluded in May 2024, clinical use capability will be available in the near term and will be part of near-term submissions in support of current study updates as well as new feasibility and pivotal trials. The development phase for the ARC^{IM} lumbar lead has also been completed, with manufacturing set-up tasks remaining. No new risks have been identified.
- ARC^{IM} platform: ARC^{IM} implantable pulse generator (IPG) manufacturing updates and refinements continue. Manufacturing ramp-up for clinical trial quantities is underway in anticipation of clinical trial needs.

In August 2023, the first ever in-human implantation of an ARC^{BCI} system was successfully carried out by a neurosurgeon at CHUV in Lausanne, Switzerland. Working in concert with the ARC^{IM} stimulator the BCI is engineered to capture the intention of a paralyzed individual to move their upper extremities and uses artificial intelligence to decode those thoughts. Post-rehabilitation assessments were completed in March 2024. The participant is now in the home-use phase, with remote monitoring by the study team. Initial results indicate significant improvements in clinical assessments, particularly in motor function. The BCI has also enabled previously impossible or severely limited joint movements, such as elbow extension and grasping. Additionally, the Company and its collaborators have secured a USD 1.1 million grant towards the clinical trial focusing on restoring hand and arm function with the ARC^{BCI} system from the Christopher and Dana Reeve Foundation. The Company will utilize this US-based funding to increase the number of participants in the clinical trial. In August 2024, the Company and a group of international collaborators received an initial commitment from the European Innovation Council (EIC) to provide EUR 3.0 million for a project evaluating the ARC^{BCI} system for restoration of hand and arm function after subcortical stroke. The Company is currently negotiating with the European Innovation Council (EIC) and the funding is likely to materialize starting in early 2025. The Swiss collaborators in this group are also working to establish additional funding with a Swiss-based funding agency to bring the total funding for this project to EUR 6.0 million. This project will capitalize on the knowledge and work done in the Company's project focused on SCI, and further research and development done in the subcortical stroke project will be transferrable to the ARC^{BCI} system in its use for SCI symptoms. In September 2024, an in-human implantation of an ARC^{BCI} system to restore lower limb mobility after SCI was successfully carried out by a neurosurgeon at CHUV in Lausanne, Switzerland.

Clinical Trials

ONWARD's clinical and regulatory team had a productive 2023 and 2024 so far, filling the indication pipeline and advancing the core ARC^{EX} and ARC^{IM} therapies forward toward market approval for the SCI population. With completion of the Up-LIFT study as well as initiation of work necessary for the ARC^{IM} pivotal study, the team is poised to deliver on several major clinical and regulatory initiatives in late 2024 or early 2025, such as the IDE submission and approval for the EmpowerBP pivotal trial, first patient enrolment in the trial and preparatory activities for the ARC^{EX} / Upper limb CE Mark submission.

On 11 March 2024, the Company has been accepted into the FDA's Total Product Lifecycle Advisory Program for its BCI technology. The Company is only the second BCI company to be accepted into the program. The program provides the Company with early and frequent strategic engagement from the FDA, patients, providers, and payers to facilitate more rapid development and widespread patient access to safe, effective, high-quality medical devices of public health importance. As part of the

program the Company benefits from more timely premarket interactions, earlier identification and mitigation of device development risk, and a more efficient premarket review process.

On 2 April 2024, following the global pivotal Up-LIFT study, the Company submitted its de novo application to the FDA to allow marketing of its ARC^{EX} system to restore function of the upper extremities after SCI. Once cleared by the FDA, ARC^{EX} will be the first-ever spinal cord stimulation therapy to restore hand and arm function after SCI and the first commercial product for the Company. The Company expects clearance and the first commercial sale in the US sometime in the fourth quarter of 2024.

The Company announced four new Breakthrough Device Designations (BDD) from the US Food and Drug Administration (FDA) in the first half of 2023 and one additional BDD on 29 February 2024. These include BDDs for the use of its ARC^{EX} platform for bladder control (awarded late 2022), alleviation of spasticity, and blood pressure regulation in people with SCI. In addition, the Company received an additional BDD for its ARC^{IM} platform for spasticity in people with SCI as well as for its ARC^{BCI} system. The Company now has a total of ten BDDs, which affords it priority FDA review and the opportunity to interact with FDA experts throughout the premarket review phase as the technology moves toward commercialization.

Clinical Trials of ARC^{EX} Therapy

In 2022, the Company completed the Up-LIFT study, the first large-scale pivotal trial of non-invasive spinal cord stimulation technology. It enrolled 65 subjects at 14 leading SCI research sites throughout the United States, Canada, the United Kingdom, and the Netherlands. The Up-LIFT study is a prospective, single-arm study designed to evaluate the safety and effectiveness of non-invasive electrical spinal cord stimulation to treat upper extremity functional deficits in people with chronic tetraplegia.

Positive topline results from the Up-LIFT study were announced on 13 September 2022, showing that the study had met its primary effectiveness endpoint with no reported serious device-related adverse events, as adjudicated by an independent Data Safety Monitoring Board (DSMB). Detailed results will be made available following review by FDA.

In October 2022, the Company announced the successful completion of the LIFT Home study, designed to assess the safety and performance of ARC^{EX} Therapy when used in a home setting. The study enrolled 17 subjects at five leading centers in the US who continued treatment at home subsequent to the Up-LIFT study. Observational data demonstrated that the use of ARC^{EX} system at home resulted in no reported serious adverse events. Participants performed training on activities of daily living three times per week over a one-month period with approximately 97% of these treatment sessions completed, without usability issues, supporting the feasibility of home-based therapy.

On 20 May 2024, *Nature Medicine* published global Up-LIFT pivotal trial results. The study achieved all primary safety and effectiveness endpoints, and ARC^{EX} Therapy demonstrated significant improvements in upper limb strength, function, and sensation among people with chronic tetraplegia due to cervical SCI. At the end of the trial, 72% of trial participants were considered responders to non-invasive ARC^{EX} Therapy based on a conservative definition requiring responders to meet improvement criteria in both strength and functional domains vs. standard of care rehabilitation alone. Notably, the number of responders increased to 90% when the definition included participants with improvements in at least one strength or functional outcome. Study participants also reported reduced spasm frequency, improved sleep, and improved upper body sensation, including the sense of touch. 87% of participants reported that ARC^{EX} Therapy delivered improvement in overall quality of life. Self-care, a key component of independence after SCI, also improved significantly.

On 9 July 2024, the Company announced a publication in *Neuromodulation: Technology at the Neural Interface*, providing an evidenced-based framework to determine stimulation parameters for ARC^{EX} Therapy based on analysis of device parameters, usage data, and clinician and participant feedback from the Up-LIFT pivotal trial and follow-on LIFT home study.

Clinical Trials of ARC^{IM} Therapy

In May 2023, the Company announced its ARC Therapy was paired with an investigational implanted wireless BCI, resulting in an individual gaining thought-driven, augmented control over when and how he moved his paralyzed legs. This breakthrough was published in the journal *Nature* and highlighted in major media outlets around the globe. In April, the *New England Journal of Medicine* highlighted the use of the Company'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.

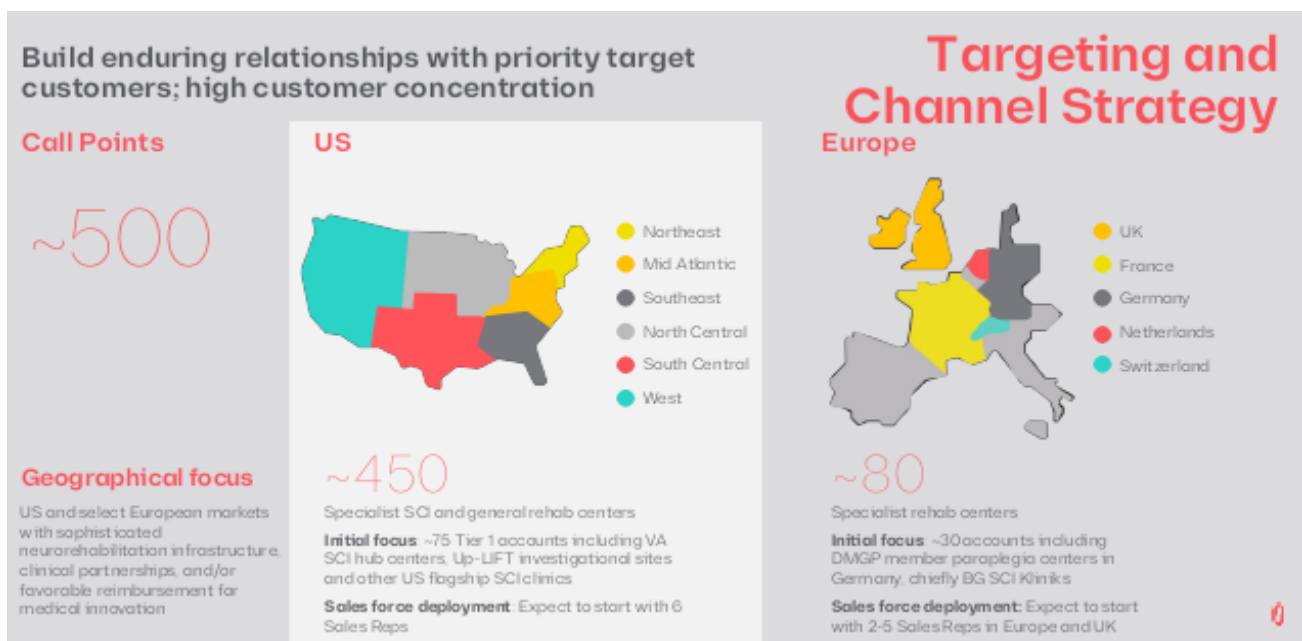
Also in May 2023, the Company announced the successful first-in-human use of its investigational ARC^{IM} Lead to deliver targeted electrical pulses to the spinal cord. The ARC^{IM} Lead is a key component of the ONWARD ARC^{IM} system, engineered to address multiple indications by precisely delivering ARC Therapy to the point in the spine responsible for a specific function. The ARC^{IM} Lead is designed to be used with the ARC^{IM} Neurostimulator (IPG) and is purpose-built for placement along the spinal cord to restore movement and function in people with SCI.

On 14 January 2024, the Company announced the start of the HemON NL clinical study. Building on the previous Swiss HemON clinical feasibility study, the HemON NL clinical study prepares the Company for the global pivotal trial EMPOWER BP, which is designed to provide the evidence necessary to submit a PMA to the FDA and other global regulatory authorities. The study aims to assess the safety and effectiveness of ARC Therapy based on ARC^{IM} to address hemodynamic instability after SCI.

The Company has had a highly productive year 2023 and 2024 so far, preparing for several key submissions with the FDA and EU-MDR in 2024 and beyond. The Company made clear progress in finalizing the study design and gearing up for study start of EMPOWER BP, the pivotal clinical trial investigating the effect of ARC^{IM} Therapy on hemodynamic instability following SCI.

Commercialization

The Company does not currently offer any products for commercial sale. The Company submitted a de novo application to the FDA for its ARC^{EX} system on 2 April 2024, with expected clearance sometime in the fourth quarter of 2024 and is pursuing clearance in selected European markets thereafter. The Company's pivotal trial for ARC^{IM} system, Empower BP, is expected to start in the fourth quarter of 2024 or the first quarter of 2025 and will focus on the safety and effectiveness of ARC^{IM} Therapy for regulating blood pressure to achieve hemodynamic stability in patients after SCI. The plans to commercialize its products depend on the Company's ability to demonstrate their safety and effectiveness to regulatory authorities.



Geographical focus, commercial objectives and marketing strategies

The Company plans to market ARC Therapy platforms in the US and Europe, where most people with SCI are cared for by a limited number of trauma and rehabilitation centers. When people suffer an SCI, they typically undergo emergency surgery in a trauma center, after which they spend one week in intensive care. Thereafter, they begin acute phase rehabilitation training, which is generally provided by specialized clinics with the necessary expertise and equipment and lasts three to twelve months. One year post-injury, people with SCI are considered to be in the chronic phase, where many insurance companies cover a limited amount of continued outpatient therapy for the purpose of maintaining functional gains or as the patient encounters complications.

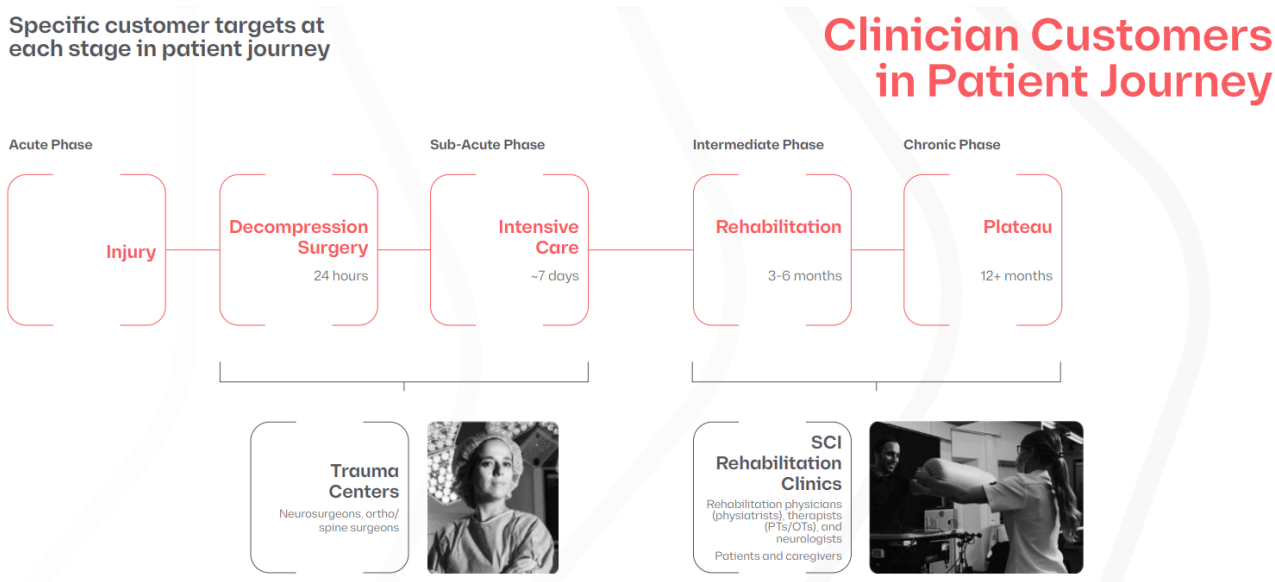
Based on market research as well as outcomes from its pilot studies with both ARC^{IM} and ARC^{EX} as well as its Up-LIFT pivotal study with ARC^{EX}, the Company believes that people with SCI may benefit from ARC Therapy even when applied many years after their injury. Given these promising outcomes and ongoing demand for innovative therapies in the rehabilitation space, it is likely that there is considerable demand that can be realized when the Company commercializes its first product, ARC^{EX}. In fact, those with chronic SCI may reinstate rehabilitation in response to the availability of these new therapies.

In the initial period following commercial launch, the focus will be on the US and five select European markets: Germany, France, the UK, the Netherlands, and Switzerland. These markets were selected based on the sophistication of their rehabilitation and/or reimbursement infrastructure as well as current ONWARD clinical partnerships and awareness of our investigational therapies. The Company may modify target markets or change the cadence of the markets to optimize likelihood of commercial success based on evolving drivers of regulatory approval and reimbursement for new medical technologies.

The Company plans to deploy a direct sales and service organization, as the total number of facilities to be targeted — whether to market its therapies or to support surgical interventions — is around 500. As FDA clearance or approval or CE marking supports entry into non-target European or Asian markets, the Company will likely do so via a distribution partner.

The Company will continue to evolve its commercial strategy to optimize the Company's probability of success.

Specific customer targets at each stage in patient journey



Rehabilitation clinics

The Company's marketing efforts will focus on clinicians managing SCI patients in specialty rehabilitation clinics. These include rehabilitation physicians such as physical medicine and rehabilitation physicians – also called physiatrists – as well as physical therapists and occupational

therapists who provide post-injury rehabilitation training and ongoing support to those who are chronically injured. The latter constitutes the largest pool of SCI patients globally.

The Company expects clinicians to use our therapies as follows:

- Apply ARC Therapy using ARC^{EX} in clinics
- Prescribe ARC^{EX} for use at home
- Refer patients to functional neurosurgeons and orthopedic spine surgeons for implantation of ARC^{IM}

There are a limited number of specialty rehabilitation clinics in the US and Europe. In the US, there are approximately 450 specialist SCI and general rehabilitation centers. The Company's initial focus will be on approximately 75 Tier 1 accounts including Veterans Affairs SCI hub centers, Up-LIFT investigational sites, and other US flagship SCI clinics. These clinics will provide a robust referral base for the Company's products and will serve as focused and fertile marketing targets. In four of the five selected European markets, there are a total of 83 SCI specialty rehabilitation centers: 27 in Germany⁸, 10 in the UK⁹, 8 in the Netherlands¹⁰, and 38 in France.¹¹

Hospitals and ambulatory surgery centers

When patients are referred for an implant of ARC^{IM}, surgery is typically carried out in hospitals or ambulatory surgery centers by neurosurgeons or orthopedic surgeons focused on the spine. These neurosurgeons are already familiar with device therapy and neuromodulation and routinely perform implants for deep brain stimulation and spinal cord stimulation for pain therapy. Primary targets will include those hospitals and ambulatory surgery centers with established neuromodulation referral pathways from physiatrists, as well as integrated SCI systems with multi-disciplinary approaches to caring for acute and chronic stages of SCI.

US Reimbursement landscape – in general

In both US and non-US markets, the Company's ability to successfully commercialize and achieve market acceptance of its products depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including governmental payors, managed care organizations, and private health insurers. Third-party payors decide which treatments they will cover and establish reimbursement rates for those treatments, and they increasingly examine the cost effectiveness of medical devices as well as safety and efficacy when making coverage and payment decisions.

Given that no uniform policy for coverage and payment exists across the Company's target markets, or even within some markets, and reimbursement can differ significantly from payor to payor, commercialization efforts to identify optimized pathways for reimbursement, coverage, and payment started in 2022 and will continue throughout 2024.

MCIT repeal and TCET pathway

In November 2021, the Centers for Medicare and Medicare Services (CMS) rescinded the Medicare Coverage of Innovative Technology (MCIT) final rule. This rule was originally proposed in September 2020 with the intent of ensuring Medicare coverage upon FDA clearance for devices which were awarded FDA Breakthrough Designation. Concerns regarding lack of controls to ensure Medicare populations were studied and lack of a mechanism to remove coverage if safety concerns arise were cited as reasons for repeal.

Despite the repeal, CMS reiterated its commitment in 2023 to create a pathway for coverage upon FDA clearance for Breakthrough Devices and is working with industry stakeholders, physician

⁸ Deutsche Behandlungszentren (dmgp.de).

⁹ Medical Management Advice: Royal National Orthopaedic Hospital (rnoh.nhs.uk).

¹⁰ PHM50279 93..95 (inisci.network).

¹¹ Nature Article: Rehabilitation of SCI in France, 148 rehab clinics, however 38 clinics treated six or more SCI in past year

societies, and patient groups to develop an alternate pathway called Transitional Coverage for Emerging Technologies (TCET). While this pathway is still under consideration, it could positively affect devices with Breakthrough Device Designations, such as ARC^{EX} and ARC^{IM}, by providing Medicare coverage from day one through a post-FDA clearance period. CMS presented the proposed rule in June 2023 and accepted comments on the proposal until 28 August 2023. TCET has still not been finalized.

Europe Reimbursement Landscape – in general

The path forward in Europe is more varied than in the United States. The Company is finalizing its in-depth reimbursement analysis of Germany, the largest of its target European markets, and continues to evaluate the other four target markets (the UK, France, the Netherlands, and Switzerland).

Based on its initial evaluation of the criteria for reimbursement of breakthrough medical technology as well as the sophistication of SCI rehabilitation infrastructure that will be further validated throughout 2024, the Company's most likely first European market for ARC^{EX} is Germany. All five markets are also viable ARC^{IM} targets, with plans to further undertake reimbursement planning in 2024.

Global Plans for ARC^{EX} Reimbursement

US

Upon FDA clearance of ARC^{EX} in the US, the Company plans to sell the devices to specialty rehabilitation clinics to be used in patient rehab sessions as well as directly to SCI patients for personal use in the home as prescribed by rehabilitation physicians.

The Company believes it will have rapid access to almost one-third of the covered lives in the US by targeting patients cared for by the Veterans Affairs (VA) healthcare system, those covered by workers' compensation insurance, and the estimated 10 – 15% patients with the means to self-pay for the ARC^{EX} system.

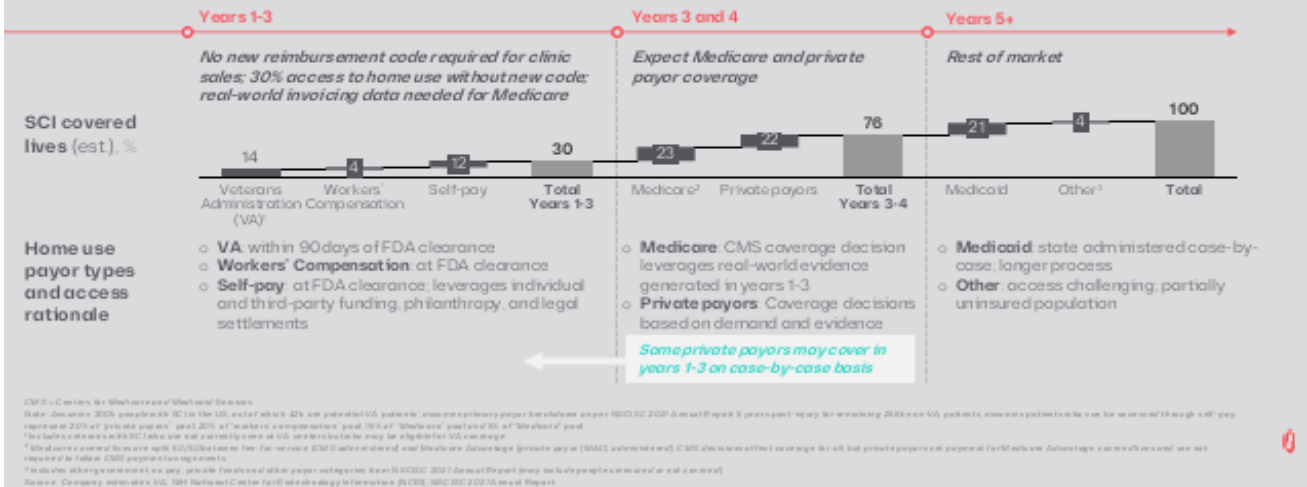
ARC^{EX} is designed as Durable Medical Equipment and will be categorized under a different set of codes called HCPCS. Given the novelty of ARC^{EX} and its potential to restore upper limb strength and function after SCI that was granted a Breakthrough Device Designation by the FDA, the Company plans to pursue a new HCPCS code for Medicare reimbursement. To support this, its clinical and economic evidence generation plan for ARC^{EX} in the US includes the necessary clinical and economic data collection to achieve optimized coverage and reimbursement reflective of the clinical benefit of the therapy in the US within 5 years. The Company plans to establish claims and invoicing history by focusing at launch with Veterans Affairs (VA) coverage, the world's largest healthcare system providing care to Veterans with an SCI.

The Company has partnered with Lovell Government Services (Lovell), a Service-Disabled Veteran-Owned Small Business (SDVOSB) to gain access to the VA market for ARC^{EX} sales for both in-clinic and home use. Under this agreement, Lovell will add ONWARD therapies to its relevant federal contracts once those technologies are authorized by the US FDA for sale in the US, which is expected to provide the Company with rapid access to the Federal Supply Schedule (FSS), General Services Administration (GSA), Distribution and Pricing Agreement (DAPA), and Electronic Catalog Contract (ECAT).

In addition to the claims and invoicing data from sales to the VA, the Company also plans to patient-reported real-world evidence via an ARC^{EX} companion app to strengthen the Company's coverage and payment opportunities with Medicare and private payors, which will ultimately broaden access to more than 90% of the total US SCI market.

Success in clinics will drive home use, which will generate data required for broad reimbursement; access to ~30% of market shortly after launch

Home Market Access Landscape and Evolution



Germany

While ARCEX will be immediately available upon CE marking for clinics to purchase for use with patients during in-clinic rehabilitation sessions, preliminary analysis indicates that the timeframe for home-use reimbursement of ARCEX will be up to two to four years from CE marking.

In Germany, medical devices in the outpatient and physician clinic setting require a new Einheitlicher Bewertungsmaßstab code. Devices used in the home-use setting are governed by the Hilfsmittelverzeichnis ("HMV"), a positive coverage list for home-use medical equipment. HMV categories tend to be highly specific to indication; as a result, ARCEX will likely need a new HMV category. To achieve a new product category, a positive evaluation by Gemeinsamer Bundesausschuss will be necessary. Following successful inclusion in the home-use medical aids directory by the GKV-Spitzenverband, these products are recommended as reimbursable, but are subject to different price and contractual reimbursement rules and will be negotiated between statutory health insurance funds and medical suppliers as part of individual contracts for the provision of ARCEX.

Reimbursement Landscape in the United States – ARCEX^{IM}

Upon FDA approval of ARCEX^{IM}, the device will be sold to hospitals and ambulatory surgery centers for implantation by neurosurgeons and other qualified surgeons, with post-operative care, including any necessary reprogramming visits to be done by physiatrists (PM&R physicians) and other rehabilitation professionals (physical and occupational therapists), as the primary site of chronic phase care for people with SCI.

The Company's market access plans for ARCEX^{IM} are ongoing, with the Empower BP global pivotal trial design taking necessary clinical data for reimbursement into account. These plans will continue throughout 2024.

US

Procedure codes (CPT) exist today for physician, hospital outpatient, and ambulatory surgery center (ASC) payment for spinal cord stimulation (SCS) for chronic pain. However, the Company believes that ARCEX^{IM} may need to pursue separate coding, given the procedural intensity differences of implanting this novel technology compared to traditional SCS. With the potential for new codes, the Company will pursue provider payment levels commensurate with the value that ARCEX^{IM} provides to people with SCI, who otherwise have no treatment options. The Company is also designing its global

pivotal trial for stabilizing blood pressure after SCI, Empower BP, to take into account the data required to pursue a new procedural code for ARC^{IM}.

The Company believes patients will have rapid access to the ARC^{IM} system in the US by using a Category 3 code, which the Company expects will be available upon FDA approval of the initial indication.

These US facility payment systems are prospective and payment rates for a given procedure, which are a combination of diagnosis and procedure codes (i.e., MS-DRGs and APCs), are based on historical claims data. Thus, the cost of new technology cannot be included in the current payment rates. Because the Center for Medicare and Medicaid Services (CMS) employs a prospective payment system, the payment levels underpay for new, more impactful technologies. To enable payment for new innovation, therefore, Medicare has established two pathways to potential incremental payment for the ARC^{IM} implant procedure – one for inpatient and one for outpatient procedures.

In the inpatient setting, Medicare's New Technology Add-on Payment (NTAP) provides additional payment for implantable devices for a limited duration, typically up to 2 years. Similarly, Medicare provides a Transitional Pass Through (TPT) payment for the outpatient setting for a limited duration of 3 years.

The Company's Breakthrough Device Designations for ARC^{IM} for multiple indications, including the expected first indication for hemodynamic stability after SCI, increase the probability of securing incremental payments in both settings and the Company plans to apply for both as appropriate.

Germany

Among the selected five entry markets for the Company in Europe, Germany may offer the most accessible pathway for ARC^{IM}, as it operates a DRG-based system to compensate hospital inpatient admissions and a pathway for inpatient add-on payment for high-cost medical devices, such as the ARC^{IM} procedure.

For the regulation of blood pressure after SCI, diagnosis (ICD) and procedure codes (OPS) are already in place. They initiate a specific DRG and add-on payment. The reimbursement of add-on payments is negotiated by hospitals with the payors as part of the annual budget negotiations and depends on the additional costs for the new treatment compared to the costs defined in the DRG. This means that there is already a method of payment in place to reimburse hospitals for the costs of treatment with ARC^{IM}.

In Germany, it is also required that work-related SCI is treated at one of nine national BG Clinics. These specialty clinics. Which provide integrated surgical and rehabilitation services, also care for patients who are not injured on the job and are highly familiar with and skilled at the process of negotiating add-on payment for their SCI patients.

The Company's sustainability strategy

The Company is committed to being a responsible organization that creates long-term value for all stakeholders. Environmental, social, and governance principles are integral to the way the Company does business. They are captured in the ONWARD code of values, the Articles of Association, the Group's code of conduct, the Company's culture, business practices, operations and supplier agreements.

The Company's sustainability strategy rests on five core principles, which are described below and support seven of the UN Sustainable Development Goals.

Our Sustainability Priorities

	Social	Environmental	Supply Chain	Governance
Our Principles	Innovating for the underserved Attracting & retaining top talent	Minimizing our environmental footprint	Maintaining high ethical standards	
Our Priorities	<ul style="list-style-type: none"> Access & affordability Product & customer safety Career management Diversity, equity & inclusion 	<ul style="list-style-type: none"> Environmental management GHG emission reductions Product design & lifecycle 	<ul style="list-style-type: none"> Supplier risk management Critical materials 	<ul style="list-style-type: none"> Anti-bribery & corruption Responsible marketing Privacy and information security
Our support for the Sustainable Development Goals				

- Innovating for the underserved (UN Goals 3, 9 and 10):** The Company is committed to provide access to healthcare, regardless of a person’s location or situation. The Company’s intention is to make its platforms broadly available starting in the fourth quarter of 2024 in the US, and then in Europe. Its long-term strategy is to expand into other regions with the goal of reaching as many of the 7 million people worldwide with SCI as possible. Making sure that the Company’s devices meet the highest levels of quality and safety is the most fundamental requirement of its business. The Company partners with regulatory authorities globally to ensure that clinical trials are designed and executed in accordance with their requirements. Its quality system complies with applicable regulations and standards related to the medical devices industry in the EU and the US, and the Group’s quality management system is ISO 13485 certified and passed its most recent independent audit in late 2023.
- Partnering with patient groups:** The Company enjoys excellent relationships with the world’s leading patient advocacy groups for people with SCI. The Christopher and Dana Reeve Foundation, the world’s largest such organization, is an investor in the Company. The Company also collaborates with Wings for Life in Europe, the Praxis Foundation in Canada and International Spinal Research Trust in the UK. Its collaboration with these groups helps the Company innovate in ways that make the greatest difference for people with SCI.
- Attracting and retaining the best talent (UN Goal 8):** To deliver on its vision, the Company is committed to creating an unrivaled and inclusive environment for its employees. The Company cares deeply about the well-being and continuous development of its staff as evidenced by the various programs it has put in place, such as a well-being program. In 2023, the Company implemented new measures including a check-in survey after 90 days of employment, employee interviews, and offboarding interviews. Having a highly motivated and engaged workforce enables the Company to retain and attract top talent. The Company also engages with partners with SCI as consultants, who enable the Company’s workforce to have a better understanding of the challenges that they face. The Company recognizes and welcomes the value of diversity with respect to age, gender, race, ethnicity, nationality, sexual orientation and other important cultural differences.
- Minimizing the Company’s environmental footprint (UN Goals 12 and 13):** The Company strives to reduce its carbon footprint, for instance by replacing air travel with videoconferencing except for the most pressing business needs and by encouraging a hybrid workplace, thus

reducing its employees' commute. The Company's environment, health and safety quality plan sets out responsibilities for managing different waste streams in its science and engineering center in Lausanne. All of the Company's devices comply with the Registration, Evaluation, Authorization and Restriction of Chemicals Regulation ((EC) 1907/2006) and the Restriction of Hazardous Substances Directive ((EU) 2011/65). Additionally, the Company prioritizes efficient manufacturing processes, and recyclability in its product and packaging design. The Company consumes electricity generated mostly from renewable sources.

- **Maintaining high ethical standards (UN Goal 16):** The Company is committed to high ethical standards in dealing with its business partners as outlined in the Company's code of conduct, which covers anti-bribery and anti-money laundering, government relations and political affairs, international business practices and whistleblowing. The Company's code of conduct ensures its people across the organization understand what is expected of them when acting on behalf of the Company. The Company aims to comply with all applicable anti-bribery laws, including the US Foreign Corrupt Practices Act. In July 2023, the Company introduced its marketing code of conduct for interaction with healthcare professionals, which guides relevant employees on appropriate and compliant engagement with healthcare professionals during consulting relationships, sales and promotional activities. The Company applies the highest quality and safety standards to everything that it does, and ensures strong labour practices in its supply chain. The Company also works hard to secure key personal data and comply with the General Data Protection Regulation ((EU) 2016/679), or GDPR, and the Health Insurance Portability and Accountability Act ("HIPAA"). In July 2023, the Company introduced its global data privacy policy, which is designed to comply with all applicable data privacy laws where the Company operates. The Company also appointed an experienced external data protection officer, established data protection audits and an internal data privacy committee. The Company assesses new suppliers on sustainability via a pre-qualification questionnaire and introduced its code of conduct for third parties in 2024, which sets standards and responsibilities in areas including legal compliance, ethical business practices, human rights and labor practices, environmental responsibility, and reporting. It upholds human rights and operates in geographies with a strong track record on this topic.

In 2023, EcoVadis, the world's largest provider of business sustainability ratings, rated the Company in the top 40% in the industry for its sustainability performance. EcoVadis has compared the Company to 67 industry peers previously rated on their sustainability performance. Industry peers are defined based on 1) the company's activities and 2) the company's size. For 1), the Company was classified as a company that manufactures electromedical equipment based on the International Standard Industrial Classification of All Economic Activities (ISIC) used by the Department of Economic and Social Affairs of the United Nations. At the beginning of the rating process, EcoVadis was informed by the Company that its production phase has not yet started. EcoVadis still categorized the Company as a manufacturer of electromedical equipment, based on EcoVadis' standard categorization practices, and accounted for this specificity in their assessment. For 2), the Company's size was defined as a company of medium size (100-999 employees). The EcoVadis assessment evaluates 20+ sustainability criteria across four core themes: Environment, Labor & Human Rights, Ethics, and Sustainable Procurement. More than 130,000 companies globally have been rated by EcoVadis.

In June 2024, the Company published its Annual Sustainability Summary for the full year 2023, which can be found on the Company's website (https://ir.onwd.com/esg-information?b3130968_year%5Bvalue%5D=_none). The summary focuses on the Group's efforts to integrate good social, environmental, supply chain and governance practices throughout the Group and its performance in doing so. These sustainability priorities were defined by the Group in a multi-stage process built on sustainability assessments from external agencies and the Sustainability Accounting Standards Board Medical Equipment and Supplies Standard and are reflected in the Group's five core sustainability principles (see above). The summary also provides an overall 2023 performance summary (see below). The summary's key points for the sustainability priorities include:

- **Social impact:** The Group's ISO 13485 certified quality management system passed its most recent independent audit in late 2023 and the Group's quality function has been strengthened

by hiring additional qualified leadership and staff with competencies in medical software, supplier quality management, design control and risk management. None of the Group's devices have been recalled during 2023 (all devices in the field are currently in use in clinical trials). In 2023, the Group implemented new employee-related measures including a check-in survey after 90 days of employment, employee interviews and offboarding interviews. In addition, an employee survey takes place at least annually and the Group provides mandatory training tailored to people's roles. In 2023, the employees of the Group had an average of 13 hours of mandatory training each and 75% participated in the employee survey. The Group's diversity policy commits it to broad representation at all levels, from the board of directors down. To put this policy into action, the Group's diversity, equity and inclusion charter includes concrete actions such as a pay gap assessment and steps to promote the hiring and inclusion of people with disabilities and from different cultures and ethnicities. To increase the number of women at all levels of the Group, it aims for 50% of the interviewees to be female and is developing a sponsorship program for high-potential women at the Group. In 2023, 20 nationalities were represented in the Group's workforce. At year-end, women at the Group represented 39% of the workforce, 45% of supervisors and managers¹², 29% of the leadership team, 25% of the board members and 50% of the top 20% earners. In 2023, the Group offered workshops and other activities on mental health and well-being and developed trainings on the emergency response procedure for the science and engineering center in Lausanne. There were no lost-time work-related injuries in 2023.

- **Environmental management:** The Group has a limited environmental footprint solely based on its scope 1 and scope 2 emissions (as specified in the Greenhouse Gas protocol) as it did not run any manufacturing operations in 2023 – the devices used in clinical trials so far were made by suppliers on the Group's behalf and suppliers will continue to be the primary manufacturers. The Group's scope 3 emissions (as specified in the Greenhouse Gas protocol) have not been assessed yet and are therefore not reflected in the above statement regarding its environmental footprint. The Group's aim is to build resource efficiency into the way it operates, so that its business maintains minimal environmental impact as it grows. The Group strives to reduce greenhouse gas emissions by replacing air travel with videoconferencing except for the most pressing business needs, and by encouraging hybrid working that reduces commuting. The Group's environment, health and safety quality plan sets out responsibilities for managing different waste streams in the Group's science and engineering center in Lausanne, with general, chemical and biological waste already accounted for and a plan in development for handling electrical waste. In 2024, the Group published an updated environmental policy, that confirms its commitment to assess and address its environmental impacts as the Group's business evolves. In 2023, the Group consumed 63.9 MWh of purchased electricity, of which 56.0 MWh (88%) was from renewable sources¹³. The Group's electricity usage roughly halved from 2022 after its Netherlands headquarters moved to smaller premises. This change also led to a drop from 99% renewable electricity sourced in 2022. The Group plans to develop more detailed carbon accounting and emissions reporting as part of its new sustainability roadmap. No non-compliances with environmental legislation have been experienced by the Group until June 2024. In 2023, the Group introduced its device design and development procedure, which describes the governance, phases, reviews and documentation of its design and development process. The Group prioritizes efficient manufacturing processes and recyclability in its product and packaging design and intends to incorporate circular economy principles where it can, to extend product lifespans through repair, refurbishment, and recycling initiatives. All of the Group's devices comply with the Registration, Evaluation, Authorization and Restriction of Chemicals Regulation ((EC) 1907/2006) and the Restriction of Hazardous Substances Directive ((EU) 2011/65).
- **Supply chain:** The Group is updating its supplier relationship management process to include environmental, social and governance considerations during supplier selection, evaluation,

¹² Supervisor or manager role defined as managing one or more reports.

¹³ Weighted average of Lausanne and Eindhoven offices based on data provided by Services industriels de Lausanne (2022 data) and own estimates for the Eindhoven site.

approval and monitoring. The Group already assesses new suppliers on sustainability via a pre-qualification questionnaire. 100% of new suppliers have answered sustainability questions in the Group's questionnaire since it was introduced in October 2023. In 2024, the Group introduced a comprehensive code of conduct for third parties, including suppliers and contractors, to set standards and responsibilities in areas including legal compliance, ethical business practices, human rights and labor practices, environmental responsibility, and reporting.

- Governance:** The Group's code of conduct sets out its expectations for anyone acting on behalf of the Group in areas such as anti-bribery and corruption, international business practices and whistleblowing. In 2024, the Group will roll out a fresh policy on whistleblower protection, bolstering its code of conduct as part of ongoing efforts to enhance accountability and support for ethical practices. There were no incidents of bribery or corruption confirmed or suspected within the Group in 2023. In early 2024, the Group performed an initial corruption risk assessment of its countries of operation (the Netherlands, Switzerland and the US) against the Transparency International Corruption Perceptions Index and determined that none presents a high risk. In July 2023, the Group introduced its marketing code of conduct, which guides relevant employees on appropriate and compliant engagement with healthcare professionals during consulting relationships, sales and promotional activities, along with mandatory training on field interactions for all relevant employees. In 2024, templates for consultancy agreements with healthcare professionals will be introduced to ensure they are compliant with the code. In 2023, the Group incurred no monetary losses as a result of legal proceedings associated with false marketing claims. In July 2023, the Group introduced its global data privacy policy, which complies with the European General Data Protection Regulation and all other applicable laws where the Group operates and commits it to protecting all data collected in the course of its business. To protect its business system and information, the Group's IT security awareness program trains users on best practices to create a culture of security as the best defense against threats. An expert third-party provides 24/7 security monitoring and incident response capabilities. In 2023, data governance was strengthened by appointing an experienced external data protection officer, by establishing data protection audits and an internal data privacy committee. As part of the Group's security awareness program, it ran periodic phishing simulations and mandatory cybersecurity training for all employees. In 2024, it is planned to publish a suite of IT policies and a disaster recovery plan to increase the Group's resilience. During 2023 there were no confirmed data privacy breaches and no confirmed information security breaches.

2023 Performance Summary

We have established performance indicators to set a baseline for measuring progress against each priority topic. The following pages of this summary provide further explanation of our performance.

Social

- 0 product recalls
- 13 average hours of mandatory training per employee
- 75% participation rate in employee survey
- 20 nationalities represented in our workforce
- At year-end, women at ONWARD Medical represented:
 - 39% of our workforce
 - 45% of supervisors and managers
 - 29% of the Leadership Team
 - 25% of Board members
 - 50% of the top 20% of earners
- 0 last-time work-related injuries

Environmental

- 88% of purchased electricity from renewable sources
- 0 environmental non-compliances

Supply Chain

- 100% of new suppliers have answered sustainability questions in our pre-qualification questionnaire since it was introduced in October 2023

Governance

- 0 cases of bribery or corruption confirmed or suspected within the company
- 0 monetary losses as a result of legal proceedings associated with false marketing claims
- 0 confirmed data privacy breaches during the year
- 0 confirmed information security breaches during the year

History

The Company was formed in 2015 by Professor Courtine, Professor Bloch and other researchers in neuroscience and neurosurgery operating out of EPFL (École polytechnique fédérale de Lausanne) and CHUV (Centre Hospitalier Universitaire Vaudois). Professors Courtine and Bloch currently lead NeuroRestore, a research center that aims to develop innovative therapeutic strategies including bioengineering and neurosurgical interventions to restore neurological functions. The Company was originally named G-Therapeutics B.V., raising EUR 36 million in 2016 when it moved its corporate headquarters from Lausanne, Switzerland to Eindhoven, the Netherlands. This Series A financing was led by several of Europe's leading life science venture capital funds, including Life Sciences Partners Management B.V. (now EQT Life Sciences), Wellington Partners Advisory AG, INKEF Capital B.V., and Gimv N.V.

In 2018, Professor Courtine and colleagues published clinical results in *Nature* demonstrating for the first time in humans that motor control and the ability to walk continuously for at least 20 and up to 90 minutes could be restored even after complete paralysis.¹⁴ These results were obtained using an implantable platform consisting of an IPG (implantable pulse generator) and a lead placed in the epidural space (i.e. the inside surface of the spinal canal). That same year the Company was renamed GTX Medical B.V.

In 2019, GTX Medical B.V. acquired NRT¹⁵. After the acquisition, NRT was renamed GTX Medical, Inc. The acquisition brought several important assets to GTX Medical B.V.:

- an external spinal cord stimulation platform that delivers therapy transcutaneously (through the skin);
- intellectual property licensed from the University of California, Caltech, and the University of Louisville;
- a shareholder relationship with the Reeve Foundation, and;
- an additional investment of EUR 5 million in cash from the former NRT investors through NRT Holdings, that was fully paid as of November 2020.

As a result of the NRT acquisition GTX Medical B.V. became, in the view of the Company the only commercial entity with both an implantable and non-invasive spinal cord stimulation treatment option for people with SCI.

In 2020, the Company changed its name to ONWARD Medical B.V. and appointed Dave Marver as Chief Executive Officer. Company subsidiaries GTX Medical SA and GTX Medical Inc. were renamed Onward Medical SA and Onward Medical Inc., respectively.

In 2021, the Company successfully completed a EUR 30 million convertible note financing. All of the Company's current large institutional shareholders participated in the 2021 financing and the Company recruited several additional investors, including the Dutch impact investment fund, Invest-NL Capital N.V., and Olympic Investments Inc., the private investment arm of the Onassis Foundation.

In October 2021, the Company completed its initial public offering raising gross proceeds of EUR 80.1 million (including a subsequent partial exercise of an over-allotment option) and was listed on

¹⁴Wagner, F.B., Mignardot, J.B., Le Goff-Mignardot, C.G. *et al.* Targeted neurotechnology restores walking in humans with spinal cord injury. *Nature* 563, 65–71 (2018), doi: 10.1038/s41586-018-0649-2.

¹⁵The acquisition of NRT resulted in a goodwill recognized in the Company's intangible assets. After initial recognition, goodwill is measured at cost less any accumulated impairment losses. For the purpose of impairment testing, goodwill acquired in a business combination is, from the acquisition date, in general allocated to the group's cash-generating units that are expected to benefit from the combination, irrespective of whether other assets or liabilities of the acquiree are assigned to those units. For purposes of impairment testing, the Group's business as a whole is considered to be one sole cash generating unit since both the existing technologies of the Company (ARC^{EX} and ARC^{IM}) are moving towards one technology platform, which is considered the base of the products from which different indications (therapies) derive.

Euronext Brussels and Euronext Amsterdam. In this context, the Company was converted into a public company with limited liability (*naamloze vennootschap*) with its statutory seat (*statutaire zetel*) in Amsterdam, the Netherlands, and renamed to ONWARD Medical N.V.

On 21 March 2024, the Company raised an amount of EUR 20.0 million in gross proceeds by way of an accelerated bookbuild offering through a private placement with institutional investors, certain founders, and certain management and members of the Board of 4,307,641 new ordinary shares and a separate public offering via the PrimaryBid platform with retail investors in France of 136,803 new ordinary shares, representing a total of 4,444,444 new ordinary shares and published a prospectus, which was approved by the AFM on the same day, for the admission to listing and trading of these new ordinary shares on Euronext Brussels and Euronext Amsterdam. The new ordinary shares were offered at an issue price of EUR 4.50 per share.

On 28 June 2024, the Runway Loan of up to EUR 52.5 million was signed. The Runway Loan bears an interest rate equal to Term Secured Overnight Financing Rate (SOFR) for a three-month interest period (currently at 6.00% and subject to a 4.25% floor), plus margin of 6.50%. The loans under the Runway Loan are secured by a security interest in substantially all of the Group's assets. In addition, upon signing of the Runway Loan, the Company issued warrants to Runway which entitle it to purchase Ordinary Shares in the capital of the Company at an exercise price per newly issued share of EUR 4.83. The number of shares subject to the warrants are 5.00% of the drawn down principal amount initially and upon each subsequent loan advance, divided by the exercise price.

On 24 September 2024, the Ordinary Shares were admitted to listing and trading on Euronext Paris under the symbol "ONWD".

The Company is headquartered in Eindhoven, the Netherlands, and has two wholly owned subsidiaries: ONWARD Medical SA (located in Lausanne, Switzerland), established on 12 December 2014 and ONWARD Medical Inc., a C-Corporation registered in Delaware, USA, established on 13 September 2013. ONWARD Medical SA serves as the Company's principal research entity, employing engineers, scientists, and other staff working in close collaboration with researchers at EPFL and CHUV and facilitating development of new therapies. ONWARD Medical Inc. serves as the Company's entity in the US, employing field clinical research staff. In the future, the Company expects ONWARD Medical Inc. to also employ the field sales and service professionals required to market ARC^{IM} and ARC^{EX} to US-based customers.

Principal Investments

Since 31 December 2023 and as of the date of this Prospectus, the Company has not made any material investments, and which are in progress other than as set out below.

The Company continuously invests in research and development. In the six-month period ended 30 June 2024, the Company incurred research and development costs in the amount of EUR 6.1 million.

The Company develops its technologies and therapies internally and in collaboration with its partners who bring expertise in critical areas. The Company currently invests to optimize ARC^{EX} and ARC^{IM} platforms, software, hardware, and additional features or services that could potentially provide opportunities for future revenue generation.

In 2022 and 2023, considerable progress was made on all aspects of the ARC^{EX} system including multiple rounds of user-centric formative studies and incorporation of learnings from the Up-LIFT Study. Design inputs then were locked and development of the ARC^{EX} system is now nearing completion. Work has begun on transferring the design to manufacturing, procuring production materials, and initiating supply-chain activities.

ARC^{IM} investments include the Company's own IPG (implantable pulse generator), which was implanted in a human for the first time in May 2022. Now the Company is focusing on ARC^{IM} features, required for the blood pressure indication as well as thoracic and lumbar lead development.

Following the developments above, the Company plans to continue to improve both the ARC^{EX} and ARC^{IM} platforms and device performance, incorporating learnings from the Up-LIFT, HemOn and future clinical studies.

Trend Information

The Company has continued to develop in line with its expectations in 2023 and in 2024 so far and achieved many of its objectives relating to the technical and clinical development of the products as well as other commercial goals. Examples of the Company's goals achieved in 2023 include the successful first-in-human use of the Company's ARC^{IM} Lead and the successful first-in-human use of an investigational implanted wireless BCI to help a person with SCI recover use of paralyzed arms and hands with thought-driven movement. For more details regarding the Company's clinical and development achievements please refer to the sections "Important Information—Regulatory Disclosures—Disclosure related to Clinical Studies", "Business—Overview—Research & Development" and "Business—Overview—Clinical Trials". The Company will focus on two main topics, consisting of (i) innovation, clinical, and regulatory developments and (ii) corporate, in the current fiscal year and beyond.

With respect to innovation, clinical, and regulatory developments, in May 2023, the Company announced the first-in-human use of its ARC^{IM} Lead, a purpose-designed lead that is optimized for placement along the spinal cord to stimulate the dorsal roots to restore mobility and autonomic function after SCI. Previous clinical and proof-of-concept studies used commercially available leads marketed by other companies or a previous lead developed by the Company (called the "Go-2 Lead"). The Company has since developed a new lead platform (the ARC^{IM} Lead) which has been used in a human for the first time in May 2023. The ARC^{IM} Lead was successfully implanted by a neurosurgeon at CHUV in Lausanne, Switzerland. The ARC^{IM} Lead was placed in the "Hemodynamic Hotspot" along the thoracic spinal cord, an area in which targeted electrical stimulation may restore better blood pressure regulation after an SCI. The Company announced in August 2023 the first-in-human use of ARC^{BCI}, its BCI platform for upper extremities. The Company is investigating ARC^{BCI} as its second-generation implantable platform to enable movement. The ARC^{BCI} platform harvests brain signals and wirelessly transmits a person's intention to move to the Company's ARC^{IM} system to enable more natural movement. This program is supported by a grant from the European Innovation Council. In September 2023, the Company has expanded its clinical feasibility study for blood pressure regulation to the Netherlands. Furthermore, the Company began an early feasibility clinical study for the mobility indication of its ARC^{IM} platform in September 2023. The Company submitted a de novo application (for further details on the de novo classification process, see "Regulatory Framework—De Novo Classification Process" below) for FDA clearance for its ARC^{EX} system on 2 April 2024, which the Company anticipates will result in marketing authorization to commercialize that platform in the US sometime in the fourth quarter of 2024. The Company aims to obtain CE mark and European authorization sometime in 2025. On 20 May 2024, *Nature Medicine* published detailed results from the Company's Up-LIFT Study for ARC^{EX} Therapy. The study achieved all primary safety and effectiveness endpoints and ARC^{EX} Therapy demonstrated significant improvements in upper limb strength, function, and sensation among people with chronic tetraplegia due to cervical SCI. On 9 July 2024, *Neuromodulation: Technology at the Neural Interface* published an article, providing an evidenced-based framework to determine stimulation parameters for ARC^{EX} Therapy based on analysis of device parameters, usage data, and clinician and participant feedback from the Up-LIFT pivotal trial and follow-on LIFT home study. In September 2024, another investigational ARC^{BCI} system to restore lower limb mobility after SCI was implanted successfully. This implant is part of an ongoing early feasibility clinical study supported by a grant from the European Innovation Council under the Reverse Paralysis project and coordinated by .NeuroRestore. It marks the third human implant of the ARC^{BCI} system to restore thought-enabled movement after SCI and the second for lower limb mobility.

Furthermore, and focusing on the corporate trends affecting the Company, the Company expects its current cash position (cash and cash equivalents (unaudited) of EUR 20.6 million as of 31 July 2024) to fuel operations into spring of 2025. Through the Private Placement the Company will further strengthen its balance sheet and extend its cash runway to support future investments in product

development, clinical trials, operational capabilities, and commercial capabilities. In particular, the Company intends to distribute the net proceeds from the Private Placement as follows: (i) approximately 40% to fund research and development initiatives, including continued product development, clinical studies, and regulatory activities for the investigational ARC^{EX} system to restore hand and arm function, the investigational ARC^{IM} system for improved blood pressure regulation and other exploratory indications, and the investigational ARC^{BCI} system to restore thought-driven movement of the human body after SCI, (ii) approximately 30% to support the expected commercial launch of the ARC^{EX} system in the United States of America in the second half of 2024, including hiring a field sales organization and conducting selling activities, producing training and education materials and conducting training events, attending congresses, developing customer support capabilities and conducting customer support activities, and conducting market access and reimbursement activities, (iii) approximately 20% for building quality, operations and administrative capabilities, (iv) approximately 5% for working capital requirements and potential strategic opportunities, aimed at establishing, maintaining, or strengthening competitive advantage through license arrangements, acquisitions whether by assets or shares, or other arrangements (partnering or otherwise) and (v) approximately 5% of the funds will be allocated to cover financing costs associated with existing obligations under current and anticipated debt funding. The Company may be required to raise additional capital in the future in order to meet its funding requirements.

As of the date of the Prospectus, there have been no significant changes in the financial performance and the financial position of the Company since 30 June 2024, except for:

- the effects of the Private Placement, where the Company will issue 10,000,000 New Ordinary Shares on 28 October 2024 at a placement price of EUR 5.00, raising an amount of EUR 50.0 million in gross proceeds. The Private Placement will influence the Company's financial position by increasing its capital through an equity offering and contribute to the Company's financial stability and growth potential. The overall impact includes enhanced liquidity and dilution of voting interests of the Shareholders of the Company holding shares in the Company prior to the Private Placement; and
- the effects of the Runway Loan in an amount of up to EUR 52.5 million. The Runway Loan diversifies the Company's capital structure, increases its cash flow and contributes to the Company's growth potential. It does not dilute any voting interests of the Shareholders of the Company but increases the Company's liabilities. The interest payments under the Runway Loan reduce the Company's net income and cash flow. For more information regarding the Runway Loan see "*Material Contracts – Loan agreements*" below and for more information regarding the effects of the Private Placement on the capitalization and indebtedness of the Company see "*Capitalization and Indebtedness*" above.

Material contracts

The Company develops and manufactures most of the software and firmware components of the ARC^{IM} and ARC^{EX} in-house with specific content knowledge insourced from third parties, and works with external suppliers on the hardware and electronic components through a combination of development, manufacturing and supply agreements, quality agreements and statements of work.

All these suppliers, most of which are based in the US or Western Europe, are well-known and well-respected manufacturers with a larger customer base and existing quality management systems that comply with the appropriate regulatory authorities.

Production volumes at the Company's suppliers are at this stage small and concentrated around manufacturing components for use in clinical settings. Once the Company receives approval to commercialize the ARC^{EX} and ARC^{IM} products, the production volumes will increase and longer-term supply arrangements will need to be negotiated.

Supplier agreements

ARC^{IM} IPG agreements

For the ARC^{IM} IPG (implantable pulse generator) development the Company entered into a development, manufacturing and supply agreement on 20 June 2018 with a German headquartered supplier named Osypka AG for the development of the IPG can, including the header. This supplier has the required experience and capabilities to manufacture active implantable devices such as the ARC^{IM} IPG (implantable pulse generator). Moreover, this supplier has a track record that spans several decades and demonstrates its ability to deliver products at the required quantities and with the required levels of quality. Since the IPG (implantable pulse generator) can is a key component of the ARC^{IM} system this agreement can be considered as material.

Delivery of the initial design is complete. The Company engages the supplier for continuing engineering improvements on an as-needed basis. The IP generated throughout the development services under the agreement (the "**Foreground IP**") are assigned to ONWARD. The supplier has negotiated an exclusivity period of 48 months to supply products for commercial use.

ARC^{IM} IPG PCBA Manufacturer

For the ARC^{IM} IPG development the Company entered into development, manufacturing and supply agreement on 13 February 2019 with a Swiss headquartered supplier for the development of the printed circuit board assembly process ("**PCBA**"). This supplier is specialized in the manufacture of PCBA's with over three decades of supply to the high tech and medical device industries and is both ISO9001 and 13485 certified, making them a solid supplier for the ARC^{IM} IPG PCBA. Since the PCBA is a key component of the ARC^{IM} platform this agreement can be considered as material.

Delivery of the initial design is complete. The Company engages the supplier for continuing engineering improvements on an as-needed basis. The Foreground IP (IP generated throughout the development services under the agreement) are assigned to the Company. The contract will end at time of the completion of the Statement of Work. A statement of work is a document frequently employed in the field of project management, defining project-specific activities, deliverables and timelines as an accompaniment to a master agreement.

ARC^{IM} Lead portfolio agreements

For the ARC^{IM} lead portfolio the Company entered into a development, manufacturing and supply agreement on 18 February 2021 with a US headquartered supplier named Ocor Inc. (now Integer, Inc.) to develop and supply a range of different lead-paddles for the specific use indications mentioned earlier in this document. Since the lead paddle is a key component of the ARC^{IM} system this agreement can be considered as material.

The collaboration with the supplier and the specific activities are documented in detail in the Statement of Work, which is ongoing. On a regular basis the progress is discussed with the supplier and changes to the Statement of Work are discussed and agreed upon in writing. The Foreground IP (IP generated throughout the development services under the agreement) are assigned to the Company. The contract will end on 18 February 2026 and can be extended for additional one-year periods.

Medical Manufacturing and Supply agreement

For the ARC^{IM} lead portfolio the Company entered into a medical manufacturing and supply agreement on 29 March 2018 with a US headquartered supplier to supply a Lead System Kit consisting of a medical device packaging system and an accessory kit to implant the paddle leads. The accessory kit is a key component of the ARC^{IM} platform and therefore, this agreement can be considered as material. The part of the agreement relating to the packaging system and the paddle leads has been discontinued. The Company, however, still purchases accessory kits for the implant of the Integer manufactured lead-paddles.

The collaboration with the supplier and the specific activities are documented in detail in the Statement of Work and are near completion. The Foreground IP (IP generated throughout the development services under the agreement) are assigned to the Company. The initial term of the contract ended on 29 March 2023 and has been automatically renewed for an additional year. The agreement will automatically renew on a yearly basis, unless terminated in advance by the parties.

ARC^{IM} main controller agreement

For the ARC^{IM} Main Controller development the Company entered into development, manufacturing and supply agreement on 13 February 2019 with a Belgium headquartered supplier for the development of the hardware and electronic build of the main controller. This is a specialized supplier called Zenso (now Comate after a recent acquisition). After over a decade of contract engineering and manufacturing, Comate has delivered over 800 projects to customers across multiple industries including many in medical devices. Since the main controller is a key component of the ARC^{IM} platform this agreement can be considered as material.

The collaboration with the supplier and the specific activities are documented in detail in the Statement of Work. On a regular basis the progress is discussed with the supplier and changes to the Statement of Work are discussed and agreed upon in writing. The Foreground IP (IP generated throughout the development services under the agreement) are assigned to the Company. The contract will end at time of the completion of the Statement of Work. The Company is also insourcing two dedicated engineers from this supplier to support the firmware development of the ARC^{IM} platform. This Belgium headquartered party also assisted in the design of the electronics development of the ARC^{IM} IPG. All rights to such designs are vested in the Company.

ARC^{EX} stimulator agreement

For the ARC^{EX} stimulator development the Company has entered into a development agreement on 3 November 2021 with the Netherlands headquartered supplier Demcon for the development of the mechanical stimulator enclosure which houses a portion of the user interface and electronics of the ARC^{EX} stimulator. Since the stimulator is a critical component for timely delivery of the ARC^{EX} platform for regulatory submission and product launch, this agreement can be considered as material. The development of the stimulator is concluded, and the portion of the Statement of Work for design transfer to Manufacturing is now in effect.

In addition, the company has now entered into an agreement with Demcon for the manufacture of the ARC^{EX} stimulator and related accessories. The contract is for a one year term with extensions available. Since manufacturing of the prime component of the ARC^{EX} system is essential for commercialization, this agreement can be considered as material.

The Foreground IP (IP generated throughout the development services under the agreement) are assigned to the Company. The contract will end on 3 November 2026 and automatically extends for additional one-year periods unless terminated by either party.

Grant Agreements and License Agreements with EPFL, NeuroRestore and other Parties

Contracts & Agreements	Description	Status
Reverse Paralysis Consortium agreement	The contract creates the legal framework for the activities to be performed by the parties that form part of the Reverse Paralysis consortium.	Active until completion of all activities contemplated in the Agreement, expected to be completed until 30 April 2025
Reverse Paralysis EISMEA (European Innovation Council) grant agreement	The EISMEA grant provides funding to study the integration between ARC ^{IM} and Clinathec's WIMAGINE system, which records and decodes the brain's cortical signal to predict a person's desired movement intentions, and the conduct of two clinical feasibility studies for upper- and lower-limb control and rehabilitation. The Company	Active until completion of all the activities contemplated in the Agreement, which are currently expected to be completed by 30 April 2025

	received a grant of EUR 1.2 million (see below). Recently, an amendment was executed to add ONWARD SA to the project, alongside the Company.	
NEMO BMI Consortium agreement	The contract provides the legal framework for the activities contemplated in the NEMO BMI project.	Active until the completion of all the activities contemplated in the Agreement, which are currently expected to be completed by 30 September 2025
NEMO BMI EISMEA (European Innovation Council) grant agreement	The NEMO-BMI grant provides funding to support usability improvements that enable the use of a Brain Computer Interface to support upper and lower limb movement. Auto-adaptive algorithms are developed for brain decoding and brain-guided spinal cord stimulation patterns and will then be embedded in miniaturized hardware. The Company received a grant of EUR 1.0 million (see below). Currently an amendment is prepared to add ONWARD SA to the project, alongside the Company.	Active until the completion of all activities contemplated in the Agreement, which are currently expected to be completed by 30 September 2025
HEMO + DARPA (US Defense Advanced Research Projects Agency)	The DARPA grant was a five-year project that started in October 2020. The award was divided into 3 phases. The funding agreement for phase 1 and phase 2 was approved for a total amount of EUR 3.172 million (or USD 3.402 million), which is a material amount for the Company (see below). The Company completed its contribution to the DARPA project in 2023 within the final cumulative amount being recognized amounting to EUR 3.004 million (or USD 3.307 million).	The US government cut the Bridging the Gap Plus (BG+) funding program and Phase 3 activities were cancelled. ONWARD has completed all activities and responsibilities for the project.
HEMO+ DARPA (US Defense Advanced Research Projects Agency) Subcontracting amendment 1	The subcontract was amended to reflect the modifications made in the subaward contract between University of California Davis and EPFL on 7/8 April 2021 and 16 December 2021.	Executed

HEMO+ DARPA (US Defense Advanced Research Projects Agency) Subcontracting amendment 2	In 2022, the consortium proposed accelerating the project timeline, and thus the costs. EPFL paid ONWARD at the accelerated timeline, but no amendment has been executed to reflect the accelerated payment. EPFL has recently asked for the creation of such an amendment.	<i>*ONWARD is working with EPFL to create this amendment</i>
Michael J Fox Foundation (MJFF, US) subaward contract with EPFL	Support an early feasibility study for mobility in Parkinson's disease	Executed
The Christopher and Dana Reeve Foundation (US) subaward contract with EPFL	The subaward contract will allow for EPFL to disperse funds from the Reeve foundation. The funds will support the addition of additional participants in a clinical trial utilizing a BCI for upper limb movement.	<i>*On-going work with EPFL to execute the subaward agreement</i>

Contracts & Agreements .NeuroRestore (CHUV (Centre Hospitalier Universitaire Vaudois) + EPFL (École polytechnique fédérale de Lausanne))	Description	Status
Framework Agreement Include an appendix for each .NeuroRestore studies supported by ONWD	<p>The contract establishes the legal framework for research projects between ONWARD, EPFL and CHUV, (EPFL and CHUV, jointly known as .NeuroRestore). The contract establishes the framework conditions regulating the conduct, financials, supply of devices, and responsibilities of clinical research projects between the three entities. The clinical data generated in the studies conducted between the parties is critical for the Company to support the regulatory approval pathway for ARC^{IM} in multiple targeted indications. All .NeuroRestore studies are supported under this agreement except for a clinical feasibility study called STIMO (STimulation Movement Overground).</p>	<p>Active until either ten years from the effective date (1 December 2019) or until all obligations for the clinical trials have been completed</p>
STIMO Research support agreement between EPFL, CHUV and ONWARD	<p>This contract establishes the legal framework for the execution of the STIMO clinical study. Devices were provided by Medtronic and ONWARD (GTX medical SA at the time) provided regulatory and technical support. The study utilizes epidural electrical stimulation with robot-assisted rehabilitation in patients with SCI.</p>	<p>Effective since 1 February 2019 and expires when study is complete</p>
HemON	<p>The contract establishes a clinical program for ONWARD's feasibility study in Switzerland for ARC^{IM} in blood pressure control. The Company relies on the data generated in the study for the regulatory approval for ARC^{IM} to improve blood pressure management and trunk control in people with spinal cord injury who suffer from orthostatic hypotension.</p>	<p>Active until 31 May 2025 or study completion</p>
HemON NL Collaboration agreement with EPFL and CHUV	<p>Clinical support for ONWARD's feasibility study in The Netherlands for ARC^{IM} in blood pressure control. The Company relies on the data generated</p>	<p>Active until 24 months from the effective date (15 June 2023) or study completion</p>

in the study for the regulatory approval for ARC^{IM} in blood pressure.

Licenses	Status
EPFL – Neurostimulation – license 1	This is a long term agreement that is active until the expiration of the last valid patent claim and any possible patent extension.
EPFL/UBC (University of British Columbia), Uca (University of Calgary), Umi (University of Minnesota) – Autonomic functions – license 3	This is a long term agreement that is active until the expiration of the last valid patent claim and any possible patent extension.
UCLA (University of California) – Neurostimulation	This is a long term agreement that is active until the expiration of the last valid patent claim and any possible patent extension.
Caltech (California Institute of Technology)/UCLA, UoL (University of Louisville)– Neurostimulation	This is a long term agreement that is active until the expiration of the last valid patent claim and any possible patent extension.
CEA (Commissariat a l’Energie Atomique et aux Energies Alternatives) – Brain-Computer-Interface (BCI)	Active for 15 years from the effective date (14 October 2024), but, upon expiry of the 15-year period and if necessary for the pursuance of the Company’s activities, the license agreement will continuously and automatically renew for subsequent 3-year-periods.

The Company has entered into several IP licensing agreements with leading neuroscience research institutions. Each licensed patent family is linked to one of the Company's products and royalty rates only apply to relevant product sales (for example, transcutaneous stimulation related technology applies to sales of ARC^{EX} but not to sales of ARC^{IM}).

Research funding schemes from which the Company currently benefits, including European projects funding, require the Company to grant a fully paid-up royalty free license to certain public institutions, for research and education purposes only. In June 2024, the Runway Loan was signed. To secure the Runway Loan the Group pledged substantially all of its assets, including intellectual property. The collateral may be disposed of in the case of events of default (including but not limited to the Company's or a Group Company's bankruptcy). In such case, any in-licensed intellectual property would return to any of the Company's licensors. Please refer to “Material Contracts—*Loan agreements*” for a detailed description of the Runway Loan.

EPFL

License 1

On 30 March 2016, the Company and its Swiss subsidiary entered into a license agreement with EPFL, as amended from time to time, through which agreement the Company has been granted an exclusive license to make, have made, use, sell and have sold products or parts thereof which is covered in whole or in part by any of certain patents in the country in which any such product is made, used or sold and to practice processes covered by the patents within the following field of use: Central Nervous System Neuromodulation (including dorsal and ventral roots), and associated Neurorehabilitation and physical therapy as well as certain spine-located stimulation of the central nervous system and/or recording of cortical activity. In addition, it has been granted an exclusive license on certain software. As consideration for these licenses (including License 3, as described

below) EPFL has been granted an option to obtain Ordinary Shares, which was exercised at the time of the initial public offering at Euronext Brussels and Euronext Amsterdam and led to 269,213 ordinary shares being issued to EPFL. In addition a percentage of proceeds of the sale of ONWARD Medical SA would need to be paid to EPFL. Lastly maintenance and – net sale base – royalty payments will need to be made to EPFL on sales of licensed products. The agreement contains various milestone and diligence obligations which includes those tied to the patents. In the event the milestones are not met, the license agreement provides EPFL the right to convert the license to a non-exclusive license.

License 2

EPFL has separately granted an exclusive license regarding an apparatus to apply forces in a three-dimensional space to the Company and ONWARD Medical SA. Maintenance and – net sale based – royalty payments will need to be made to EPFL on sales of licensed products plus a payment on first commercial use. More specifically, the Company is obliged to pay royalties of 3% on related net sales and 10% to 20% in the case of sublicensing income, in both cases depending on the amount of cumulative income. The agreement contains various milestone and diligence obligations.

License 3

EPFL has separately granted an exclusive license to certain patents in the field of neuromodulation for autonomic function to the Company and ONWARD Medical SA. Maintenance and – net sale based – royalty payments will need to be made to EPFL on sales of licensed products. The agreement contains various milestone and diligence obligations. On 3 October 2022, the parties agreed on an amendment to the license agreement under which the Company and ONWARD Medical SA agreed to pay to EPFL success fees upon achievement of certain milestones.

License 4

EPFL has separately granted an exclusive license to one patent in the field of Central Nervous System Neuromodulation (including dorsal and ventral roots), and associated Neurorehabilitation and physical therapy as well as certain spine-located stimulation of the central nervous system and/or recording of cortical activity to the Company and ONWARD Medical SA, which was originally part of License 1 and was separated in a standalone license. Specifically, the license technology covers flexible electronics for neuromodulation. Maintenance and – net sale based – royalty payments will need to be made to EPFL on sales of licensed products. The agreement contains various milestone and diligence obligations.

Sub-license of License 4 to Neurosoft Bioelectronics SA

The Company has sub-licensed some technology pertaining to flexible electronics for neuromodulation to Neurosoft Bioelectronics SA. Maintenance costs will be shared between the Company and Neurosoft, and – net sale based – royalty payments need to be made by Neurosoft to the Company on sales of licensed products.

Caltech

On 8 October 2019, Neurorecovery Technologies Inc. (now ONWARD Medical Inc.) entered into a license agreement with Caltech, the latter on behalf of various intellectual property owners, including UCLA, University of Louisville, DEI and USC, granting an exclusive license on certain technologies in certain fields of epidural and transcutaneous neuromodulation and a non-exclusive license of certain other intellectual property. Various revenue milestone payments, diligence obligations and fixed royalty payments are due under the license. Lastly, the Company was obliged to pay a fee to Caltech upon completion of its initial public offering of shares on Euronext Amsterdam and Euronext Brussels in October 2021 (the "IPO").

UCLA

On 27 September 2019, Neurorecovery Technologies Inc. (now ONWARD Medical Inc.) entered into a license agreement with the Regents of the University of California acting through Technology Development Group UCLA campus granting an exclusive license on certain patents in certain fields

of neuromodulation and spinal cord stimulation and a non-exclusive license on certain other patent rights. Various revenue milestone payments are due under the exclusive license and fixed royalty payments are due under the non-exclusive license. The agreement contains various milestone and diligence obligations.

Lastly, the Company was obliged to pay a fee to UCLA upon completion of the IPO.

CEA

On 14 October 2024, the Company entered into a license agreement with the Commissariat à l'Énergie Atomique et aux Énergies Alternatives, a French state-owned entity with a scientific, technical and industrial activity, through which the Company has been granted an exclusive license on certain patents, an exclusive right to use certain know-how and an exclusive right to use certain software, all in the field of BCI. The agreement contains various event-based and milestone payment obligations. Under the agreement, the Company must pay a minimum annual license fee, whereby such fee is replaced by annual royalties, based on net-sales of licensed products, as soon as they are higher than the minimum annual license fee due. The agreement also provides for various diligence obligations.

Grant agreements

As of the date of this Prospectus, the Company is party to several grant agreements, e.g. with the European Innovation Council and SMEs Executive Agency ("**EISMEA**") and the European Research Executive Agency ("**REA**"), under which it receives grants funding certain projects of the Company and other beneficiaries.

Grants	Status	Maximum grant amount
EISMEA – ReverseParalysis	Active	EUR 1,227,947.00
EISMEA – NEMO BMI	Active	EUR 1,020,260.00
REA – ReWire	Active	EUR 274,370.40

As of 30 June 2024, the following grants have been received by the Company and been recognized in the Company's revenues in the following way:

<i>(In EUR 000)</i>	Total Grant (unaudited)	Cumulatively at 30 June 2024 (unaudited)		
		Recognized as Grant Income	Received in advance	Amount receivable
Grants				
CONFIRM	416	405	–	–
BESTABLE	100	100	–	–
SWISS LOCAL (one -offs)	–	172	–	–
PREP2GO	363	363	–	–
DARPA	3,004	3,004	–	–
ZonMW	250	250	–	50
EISMEA – Reverse Paralysis	1,228	80	841	–
EISMEA – NEMO BMI	1,020	–	765	–
Eurostars Impulse	500	254	–	23
ReWire	360	75	103	–
SH-ARC	500	53	135	–
Total		4,756	1,844	73

Loan agreements

On 28 June 2024, the Runway Loan in the amount of up to EUR 52.5 million was signed. The Runway Loan is divided into five individual credit tranches:

- (i) The first initial credit tranche of EUR 16.0 million was available upon signing of the Runway Loan and was drawn down immediately. The funds were received by the Company on 2 July 2024.
- (ii) Three subsequent credit tranches of EUR 14.0 million, up to EUR 5.0 million and up to EUR 7.5 million will be available to be drawn by the Company until 31 March 2025 (second credit tranche) and 31 July 2026 (third and fourth credit tranche), in each case subject to the Company's achievement of specific milestones under the Runway Loan. The milestones relate to (i) FDA clearance for ARC^{EX} for upper limb mobility or for a similar indication for the second credit tranche, and (ii) revenue achieved by the Company and the Group Companies on a consolidated basis for the most recent consecutive 12 month period ended on or before 30 June 2026, whereby (a) revenue of EUR 12.5 million is required for the third credit tranche, and (b) revenue of EUR 20.0 million is required for the fourth credit tranche. The milestone for the third credit tranche also requires the completion of the previous milestone and the milestone for the fourth credit tranche additionally requires that the second and third credit tranche have been fully funded.
- (iii) The fifth credit tranche of up to EUR 10.0 million is uncommitted and available in the first quarter of 2027 upon the sole discretion of Runway.

As at the date of this Prospectus, the Company has only received the first credit tranche, as none of the aforementioned milestones have been achieved so far. However, the Company expects to achieve the milestone for the second credit tranche sometime in the fourth quarter of 2024, as the

Company submitted its de novo application to the FDA on 2 April 2024 to allow marketing of its ARC^{EX} system to restore function of the upper extremities after SCI.

The first credit tranche was dedicated and has been used to repay all of the Company's outstanding debt. All other tranches will be used for ongoing business purposes in line with the Company's current business plan; specific uses were not defined under the Runway Loan.

The Runway Loan bears an interest rate equal to Term Secured Overnight Financing Rate (SOFR) for a three-month interest period (currently at 6.00% and subject to a 4.25% floor), plus margin of 6.50%. The first repayment under the Runway Loan is not due before 15 June 2027 at the earliest and the loan and the accrued and unpaid interest and any other outstanding obligations under the Runway Loan need to be fully repaid by latest 15 June 2029.

The Runway Loan provides for a number of customary affirmative and negative covenants by the Company and the Group Companies for financings of that type, including with respect to financial statements and reporting, taxes, insurance, intellectual property as well as financial covenants relating to minimum revenue, EBITDA (earnings before interest taxes depreciation and amortization) and liquidity requirements.

The negative covenants restrict the Company and the Group Companies, among other things, with regard to changes in business, encumbrances, certain disposals of assets and the entering into certain financial indebtedness.

In particular, with regard to the negative covenant relating to the disposal of assets, the Company and the Group Companies are not allowed to convey, sell, lease, transfer, assign, or otherwise dispose of all or any part of their business or property, except for (a) sales of inventory in the ordinary course of business; (b) non-exclusive licenses and similar arrangements for the use of the Company's or the Group Companies' intellectual property in the ordinary course of business; (c) exclusive licenses that could not result in a legal transfer of title of the licensed property but that may be exclusive with respect to territory only as to specific geographical regions outside of the US or exclusive globally with respect to secondary fields of use (relative to the Company's and the Group Companies' primary business) and so long as after giving effect to such license, the Company and the Group Companies retain sufficient rights to use the subject intellectual property so as to be enabled to continue to conduct their business in the ordinary course of business and without material impairment of the value of the subject intellectual property; (d) dispositions of worn-out, obsolete or surplus equipment in the ordinary course of business that is, in the reasonable judgement of the Company or a Group Company (depending on who is concerned), no longer economically practicable to maintain or useful; (e) transfers consisting of the granting of certain liens and the making of certain investments; (f) the use or transfer of money or cash equivalents in the ordinary course of business for the payment of ordinary course business expenses in a manner that is not prohibited by the Runway Loan; and (g) other transfers of assets having a fair market value of not more than EUR 0.5 million per fiscal year.

In particular, with regard to the negative covenant relating to entering into financial indebtedness, the Company and the Group Companies are not allowed to create, incur, assume, or be liable for any indebtedness, other than permitted indebtedness, meaning (a) the Company's and the Group Companies' indebtedness under the Runway Loan; (b) indebtedness existing on 28 June 2024 and shown on a perfection certificate, provided that (i) to the extent the amount of such type of indebtedness is limited pursuant to a clause of this definition of permitted indebtedness, amounts existing on 28 June 2024 or any permitted refinancing thereof shall count towards such limit, (ii) to the extent such indebtedness is required to be repaid on 28 June 2024, in accordance with a payoff letter delivered as a condition to closing, such indebtedness shall not constitute permitted indebtedness after such repayment, and (iii) to the extent any such indebtedness is required to be made subject to the terms of a subordination agreement as of 28 June 2024 or thereafter in which indebtedness incurred by the Company or a Group Company is subordinated to all the obligations under the Runway Loan, pursuant to the terms of the Runway Loan, such indebtedness shall be permitted only to the extent the applicable subordination agreement is in effect at 28 June 2024 (or if required thereafter, at such required date); (c) indebtedness that is subordinated in writing to all of the Company's and the Group Companies' obligations under the Runway Loan, pursuant to a

subordination agreement; (d) unsecured indebtedness to trade creditors incurred in the ordinary course of business; (e) indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of business; (f) indebtedness secured by certain liens; (g) indebtedness (i) among the Group, (ii) of the Company or a Group Company to any future subsidiary that is not a party to the Runway Loan, provided that the indebtedness shall be subordinated to the obligations under the Runway Loan on terms satisfactory to Runway, and (iii) of any future subsidiary that is not a party to the Runway Loan to the Company or a Group Company provided that the aggregate amount of such indebtedness shall not exceed USD 0.5 million; (h) any indebtedness arising under guarantees entered into pursuant to Section 2:403 of the Dutch Civil Code in respect of the Company and any residual liability with respect to such guarantees arising under Section 2:404 of the Dutch Civil Code; (i) any joint or several liability arising as a result of a fiscal unity (*fiscale eenheid*) for Dutch tax purposes; (j) indebtedness approved by Runway in its sole discretion; (k) unsecured indebtedness not exceeding EUR 0.5 million; and (l) extensions, refinancings, modifications, amendments and restatements of any items of permitted indebtedness described in clause (b) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose more burdensome terms upon the Company or a Group Company (depending on who is concerned).

The loans under the Runway Loan are secured by a security interest in substantially all of the Group's assets, including inter alia, intellectual property, cash, deposit accounts, equipment and contract rights or rights to payment of money. Runway is entitled to declare all obligations of the Company and the Group Companies immediately due and payable in an event of default, that can be constituted by a number of circumstances, including, but not limited to, (i) if the Company or a Group Company is in breach of their obligations (including payment obligations and breaches of covenants) under the Runway Loan, (ii) the Company's or a Group Company's insolvency, and (iii) the Company or a Group Company or any person acting on their behalf makes material misrepresentations to Runway. In such cases Runway may also dispose of the collateral the Group furnished to secure the Runway Loan. However, Runway's entitlement is subject to certain exemptions and cure periods.

In particular, with regard to cure periods, a breach of the Company's and the Group Companies' payment obligations under the Runway Loan does not constitute an event of default if the breach has been cured within 3 days of the due date for the respective payment obligation. Regarding a breach of covenants, a breach relating to (a) the delivery of post-closing documents; (b) the Company's and the Group Companies' representation that the security interest granted under the Runway Loan is and shall at all times continue to be a first priority perfected security interest; (c) the provision of certain financial statements, reports and certificates for Runway; (d) the timely filing and payment of taxes and pensions; (e) the insurance of the collateral that has been furnished by the Group to secure the Runway Loan; (f) the maintenance of certain deposit and securities accounts; (g) litigation cooperation; (h) granting Runway access to the pledged collateral and the Groups' books and records; or (j) the financial covenants concerning minimum revenue, EBITDA (earnings before interest taxes depreciation and amortization) and liquidity requirements, shall only constitute an event of default if such breach, to the extent capable of cure, continues without cure for at least 20 days after the date of its first occurrence. Regarding the financial covenant relating to the Group's minimum revenue and EBITDA requirements, the Company may also cure such breach by way of an equity cure, meaning that the Company shall provide to Runway evidence that it has received net cash proceeds from the issuance of its equity interests no later than 30 days after the date of the breach and in an amount of at least the shortfall in revenue or EBITDA, as applicable. In case of a successful equity cure no breach of the covenant and therefore no event of default shall be deemed to have occurred. Such equity cure cannot be used in two successive covenants test periods and the right to equity cure terminates after it has been exercised two times, or to the extent the amount of equity cure required would exceed EUR 10.0 million with respect to any such covenant failure. No cure periods exist for the Company's or a Group Company's failure to comply with the negative covenants. If the Company or a Group Company fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in the Runway Loan, no event of default shall be deemed to have occurred if such default, to the extent capable of cure, was cured within 20 days after its occurrence. Other cure periods exist in case of (a) a service of process seeking to attach, by trustee or similar process, any funds of the Company or a Group Company (cure period of 10 days for the

service of process to be discharged or stayed); (b) a filing of notice of lien or levy against the assets of the Company or a Group Company by any governmental authority (cure period of 10 days for the notice to be discharged or stayed); (c) an insolvency proceeding against the Company or a Group Company (cure period of 30 days for the insolvency proceeding to be dismissed or stayed); (d) judgements and penalties rendered against the Company or a Group Company, in an amount, individually or in the aggregate, of at least EUR 0.5 million by any governmental authority (cure period of 10 days for the judgement or penalty to be paid, vacated, or after execution thereof, stayed or bonded pending appeal); (e) any subordination agreement subordinating the Company's or a Group Company's indebtedness to all of the Company's and the Group Companies' obligations under the Runway Loan, being revoked, invalidated or otherwise ceasing to be in full force and effect, any party thereto being in breach thereof or contesting in any manner the validity or enforceability thereof or denying that it has any further obligations thereunder, or the obligations under the Runway Loan for any reason not having the priority contemplated by the Runway Loan (cure period of 10 business days to take corrective action); and (f) deficiencies identified in an inspection of the FDA or any other applicable governmental authority (cure period of 6 months to remediate such deficiencies); in case of a cure during the aforementioned cure periods no event of default shall be deemed to have occurred.

With regard to exemptions, certain events only constitute an event of default if they have resulted in or could reasonably be expected to result in a material adverse effect, meaning (a) a material impairment in the perfection of Runway's lien in the collateral or in the value of the collateral; or (b) a material adverse effect upon: (i) the business, operations, properties, assets or condition (financial or otherwise) of the Group as a whole; (ii) the prospect or repayment of any part of the obligations under the Runway Loan; or (iii) the ability of Runway to enforce any of its rights or remedies with respect to any obligations under the Runway Loan. This exemption applies to (a) any breach or default by the Company or a Group Company under any agreement to which one of them is a party with a third party or parties; (b) any governmental approval that has been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term; (c) a regulatory action or any other enforcement action against the Company or a Group Company or any of their suppliers that causes the Company or a Group Company to recall, withdraw, remove or discontinue manufacturing, distributing, and/or marketing any of its products, initiated by the FDA or any other applicable governmental authority; (d) a warning letter or regulatory action issued by the FDA or any other applicable governmental authority to the Company or a Group Company with respect to any of its activities or products; (e) a settlement agreement with the FDA or any other applicable governmental authority entered into by the Company or a Group Company (whereby it constitutes an event of default if the agreement results in aggregate liability as to any single or related series of transactions, incidents or conditions, of USD 0.5 million or more, regardless of whether such agreement could reasonably be expected to result in a material adverse effect); and (f) the withdrawal of any registration form by the Company or a Group Company from the FDA or any other applicable governmental authority. Also, some events only constitute an event of default in case certain financial thresholds are met. This applies to (a) any default under any agreement to which the Company or a Group Company is a party with a third party or parties that results in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any indebtedness, except if such third party is restricted from accelerating the maturity of such indebtedness (only for indebtedness in an amount individually or in the aggregate in excess of EUR 0.5 million); (b) judgements and penalties rendered against the Company or a Group Company by any governmental authority (only in case of an amount, individually or in the aggregate, of at least EUR 0.5 million); (c) mandatory or voluntary recalls conducted by the Company or a Group Company which could reasonably be expected to result in liability and expenses to the Company and the Group Companies, on a consolidated basis, of USD 0.5 million or more; and (d) a settlement agreement with the FDA or any other applicable governmental authority entered into by the Company or a Group Company resulting in aggregate liability as to any single or related series of transactions, incidents or conditions, of USD 0.5 million or more (whereby it constitutes an event of default if the settlement agreement could reasonably be expected to result in a material adverse effect, regardless of whether the financial threshold is met).

In addition, upon signing of the Runway Loan the Company issued warrants to Runway which entitle it to purchase Ordinary Shares in the capital of the Company at an exercise price per newly issued

share of EUR 4.83. The number of shares subject to the warrants are 5.00% of the drawn down principal amount initially and upon each subsequent loan advance, divided by the exercise price. Upon exercise of the warrants the Company will have to issue the corresponding number of Ordinary Shares to Runway. The warrants may be exercised within a period of 10 years as from (and including) 26 September 2024. The warrants will be classified as current liabilities and accounted for at fair value through profit and loss in the consolidated statement of financial position. The initial recognition will be aligned with the effectiveness of the Runway Loan as of 2 July 2024.

Legal proceedings

There are no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which the Company is aware) that may have, or have had in the 12 months before the date of this Prospectus, significant effects on the Company and/or the Group's financial position or profitability.

Regulatory framework

Clinical and Regulatory

As of June 2024, the Company had 14.8 full-time equivalents working on clinical and regulatory matters, filing submissions with the FDA, competent authorities, and other regulatory bodies and supporting the conduct of clinical trials in the US and Europe. The team is divided into two groups: (i) Clinical and (ii) Regulatory. Team members are currently based in the Netherlands, Switzerland, and the US. The Company manages regulatory matters internally and in collaboration with partners who bring required expertise in critical areas.

The Company's products and operations are subject to extensive international regulations. These regulations define guidelines for achieving commercial approvals, conducting clinical trials, and maintaining proper post-market oversight and vigilance. Once the Company commercializes its products, certain laws and regulations will govern reimbursement relationships with third-party payers, including both governmental and private health insurance plans.

In the next five years, the Company aims to seek regulatory approval to use ARC[™] to restore the ability of people with SCI to walk, normalize hypotension (low blood pressure) and potentially hypertension (high blood pressure), and regain trunk (torso) control. There are several additional potential indications that can be pursued with ARC[™].

Quality

The Company has a robust quality system that is compliant with current applicable standards such as ISO 13485, which is "designed to be used by organizations involved in the design, production, installation, and servicing of medical devices and related services"¹⁶. The Company's ISO 13485 certification has been in place since 2018 with the most recent audit conducted in late 2023 by TÜV SÜD, a well-respected Notified Body with global reach.

The Company also conducts audits of key suppliers and partners to assure their compliance with appropriate regulatory standards and company requirements.

Regulatory

The Company currently plans to commercialize its products in the US and Europe. While it is possible the Company will expand the Company's commercial operations into other markets sometime in the future, expansion into those geographies is not contemplated at this time.

Applicable Regulatory Matters

The Company's products and operations are subject to extensive and ongoing regulation by the FDA and other federal and state authorities in the United States, including the United States Federal

¹⁶ ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes.

Communications Commission ("**FCC**") as well as comparable authorities in the EEA. In the United States, the Company's ARC^{IM} and ARC^{EX} platforms are subject to regulation as a medical device under the FDCA, as implemented and enforced by the FDA.

In addition to US regulations, the Company is subject to a variety of regulations in the EEA governing clinical trials and the commercial sales and distribution of the Company's products. Whether or not the Company has or is required to obtain FDA clearance or approval for a product, the Company will be required to obtain authorization before commencing clinical trials and to obtain marketing authorization or approval of the Company's product from the comparable regulatory authorities of countries outside of the US before the Company can commence clinical trials or commercialize the Company's product in those countries. The product approval process varies from country to country and the time may be longer or shorter than that required for FDA clearance or approval.

FDA Approval and Clearance Requirements

Unless an exemption applies, each medical device in the US requires regulatory clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are clearance of a premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval. However, other devices may be commercialized after the FDA grants a de novo request for classification, or de novo classification.

Under the FDCA, medical devices are classified into one of three classes – Class I, Class II or Class III – depending on the degree of risk associated with each medical device and the level of control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to a set of regulations referred to as General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events and malfunctions, which is referred to as medical device reporting, and truthful and non-misleading labeling and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to provide a reasonable assurance of the safety and effectiveness of the device for its intended use. These special controls can include performance standards, specialized labeling and post-market surveillance. While most Class I devices are exempt from the 510(k) premarket notification requirements, most Class II devices are subject to the 510(k) premarket notification requirements. Class III devices include devices deemed by FDA to pose the greatest risk, such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. With few exceptions for certain types of devices classified into Class III that were in commercial distribution in the US before 28 May 1976, these devices are subject to the PMA application process, which is generally more costly and time consuming than the 510(k) process.

The Company believes ARC^{EX} is a Class II device that will require clearance via 510(k) de novo authorization in order to be lawfully marketed in the US. The LIFT system is currently unclassified.

Based on the similarities in risks and benefits of the ARC^{EX} system and other Class II neurostimulation and physical medicine devices, the Company believes that Class II is an appropriate level of control for the ARC^{EX} device. As such, on 2 April 2024, the Company submitted a de novo application for the ARC^{EX} system to the FDA to allow marketing of the ARC^{EX} system to restore function of the upper extremities after SCI.

The Company completed the Up-LIFT study in the fourth quarter of 2022 to seek regulatory approval to market and offer the ARC^{EX} platform for commercial sale in the US and Europe. In the US, the Company expects to pursue the de novo 510(k) clearance pathway for ARC^{EX}, first for use in the clinic and later for use in the home. Prior to initiating Up-LIFT, eight pilot studies were conducted with transcutaneous spinal cord stimulation, involving more than 50 subjects.

The Company believes ARC^{IM} is a Class III device that will require approval of a premarket approval ("**PMA**") application in order to be lawfully marketed in the US.

In Europe, under the MDR, the Company believes ARC^{EX} will be classified as a Class IIa device and ARC^{IM} will be designated as Class III. The Company expects that both devices will obtain regulatory approval (CE-mark) after review by the Notified Body, TÜV SÜD, which verifies and confirms compliance with the relevant "General Safety and Performance Requirements" of the MDR. Because MDR is a new regulatory framework, the Company cannot accurately predict the timing of expected market authorizations in Europe. While it is possible these authorizations will occur three to six months in advance of US authorization, the Company is conservatively projecting concurrent authorizations.

510(k) Clearance Process

The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, or 510(k), demonstrating to the FDA's satisfaction that the proposed device is "substantially equivalent" to a previously 510(k)-cleared device or a device that was in commercial distribution before 28 May 1976 for which the FDA has not yet called for the submission of a PMA application. The previously cleared device is known as a predicate device. A proposed device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics or (ii) different technological characteristics and does not raise different questions of safety and effectiveness and the information submitted to the FDA demonstrates that the proposed device is as safe and effective as the legally marketed device.

Before the FDA will accept a 510(k) for substantive review, the FDA will first assess whether the submission satisfies a minimum threshold of acceptability to ensure that the 510(k) is administratively complete. The acceptance review, which occurs prior to the substantive review, is generally conducted and completed under a MDUFA IV performance goal of within 15 calendar days of the FDA receiving the 510(k). If the FDA determines that the 510(k) is incomplete, the FDA will issue a "Refuse to Accept" letter which generally outlines the information the FDA believes is necessary to permit a substantive review and to reach a determination regarding substantial equivalence. The 510(k) submitter must submit the requested information within 180 days before the FDA will proceed with additional review of the submission. Once a 510(k) is accepted for review, under MDUFA IV, the FDA has 90 FDA Days to review and issue a determination, although clearance often takes longer in practice. FDA Days are calculated as the number of calendar days between the date the submission was received by the FDA and the date of the FDA's decision, excluding the days the submission was on hold pending a response to an FDA additional information request. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, for example, due to a finding of a lack of a predicate device, that the proposed device has a new intended use or different technological characteristic that raises different questions of safety or effectiveness when the proposed device is compared to the cited predicate device, the proposed device is automatically designated as a Class III device. The proposed device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the de novo process.

Alternatively, if the FDA determines that the information provided in a 510(k) submission is insufficient to demonstrate substantial equivalence to the predicate device, the FDA generally identifies the specific information that is needed so that the FDA may complete its evaluation of substantial equivalence, and such information may be provided to the 510(k) within the time allotted by the FDA or in a new 510(k) submission should the original 510(k) be withdrawn by the 510(k) submitter.

If the FDA agrees that the proposed device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance, or depending on the modification, PMA approval. The determination as to whether or not a modification could significantly affect the device's safety or effectiveness is initially left to the manufacturer. Many minor modifications are accomplished by a "letter to file" in which the manufacturer documents the rationale for the change and why a new 510(k) is not required. However, the FDA may review such letters to file to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties for marketing a modified device without the requisite 510(k) clearance or PMA approval.

De Novo Classification Process

For novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device, a manufacturer may request a risk-based classification determination, called a "Request for Evaluation of Automatic Class III Designation", for the device in accordance with the de novo classification process. This procedure allows a de novo requester whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Under MDUFA IV, the FDA's goal is to make a decision on a de novo request within 150 FDA Days, although in practice the FDA's review may take significantly longer. During the pendency of FDA's review, the FDA may issue an additional information letter, which places the de novo request on hold and stops the review clock pending receipt of the additional information requested. In the event the de novo requestor does not provide the requested information within 180 calendar days, the FDA will consider the de novo request to be withdrawn.

The FDA may reject the de novo request if it identifies a legally marketed predicate device that would be appropriate for a 510(k) submission or determines that the device is not low to moderate risk or that General Controls would be inadequate to control the risks and Special Controls cannot be developed. In the event the FDA determines that the data and information submitted demonstrate that General Controls or General and Special controls are adequate to provide reasonable assurance of safety and effectiveness, the FDA will grant the de novo request and a classification regulation will be established for the device type. When the FDA grants a de novo request for classification, the device is granted marketing authorization and can further serve as a predicate device for future 510(k) submissions by any person for future devices of that type.

PMA Approval Process

The PMA application process requires proof of safety and effectiveness of the device to the FDA's satisfaction. In a PMA, the manufacturer must provide extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, the FDA review process can often take up to several years. In some cases, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a preapproval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-

term follow-up data from patients in the clinical trial that supported PMA approval or requirements to conduct additional clinical trials post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and effectiveness data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which may affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may require no clinical data or less extensive clinical data than the original PMA or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new supplement or PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

Clinical Trials

Clinical trials are almost always required to support a PMA and are increasingly required to support a 510(k) submission. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a subject and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the applicant that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a cap on a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical trial are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, the Company, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Information about certain clinical trials must be submitted within specific timeframes for public dissemination on the ClinicalTrials.gov website. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment, registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling;
- FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- the federal Physician Sunshine Act and various state and foreign laws on reporting remunerative relationships with healthcare providers;
- the federal Anti-Kickback Statute (and similar state laws) prohibiting, among other things, soliciting, receiving, offering or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not have to have actual knowledge of this statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act (and similar state laws) prohibiting, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing, or knowingly and improperly avoiding or decreasing, an obligation to pay or transmit money to the federal government. The government may assert that items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of a cleared device, or approval of a supplement for certain modifications to PMA devices;

- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- complying with the new federal law and regulations requiring Unique Device Identifiers, or UDI, on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database, or GUDID;
- the FDA's recall authority, whereby the agency can under certain circumstances order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device. The Company may be subject to similar foreign laws that may include applicable post-marketing requirements such as safety surveillance.

The Company's manufacturing processes will be required to comply with the applicable portions of the QSR, which covers the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master record, device history file, and complaint files. As a manufacturer, the Company's facilities, records and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA. The Company's failure to maintain compliance with the QSR or other applicable regulatory requirements could result in the shut-down of, or restrictions on, the Company's manufacturing operations and the recall or seizure of the Company's products.

The discovery of previously unknown problems with a Company product candidate, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its approval, could result in restrictions on the device, including the removal of the Company product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that the Company failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of the Company's products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing PMA approvals that have already been granted;
- refusal to permit the export or import of the Company's products; or
- criminal prosecution.

Humanitarian Device Exemption Process

Obtaining approval from the FDA through the HDE, process is a two-step process. The applicant must first obtain a HUD, designation from the FDA and then submit a HDE application for premarket review by the FDA.

To qualify for HUD designation, an applicant must demonstrate that the device that will be the subject of the HDE application is designed to treat or diagnose a disease or condition, or an orphan subset of a disease or condition, that affects or is manifested in not more than 8,000 individuals in the United States per year. To be eligible to submit an HDE application, an applicant must have obtained HUD designation and there cannot be another comparable device that is legally marketed for the same intended use, other than another device approved under an HDE or IDE. Should these criteria be met, the FDA may grant an HDE, which is an exemption from the effectiveness requirements of Sections 514 and 515 of the FDCA, if FDA determines that the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from use of the devices outweighs the risk of injury or illness from its use while taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. After approval of an original HDE application, an applicant is required to submit an HDE supplement for review and approval by FDA before making any change affecting the safety or probable benefit of the device. The review timeframe for an original HDE application or HDE supplement is 75 days, although in practice the FDA's review may take significantly longer.

The total incidence number of people with SCI exceeds 8'000. However for the IDE study leading to an HDE, the inclusion criteria will be defined such that the eligible patient population will not exceed 8'000. After approval of the HDE, the Company will continue to collect clinical data that the Group expects will lead to a full PMA within 1-2 years after the HDE. This will ensure access to ARC Therapy for the broader SCI population. Holders of approved HDE applications are subject to a number of post-approval requirements unique to HDE approved devices. A HDE holder is responsible for ensuring that a HUD under an approved HDE is administered only in facilities having appropriate IRB oversight. In addition, with the exception of emergency use, approval by an IRB or an appropriate local committee is required before a HUD under an approved HDE can be used at a facility for clinical care. An HDE holder must further submit periodic reports to the FDA, which must include, among other information, information to demonstrate that the HUD designation is still valid.

Additionally, HUDs under an HDE cannot be sold for profit (i.e. an amount that exceeds the costs of research and development, fabrication, and distribution of the device), except in limited circumstances. Specifically, under section 520(m)(6)(A)(i) of the FDCA, an HUD is only eligible to be sold for profit after receiving an HDE approval if the HUD is intended for the treatment or diagnosis of a disease or condition that either:

1. Occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs;
or
2. Occurs in adult patients and does not occur in pediatric patients or occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

Even if a HUD meets the eligibility criteria to be sold for profit, the number of HDE devices that may be sold for profit in any given calendar year is limited to a quantity known as the Annual Distribution Number ("**ADN**"). If the FDA determines that an HDE holder is eligible to sell the device for profit, FDA will determine the ADN and notify the HDE holder. The ADN is calculated by taking the number of devices reasonably necessary to treat or diagnose an individual per year and multiplying it by 8,000. For example, if the typical course of treatment using an HDE device, in accordance with its intended use, requires the use of two devices per patient per year, then the ADN for that HDE device would be 16,000 (i.e. 2 x 8,000). If the number of devices distributed in a year exceeds the ADN, the HDE holder can continue to sell the device but cannot earn a profit for the remainder of the year.

If FDA is concerned that the HUD designation may no longer apply to a device, for example based on information contained in the HDE periodic reports, FDA may seek to revoke the HUD designation and/or withdraw HDE approval. Holders of approved HDE applications are further subject to similar post-approval requirements as other FDA approved devices, including medical device reporting and the requirement to conduct any post-approval study that may be required and described in an HDE approval order.

Regulation of Medical Devices in the EEA

Medical devices, other than active implantable medical devices, or AIMDs, placed on the market in the EEA (which is comprised of the 27 Member States of the EU plus Norway, Liechtenstein and Iceland) must comply with the essential requirements set out in Annex I of the Directive 93/42/EEC, also known as the Medical Devices Directive. Therefore, the Company's ARC^{EX} system, is subject to this directive.

Separately, active implantable medical devices are governed by Directive 90/385/EEC, also known as the Active Implantable Medical Devices Directive, or AIMD Directive. AIMDs are defined as medical devices that rely on a source of electrical energy or any source of power other than that generated by the body, which are totally or partially introduced, either surgically or medically, into the human body and intended to remain after the procedure. The Company believes that its products qualify as an AIMD and must therefore comply with the AIMD Directive, more specifically with the essential requirements it sets out at Annex I.

An overarching essential requirement proscribed under both the AIMD Directive and the Medical Devices Directive is that any device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in a suitable manner.

In addition to the essential requirements set out under both the AIMD and Medical Devices Directives, the European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment, and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements, creating a rebuttable presumption that the device satisfies the essential requirements.

Under the AIMD Directive, manufacturers must demonstrate compliance with the essential requirements laid down in Annex I by undergoing a conformity assessment procedure. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed to ensure and declare that the products in question comply with the standards set out in Annex I of the AIMD Directive. In addition, a conformity assessment procedure requires the intervention of a Notified Body. Notified Bodies are separate entities that are authorized or licensed to perform such assessments by the governmental authorities of each EU Member State. Manufacturers of AIMDs must make an application to a Notified Body for an assessment of its technical dossiers and quality system. Alternatively, manufacturers can seek approval from the Notified Body that a representative sample of the products it has manufactured satisfies the requirements set out in the AIMD Directive and subsequently ensure and declare that all of its products conform to the standard of the approved sample. This is also known as "type approval".

Similar requirements for conformity assessment procedures apply under the Medical Devices Directive, which vary according to the type of medical device and its classification. The Company believes that the Company's external device is categorized as a Class IIa device under Annex IX of the Medical Devices Directive. As such, the conformity assessment procedure requirements for the Company's external device are identical to those detailed above for the Company's internal product under the AIMD Directive.

If satisfied that the AIMD or other medical device conforms to the relevant essential requirements, the Notified Body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity (see above). The manufacturer may then apply the CE mark to the device, which allows the device to be legally placed on and traded within the market throughout the EEA. Once the product has been placed on the market in the EEA, the manufacturer must comply with requirements for reporting incidents and field safety corrective actions associated with the product.

In order to demonstrate safety and effectiveness for their AIMDs and other medical devices, manufacturers must conduct clinical investigations in accordance with the requirements of Annex X to the Medical Devices Directive and Annex 7 to the AIMD Directive, as well as standards (if any) which may be imposed by national authorities of EEA states in addition to those set out in Annex X to the Medical Devices Directive and Annex 7 to the AIMD Directive, or the Directives. Clinical studies for medical devices usually require the approval of an ethics review board and approval by or notification to the national regulatory authorities. Both regulators and ethics committees also require the submission of serious adverse event reports during a study and may request a copy of the final study report.

On 5 April 2017, the European Parliament adopted the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces both AIMD and Medical Devices Directives. The Medical Devices Regulation is directly applicable in the EEA. This is intended to eliminate current differences in the regulation of medical devices among EEA countries. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation became applicable on 26 May 2021. Up until this date, conformity certificates continued to be issued validly by Notifiable Bodies under the AIMD and Medical Devices Directives. Alternatively, during the three-year transition period, manufacturers could choose to conform with and have their products certified under the Medical Devices Regulations. Certificates of compliance issued pursuant to these Directives prior to 26 May 2021 will continue to be valid for up to a period of 4 years. However, after 26 May 2021, new products placed on the market may only be certified under the Medical Device Regulations regime. This new regime will, among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in Europe; and
- strengthen rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

Implementation of the MDR introduces uncertainties surrounding timelines for regulatory clearance in Europe. There are thousands of legacy devices that must be re-certified. The Company does not know what impact that will have on the capacity for Notified Bodies to assess new device applications. In the past, European clearance was generally granted in advance of US authorization and that may continue to be the case under MDR. However, the Company prefers to project conservatively and has therefore modeled European clearance at the same time as US clearance. This assumption may change as the Company has an opportunity to observe the timelines for other new device applications under MDR and its understanding of expected timelines in Europe becomes clearer.

United Kingdom's Vote to Leave the EU

Since the UK has left the EU, the regulatory system in Great Britain will differ from the EU regulatory system for medical devices (under the Northern Ireland Protocol, the EU regulatory framework on medical devices will continue to be applicable in Northern Ireland). The new Medical Devices Regulation (2017/745) ("**MDR**") is not directly applicable in Great Britain and the current regulatory framework in Great Britain is based on the Medical Devices Directive (93/42/EEC), which has now been superseded by the MDR in the EU. It is possible that, in future, the regulatory framework in Great Britain may move further away from the regulatory framework in the EU, now that divergence from EU legislation is possible.

There has been a transitional period until 30 June 2023 during which EU CE marks continued to be valid in Great Britain, however all medical devices must be registered with the Medicines and Healthcare products Regulatory Agency ("**MHRA**") before being placed on the UK market. There is a grace period to allow time for compliance with the new registration process, with high-risk devices (i.e. Class III devices and Class IIb implantables) requiring registration by 1 May 2021, and lower risk devices requiring registration later in 2021 and early 2022 (Class IIb and IIa devices from 1 September 2021 and Class I devices from 1 January 2022). Since 30 June 2023, a UK Conformity Assessed ("**UKCA**") mark is required to place a medical device on the Great Britain market (EU CE marks will continue to be recognized in Northern Ireland).

There will also be greater restrictions on some imports and exports between the UK and EU countries, and there may be increased regulatory complexities, and economic and political uncertainty in the region. Because of the continued uncertainty about the long-term effects of Brexit, the Company cannot quantify or predict with any certainty the likely long-term impact of Brexit or related legislation on the Company's business, financial condition, and results of operations.

Regulation of Medical Devices in Other Jurisdictions

The Company is subject to regulations and product registration requirements in many foreign countries in which the Company may sell the Company's products, including in the areas of:

- design, development, manufacturing and testing;
- product standards;
- product safety;
- product safety reporting;
- marketing, sales and distribution;
- packaging and storage requirements;
- labeling requirements;
- content and language of instructions for use;
- clinical studies;
- record keeping procedures;
- advertising and promotion;
- recalls and field corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- import and export restrictions;
- tariff regulations, duties and tax requirements;

- registration for reimbursement; and
- necessity of testing performed in country by distributors for licensees.

The time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

Healthcare Laws

In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal and state laws restrict the Company's business practices. These laws include, without limitation, foreign, federal, and state anti-kickback and false claims laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

Healthcare providers and third-party payors play a primary role in the distribution, recommendation, ordering and purchasing of any medical device for which the Company has to obtain marketing clearance or approval. Through its arrangements with principal investigators, healthcare professionals and customers, the Company is exposed to broadly applicable anti-fraud and abuse, anti-kickback, false claims and other healthcare laws and regulations that may constrain its business, its arrangements and relationships with customers, and how it markets, sells and distributes its marketed medical devices. The Company has a compliance program, code of business conduct and ethics and associated policies and procedures, but it is not always possible to identify and deter misconduct by its employees and other third parties, and the precautions it takes to detect and prevent noncompliance may not be effective in protecting it from governmental investigations for failure to comply with applicable fraud and abuse or other healthcare laws and regulations.

In the United States, the Company is subject to various state and federal anti-fraud and abuse laws, including, without limitation, the federal healthcare Anti-Kickback Statute and federal civil False Claims Act, federal data privacy and security laws and federal transparency laws related to payments and/or other transfers of value made to physicians and other healthcare professionals and teaching hospitals. There are similar laws in other countries. Its relationships and its distributors' relationships with physicians, other healthcare professionals and hospitals are subject to scrutiny under these laws.

Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect the Company's ability to operate include:

- the Anti-Kickback Statute, which prohibits, among other things, knowingly and willingly soliciting, offering, receiving or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual, or the purchase, order or recommendation of, items or services for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value, and the government can establish a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate. In addition, the government may assert that a claim, including items or services resulting from a violation of the Anti-Kickback Statute, constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. The Anti-Kickback Statute is subject to evolving interpretations and has been applied by government enforcement officials to a number of common business arrangements in the medical device industry. There are a number of statutory exceptions and regulatory safe harbors protecting certain business arrangements from prosecution under the Anti-Kickback Statute; however, those exceptions and safe harbors are drawn narrowly, and there may be limited or no exception or safe harbor for many common business activities, such as reimbursement support programs, educational and research grants or charitable donations. Practices that involve remuneration to those who prescribe, purchase or recommend medical devices, including discounts, providing items or services for free or engaging such individuals as consultants, advisers or speakers, may be subject to scrutiny if they do not fit squarely

within an exception or safe harbor and would be subject to a facts and circumstances analysis to determine compliance with the Anti-Kickback Statute. The Company's practices, such as trial periods or purchase of certain components from customers, may not in all cases meet all of the criteria for statutory exception or regulatory safe harbor protection from anti-kickback liability. On 30 November 2020, U.S. Department of Health and Human Services Office of Inspector General, or OIG, published a final rule effective 1 January 2022 amending the existing safe harbor protecting certain discounts to eliminate safe harbor protection for certain rebates provided by a manufacturer of prescription pharmaceutical products to a plan sponsors under Part D or pharmacy benefit managers ("**PBMs**") under contract with them. The final rule also creates new safe harbors effective 29 January 2021 for point-of-sale reductions in price on prescription pharmaceutical products and certain PBM service fees. Pursuant to an order entered by the U.S. District Court for the District of Columbia, the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D has been delayed to 1 January 2023. Implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed;

- federal civil and criminal false claims laws, including the federal civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, persons or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds and knowingly making, using or causing to be made or used, a false record or statement to get a false claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Actions under the federal civil False Claims Act may be brought by the government or as a qui tam action by a private individual in the name of the government. These individuals, sometimes known as "relators" or, more commonly, as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. Many pharmaceutical and medical device manufacturers have been investigated and have reached;
- substantial financial settlements with the federal government under the federal civil False Claims Act for a variety of alleged improper activities, including causing false claims to be submitted as a result of the marketing of their products for unapproved and thus non-reimbursable uses and interactions with prescribers and other customers, including those that may have affected their billing or coding practices and submission of claims to the federal government. Federal civil False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory monetary penalties for each false or fraudulent claim or statement. Because of the potential for large monetary exposure, healthcare and medical device companies often resolve allegations without admissions of liability for significant and material amounts to avoid the uncertainty of treble damages and per claim penalties that may be awarded in litigation proceedings;
- the HIPAA, which imposes criminal and civil liability for, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or knowingly and willfully falsifying, concealing or covering up a material fact or making a materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, ("**HITECH Act**"), and their implementing regulations, also impose obligations, including mandatory contractual terms, on covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services for them or on their behalf involving the use or

disclosure of individually identifiable health information with respect to safeguarding the privacy, security and transmission of individually identifiable health information. The Company believes it is not a covered entity or typically a business associate for purposes of HIPAA;

- the federal Physician Payments Sunshine Act, also known as Open Payments, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually, with certain exceptions, to the CMS information related to payments or other "transfers of value" made to physicians, as defined by such law, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and certified nurse-midwives; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state beneficiary inducement laws, which are state laws that require medical device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

State and federal regulatory and enforcement agencies continue to actively investigate violations of healthcare laws and regulations, and the U.S. Congress continues to strengthen the arsenal of enforcement tools. Most recently, the Bipartisan Budget Act of 2018, or BBA, increased the criminal and civil penalties that can be imposed for violating certain federal healthcare laws, including the Anti-Kickback Statute. Enforcement agencies also continue to pursue novel theories of liability under these laws. In particular, government agencies have continued regulatory scrutiny and enforcement activity with respect to manufacturer reimbursement support activities and patient support programs, including bringing criminal charges or civil enforcement actions under the Anti-Kickback Statute, federal civil False Claims Act and HIPAA's healthcare fraud and privacy provisions.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of the Company's business activities, including certain sales and marketing practices, and financial arrangements with physicians, other healthcare providers and other customers, could be subject to challenge under one or more such laws. If an arrangement were deemed to violate the Anti-Kickback Statute, it may also subject the Group to violations under other fraud and abuse laws such as the federal civil False Claims Act and civil monetary penalties laws. Moreover, such arrangements could be found to violate comparable state fraud and abuse laws.

Achieving and sustaining compliance with applicable federal and state anti-fraud and abuse laws may prove costly. If the Company or its employees are found to have violated any of the above laws, it may be subjected to substantial criminal, civil and administrative penalties, including imprisonment, exclusion from participation in federal healthcare programs, such as Medicare and Medicaid, and significant fines, monetary penalties, forfeiture, disgorgement and damages, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of the Company's operations, any of which could adversely affect its ability to operate its business and its financial results. Any action or investigation against the Company for the violation of these healthcare fraud and abuse laws, even if successfully defended, could result in significant

legal expenses and could divert its management's attention from the operation of its business. Companies settling federal civil False Claims Act, Anti-Kickback Statute or civil monetary penalties law cases also may be required to enter into a Corporate Integrity Agreement with the OIG in order to avoid exclusion from participation (i.e. loss of coverage for their products) in federal healthcare programs such as Medicare and Medicaid. Corporate Integrity Agreements typically impose substantial costs on companies to ensure compliance. Defending against any such actions can be costly, time-consuming and may require significant personnel resources, and may have a material adverse effect on its business, financial condition and results of operations.

FCC Regulation

Because the Company's products include a wireless radio frequency transmitter and receiver, it is subject to equipment authorization requirements in the United States. The Federal Communication Commission, or FCC, requires advance clearance of all radio frequency devices before they can be imported into, sold or marketed in the United States. These clearances ensure that the proposed products comply with FCC radio frequency emission and power level standards and will not cause interference.

The Company intends to submit an equipment certification application for non-experimental use to the FCC for the Company's products. Any modifications to the Company's products after FCC approval, if obtained, may require new or further FCC approval before the Company is permitted to import, market and sell a modified system, and it could take several months to obtain any necessary FCC approval. FCC approval has no impact on whether the Company will receive PMA approval.

Data Privacy and Security Laws

The Company is also subject to various federal, state and foreign laws that protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers, such as HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act, or HITECH, in the United States.

HIPAA established uniform standards governing the conduct of certain electronic healthcare transactions and requires certain entities, called covered entities, to comply with standards that include the privacy and security of protected health information, or PHI. HIPAA also requires business associates, such as independent contractors or agents of covered entities that have access to PHI in connection with providing a service to or on behalf of a covered entity, of covered entities to enter into business associate agreements with the covered entity and to safeguard the covered entity's PHI against improper use and disclosure.

The HIPAA privacy regulations cover the use and disclosure of protected health information by covered entities as well as business associates, which are defined to include subcontractors that create, receive, maintain, or transmit protected health information on behalf of a business associate. They also set forth certain rights that an individual has with respect to his or her protected health information maintained by a covered entity, including the right to access or amend certain records containing protected health information, or to request restrictions on the use or disclosure of protected health information. The security regulations establish requirements for safeguarding the confidentiality, integrity, and availability of protected health information that is electronically transmitted or electronically stored. HITECH, among other things, established certain health information security breach notification requirements. A covered entity must notify any individual whose protected health information is breached according to the specifications set forth in the breach notification rule. The HIPAA privacy and security regulations establish a uniform federal "floor" and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing protected health information or insofar as such state laws apply to personal information that is broader in scope than protected health information as defined under HIPAA.

HIPAA requires the notification of patients, and other compliance actions, in the event of a breach of unsecured protected health information, or PHI. If notification to patients of a breach is required, such

notification must be provided without unreasonable delay and in no event later than 60 calendar days after discovery of the breach. In addition, if the PHI of 500 or more individuals is improperly used or disclosed, the Company would be required to report the improper use or disclosure to the US Department of Health and Human Services, or HHS, which would post the violation on its website, and to the media. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to USD 55,910 per violation, not to exceed USD 1.68 million per calendar year for non-compliance of an identical provision, and, in certain circumstances, criminal penalties with fines up to USD 250,000 per violation and/or imprisonment.

HIPAA authorizes state attorneys general to file suit on behalf of their residents for violations. Courts are able to award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to file suit against the Group in civil court for violations of HIPAA, its standards have been used as the basis for duty of care cases in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities, such as the Group, and their business associates for compliance with the HIPAA privacy and security standards. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the civil monetary penalty paid by the violator.

In the EU, the Company may be subject to laws relating to the Company's collection, control, processing and other use of personal data (i.e. information relating to an identified or identifiable living individual). The Company processes personal data in relation to the Company's operations. The processing activities are likely not limited to these categories of data subjects: contact persons of suppliers and business contacts, applicants, visitors and website visitors, the Company's employees and the Company's customers, including health and medical information. The data privacy regime in the EU includes the General Data Protection Regulation ((EU) 2016/679), or GDPR, regarding the processing of personal data and the free movement of such data, the E-Privacy Directive 2002/58/EC and national laws supporting aspects of the GDPR and implementing the E-Privacy Directive. Each EU Member State has transposed the requirements laid down by the E-Privacy Directive into its own national data privacy regime, while the GDPR permits EU Member States to implement local legislation to supplement the GDPR, and therefore the laws may differ by jurisdiction, sometimes significantly. The Company needs to ensure compliance with the rules in each jurisdiction where the Company's processing activities are established or are otherwise subject to local privacy laws.

The GDPR became applicable on 25 May 2018, replacing the previous data protection laws issued by each EU member state based on the Directive 95/46/EC. Unlike the Directive (which needed to be transposed at national level), the GDPR text is directly applicable in each EU Member State, resulting in a more uniform application of data privacy laws across the EU. Like the previous Directive, the GDPR requires that personal data may only be collected for specified, explicit and legitimate purposes based on legal bases for processing set out in the GDPR and local laws, and may only be processed in a manner consistent with those purposes. Personal data must also be adequate, relevant, not excessive in relation to the purposes for which it is collected, be secure, not be transferred to recipients outside of the EEA unless certain steps are taken to ensure an adequate level of protection and must not be kept for longer than necessary for the purposes of collection. To the extent that the Company processes, controls or otherwise uses special categories of personal data relating to living individuals (for example, patients' health or medical information), more stringent rules apply, limiting the circumstances and the manner in which the Company is legally permitted to process that personal data and transfer that personal data outside of the EEA. In particular, in order to process such personal data, explicit consent to the processing (including any transfer) is usually required from the personal data subject (being the person to whom the personal data relates). The GDPR additionally imposes onerous accountability obligations requiring controllers and processors to maintain a record of their data processing and policies. It requires controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of information, increases requirements pertaining to pseudonymized (i.e. key-coded) data, introduces mandatory personal data breach notification requirements and sets higher standards for controllers to demonstrate that they have obtained valid

consent for certain personal data processing activities. Fines for non-compliance with the GDPR are significant—EUR 20 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher. The GDPR provides that EU member states may introduce further conditions, including limitations, to the processing of genetic data, biometric data for the purpose of uniquely identifying natural persons, or health data, which could limit the Company's ability to collect, use and share personal data, or could cause the Company's compliance costs to increase, ultimately having an adverse impact on the Company's business. In the field of handling genetic and health data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and EU member state laws have historically differed quite substantially in this field, leading to uncertainty.

The Company is subject to the supervision of local data protection authorities in those jurisdictions where the Company is established or otherwise subject to applicable law. Applicable data protection laws include numerous open norms and consequently, the Company may face uncertainty as to the exact interpretation thereof and the Company may be unsuccessful in implementing all measures required by data protection authorities or courts in the interpretation of applicable data protection laws. If the Company is investigated by a data protection authority, the Company may face fines and other penalties. Any such investigation or sanctions by data protection authorities could have a negative effect on the Company's existing business and on the Company's ability to attract and retain new clients or partners.

The Company depends on a number of third parties in relation to the Company's provision of the Company's services, a number of which process personal data on the Company's behalf. With each such provider the Company enters into contractual arrangements to ensure that they only process personal data according to the Company's instructions, and that they have sufficient technical and organizational security measures in place, and that they comply with the other contractual requirements for third-party processors set out in the GDPR. Where the Company transfers personal data to recipients outside the EEA, the Company does so in compliance with the relevant data export requirements which are also shaped by developments in the administration of justice. The EU Standard Contractual Clauses ("**SCCs**") are currently the most widely used data transfer mechanism. The European Commission published a new set of SCCs on 4 June 2021 which means that all existing agreements based on SCCs will have to be replaced by the new SCCs. The Company takes the Company's data protection obligations seriously, as any improper disclosure, particularly with regard to the Company's customers' sensitive personal data, could negatively impact the Company's business and/or the Company's reputation.

The Company may experience hesitancy, reluctance, or refusal by European or multinational clients or partners to continue to use the Company's products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with the Group. Any of the foregoing could materially harm the Company's business, reputation, prospects, financial condition and results of operations.

Healthcare Reform

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 products. The adoption of proposals to control costs could have a material adverse effect on its business, financial condition and results of operations.

For example, in the United States, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, is a sweeping measure intended to expand healthcare coverage within the United States,

primarily through the imposition of health insurance mandates on employers and individuals, the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges and the expansion of the Medicaid program. Implementation of the Affordable Care Act will impact existing government healthcare programs and will result in the development of new programs.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. On 17 June 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an Executive Order to initiate a special enrollment period from 15 February 2021 through 15 August 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact the Group's business.

To date, there have been several US Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products.

At a federal level, President Biden signed an Executive Order on 9 July 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on 24 September 2020, which went into effect on 30 November 2020, providing guidance for states to build and submit importation plans for drugs from Canada.

Further, on 20 November 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologics based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all US states and territories for a seven-year period beginning 1 January 2021, and ending 31 December 2027. The MFN is currently subject to ongoing litigation. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price the Group receives for any of the Group's product candidates.

Additionally, on 2 December 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Further, implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. Although a number of these and other proposed measures may require authorization through additional legislation to become

effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that it will continue to seek new legislative measures to control drug costs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On 2 August 2011, the Budget Control Act of 2011 was signed into law, which, among other things, includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on 1 April 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2030 unless additional Congressional action is taken. However, pursuant to the CARES Act, these reductions were suspended from 1 May 2020 through 31 December 2020 due to the Covid-19 pandemic. The Consolidated Appropriations Act of 2021, extended the suspension period to 31 March 2021. An Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes, signed into law on 14 April 2021, has extended the suspension period to 31 December 2021. On 2 January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The Company expects additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for the Company's products or additional pricing pressure.

Anti-Bribery and Anti-corruption Laws, Trade and Economic Sanctions, Export Controls and Anti-Money Launderings Laws

The Company's operations in the United States are subject to the Foreign Corrupt Practices Act, or FCPA. The Company is required to comply with the FCPA, which generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments to foreign officials for the purpose of obtaining or retaining business or other benefits. In addition, the FCPA imposes accounting standards and requirements on publicly traded US corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made.

The Company's operations are also subject to (similar) anti-bribery and anti-corruption laws, regulations and rules in other relevant countries for the Company's activities. In some jurisdictions these laws, regulations and rules also prohibit commercial bribery, such as the anti-bribery prohibitions in the Dutch Criminal Code (*Wetboek van Strafrecht*). This law generally prohibits companies and persons from offering, providing, requesting or accepting, directly or indirectly, a gift, promise or service, or anything else of value, to or from domestic or foreign government officials or to or from other persons employed or acting as an agent in relation to an act or omission to be committed or having been committed in the official's office or in violation of the other person's duty.

Sales, marketing and business arrangements in the healthcare industry are generally subject to extensive laws, regulations and rules intended to prevent fraud, misconduct, bribery, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements, for example, business arrangements for and with healthcare professionals.

The Company is further subject to trade and economic sanctions and embargoes on certain countries, persons, groups, entities, projects and/or activities, and export control regulations, applicable in the relevant jurisdictions for the Company's activities.

In addition, the Company is subject to other laws, regulations and rules, such as relating to (the prevention of) money laundering and the financing of terrorism in the relevant jurisdictions for the Company's activities, including but not limited to the money laundering and terrorism financing prohibitions in the Dutch Criminal Code (*Wetboek van Strafrecht*).

Group structure

The Company is composed of ONWARD Medical N.V. (incorporated on 20 November 2015) and its wholly-owned subsidiaries:

- ONWARD Medical SA (the Swiss subsidiary established on 12 December 2014); and,
- ONWARD Medical Inc. (the US subsidiary established on 13 September 2013).

The Company and its subsidiaries act as one company, the subsidiaries are mainly established to follow local regulation.

MANAGEMENT AND CORPORATE GOVERNANCE

This section gives an overview of the material information concerning the Board and its corporate governance as reflected in the Articles of Association, the rules regarding the Board's functioning and internal organization (the "**Board Rules**"). This summary does not purport to give a complete overview and should be read in conjunction with, and is qualified in its entirety by reference to the relevant provisions of Dutch law in effect as at the date of this Prospectus as well as the Articles of Association and the Board Rules. The full text of the Articles of Association (in Dutch, and an unofficial English translation thereof) and the Board Rules (in English) are available free of charge on the Company's website (<https://ir.onwd.com/corporate-governance/documents/articles-of-association> and <https://ir.onwd.com/corporate-governance>).

Board Structure

The Company has a one-tier board consisting of one or more executive directors (uitvoerend bestuurders) (the "**Executive Directors**") and one or more non-executive directors (*niet-uitvoerend bestuurders*) (the "**Non-Executive Directors**").

Board

Powers, responsibilities and functioning

The Board is charged with the management of the Company, subject to the restrictions contained in the Articles of Association, with the Executive Directors being primarily charged with the Company's day-to-day operations and the Non-Executive Directors being primarily charged with the supervision of the performance of the duties of the Executive Directors. As a matter of Dutch law, the Board's duties include determining the policies and strategy of the Company. In performing their duties, Directors are guided by the interests of the Company and of the business connected with it, taking into consideration the interests of the Company's stakeholders (which includes but is not limited to its business partners, its employees and the Shareholders). The Board has drawn up a profile for its size and composition taking into account the nature of the Company's business, the Company's activities and the desired expertise, independence and background of the Non-Executive Directors

Each Director is charged with all tasks and duties of the Board that are not delegated to one or more other specific Directors by virtue of Dutch law, the Articles of Association or an arrangement catered for in the Articles of Association, such as the Board Rules. The Directors may allocate their duties among themselves in or pursuant to the Board Rules or otherwise pursuant to resolutions adopted by the Board, provided that:

1. the Executive Directors shall be charged with the Company's day-to-day operations;
2. the task of supervising the performance of the duties of the Directors cannot be taken away from the Non-Executive Directors;
3. the Chairperson of the Board must be a Non-Executive Director; and
4. the making of proposals for the appointment of a Director, the determination of the compensation of the Executive Directors and the instruction of an external accountant (in cases where the General Meeting did not instruct an external auditor) cannot be allocated to an Executive Director.

The Board must submit certain important decisions to the General Meeting for approval, as described below in more detail under "*Board Meetings and decisions*".

The Board is entitled to represent the Company. The power to represent the Company also vest in two Executive Directors acting jointly or an Executive Director acting jointly with the holder of a power of attorney to that effect, granted in accordance with the Articles of Association. The Board is authorized to appoint proxy holders (*procuratiehouders*) who are authorized to represent the Company within the limits of the specific delegated powers provided to them in the proxy.

Board Rules

The Board has adopted the Board Rules that govern, among other things, its decision-making process and conduct of meetings. The Board Rules are in effect since 21 October 2021 and may be amended from time to time.

Composition, appointment and removal

The Company has a Board composed of individuals. The Board shall consist of one or more Executive Directors and one or more Non-Executive Directors. The Board may determine the exact number of Executive Directors and Non-Executive Directors. When appointing a Director, the General Meeting shall specify, at the proposal of the Board, whether the Director is appointed as an Executive Director or as a Non-Executive Director.

The General Meeting shall appoint the Directors and may at any time suspend or dismiss any Director. In addition, the Board may at any time suspend an Executive Director. A resolution of the General Meeting to suspend or dismiss a Director shall require a majority of at least two-thirds of the votes cast representing more than half of the issued share capital, unless the resolution is passed at the proposal of the Board. The General Meeting can only appoint Directors upon a nomination by the Board. The General Meeting may at any time resolve to render such nomination to be non-binding by a majority of at least two thirds of the votes cast representing more than half of the issued share capital. If a nomination is rendered non-binding, a new nomination shall be made by the Board. If the nomination comprises one candidate for a vacancy, a resolution concerning the nomination shall result in the appointment of the candidate, unless the nomination is rendered non-binding.

At a General Meeting, a resolution to appoint a Director can only be passed in respect of candidates whose names are stated for that purpose in the agenda of that General Meeting or the explanatory notes thereto.

The Board shall elect one of the Non-Executive Directors to be the Chairperson of the Board (the "**Chairperson**") and one of the Non-Executive Directors to be the Vice-Chairperson of the Board (the "**Vice-Chairperson**"). The Board may dismiss the Chairperson or Vice-Chairperson, provided that the Chairperson or Vice-Chairperson so dismissed shall subsequently continue his or her term of office as Non-Executive Director without having the title of Chairperson or Vice-Chairperson.

If a Director is absent or incapacitated, he or she may be replaced temporarily by a person whom the Board has designated for that purpose and, until then, the other Director(s) shall be charged with the management of the Company. If all of the Directors are absent or incapacitated, the management of the Company shall be attributed to the person who most recently ceased to hold office as the Chairperson, provided that if such former Chairperson is unwilling or unable to accept that position, the management shall be attributed to the person who most recently ceased to hold office as the Company's Chief Executive Officer. If such former Chief Executive Officer is also unwilling or unable to accept that position, the Company's management shall be attributed to one or more persons whom the General Meeting has designated for that purpose. The person(s) charged with the Company's management in this manner may designate one or more persons to be charged with the Company's management instead of, or together with, such person(s).

Term of appointment

There are no rules of mandatory Dutch law concerning the maximum terms of office, or the maximum number of consecutive terms of office, of Directors. Under the Code (as defined below), a person may be appointed as Executive Director for maximum terms of four years each, without a limitation on the number of consecutive terms. A person may be appointed as Non-Executive Director for a maximum of two consecutive four-year terms and, subsequently, for a maximum of two consecutive two-year terms. In the case of a reappointment of a Non-Executive Director after an eight-year period, the Company's board report should disclose the reasons for such reappointment.

Each of the Directors of the Board have been appointed prior to the date of this Prospectus (see table under the heading "Directors" below) and each of the appointments shall terminate:

- In respect of Grégoire Courtine, at the end of the annual General Meeting 2027;
- In respect of Jan Øhrstrøm and John de Koning, at the end of the annual General Meeting 2028;
- In respect of Dave Marver, Ian Curtis and Fredericus Colen, at the end of the annual General Meeting 2025;
- In respect of Rob ten Hoedt and Rahma Samow, who are interim Non-Executive Directors, at the end of the annual General Meeting 2025;
- In respect of Kristina Dziekan, at the end of the annual General Meeting 2026; and
- In respect of Vivian Riefberg, at the end of the annual General Meeting 2027.

Board Meetings and decisions

The Board meets as often as any Director considers necessary or appropriate. Decisions of the Board shall be passed by simple majority of votes cast. Where there is a tie in any vote of the Board the relevant resolution shall not have been passed.

The approval of the General Meeting is required for resolutions of the Board concerning a material change to the identity or the character of the Company or the business, including in any event:

1. transferring the business or materially all of the business to a third party;
2. entering into or terminating a long-lasting alliance of the Company or of a subsidiary either with another entity or company, or as a fully liable partner of a limited partnership or general partnership, if this alliance or termination is of significant importance for the Company; and
3. acquiring or disposing of an interest in the capital of a company by the Company or by a subsidiary with a value of at least one third of the value of the assets, according to the balance sheet with explanatory notes or, if the Company prepares a consolidated balance sheet, according to the consolidated balance sheet with explanatory notes in the Company's most recently Adopted Annual Accounts.

Conflict of interest

Dutch law provides that a Director may not participate in the adoption of resolutions (including deliberations in respect of these) if he or she has a direct or indirect personal interest conflicting with the interests of the Company. The mere fact that a Director has a personal interest in relation to a specific matter does not necessarily lead to the qualification of a conflict of interests. In order to qualify as a conflict of interests, the personal interests involved must be so incompatible with those of the Company and its business, that there are reasonable grounds for doubting whether the actions and decisions of the Director concerned were guided exclusively by the interests of the Company. If no resolution can be adopted by the Board as a consequence of such a personal conflict of interest, the resolution concerned may nevertheless be passed by the Board as if none of the Directors has a conflict of interest. If a Director does not comply with these provisions on conflicts of interest, the resolution concerned is subject to nullification (*vernietigbaar*) in accordance with Dutch law. The existence of a conflict of interest does not affect the authority to represent the Company, as described under "*Board—Powers, responsibilities and functioning*" above.

Under the Code (as defined below) and the Board Rules, each Director shall immediately report any actual or potential conflict of interest that is of material significance to the Company and/or to the relevant Director, to the Chairperson and to the other Directors and shall provide all information relevant to the conflict, including any relevant information concerning his or her spouse, registered partner or other life companion, foster child and relatives by blood or marriage up to the second degree. The determination whether a Director has a conflict of interest shall primarily be the responsibility of that Director. However, in the case of debate, the Board has the authority, after having heard the relevant Director and without that relevant Director being present, to determine whether a reported matter qualifies as a conflict of interest within the meaning of Dutch law.

Under the Code (as defined below) and the Board Rules, all transactions in which there are conflicts of interests with Directors will be agreed on terms that are customary, must be disclosed in the Company's board report and, if the conflict of interest is of material significance to the Company and/or the relevant Director, require the approval of the Board.

Directors

At the date of this Prospectus, the Board is composed of the following Directors:

Name	Year of birth	Position	Initial Year of Appointment	Expiration of appointment
Dave Marver	1968	Executive Director and CEO	2020	End of the annual General Meeting to be held in 2025
Jan Øhrstrøm	1957	Non-Executive Director and Chairperson	2016	End of the annual General Meeting to be held in 2028
Grégoire Courtine	1975	Non-Executive Director and CSO	2016	End of the annual General Meeting to be held in 2027
Fredericus Colen	1952	Non-Executive Director	2017	End of the annual General Meeting to be held in 2025
Ian Curtis	1968	Non-Executive Director and Vice-Chairperson	2019	End of the annual General Meeting to be held in 2025
Kristina Dziekan	1968	Non-Executive Director	2022	End of the annual General Meeting to be held in 2026
John de Koning	1968	Non-Executive Director	2016	End of the annual General Meeting to be held in 2028
Vivian Riefberg	1960	Non-Executive Director	2023	End of the annual General Meeting to be held in 2027
Rahma Samow	1979	Interim Non-Executive Director	2024	End of the annual General Meeting to be held in 2025
Rob ten Hoedt	1960	Interim Non-Executive Director	2024	End of the annual General Meeting to be held in 2025

The Company's registered address, Schimmelt 2, 5611 ZX Eindhoven, the Netherlands, serves as the business address for all Directors.

Biographies Executive Director and Non-Executive Directors

Mr. D.L. (Dave) Marver (born 1968, United States) is the CEO and the Company's Executive Director since 1 July 2020. Dave Marver has over twenty-five years of management experience in the medical technology industry. From 1994 to 2008, Dave Marver worked at Medtronic PLC, one of the world's largest medical device companies, where he held a number of senior leadership roles in the USA and Europe. Dave Marver's roles at Medtronic PLC included Vice President Sales, Vice President Marketing, and Vice President Strategy and Business Development for the Cardiac Rhythm Management, Cardiac Surgery, and Diabetes businesses. Dave Marver later served as CEO and Director of Cardiac Science Corporation and its successor (2008 to 2012), a NASDAQ-listed company that was a leader in automatic external defibrillators and other medical equipment for cardiology. Dave Marver has served as a Director or Officer for several other companies, including Vicis, Inc. (2014 to 2019), Marine Construction Technologies, PBC (2012 to 2020), Buttonwood Network, Inc. (2019 to 2021), Cirtec Medical, Inc. (2014 to 2017) and JointMetrix Medical, LLC (2012 to 2019). He also served as medical technology adviser to the International Finance Corporation's World Bank Group in 2013. Vicis Inc. was placed into receivership in December 2019, Dave Marver was no longer a director or officer at that time. Dave Marver holds a Bachelor's degree in Psychology from Duke

University and a Master's in Business Administration from the University of California Los Angeles, United States.

Mr. J.K. (Jan) Øhrstrøm (born 1957, Denmark) is the Company's Chairperson and a Non-Executive Director since March 2016. Jan Øhrstrøm has over ten years of management experience in the medical technology industry. Next to his position as independent Chairperson of the Company, Jan Øhrstrøm is also Chairman of the Board of Directors of (i) Blaze Bioscience Inc. (since 2015), specializing in injectables for fluorescence guided surgery, and (ii) VarmX B.V. (since 2018), specializing in FXa reversal agent (blood clotting). He was an independent Board Director at Polyganics B.V. (2016 to 2022), specializing in polymer based surgical products. From 2015 to 2019, Jan Øhrstrøm was Chairman of Biomup SA, a medical company specializing in blood clotting. Biomup SA went into bankruptcy in December 2019 after not being able to penetrate the US market. The assets were sold off to the company's biggest debt holder and thereafter the company was delisted and went into liquidation. Jan Øhrstrøm holds the title of Medical Doctor from the University of Copenhagen. Jan Øhrstrøm is the Chair of the Nominating and Corporate Governance Committee as well as the Chair of the Compensation Committee.

Professor Mr. G.R. (Grégoire) Courtine (born 1975, France) is the Company's Chief Scientific Officer (since founding), a Non-Executive Director and the founder of the Company. Prof. Grégoire Courtine is full Professor of neuroscience and neurotechnology in the faculty of Life Science at the Swiss Federal Institute of Technology and at the faculty of biology and Medicine at the University of Lausanne, Switzerland. Prof. Grégoire Courtine is also Director of the Defitech center for interventional neurotherapies (.NeuroRestore) at the University hospital of Lausanne, Lausanne Switzerland. Professor Courtine has received several international research and innovation prizes, including the Chancellor's Award for post-doctoral research from University of California (Los Angeles), the International Foundation for Research in Paraplegia Schellenberg Research prize, the Debiopharm Group Life Science Award, the Leenaard Award, Bing Prize, the Rolex Award, and the IET AF Harvey Prize. In May 2024, he was recognized in the Time 100 Health list recognizing the 100 most influential individuals in health.

Mr. F.A. (Fredericus) Colen (born 1952, The Netherlands) is a Non-Executive Director of the Company. Fredericus Colen has over 40 years of experience in the medical device industry. He served as President and Chief Executive Officer of Neovasc, a public medical device company developing, manufacturing and marketing products for the cardiovascular marketplace (2018 to 2023) and was a Board Member at Mölnlycke Healthcare from 2012 to 2017 and a Board Member at Middle Peak Medical from 2015 to 2017. He currently serves as President for MedTech Lighthouse (since 2015) and as Chairman of the Board for Xeltis (since 2023). Fredericus Colen holds an MS at the RWTH Aachen, Germany. Fredericus Colen is a Member of the Compensation Committee as well as a Member of the Audit Committee.

Mr. I. (Ian) Curtis (born 1968, United Kingdom) is a Non-Executive Director since October 2019. Next to his position at the Company Ian Curtis is Company Director at HPC plc, a UK based engineering company (from 2004 onwards). Ian Curtis is also director at the Christopher and Dana Reeve Foundation (since 2015), director at the International Spinal Research Trust (since 2015), and director at the Neurokinex Charitable Trust (since 2016). Ian Curtis was formerly an Audit and Assurance Partner with PricewaterhouseCoopers LLP (1990 to 2004). Ian Curtis holds a BA in History from Durham University, United Kingdom, and is an FCA (Fellow Chartered Accountant) member of the Institute of Chartered Accountants in England and Wales. Ian Curtis is the Chair of the Audit Committee.

Mrs. K. (Kristina) Dziekan (born 1968, Germany) is currently an independent strategy advisor working with various innovative medical technology and digital health companies and was Head of Market Access, Government Affairs, and Tendering for Alcon's Surgical Division in Europe (2020 to 2023). She previously served as Senior Global Reimbursement and Health Economics Director for Medtronic Neuromodulation and was Health Outcomes Manager for GlaxoSmithKline in the UK and parts of Asia. She earned an MSc in health policy, planning, and financing from the London School of Economics, an MA in international economics and European Studies from Johns Hopkins University,

a BA in philosophy, politics, and economics from Oxford University, and a Vordiplom in business administration and economics from Georg August University.

Dr. Mr. J.P. (John) de Koning (born 1968, The Netherlands) is a Non-Executive Director since 2016. John de Koning is a general partner at EQT Life Sciences, one of Europe's largest healthcare investment firms that supported the growth of hundreds of companies since its inception. John de Koning joined EQT (formerly LSP) in 2006 and holds various board memberships, he was amongst others a board member of Argenx (2009 to 2017) and Merus (2010 to 2020), and is currently a board member of eTheRNA (2016), VarmX (2020) and Visus Therapeutics (2021). John de Koning holds a Ph.D. Oncology at Erasmus University Rotterdam, the Netherlands and a post-doctorate at the UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, USA. John de Koning is a Member of the Nominating and Corporate Governance Committee.

Mrs. V. (Vivian) Riefberg (born 1960, United States) is currently the David C. Walentas Jefferson Scholars Chair Professor of Practice at the Darden School of Business at the University of Virginia and serves on the boards of Waystar, Accompany Health, K Health, and Lightrock, an impact investing firm, as well as of the Public Broadcasting System (PBS), Johns Hopkins Medicine, the Lorna Breen Heroes Foundation, and the National Education Equity Lab. She is also an advisory board member for the Smithsonian's planned American Women's History Museum. She previously served on the US National Institutes of Health (NIH) Clinical Center Board of Governors and the NIH Advisory Board for Clinical Research. She also served on the Board of Directors of the Partnership for a Healthier America (PHA), a non-profit organization created to mobilize efforts to solve the child obesity challenge as an outgrowth of First Lady Michelle Obama's Let's Move campaign. She holds a BA, magna cum laude in history from Harvard-Radcliffe College and an MBA with distinction from Harvard Business School.

Mrs. R. (Rahma) Samow (born 1979, Germany) is an interim Non-Executive Director since 14 October 2024. She was previously President and CEO of ClearChoice Dental Implant Centers, a rapidly growing US-based provider of cosmetic dental services with over 2,000 employees. Before her tenure at ClearChoice, she served on the Executive Management Board of the Swiss-based Straumann Group. She also boasts a 15-year career with Siemens, where she held various roles in sales, marketing, and communications, with geographic responsibilities spanning the US, Germany, Middle East, and Africa. Mrs. Samow holds a Diploma in Medical Radiology, Radiation Therapy and Nuclear Medicine Technology from the Medical University of Bonn, Germany.

Mr. R.J.W. (Rob) ten Hoedt (born 1960, The Netherlands) is an interim Non-Executive Director since 14 October 2024. He was previously Executive Vice President & President of Global Regions at Medtronic, overseeing the Americas, EMEA, and Asia Pacific. With over 30 years in the medical device industry, he has held senior roles at Medtronic, including General Manager of Vitatron, a Medtronic subsidiary, and leader of the Western European Cardiovascular business. Before joining Medtronic, Mr. ten Hoedt held roles at Arjo Hospital Equipment and Polystan Benelux and ran his own medical technology distribution company. He is Chairman of the Board at MedTech Europe and serves on the boards of Fagron International, NLC Health, and Pixium Vision. He holds a degree in Commercial Economy from H.E.A.O. and a master's in Marketing from NIMA Business School in the Netherlands.

Management Team

The Company's Management Team consists of the following persons

Name	Year of birth	Position	Member Since
Dave Marver	1968	CEO	2020
Grégoire Courtine	1975	CSO	2016

Amori Fraser	1983	Interim Chief Financial Officer and Finance Director	2024
Julien Camisani	1978	Vice President Engineering	2024
Erika Ross	1987	Vice President Global Clinical and Regulatory	2023
Sarah Moore ¹	1977	Vice President Global Marketing	2023
Robert Odell	1960	Vice President Operations	2023 ²

1 Sara Moore's contract will terminate with effect from 31 October 2024.

2 Robert Odell joined as VP Operations on 1 July 2023, succeeding Zouhir Mechta.

Biographies Management Team

Mr. D.L. (Dave) Marver (born 1968, United States), see above.

Professor Mr. G.R. (Grégoire) Courtine (born 1975, France), see above.

Mrs. A. (Amori) Fraser (born 1983, South Africa) serves as the Interim Chief Financial Officer and Finance Director at the Company, leveraging over 18 years of experience in both finance and auditing. Prior to her current role, she worked as a Senior Manager at EY, specializing in financial reporting, regulatory compliance, financial analysis and internal controls serving multi-national listed groups. Amori holds a BComHons degree in Accounting Sciences from the University of Pretoria and is a qualified Chartered Accountant (CA) with the South African Institute of Chartered Accountants (SAICA).

Mr. J (Julien) Camisani (born 1978, Switzerland) brings more than 20 years of experience, fifteen of which are in the life sciences industry, where he has been instrumental in inventing, developing, marketing, and sustaining advanced laboratory, medical and bio-manufacturing technologies. Prior to joining the Company, Julien led diverse and global teams and managed large-scale projects with proven leadership across research and development, manufacturing, intellectual property and product management for companies like Cytiva, GE Healthcare and Biosafe. He holds dual master's degrees in Embedded Systems from the University of Lugano, collaborating with ETH Zurich and Politecnico di Milano, completed by an MBA from the University of Cumbria and a professional certificate in Technology Road Mapping and Strategic Innovation from MIT.

Dr. E. (Erika) Ross (born 1987, United States) joined ONWARD from Abbott Neuromodulation, where she was Director, Global Clinical & Applied Research. Previously, as Neuroscience Director at Cala Health, she managed the scientific research program that led to de novo clearance and launch of the company's neurostimulation technology. Erika also served as Deputy Director, Medical Device Innovation Accelerator, Department of Surgery and Assistant Professor, Department of Neurologic Surgery at Mayo Clinic. Erika holds a BSc in Biology and Business and an MSc in Molecular Biology from the University of Denver, and a PhD in Neuroscience from Mayo Clinic.

Mrs. S. (Sarah) Moore (born 1977, United States) has over 20 years of experience in marketing and general management. Before joining ONWARD, Sarah served as Head of Commercial Marketing for Nevro, an implantable neuromodulation company. Prior to that, she held various leadership roles in global marketing across multiple Johnson & Johnson medical device franchises, most recently as the business unit leader for J&J's Advanced Imaging business. Sarah earned an MBA from Duke University and a BA in German from Washington and Lee University.

Mr. R. (Bob) Odell (born 1960, United States) brings to ONWARD decades of technology and leadership experience in the medical device industry. Prior to joining ONWARD, Bob was President and Chief Operating Officer of Cardiac Insight, Inc., a successful startup who created and introduced disruptive cardiac monitoring technology. Prior to Cardiac Insight, he served as COO for Cardiac

Insight, a publicly traded manufacturer of Class II and Class III devices. Bob has held executive assignments in Operations, Engineering, Marketing, Business Development, Information Technology, and QA/RA with such notables as GE Healthcare, Siemens Medical Solutions, Philips Medical Systems, Medtronic, and Analogic. The foundation for his career is a degree in electrical engineering from Syracuse University.

Diversity

Dutch companies with a listing on a regulated market in the Netherlands, such as the Company, have to comply with a quota of at least one-third for both women and men on supervisory boards, in each case rounded up to the nearest integer. In a one-tier board, such as the Board, this one-third quota applies to the non-executive directors. Under these rules, for as long as the Board is not 'gender balanced' under this quota, a Non-Executive Director of the overrepresented gender cannot be appointed or re-appointed, unless (a) it concerns the re-appointment of an incumbent Non-Executive Director within the first eight years of his/her service on the Board or (b) the appointment or re-appointment is necessary in order to serve the long-term interests and sustainability of the Company or to safeguard the Company's viability, provided that the (re)appointment is for a period of no more than two years. An appointment or reappointment in violation of these rules is in principle regarded as null and void (*nietig*). As a result, the person in question would not become a Non-Executive Director.

As of the date of this Prospectus, the Company is compliant with these rules.

In addition to the quota described above, if the Company qualifies as a "large company" for audit purposes under Dutch law (see below under *Maximum Number of Non-executive Positions of Directors*), the Company must set itself suitable and ambitious targets, in the form of a target percentage or number, in order to improve the 'gender balance' within senior management (as defined by the Company) and the Company must report on these diversity matters to the Dutch Social Economic Council and in its annual corporate governance statement.

Diversity Policy

The Board has adopted a diversity policy with respect to the composition of the Board that became effective on 21 October 2021. The Company believes that it is important for the Board to represent a diverse composite mix of personal backgrounds, experiences, qualifications, knowledge, abilities and viewpoints. The Company seeks to combine the skills and experience of long-standing members of the Board with the fresh perspectives, insights, skills and experiences of new members. For this reason, the Company commits to, as part of its diversity policy, to support, value and leverage diversity and to comply with all applicable statutory provisions. The Company discloses its diversity policy, as well as the objectives, implementation and results of such policy, as part of its annual corporate governance statement. If the composition of the Board diverges from the objectives included in the Company's diversity policy, the Company's current state of affairs should be outlined in the Company's annual corporate governance statement, indicating which measures are being taken to achieve the intended objectives, and by when these objectives are likely to be achieved.

Maximum Number of Non-executive Positions of Directors

Under Dutch law, restrictions apply with respect to the overall number of supervisory positions that executive or non-executive directors (including managing directors or supervisory directors on a two-tier board) of "large Dutch companies" may hold. The term "large Dutch companies" applies to Dutch public limited liability companies, Dutch private limited liability companies and Dutch foundations that meet at least two of the following three criteria on two consecutive balance sheet dates without interruption (in principle, determined on a consolidated basis): (i) the value of the company's/foundation's assets according to its balance sheet together with explanatory notes, on the basis of the purchase price or manufacturing costs exceeds EUR 20 million; (ii) its net turnover in the applicable year exceeds EUR 40 million; and (iii) its average number of employees in the applicable year is 250 or more. For purposes of these limitations, positions with non-Dutch entities will not be

taken into account and large companies and large foundations which belong to the same group are considered to be one and the same entity.

A person cannot be appointed as an executive or managing director of a "large Dutch company" if he or she already holds a position as supervisory director or non-executive director at more than two other "large Dutch companies" or if he or she is the chairperson of the supervisory board or one-tier board of another "large Dutch company". Also, a person cannot be appointed as a non-executive director or supervisory director of a "large Dutch company" if he or she already holds a supervisory position at five or more other "large Dutch companies", whereby the position of chairperson of the one-tier board or supervisory board of another "large Dutch company" is counted twice.

In addition, under certain circumstances in bankruptcy proceedings, a person may be prohibited by a Dutch court from being appointed as executive or non-executive director (or as managing director or supervisory director on a two-tier board). Such a prohibition can be imposed for up to five years and would be registered with the Dutch Trade Registry.

As of the date of this Prospectus, the Company does not qualify as a large Dutch company for purposes of these provisions.

Potential Conflicts of Interest and Other Information

Other than the circumstances described below, there are no potential conflicts of interests between any duties to the Company, of each of the Directors and members of the Management Team, and their private interests and/or other duties. According to best practice principle 2.7.4 of the Dutch corporate governance code issued on 20 December 2022 ("**Dutch Corporate Governance Code**" or the "**Code**"), the Company will report on Directors' conflicts of interest in transactions in its management report where the conflict of interest is of material significance to the Company and/or to the relevant Director.

Certain Directors and members of the Management Team have a direct or indirect beneficial interest in Ordinary Shares. See "*Interests of the Directors and the Management Team*" for the interests of the Directors and members of the Management Team in the share capital of the Company. In addition:

- Grégoire Courtine is the Chief Science Officer and also a Non-Executive Director of the Company
- John de Koning has been designated as Non-Executive Director by LSP V Coöperatieve U.A. (now EQT Life Sciences), a major Shareholder of the Company at the date of the Prospectus.

Since certain Directors have been designated by major Shareholders of the Company, their interests may not be aligned with the interest of the Company, which may result in a conflict of interest. In their capacity as Non-Executive Directors, the primary duty of each of the Non-Executive Directors is to supervise the performance of the duties of the Executive Directors and the general course of affairs in the Company and the business affiliated with the Company. A conflict of interest between the Company and any of the Non-Executive Directors listed above could arise where a decision that aims to contribute to the long-term and sustainable success of the Company would impact the (short-term) share price of the Ordinary Shares and thus the (indirect) shareholding of the respective Non-Executive Director.

Independence of Board members

At the date of this Prospectus the Board consists of ten members, nine of which are Non-Executive Directors. At the date of this Prospectus, two of the Non-Executive directors are deemed "not independent" within the meaning of the Dutch Corporate Governance Code at the date of the Prospectus.

Prof. Courtine, one of the Company's founders, is considered "not independent" as he is the Chief Science Officer of the Company and receives personal compensation for such role. John de Koning is considered "not independent" as he is a representative of major shareholders holding at least 10%

of the shares in the Company (EQT Group (formerly LSP)). The Board considers that Grégoire Courtine and John de Koning fit the intended profile of the Board and that their contributions outweigh any perceived disadvantage of non-independence. In addition, the Company deems continuity in the composition of the Board to be of great importance.

Other than the circumstances noted above, there are as of the date of this Prospectus no potential conflicts between the personal interests or other duties of the Directors on the one hand and the interests of the Company on the other hand. Other than the circumstances noted above (see "*Biographies Executive Director and Non-Executive Director*" under Dave Marver and Jan Øhrstrom), during the last five years, none of the Directors: (i) has been convicted of fraudulent offenses; (ii) has served as a director or officer of any entity subject to bankruptcy proceedings, receivership; or (iii) has been subject to any official public incrimination and/or sanctions by statutory or regulatory authorities (including designated professional bodies), or disqualification by a court from acting as a member of the administrative, management or supervisory body of an issuer, or from acting in the management or conduct of the affairs of any issuer.

Other than as disclosed in the section "*Shareholder Structure and Related Party Transactions*" below, the Company is not aware of any arrangement or understanding with any shareholders, customers, suppliers or others, pursuant to which any person was selected as a member of a corporate body of the Company.

Related Party Transaction Policy

The Company does not have and does not expect to have a related party transaction policy. However, the Company intends to follow the recommendation of the Code (as defined below) that all transactions between the Company and a shareholder holding 10% or more of the Company's issued share capital should be agreed on customary terms, that decisions to enter into such a transaction that is of material significance to the Company and/or to the shareholder concerned should be approved by the Board and that any such transaction will be disclosed in the Company's board report, together with an affirmative statement that these recommendations of the Code (as defined below) have been complied with. Furthermore, as noted under "*Description of Share Capital—Obligations to Disclose Holdings—Related Party Transactions*", certain rules apply under the DCC with respect to transactions with a "related party" (as defined in those rules) and, under those rules, the Board is required to, and shall, establish an internal procedure to periodically assess whether transactions with related parties are concluded in the ordinary course of business and on normal market terms.

Liability of Directors

Under Dutch law, Directors may be liable towards the Company and, under circumstances, third parties for damages in the event of improper or negligent performance of their duties. They may be held liable for damages towards the Company for infringement of the Articles of Association or of certain provisions of Dutch law. In addition, they may be liable towards third parties for infringement of certain provisions of the DCC. Depending on the circumstances, they may also incur additional specific civil, administrative and criminal liabilities.

Subject to certain exceptions, the Articles of Association provide for indemnification of current and former Directors and other current and former officers and employees of the Company as designated by the Board as described below under *Indemnification*.

Insurance

The Executive Director and Non-Executive Directors are insured under a Directors and Officers Liability Insurance policy taken out by the Company against damages resulting from their conduct

when acting in their capacities as Directors. The insurance also covers for the directors at the Company's subsidiaries level.

Indemnification

Based on the Articles of Association, the Company shall indemnify and hold harmless each of its current or former Directors or such current or former officer or employee of the Company or its Group Companies as the Board may determine at its absolute discretion (an "**Indemnified Officer**") against:

- any financial losses or damages incurred by such Indemnified Officer; and
- any expense reasonably paid or incurred by such Indemnified Officer in connection with any threatened, pending or completed suit, claim, action or legal proceedings of a civil, criminal, administrative or other nature, formal or informal, in which he becomes involved,

to the extent this relates to the Indemnified Officer's current or former position with the Company and/or a Group Company and in each case to the extent permitted by applicable law.

No indemnification shall be given to an Indemnified Officer:

- if a competent court or arbitral tribunal has established, without having (or no longer having) the possibility for appeal, that the acts or omissions of such Indemnified Officer that led to the financial losses, damages, expenses, suit, claim, action or legal proceedings are of an unlawful nature (including acts or omissions which are considered to constitute malice, gross negligence, intentional recklessness and/or serious culpability attributable to such Indemnified Officer);
- to the extent that the Indemnified Officer's financial losses, damages and expenses are covered under insurance and the relevant insurer has settled, or has provided reimbursement for, these financial losses, damages and expenses (or has irrevocably undertaken to do so);
- in relation to proceedings brought by such Indemnified Officer against the Company, except for proceedings brought to enforce indemnification to which the Indemnified Officer is entitled pursuant to the Articles of Association, pursuant to an agreement between such Indemnified Officer and the Company which has been approved by the Board or pursuant to insurance taken out by the Company for the benefit of such Indemnified Officer; or
- for any financial losses, damages or expenses incurred in connection with a settlement of any proceedings effected without the Company's prior consent.

Pension Schemes

The Group ensures that all mandatory pension and social security contributions are paid in accordance with the applicable local laws.

The Company operates old age pension plans, as well as death and disability pension plans for all its employees in the Netherlands and Switzerland. The plans are operated with external insurance companies in each country.

With respect to the employees in the Netherlands the following applies. The Company operates a company pension scheme administrated by a.s.r. (insurance company) and Brand New Day PPI. The scheme provides the following benefits: old age pension, based on defined contribution, survivor's dependents pension, orphans pension and a premium waiver in case of disability. Retirement age is 67. Contribution rates vary depending on age from 6.44% to 15.89% of pension base. Pensionable salary is maximized to EUR 114,866 (2022). Offset (franchise with respect to DC accrual) is EUR 14,802 (2022). Employees contribute 5% of the pension base to the premium costs.

With respect to the employees in Switzerland the following applies. The Company provides standard Swiss cash balance type pension benefits to its employees through the Collective Foundation BVG of Allianz Suisse. Benefits are insured for the life-time of the contract. However, the contract does not have a guaranteed renewability.

Employer and employee contributions are accumulated in individual savings capital accounts with interest to retirement (or earlier withdrawal on changing employment).

The Company finances 50% of the total pension contributions.

At retirement, an employee's savings capital is converted into pension using rates set out in the governing documentation (or taken as a lump sum, at an employee's discretion up to 100%). Death and disability benefits are also provided whilst the employee is employed.

Swiss law requires a legal minimum level of benefits to be provided, based around minimum contribution levels, an annual statutory mandated minimum interest credit rate and minimum retirement conversion rates. The Company's benefit levels are more generous than the legal minimum as a result of more generous contribution rates and salary definitions.

There is no risk of additional contributions (such as deficit contributions) on top of ordinary contributions as set out in the plan rules over the period of the current contract.

Independently of how pensions are financed and any economic interpretations, under IFRS, defined benefit accounting – giving rise to a balance sheet provision – is always required for Swiss pension plans as such plans do not meet the IFRS definition of defined contribution plans or fully insured plans (this interpretation is applied consistently across audit firms).

Works Council

The Company currently has no works council in place in the Netherlands, nor is it obliged to have an employee representative body based on its current number of employees, in the Netherlands, the United States or Switzerland.

DESCRIPTION OF SHARE CAPITAL

Set out below is a summary of the material information concerning the Company's share capital and of material provisions of Dutch law and the Articles of Association. It is based on relevant provisions of Dutch law, the Articles of Association and the Board Rules in effect on the date of this Prospectus. This summary does not purport to give a complete overview and should be read in conjunction with, and is qualified in its entirety by reference to, the relevant provisions of Dutch law, the Articles of Association and the Board Rules. The full text of the Articles of Association (in Dutch, and an unofficial English translation) and the Board Rules (in English) are available free of charge on the Company's website (<https://ir.onwd.com/corporate-governance/>). See also "Management and Corporate Governance" for a summary of the other material provisions of the Articles of Association, the Board Rules and Dutch law relating to the Board.

General

The Company was incorporated as G-Therapeutics B.V., a private limited liability company (*besloten vennootschap met beperkte aansprakelijkheid*) under the laws of the Netherlands on 20 November 2015. On 20 November 2020, the Company changed its name to ONWARD Medical B.V. On 21 October 2021, the Company was converted into a public company with limited liability (*naamloze vennootschap*) with its statutory seat (*statutaire zetel*) in Amsterdam, the Netherlands, and renamed to ONWARD Medical N.V. The Company is registered with the Dutch Chamber of Commerce (*Kamer van Koophandel*) under number 64598748. The Company's telephone number is +31 40 2882830. The Company's Legal Entity Identifier ("**LEI**") is 9845007A2CC4C8BFSB80. The Ordinary Shares' International Securities Identification Number ("**ISIN**") is NL0015000HT4.

Corporate Purpose

Pursuant to its Articles of Association, the objects of the Company are:

- to develop and provide products for special neuro-stimulation systems with real-time motion feedback for patients with neurological problems, for example due to damage to the spinal cord, as well as to develop robot-supported devices for therapy for these patients, in order to enable hospitals and rehabilitation centres to apply neuro-stimulation therapy;
- to establish and otherwise acquire patents and other intellectual property rights and the exploitation (including disposal, conclusion of licence agreements, etc.) of those rights;
- to incorporate, to participate in, to finance, to hold any other interest in and to conduct the management or supervision of other entities, companies, partnerships and businesses;
- to acquire, to manage, to invest, to exploit, to encumber and to dispose of assets and liabilities;
- to furnish guarantees, to provide security, to warrant performance in any other way and to assume liability, whether jointly and severally or otherwise, in respect of obligations of group companies or other parties; and
- to do anything which, in the widest sense, is connected with or may be conducive to the objects described above.

In pursuing its objects, the Company shall also take into account the interests of the legal entities and companies with which it forms a group.

Share Capital

Authorized and issued share capital of the Company

On the date of this Prospectus, the Company's authorized (*maatschappelijk kapitaal*) share capital amounts to EUR 18,000,000 divided into 75,000,000 Ordinary Shares, and 75,000,000 Preferred Shares with a nominal value of EUR 0.12 each. Upon the Company's issued share capital increasing to an amount of at least EUR 4,800,000 the Company's authorized share capital shall immediately and automatically increase to an amount of EUR 24,000,000 and shall be divided into 100,000,000 Ordinary Shares and 100,000,000 Preferred Shares with a nominal value of EUR 0.12 each. The authorized share capital forms the maximum above which no shares can be issued by the Company without first amending the Articles of Association and increasing the authorized share capital. As of the date of this Prospectus, the issued share capital amounts to EUR 4,155,459.84, which is divided into 34,628,832 Ordinary Shares. All issued and outstanding shares have been fully paid-up.

All Shares in the Company's capital have been or will be, as applicable, created under, and are and will be subject to, Dutch law.

All of the issued Ordinary Shares, including the New Ordinary Shares, will be fully paid-up. There are no convertible securities, exchangeable securities or securities with warrants in the Company and there are no acquisition rights and/or obligations over unissued share capital of the Company (or any undertaking to increase the share capital of the Company, other than (a) awards granted pursuant to the Company's long-term incentive plan from time to time or (b) pursuant to the Call Option Agreement (as defined below) if and when entered into), other than the warrants the Company issued to Runway on 28 June 2024 in relation with the Runway Loan, which entitle Runway to purchase ordinary shares in the share capital of the Company at an exercise price per newly issued share of EUR 4.83. The number of shares subject to the warrants are 5.00% of the drawn down principal amount initially and upon each subsequent loan advance, divided by the exercise price. Upon exercise of the warrants the Company will have to issue the corresponding number of ordinary shares to Runway. The warrants may be exercised within a period of 10 years as from (and including) 26 September 2024. No share or loan capital of any member of the Group is under option or agreed, conditionally or unconditionally, to be put under option.

No Shareholders have any voting rights different from any other Shareholder.

History of Share Capital

At 30 June 2024, the Company's issued capital was represented by 34,628,832 Ordinary Shares.

Anti-Takeover Measures

The General Meeting has authorized the Board to grant a call option for a period of five years after the conversion into ONWARD Medical N.V. on 21 October 2021, to an independent foundation under Dutch law (if and when incorporated) (the "**Protective Foundation**") to acquire Preferred Shares pursuant to a call option agreement (the "**Call Option Agreement**"), which may be entered into between the Company and such Protective Foundation, if then existing. This call option, if and when granted, shall be continuous in nature and can be exercised repeatedly on multiple occasions. If the Protective Foundation, if and when incorporated, would exercise such call option, if and when granted, a number of Preferred Shares up to 100% of the Company's issued share capital held by others than the Protective Foundation, minus one share, will be issued to the Protective Foundation. After exercising the Call Option, the Protective Foundation shall acquire Preferred Shares representing up to 50% of the voting rights, minus one vote. These Preferred Shares would be issued to the Protective Foundation under the obligation to pay up 25% of their nominal value. In order for the Protective Foundation to finance the issue price in relation to the Preferred Shares, the Protective Foundation may enter into a finance arrangement with a bank or other financial institution. As an alternative to securing this external financing, subject to applicable restrictions under Dutch law, the Call Option Agreement, if and when entered into, may provide that the Protective Foundation may request the Company to provide, or cause the Company's subsidiaries to provide, sufficient funding to the Protective Foundation to enable the Protective Foundation to satisfy the payment obligation (or part

thereof) in cash and/or to charge an amount equal to the payment obligation (or part thereof) against the Company's profits and/or reserves in satisfaction of such payment obligation. The articles of association of the Protective Foundation, if and when incorporated, will provide that it will promote and protect the interests of the Company, the business connected with it and the Company's stakeholders from time to time, and repressing possible influences which could threaten the strategy, continuity, independence and/or identity of the Company or the business connected with it, to such an extent that this could be considered to be damaging to the aforementioned interests. These influences may include a third party acquiring a significant percentage of Ordinary Shares, the announcement of an unsolicited public offer for Ordinary Shares, shareholder activism, other concentration of control over Ordinary Shares or any other form of undue pressure on the Company to alter the Company's strategic policies. The Protective Foundation, if and when incorporated, shall be structured to operate independently of the Company.

The voting rights of the Shares are based on nominal value and, as the Company expects the Ordinary Shares to trade substantially in excess of their nominal value, Preferred Shares issued at 25% of their nominal value can carry significant voting power for a substantially reduced price compared to the price of Ordinary Shares and thus can be used as a defensive measure. These Preferred Shares, if and when issued, will have both a liquidation and dividend preference over Ordinary Shares and will accrue cash dividends at a fixed rate calculated over the amount paid-up on those Preferred Shares pro rata tempore for the period during which they were outstanding. The Protective Foundation would be expected to require the Company to cancel its Preferred Shares, if and when issued to the Protective Foundation, once the perceived threat to the Company, its business and its stakeholders has been removed or sufficiently mitigated or neutralized. However, subject to the same limitations described above, the Protective Foundation would, in that case, continue to have the right to exercise the call option in the future in response to a new threat to the interests of the Company, the Company's business and the Company's stakeholders from time to time. Every Share will carry one vote. Preferred Shares shall only be issued to the Protective Foundation, if and when incorporated, in accordance with the previous paragraph.

Also, certain provisions of the Articles of Association may make it more difficult for a third party to acquire control of the Company or effect a change in the composition of the board of directors. These include:

- (i) a provision that Board members can only be appointed on the basis of a binding nomination prepared by the Board which can only be overruled by a two-thirds majority of votes cast representing more than half of the Company's issued share capital,
- (ii) a provision that Board members can only be dismissed by the General Meeting by a two-thirds majority of votes cast representing more than half of the Company's issued share capital, unless the dismissal is proposed by the Board in which latter case a simple majority of the votes cast would be sufficient,
- (iii) a provision allowing, among other matters, the former chairperson of the Board or former Chief Executive Officer to manage affairs of the Company if all Board members are dismissed and to appoint others to be charged with the affairs of the Company, including the preparation of a binding nomination for Board members as discussed above, until new directors are appointed by the General Meeting on the basis of such binding nomination,
- (iv) a requirement that certain matters, including an amendment of the Articles of Association, may only be resolved upon by the General Meeting if proposed by the Board, and
- (v) a provision that Shareholders are required to observe any cooling-off period and response period provided under applicable law and/or the Dutch Corporate Governance Code if invoked by the Board in response to Shareholders exercising their right to put an item on the agenda for the General Meeting or to request the convening of a General Meeting.

Dutch law also allows for staggered multi-year terms of the Company's directors, as a result of which only some of the Company's Directors may be subject to appointment or re-appointment in any given year.

Furthermore, the Board can, under circumstances, invoke a reasonable period of up to 180 days to respond to certain shareholder proposals or the statutory cooling-off period of up to 250 days to respond to certain shareholder proposals or a hostile bid. See below under "*General Meetings and Voting Rights—Response Period and Cooling-Off Period*".

Form of Ordinary Shares and Preferred Shares

All Shares are in registered form and are only available in the form of an entry in the Shareholders' Register (as defined below) and not in certificate form and shall at all times remain in dematerialized form. See also "*The Listing – Delivery*" in relation to the delivery, clearing and settlement of the New Ordinary Shares.

Shareholders' Register

Pursuant to Dutch law and the Articles of Association, the Company must keep a shareholders' register (the "**Shareholders' Register**"). A copy of the Shareholders' Register will be kept by the Board at the offices of the Company in the Netherlands. In the Shareholders' Register, the names and addresses of all Shareholders must be recorded, as well as the date they acquired their Shares, the date of acknowledgment or service and the paid-up amount on each Share. The Shareholders' Register also contains the names and addresses of usufructuaries (*vruchtgebruikers*) and pledgees (*pandhouders*) of Shares, stating when they acquired their usufruct or pledge, the date of acknowledgment or service and whether they hold the rights attached to such Shares pursuant to Section 2:88 paragraphs 2 and 4 DCC, as it relates to usufructuaries (*vruchtgebruikers*), and Section 2:89 paragraphs 2 and 4 DCC, as it relates to pledgees (*pandhouders*). If requested, the Board will provide a Shareholder, usufructuary or pledgee of Shares with an extract from the Shareholders' Register relating to its title to such Shares free of charge. If the Shares are encumbered with a right of usufruct or pledge, the extract will state who holds the rights attached to such Shares pursuant to Section 2:88 paragraphs 2 and 4 DCC, as it relates to usufructuaries (*vruchtgebruikers*), and Section 2:89 paragraphs 2 and 4 DCC, as it relates to pledgees (*pandhouders*).

For Ordinary Shares, including the New Ordinary Shares, which are included in (i) a collective depot (*verzameldepot*) as referred to in the Dutch Securities Giro Transactions Act (*Wet giraal effectenverkeer*) (the "**Dutch Securities Giro Transactions Act**"), of which Ordinary Shares form part, as being kept by an intermediary, as referred to in the Dutch Securities Giro Transactions Act, or (ii) a giro depot (*girodepot*) as referred to in that Act, of which Ordinary Shares form part, as being kept by a central institute as referred to in that Act, the name and address of the relevant intermediary or the relevant central institute shall be entered in the Shareholders' Register, stating the date on which those Ordinary Shares became part of such collective depot or giro depot, the date of acknowledgment or service, as well as the paid-up amount on each Ordinary Share.

A person who is entitled to, and wishes to, inspect the Shareholders' Register may do so only through the Company and in accordance with Dutch law.

Issuance of Shares

The General Meeting is the corporate body authorized to resolve on the issuance of Shares and the granting of rights to subscribe for Shares. The General Meeting can delegate such authority to another corporate body of the Company for a period not exceeding five years; this authorization may only be extended from time to time for a maximum period of five years.

The General Meeting on 13 June 2024 authorized the Board for a period of 18 months following 13 June 2024 to issue ordinary shares and grant rights to subscribe for ordinary shares for up to a maximum of 10% of the Ordinary Shares issued and outstanding at the close of business on 13 June 2024 and to limit or exclude the pre-emptive rights in connection therewith. In addition, in connection with one or more potential capital raises, or for other strategic purposes, the General Meeting on 13

June 2024 authorized the Board to issue up to an additional 50% of Ordinary Shares of the Company's issued share capital as at close of business on 13 June 2024. The New Ordinary Shares will be issued pursuant to resolutions of the Board dated 22 October 2024. The Company may not subscribe for its own Shares upon issuance. The Board may resolve to charge amounts to be paid up on shares against the Company's reserves, irrespective of whether those shares are issued to existing shareholders.

Pre-emptive Rights

In the event of an issuance of ordinary shares, each Shareholder will have a pro rata pre-emption right in proportion to the aggregate nominal value of the Ordinary Shares held by such Shareholder (except in the case of an issue of ordinary shares to employees of the Company or a Group Company, against a contribution other than in cash or pursuant to the exercise of a previously acquired right to subscribe for Ordinary Shares). No pre-emption rights are attached to Preferred Shares and no pre-emption rights apply in the event of an issue of Preferred Shares. Pre-emption rights in respect of newly issued ordinary shares may be restricted or excluded by a resolution of the General Meeting. Another corporate body may restrict or exclude the pre-emption rights in respect of newly issued ordinary shares if it has been designated as the authorized body to do so by the General Meeting. Such designation can be granted for a period not exceeding five years. A resolution of the General Meeting to restrict or exclude the pre-emption rights or to designate another corporate body as the authorized body to do so requires a majority of not less than two-thirds of the votes cast, if less than one-half of the Company's issued share capital is represented at the meeting.

As of the date of this Prospectus, the Board is authorized for a period of 18 months from 13 June 2024 to limit or exclude pre-emption rights in relation to an issuance of ordinary shares or a grant of rights to subscribe for ordinary shares that the Board is authorized to resolve upon as described above under "*Issuance of Shares*".

Acquisition by the Company of its Shares

The Company may acquire fully paid-up Shares at any time for no consideration. The Company may also acquire fully paid-up Shares at any time for valuable consideration if (i) the Company's shareholders' equity (*eigen vermogen*) less the payment required to make the acquisition does not fall below the sum of paid-in and called-up share capital plus any reserves required by Dutch law or the Articles of Association and (ii) the aggregate nominal value of Shares which the Company acquires, holds or on which the Company holds a pledge (*pandrecht*) or which are held by a subsidiary of the Company, would not exceed 50% of the Company's issued share capital. An acquisition by the Company of Shares for valuable consideration must be authorized by the General Meeting. Such authorization may be granted for a maximum period of 18 months and must specify the number of Shares that may be acquired, the manner in which Shares may be acquired and the price limits within which Shares may be acquired. The actual acquisition may only be effected pursuant to a resolution of the Board.

The Board is authorized for a period of 18 months following 13 June 2024 to cause the repurchase of Ordinary Shares by the Company of up to 10% of the Company's issued share capital on 13 June 2024, for a price per share not exceeding 110% of the average market price of the Ordinary Shares on Euronext (such average market price being the average of the closing prices on each of the five consecutive trading days preceding the date the acquisition is agreed upon by the Company).

No authorization of the General Meeting is required if fully paid-up Ordinary Shares are acquired by the Company with the intention of transferring such Ordinary Shares to employees under an applicable employee share purchase plan.

Under the Runway Loan, the Company and the Group Companies are not allowed to purchase any of their own shares, with the exception, that the Company may repurchase its Ordinary Shares pursuant to stock repurchase agreements approved by the Board, provided that the aggregate amount of all such repurchases does not exceed EUR 0.5 million per fiscal year and only if at the time of the repurchase and immediately after giving effect thereto (i) no default or event of default under

the terms of the Runway Loan (including, but not limited to, a breach of covenants or a payment default) exists or could reasonably be expected to occur, (ii) the Company and the Group Companies are solvent, and (iii) such repurchase is permitted under and is made in compliance with all applicable laws.

Transfer of Shares

The Shares are in registered form (*op naam*). The transfer of a Share that is not included in a collective depot (*verzameldepot*) or giro depot (*girodepot*) as referred to in the Dutch Securities Giro Transactions Act or of a restricted right (*beperkt recht*) thereto requires a deed of transfer drawn up for that purpose and acknowledgment of the transfer by the Company in writing (or service of the deed of transfer or an excerpt thereof to the Company in accordance with the DCC). Such acknowledgment is not required in the event that the Company is party to the transfer. Shares may be included in a collective depot (*verzameldepot*) or a giro depot (*girodepot*) in accordance with the provisions of the Dutch Securities Giro Transactions Act. If a Share is transferred or issued for inclusion in a collective depot (*verzameldepot*), the transfer or issue will be made to the intermediary concerned. If a Share is transferred or issued for inclusion in a giro depot (*girodepot*), the transfer or issue will be made to the central institute, being Euroclear Nederland. Upon transfer or issuance of a Share to Euroclear Nederland or to an intermediary in order to include the Share in a giro depot (*girodepot*) or a collective depot (*verzameldepot*), respectively, this will be effected without the cooperation of the other participants in the giro depot (*girodepot*) or collective depot (*verzameldepot*), as applicable.

Shares included in a collective depot (*verzameldepot*) or giro depot (*girodepot*) can only be delivered from that collective depot or giro depot with due observance of the related provisions of the Dutch Securities Giro Transactions Act. The transfer by a Shareholder who participates in a collective depot (*verzameldepot*) of its book-entry rights representing its Shares shall be effected in accordance with the provisions of the Dutch Securities Giro Transactions Act. The same applies to the establishment or transfer of a right of pledge and the establishment or transfer of a usufruct on these book-entry rights.

Capital Reduction

Subject to the provisions of Dutch law and the Articles of Association, the General Meeting may resolve to reduce the Company's issued share capital by (i) reducing the nominal value of the Shares through an amendment of the Articles of Association or (ii) cancellation of Shares held by the Company itself. A resolution to cancel Shares can only relate to (i) Shares held by the Company itself or in respect of which the Company holds the depository receipts and (ii) all Preferred Shares held by the Company itself, with repayment of the amounts paid up in respect thereof and provided that, to the extent allowed under the Articles of Association, a distribution is made on those Preferred Shares, in proportion to the amounts paid up on those Preferred Shares, immediately prior to such cancellation becoming effective. A resolution to reduce the Company's issued share capital shall require a prior or simultaneous approval from each class meeting of shares whose rights are prejudiced. However, if such a resolution relates to Preferred Shares, such resolution shall always require the prior or simultaneous approval of the class meeting concerned.

A resolution of the General Meeting to reduce the issued share capital requires a majority of at least two-thirds of the votes cast if less than 50% of the issued share capital is represented at the General Meeting. If at least 50% of the issued share capital is represented at the General Meeting, the resolution of the General Meeting requires a simple majority of the votes cast. A reduction of the nominal value of Shares, without repayment and without dispensation from the obligation to satisfy a payment obligation must be made pro rata on all Shares concerned. This pro rata requirement may be deviated from if all Shareholders concerned so approve.

In addition, Dutch law contains detailed provisions regarding the reduction of capital. A resolution to reduce the issued share capital shall not take effect as long as creditors may oppose the resolution under the relevant provisions of the DCC (and, if timely opposed by a creditor, such resolution shall not take effect until the opposition has been withdrawn or the lifting of the opposition is enforceable).

Dividends and Other Distributions

General

The Company may only make distributions, whether a distribution of profits or of freely distributable reserves, to its Shareholders if its Shareholders' equity exceeds the sum of the paid-in and called-up share capital plus the reserves as required to be maintained by Dutch law or by the Articles of Association and – if it concerns a distribution of profits – after adoption of the Annual Accounts by the General Meeting from which it appears that such profit distribution is allowed. See "*Dividend Policy*" for a more detailed description regarding dividends.

Annual Profit Distribution and Right to reserve

Under the Articles of Association, if any Preferred Shares are or have been outstanding, a dividend is first paid out of the Company's profits, if available for distribution, to the holders or former holders, as applicable, of those Preferred Shares to the extent they are entitled to such distribution under the Articles of Association, which is referred to as preferred dividend. Thereafter, the Board may decide that all or part of the profits shown in the adopted Annual Accounts will be added to the Company's reserves. After reservation of any such profits, any remaining profits will be at the disposal of the General Meeting at the proposal of the Board with the approval of the Board for distribution on the Ordinary Shares, subject to applicable restrictions of Dutch law described above.

Interim Distribution

Under the Articles of Association, the Board is permitted, subject to certain requirements and the applicable restrictions of Dutch law described above, to declare and pay interim dividends without the approval of the General Meeting.

Distributions from and Charges against the Reserves

Under the Articles of Association, the General Meeting may, subject to the applicable restrictions of Dutch law described above, make distributions from the Company's freely distributable reserves at the proposal of the Board.

In addition, under the Articles of Association, the Board may, subject to the applicable restrictions of Dutch law described above, charge amounts to be paid on Shares against the Company's reserves, irrespective of whether those Shares are issued to existing Shareholders.

Distribution in kind

Under the Articles of Association, the General Meeting may, subject to the applicable restrictions of Dutch law described above, decide that a distribution be made in the form of Ordinary Shares or in the form of the Company's assets, instead of being made in cash, at the proposal of the Board.

Payment

Payment of any future dividend or other distribution on Shares in cash will in principle be made in euro, but the Board may decide that payment will be made in another currency. The parties entitled to a distribution shall be the relevant Shareholders, usufructuaries and pledgees, as the case may be, at a date to be determined by the Board for that purpose; this date shall not be earlier than the date on which the distribution is announced. Any dividends and other distributions on Ordinary Shares that are paid to Shareholders through Euroclear Nederland will be automatically credited to the relevant Shareholders' accounts. There are no restrictions in relation to the payment of dividends or distributions under the DCC in respect of holders of Shares who are non-residents of the Netherlands.

However, see "*Taxation*" for a discussion of certain aspects of taxation of dividends. Payments of profit and other distributions shall be announced in a notice by the Company. A Shareholder's claim to payments of profits and other distributions lapses after five years have expired after the day on which the claim became payable. Any profit or other distributions that are not claimed within this period will be considered to have been forfeited to the Company and will be carried to the reserves of the

Company. For the purpose of calculating the amount or allocation of any distribution, Shares held by the Company in its own capital shall not be taken into account. No distribution shall be made to the Company in respect of Shares held by it in its own capital.

Exchange Controls and other Provisions relating to non-Dutch Shareholders

Under Dutch law, subject to the 1977 Sanction Act (*Sanctiewet 1977*) or otherwise by applicable sanctions and measures, including those concerning export control, pursuant to European Union regulations, applicable anti-boycott regulations, applicable anti-money laundering regulations and similar rules, there are no exchange control restrictions on investments in, or payments on, Shares, provided that the payment in a foreign currency for any Ordinary Shares issued, or to be issued, by the Company will only result in the performance of the obligation to pay up the Shares, to the extent that the Company consents to payment in such foreign currency, the paid-up sum can be converted (exchanged) freely into euro and is equal to at least the payment obligation with respect to such Shares. There are no special restrictions in the Articles of Association or Dutch law, except as noted above, that limit the right of Shareholders who are not citizens or residents of the Netherlands to hold or vote Shares.

General Meetings and Voting Rights

General Meetings

General Meetings must be held in the Netherlands, in any of the locations specified in the Articles of Association. The annual General Meeting must be held at least once a year, within six months after the end of each financial year.

Extraordinary General Meetings may be held as often as the Board deems desirable. In addition, one or more Shareholders (or others with meeting rights under Dutch law), who solely or jointly represent at least the percentage of the issued capital as required by law, which currently is at least one-tenth of the issued capital, may request that a General Meeting be convened, the request setting out in detail matters to be considered. If the Board has not taken the steps necessary to ensure that such meeting can be held within eight weeks after the request, the Shareholder(s) (or others with meeting rights under Dutch law) making such request may, on their application and in accordance with Dutch law, be authorized by the competent Dutch court in preliminary relief proceedings to convene a General Meeting. Furthermore, within three months of it becoming apparent to the Board that the equity of the Company has decreased to an amount equal to or lower than one-half of the paid-up and called-up part of the capital, a General Meeting must be held to discuss any requisite measures.

The convocation of the General Meeting must be published through an announcement by electronic means. Shareholders registered in the Shareholders' Register may also be convened by means of convening notices sent to them at their respective addresses as included in the Shareholders' Register. Furthermore, Shareholders and others with meeting rights under Dutch law may be convened by means of electronic messages sent to them (e.g. by email) in accordance with their instructions. The notice must state the subjects to be dealt with, the time, date and place of the meeting, the record date, the manner in which persons entitled to attend the General Meeting may register and exercise their rights, the procedure for participating in the meeting by proxy, the Company's website, and such other information as may be required by Dutch law. The notice must be given by at least such number of days prior to the day of the meeting as required by Dutch law, which is currently 42 days.

The agenda for the annual General Meeting typically contains specific subjects, including, among other things, the adoption of the Annual Accounts, the discussion of substantial changes in the corporate governance structure of the Company and the distribution profits, insofar as these are at the disposal of the General Meeting, and the granting of discharge to the Directors in respect of the performance of their duties as Directors during the financial year to which the Annual Accounts relate.

One or more Shareholders (and others with meeting rights under Dutch law), who solely or jointly represent at least the percentage of the issued capital as required by law, which currently is at least 3% of the Company's issued share capital, may, in accordance with Dutch law, request that an item

is added to the agenda. Such requests must be made in writing or by electronic means, must either be substantiated or include a proposal for a resolution, and must be received by the Company at least 60 days before the day of the General Meeting. No resolutions may be adopted on items other than those that have been included in the agenda (unless the resolution would be adopted unanimously during a meeting where the entire issued capital of the Company is present or represented).

Shareholders who, individually or with other Shareholders, hold Shares that represent at least 1% of the issued share capital or a market value of at least EUR 250,000 may request the Company to disseminate information that is prepared by them in connection with an agenda item for a General Meeting, provided that the Company has done a so-called "identification round" in accordance with the provisions of the Dutch Securities Giro Transactions Act. The Company can only refuse disseminating such information, if received less than seven business days prior to the day of the General Meeting, if the information gives or could be expected to give an incorrect or misleading signal with respect to the Company or if, in light of the nature of the information, the Company cannot reasonably be required to disseminate it.

The General Meeting is chaired by the Chairperson. If no Chairperson has been elected or if he or she is not present at the meeting, the General Meeting shall be presided over by the Vice Chairperson. If no Vice Chairperson has been elected or if he or she is not present at the meeting, the General Meeting shall be presided over by another Non-Executive Director present at the meeting. If no Non-Executive Director is present at the meeting, the General Meeting shall be chaired by the CEO. If no CEO of the Board has been elected or if he or she is not present at the meeting, the General Meeting shall be presided over by a person designated in accordance with the Articles of Association. Directors may attend a General Meeting. In these General Meetings, Directors have an advisory vote. The chairperson of the General Meeting may decide at his or her discretion to admit other persons to the General Meeting.

Record date, admission and registration

Each Shareholder (as well as other persons with meeting rights under Dutch law) may attend the General Meeting, address the General Meeting and, insofar as they have such right, exercise voting rights attached to the relevant Shares, either in person or by proxy. Shareholders and others with meeting rights under Dutch law may exercise these rights, if they are the Shareholders (or holders of meeting rights under Dutch law) on the record date for the General Meeting, which, at the date of this Prospect^{us}, is the 28th day before the day of the General Meeting. Under the Articles of Association, Shareholders and others with meeting rights under Dutch law must notify the Company of their identity and their intention to attend the meeting in writing or by electronic means. This notice must be received by the Company ultimately on the seventh day prior to the General Meeting, unless indicated otherwise when such meeting is convened.

Response Period and Cooling-Off Period

In accordance with the Code and the Articles of Association, Shareholders having the right to put an item on the agenda under the rules described above shall exercise such right only after consulting the Board in that respect. If one or more Shareholders intend to request that an item be put on the agenda that may result in a change in the Company's strategy, the Board must be given the opportunity to invoke a reasonable period to respond to such intention. Such period shall not exceed 180 days (or such other period as may be stipulated for such purpose by Dutch law and/or the Code from time to time) from the moment the Board is informed by the Shareholder(s) of their intention to put an item on the agenda to the day of the General Meeting at which the item is to be dealt with. If invoked, the Board must use such response period for further deliberation and constructive consultation, in any event with the Shareholders(s) concerned, and shall explore the alternatives. At the end of the response time, the Board shall report this consultation and the exploration of alternatives to the General Meeting. The response period may be invoked only once for any given General Meeting and shall not apply (a) in respect of a matter for which a response period or a cooling off period (as described below) has been previously invoked or (b) if a Shareholder holds at least 75% of the Company's issued share capital as a consequence of a successful public bid. The response

period may also be invoked in response to Shareholders or others with meeting rights under Dutch law requesting that a General Meeting be convened, as described above.

Moreover, the Board can invoke a cooling-off period of up to 250 days when Shareholders, using their right to have items added to the agenda for a General Meeting or their right to request a General Meeting, propose an agenda item for the General Meeting to dismiss, suspend or appoint one or more directors (or to amend any provision in the Articles of Association dealing with those matters) or when a public offer for the Company is made or announced without the Company's support, provided, in each case, that the Board believes that such proposal or offer materially conflicts with the interests of the Company and its business. During a cooling-off period, the General Meeting cannot dismiss, suspend or appoint directors (or amend the provisions in the Articles of Association dealing with those matters) except at the proposal of the Board. During a cooling-off period, the Board must gather all relevant information necessary for a careful decision-making process and at least consult with Shareholders representing 3% or more of the Company's issued share capital at the time the cooling-off period was invoked, as well as with the Company's Dutch works council (if the Company or, under certain circumstances, any of the Company's subsidiaries would have one). Formal statements expressed by these stakeholders during such consultations must be published on the Company's website to the extent these stakeholders have approved that publication. Ultimately one week following the last day of the cooling-off period, the Board must publish a report in respect of its policy and conduct of affairs during the cooling-off period on the Company's website. This report must remain available for inspection by Shareholders and others with meeting rights under Dutch law at the Company's office and must be tabled for discussion at the next General Meeting. Shareholders representing at least 3% of the Company's issued share capital may request the Enterprise Chamber for early termination of the cooling-off period. The Enterprise Chamber must rule in favor of the request if the shareholders can demonstrate that:

- the Board, in light of the circumstances at hand when the cooling-off period was invoked, could not reasonably have concluded that the relevant proposal or hostile offer constituted a material conflict with the interests of the Company and its business;
- the Board cannot reasonably believe that a continuation of the cooling-off period would contribute to careful policy-making; or
- other defensive measures, having the same purpose, nature and scope as the cooling-off period, have been activated during the cooling-off period and have not since been terminated or suspended within a reasonable period at the relevant Shareholders' request (i.e. no 'stacking' of defensive measures).

Voting Rights

Each Ordinary Share and each Preferred Share, if any are outstanding, confers the right on the holder to cast one vote at a General Meeting. Pursuant to Dutch law, no votes may be cast at a General Meeting in respect of Shares that are held by, or of which the depositary receipts are held by, the Company or any of its subsidiaries. Nonetheless, the holders of a right of usufruct (*vruchtgebruik*) and the holders of a right of pledge (*pandrecht*) in respect of Shares held by the Company or its subsidiaries in the Company's share capital are not excluded from the right to vote on such Shares, if the right of usufruct (*vruchtgebruik*) or the right of pledge (*pandrecht*) was granted prior to the time such Shares were acquired by the Company or any of its subsidiaries. Neither the Company nor any of its subsidiaries may cast votes in respect of a share on which the Company or such subsidiary holds a right of usufruct (*vruchtgebruik*) or a right of pledge (*pandrecht*). Shares which are not entitled to voting rights pursuant to the preceding sentences will not be taken into account for the purpose of determining the number of shareholders that vote and that are present or represented, or the amount of the share capital that is provided or that is represented at a General Meeting. At the General Meeting, resolutions are passed by a simple majority of the valid votes cast, unless Dutch law or the Articles of Association prescribe a greater majority. If there is a tie in voting, the proposal concerned will be rejected.

The Board may decide that persons entitled to attend and vote at General Meetings may cast their vote electronically or by post prior to the General Meeting. The Board may determine the period during which votes may be cast in this manner, provided that the votes shall not be cast prior to the record date for the General Meeting. Votes validly cast electronically or by post rank as equal to votes validly cast at the General Meeting.

Virtual General Meetings

The temporary Dutch legislation relating to the outbreak of the COVID-19 pandemic, which allowed General Meetings to be held only virtually without physical attendance, has expired. On 7 December 2022, a preliminary bill for a permanent statutory regulation of the virtual-only shareholders' meeting of Dutch public limited companies and private limited companies was made available for public consultation. The bill was submitted to parliament on 11 January 2024. The aim is for the law to enter into force on 1 January 2025. If and when implemented in its current form, this bill will provide for an optional arrangement for virtual-only general meetings and lays down further conditions for the hybrid and virtual-only general meetings.

Amendment of the Articles of Association

Under the Articles of Association, the General Meeting can only resolve on the amendment to the Articles of Association at the proposal of the Board.

Dissolution and liquidation

Under the Articles of Association, the General Meeting can only resolve on the dissolution of the Company at the proposal of the Board.

In the event of the Company's dissolution, the liquidation shall be effected by the Board, unless the General Meeting decides otherwise. During liquidation, the provisions of the Articles of Association will remain in force as far as possible. To the extent that any assets remain after payment of all of the Company's liabilities, if any Preferred Shares are or have been outstanding, a liquidation distribution equal to the preferred dividend is first paid out to the holders or former holders of those Preferred Shares (to the extent they are entitled to such distribution under the Articles of Association). Thereafter, any remaining assets shall be distributed to the Shareholders in proportion to their number of Ordinary Shares.

Annual financial reporting and interim financial reporting

Annually, within four months after the end of the financial year, the Company must publish and simultaneously file with the AFM its annual financial reporting, consisting of the financial statements, a management board report, a responsibility statement, an independent auditor's report and certain other information required under Dutch law and make them available for inspection by the Shareholders (and others with meeting rights under Dutch law) at the office of the Company and on its website. The Company's financial statements must be signed by all members of the Board. If the signature of one or more of the Directors is missing, this will be stated and reasons for this omission will be given. The financial statements must be adopted by the General Meeting.

The Board must refile the adopted financial statements with the AFM within five business days following adoption by the General Meeting.

The Company must publish its interim financial statements as soon as possible, and at the latest three months after the end of the first six months of the financial year. If the interim financial statements are audited or reviewed, the independent auditor's report or the independent auditor's review report must be published together with the interim financial reporting. If the interim financial statements are unaudited or not reviewed, the interim management board report should state so.

The Company does not intend to publish interim financial statements other than interim financial statements for the six months ended 30 June of each financial year.

Dutch Financial Reporting Supervision Act

On the basis of the Dutch Financial Reporting Supervision Act (*Wet toezicht financiële verslaggeving*) (the "**FRSA**"), the AFM supervises the application of financial reporting standards by, among others, companies whose corporate seat is in the Netherlands and whose securities are listed on a regulated Dutch or foreign stock exchange, such as the Company.

Pursuant to the FRSA, the AFM has an independent right to: (i) request an explanation from the Company regarding its application of the applicable financial reporting standards if, based on publicly known facts or circumstances, it has reason to doubt that the Company's financial reporting meets such standards; and (ii) recommend the Company make available further explanations. If the Company does not comply with such a request or recommendation, the AFM may request the enterprise chamber of the court of appeal in Amsterdam (*Ondernemingskamer van het Gerechtshof te Amsterdam*) (the "**Enterprise Chamber**") to order the Company to: (i) make available further explanations as recommended by the AFM; (ii) provide an explanation of the way it has applied the applicable financial reporting standards to its financial reports; or (iii) prepare or restate its financial reports in accordance with the Enterprise Chamber's instructions.

Rules Governing Obligations of Shareholders to make a Public Takeover Bid

Pursuant to the Dutch Financial Supervision Act (*Wet op het financieel toezicht*) ("**DFSA**"), and in accordance with Directive 2004/25/EC of the European Parliament and of the Council of 21 April 2004, also known as the Takeover Directive, anyone who (individually or jointly with others) directly or indirectly obtains dominant control (*overwegende zeggenschap*) of the Company is required to make a public takeover bid for all issued and outstanding Ordinary Shares or depositary receipts for Ordinary Shares, unless an exemption applies (including an exemption for shareholders who, acting alone or in concert, already had dominant control over the Company at the time of the initial listing of the Ordinary Shares). Such control is deemed present if someone is able to exercise, alone or acting in concert, at least 30% of the voting rights in the General Meeting. For further information, see "*Shareholder Structure and Related Party Transactions— Related Party Transactions*".

In addition, no person may launch a public offer to acquire Ordinary Shares, unless an offer document has been approved by the AFM. Such a public offer may only be launched by way of publication of an approved offer document. The Dutch public offer rules are intended to ensure that in the event of a public offer, among others, sufficient information is made available to the holders of the shares, the holders of the shares are treated equally, that there is no abuse of inside information and that there is a proper and timely offer period.

Squeeze-out Proceedings

Pursuant to Section 2:92a DCC, a shareholder who contributes at least 95% of the issued share capital of a public company with limited liability (*naamloze vennootschap*) under the laws of the Netherlands for its own account, alone or together with a group of companies, may institute proceedings against such Company's minority shareholders jointly for the transfer of their shares to such shareholder(s). The proceedings are held before the Enterprise Chamber and can be instituted by means of a writ of summons served upon each of the minority shareholders in accordance with the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*). The Enterprise Chamber may grant the claim for squeeze-out in relation to all minority shareholders and will determine the price to be paid for the shares, if necessary after appointment of one or three experts who will offer an opinion to the Enterprise Chamber on the value to be paid for the shares of the minority shareholders. Once the order to transfer becomes final before the Enterprise Chamber, the person acquiring the shares shall give written notice of the date and place of payment and the price to the holders of the shares to be acquired whose addresses are known to him. Unless the addresses of all of them are known to him, he is required to publish the same in a daily newspaper with nationwide circulation.

The offeror under a public takeover bid is also entitled to start squeeze-out proceedings if, following the public takeover bid, the offeror contributes at least 95% of the outstanding share capital and

represents at least 95% of the voting rights. The claim of a takeover squeeze-out needs to be filed with the Enterprise Chamber within three months following the expiry of the acceptance period of the offer. The Enterprise Chamber may grant the claim for squeeze-out in relation to all minority shareholders and will determine the price to be paid for the shares, if necessary after appointment of one or three experts who will offer an opinion to the Enterprise Chamber on the value to be paid for the shares of the minority shareholders. In principle, the offer price is considered reasonable if the offer was a mandatory offer or if at least 90% of the shares to which the offer related were received by way of voluntary offer.

The DCC also gives the minority shareholders that have not previously tendered their shares under an offer the right to institute proceedings with the Enterprise Chamber for the transfer of their shares to the offeror, provided that the offeror has acquired at least 95% of the outstanding share capital and represents at least 95% of the voting rights. With regard to price, the same procedure as for takeover squeeze-out proceedings initiated by an offeror applies. The claim also needs to be filed with the Enterprise Chamber within three months following the expiry of the acceptance period of the offer.

Obligations to Disclose Holdings

Holders of the Shares may be subject to notification obligations under the DFSA. Shareholders are advised to seek professional advice on these obligations.

Obligations of Shareholders to Disclose Holdings

Pursuant to the DFSA, any person who, directly or indirectly, acquires or disposes of an actual or potential interest in the capital or voting rights of a Dutch listed company must immediately notify the AFM through the designated portal, if, as a result of such acquisition or disposal, the percentage of capital interest or voting rights held by such person in the Company reaches, exceeds or falls below any of the following thresholds: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%.

A notification requirement also applies if a person's capital interest or voting rights reach, exceed or fall below the abovementioned thresholds as a result of a change in the Company's total outstanding share capital or voting rights. Such notification must be made no later than the fourth trading day after the AFM has published the Company's notification of the change in its outstanding share capital. The Company is required to notify the AFM immediately of the changes to its total share capital or voting rights if its issued share capital or voting rights change by 1% or more since its previous notification. The Company must furthermore notify the AFM within eight days after each quarter, in the event its share capital or voting rights changed by less than 1% in that relevant quarter since its previous notification.

In addition, every holder of 3% or more of the Company's share capital or voting rights whose interest changes in respect of the previous notification to the AFM by reaching or crossing one of the abovementioned thresholds as a consequence of the interest being differently composed due to shares or voting rights having been acquired through the exercise of a right to acquire the same, such as options for shares, must notify the AFM of the changes within four trading days after the date on which the holder knows, or should have known, that his or her interest reaches, exceeds or falls below a threshold.

The AFM keeps a public register of all notifications made pursuant to these disclosure obligations and publishes all notifications received by it. The shareholder notifications referred to in this section should be made electronically through the notification system of the AFM.

Controlled entities, within the meaning of the DFSA, do not have notification obligations under the DFSA, as their direct and indirect interests are attributed to their (ultimate) controlling parent. Any person may qualify as a controlling parent for purposes of the DFSA, including a natural person. A person who has a 3% or larger interest in the Company's share capital or voting rights and who ceases to be a controlled entity for these purposes must immediately notify the AFM. As at that moment, all notification obligations under the DFSA will become applicable to the former controlled entity.

For the purpose of calculating the percentage of capital interest or voting rights, the following interests must, among other things, be taken into account: (i) shares and voting rights directly held (or acquired or disposed of) by any person; (ii) shares and voting rights held (or acquired or disposed of) by such person's controlled entity or by a third party for such person's account or by a third party with whom such person has concluded an oral or written voting agreement; (iii) voting rights acquired pursuant to an agreement providing for a temporary transfer of voting rights against a payment; (iv) shares which such person (directly or indirectly) or third party referred to above may acquire pursuant to any option or other right to acquire shares; (v) shares that determine the value of certain cash-settled financial instruments such as contracts for difference and total return swaps; (vi) shares that must be acquired upon exercise of a put option by a counterparty; and (vii) shares that are the subject of another contract creating an economic position similar to a direct or indirect holding in those shares.

Special attribution rules apply to shares and voting rights that are part of the property of a partnership or other community of property. A holder of a pledge or right of usufruct in respect of shares can also be subject to the reporting obligations, if such person has, or can acquire, the right to vote the shares. The acquisition of (conditional) voting rights by a pledgee or beneficial owner may also trigger the reporting obligations as if the pledgee or beneficial owner were the legal holder of the shares.

For the purpose of calculating the percentage of capital interest or voting rights, the following instruments qualify as "*shares*": (i) shares; (ii) depositary receipts for shares (or negotiable instruments similar to such receipts); (iii) negotiable instruments for acquiring the instruments under paragraph (i) or (ii) (such as convertible bonds); and (iv) options for acquiring the instruments under (i) or (ii).

The notification to the AFM should indicate whether the interest is held directly or indirectly, and whether the interest is an actual or a potential interest.

Notification of Short Positions

Each person holding a gross short position in relation to the issued share capital of a Dutch listed company that reaches, exceeds or falls below any one of the following thresholds: 3%, 5%, 10%, 15%, 20%, 25%, 30%, 40%, 50%, 60%, 75% and 95%, must immediately notify the AFM through the designated portal. If a person's gross short position reaches, exceeds or falls below one of the above-mentioned thresholds as a result of a change in the Company's issued share capital, such person must make a notification not later than the fourth trading day after the AFM has published the Company's notification in the public register of the AFM. No set-off is permitted between a long position and a short position. Shareholders are advised to consult with their own legal advisers to determine whether the gross short selling notification obligation applies to them.

In addition, pursuant to Regulation (EU) No 236/2012, each person holding a net short position which reaches or falls below 0.1% of the issued share capital of a Dutch listed company is required to notify such position to the AFM. Each subsequent increase of this position by 0.1% above 0.1% must also be notified. Each net short position equal to 0.5% of the issued share capital of a Dutch listed company and any subsequent increase of that position by 0.1% will be made public via the AFM short selling register. A final disclosure is made public once the position has fallen below 0.5%. To calculate whether a natural person or legal person has a net short position, their short positions and long positions must be set off. A short transaction in a share can only be contracted if a reasonable case can be made that the shares sold can actually be delivered, which requires confirmation of a third party that the shares have been located. The notification shall be made no later than 15:30 p.m. Central European Summer Time ("**CEST**") on the following trading day.

Obligations of Directors to Disclose Holdings

Pursuant to the DFSA, each Director must notify the AFM: (i) immediately following the initial admission to trading and listing of the number of Ordinary Shares and options they hold and the number of votes they are entitled to cast in respect of the Company's issued share capital; and (ii) subsequently of each change in the number of Ordinary Shares or options they hold and of each change in the number of votes they are entitled to cast in respect of the Company's issued share

capital, immediately after the relevant change. If a Director has notified a transaction to the AFM under the DFSA as described under "*Obligations of Shareholders to Disclose Holdings*", such notification is sufficient for purposes of the DFSA as described in this paragraph.

Obligations of PDMRs to Disclose Holdings

Pursuant to the Market Abuse Regulation, persons discharging managerial responsibilities (each a "PDMR"), must notify the AFM and the Company by means of a standard form of any transactions conducted for their own account relating to Ordinary Shares or any debt instruments of the Company or to derivatives or other financial instruments linked thereto.

PDMRs within the meaning of the Market Abuse Regulation include: (i) Directors; or (ii) senior executives who are not Directors, who have regular access to inside information relating directly or indirectly to the Company and power to take managerial decisions affecting the future developments and business prospects of the Company.

In addition, pursuant to the Market Abuse Regulation, persons who are closely associated with PDMRs for purposes of the Market Abuse Regulation are also required to notify the AFM and the Company of any transactions conducted for their own account relating to Ordinary Shares or any debt instruments of the Company or to derivatives or other financial instruments linked thereto. Closely associated persons to PDMRs under the Market Abuse Regulation are : (i) the spouse or any partner considered by national law as equivalent to the spouse; (ii) dependent children; (iii) other relatives who have shared the same household for at least one year at the relevant transaction date; and (iv) any legal person, trust or partnership, the managerial responsibilities of which are discharged by a PDMR or by a person referred to under paragraph (i), (ii) or (iii) above, which is directly or indirectly controlled by such a person, which is set up for the benefit of such a person, or the economic interest of which is substantially equivalent to those of such a person.

These notification obligations under the Market Abuse Regulation apply to any subsequent transaction once a total amount of transactions conducted by a PDMR or a person closely associated to a PDMR has reached the threshold of EUR 5,000 within a calendar year (calculated without netting). The first transaction exceeding the threshold must be notified as set out above. The transactions carried out by a PDMR and by a closely associated person should not be aggregated. The notifications pursuant to the Market Abuse Regulation described above must be made to the AFM by the PDMRs and by closely associated persons no later than the third business day following the relevant transaction date. The PDMR must notify the AFM of their transactions and transactions carried out by closely associated persons within two business days of receipt of notification of those transactions. Notwithstanding the foregoing, Directors need to notify the AFM of each change in the number of Ordinary Shares that they hold and of each change in the number of votes they are entitled to cast in respect of the Company's issued share capital, immediately after the relevant change.

The Company is required to draw up a list of all PDMRs and persons closely associated with them and notify PDMRs of their obligations in writing. PDMRs are required to notify the persons closely associated with them of their obligations in writing.

Non-compliance

Non-compliance with the notification obligations under the DFSA and the Market Abuse Regulation, set out in the paragraphs above, is an economic offence (*economisch delict*) and could lead to the imposition of criminal prosecution, administrative fines, imprisonment or other sanctions. The AFM may impose administrative penalties or a cease-and-desist order under penalty for non-compliance. If criminal charges are pressed, the AFM is no longer allowed to impose administrative penalties and, *vice versa*, the AFM is no longer allowed to seek criminal prosecution if administrative penalties have been imposed. Furthermore, a civil court can impose measures against any person who fails to notify or incorrectly notifies the AFM of matters required to be correctly notified. A claim requiring that such measures be imposed must be instituted by the Company and/or one or more Shareholders who alone or together with others represent(s) at least 3% of the Company's issued share capital or are able to exercise at least 3% of the voting rights. The measures that the civil court may impose, include:

(i) an order requiring the person violating the disclosure obligations to make appropriate disclosure; (ii) suspension of voting rights in respect of such person's Ordinary Shares for a period of up to three years as determined by the court; (iii) voiding a resolution adopted by the General Meeting, if the court determines that the resolution would not have been adopted if the voting rights of the person who is obliged to notify had not been exercised, or suspension of a resolution until the court makes a decision about such voiding; and, (iv) an order to the person violating the disclosure obligations to refrain, during a period of up to five years as determined by the court, from acquiring Ordinary Shares and/or voting rights in Ordinary Shares.

Public registry

The AFM does not issue separate public announcements of these notifications. It does, however, keep a public register of all notifications under the DFSA on its website (Registers (afm.nl)). Third parties can request to be notified automatically by email of changes to the public register in relation to a particular Company's shares or a particular notifying party.

Identity of Shareholders and distribution of information

The Company may, in accordance with Chapter 3A of the Dutch Securities Giro Act, request (i) Euroclear Nederland, (ii) admitted institutions, (iii) intermediaries, (iv) institutions abroad, and (v) managers of investment institutions, to provide certain information on the identity of its Shareholders. No information will be given on Shareholders with an interest of less than 0.5% of the issued share capital. A holder of Ordinary Shares who, individually or together with other Shareholders, holds an interest of at least 10% of the issued share capital may request the Company to establish the identity of its Shareholders. This request may only be made during a period of 60 days until (and not including) the 42nd day before the day on which the General Meeting will be held.

At the written request of a Shareholder who, individually or with other Shareholders, holds Ordinary Shares that represent at least 1% of the issued and outstanding share capital or a market value of at least EUR 250,000 the Company will disseminate information, prepared by such Shareholder or Shareholders in connection with an agenda item for the General Meeting, to other Shareholders of which the Company received certain information upon the request, at its own discretion, for such information with the entities listed in the previous paragraph under (iii), (iv) and (v). The Company can only refuse disseminating such information, if received less than seven business days prior to the day of the General Meeting, if the information gives or could give an incorrect or misleading signal or if, in light of the nature of the information, the Company cannot reasonably be required to disseminate it.

Related Party Transactions

Directive (EU) 2017/828 of the European Parliament and of the Council of 17 May 2017 amending Directive 2007/36/EC of the European Parliament and of the Council of 11 July 2007 as regards the encouragement of long-term shareholder engagement (the "**Shareholder Rights Directive II**") establishes requirements in relation to the exercise of certain shareholder rights attached to voting shares in relation to general meetings of companies which have their registered office in a Member State of the European Union and the shares of which are admitted to trading on a regulated market situated or operating within a Member State of the European Union.

The Dutch act to implement the Shareholder Rights Directive II (*bevordering van de langetermijnbetrokkenheid van aandeelhouders*) (the "**Dutch SRD Act**") entered into force on 1 December 2019. The Dutch SRD Act, among other things, added new rules on related party transactions to the DCC and provided that "material transactions" with "related parties" not entered into within the ordinary course of business or not concluded on normal market terms must be approved by the Board and be publicly announced at the time that the transaction is entered into. If information is required to be published at an earlier stage under the Market Abuse Regulation, that requirement prevails. The Board is required to establish an internal procedure to periodically assess whether transactions with related parties are concluded in the ordinary course of business and on normal market terms. Any Director that is involved in a related party transaction cannot participate in the decision-making with respect to the related party transaction concerned. In this context: a "related

party" is interpreted in accordance with IFRS (IAS 24 (Related Party Disclosures)) and includes a party that has "control", "joint control" or "significant influence" over the Company or is a member of the Company's key management personnel; and a transaction is considered "material" if it would constitute inside information within the meaning of the Market Abuse Regulation and is concluded between the Company and a related party (which for this purpose, and in line with the Dutch Corporate Governance Code, in any event includes one or more shareholders representing at least 10% of the issued share capital or a Director). Certain related party transactions are not subject to the foregoing approval and disclosure provisions, including transactions concluded between the Company and any of its subsidiaries.

In addition, under the Code, all transactions between the Company and a Shareholder holding 10% or more of the Company's issued share capital should be agreed on customary terms. Decisions to enter into such a transaction that is of material significance to the Company and/or to the Shareholder concerned should be approved by the Board. Any such transaction should be disclosed in the Company's board report, together with an affirmative statement that these recommendations of the Code have been complied with.

Market Abuse Regulation

The regulatory framework on market abuse is set out in the Market Abuse Directive (2014/57/EU) as implemented in Dutch law and the Market Abuse Regulation, which is directly applicable in the Netherlands.

Insider dealing and market manipulation prohibitions

Pursuant to the Market Abuse Regulation, no natural or legal person is permitted to: (i) engage or attempt to engage in insider dealing in financial instruments listed on a regulated market or for which a listing has been requested, such as the Ordinary Shares; (ii) recommend that another person engages in insider dealing or induce another person to engage in insider dealing; or (iii) unlawfully disclose inside information relating to the Ordinary Shares or the Company.

Insider dealing arises where a person possesses inside information, as described in the following paragraph "*Public disclosure of inside information*", and uses that information by acquiring or disposing of, for its own account or for the account of a third party, directly or indirectly, financial instruments to which that information relates. The use of inside information by cancelling or amending an order concerning a financial instrument to which the information relates where the order was placed before the person concerned possessed the inside information will be considered to be insider dealing.

The Company has adopted insider dealing rules in respect of the reporting and regulation of transactions in the Company's securities by Directors and its employees, which will be effective as at the First Trading Date. Furthermore, no person may engage in or attempt to engage in market manipulation.

Public disclosure of inside information

The Company is required to make inside information public. Pursuant to Market Abuse Regulation, inside information is (i) information (ii) of a precise nature, (iii) which has not been made public, (iv) relating, directly or indirectly, to one or more issuers or to one or more financial instruments, and (v) which, if it were made public, would be likely to have a significant effect on the prices of those financial instruments or on the price of related derivative financial instruments. Unless an exception applies, the Company must without delay publish inside information which directly concerns the Company by means of a press release which it must file with the AFM and post and maintain on its website for at least five years.

An intermediate step in a protracted process can also be deemed to be inside information if, by itself, it satisfies the criteria of inside information. Under specific circumstances, the disclosure of inside information may be delayed, which needs to be notified to the AFM after the disclosure has been

made. Upon request of the AFM, a written explanation needs to be provided setting out why a delay of the publication was considered permitted.

Manager's transactions

A PDMR is not permitted to (directly or indirectly) conduct any transactions on their own account or for the account of a third party, relating to Ordinary Shares or debt instruments of the Company or other financial instruments linked thereto, during a closed period of 30 calendar days before the announcement of an interim financial report or an annual report of the Company.

Non-compliance

In the case of non-compliance with the market abuse rules set out above, the AFM has the power to take appropriate administrative sanctions, such as fines, and/or other administrative measures in relation to possible infringements. Non-compliance with the market abuse rules set out above could also constitute an economic offense (*economisch delict*) and/or a crime (*misdrijf*) and could lead to the imposition of administrative fines by the AFM. The public prosecutor could press criminal charges resulting in fines or imprisonment. If criminal charges are pressed, it is no longer allowed to impose administrative penalties and *vice versa*.

The AFM shall in principle also publish any decision imposing an administrative sanction or measure in relation to an infringement of the Market Abuse Regulation.

Insider Trading

The Company has adopted insider trading rules in respect of the reporting and regulation of transactions in the Company's securities by its Directors and its employees, which will be effective as at the First Trading Date. The Company and any person acting on its behalf or on its account is obligated to draw up an insider list, to promptly update the insider list and provide the insider list to the AFM upon its request. The Company and any person acting on its behalf or on its account is obligated to take all reasonable steps to ensure that any person on the insider list acknowledges in writing the legal and regulatory duties entailed and is aware of the sanctions applicable to insider dealing, market manipulation and unlawful disclosure of inside information.

Transparency Directive

The Netherlands is the Company's home Member State for the purposes of Directive 2004/109/EC, as a consequence of which the Company will be subject to the DFSA in respect of certain ongoing transparency and disclosure obligations.

SHAREHOLDER STRUCTURE AND RELATED PARTY TRANSACTIONS

Holdings as of the Date of this Prospectus

The following table sets forth information with respect to the size of the shareholding of the current shareholders which have a direct or indirect capital or voting interest of 3% or more as of the date of this Prospectus:

Shareholders	Ordinary Shares as of the Date of this Prospectus*		
	Amount	Share capital	Voting rights
Ottobock SE & Co. KGaA	4,500,000	540,000.00	10.1%
INKEF Capital B.V.	3,987,754	475,530.48	8.9%
LSP Advisory B.V.	3,883,368	466,004.16	8.7%
Gimv (Private Equity)	3,201,689	384,202.68	7.2%
Wellington Partners GmbH	2,638,936	316,672.32	5.9%

* Takes into account the effect of 10,000,000 New Ordinary Shares sold in the Private Placement and to be issued on the Listing Date.

Except as disclosed above, the Company is not aware of any other person or legal entity that, as of the date of this Prospectus, has a direct or indirect capital or voting interest of 3% or more. None of the parties listed above has voting rights that differ from other holders of Shares. Each Ordinary Share gives the right to cast one vote at the General Meetings. All Shareholders have the same voting rights.

The Company is not aware of any arrangements the operation of which may at a subsequent date result in a change of control of the Company. The rights and obligations of Shareholders, including minority Shareholders, are governed by applicable laws and regulations. See, for example, "*Description of Share Capital—Obligations to Disclose Holdings—Related Party Transactions*". The Articles of Association do not provide any specific provisions in addition to the provisions of the applicable laws and regulations that ensure control by the major or controlling Shareholders is not abused.

Related Party Transactions

The Company has not entered into any transactions with related parties as defined in IAS 24 'Related Parties Disclosure', in accordance with IFRS since 31 December 2023 (i.e. the date of the Financial Statements).

The Company's policy is to enter into transactions with related parties on terms that are generally no more favorable, or no less favorable, than those available from unaffiliated third parties. Such transactions are subject to approval of disinterested members of the Board.

Shareholders' Loans

On 17 January 2023, the Company and Grégoire Courtine entered into a shareholder loan agreement, under which the Company grants to Grégoire Courtine a loan up to a total amount of EUR 195,000, payable in installments of up to EUR 65,000 per year during a three-year lending period starting 1 January 2023 to diminish the tax and financial impact of Grégoire Courtine's shareholding in the Company. The loan bears an interest rate of 1.25% *per annum* which shall be automatically lowered, respectively increased, if it is at any time found to be higher than the maximum, respectively lower than the minimum rate applicable for shareholder loans as approved by any relevant tax authorities. The loan is granted until 1 December 2037. The maturity date shall automatically be deferred by additional one year periods unless reimbursement is requested by the Company at least three months before the then relevant maturity date. As of the date of this prospectus, no amounts were drawn under the facility.

Based on the Company's experience in the businesses in which it operates and the terms of transactions with unaffiliated third parties, management believes that the shareholder loan met the standard established above at the time it occurred and was carried out on arm's length terms.

THE LISTING

Introduction

Application will be made to admit the New Ordinary Shares to listing and trading on Euronext under the symbol "ONWD".

There will be no offering in any jurisdiction. The Company is not taking any action to permit an offering of the New Ordinary Shares in any jurisdiction. The New Ordinary Shares that have already been placed in the Private Placement have been sold under an exemption from the prospectus publication requirement in accordance with the Prospectus Regulation.

Cornerstone Investment

Ottobock SE & Co. KGaA has agreed to be a Cornerstone Investor in the Private Placement and entered into the Cornerstone Investor Agreement with the Company on 22 October 2024. Under the terms of the Cornerstone Investor Agreement, the Cornerstone Investor irrevocably agreed to purchase New Ordinary Shares for an aggregate consideration of EUR 22.5 million or as near as possible to such amount excluding the issuance of fractional shares, subject to certain customary conditions. 4,500,000 New Ordinary Shares will be issued to the Cornerstone Investor on 28 October 2024, such number being calculated by dividing EUR 22.5 million by EUR 5.00 and such calculated number of New Ordinary Shares being rounded down to the next full number, (the "**Investor Shares**"). The Cornerstone Investor will pay an aggregate purchase price of EUR 22,500,000 on 28 October 2024 for the Investor Shares, being calculated by multiplying the number of Investor Shares by EUR 5.00. The Cornerstone Investor and the Company have agreed to a lock-up for a period of 180 days commencing on 28 October 2024, subject to customary exemptions (see "*Important Information—Lock-up arrangements*"). The Cornerstone Investor did not and will not receive a consideration for its investment in the Company.

Timetable

Subject to acceleration or extension of the timetable by the Company for the Listing, the Listing is expected to occur on the Listing Date.

The Company may adjust the dates, times and periods given in the timetable and throughout this Prospectus. If any of them should decide to do so, the Company will make this public through a press release, which will also be posted on the Company's website (<https://ir.onwd.com/>).

Delivery and Payment of the Net Proceeds

The New Ordinary Shares are registered shares. All New Ordinary Shares will be entered into the collection deposit (*verzameldepot*) and giro deposit (*girodepot*) on the basis of the Dutch Securities Giro Act. Application will be made for the New Ordinary Shares to be accepted for delivery through the book-entry facilities of Euroclear Nederland. Euroclear Nederland is located at Herengracht 459-469, 1017 BS Amsterdam, the Netherlands.

Delivery of the respective New Ordinary Shares will take place on 28 October 2024 against payment of the net proceeds from the Private Placement to the Company, where 10,000,000 New Ordinary Shares shall be delivered through the book-entry facilities of Euroclear Nederland, in accordance with its normal procedures applicable to equity securities.

Dilution

The private placement of the New Ordinary Shares to qualified investors as defined in Article 2 of the Prospectus Regulation (the "**Qualified Investors**") in the European Economic Area, to certain qualified investors as defined in the UK Prospectus Regulation in the United Kingdom who are also (i) investment professionals falling within Article 19(5) of the Financial Promotion Order, (ii) high net worth entities or other persons falling within Article 49(2)(a) to (d) of the Financial Promotion Order or

(iii) persons to whom an invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA 2000) in connection with the issue or sale of any New Ordinary Shares may otherwise lawfully be communicated or caused to be communicated (all such persons being referred to as "**Relevant Persons**") and to institutional investors in certain other jurisdictions (the "**Private Placement**") will result in dilution of voting interests of the shareholders of the Company holding shares in the Company prior to the Private Placement. The New Ordinary Shares, subscribed for by the investors who participated in the Private Placement, have already been allocated to the investors in the Private Placement on 24 October 2024. The dilutive effect following the consummation of the Private Placement is summarized in the table below:

	<u>Prior to the Private Placement</u>	<u>Subsequent of the Private Placement</u>
Number of ordinary shares each with a nominal value of EUR 0.12	34,628,832	44,628,832
% dilution		22.4

Listing and Trading

The Ordinary Shares are already admitted to listing and trading in euro on Euronext Brussels (primary listing), Euronext Amsterdam (secondary listing) and Euronext Paris (secondary listing) at the time of the Listing. Application will be made to admit all of the New Ordinary Shares to listing and trading on Euronext Brussels (primary listing), Euronext Amsterdam (secondary listing) and Euronext Paris (secondary listing) under the symbol "ONWD" with ISIN NL0015000HT4.

Trading in the New Ordinary Shares on Euronext Brussels (primary listing), Euronext Amsterdam (secondary listing) and Euronext Paris (secondary listing) is expected to commence on the Listing Date.

Voting Rights

Each Share confers the right to cast one vote in the General Meeting, see "*Description of Share Capital—General Meetings and Voting Rights*". All Shareholders have the same voting rights.

Ranking and Dividends

The New Ordinary Shares will, upon issue, continue to rank equally with the Ordinary Shares in all respects. The New Ordinary Shares carry dividend rights as of the date of issue. See "*Dividend Policy*".

Listing Agent

ING Bank N.V. is the Listing Agent with respect to the Ordinary Shares on Euronext.

Jurisdiction and Competent Courts

This Prospectus is governed by Dutch Law. All disputes arising in connection with this Prospectus and the Listing shall be subject to the non-exclusive jurisdiction of the courts in Amsterdam, the Netherlands.

Placement Agents Agreement

The Placement Agents Agreement concluded by and among the Placement Agents and the Company relates to the offer and sale of the New Ordinary Shares placed in the Private Placement. The Placement Agents will receive customary fees for the placement of the New Ordinary Shares. Payment of the net proceeds from the Private Placement against delivery of those New Ordinary Shares is subject to certain conditions therein: i.e.,

- the issuance and delivery of copies of the deed of issue for the New Ordinary Shares to the Placement Agents;

- the signing of the settlement agency agreement with the Listing Agent;
- the signing and delivery of the pricing statement relating to the Private Placement to the Placement Agents;
- the Placement Agents shall not have discovered and disclosed to the Company that the company's annual report for the fiscal year ended 31 December 2023, the press releases published between 2 May 2024 and 15 October 2024, the press releases published in connection with the Private Placement, certain company presentations published on the Company's website, when taken as a whole, contain an untrue statement of a fact which, in the opinion of the Placement Agents, is material or omit to state any fact which, in the opinion of the Placement Agents, is material and is required to be stated therein or is necessary to make the statements therein not misleading;
- all corporate proceedings and other legal matters incident to the authorization, form, execution, delivery and validity of the placement agents agreement and the New Ordinary Shares placed in the Private Placement and all other legal matters relating to the placement agents agreement and the transactions contemplated thereby shall be satisfactory in all material respects for the Placement Agents, and the Company shall have furnished to such counsels all documents and information that they may request to enable them to pass upon such matters;
- the Placement Agents shall have received on the Listing Date: (i) copies of (x) the minutes of the Company's annual general meeting dated 13 June 2024, (y) the resolution of the Board approving the main terms and conditions of the placement agents agreement and establishing and authorizing a pricing committee to effect the issuance of the New Ordinary Shares placed in the Private Placement; (ii) a certified copy of the articles of association of the Company; and (iii) a certified copy of the commercial register's extract relating to the Company dated less than three Amsterdam business days before the Listing Date;
- the press release announcing the Private Placement shall have been prepared and issued by the Company and simultaneously filed with the AFM in the designated AFM register without delay after the execution of the placement agents agreement;
- for the period from the date of the placement agents to and including the Listing Date, in the judgment of the Placement Agents (acting in good faith), no change or development shall have arisen that would have material adverse effect;
- the notices of Euronext Brussels, Euronext Amsterdam and Euronext Paris concerning the issue and approval of the admission to listing and trading of the New Ordinary Shares placed in the Private Placement on the regulated markets of Euronext Brussels, Euronext Amsterdam and Euronext Paris shall have been published;
- the Placement Agents shall have received from their U.S. counsel, from U.S. counsel for the Company and from Dutch counsel for the Company, such legal counsels' written opinions, addressed to the Placement Agents and dated as of the Listing Date;
- the Company shall have furnished to the Placement Agents certificates dated the date of pricing of the Private Placement (24 October 2024) and dated on the Listing Date and signed by the chief executive officer or finance director of the Company, to the effect that all the representations and warranties of the Company contained in the placement agents agreement are true and correct as of the Listing Date, and that the Company has performed and complied with all of its obligations and undertakings hereunder on or before the Listing Date;

- on or prior to signing the placement agents agreement, the Company shall have furnished to the Joint Global Coordinators a letter from each member of the Board, except for John de Koning, Rahma Samow and Rob ten Hoedt; and

- prior to the Listing Date, the Company shall have furnished to the Placement Agents such further information, certificates and documents as the Placement Agents may reasonably request.

Additionally, the Company agreed that the Placement Agents have a termination right relating to the placement agents agreement in the event of (i) a breach by the Company of the placement agents agreement, (ii) it has come to the notice of the Placement Agents that any breach of, or any event rendering untrue or incorrect in any respect, any of the representations and warranties by the Company contained in the placement agents agreement have occurred, or (iii) if any of the above mentioned conditions precedents of the placement agent agreement shall not have been fulfilled.

Fee Letter with KBC Securities NV

On 23 October 2024, KBC Securities NV entered into a separate fee letter with the Company in connection with the Private Placement, pursuant to which KBC Securities NV was appointed to act as a co-lead manager in the Private Placement (the "**Co-Lead Manager**").

Interests of Parties in the Listing and the Private Placement

The Company will receive the net proceeds from the Private Placement. Pursuant to the Placement Agents Agreement the Company has agreed with the Placement Agents that the New Ordinary Shares shall be listed on Euronext. Consequently, each of the Company and each of the Placement Agents has an interest in the completion of the Listing.

The Placement Agents and the Co-Lead Manager are acting only for the Company and not acting for anyone else in connection with the Listing and the Private Placement. The Placement Agents and the Co-Lead Manager will receive fees on and the size of the fees depended on the result of the Private Placement upon issuance of the New Ordinary Shares on the Listing Date. As a result of the contractual relationships between the Placement Agents, the Co-Lead Manager and the Company on the one hand and the investors that have participated in the Private Placement on the other hand, the Placement Agents and the Co-Lead Manager have an interest in the success of the Private Placement and in the Listing.

None of the aforementioned interests in the Private Placement and the Listing constitute a conflict of interest or a potential conflict of interest. Consequently, there are no conflicts of interest with respect to the Private Placement or the Listing.

TAXATION

TAX WARNING

Potential investors and sellers of Ordinary Shares should be aware that they may be required to pay documentation taxes (commonly referred to as stamp duties) or other fiscal duties or charges in accordance with the laws and practices of the country where the Ordinary Shares are transferred or other jurisdictions. In addition, dividends distributed on the Ordinary Shares, or income derived or deemed to be derived from the Ordinary Shares, may be subject to taxation, including withholding taxes, in the jurisdiction of the Company, in the jurisdiction of the holder of Ordinary Shares, or in other jurisdictions in which the holder of Ordinary Shares is required to pay taxes. Any such tax consequences may have an impact on the net income received from the Ordinary Shares.

Prospective investors should carefully consider the tax consequences of investing in the Ordinary Shares and consult their own tax adviser about their own tax situation. Finally, potential investors should be aware that tax regulations and their application by the relevant taxation authorities change from time to time, with or without retroactive effect. Accordingly, it is not possible to predict the precise tax treatment which will apply at any given time.

Material Dutch Tax Considerations

Scope of Discussion

This section only outlines certain material Dutch tax consequences of the acquisition, holding and disposal of the Ordinary Shares. This section does not purport to describe all possible tax considerations or consequences that may be relevant to a holder or prospective holder of Ordinary Shares and does not purport to deal with the tax consequences applicable to all categories of investors, some of which (such as trusts or similar arrangements) may be subject to special rules. In view of its general nature, this section should be treated with corresponding caution.

This section is based on the tax laws of the Netherlands, published regulations thereunder and published authoritative case law, all as in effect on the date hereof, including, for the avoidance of doubt, the tax rates, tax brackets and deemed returns applicable on the date hereof, and all of which are subject to change, possibly with retroactive effect. Any such change may invalidate the contents of this section, which will not be updated to reflect such change. Where this section refers to "the Netherlands" or "Dutch" it refers only to the part of the Kingdom of the Netherlands located in Europe.

This section is intended as general information only and is not Dutch tax advice or a complete description of all Dutch tax consequences relating to the acquisition, holding and disposal of the Ordinary Shares. Holders or prospective holders of Ordinary Shares should consult their own tax advisor regarding the Dutch tax consequences relating to the acquisition, holding and disposal of Ordinary Shares in light of their particular circumstances.

Please note that this section does not describe the Dutch tax consequences for:

- (i) a holder of Ordinary Shares if such holder has a substantial interest (*aanmerkelijk belang*) or deemed substantial interest (*fictief aanmerkelijk belang*) in the Company under the Dutch Income Tax Act 2001 (*Wet inkomstenbelasting 2001*). Generally, a holder is considered to hold a substantial interest in the Company, if such holder alone or, in the case of an individual, together with such holder's partner for Dutch income tax purposes, or any relatives by blood or marriage in the direct line (including foster children), directly or indirectly, holds (i) an interest of 5% or more of the total issued and outstanding capital of the Company or of 5% or more of the issued and outstanding capital of a certain class of shares; or (ii) rights to acquire, directly or indirectly, such interest; or (iii) certain profit sharing rights that relate to 5% or more of the Company's annual profits or to 5% or more of the Company's liquidation proceeds. A deemed substantial interest may arise if a substantial interest (or part thereof) in the Company has been disposed of, or is deemed

to have been disposed of, on a non-recognition basis;

- (ii) a holder of Ordinary Shares, if the Ordinary Shares held by such holder qualify or qualified as a participation (*deelneming*) for purposes of the Dutch Corporate Income Tax Act 1969 (*Wet op de vennootschapsbelasting 1969*). Generally, a holder's shareholding of, or right to acquire, 5% or more in a Company's nominal paid-up share capital qualifies as a participation. A holder may also have a participation if (a) such holder does not have a shareholding of 5% or more but a related entity (statutorily defined term) has a participation or (b) the company in which the shares are held is a related entity (statutorily defined term);
- (iii) a holder of Ordinary Shares which is or who is entitled to the dividend withholding tax exemption (*inhoudingsvrijstelling*) with respect to any income (*opbrengst*) derived from the Ordinary Shares (as defined in Article 4 of the Dutch Dividend Withholding Tax Act 1965 (*Wet op de dividendbelasting*)). Generally, a holder of Ordinary Shares may be entitled or required to apply, subject to certain other requirements, the dividend withholding tax exemption if it is an entity and holds an interest of 5% or more in the Company's nominal paid-up share capital;
- (iv) pension funds, investment institutions (*fiscale beleggingsinstellingen*) and tax exempt investment institutions (*vrijgestelde beleggingsinstellingen*) (each as defined in the Dutch Corporate Income Tax Act 1969) and other entities that are, in whole or in part, not subject to or exempt from Dutch corporate income tax, entities that have a function comparable to an investment institution or a tax exempt investment institution, as well as entities that are exempt from corporate income tax in their country of residence, such country of residence being another state of the European Union, Norway, Liechtenstein, Iceland or any other state with which the Netherlands has agreed to exchange information in line with international standards; and
- (v) a holder of Ordinary Shares if such holder is an individual for whom the Ordinary Shares or any benefit derived from the Ordinary Shares is a remuneration or deemed to be a remuneration for (employment) activities performed by such holder or certain individuals related to such holder (as defined in the Dutch Income Tax Act 2001).

Withholding Tax on Dividends

Regular Dutch Dividend Withholding Tax

Dividends distributed by the Company are generally subject to Dutch dividend withholding tax at a rate of 15%. Generally, the Company is responsible for the withholding of such dividend withholding tax at source; the Dutch dividend withholding tax is for the account of the holder of Ordinary Shares.

The expression "dividends distributed" includes, but is not limited to:

- distributions in cash or in kind, deemed and constructive distributions and repayments of paid-in capital not recognized for Dutch dividend withholding tax purposes;
- liquidation proceeds, proceeds from the redemption of Ordinary Shares, or proceeds from the repurchase of Ordinary Shares (other than as temporary portfolio investment (*tijdelijke belegging*) by the Company or one of its subsidiaries or other affiliated entities, in each case to the extent such proceeds exceed the average paid-in capital of those Ordinary Shares as recognized for Dutch dividend withholding tax purposes;
- an amount equal to the par value of the Ordinary Shares issued or an increase of the par value of the Ordinary Shares, to the extent that no related contribution, recognized for Dutch dividend withholding tax purposes, has been made or will be made; and
- partial repayment of the paid-in capital recognized for Dutch dividend withholding tax purposes, if and to the extent that the Company has net profits (*zuivere winst*), unless (i) the general meeting of shareholders has resolved in advance to make such repayment and (ii) the par value of the Ordinary Shares concerned has been reduced by an equal amount by way of

an amendment to the Company's articles of association. The term "net profits" includes anticipated profits that have yet to be realized.

Corporate legal entities that are resident or deemed to be resident of the Netherlands for Dutch corporate income tax purposes ("**Dutch Resident Entities**") generally are entitled to an exemption from, or a credit for, any Dutch dividend withholding tax against their Dutch corporate income tax liability. The credit in any given year is, however, limited to the amount of Dutch corporate income tax payable in respect of the relevant year with an indefinite carry forward of any excess amount. Individuals who are resident or deemed to be resident of the Netherlands for Dutch personal income tax purposes ("**Dutch Resident Individuals**"), generally are entitled to a credit for any Dutch dividend withholding tax against their Dutch personal income tax liability and to a refund of any residual Dutch dividend withholding tax. The above generally also applies to holders of Ordinary Shares that are neither resident nor deemed to be resident of the Netherlands ("**Non-Resident Holders**") if the Ordinary Shares are attributable to a Dutch permanent establishment of such Non-Resident Holder.

A holder of Ordinary Shares, resident of a country other than the Netherlands may, depending on such holder's specific circumstances, be entitled to exemptions from, reduction of, or full or partial refund of, Dutch dividend withholding tax under Dutch domestic tax law, EU law, or treaties for the avoidance of double taxation convention in effect between the Netherlands and such other country.

Exceptions and relief from Dutch dividend withholding tax may apply as set forth in the preceding paragraph.

Dividend stripping

According to Dutch domestic anti-dividend stripping rules, no credit against Dutch tax, exemption from, reduction or refund of Dutch dividend withholding tax will be granted if the recipient of the dividends the Company paid is not considered the beneficial owner (*uiteindelijk gerechtigde*; as described in the Dutch Dividend Withholding Tax Act 1965) of those dividends. This legislation generally targets situations in which a shareholder retains its economic interest in shares but reduces the withholding tax costs on dividends by a transaction with another party. It is not required for these rules to apply that the recipient of the dividends is aware that a dividend stripping transaction took place. The Dutch State Secretary of Finance takes the position that the definition of beneficial ownership introduced by this legislation will also be applied in the context of a double taxation convention.

As of 1 January 2024, more stringent rules apply to the setoff, exemption from, and reduction or refund of Dutch dividend withholding tax to address situations where a claim for setoff, exemption, reduction or refund may align with the letter of Dutch tax law or a double taxation convention but goes against the underlying intention or spirit of the dividend stripping rules, as perceived by the legislator. The burden of proof with respect to beneficial ownership of dividends distributed by the Company rests on the Dutch tax authorities. If, however, a shareholder would receive dividends, including dividends on the Ordinary Shares, in a calendar year in respect of which an aggregate amount of EUR 1,000 in Dutch dividend withholding tax would otherwise be due based on the rate of 15%, the burden of proof with respect to beneficial ownership of such dividends lies with the shareholder. Furthermore, for shares traded on a regulated market, including the Ordinary Shares, it has been codified that the record date is used when determining the person who is entitled to the dividend.

Conditional Withholding Tax on Dividends

In addition to the regular Dutch dividend withholding tax as described above, a Dutch conditional withholding tax will be imposed on dividends distributed by the Company to entities related (*gelieerd*) to the Company, if such related entity:

- (i) is considered to be resident (*gevestigd*) in a jurisdiction that is listed in the yearly updated Dutch Regulation on low-taxing states and non-cooperative jurisdictions for tax purposes

(Regeling laagbelastende staten en niet-coöperatieve rechtsgebieden voor belastingdoeleinden) (a "Listed Jurisdiction"); or

- (ii) has a permanent establishment located in a Listed Jurisdiction to which the Ordinary Shares are attributable; or
- (iii) holds the Ordinary Shares with the main purpose or one of the main purposes of avoiding taxation for another person or entity and there is an artificial arrangement or transaction or a series of artificial arrangements or transactions; or
- (iv) is not considered to be the beneficial owner of the Ordinary Shares in its jurisdiction of residence because such jurisdiction treats another entity as the beneficial owner of the Ordinary Shares (a hybrid mismatch); or
- (v) is not resident in any jurisdiction (also a hybrid mismatch); or
- (vi) is a reverse hybrid (within the meaning of Article 2(12) of the Dutch Corporate Income Tax Act 1969), if and to the extent (x) there is a participant in the reverse hybrid which is related (*gelieerd*) to the reverse hybrid, (y) the jurisdiction of residence of such participant treats the reverse hybrid as transparent for tax purposes and (z) such participant would have been subject to the Dutch conditional withholding tax in respect of dividends distributed by the Company without the interposition of the reverse hybrid,

all within the meaning of the Dutch Withholding Tax Act 2021 (*Wet bronbelasting 2021*).

The Dutch conditional withholding tax on dividends will be imposed at the highest Dutch corporate income tax rate in effect at the time of the distribution (2024: 25.8%). The Dutch conditional withholding tax on dividends will be reduced, but not below zero, by any regular Dutch dividend withholding tax withheld in respect of the same dividend distribution. As such, based on the currently applicable rates, the overall effective tax rate of withholding the regular Dutch dividend withholding tax (as described above) and the Dutch conditional withholding tax on dividends will not exceed the highest corporate income tax rate in effect at the time of the distribution (2024: 25.8%).

Taxes on income and capital gains

Dutch Resident Entities

Generally, if the holder of Ordinary Shares is a Dutch Resident Entity, any income derived or deemed to be derived from the Ordinary Shares or any capital gains realized on the disposal or deemed disposal or exercise, as applicable of the Ordinary Shares is subject to Dutch corporate income tax at a rate of 19% with respect to taxable profits up to EUR 200,000 and 25.8% with respect to taxable profits in excess of that amount (rates and brackets for 2024).

Dutch Resident Individuals

If the holder of Ordinary Shares is a Dutch Resident Individual, any income derived or deemed to be derived from the Ordinary Shares or any capital gains realized on the disposal or deemed disposal or exercise, as applicable of the Ordinary Shares is subject to Dutch income tax at the progressive rates (with a maximum of 49.5% in 2024), if:

- (i) the Ordinary Shares are attributable to an enterprise from which the holder of Ordinary Shares derives a share of the profit, whether as an entrepreneur (*ondernemer*) or as a person who has a co-entitlement to the net worth (*medegerechtigd tot het vermogen*) of such enterprise without being a shareholder (as defined in the Dutch Income Tax Act 2001); or
- (ii) the holder of Ordinary Shares is considered to perform activities with respect to the

Ordinary Shares that go beyond ordinary asset management (*normaal, actief vermogensbeheer*) or otherwise derives benefits from the Ordinary Shares that are taxable as benefits from miscellaneous activities (*resultaat uit overige werkzaamheden*).

Taxation of savings and investments

If the above-mentioned conditions (i) and (ii) do not apply to the Dutch Resident Individual, the Ordinary Shares will be subject to an annual Dutch income tax under the regime for savings and investments (*inkomen uit sparen en beleggen*). Taxation only occurs insofar the Dutch Resident Individual's net investment assets for the year exceed a statutory threshold (*heffingvrij vermogen*). The net investment assets for the year are the fair market value of the investment assets less the fair market value of the liabilities on January 1 of the relevant calendar year (reference date; *peildatum*). Actual income or capital gains realized in respect of the Ordinary Shares are in principle not subject to Dutch income tax.

The Dutch Resident Individual's assets and liabilities taxed under this regime, including the Ordinary Shares, are allocated over the following three categories: (a) bank savings (*banktegoeden*), (b) other investments (*overige bezittingen*), including the Ordinary Shares, and (c) liabilities (*schulden*). The taxable benefit for the year (*voordeel uit sparen en beleggen*) is equal to the product of (x) the total deemed return divided by the sum of bank savings, other investments and liabilities and (b) the sum of bank savings, other investments and liabilities minus the statutory threshold, and is taxed at a flat rate of 36% (rate for 2024).

The deemed return applicable to other investments, including the Ordinary Shares, is set at 6.04% for the calendar year 2024. Transactions in the three-month period before and after 1 January of the relevant calendar year implemented to arbitrate between the deemed return percentages applicable to bank savings, other investments and liabilities will for this purpose be ignored if the holder of Ordinary Shares cannot sufficiently demonstrate that such transactions are implemented for other than tax reasons.

On 6 June 2024, the Dutch Supreme Court (Hoge Raad) ruled that the current Dutch income tax regime for savings and investments in certain specific circumstances contravenes with Section 1 of the First Protocol to the European Convention on Human Rights in combination with Section 14 of the European Convention on Human Rights (the "Ruling"). This is, in short, the case in the event the deemed return on the investment assets exceeds the actual return realized in respect thereof (calculated in line with the rules set out in the Ruling and successfully demonstrated by the taxpayer). Holders of Ordinary Shares are advised to consult their own tax advisor to ensure that the tax in respect of the Ordinary Shares is levied in accordance with the applicable Dutch tax rules at the relevant time.

Holders of Ordinary Shares are advised to consult their own tax advisor to ensure that the tax in respect of the Ordinary Shares is levied in accordance with the applicable Dutch tax rules at the relevant time.

Non-residents of the Netherlands

A holder of Ordinary Shares that is neither a Dutch Resident Entity nor a Dutch Resident Individual will not be subject to Dutch income tax in respect of income derived or deemed to be derived from the Ordinary Shares or in respect of any capital gains realized on the disposal or deemed disposal or exercise, as applicable, of the Ordinary Shares, provided that:

- (i) such holder does not have an interest in an enterprise or deemed enterprise (as defined in the Dutch Income Tax Act 2001 and the Dutch Corporate Income Tax Act 1969, as applicable) which, in whole or in part, is either effectively managed in the Netherlands or carried on through a permanent establishment, a deemed permanent establishment or a permanent representative in the Netherlands and to which enterprise or part of an

enterprise the Ordinary Shares are attributable; and

- (ii) in the event the holder is an individual, such holder does not carry out any activities in the Netherlands with respect to the Ordinary Shares that go beyond ordinary asset management and does not otherwise derive benefits from the Ordinary Shares that are taxable as benefits from miscellaneous activities in the Netherlands.

Gift and inheritance taxes

Residents of the Netherlands

Gift or inheritance taxes will arise in the Netherlands with respect to a transfer of Ordinary Shares by way of a gift by, or on the death of, a holder of Ordinary Shares who is resident or deemed resident of the Netherlands at the time of the gift or such holder's death.

Non-residents of the Netherlands

No gift or inheritance taxes will arise in the Netherlands with respect to a transfer of Ordinary Shares by way of a gift by, or on the death of, a holder of Ordinary Shares who is neither resident nor deemed to be resident of the Netherlands, unless:

- (i) in the case of a gift of an Ordinary Share by an individual who at the date of the gift was neither resident nor deemed to be resident of the Netherlands, such individual dies within 180 days after the date of the gift, while being resident or deemed to be resident of the Netherlands; or
- (ii) in the case of a gift of an Ordinary Share is made under a condition precedent, the holder of the Ordinary Shares is resident or is deemed to be resident of the Netherlands at the time the condition is fulfilled; or
- (iii) the transfer is otherwise construed as a gift or inheritance made by, or on behalf of, a person who, at the time of the gift or death, is or is deemed to be resident of the Netherlands.

For purposes of Dutch gift and inheritance taxes, amongst others, a person that holds the Dutch nationality will be deemed to be resident of the Netherlands if such person has been a resident of the Netherlands at any time during the ten years preceding the date of the gift or such person's death. Additionally, for purposes of Dutch gift tax, amongst others, a person not holding the Dutch nationality will be deemed to be resident of the Netherlands if such person has been a resident of the Netherlands at any time during the 12 months preceding the date of the gift. Applicable tax treaties may override deemed residency.

Value added tax (VAT)

No Dutch VAT will be payable by a holder of Ordinary Shares in respect of any payment in consideration for the holding or disposal or exercise, as applicable of the Ordinary Shares.

Real Property Transfer Tax

Under circumstances, the Ordinary Shares could, for the purposes of Dutch real property transfer tax (*overdrachtsbelasting*), be treated as real property (*fictieve onroerende zaken*) located in the Netherlands, in which case this tax could be payable upon acquisition of Ordinary Shares.

The Ordinary Shares will generally not be treated as real property if at the time of, or at any time during the year preceding, the acquisition of the Ordinary Shares:

- (i) our assets do not and did not include real property situated in the Netherlands; or
- (ii) our assets only include and included real property, situated either in or outside the Netherlands, that we do not and did not hold, and currently do not intend to hold, predominantly as a financial investment.

Real property as referred to under (i) and (ii) above includes legal ownership and more limited legal rights over the property (rights in rem) (*zakelijke rechten*) as well as contractual rights that give us economic exposure to the value of such real property, and certain participations or interests in entities that are treated as real property.

The Company's assets do not include and have not included real property situated in the Netherlands as described above.

Consequently, no Dutch real property transfer tax becomes payable upon an acquisition of the Ordinary Shares.

Stamp Duties

No Dutch documentation taxes (commonly referred to as stamp duties) will be payable by a holder of Ordinary Shares in respect of any payment in consideration for the holding or disposal or exercise, as applicable of the Ordinary Shares.

Residency

A holder of Ordinary Shares will not become, and will not be deemed to be, resident of the Netherlands for Dutch tax purposes by reason only of the acquisition and holding of the Ordinary Shares.

Material Belgian Tax Considerations

The paragraphs below present a summary of certain material Belgian federal income tax consequences of the ownership and disposal of the Ordinary Shares. The summary is based on laws, treaties and regulatory interpretations in effect in Belgium on the date of this Prospectus, all of which are subject to change, including changes that could have retroactive effect. Investors should appreciate that, as a result of evolutions in law or practice, the eventual tax consequences may be different from what is stated below.

This summary does not purport to address all tax consequences of the ownership and disposal of the Ordinary Shares, and does not take into account the specific circumstances of particular investors, some of which may be subject to special rules, or the tax laws of any country other than Belgium. This summary does not describe the tax treatment of investors that are subject to special rules, such as banks, insurance companies, collective investment undertakings, dealers in securities or currencies, persons that hold, or will hold, the Ordinary Shares as a position in a straddle, share-repurchase transaction, conversion transactions, synthetic security or other integrated financial transactions. Investors should consult their own advisers regarding the tax consequences of an investment in the Ordinary Shares in the light of their particular circumstances, including the effect of any state, local or other national laws. This summary does not address the local taxes that may be due in connection with an investment in shares, other than the additional municipal taxes which generally vary between 0% and 9% of the investor's income tax liability in Belgium.

For the purposes of this summary, a Belgian tax resident investor is:

- an individual subject to Belgian personal income tax, i.e. (i) an individual having its domicile in Belgium, (ii) when not having its domicile in Belgium, an individual having its seat of wealth in Belgium, or (iii) an individual assimilated to a resident for purposes of Belgian tax law;

- a company (as defined by Belgian tax law) subject to Belgian corporate income tax, i.e. a corporate entity having its principal establishment, administrative seat or effective place of management in Belgium (and that is not excluded from the scope of the Belgian corporate income tax) (a company having its registered seat in Belgium shall be presumed, unless the contrary is proved, to have its principal establishment, administrative seat or effective place of management in Belgium); or
- a legal entity subject to the Belgian tax on legal entities, i.e. a legal entity other than a company subject to Belgian corporate income tax having its principal establishment, administrative seat or effective place of management in Belgium.

A non-resident investor is any individual, company or legal entity that does not fall in any of the three previous classes.

Dividends

For Belgian income tax purposes, the gross amount of all benefits paid on or attributed to the Ordinary Shares is generally treated as a dividend distribution.

By way of exception, the repayment of capital carried out in accordance with applicable Dutch company law provisions is not treated as a dividend distribution to the extent that such repayment is imputed to fiscal capital. This fiscal capital includes, in principle, the actual paid-up statutory share capital and, subject to certain conditions, the paid-up share premiums and the cash amounts subscribed to at the time of the issue of profit sharing certificates. However, it is not possible to fully impute a repayment of capital to fiscal capital if the Company also has certain reserves. Under this imputation rule, a reimbursement of capital is proratedly imputed on, on the one hand, fiscal capital and, on the other hand, taxed reserves (whether or not incorporated in capital) and tax-exempt reserves incorporated in capital (according to a specific priority rule). The part imputed on the reserves is treated as a dividend distribution subject to applicable tax rules.

Belgian withholding tax at the current rate of 30% is normally levied on dividends by any intermediary established in Belgium that is in any way involved in the processing of the payment of non-Belgian sourced dividends (e.g. a Belgian financial institution). This withholding tax rate is however subject to such relief as may be available under applicable domestic or tax treaty provisions.

The Belgian withholding tax is calculated on the dividend amount after deduction of any non-Belgian dividend withholding tax.

In the case of a redemption of the Ordinary Shares, the redemption distribution (after deduction of the part of the fiscal capital represented by the redeemed Ordinary Shares) will be treated as a dividend subject to a Belgian withholding tax of 30%, subject to such relief as may be available under applicable domestic or tax treaty provisions. No withholding tax will be triggered if this redemption is carried out on a stock exchange and meets certain conditions.

In the event of a liquidation, any amounts distributed in excess of the fiscal capital will in principle be subject to the 30% withholding tax, subject to such relief as may be available under applicable domestic or tax treaty provisions.

Under Belgian law, non-Belgian dividend withholding tax is not creditable against Belgian income tax and is not reimbursable to the extent that it exceeds Belgian income tax.

Belgian Resident Individuals

For Belgian resident individuals who acquire and hold the Ordinary Shares as a private investment, the Belgian dividend withholding tax fully discharges their personal income tax liability. This means that they do not have to declare the dividends in their personal income tax return and that the Belgian withholding tax constitutes a final tax.

They may nevertheless need to report the dividends in their personal income tax return if no intermediary established in Belgium was in any way involved in the processing of the payment of the non-Belgian sourced dividends and the dividends have not been subject to Belgian withholding tax. Moreover, even if an intermediary established in Belgium was involved, they can opt to report the income in their personal income tax return. If (and only if) the dividends are reported, they will

normally be eligible for a tax exemption with respect to ordinary dividends in an amount of up to EUR 833 per year (amount applicable for income year 2024 – tax year 2025) and per taxpayer (Article 21, first subsection, 14°, of the Belgian Income Tax Code ("ITC")). The liquidation and redemption bonuses cannot benefit from the exemption described above, even if the threshold of EUR 833 has not been reached. For the avoidance of doubt, all reported dividends (not only dividends distributed on the Ordinary Shares) are taken into account to assess whether said maximum amount is reached.

Where the beneficiary needs or, as applicable, opts to report them, dividends will normally be taxable at the lower of the generally applicable 30% Belgian withholding tax rate on dividends or, in case globalization is more advantageous, at the progressive personal income tax rates applicable to the taxpayer's overall declared income. In addition, if the dividends are reported, the Belgian dividend withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, provided that the dividend distribution does not result in a reduction in value of or a capital loss on the Ordinary Shares. The latter condition is not applicable if the individual can demonstrate that it has held the Ordinary Shares in full legal ownership for an uninterrupted period of 12 months prior to the attribution of the dividends.

For Belgian resident individual investors who acquire and hold the Ordinary Shares for professional purposes, the Belgian withholding tax does not fully discharge their Belgian income tax liability. Dividends received must be reported by the investor and will, in such a case, be taxable at the investor's personal income tax rate (from 25% up to 50%, depending on the bracket, plus local surcharges). Belgian withholding tax levied may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own the Ordinary Shares in full legal ownership on the day the beneficiary of the dividend is identified; and (ii) the dividend distribution may not result in a reduction in value of or a capital loss on the Ordinary Shares. The latter condition is not applicable if the investor can demonstrate that it has held the full legal ownership of the Ordinary Shares for an uninterrupted period of 12 months prior to the attribution of the dividends.

Belgian Resident Companies

Dividends on the Ordinary Shares received by Belgian resident companies are in principle exempt from Belgian withholding tax provided that the investor satisfies the identification requirements in Article 106, par. 1 *jo* 117, par. 11 of the Royal Decree implementing the Belgian Income Tax Code.

For Belgian resident companies, the gross dividend income (after deduction of any non-Belgian withholding tax but including any Belgian withholding tax) must be declared in the corporate income tax return and will be subject to a corporate income tax rate of 25%, except that a reduced corporate income tax rate of 20% applies to small companies and Medium Sized Enterprises (as defined by Article 1:24, §1 to §6 of the Belgian Code on Companies and Associations) on the first EUR 100,000 of taxable profits (subject to certain conditions).

Belgian resident companies can generally (although subject to certain limitations) deduct 100% of the gross dividend received from their taxable income, or the Dividend Received Deduction, provided that at the time of a dividend payment or attribution: (i) the Belgian resident company holds Ordinary Shares representing at least 10% of the share capital or a participation with an acquisition value of at least EUR 2,500,000 (it being understood that only one out of the two tests must be satisfied); (ii) the Ordinary Shares representing the share capital have been or will be held in full ownership for an uninterrupted period of at least one year; and (iii) the conditions described in Article 203 ITC (relating to the taxation of the underlying distributed income and the absence of abuse), or the Article 203 ITC Taxation Condition, are met, or together, the Conditions for the application of the Dividend Received Deduction regime.

Conditions (i) and (ii) above are, in principle, not applicable to dividends received by an investment company within the meaning of art. 2, §1, 5°, f) ITC. The Conditions for the application of the Dividend Received Deduction regime depend on a factual analysis and for this reason the availability of this regime should be verified upon each dividend distribution.

Any Belgian dividend withholding tax levied at source can be credited against the ordinary Belgian corporate income tax and is reimbursable to the extent it exceeds such corporate income tax, subject

to two conditions: (i) the taxpayer must own the Ordinary Shares in full legal ownership on the day the beneficiary of the dividend is identified and (ii) the dividend distribution does not result in a reduction in value of or a capital loss on the Ordinary Shares. The latter condition is not applicable: (i) if the taxpayer can demonstrate that it has held the Ordinary Shares in full legal ownership for an uninterrupted period of 12 months immediately prior to the attribution of the dividends or (ii) if, during that period, the Ordinary Shares never belonged to a taxpayer other than a Belgian resident company or a non-resident company that has, in an uninterrupted manner, invested the Ordinary Shares in a permanent establishment, or PE, in Belgium.

Belgian Resident Organizations for Financing Pensions

For organizations for financing pensions, or OFPs, i.e., Belgian pension funds incorporated under the form of an OFP (*organisme de financement de pensions/organisme voor de financiering van pensioenen*) within the meaning of Article 8 of the Belgian Law of 27 October 2006, the dividend income from the Ordinary Shares is generally tax exempt.

Dividends distributed through the intervention of a Belgian intermediary are generally subject to Belgian dividend withholding tax. The Belgian dividend withholding tax can in principle, subject to certain limitations, be credited against the OFPs' corporate income tax and is reimbursable to the extent it exceeds the corporate income tax due.

Belgian (or foreign) OFPs not holding the Ordinary Shares – which give rise to dividends – for an uninterrupted period of 60 days in full ownership amounts to a rebuttable presumption that the arrangement or series of arrangements ("*rechtshandeling of geheel van rechtshandelingen*" / "*acte juridique ou un ensemble d'actes juridiques*"), which are connected to the dividend distributions, are not genuine ("*kunstmatig*" / "*non authentique*"). The withholding tax exemption will in such case not apply and/or any Belgian dividend withholding tax levied on the dividends will in such case not be credited against the corporate income tax, unless counterproof is provided by the OFP that the arrangement or series of arrangements are genuine (Article 281/1 ITC).

Other Belgian Resident Taxable Legal Entities

For taxpayers subject to the Belgian income tax on legal entities, the Belgian dividend withholding tax in principle fully discharges their income tax liability.

Belgian Non-Resident Individuals and Companies

Dividend payments on the Ordinary Shares through a professional intermediary in Belgium will, in principle, be subject to the 30% withholding tax, unless the Shareholder is resident in a country with which Belgium has concluded a double taxation agreement and delivers the requested affidavit. If the dividend income is not collected through a financial institution or other intermediary established in Belgium, no Belgian withholding tax should become due. Non-resident investors can also obtain an exemption of Belgian dividend withholding tax if they are the owners or usufructors of the Ordinary Shares and they deliver an affidavit confirming that they have not allocated the Ordinary Shares to business activities in Belgium and that they are non-residents, provided that the dividend is paid through a Belgian credit institution, stock market company or recognized clearing or settlement institution.

If the Ordinary Shares are acquired by a non-resident investor in connection with a business in Belgium, the investor must report any dividends received, which are taxable at the applicable non-resident individual or corporate income tax rate, as appropriate. Any Belgian withholding tax levied at source can be credited against the non-resident individual or corporate income tax and is reimbursable to the extent it exceeds the income tax due, subject to two conditions: (i) the taxpayer must own the Ordinary Shares in full legal ownership on the day the beneficiary of the dividend is identified and (ii) the dividend distribution does not result in a reduction in value of or a capital loss on the Ordinary Shares. The latter condition is not applicable if: (i) the non-resident individual or the non-resident company can demonstrate that the Ordinary Shares were held in full legal ownership for an uninterrupted period of 12 months immediately prior to the attribution of the dividends or (ii) with regard to non-resident companies only, if, during the said period, the Ordinary Shares have not belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the Ordinary Shares in a Belgian PE.

Dividends paid or attributed to Belgian non-resident individuals who do not use the Ordinary Shares in the exercise of a professional activity, may, subject to certain conditions and formalities, be exempt from Belgian non-resident individual income tax up to the amount of EUR 833, per year and per taxpayer (for income year 2024). The liquidation and redemption bonuses cannot benefit from the exemption described above, even if the threshold of EUR 833 has not been reached. Consequently, if Belgian withholding tax has been levied on dividends paid or attributed to the Ordinary Shares, such Belgian non-resident individual may request in his or her Belgian non-resident income tax return that any Belgian withholding tax levied on dividends up to the amount of EUR 833 (for income year 2024) be credited and, as the case may be, reimbursed. However, if no such Belgian income tax return has to be filed by the Belgian non-resident individual Shareholder, Belgian withholding tax levied on such an amount could in principle be reclaimed by filing a request thereto addressed to the tax official to be appointed in a Royal Decree, subject to formalities.

Non-resident companies that have invested the Ordinary Shares in a Belgian establishment can deduct up to 100% of the gross dividends included in their taxable profits if, at the date dividends are paid or attributed, the Conditions for the application of the Dividend Received Deduction regime are satisfied. Application of the Dividend Received Deduction regime depends, however, on a factual analysis to be made upon each distribution and its availability should be verified upon each distribution.

Capital Gains and Losses on Ordinary Shares

Belgian Resident Individuals

In principle, Belgian resident individuals acquiring the Ordinary Shares as a private investment should not be subject to Belgian capital gains tax on the disposal of the Ordinary Shares; capital losses are not tax deductible. Such capital gains are however taxable at 33% (plus local surcharges) if the capital gains are deemed to be speculative or realized outside the scope of the normal management of the individual's private estate. Capital losses are, however, not tax deductible in such event.

Belgian resident individuals who hold the Ordinary Shares for professional purposes are taxable at the ordinary progressive personal income tax rates (which are currently in the range of 25% to 50%, plus local surcharges) on any capital gains realized upon the disposal of the Ordinary Shares, except for Ordinary Shares held for more than five years, which are taxable at a flat rate of 16.5% (plus local surcharges). Capital losses on the Ordinary Shares incurred by Belgian resident individuals who hold the Ordinary Shares for professional purposes are in principle tax deductible.

Capital gains realized by Belgian resident individuals upon the redemption of the Ordinary Shares or upon the Company's liquidation are generally taxable as a dividend (see above).

Belgian Resident Companies

Belgian resident companies are normally not subject to Belgian capital gains taxation on gains realized upon the disposal of the Ordinary Shares provided that the Conditions for the application of the Dividend Received Deduction regime are met.

If one of the above conditions is not met, the capital gains are taxable at the standard corporate tax rate of 25%, unless the reduced corporate income tax rate of 20% on the first EUR 100,000 of taxable profits applies (see above).

Capital gains realized by Belgian resident companies (both non-SMEs and SMEs and both ordinary Belgian resident companies and qualifying credit institutions, investment enterprises and management companies of collective investment undertakings) upon the redemption of Ordinary Shares or upon the Company's liquidation are, in principle, subject to the same taxation regime as dividends. See "Dividends" above.

Capital losses on the Ordinary Shares incurred by resident companies are as a general rule not tax deductible.

Ordinary Shares held in the trading portfolios (*portefeuille commercial/handelsportefeuille*) of qualifying credit institutions, investment enterprises and management companies of collective investment undertakings which are subject to the Royal Decree of 23 September 1992 on the annual accounts of credit institutions, investment firms and management companies of collective investment undertakings (*comptes annuels des établissements de crédit, des entreprises d'investissement et des sociétés de gestion d'organismes de placement collectif/jaarrekening van de kredietinstellingen, de beleggingsondernemingen en de beheervennootschappen van instellingen voor collectieve belegging*) are subject to a different regime. The capital gains on such shares are taxable at the ordinary corporate income tax rate of 25%. Capital losses on such shares are tax deductible. Internal transfers to and from the trading portfolio are assimilated to a realization.

Belgian Resident Organizations for Financing Pensions

Capital gains on the Ordinary Shares realized by OFPs are, in principle, exempt from Belgian corporate income tax and capital losses are not tax deductible.

Capital gains realized by Belgian OFPs upon the redemption of Ordinary Shares or upon the Company's liquidation will in principle be taxed as dividends (see above).

Other Belgian Resident Taxable Legal Entities

Belgian resident legal entities subject to the legal entities income tax are, in principle, not subject to Belgian capital gains taxation on the disposal of the Ordinary Shares. Capital losses on Ordinary Shares incurred by Belgian resident legal entities are not tax deductible.

Capital gains realized by Belgian resident legal entities upon the redemption of the Ordinary Shares or upon the Company's liquidation will in principle be taxed as dividends (see above).

Belgian Non-Resident Individuals and Companies

Non-resident individuals or companies are, in principle, not subject to Belgian income tax on capital gains realized upon disposal of the Ordinary Shares, unless the Ordinary Shares are held as part of a business conducted in Belgium through a Belgian establishment. In such a case, the same principles apply as described with regard to Belgian individuals (holding the shares for professional purposes) or Belgian resident companies.

Non-resident individuals who do not use the Ordinary Shares for professional purposes and who have their fiscal residence in a country with which Belgium has not concluded a tax treaty or with which Belgium has concluded a tax treaty that confers the authority to tax capital gains on the Ordinary Shares to Belgium, might be subject to tax in Belgium if the capital gains are obtained or received in Belgium and arise from transactions which are to be considered speculative or beyond the normal management of one's private estate. See "*Material Belgian Tax Considerations—Capital Gains and Losses on Ordinary Shares—Belgian Resident Individuals*". Such non-resident individuals might therefore be obliged to file a tax return and should consult their own tax adviser.

Capital gains realized by non-resident individuals or non-resident companies upon redemption of the Ordinary Shares or upon the Company's liquidation will, in principle, be subject to the same taxation regime as dividends (see above).

Tax on Stock Exchange Transactions

Upon the issue of the Ordinary Shares (primary market), no Tax on Stock Exchange Transactions ("*taks op de beursverrichtingen*" / "*taxe sur les opérations de bourse*") is due.

The purchase and the sale and any other acquisition or transfer for consideration of the Ordinary Shares (secondary market transactions) is subject to the Tax on Stock Exchange Transactions if (i) it is executed in Belgium through a professional intermediary, or (ii) deemed to be executed in Belgium, which is the case if the order is directly or indirectly made to a professional intermediary established outside of Belgium, either by private individuals with habitual residence in Belgium, or legal entities for the account of their seat or establishment in Belgium (both, a "**Belgian Investor**").

The Tax on Stock Exchange Transactions is levied at a rate of 0.35% of the purchase price, capped at EUR 1,600 per transaction and per party.

For the Tax on Stock Exchange Transactions, a separate tax is due by each party to the transaction, and both taxes are collected by the professional intermediary. However, if the order is made directly or indirectly to a professional intermediary established outside of Belgium, the tax will in principle be due by the Belgian Investor, unless that Belgian Investor can demonstrate that the tax has already been paid. In the latter case, the foreign professional intermediary also has to provide each client (which gives such intermediary an order) with a qualifying order statement ("*bordereau*"/"*borderel*"), at the latest on the business day after the day the transaction concerned was realized. The qualifying order statements must be numbered in series and a duplicate must be retained by the financial intermediary. The duplicate can be replaced by a qualifying day-to-day listing, numbered in series. Alternatively, professional intermediaries established outside of Belgium can, subject to certain conditions and formalities, appoint a Belgian Stock Exchange Tax Representative, which will be liable for the Tax on Stock Exchange Transactions in respect of the transactions executed through the professional intermediary and for complying with the reporting obligations and the obligations relating to the order statement in that respect. If the Stock Exchange Tax Representative would have paid the Tax on Stock Exchange Transactions due, the Belgian Investor will, as per the above, no longer be the debtor of the Tax on Stock Exchange Transactions.

No Tax on Stock Exchange Transactions is due on transactions entered into by the following parties, provided they are acting for their own account: (i) professional intermediaries described in Article 2, 9° and 10° of the Belgian Law of 2 August 2002; (ii) insurance companies described in Article 2, §1 of the Belgian Law of 9 July 1975; (iii) professional retirement institutions referred to in Article 2, 1° of the Belgian Law of 27 October 2006 concerning the supervision on institutions for occupational pension; (iv) collective investment institutions; and (v) Belgian non-residents provided they deliver a certificate to their financial intermediary in Belgium confirming their non-resident status. Furthermore, no Tax on Stock Exchange Transactions is due on transactions entered into by regulated real estate companies, provided they are acting for their own account.

On 14 February 2013, the European Commission published a proposal (the "**Commission's Proposal**") for a Directive for a common financial transaction tax ("**FTT**"). The Commission's Proposal currently stipulates that once the FTT enters into force, the Participating Member States shall not maintain or introduce taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax). For Belgium, the Tax on Stock Exchange Transactions should thus be abolished once the FTT enters into force. Due to the lack of progress in the negotiations on the Directive, a new timeline has been agreed upon by the Participating Member States. This should lead the European Commission to issue a new proposal by 2024.

Annual tax on securities accounts

The tax on securities accounts is an annual tax of 0.15% that is levied on securities accounts of which the average value of the taxable financial instruments (covering, amongst others, financial instruments such as the Notes) exceeds EUR 1 million during a reference period of twelve consecutive months (in principle) starting on 1 October and ending on 30 September of the subsequent year. The taxable base is determined based on four reference dates: 31 December, 31 March, 30 June and 30 September. The amount of tax due is limited to 10% of the difference between the said average value of the taxable financial instruments and the threshold of EUR 1 million.

The tax targets securities accounts held by resident individuals subject to Belgian personal income tax, resident companies subject to Belgian corporate income tax and resident legal entities subject to Belgian legal entities tax, wherever the intermediary is incorporated or established (in Belgium or abroad). The tax also applies to securities accounts held with an intermediary incorporated or established in Belgium by non-residents (individuals, companies and legal entities subject to Belgian non-resident tax). Securities accounts that form part of the business property of a Belgian establishment of a non-resident as referred to in Article 229 ITC, wherever the intermediary is incorporated or established (in Belgium or abroad), are also subject to the annual tax.

There are various exemptions, such as securities accounts held by specific types of regulated entities for their own account.

A financial intermediary is defined as (i) the National Bank of Belgium, the European Central Bank and foreign central banks performing similar functions, (ii) a central securities depository included in Article 198/1, §6, 12° of the Belgian Income Tax Code, (iii) a credit institution or a stockbroking firm as defined by Article 1, §3 of the Law of 25 April 2014 on the status and supervision of credit institutions and investment companies and (vi) the investment companies as defined by Article 3, §1 of the Law of 25 October 2016 on access to the activity of investment services and on the legal status and supervision of portfolio management and investment advice companies, which are, pursuant to national law, admitted to hold financial instruments for the account of customers.

A Belgian intermediary is an intermediary incorporated under Belgian law as well as an intermediary established in Belgium.

The Belgian intermediary in principle withholds, declares and pays the tax. In all other cases, the holder will declare and pay the tax himself, unless he can prove that the tax has already been declared and paid by an intermediary, irrespective as to whether the intermediary is incorporated or established in Belgium or abroad. When multiple holders hold a securities account, each holder may fulfil the declaration requirements for all holders and each holder shall be jointly and severally liable for the payment of the tax. An intermediary not incorporated or established in Belgium, when managing a securities account subject to the tax, may have a representative established in Belgium recognized by or on behalf of the Minister of Finance. The representative shall be jointly and severally liable towards to Belgian State to declare and pay the tax, as well as to perform all obligations to which an intermediary is bound.

A general anti-abuse provision is included to counter certain actions to avoid the application of the tax.

Investors are advised to consult their tax advisors about the consequences of the tax on securities accounts on their own tax situation.

The proposed financial transactions tax ("FTT")

As mentioned above, on 14 February 2013, the European Commission published the "Commission's Proposal" for a Directive for a common FTT, to be levied on transactions in financial instruments by financial institutions if at least one of the parties to the transaction is located in the 'FTT-zone' as defined in the Commission's Proposal. It was approved by the European Parliament in July 2013. Originally, the adopted Commission's Proposal foresaw the financial transaction tax for 11 "Participating Member States" (Belgium, Germany, Estonia, Greece, Spain, France, Italy, Austria, Portugal, Slovenia and Slovakia). However, on 16 March 2016 Estonia formally withdrew from the group of states willing to introduce the FTT. The actual implementation date of the FTT would depend on the future approval of the European Council and consultation of other EU institutions, and the subsequent transposition into local law.

If the financial transaction tax is introduced, under current published proposals financial institutions and certain other parties would be required to pay tax on transactions in financial instruments with parties (including, with respect to the EU-wide proposal, its affiliates) located in the FTT-zone. The proposed FTT has very broad scope and could, if introduced in its current form, apply to certain dealings in the Ordinary Shares in certain circumstances. It is a tax on derivatives transactions (such as hedging activities) as well as on securities transactions, i.e. it applies to trading in instruments such as shares and bonds. The initial issue of instruments such as shares and bonds is exempt from financial transaction tax in the current Commission's Proposal. This means that the issuance and subscription of the Ordinary Shares should not become subject to financial transaction tax.

Under current proposals, the FTT could apply in certain circumstances to persons both within and outside of the participating Member States. Generally, it would apply to certain dealings in the Ordinary Shares where at least one party is a financial institution, and at least one party is established in a participating Member State. A financial institution may be, or be deemed to be, "established" in a

participating Member State in a broad range of circumstances, including (a) by transacting with a person established in a participating Member State or (b) where the financial instrument which is subject to the dealings is issued in a participating Member State.

In 2019, Finance Ministers of the Member States participating in the enhanced cooperation indicated that they were discussing a new FTT proposal based on the French model of the tax and the possible mutualization of the tax as a contribution to the EU budget.

According to the latest draft of this new FTT proposal (submitted by the German government), the FTT would be levied at a rate of at least 0.2% of the consideration for the acquisition of ownership of shares (including ordinary and any preference shares) admitted to trading on a trading venue or a similar third country venue, or of other securities equivalent to such shares or similar transactions (e.g. an acquisition of financial instruments by means of an exchange of Financial Instruments or by means of a physical settlement of a derivative). The FTT would be payable to the Participating Member State in whose territory the issuer of a financial instrument has established its registered office. According to the latest draft of the new FTT proposal, the FTT would not apply to straight notes. Like the Commission's Proposal, the latest draft of the new FTT proposal also stipulates that once the FTT enters into force, the Participating Member States shall not maintain or introduce taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax). As a consequence, Belgium should abolish the tax on stock exchange transactions once the FTT enters into force.

In June 2023, the European Commission stated that 'the prospects of reaching an agreement' (on the FTT) in the future were 'limited' adding there was 'little expectation that any proposal would be agreed in the short term.'

However, the FTT remains subject to negotiation between the participating Member States. Further, its legality is at present uncertain. It may therefore be altered prior to any implementation, the timing of which remains unclear. Additional EU Member States may decide to participate. Prospective investors are advised to seek their own professional advice in relation to the FTT.

Common Reporting Standard

As of 16 May 2024, 123 jurisdictions had signed the multilateral competent authority agreement ("**MCAA**"), which is a multilateral framework agreement to automatically exchange financial and personal information, with the subsequent bilateral exchanges coming into effect between those signatories that file the subsequent notifications.

Forty-nine jurisdictions, including Belgium, have committed to a specific and ambitious timetable leading to the first automatic information exchanges in 2017, relating to income year 2016. More than 50 jurisdictions have committed to exchange information as from 2018, two jurisdictions as from 2019, seven jurisdictions as from 2020, two jurisdictions as from 2021, 3 jurisdictions as from 2022 and 3 jurisdictions as from 2023.

Under CRS, financial institutions resident in a CRS country are required to report, according to a due diligence standard, financial information with respect to reportable accounts, which includes interest, dividends, account balance or value, income from certain insurance products, sales proceeds from financial assets and other income generated with respect to assets held in the account or payments made with respect to the account. Reportable accounts include accounts held by individuals and entities (which includes trusts and foundations) with fiscal residence in another CRS country. The standard includes a requirement to look through passive entities to report on the relevant controlling persons.

On 9 December 2014, EU Member States adopted Directive 2014/107/EU on administrative cooperation in direct taxation ("**DAC2**"), which provides for mandatory automatic exchange of financial information as foreseen in CRS. DAC2 amends the previous Directive on administrative cooperation in direct taxation, Directive 2011/16/EU.

Belgium has implemented the DAC2 and respectively CRS by the law of 16 December 2015 regulating the exchange of financial account information between Belgian financial institutions and the FPS Finances in the framework of automatic information exchange at the international level and for tax purposes (the "**Law of 16 December 2015**").

As a result of the Law of 16 December 2015, the mandatory automatic exchange of information applies in Belgium (i) as of income year 2016 (first information exchange in 2017) towards the EU Member States (including Austria, irrespective of the fact that the automatic exchange of information by Austria towards other EU Member States is only foreseen as of income year 2017), (ii) as of income year 2014 (first information exchange in 2016) towards the US and (iii), with respect to any other non-EU States that have signed the MCAA, as of the respective date to be further determined by Royal Decree. In a Royal Decree of 14 June 2017, as amended, it has been provided that the automatic exchange of information has to be provided (i) as from 2017 (for the 2016 financial year) for a first list of 18 foreign jurisdictions, (ii) as from 2018 (for the 2017 financial year) for a second list of 44 jurisdictions, (iii) as from 2019 (for the 2018 financial year) for a third list of another jurisdiction, (iv) as from 2020 (for the 2019 financial year) for a fourth list of six jurisdictions, (v) as from 2023 (for the 2022 financial year) for a fifth list of 2 jurisdictions, and (vi) as from 2024 (for the 2023 financial year) for a sixth list of 4 jurisdictions.

The Ordinary Shares are subject to DAC2 and the Law of 16 December 2015. Under DAC2 and the Law of 16 December 2015, Belgian financial institutions holding the Ordinary Shares for tax residents in another CRS contracting state shall report financial information regarding the Ordinary Shares (e.g. in relation to income and gross proceeds) to the Belgian competent authority, which shall communicate the information to the competent authority of the state of the tax residence of the beneficial owner.

Investors who are in any doubt as to their position should consult their professional advisers.

Material French Tax Considerations

The following summary is based on the tax laws and regulations in force in France as of the date of this Prospectus and such as applied by the French tax authorities, all of which are subject to changes or to different interpretation, potentially with retroactive effect.

It generally summarizes certain French tax consequences for French resident for tax purposes of acquiring, holding and disposing of the Company's Ordinary Shares. It does not purport to be a comprehensive description of all the tax considerations that may be relevant to a decision to purchase, own or dispose of the Company's Ordinary Shares. Potential investors/holders of the Ordinary Shares are advised not to rely upon the tax summary contained in this Prospectus but to ask for their own tax adviser's advice on their individual taxation with respect to the purchase, ownership, or disposal of the Ordinary Shares and in determining the tax consequences to their particular situation. In particular, this tax summary does not address the tax treatment of shareholders that are subject to special rules, such as partnerships, trusts or regulated investment companies, banks or other financial institutions, insurance companies, among others, or who hold their Ordinary Shares in a PEA (*plan d'épargne en actions*). Prospective investors/holders of the Ordinary Shares should consult their tax advisers as to the French and foreign tax treatment especially in light of their particular circumstances.

Dividends

French Resident Individuals

The following is an overview of certain French tax rules applicable to individuals who are French tax resident holding Ordinary Shares of the Company in connection with the management of their private assets and not engaging in transactions on securities markets on a regular basis and, accordingly, who are not considered as professional traders. Individuals who engage in professional trading transactions should consult their tax advisers concerning the tax rules applicable to their specific case.

Income tax and additional contribution to such tax

Dividends paid by the Company to French resident individuals are subject to income tax in France on the terms and conditions set forth below.

Dividends are subject to a single flat-rate income tax ("*Prélèvement forfaitaire unique*") set at 12.8% of the gross amount of dividends paid accordingly to article 200 A of the French Tax Code.

The gross amount of dividends received may also be subject to the 3% or 4% contribution on high-income taxpayers set out in article 223 *sexies* of the French Tax Code, which is applicable as follows:

- (i) single, widowed, separated or divorced taxpayers are subject to the 3% contribution rate for their reference taxable income ("*revenu fiscal de référence*") between EUR 250,000 and EUR 500,000, and to the 4% contribution rate for their reference taxable income above EUR 500,000, and
- (ii) taxpayers subject to joint taxation are subject to the 3% contribution rate for their reference taxable income between EUR 500,000 and EUR 1,000,000, and to the 4% contribution rate for their reference taxable income above EUR 1,000,000.

Subject to the exceptions set forth below, a mandatory levy at the rate of 12.8% is due on dividends under article 117 *quarter* of the French Tax Code ("*Prélèvement forfaitaire non libératoire*"). Such levy constitutes an advance payment of income tax, which is credited against the income tax due in respect of the year in which it was applied and the surplus, if any, is refunded to the taxpayer.

This advance payment is (i) directly withheld by the paying agent, when such paying agent is established in a Member State of the European Union or when it is established in a State party to the Convention on the European Economic Area which has concluded an administrative assistance agreement with France to combat tax evasion and avoidance, and has been mandated to do so by the taxpayer, or (ii) paid by the taxpayer himself or herself no later than the 15th of the month following payment of the dividend.

However, when the paying agent is established in France, individual taxpayers may be exempt from such 12.8% levy where their reference taxable income for the penultimate year, as defined in 1° of IV of article 1417 of the French Tax Code, is lower than EUR 50,000 for single, divorced or widowed taxpayers and EUR 75,000 for taxpayers subject to joint taxation. The benefit of such exemption is to be requested in the conditions provided for in article 242 *quater* of the French Tax Code, *i.e.*, by providing the paying agent at the latest on 30 November of the year preceding that of the payment of the distributed income, with a certificate on honor stating that their reference taxable income appearing on the tax notice drawn up in respect of the income of the penultimate year preceding the payment of the said income is below the above-mentioned thresholds. Individual taxpayers who acquire shares of the Company after the deadline for filing the aforementioned request for exemption may, under certain conditions, file this request to be exempted from the levy with the paying agent at the time of acquisition of these shares as provided by the French tax authorities guidelines (BOI-RPPM-RCM-30-20-10-06/07/2021, n°320).

When the paying agent is established outside of France, the 12.8% levy only applies to such taxpayers whose reference taxable income for the penultimate year exceeds the abovementioned threshold.

Upon final taxation, the dividends are subject to personal income tax at a flat rate of 12.8% (against which the 12.8% previously paid is credited) or, upon an irrevocable election which covers all income within the scope of the 12.8% flat rate, at the progressive rates of the personal income tax (from 0% up to 45% depending on the bracket). In the event the recipient elected to be subject to the progressive rates, pursuant to article 158 of the French Tax Code a rebate of 40% (*abattement de 40%*) is deducted from the gross amount of the distributions (to the extent they arise from a regular decision); in addition, certain costs and expenses may also be deducted. However, the social levies are still levied on the gross amount of the dividends.

Furthermore, pursuant to article 24 B-b of the tax treaty entered into between France and the Netherlands on 16 March 1973 (the "**Treaty**"), France grants French residents who receive such income a tax credit equal to the amount of the withholding tax levied by the Netherlands; such a

withholding tax is levied at a rate not exceeding 15% under the Treaty where the recipient is a resident of France.

Social security contributions

In addition, the gross amount of dividends paid by the Company to French resident individuals will also be subject to social security contributions at an aggregate rate of 17.2%, consisting of the following:

- The general social contribution ("*contribution sociale généralisée*" - CSG) at the rate of 9.2%, of which 6.8% is deductible from the income subject to income tax if the taxpayer opts for the taxation of the dividends at the progressive income tax rates;
- The solidarity contribution ("*prélèvement de solidarité*") of 7.5%, which is not deductible for income tax purposes;
- The contribution for repayment of the social insurance debt ("*contribution pour le remboursement de la dette sociale*" - CRDS) at the rate of 0.5%, which is not deductible for income tax purposes.

Note that social security contributions on dividends is also subject to an advance payment under the same principles as applicable to the income tax (see above).

French Resident Companies

Shareholders subject to French corporate income tax and not qualifying for the participation exemption regime (régime des sociétés mères et filiales)

Dividends paid by the Company to French resident corporates will be subject to corporate income tax in France on the following terms and conditions.

The gross amount of the dividends received will be included in the taxable income of such French resident corporates at the ordinary corporate income tax rate of 25%. SMEs complying with the terms and conditions set forth in article 219, I-b of the French Tax Code automatically and *ipso jure* benefit from a reduced rate of 15% on the fraction of their taxable profits not exceeding EUR 42,500.

In addition, shareholders whose turnover excluding VAT is EUR 7,630,000 or more are liable to a social contribution of 3.3% (article 235 *ter* ZC of the French Tax Code) assessed on such portion of the corporate income tax liability in excess of EUR 763,000 per twelve-month period.

Shareholders subject to French corporate income tax and qualifying for the participation exemption regime (régime des sociétés mères et filiales)

Pursuant to articles 145 and 216 of the French Tax Code, legal entities may benefit from the participation exemption regime if shares are *inter alia*:

- (i) in registered form or deposited or recorded in an account held by an authorized intermediary;
- (ii) represent at least 5% of the subsidiary's share capital; or, if this threshold is not reached, 2.5% of the subsidiary's share capital and 5% of the subsidiary's voting rights, provided that the parent is controlled by one or more non-profit organizations (mentioned in 1 *bis* of article 206 of the French Tax Code);
- (iii) and kept for a period of two years when the shares represent at least 5% of the subsidiary's share capital; or five years when the shares represent 2.5% of the subsidiary's share capital and 5% of the voting rights.

Under this regime, dividends are exempt from corporation tax, except that 5% of the dividends received (including any foreign tax credit) must be added back to the shareholder's taxable income (*quote-part de frais et charges*).

Furthermore, in application of article 10 of the Treaty, dividends paid by a Dutch resident company to a French resident are subject to tax in France. However, such dividends may be taxed in the Netherlands, but the amount of tax thus assessed may not exceed:

- 5% in favor of French joint-stock companies or limited liability companies that directly own at least 25% of the capital of the Dutch distributing company;
- 15% of gross dividends in all other cases.

Moreover, pursuant to article 24 B-b of the Treaty, the Dutch withholding tax, if any, is creditable against the French corporate tax payable by the recipient, up to the rate of 5% or 15%, as the case may be, of the gross amount of the received dividends.

Capital gains

French Resident Individuals

Income tax and additional contributions to such tax

Pursuant to article 13.4 of the Treaty, capital gains realized by a French resident individual shareholder upon the disposal of the shares of the Company will only be taxable in France.

Net capital gains realized by French resident individuals on the sale of the Company's shares during a given fiscal year are taxable at the single flat-rate income tax ("*Prélèvement forfaitaire unique*") set at 12.8% according to article 200 A of the French Tax Code.

However, French resident individuals may elect for the taxation of their net capital gains at the progressive rates of income tax. In this situation, French resident individuals may benefit from a proportional allowance on capital gains of shares acquired before 1 January 2018, depending on the holding period, as set forth in article 150-0 d of the French Tax Code. If the shares were acquired on or after 1 January 2018, the capital gains cannot benefit from this allowance. Such allowances do not apply to the contribution on high-income taxpayers and to the social security contributions.

These allowances are equal to (i) 50% of the amount of the net capital gains, when the shares sold have been held for at least two (2) years and less than eight (8) years on the date of sale, or (ii) 65% of the amount of net capital gains, when the shares sold have been held for at least eight (8) years on the sale date. No exemption is applicable in event of a sale during the first two (2) years of ownership.

As stated above for dividends, the option for the taxation at the progressive rates of income tax is irrevocable and global for all investment income earned during the fiscal year concerned.

The capital gains on the disposal of shares may also be subject to the exceptional tax on high income (*contribution exceptionnelle sur les hauts revenus*), as mentioned under paragraph "Income tax" above.

According to article 150-0 D of the French Tax Code, capital losses realized on the sale of the Company's shares during a given fiscal year by French resident individuals are deductible from capital gains upon the sale of shares and securities (no other assets) realized by such French resident individuals during the same fiscal year and during the following ten (10) years for the surplus.

Social security contributions

Capital gains realized by French resident individuals upon the sale of the Company's shares will also be subject to social security contributions at a global rate of 17.2%, consisting of the contributions mentioned above in the paragraph regarding dividends.

French Resident Companies

Pursuant to article 13.4 of the Treaty, capital gains realized by a French resident corporate shareholder upon the disposal of the shares of the Company will only be taxable in France (provided

that such capital gains are not attributable to a permanent establishment of that shareholder located in the Netherlands).

General regime

Net capital gains realized by French resident companies upon the sale of the Company's shares are included in their taxable income for corporate tax purposes at the ordinary corporate income tax rate and, if applicable, at the social contribution of 3.3%, as described in the paragraph entitled "Shareholders subject to French corporate income tax and not qualifying for the participation exemption regime (*régime des sociétés mères et filiales*)", under "Dividends".

Net capital losses are deductible from the taxable income.

Special rules applicable to long-term capital gains and losses

The net capital gain on the sale of the relevant shares and securities may be exempted under and pursuant to article 219 I-a *quinquies* of the French Tax Code if it arises from the disposal of participating interests ("*titres de participations*") held for at least two (2) years. A fixed portion of expenses and charges equal to 12% of the gross amount of the capital gain, however, must be added back to the taxable income of the selling entity and subject to the ordinary applicable corporate income tax rate (25%) and, if applicable, to the social contribution of 3.3%, as described above.

For purposes of the specific treatment of long-term capital gain, participating interest are:

- (i) shares that qualify as such for accounting purposes
- (ii) shares acquired within the course of a public takeover bid or share exchange offer, and
- (iii) shares qualifying for the parent-subsidary regime mentioned above provided the shareholder holds at least 5% of the voting rights, with the exception of shares in real estate companies.

Long-term capital losses are not deductible for corporation tax purposes and cannot be deducted from long-term capital gains for the purposes of computation of the *quote-part de frais et charges*.

Registration duties

A sale of the Company's shares will not be subject to registration duties in France, unless it is formalized by a deed made in France. In such case, French registration duties apply on the purchase price (or the fair market value, if higher) at the rate of 0.1% and are due by the purchaser.

Other situations

Prospective investor who are subject to taxation regimes other than those described above should consult their own tax adviser in respect of their specific situation.

INDEPENDENT AUDITORS

Ernst & Young Accountants LLP, independent auditor, has audited the Consolidated Financial Statements and the Company Financial Statements and has issued an unqualified independent auditor's report thereon, which is included in this Prospectus.

Ernst & Young Accountants LLP changed its legal form from LLP to B.V. as from 29 June 2024. EY Accountants B.V. is an independent registered audit firm with its principal place of business at Boompjes 258, 3011 XZ Rotterdam, The Netherlands. EY Accountants B.V. is registered at the Chamber of Commerce of Rotterdam in The Netherlands under number 92704093. The office address of the independent auditor of EY Accountants B.V. is Prof.Dr. Dorgelolaan 12, 5613 AM Eindhoven, The Netherlands. The auditor signing the auditor's report on behalf of EY Accountants B.V. is a member of the Royal Netherlands Institute of Chartered Accountants (*Koninklijke Nederlandse Beroepsorganisatie van Accountants*).

EY Accountants B.V., independent auditor, has neither audited nor reviewed the Interim Condensed Consolidated Financial Statements and no auditor's report was issued in relation to the Interim Condensed Consolidated Financial Statements.

GENERAL INFORMATION

Domicile, Legal Form and Incorporation

The Company's legal and commercial name is ONWARD Medical N.V. The Company's registered office is at Schimmelt 2, 5611 ZX Eindhoven, the Netherlands.

The Company is registered with the Dutch Chamber of Commerce (*Kamer van Koophandel*) under number 64598748. The Company's telephone number is +31 40 288 2830. The Company's Legal Entity Identifier (LEI) is 9845007A2CC4C8BF5B80. The ISIN for the Ordinary Shares is NL0015000HT4. The Company's website www.onwd.com.

Significant Changes in the Group's financial performance and its financial position

As at the date of this Prospectus, there has been no significant change in the financial performance and the financial position of the Group since 30 June 2024 except for:

- the effects of the Private Placement, where the Company will issue 10,000,000 New Ordinary Shares on 28 October 2024 at a placement price of EUR 5.00, raising an amount of EUR 50.0 million in gross proceeds. The Private Placement will influence the Company's financial position by increasing its capital through an equity offering and contribute to the Company's financial stability and growth potential. The overall impact includes enhanced liquidity and dilution of voting interests of the Shareholders of the Company holding shares in the Company prior to the Private Placement; and
- the effects of the Runway Loan in an amount of up to EUR 52.5 million. The Runway Loan diversifies the Company's capital structure, increases its cash flow and contributes to the Company's growth potential. It does not dilute any voting interests of the Shareholders of the Company but increases the Company's liabilities. The interest payments under the Runway Loan reduce the Company's net income and cash flow. For more information regarding the Runway Loan see "*Business – Material Contracts – Loan agreements*" and for more information regarding the effects of the Private Placement on the capitalization and indebtedness of the Company see "*Capitalization and Indebtedness*" above.

Expenses

The expenses related to the Private Placement and the Listing are estimated at approximately EUR 3.4 million and include, among other items, the Placement Agents' fees and the Co-Lead Manager's fees (appr. EUR 2.8 million) and legal fees (appr. EUR 0.5 million).

Availability of Documents

Subject to any applicable securities laws, copies of the following documents will be available and can be obtained free of charge from the Company's website (<https://ir.onwd.com> <https://ir.onwd.com/prospectus> and <https://ir.onwd.com/corporate-governance/>) from the date of this Prospectus until at least 12 months thereafter:

- this Prospectus;
- the Articles of Association (in Dutch, and an unofficial English translation);
- the Board Rules;
- the charter of the Compensation Committee;
- the charter of the Audit Committee; and
- the charter of the Nomination Committee.

DEFINITIONS

The following definitions are used in this Prospectus:

510(k)	Clearance under Section 510(k) of the FDCA
ADN	Annual Distribution Number
Affordable Care Act	the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010
AFM	The Dutch Authority for the Financial Markets (<i>Stichting Autoriteit Financiële Markten</i>)
AMF	The French Authority of the Financial Markets (<i>Autorité des Marchés Financiers</i>)
Annual Accounts	The annual accounts referred to in Article 2:391 DCC
APMs	Alternative Performance Measures as defined by the "ESMA Guidelines on Alternative Performance Measures" issued by the European Securities and Markets Authority on 5 October 2015
ARC Therapy	ONWARD ARC™ Therapy
ARC^{BCI}	The system, that uses BCI technology in conjunction with the ARC™ Therapy
ARC^{EX}	The external platform of the ARC Therapy to address a broad spectrum of challenges that result from movement disabilities
ARC^{IM}	The implantable platform of the ARC Therapy to address a broad spectrum of challenges that result from movement disabilities
Articles of Association	The articles of association of the Company
Belgian Investor	private individuals with habitual residence in Belgium, or legal entities for the account of their seat or establishment in Belgium
Board	The board of directors (<i>bestuur</i>) of the Company
Board Rules	The rules regarding the Board's functioning and internal organization
BCI	Brain-computer interface
Call Option Agreement	A call option agreement to be entered into between the Company and the Protective Foundation
Caltech	California Institute for Technology
CE	Conformité Européene
CEO	The Company's Chief Executive Officer
CEST	Central European Summer Time
Chairperson	The Chairperson of the Board
CHUV	Centre Hospitalier Universitaire Vaudois

Co-Lead Manager	KBC Securities NV
Commission's Proposal	the European Commission published a proposal
Company	ONWARD Medical N.V., a public limited liability company (<i>naamloze vennootschap</i>)
Company Financial Statements	The company financial statements of ONWARD Medical N.V. as of and for the year ended 31 December 2023, prepared in accordance with Part 9 of Book 2 of the Dutch Civil Code
Consolidated Financial Statements	The consolidated financial statements of ONWARD Medical N.V., as of and for the year ended 31 December 2023, prepared in accordance with IFRS and Part 9 of Book 2 of the Dutch Civil Code
Cornerstone Investor	Ottobock SE & Co. KGaA, who entered into a Cornerstone Investor Agreement with the Company
Cornerstone Investor Agreement	The agreement entered into by the Cornerstone Investor and the Company on 22 October 2024 in connection with the Private Placement
CRO	Contract research organizations
CSO	The Company's Chief Scientific Officer
DAC2	Directive 2014/107/EU on administrative cooperation in direct taxation
DARPA	The US Defense Advanced Research Projects Agency
DCC	Dutch Civil Code (<i>Burgerlijk Wetboek</i>)
DFSA	The Dutch Financial Supervision Act (<i>Wet op het financieel toezicht</i>)
Director	an Executive Director or Non-Executive Director
Dutch Corporate Governance Code or "Code"	The Dutch corporate governance code issued on 20 December 2022
Dutch Resident Entity	an entity that is a resident or deemed to be resident of the Netherlands for Dutch corporate income tax purposes
Dutch Resident Individual	an individual resident or deemed to be resident of the Netherlands for Dutch income tax purposes
Dutch SRD Act	The Dutch act to implement the Shareholder Rights Directive II (<i>bevordering van langetermijnbetrokkenheid van aandeelhouders</i>)
Dutch Securities Giro Transactions Act	Dutch Securities Giro Transactions Act (<i>Wet giraal effectenverkeer</i>)
EEA	European Economic Area
EES	Epidural Electrical Stimulation - application of a current to the spinal cord via an electrode implanted on the spinal cord.
EISMEA	The European Innovation Council and SMEs Executive Agency

Enterprise Chamber	The Dutch enterprise chamber of the court of appeal in Amsterdam (<i>Ondernemingskamer van het Gerechtshof te Amsterdam</i>)
EPFL	École polytechnique fédérale de Lausanne
EU Medical Devices Directive	Council Directive 93/42/EEC
EU Pillar II Directive	Council Directive (EU) 2022/2523
EUR or euro or €	The lawful currency of the European Economic and Monetary Union
Euroclear Nederland	The Netherlands Central Institute for Giro Securities Transactions (<i>Nederlands Centraal Instituut voor Giraal Effectenverkeer B.V.</i>)
Euronext	Euronext Amsterdam, Euronext Brussels and Euronext Paris
Euronext Amsterdam	Euronext in Amsterdam, a regulated market of Euronext Amsterdam N.V.
Euronext Brussels	Euronext in Brussels, a regulated market of Euronext Brussels SA/N.V.
Euronext Paris	Euronext in Paris, a regulated market of Euronext Paris S.A.
Executive Directors	Executive directors (<i>uitvoerend bestuurders</i>) of the Company
EY	EY Accountants B.V.
Family Member	The spouse of a Restricted Shareholder, an immediate family member (in the meaning set forth in Rule 16a-1(e) under the Exchange Act) of a Restricted Shareholder or an immediate family member of the relevant Restricted Shareholder's spouse, in each case living in the Restricted Shareholder's household or whose principal residence is the Restricted Shareholder's household (regardless of whether such spouse or family member may at the time be living elsewhere due to educational activities, health care treatment, military service, temporary internship or employment or other-wise)
FCC	US Federal Communications Commission
FDA	US Food and Drug Administration
FDCA	US Federal Food, Drug, and Cosmetic Act
FES	Functional Electrical Stimulation - Application of a current to peripheral nerves and/or muscles to allow the performance of a task
Financial Promotion Order	The FSMA 2000 Financial Promotion Order 2005, as amended
Financial Statements	The Company Financial Statements, together with the Consolidated Financial Statements
Foreground IP	IP generated throughout the development services under the agreement
FRSA	Dutch Financial Reporting Supervision Act (<i>Wet toezicht financiële verslaggeving</i>)

FSMA	The Belgian Financial Services and Markets Authority (<i>Autorité des services et marchés financiers</i>)
FSMA 2000	The Financial Services and Markets Act 2000, as amended
FTT	financial transaction tax
GCP	Good Clinical Practice
General Meeting	General meeting of the Company, being the corporate body, or where the context so requires, the physical meeting of Shareholders (<i>algemene vergadering</i>)
GloBE Rules	The Global Anti-Base Erosion Model Rules published by the Organization for Economic Cooperation and Development, also known as Pillar II
Group	The Company and its Group Companies
Group Companies	The Company's subsidiaries within the meaning of Article 2:24b DCC
Group Company	Each of the Company's subsidiaries within the meaning of Article 2:24b DCC
HDE	Humanitarian Device Exemption
HIPAA	The Health Insurance Portability and Accountability Act
HITECH Act	The Health Information Technology for Economic and Clinical Health Act
HMV	Hilfsmittelverzeichnis
HUD	Humanitarian Use Device
IAS	International Accounting Standards
IFRS	The International Financial Reporting Standards as adopted by the European Union
Indemnified Officer	each of the Company's current or former Directors or such current or former officer or employee of the Company or its Group Companies as the Board may determine at its absolute discretion
Interim Condensed Consolidated Financial Statements	The Company's interim condensed consolidated financial statements as of and for the six-month-period ended 30 June 2024, which have been prepared in accordance with IAS 34, "Interim Financial Reporting" as adopted by the European Union and which have not been audited or reviewed
Internal Revenue Code	The Internal Revenue Code of 1986, as amended
Investor Shares	The 4,500,000 New Ordinary Shares that will be issued to the Cornerstone Investor on 28 October 2024, such number being calculated by dividing EUR 22.5 million by EUR 5.00 and such calculated number of New Ordinary Shares being rounded down to the next full number
IPG	Implantable pulse generator

IPO	The Company's initial public offering of shares on Euronext Amsterdam and Euronext Brussels in October 2021
IRBs	institutional review boards
ISIN	International securities identification number
ITC	the Belgian Income Tax Code
Joint Global Coordinators	UBS AG London Branch, Bryan, Garnier & Co. Limited and Bryan Garnier Securities SAS
Law of 16 December 2015	Belgian law of 16 December 2015 implementing the DAC2 and respectively CRS
LEI	Legal Entity Identifier
Listed Jurisdiction	A jurisdiction that is listed in the yearly updated Dutch Regulation on low-taxing states and non-cooperative jurisdictions for tax purposes (<i>Regeling laagbelastende staten en niet-coöperatieve rechtsgebieden voor belastingdoeleinden</i>)
Listing	The admission to listing and trading of all New Ordinary Shares on Euronext
Listing Agent	ING BANK N.V.
Listing Date	Trading day of the New Ordinary Shares on Euronext, expected to commence at 9:00 am Central European Time on or around 28 October 2024.
Lock-up Period	A period of 180 days following 22 October 2024
Market Abuse Regulation	Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse, and the regulations promulgated thereunder
MCAA	multilateral competent authority agreement
MDR	Medical Device Regulation
Medical Devices Regulation	Regulation (EU) 2017/745
MHRA	Medicines and Healthcare products Regulatory Agency
New Ordinary Shares	10,000,000 ordinary shares in the Company's share capital, with a nominal value of EUR 0.12 each
NOLs	Net operating losses
Non-Executive Directors	Non-executive directors (<i>niet-uitvoerend bestuurders</i>) of the Company
Non-Resident Holder	Holders of Ordinary Shares that are neither resident nor deemed to be resident of the Netherlands
NRT	NeuroRecovery Technologies, Inc.
PBMs	Pharmacy benefit managers
PCBA	Printed circuit board assembly process

PDMR	Person discharging managerial responsibilities within the meaning of Article 3(25) of the Market Abuse Regulation
PFIC	Passive foreign investment company
Placement Agents	UBS AG London Branch, Bryan, Garnier & Co. Limited, Bryan Garnier Securities SAS and Bank Degroof Petercam SA/NV
PMA	Pre-market approval
PNS	Peripheric Nerve Stimulation
Preferred Shares	Preferred shares in the Company's share capital, with a nominal value of EUR 0.12 each, if and when issued
Private Placement	Private placement of the New Ordinary Shares to Qualified Investors in the European Economic Area, to Relevant Persons in the United Kingdom and to institutional investors in certain other jurisdictions
Prospectus	This document or prospectus dated 24 October 2024
Prospectus Regulation	Regulation (EU) 2017/1129 (and amendments thereto), and includes any relevant implementing measure in each Relevant Member State
Protective Foundation	An independent foundation (<i>Stichting Continuïteit</i>) under Dutch law
QSR	Quality System Regulations
Qualified Investors	Qualified investors as defined in Article 2 of the Prospectus Regulation
REA	The European Research Executive Agency
Regulation S	Regulation S under the US Securities Act
Related Securities	Any securities convertible into or exercisable or exchangeable for Ordinary Shares or any other similar instrument that would give an equity-like economic interest in the Company to its holders
Relevant Member State	Each member state of the EEA
Relevant Persons	Qualified investors as defined in the UK Prospectus Regulation in the United Kingdom who are also (i) investment professionals falling within Article 19(5) of the Financial Promotion Order, (ii) high net worth entities or other persons falling within Article 49(2)(a) to (d) of the Financial Promotion Order, or (iii) persons to whom an invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA 2000) in connection with the issue or sale of any New Ordinary Shares may otherwise lawfully be communicated or caused to be communicated
Restricted Shareholders	The Directors, except for John de Koning, Rahma Samow and Rob ten Hoedt
Rule 144A	Rule 144A under the US Securities Act
Runway	Runway Growth Finance Corp.

Runway Loan	The loan and security agreement between the Company, ONWARD Medical S.A. and ONWARD Medical Inc. as borrowers and Runway as lender, dated 28 June 2024, in the amount of up to EUR 52.5 million
SCCs	The EU Standard Contractual Clauses
SCI	Spinal Cord Injury – damage to the nerves in the spine that circulate signals from the brain to and from the body. It can be caused by a trauma or a disease. This damage can lead to temporary or permanent dysfunctions
Shareholder(s)	A holder of Shares
Shareholders' Register	The shareholders' register of the Company
Shareholder Rights Directive II	Directive (EU) 2017/828 of the European Parliament and of the Council of 17 May 2021 amending Directive 2007/36/EC of the European Parliament and of the Council of 11 July 2007 as regards the encouragement of long-term shareholder engagement
Shares	The Ordinary Shares, the New Ordinary Shares and the Preferred Shares
The Netherlands	The part of the Kingdom of the Netherlands located in Europe
The Treaty	The tax treaty entered into between France and the Netherlands on 16 March 1973
UCLA	University of California, Los Angeles
United States or US	United States of America
Up-LIFT	Title of a pivotal trial using the Company's ARC ^{EX} System
UKCA	UK Conformity Assessed
UKNI	UK Northern Ireland
UK Prospectus Regulation	The Prospectus Regulation as it forms part of domestic law by virtue of the European Union Withdrawal Act 2018
US dollars or US\$ or USD or \$	The US Dollar, the lawful currency in the US
US Exchange Act	The U.S. Securities Exchange Act of 1934, as amended
US Holder	A beneficial owner of Ordinary Shares that is, for US federal income tax purposes: (i) a citizen or individual resident of the United States; (ii) a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state thereof or the District of Columbia; (iii) an estate the income of which is subject to US federal income taxation regardless of its source; or (iv) a trust if a United States court can exercise primary supervision over the trust's administration and one or more United States persons are authorized to control all substantial decisions of the trust, or the trust has validly elected to be treated as a domestic trust for US federal income tax purposes
US Securities Act	The United States Securities Act of 1933, as amended

VAT

Value added tax

Vice-Chairperson

The vice-chairperson of the Board

FINANCIAL STATEMENTS

ONWARD Medical N.V. page

Interim Condensed Consolidated Financial Statements

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ONWARD[®] Medical N.V.

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In this Half Year Report 'ONWARD Medical', 'the Company', 'the Group', 'we', 'us' and 'our' are sometimes used for convenience in contexts where reference is made to ONWARD Medical N.V. and/or any of its subsidiaries in general or where no useful purpose is served by identifying the particular company.

Condensed Consolidated Interim Statement of Profit and Loss

for the six-month period ended 30 June

	2024 Unaudited	2023 Unaudited
	Notes	
<i>All amounts in EUR '000</i>		
Grants & Other Income	208	928
Total Revenues and Other Income	208	928
Research & Development expenses	(6,134)	(7,638)
Clinical & Regulatory expenses	(2,689)	(2,177)
Marketing & Market Access expenses	(1,387)	(1,568)
Patent Fees & Related expenses	(547)	(950)
Quality Assurance expenses	(1,052)	(799)
General & Administrative expenses	(7,148)	(6,576)
Total Operating Expenses	(18,957)	(19,708)
Operating Loss for the period	(18,749)	(18,780)
Net Finance Result	179	(457)
Net finance costs	179	(457)
Loss for the period before tax	(18,570)	(19,237)
Income taxes	11 318	(45)
Net Loss for the period	(18,252)	(19,282)
Attributable to:		
Equity holders of the parent	(18,252)	(19,282)
	(18,252)	(19,282)
Earnings per share (€):	9	
Basic earnings per ordinary share attributable to shareholders	(0.53)	(0.64)
Diluted earnings per ordinary share attributable to shareholders	(0.53)	(0.64)

Condensed Consolidated Interim Statement of Comprehensive Income

for the six-month period ended 30 June

	2024 Unaudited	2023 Unaudited
	Notes	
<i>All amounts in EUR '000</i>		
Net Loss for the period	(18,252)	(19,282)
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods	–	–
Other comprehensive income	–	–
Currency translation differences	(606)	(250)
Other comprehensive income that will be reclassified to profit or loss in subsequent periods	(606)	(250)
Total Comprehensive Result for the period, net of tax	(18,858)	(19,532)
Attributable to:		
Equity holders of the parent	(18,858)	(19,532)
	<u>(18,858)</u>	<u>(19,532)</u>

Condensed Consolidated Interim Statement of Financial Position

		30 June 2024 Unaudited	31 December 2023
<i>All amounts in EUR '000</i>			
	Notes		
ASSETS			
Non-current Assets			
Intangible fixed assets	6	10,130	9,804
Property, plant and equipment		470	609
Right of use assets		1,162	1,483
Deferred tax assets		310	310
		12,072	12,206
Current Assets			
Indirect tax receivables		101	117
Receivable from related parties	13	34	37
Other current assets		2,594	1,501
Fixed term deposits		7,500	–
Cash and cash equivalents		24,553	29,768
		34,782	31,423
		46,854	43,629
EQUITY AND LIABILITIES			
Equity and Reserves			
Shareholders' equity		4,155	3,622
Share premium		172,662	155,249
Other reserves	8	4,616	4,488
Retained earnings		(163,085)	(145,428)
		18,348	17,931
Total equity attributable to shareholders		18,348	17,931
Non-current Liabilities			
Interest-bearing loans	7	16,022	15,255
Deferred tax liability		195	631
Lease liability		743	1,051
Post-employment benefits		2,006	2,081
		18,966	19,018
Current Liabilities			
Income tax liabilities		157	221
Lease liability		549	568
Trade payables	12	3,312	1,369
Other payables	12	5,522	4,522
		9,540	6,680
		48,854	43,629

The above balance sheet should be read in conjunction with the accompanying notes.

Condensed Consolidated Interim Statement of Changes in Equity

for the six-month period ended June 30		Issued Capital	Share Premium	Other reserves	Retained Earnings	Total Equity
<i>All amounts in EUR '000</i>	Notes					
At January 1, 2024		3,622	155,249	4,488	(145,428)	17,931
Loss for the period		–	–	–	(18,252)	(18,252)
Other comprehensive income		–	–	(606)	–	(606)
Total comprehensive result		–	–	(606)	(18,252)	(18,858)
Issue of Shares	8	533	19,467	–	–	20,000
Issue of Shares- Closing costs	8	–	(2,054)	–	–	(2,054)
Share based payments	10	–	–	734	595	1,329
At June 30, 2024 (Unaudited)		4,155	172,662	4,616	(163,085)	18,348

for the six-month period ended June 30		Issued Capital	Share Premium	Other reserves	Retained Earnings	Total Equity
<i>All amounts in EUR '000</i>	Notes					
At January 1, 2023		3,622	155,249	2,079	(108,319)	52,631
Loss for the period		–	–	–	(19,282)	(19,282)
Other comprehensive income		–	–	(250)	–	(250)
Total comprehensive result		–	–	(250)	(19,282)	(19,282)
Share based payments	10	–	–	1,171	–	1,171
At June 30, 2023 (Unaudited)		3,622	155,249	3,000	(127,601)	34,270

Condensed Consolidated Interim Statement of Cash Flows

for the six-month period ended 30 June

	2024 Unaudited	2023 Unaudited
Notes		
<i>All amounts in EUR '000</i>		
Loss for the period before taxes	(18,570)	(19,237)
Adjusted for:		
• Depreciation and impairment of property, plant and equipment and right-of-use assets	434	329
• Share based payment transaction expense	1,329	1,171
• Post-employment benefits	–	22
• Net finance costs	(179)	404
• Net foreign exchange differences	–	–
• Other non-cash items	(54)	61
Changes in working capital:		
(Increase) / Decrease in Trade and other receivables	(828)	(566)
Increase / (Decrease) in Trade and other payables	3,104	(713)
Interest received	194	237
Interest paid	–	–
Bank charges paid	(10)	(9)
Income tax paid	(225)	(91)
Net cash generated /(used) from operating activities	(14,805)	(18,391)
Cash flows from investing activities		
Investments in fixed assets	(24)	(287)
Investments in intangible fixed assets	–	(16)
Investments in fixed term deposits	(7,500)	(5,000)
Net cash generated/(used) from investing activities	(7,524)	(5,303)
Cash flows from financing activities		
Proceeds from Borrowings	7	1,037
Payment of principal portion of lease liabilities	(304)	(263)
Proceeds from issuance of shares	8	–
Transaction costs on issuance of shares	8	–
Net cash generated/(used) from financing activities	17,642	775
Movement in cash and cash equivalents		
Cash and cash equivalents at 1 January	29,768	41,760
Effect of exchange rates on cash and cash equivalents	(527)	52
Changes in cash and cash equivalents during the period	(4,688)	(22,920)
Cash and cash equivalents at 30 June	24,553	18,788

Notes to the Condensed Consolidated Interim Financial Statements

1. General Information

ONWARD Medical B.V. was a Dutch private company with limited liability (besloten vennootschap met beperkte aansprakelijkheid), incorporated on 20 November 2015. On 21 October 2021 (the First Trading Date) the Company completed a corporate conversion, converting into a public limited company under Dutch law (naamloze vennootschap). The legal name changed to ONWARD Medical N.V. (“ONWARD”). The registered office is located at Schimmelt 2, Eindhoven, the Netherlands. ONWARD Medical N.V. is registered in the Commercial Register of the Chamber of Commerce under number 64598748.

ONWARD and its subsidiaries (the “Group”) are developing implantable and non-invasive neuromodulation systems to deliver the company’s proprietary therapies to the spinal cord. These Condensed Consolidated Interim Financial Statements are comprised of statements for ONWARD and its two wholly owned subsidiaries: ONWARD Medical SA (incorporated in Switzerland) and ONWARD Medical Inc. (incorporated in the United States of America).

The interim financial statements of ONWARD Medical N.V. and its subsidiaries for the six months ended 30 June 2024 have not been audited or reviewed. The interim consolidated financial statements were authorized for publication by the Board on 10 September 2024.

2. Basis of Preparation

The Company’s Condensed Consolidated Interim Financial Statements (“Interim Financial Statements” or “Interim Report”) for the six-month period ended 30 June 2024 have been prepared in accordance with International Accounting Standard 34 – Interim Financial Reporting as endorsed by the European Union (“IFRS”) and should be read in conjunction with the Company’s last annual consolidated financial statements as at and for the year ended 31 December 2023.

The significant accounting policies used in the preparation of the Interim Financial Statements are consistent with those followed in the preparation of the Company’s annual consolidated financial statements as of and for the year ended 31 December 2023.

The Interim Financial Statements are presented in thousands of euros and all values are rounded to the nearest thousand (€000), except when otherwise indicated, and for the number of shares and the per share amount. Due to rounding, amounts may not add up to totals provided.

The preparation of the Interim Financial Statements requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Company’s accounting policies. The areas involving a higher degree of judgment or complexity, are areas where assumptions and estimates are significant to the Consolidated Financial Statements. The critical accounting estimates used in the preparation of the Interim Financial Statements are consistent with those followed in the preparation of the Company’s annual consolidated financial statements as of and for the year ended 31 December 2023.

3. Continuity of the Group

As of 30 June 2024, the Company had a net cash position of EUR 32.1 million. Based on cash flow forecasts for the years 2024 and 2025, which include significant expenses and cash outflows related to commercial readiness, the continuation of research and development projects, and upcoming clinical trials, the Company believes that this cash position will be sufficient to meet the Company’s capital requirements and fund its operations for the near term. However, it is not expected to be sufficient for the next 12 months. Given the current cash position, a material uncertainty remains about the Company’s ability to continue as a going concern.

Inherent uncertainties in these forecasts may impact the Company’s cash position. The Company’s long-term success is contingent on achieving FDA clearance or approval and CE mark for its therapies. To continue development and commercialization activities as planned, the Company will need to secure additional funding in the near future.

The Runway Growth debt facility closed earlier this year will provide cash as tranches are unlocked upon the Company's achievement of pre-determined milestones. In addition, the Company is actively engaged in discussions and activities that carry the potential to raise significant cash through equity financing.

The Board of Directors is aware that the continuity of the Company's operations depends on its ability to close additional funding and that there are uncertainties in this regard. Considering the Company's history of successfully raising necessary capital, the Board of Directors have a reasonable expectation of success.

In view of the above, and notwithstanding a loss brought forward of EUR 163 million as of 30 June 2024, the Interim Financial Statements have been prepared on a going concern basis.

4. Standards Issued but not yet Effective

The accounting policies adopted in the preparation of the Interim Financial Statements are consistent with those followed in the preparation of the Group's Annual Consolidated Financial Statements for the year ended 31 December 2023, except for the adoption of new standards effective as of 1 January 2024. The Group has not early adopted any standard, interpretation or amendment that has been issued but is not yet effective.

Several amendments apply for the first time in 2024, but they do not have an impact on the Interim Financial Statements of the Group.

5. Segment Reporting

Based on the organizational structure, as well as the nature of financial information available and reviewed by the Company's chief operating decision-makers to assess performance and make decisions about resource allocations, the Company has concluded that its total operations represent one reportable segment and that the consolidated disclosures address the requirements.

6. Intangible Fixed Assets

	30 June 2024 Unaudited	31 December 2023
Goodwill	1,906	1,845
In-Process R&D	5,888	5,698
License fees	2,336	2,261
Closing net book value	10,130	9,804

The Company has reviewed whether changes in market conditions require an update to the impairment assessment performed in December 2023 and concluded that no update is required. The movement since 31 December 2023 is the result of foreign exchange rate movements.

7. Financial Liabilities

7.1 Interest Bearing Loans

Innovation loan

On 5 February 2016, the Group was granted a loan from the Netherlands Enterprise Agency (RVO) of € 10 million payable according to a set repayment scheme.

	30 June 2024 Unaudited
Loan opening balance (at 31 December 2023)	15,255
Loan amount received	–
Interest accrued during the period	767
Closing net book value	<u>16,022</u>

The loan carries interest at 10%.

The current repayment plan for the loan was as presented below:

<i>Date</i>	% of Loan amount
1 January 2026	15.0
1 April 2026	15.0
1 July 2026	17.5
1 October 2026	17.5
1 January 2027	17.5
1 April 2027	17.5
1 July 2027	All due interest

Refer to Note 15 for information on the repayment of this loan in July 2024.

7.2 Financial Risk Management

The Group's financial risk management objectives and policies are consistent with those disclosed in the Consolidated Financial Statements for the year ended 31 December 2023.

Fair value hierarchy

The valuation techniques and inputs used to develop measurements for financial liabilities are consistent with those disclosed in the Consolidated Financial Statements for the year ended 31 December 2023. The carrying amounts and fair values of the Group's financial instruments are as follows, including its fair value hierarchy:

Balance at 30 June 2024	Carrying amount	Fair value
Financial liabilities		
Innovation credit loan (Level 2)	16,022	16,022
Total financial liabilities	<u>16,022</u>	<u>16,022</u>
Balance at 31 December 2023	Carrying amount	Fair value
Financial liabilities		
Innovation credit loan (Level 2)	15,255	15,460
Total financial liabilities	<u>15,255</u>	<u>15,460</u>

There were no changes in the Group's valuation processes, valuation techniques, and types of inputs used in the fair value measurements during the period.

Management has assessed that the fair values of cash and cash equivalents, accounts payable, taxes and social securities and other payables approximate to their carrying amounts largely due to the short-term maturities of these instruments.

During the period, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.

The following table details the remaining undiscounted contractual maturity for the Company's financial liabilities with agreed repayment periods, including both interest and principal cash flows:

At 30 June 2024:

	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Innovation loan	16,022	–	–	–	16,022
Lease liability	549	743	–	–	1,293
Trade & other payables	3,312	–	–	–	3,312
Total (Unaudited)	19,883	743	–	–	20,626

At 31 December 2023:

	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Innovation loan	–	6,500	14,295	–	20,795
Lease liability	615	1,084	–	–	1,699
Trade & other payables	1,369	–	–	–	1,369
Total	1,984	7,584	14,295	–	23,863

8. Issued Capital and Reserves

The authorized share capital (“maatschappelijk kapitaal”) amounts to EUR 18 million divided into 75,000,000 Ordinary Shares and 75,000,000 Preferred Shares with a nominal value of EUR 0.12 each. At 30 June 2023, 34,628,832 Ordinary Shares were issued (31 December 2023: 30,184,388 shares). The increase is the result of a capital raise in March 2024 where 4,444,444 new ordinary shares were issued at an issue price of EUR 4.50. The transaction costs directly attributable to the capital raise have been deducted from share premium. All of the issued Ordinary Shares are fully paid-up and represent capital in the Company. No Shareholders have any voting rights different from any other Shareholder.

Other Reserves

	Currency Translation Differences	Stock compensation reserve	Total Reserves
Balance at 1 January 2024	164	4,324	4,488
Share based payment expense for the period	–	1,329	1,329
Reclassification of the fair value of forfeited options	–	(595)	(595)
Currency translation differences	(606)	–	(606)
Balance at 30 June 2024 (Unaudited)	(442)	5,058	4,616

	Currency Translation Differences	Stock compensation reserve	Total Reserves
Balance at 1 January 2023	319	1,760	2,079
Share based payment expense for the period	–	1,179	1,179
Currency translation differences	(250)	–	(250)
Balance at 30 June 2023 (Unaudited)	69	2,931	3,000

9. Loss per share

The objective of determining diluted EPS is to reflect the maximum possible dilutive effect arising from potential ordinary shares outstanding during the period. The Group has stock option plans that may be settled in ordinary shares of the Group, and that are considered anti-dilutive considering the Group is currently loss making. Therefore, diluted EPS is disregarded.

There have been no other transactions involving ordinary shares or potential ordinary shares between the reporting date and the date of authorization of these Interim Financial Statements. The following tables reflect the income and share data used in the EPS calculation:

Profit (loss) attributable to ordinary shareholders

	2024 Unaudited	2023 Unaudited
Profit (loss) for the year, attributable to equity holders of the parent	(18,252)	(36,181)

Weighted-average number of ordinary shares

	2024 Thousands	2023 Thousands
Weighted average number of ordinary shares for basic EPS	34,627	30,184

10. Share-based Payments

	30 June 2024 Unaudited	30 June 2023 Unaudited
Opening balance	4,324	1,760
Addition to the reserve	1,329	1,171
Reclassification of the fair value of forfeited options	(595)	–
Closing balance	5,058	2,931

Long-term incentive plan (LTIP)

The LTIP plan aims to align the Employee's interest with the interests of the Shareholders and to allow the employee to participate in the long-term growth of the Company. The LTIP is an omnibus plan with the flexibility to issue a different type of equity incentive(s). ONWARD awarded options over its ordinary shares to participants (referred to as the "Award" or "Grant") on the Grant Dates as specified in the table

below. Each option represents the right to receive one ordinary share of ONWARD against payment of the exercise price. The options expire 10 years after the Grant Date and become exercisable on vesting. The Grant is subject to continued provision of services to the Company under a graded vesting schedule, with 25% of the Grant vesting on the first anniversary of the Grant Date, and the remaining 75% of the Grant vesting in equal, monthly tranches over the 3 years following the first anniversary of the Grant Date (2.083% per month). The number of Options that will vest and become unconditional is subject only to a continued service condition. All options granted have the same conditions. Options do not settle automatically and are exercised at the option of the participant.

Financial Year	Grant Date	Type of Security	Number of options granted	Exercise Price	Expiration Date	Fair Value
2021	15/12/2021	Stock options	612,000	EUR 9.70	15/12/2031	EUR 4.89
2022	01/04/2022	Stock options	169,800	EUR 7.64	01/04/2032	EUR 4.18
2022	26/09/2022	Stock options	166,350	EUR 5.70	26/09/2032	EUR 3.19
2023	03/01/2023	Stock options	978,050	EUR 6.12	03/01/2033	EUR 3.37
2023	28/02/2023	Stock options	132,000	EUR 4.95	28/02/2033	EUR 2.72
2024	15/01/2024	Stock options	710,975	EUR 2.94	15/01/2034	EUR 1.60

The following parameters were used in the option model for the calculation of the fair value of the options per grant in 2024:

2024-01

Fair value on date of measurement (EUR)	1.60
Share price (EUR)	2.94
Exercise price (EUR)	2.94
Expected volatility	57.0%
Term of the option	4 ^a
Expected dividend	–
Risk-free interest rate	2.23%
Time to expiration	10

a: Vesting period is 1 – 4 years and depends on the vesting date of the specific tranche.

The weighted average fair value of the options granted during the six months ended 30 June 2024 was EUR 1.60 (year ended 31 December 2023: EUR 3.20).

For the six months ended 30 June 2024, the Group has recognized EUR 1.33 million of share-based payment expense in the statement of profit or loss (30 June 2023: EUR 1.17 million).

11. Income Taxes

Income tax expense is recognized at an amount determined by multiplying the profit (loss) before tax for the interim reporting period by management's best estimate of the weighted-average annual income tax rate expected for the full financial year, adjusted for the tax effect of certain items recognized in full in the interim period. As such, the effective tax rate in the interim financial statements may differ from management's estimate of the effective tax rate for the annual financial statements.

The Group's consolidated effective tax rate in respect of continuing operations for the six months ended 30 June 2024 was 1.7% (six months ended 30 June 2023: (0.2%)). Deferred tax assets increased primarily due to net operating losses and tax credit carry forwards in the US subsidiary. The major components of income tax expense in the Interim condensed consolidated statement of profit or loss are:

	2024	2023
Current income tax	138	(46)
Deferred income tax	(456)	1
Total corporate income tax in profit and loss	(317)	(45)

12. Trade & Other Payables

The increase in Trade Payables is driven by activities preparing for the manufacturing and commercial launch of ARC^{EX} expected by the end of 2024, and transaction costs relating to the venture debt financing concluded by the end of June 2024.

The increase in Other Payables is due to the higher leave pay accrual in June ahead of the summer holiday period compared to December.

13. Related Party Transactions

Receivables from related parties result from the settlement of withholding taxes on behalf of employees related to the EIP (Employee Investment Plan).

Except as disclosed, there are no material changes to the Group's related parties, related party transactions (including their terms and conditions) and future obligations towards related parties, compared to 31 December 2023. Transactions between the Company and its subsidiaries have been eliminated on consolidation and are not disclosed in the notes.

Remuneration of Key Management

	30 June 2024 Unaudited	30 June 2023 Unaudited
Salary, bonuses and other (short-term employee benefits)	1,952	2,392
Pension premiums (post-employment benefits)	80	86
Share based payments	1,650	1,235
Net liability	3,682	3,713

14. Commitments and Contingencies

Legal claim contingencies

At 30 June 2024, the Group had no legal claim contingencies.

Guarantees

The Group has provided a guarantee to Wincasa for EUR 294k and EUR 8k to SPACES as collateral for the lease of its office spaces.

Royalties

The Group has entered into three license agreements with EPFL that will require royalty payment in the event the Company is able to generate revenues in the future for products directly linked to these licenses. The royalty scheme with EPFL is based on net sales. On 27 September 2019, NeuroRecovery Technologies, Inc. (now ONWARD Medical, Inc.) entered into a license agreement with the Regents of the University of California acting through Technology Development Group UCLA Campus granting an exclusive license on certain patents in certain fields of neuromodulation and spinal cord stimulation and a non-exclusive license on certain other patent rights. Various revenue milestone payments are due under the exclusive license and fixed royalty payments are due under the nonexclusive license. The agreement contains various milestone and diligence obligations ranging from USD 10k to USD 50k payable upon entering a phase III clinical trial, regulatory approval and/or first commercial sale. On 8 October 2019, NeuroRecovery Technologies, Inc. (now ONWARD Medical, Inc.) entered into a license agreement with the California Institute of Technology ("Caltech"), the latter on behalf of various intellectual property owners, including UCLA, University of Louisville, DEI and USC, granting an exclusive license on certain technology in certain fields of epidural and transcutaneous neuromodulation and a non-exclusive license of certain other intellectual property. Various revenue milestone payments, diligence obligations and fixed royalty payments are due under the license. These payments range from USD 20k to USD 75k payable upon FDA approval, CE mark and/or first commercial sale.

15. Events after the Reporting Period

On 28 June 2024 the Company and its subsidiaries, ONWARD Medical, Inc. and ONWARD Medical S.A., signed a loan agreement in the amount of up to €52.5 million (the "Loan Agreement") with U.S.-based lender Runway Growth Capital LLC (the "Lender"). The loan was used to (i) repay all of the Company's outstanding debt, (ii) fund the Company's upcoming commercial and clinical activities, and (iii) support for working capital and general corporate purposes. The facility is divided into five individual credit tranches. The first initial credit tranche of €16.0 million was available upon signing of the Loan Agreement and was drawn down immediately. Three subsequent credit tranches of €14.0 million, up to €5.0 million and up to €7.5 million will be available to be drawn by the Company until 31 March 2025 and 31 July 2026 respectively, in each case subject to the Company's achievement of certain milestones under the Loan Agreement. The fifth credit tranche of up to €10.0 million is uncommitted and available in the first quarter of 2027 upon the sole discretion of the Lender. The loan bears interest at a rate equal to Term Secured Overnight Financing Rate (SOFR) for a three-month interest period (currently at 6.00% and subject to a 4.25% floor), plus a margin of 6.50%. The loan documents provide for a number of affirmative and negative covenants by the Company customary for financings of this type, including financial covenants relating to revenue, earnings before interest taxes, depreciation and amortization (EBITDA) and minimum liquidity targets. The loans advanced under the Loan Agreement will be secured by a security interest in substantially all of the assets of the ONWARD Medical, N.V. and its subsidiaries. In addition, upon the signing of the debt financing the Company will issue to the Lender warrants which will entitle the Lender to purchase ordinary shares in the capital of the Company at an exercise price per newly issued share calculated on the basis of the lowest 30-day volume weighted average price (VWAP) between 9 April 2024 and the signing of the debt financing. The number of shares subject to the warrants are five percent (5.00%) of the drawn down principal amount initially and upon each subsequent loan advance, divided by the exercise price of €4.83. In accordance with IFRS 9, the Company recognizes a loan when it becomes a party to the contractual provisions of the instrument. The conditions precedent for the recognition of the new loan included the repayment of the existing Innovation Loan from the RVO. The existing securities and pledges were contingent upon this repayment, and their release was necessary to secure and pledge assets to the new lender. The funds required for the repayment of the existing (RVO) loan,

representing the first tranche, were received on 2 July 2024, at which point the conditions for the recognition of the new loan were satisfied. The RVO loan was also repaid on 2 July 2024.

On 2 July 2024 the Group granted 457,838 stock options to employees with an exercise price of EUR 5.08. The conditions of the existing plan as explained in Note 10 applies to this grant.

On 10 July 2024 the Company concluded the process to secure replacement funding from the Swiss State Agency (Secrétariat d'État à la formation, à la recherche et à l'innovation "SEFRI") in relation to the European Innovation Council and SMEs Executive Agency (EISMEA), Project 101057450 — ReverseParalysis for retroactive effect. EISMEA agreed to an amendment for the existing agreement that allows for the transferring of tasks required under the grant agreement from the Dutch entity to its Swiss subsidiary. The recognition of revenue related to activity performed by the Company's Swiss subsidiary is anticipated in the second half of 2024. Amendment procedures are still ongoing for the second grant Project 101070891 — NEMO BMI.

Annual Report 2023

ONWARD Medical N.V.

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Consolidated Financial Statements

Consolidated Statement of Profit and Loss

For the year ended 31 December

All amounts in EUR '000

	Notes	2023	2022
Grants and Other Income	2.1	532	2,148
Total Revenues and Other Income		532	2,148
Research & Development Expenses	2.2,2.8	(13,841)	(13,138)
Clinical & Regulatory Expenses	2.3,2.8	(4,911)	(5,747)
Marketing & Market Access Expenses	2.4,2.8	(2,943)	(1,951)
Patent fees & Related Expenses	2.5,2.8	(1,509)	(1,549)
Quality Assurance Expenses	2.6,2.8	(1,464)	(1,228)
General & Administrative Expenses	2.7,2.8	(11,327)	(10,563)
Total Operating Expenses		(35,995)	(34,176)
Operating Loss for the Period		(35,463)	(32,028)
Financial Income	4.5	972	62
Financial Expense	4.5	(1,583)	(1,572)
Net Finance Expense		(611)	(1,510)
Loss for the Period Before Taxes		(36,074)	(33,538)
Income Tax expense	2.10	(107)	766
Net Loss for the Period		(36,181)	(32,772)
Attributable to:			
Equity holders of the parent		(36,181)	(32,772)
Non-controlling interests		–	–
		(36,181)	(32,772)
Earnings Per Share (EUR):			
Basic earnings per share:	4.1	(1.20)	(1.09)
Diluted earnings per share:	4.1	(1.20)	(1.09)

Consolidated Statement of Comprehensive Income

<i>All amounts in EUR '000</i>	Notes	For the year ended 31 December	
		2023	2022
Net Loss for the Period		(36,181)	(32,772)
Remeasurement of post-employment benefits	5.0,2.10	(928)	427
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods (net of tax)		(928)	427
Currency translation differences		(155)	602
Other comprehensive income that will be reclassified to profit or loss in subsequent periods (net of tax)		(155)	602
Total Comprehensive Result for the Year, Net of Tax		(37,264)	(31,743)
Attributable to:			
Equity holders of the parent		(37,264)	(31,743)
Non-controlling interests		–	–
		(37,264)	(31,743)

Consolidated Statement of Financial Position

All amounts in EUR '000

	Notes	31 December 2023	31 December 2022
ASSETS			
Non-Current Assets			
Intangible assets	3.0	9,804	10,158
Property, plant & equipment	3.1	609	415
Right of use assets	3.2	1,483	1,681
Deferred tax assets	2.10	310	163
		12,206	12,417
Current Assets			
Indirect tax receivables	3.3	117	709
Receivable from related parties		37	251
Other current assets	3.4	1,501	1,456
Fixed term deposits	3.5	-	20,000
Cash and cash equivalents	3.5	29,768	41,760
		31,423	64,176
		43,629	76,593
EQUITY AND LIABILITIES			
Equity and Reserves			
Issued capital	4.0	3,622	3,622
Share premium	4.0	155,249	155,249
Other reserves *	4.0	4,488	2,079
Retained earnings		(145,428)	(108,319)
Total equity attributable to shareholders		17,931	52,631
Non-Current Liabilities			
Interest-bearing loans	4.2	15,255	12,656
Deferred tax liability	2.10	631	670
Lease liability	3.2	1,051	1,294
Post-employment benefits	5.0	2,081	1,121
		19,018	15,741
Current Liabilities			
Income tax liabilities		221	219
Lease liability	3.2	568	427
Trade payables	3.6	1,369	1,909
Other payables	3.7	4,522	5,666
		6,680	8,221
		43,629	76,593

* Other reserves include the foreign currency translation reserve that qualifies as a legal reserve under Dutch Law.

Consolidated Statement of Changes in Equity

All amounts in EUR '000

	Notes	Issued capital	Share premium	Other reserves *	Retained earnings	Total equity
At 1 January 2022		3,622	155,249	(214)	(75,974)	82,683
Loss for the year 2022		–	–	–	(32,772)	(32,772)
Other comprehensive income		–	–	602	427	1,029
<i>Total comprehensive result</i>		–	–	602	(32,345)	(31,743)
Share-based payments: LTIP	2.9	–	–	1,691	–	1,691
At 31 December 2022	4.0	3,622	155,249	2,079	(108,319)	52,631
At 1 January 2023		3,622	155,249	2,079	(108,319)	52,631
Loss for the year 2023		–	–	–	(36,181)	(36,181)
Other comprehensive income		–	–	(155)	(928)	(1,083)
<i>Total comprehensive result</i>		–	–	(155)	(37,109)	(37,264)
Share-based payments: LTIP	2.9	–	–	2,564	–	2,564
At 31 December 2023	4.0	3,622	155,249	4,488	(145,428)	17,931

* Other reserves include the foreign currency translation reserve that qualifies as a legal reserve under Dutch Law.

Consolidated Statement of Cash Flows

<i>All amounts in EUR '000</i>	Notes	For the period ended December 31,	
		2023	2022
Cash flows from operating activities			
Loss for the period before taxes		(36,074)	(33,538)
Adjusted for:			
Depreciation and impairment of property, plant and equipment and right-of-use assets	3.1, 3.2	726	735
Share-based payment transaction expense	2.9	2,564	1,691
Post-employment benefits		76	154
Net finance costs		611	1,510
Other non-cash items		197	106
Changes in working capital:			
Increase (-) Decrease (+) in Trade and other receivables		491	140
Increase (+) Decrease (-) in Trade and other payables		(1,654)	2,813
Interests received		916	15
Interests paid		–	(229)
Income tax paid		(106)	(49)
Bank charges paid	4.5	(17)	(33)
Net cash generated/(used) from operating activities		(32,270)	(26,685)
Cash flows from investing activities			
Investments in fixed assets	3.1	(422)	(386)
Investments in intangible fixed assets	3.0	–	(31)
Investment in fixed term deposits	3.5	–	(20,000)
Withdrawal of term deposits		20,000	
Net cash generated/(used) from investing activities		19,578	(20,417)
Cash flows from financing activities			
Proceeds from interest-bearing loans	4.2	1,292	–
Payment of principal portion of lease liabilities	3.2	(479)	(557)
Proceeds from issuance of shares		–	–
Transaction costs on issuance of shares	4.0	–	–
Net cash generated/(used) from financing activities		813	(557)
Movement in cash and cash equivalents			
Cash and cash equivalents at 1 January		41,760	89,443
Effect of exchange rates on cash and cash equivalents		(113)	(24)

<i>All amounts in EUR '000</i>	Notes	For the period ended December 31,	
		2023	2022
Changes in cash and cash equivalents during the period		<u>(11,879)</u>	<u>(47,659)</u>
Cash and cash equivalents at 31 December	3.5	<u>29,768</u>	<u>41,760</u>

Notes to the Consolidated financial statements

1. General Information and Basis of Preparation

1.0 Corporate Information

General

Onward Medical N.V. (“ONWARD”) is a public limited company under Dutch law (naamloze vennootschap). The registered office is located at Schimmelt 2, Eindhoven, the Netherlands. ONWARD is registered in the Commercial Register of the Chamber of Commerce under number 64598748.

ONWARD and its subsidiaries (the “Group”) are developing both an Implantable Neuro-stimulation System (INS) and a non-invasive system for electrical stimulation of specific areas of the spinal cord.

The financial statements for the year ended 31 December 2023 have been prepared by the Board of Directors and were authorized for issue on 24 April 2024. The financial statements will be submitted for adoption to the General Meeting on 14 June 2024.

1.1 Group Information

Information about subsidiaries

The consolidated financial statements of the Group include:

- ONWARD Medical SA, Switzerland (holding 100%)
- ONWARD Medical Inc, United States of America (holding 100%)

1.2 Basis of Preparation

The consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards (IFRS) and IFRIC interpretations as adopted by the European Union and with Part 9 of Book 2 of the Dutch Civil Code.

The consolidated financial statements have been prepared on a historical cost basis, unless otherwise stated. Income and expenses are accounted for on an accrual basis. The consolidated financial statements provide comparative information in respect of the previous period.

The consolidated financial statements are presented in euros and all values are rounded to the nearest thousand (EUR 000), except when otherwise indicated, and for the number of shares and the per share amount. Due to rounding, amounts may not add up to totals provided.

1.3 Basis of Consolidation

The consolidated financial statements comprise the financial statements of the Group and its subsidiaries as at 31 December 2023. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee. Specifically, the Group controls an investee if and only if the Group has:

- Power over the investee (i.e., existing rights that give it the current ability to direct the relevant activities of the investee)
- Exposure, or rights, to variable returns from its involvement with the investee, and
- The ability to use its power over the investee to affect its returns

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control. Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary.

Profit or loss and each component of other comprehensive income (OCI) are attributed to the equity holders of the parent of the Group. When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with the Group’s accounting policies. All

intragroup assets and liabilities, equity, income, expenses, and cash flows relating to transactions between members of the Group are eliminated in full-on consolidation.

1.4 Going Concern

In determining the appropriate basis for preparing the financial statements for the year ended 31 December 2023, Management considered the cash flow forecasts over a time horizon of one year after the date of these financial statements. The 2024 cash flow forecasts, include significant expenses and cash outflows in relation to -among others- the ongoing clinical trials, the continuation of research and development projects and FDA submission and approval for the ARCEX indication. Inherent uncertainties in these forecasts may have an impact on the Company's cash position. To continue development and reach commercialization as planned, the Company will need to attract additional funding in future. The Company's long-term success and existence is contingent on achieving FDA approval and CE mark of its products.

At 31 December 2023, the Company had cash and cash equivalents of EUR 29.8M. This was expected to fund operations to the end of 2024. On 25 March 2024, the Company completed a private placement and French retail public offering, adding EUR 20M gross to the year-end cash position. The cash and cash equivalents including the offering in March 2024 amounted to EUR 42M at 31 March 2024.

The Company believes that this cash position, after the offering, will be sufficient to meet the Company's capital requirements and fund its operations for at least 12 months as from the date of this Annual Report. We anticipate this would extend our cash runway to May 2025. The Company is currently in the process of attracting additional funding, which would extend the runway to Q3 2025. In case this or other funding opportunities are not successful, management sees cost savings opportunities to further extend the cash run rate beyond May 2025.

In view of the above, and notwithstanding a loss brought forward of EUR 145M as of 31 December 2023, the consolidated financial statements have been prepared on a going concern basis.

1.5 Summary of Material Accounting Policies

a) Current versus non-current classification

The Group presents assets and liabilities in the statement of financial position based on current/non-current classification. An asset is current when it is:

- Expected to be realized or intended to be sold or consumed in normal operating cycle
- Held primarily for the purpose of trading
- Expected to be realized within twelve months after the reporting period, or
- Cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period

All other assets are classified as non-current.

A liability is current when:

- It is expected to be settled in normal operating cycle
- It is held primarily for the purpose of trading
- It is due to be settled within twelve months after the reporting period, or
- There is no unconditional right to defer the settlement of the liability for at least twelve months after the reporting period

The Group classifies all other liabilities as non-current.

Deferred tax assets and liabilities are classified as non-current assets and liabilities.

b) Foreign currencies

The Group's consolidated financial statements are presented in euros, which is also the parent company's functional currency. For each entity, the Group determines the functional currency and items included in the financial statements of each entity are measured using that functional currency.

Transactions and balances

Transactions in foreign currencies are initially recorded by the Group entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currencies are retranslated at the functional currency spot rate of exchange at the reporting date.

Differences arising on settlement or translation of monetary items are recognized in profit or loss with the exception of monetary items that are designated as part of the hedge of the Group's net investment of a foreign operation. These are recognized in other comprehensive income until the net investment is disposed of, at which time, the cumulative amount is reclassified to profit or loss. Tax charges and credits attributable to exchange differences on those monetary items are also recorded in other comprehensive income.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates as at the dates of the initial transactions. Non-monetary items measured at fair value in a foreign currency are translated using the exchange rates at the date when the fair value is determined. The gain or loss arising on translation of non-monetary items measured at fair value is treated in line with the recognition of gain or loss on change in fair value of the item (i.e., translation differences on items whose fair value gain or loss is recognized in other comprehensive income or profit or loss are also recognized in other comprehensive income or profit or loss, respectively).

Any goodwill arising on the acquisition of a foreign operation and any fair value adjustments to the carrying amounts of assets and liabilities arising on the acquisition are treated as assets and liabilities of the foreign operation and translated at the spot rate of exchange at the reporting date.

Group companies

On consolidation, the assets and liabilities of foreign operations are translated into euros at the rate of exchange prevailing at the reporting date and their income statements are translated at the monthly average exchange rates.

The exchange differences arising on translation for consolidation are recognized in other comprehensive income. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is recognized in profit or loss.

1.6 Significant Accounting Judgments, Estimates and Assumptions

The preparation of the Group's consolidated financial statements requires Management to make judgments, estimates, and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and the disclosure of contingent liabilities, at the end of the reporting period. However, uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of the asset or liability affected in future periods.

The Group based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of revision and the future periods if the revision affects both current and future periods.

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date, that are most relevant to the carrying amounts of assets and liabilities within the next financial year, are included in each of the respective notes as referenced below:

Research & development	Note 2.2
Share-based payments	Note 2.9
Impairment of intangible assets	Note 3.0
Post-employment benefits	Note 5.0
Taxes	Note 2.10

1.7 New Accounting Standards and Developments

1.7.1 New and Amended Standards and Interpretations

Several amendments applied for the first time in 2023:

- IFRS 17 Insurance Contracts, effective 1 January 2023
- Disclosure of Accounting Policies - Amendments to IAS 1 and IFRS Practice Statement 2, effective 1 January 2023
- Definition of Accounting Estimates - Amendments to IAS 8, effective 1 January 2023
- Deferred Tax related to Assets and Liabilities arising from a Single Transaction – Amendments to IAS 12, effective 1 January 2023

None of these had a material impact on the consolidated financial statements of the Group in 2023.

1.7.2 Standards Issued but Not Yet Effective

The new and amended standards and interpretations that are issued, but not yet effective, up to the date of issuance of the Group's financial statements are listed below. The Group has not early adopted any standards, interpretations or amendments that have been issued but are not yet effective. The Group intends to adopt these new and amended standards and interpretations, if applicable, when they become effective.

- Classification of Liabilities as Current or Non-current - Amendments to IAS 1, effective 1 January 2024
- Lease Liability in a Sale and Leaseback – Amendments to IFRS 16, effective 1 January 2024
- Disclosures: Supplier Finance Arrangements - Amendments to IAS 7 and IFRS 7, effective 1 January 2024
- Lack of exchangeability – Amendments to IAS 21, effective 1 January 2025
- Sale or Contribution of Assets between an Investor and its Associate or Joint Venture - Amendments to IFRS 10 and IAS 28. In December 2015, the IASB postponed the effective date of this amendment indefinitely pending the outcome of its research project on the equity method of accounting.

Based on the nature and impact of each of the new standards, amendments and/or interpretations, the Group expects no material impact considering the circumstances as at the date of Annual Report.

2. Results of The Year

2.0 Segment Reporting

Based on the organizational structure, as well as the nature of financial information available and reviewed by the Company's chief operating decision-makers to assess performance and make decisions about resource allocations, the Company has concluded that its total operations represent one reportable segment and that the consolidated disclosures address the requirements.

	2023	2022
Non-current assets		
Netherlands	118	61
Switzerland	2,273	2,194
United States of America	9,815	10,162
Non-current assets	12,206	12,417

2.1 Revenues and Other Income

Accounting policy: Government subsidies are recognized where there is reasonable assurance that the subsidy will be received, and all attached conditions will be complied with. When the subsidy relates to an expense item, it is recognized as income on a systematic basis over the periods that the related costs, for which it is intended to compensate, are expensed. Any outstanding receivables related to these subsidies are recorded as grants receivable. The government subsidies are presented on a gross basis except for the WBSO (“Wet Bevordering Speur & Ontwikkeling”) that is presented on a net basis with the expensed amount for personnel expenses.

	2023	2022
Government subsidies (EU)	464	2,044
Other income	68	104
Total revenues and other income	532	2,148

Government subsidies have been received for the research and development of several development projects. There are no unfulfilled conditions or contingencies attached to these subsidies.

<i>(In EUR 000)</i>	Total Grant*	Recognized as Grant Income 2023	Recognized as Grant Income 2022	Recognized as Grant Income cumulative before 2022	Grant received in advance as per 31-12-2023
Grants					
CONFIRM	416	–	(12)	416	–
SWISS LOCAL (one-offs)**	–	–	85	65	–
PREP2GO	362	15	104	243	–
DARPA	3,004	419	1,412	1,173	–
ZonMW	250	83	83	83	–
EISMEA – ReverseParalysis***	292	(237)	273	–	183
EISMEA - NEMO BMI***	144	(85)	85	–	108
Eurostars Impulse	500	160	14	–	–
Rewire	347	56	–	–	122
SH-ARC	500	53	–	–	60
Total		464	2,044	1,980	473

* Please refer to the terms and conditions of the subsidies included below.

** Except for the Swiss local grant received by ONWARD Medical SA (In Switzerland), all other grants were received by ONWARD Medical N.V. (In the Netherlands).

*** Refer to EISMEA pending amendment note included below

Terms & conditions

CONFIRM

This Eurostars funding agreement with the Swiss Innovation Agency Innosuisse for a total amount of EUR 416k started in May 2019 and ended in October 2021, with follow up reporting resulting in the additional 25.75% granting of the allocated amount. The remainder of the grant was receivable in 2022 after submission of the final report. Due to lesser expenses declared, the final amount was decreased. In this project, ONWARD collaborated with Inomed A.G., Universitätsklinikum Heidelberg, and EPFL to develop an intra-operative neuromonitoring system and algorithms facilitating the surgical implantation of ARC^{IM}.

PREP2GO

This Eurostars funding agreement with the Netherlands enterprise agency RVO for a total amount of EUR 348k started in April 2020 and ended in September 2022. An amount equal to 90% of the grant is paid during the grant period in tranches in 2020, 2021, and 2022. The remaining 10% of the grant is payable after evaluation of the final report. In this project, ONWARD collaborated with Zurich Medtech A.G., IT'IS Foundation, Universitair Medisch Centrum Utrecht and EPFL to automatize the simulation framework that was developed in the RESTORE project, to facilitate the pre-operative planning for ARC Therapy for clinicians.

DARPA

The DARPA grant is a five-year project that started in October 2020. The award has been divided into 3 phases. The funding agreement for phase 1 and phase 2 was approved for a total amount of EUR 3.172M (or USD 3.402M). The grant amounts are being charged on a monthly basis over the period based on actual costs incurred. In this project, ONWARD is collaborating with a large consortium of academic partners, companies, and consultants to develop a new clinical intervention to modulate blood pressure and spinal cord perfusion and oxygenation in the hours following SCI. This corresponds to a roadmap development of ARC-IM to be used in the hours following SCI. ONWARD completed its contributions to the DARPA project in 2023 within the final cumulative amount being recognized amounting to EUR 3.004M (or USD 3.307M). The US government has announced that the DARPA project is cancelled and phase 3 will not continue.

ZonMW

This Dutch funding agreement is with the Netherlands Organisation for Health Research and Development for a total amount of EUR 250k that started in January 2021 and ends in January 2024. An amount equal to 80% of the grant is being paid during the grant period in three equal tranches in 2021, 2022, and 2023. The remaining 20% of the grant will be paid after submission of the final report. In this project, ONWARD is collaborating with the University of Bordeaux, CHUV, and EPFL to develop a research interface for ARCIM and evaluate its use to alleviate locomotor deficits in Parkinson's disease.

EISMEA – Reverse Paralysis

The European Innovation Council and SMEs Executive Agency (EISMEA) awarded a grant to support the development of an innovative Brain-Spine Interface technology for restoring mobility and upper limb function. The EUR 3.6M grant was awarded to ONWARD and its research partners EPFL, CEA-Clinattec and Sint Maartenskliniek. Under the terms of the award, ONWARD receives EUR 1.2M. The project started 1 May 2022 and has an end date of 30 April 2025, a duration of 36 months. ONWARD has received 75% as prefinancing; an additional 15% is receivable 90 days after the first periodic reporting, and the final payment 90 days after receiving the second periodic reporting. See note EISMEA pending amendment.

EISMEA - NEMO BMI

The European Innovation Council and SMEs Executive Agency (EISMEA) awarded a grant to support the development of Motor Brain-Machine Interfaces (BMIs). BMIs translate brain neural signals into commands to external effectors. The NEMO BMI project will conduct the exploration of assistance-free and easy-to-use portable neuroprosthetics including wireless neuronal activity recorder, a real-time neuronal activity decoder based on integrated technologies, and a spinal cord stimulator. The EUR 3.8M grant was awarded to ONWARD and its research partners Ecole Polytechnique Federale de Lausanne (EPFL), Commissariat a l'Energie Atomique et aux energies alternatives (CEA), and

Institute of Information and Communication Technologies (IICT). Under the terms of the award, ONWARD receives EUR 1M. The project started 1 October 2022 and has an end date of 30 September 2025, a duration of 36 months. ONWARD has received 75% as prefinancing; an additional 15% (up to 90% of the total grant) is receivable 90 days after the first periodic reporting, and the final payment is receivable 90 days after receiving the second periodic reporting. See note below, EISMEA pending amendment.

EISMEA pending amendment

The Company was awarded two grants from the European Innovation Council and SMEs Executive Agency (EISMEA), Project 101057450 — ReverseParalysis and Project 101070891 — NEMO BMI. Both projects work on the development, refinement, and clinical validation of a brain-computer interface for reversing paralysis after SCI. During the application process for both projects, the Company's research and development activities were primarily based at its headquarters in Eindhoven, the Netherlands, however, the Company opened an office and shifted R&D activities to Lausanne, Switzerland to be closer to its primary clinical partner, EPFL. The Company's headquarters are in the Netherlands and will continue to be responsible for the launch of products on the European market as legal manufacturer, ensuring European patients across the European Union benefit from these projects. Both projects were applied for and awarded to the Company. While there are personnel in the Netherlands office working on both ReverseParalysis and NEMO-BMI, certain R&D personnel are now located in Switzerland. The Company recognized grant income, in terms of the accounting policy in the Financial Statements, assuming that the effort and hours of Swiss employees could be leveraged under the definition of an affiliated entity or a beneficiary. During the first yearly project review of ReverseParalysis, the EISMEA project coordinators inquired about the location of personnel whose hours were declared. As Switzerland is not in the European Union and no longer associated to the European Horizon framework, ONWARD Medical SA cannot be added as a beneficiary in the grant agreement and have funding dispersed by the EISMEA. An amendment to the grant agreement is required to show what work and budget has been/will be transferred from the Dutch entity to the Swiss entity. The EISMEA will only fund the work to be performed in the Netherlands (EU). The grant amendment has been drafted and submitted to EISMEA for review. The Company has started discussions with a Swiss State Agency (SSA) regarding replacement funding. This SSA is an organization in Switzerland that covers costs associated with work done by Swiss entities in innovation Horizon Europe. A formal application with SSA can only be submitted, once the amendment with EISMEA has been approved. For the year ended 31 December 2023, the Company updated the grant income recognized to take into account this change in recognition in accordance with IAS 8.34 as required by IAS 20.32. This resulted in the reversal of grant income that is expected (but not yet confirmed) to be taken over by SSA. An accrual for EUR 1,358k was also raised for the advance received, which the Company expects to repay to EISMEA following approval of the amendment. The impact on grant income recognized for the year ended 31 December 2022 amounted to EUR 325k.

Eurostars Impulse

The Eurostars Independent Evaluation Panel has provided a subsidy for a total amount of EUR 500k that started 1 December 2022 and ends 30 November 2025, a duration of 36 months. The Impulse project focuses on closed-loop control of blood pressure for people with SCI.

ReWIRE

ONWARD has joined other global neuroscience and rehabilitation stakeholders to create ReWIRE, a groundbreaking initiative aimed at equipping next-generation scientists with the skills to develop therapeutic solutions for patients with paralysis caused by SCI. ReWIRE will build on recent technological breakthroughs by leveraging multiple PhD projects that will drive effective combinatorial treatments for SCI. The project is funded by the European Research Executive Agency (REA) as part of the Marie Skłodowska-Curie Actions (MSCA) Doctoral Networks for an amount of EUR 360k and started in 1 January 2023 and ends 31 December 2026.

SH-ARC

The Eurostars Independent Evaluation Panel has provided a subsidy for a total amount of EUR 500k that started 1 April 2023 and ends 31 March 2026, a duration of 36 months. SH-ARC works to integrate NUSHU sensorised shoes in a clinical-grade neuroprosthesis that will utilize spinal cord stimulation to alleviate parkinsonian gait deficits.

2.2 Research & Development Expenses

Accounting policy: Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset when the Group can demonstrate:

- The technical feasibility of completing the intangible asset so that it will be available for use or sale
- Its intention to complete and its ability to use or sell the asset
- How the asset will generate future economic benefits
- The availability of resources to complete the asset
- The ability to measure reliably the expenditure during development
- The ability to use the intangible asset generated

Significant estimate: The Group has evaluated the nature of the project research and development costs and concluded that all expenses incurred were related to research and pre-development of future products. Therefore, all costs have been expensed and are recognized in the statement of profit and loss.

	2023	2022
Staff expenses	9,200	8,385
Operating expenses	4,641	4,753
	13,841	13,138

The Company's research and development expenses consist primarily of the cost of external suppliers and third-party contractors involved in the design and development of the ARC^{EX} and ARC^{IM} systems, as well as employee-related expenses including salaries and benefits. The increase in 2023 is driven by advancements made on our ARC^{EX} and ARC^{IM} platforms and preparing for FDA submission of ARC^{EX} in the first half of 2024.

2.3 Clinical & Regulatory Expenses

	2023	2022
Staff expenses	3,472	3,204
Operating expenses	1,439	2,543
	4,911	5,747

The Company's clinical and regulatory expenses consist of the employee-related expenses including salaries and benefits for employees working on clinical trials. Clinical expenses in 2023 primarily relate to the clinical proof-of-concept studies, HemonNL and supporting the preparation of ARC^{EX} for FDA submission.

2.4 Marketing & Market Access Expenses

	2023	2022
Staff expenses	1,830	949
Outsourced expenses	1,113	1,002
	<hr/>	<hr/>
	2,943	1,951

The Company's marketing and market access expenses include the investigating activities on the future therapy reimbursement performed by third-party consultants and attendance of key events to create awareness within the SCI community of our ARC therapies and technology.

2.5 Patent fees & Related Expenses

	2023	2022
Staff expenses	373	400
Operating expenses	1,136	1,149
	<hr/>	<hr/>
	1,509	1,549

The Company's patent fees and related expenses include the cost for patent prosecution applications, consulting fees for new innovative ideas, as well as annuity maintenance fees and license fees for existing ideas, related employee expenses, including salary and benefits in the area of business development.

2.6 Quality Assurance expenses

	2023	2022
Staff expenses	1,204	1,045
Operating expenses	260	183
	<hr/>	<hr/>
	1,464	1,228

Quality assurance expenses consist primarily of quality control and quality assurance expenses. These expenses include employee expenses, including salary benefits for personnel, consulting, testing, and travel expenses.

2.7 General & Administrative Expenses

	2023	2022
Staff expenses	5,419	4,299
Depreciation and amortization	726	735
Other operating expenses	5,182	5,529
	<hr/>	<hr/>
	11,327	10,563

The Company's general and administrative expenses consist of employee expenses, including salary and benefits for personnel and contractors in executive, finance, accounting, tax, and human resources, as well as operating expenses relating to audit, legal, and supply chain.

2.8 Employee Benefit Expenses

Accounting policy:

Short-Term Employee Benefits

Short-term employee benefits include salaries and social security contributions, social taxes, paid vacation, and bonuses. They are recognized as expenses for the period in which employees perform the corresponding services. Outstanding payments at the end of the period are shown as other current liabilities.

Post-Employment Benefits

Group companies operate various pension schemes. The schemes are funded through payments to insurance companies or trustee-administered funds, determined by periodic actuarial calculations. The Group has both defined benefit and defined contribution plans.

Defined Contribution Plan

A defined contribution plan is a pension plan under which the Group pays fixed contributions into a separate entity. The Group has no legal or constructive obligations to pay further contributions if the fund does not hold sufficient assets to pay all benefits to employees relating to employee services in the current and prior periods. For defined contribution plans, the Group pays contributions to publicly or privately administered pension insurance plans on a mandatory, contractual, or voluntary basis. The Group has no further payment obligations once the contributions have been paid. The contributions are recognized as personnel expenses in the consolidated income statement when due.

All related expenses are recognized in the consolidated statement of profit and loss. Contributions payable or prepaid contributions as at year-end are recognized under accruals and deferred income, and prepayments and accrued income, respectively.

Defined Benefit Plan

The Group operates a defined benefit pension plan in Switzerland, which requires contributions to be made to a separately administered fund. The cost of providing benefits under the defined benefit plan is determined using the projected unit credit method.

Remeasurements, comprising of actuarial gains and losses are recognized in the statement of financial position with a corresponding debit or credit to retained earnings through OCI in the period in which they occur. Remeasurements are not reclassified to profit or loss in subsequent periods.

Past service costs are recognized in profit or loss on the earlier of:

- The date of the plan amendment or curtailment, and
- The date that the Group recognizes related restructuring costs

Net interest is calculated by applying the discount rate to the net defined benefit liability or asset. The Group recognizes the changes in the net defined benefit obligation due to service costs comprising current service costs, past-service costs, gains and losses on curtailments and non-routine settlements as part of operating expenses, and the net interest expense or income as part of net finance costs in the consolidated statement of profit and loss.

Significant Estimate: The cost of the defined benefit pension plan and the present value of the pension obligation are determined using actuarial valuations. An actuarial valuation involves making various assumptions that may differ from actual developments in the future. These include the determination of the discount rate, future salary increases, mortality rates, and future pension increases. Due to the complexities involved in the valuation and its long-term nature, a defined benefit obligation is sensitive to changes in these assumptions. All assumptions are reviewed at each reporting date.

	2023	2022
Wages and salaries	15,356	11,653
Social security costs	1,512	1,275
Pension costs – defined benefit plan	720	604
Pension costs – other	69	82
Share-based benefit expenses	2,564	1,691
Other labor costs	1,277	2,977
	21,498	18,282

The increase in wages and salaries is driven by the composition of new hires versus leavers and not full-time equivalents. This shift in expertise aligns with the Company's strategic goals. As at 31 December 2023, the Group employed 99.2 full-time equivalents, including white-collar employees and contractors. The following table presents a breakdown of the Company's full-time equivalents as at 31 December 2023 and 2022:

	2023	2022
Research & Development	50.0	48.8
Clinical & Regulatory	14.6	18.9
Marketing & Market Access	5.0	3.8
Patent Fees & related	1.0	1.0
Quality Assurance	8.8	7.8
General & Administrative	19.8	15.8
	99.2	96.1

As at 31 December 2023, the Company had 11.9 full-time equivalents located in the Netherlands (2022: 16.3), 75.3 full-time equivalents located in Switzerland (2022: 68.3), and 12 (2022: 11.5) full-time equivalents located in the United States.

2.9 Share-Based Payments

Accounting policy: Employees (including senior executives) of the Group receive remuneration in the form of share-based payments, whereby employees render services as consideration for equity instruments (equity-settled transactions).

Equity-Settled Transactions

The cost of equity-settled transactions is determined by the fair value at the date when the grant is made using an appropriate valuation model.

That cost is recognized, together with a corresponding increase in other reserves in equity, over the period in which the performance and/or service conditions are fulfilled in employee benefits expense. The cumulative expense recognized for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest. The statement of profit or loss expense or credit for a period represents the movement in cumulative expense recognized as at the beginning and end of that period and is recognized in operating expenses.

No expense is recognized for awards that do not ultimately vest, except for equity-settled transactions for which vesting is conditional upon a market or non-vesting condition. These are treated as vesting irrespective of whether or not the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

When the terms of an equity-settled award are modified, the minimum expense recognized is the expense had the terms not been modified, if the original terms of the award are met. An additional expense is recognized for any modification that increases the total fair value of the share-based payment transaction or is otherwise beneficial to the employee as measured at the date of modification.

Significant estimate: The Group measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. Estimating fair value for share-based payment transactions requires determination of the most appropriate valuation model, which is dependent on the terms and conditions of the grant.

Long-Term Incentive Plan (LTIP)

The LTIP plan is aimed at aligning the employee's interest with the interests of the Shareholders and to allow the employee to participate in the long-term growth of the Company. The LTIP is an omnibus plan with the flexibility to issue different type of equity incentives.

ONWARD awarded options over its Ordinary Shares to participants (referred to as the "Award" or "Grant") on the Grant Dates as specified in the table below. Each option represents the right to receive one Ordinary Share of ONWARD against payment of the exercise price. The options expire 10 years after the Grant Date and become exercisable on vesting. The Grant is subject to continued provision of services to the Company under a graded vesting schedule, with 25% of the Grant vesting on the first anniversary of the Grant Date, and the remaining 75% of the Grant vesting in equal, monthly tranches over the three years following the first anniversary of the Grant Date (i.e, 2.083% per month). The number of options that will vest and become unconditional is only subject to a continued service condition. All options granted have the same conditions. Options do not settle automatically and are exercised at the option of the participant.

Financial Year	Grant Date	Type of Security	Number of Options Granted	Exercise Price	Expiration Date	Fair Value
2021	15/12/2021	Stock options	612,000	EUR 7.41	15/12/2031	EUR 4.89
2022	01/04/2022	Stock options	169,800	EUR 7.64	01/04/2032	EUR 4.18
2022	26/09/2022	Stock options	166,350	EUR 5.70	26/09/2032	EUR 3.19

2023	03/01/2023	Stock options	978,050	EUR 6.12	03/01/2033	EUR 3.37
2023	28/02/2023	Stock options	132,000	EUR 4.95	28/02/2033	EUR 2.73
2023	03/07/2023	Stock options	308,175	EUR 5.18	03/07/2033	EUR 2.85

This fair value per option has been applied to the options granted for the recognition of the share-based payment expense recognized:

	2023	2022
Share-based payment expense	2,564	1,691
	<u>2,564</u>	<u>1,691</u>

The table below summarizes the number and weighted average exercise prices (WAEP) of, and movements in, share options during the year:

	2023 Number	2023 WAEP	2022 Number	2022 WAEP
Outstanding at 1 January	873,125	EUR 7.41	612,000	EUR 9.70
Granted during the year	1,418,225	EUR 5.81	336,150	EUR 6.68
Forfeited during the year	(462,700)	EUR 6.90	(75,025)	EUR 9.40
Exercised during the year	–	–	–	–
Outstanding at 31 December	<u>1,828,650</u>	EUR 6.85	<u>873,125</u>	EUR 7.41

	Number	WAEP
Exercisable at 31 December 2023	298,961	EUR 9.10
Exercisable at 31 December 2022	143,089	EUR 9.70

The weighted average remaining contractual life for the share options outstanding at 31 December 2023 was 8.79 years (2022: 9.2 years).

The weighted average fair value of options granted during the year was EUR 3.20 (2022: EUR 3.69).

The range of exercise prices for options outstanding at the end of the year was EUR 4.95 to EUR 9.70 (2022: EUR 5.70 to EUR 9.70).

The fair value of the awarded options was determined by applying a Binomial Option Pricing Model that allows for exercising of the option before the end of the option's life.

As the options cannot be exercised between the Grant Date and the vesting date, the Hull-White binomial formula, commonly used to value American options, was used. With the Hull-White model the impact of a certain time-based event – such as a vesting period, or an early exercise – can be taken into account.

Due to the different vesting dates for the different tranches in the option, we have calculated the unique option values per tranche according to each vesting date. The total option value per employee is then derived using a weighted average overall calculated option value for each vesting date.

The following parameters were used in the option model for the calculation of the fair value of the options as per each grant date:

	2023-07	2023-02	2023-01	2022-09	2022-04
Fair value on date of measurement (EUR)	2.85	2.73	3.37	3.19	4.18
Share price (EUR)	5.18	4.97	6.12	5.70	7.64
Exercise price (EUR)	5.18	4.95	6.12	5.70	7.64
Expected volatility	56.10%	57.20%	57.80%	59.30%	59.20%
Term of the option	4 ^a	4 ^a	4 ^a	4 ^a	4 ^a
Expected dividend	—	—	—	—	—
Risk-free interest rate	2.44%	2.65%	2.38%	2.1%	0.55%
Time to expiration	10	10	10	10	10

a: Vesting period is 1 – 4 years and depends on the vesting date of the specific tranche.

2.10 Income Tax

Accounting Policy:

Current Income Tax

Current income tax assets and liabilities for the current period are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted, at the reporting date in the countries where the Group operates and generates taxable income.

Current income tax relating to items recognized directly in equity is recognized in equity and not in the statement of profit or loss. Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

Deferred Tax

Deferred tax is provided using the liability method on temporary differences between the tax basis of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

Deferred tax liabilities are recognized for all taxable temporary differences, except:

- When the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss
- In respect of taxable temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future

Deferred tax assets are recognized for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the deductible temporary differences and the carry forward of unused tax credits and unused tax losses can be utilized, except:

- When the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss

- In respect of deductible temporary differences associated with investments in subsidiaries, associates and interests in joint ventures, deferred tax assets are recognized only to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilized

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilized. Unrecognized deferred tax assets are reassessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realized or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Significant Estimate: The Group has losses before tax which arose in the Netherlands that are available to offset against future profits of the Dutch entity in which the loss arose. However, these losses may not be used to offset taxable income elsewhere in the Group. The Group evaluated and judged that at this moment it is not sufficiently likely that future profits will be generated in the Dutch entity that can offset a deferred tax asset.

All Switzerland operations have a cost-plus agreement. The taxable amounts are settled. There are no NOL's. Last fiscal year settled is 2021. Due to expected profits based on the cost-plus the Swiss deferred tax assets relating to temporary differences have been recognized.

NOL's in the US entity prior to 2018 can be carried forward for 20 years. NOL's after 2018 can be carried forward indefinitely, limited to 80% of taxable income. On the acquisition of ONWARD Medical Inc. (formerly known as NeuroRecovery Technologies Inc) a deferred tax liability was recognized for the intangible asset (in-process R&D) identified in the PPA. In 2022, the Company, after reassessment, recognized a deferred tax asset of EUR 987k in the US entity that offsets the deferred tax liability as allowed under IAS 12, with no impact on previously reported results.

	2023	2022
Current income tax	(148)	(185)
Deferred income tax	41	951
Total corporate income tax in profit and loss	(107)	766
Current income Tax charge at tax rate of 25.8%	9,307	8,653
Tax rate differences in foreign jurisdictions	152	208
Non-deductible expenses	(662)	(433)
Non-recognized deferred tax asset on temporary differences	66	(111)
Non-recognized deferred tax asset on permanent differences	(203)	–
Net operating losses not recognized	(8,709)	(8,527)
Recognition of prior year deferred tax adjustments	–	976
Other	(58)	–
	(107)	766

The effective tax rate was -0.3% in 2023 (2022: 2.3%), which is lower than the statutory income tax rate of 25.8% (2022: 25.8%) in the Netherlands. The difference is primarily due to the net operating losses and temporary differences for which no deferred tax asset can be recognized. The uncertainty is based on insufficient evidence of future sources of income to support the realization of a deferred tax asset due to the Company being loss-making with limited tax planning opportunities.

Recognized Deferred Tax Assets & Liabilities

	Assets	Liabilities	Net
2023			
Intangible assets, including Goodwill	–	(1,639)	(1,639)
Right of use assets	–	(209)	(209)
Lease liability	228	–	228
Post-employment benefits	291	–	291
Losses available for offset against future Taxable income	1,008	–	1,008
Set-off of deferred tax	(1,217)	1,217	–
Net deferred tax liability	310	(631)	(321)
	Assets	Liabilities	Net
2022			
Intangible assets, including Goodwill	–	(1,656)	(1,656)
Right of use assets	–	(235)	(235)
Lease liability	240	–	240
Post-employment benefits	157	–	157
Losses available for offset against future Taxable income	987	–	987
Set-off of deferred tax	(1,221)	1,221	–
Net deferred tax liability	163	(670)	(507)

	2023	2022
Opening balance at January 1	(507)	(1,991)
Recognized in profit & loss	41	951
Remeasurement (gain)/loss on actuarial gains and losses in OCI	125	(59)
Foreign currency translation difference	20	26
Addition	–	–
Reclassification	–	566
Net deferred tax liability at December 31	(321)	(507)

Of the estimated amount of tax losses carried forward and available as at 31 December 2023, a deferred tax asset of EUR 1,007k has been recognized to offset the reversal of temporary differences in the US. For the remaining unused operating losses in the Netherlands of EUR 120M (2022: EUR 91M) and in the US of EUR 28.5M (2022: EUR 16M) no deferred tax is recognized. These losses can be carried forward indefinitely subject to local tax rules, except for approximately EUR 3.1M of losses in the US, which can be carried forward for 20 years (ultimately by 2037).

The Company offsets tax assets and liabilities if it has a legally enforceable right to set off current tax assets and current tax liabilities, and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same tax authority.

The deferred tax liability initially arose on the acquisition of NRT Inc (subsequently renamed to ONWARD Medical Inc.).

3. Non-Current Assets and Working Capital

3.0 Intangible Assets

	2023	2022
Goodwill	1,845	1,902
In-Process R&D	5,698	5,873
License fees	2,261	2,383
	<hr/>	<hr/>
Net book value at December 31	9,804	10,158

Goodwill

Accounting policy: Goodwill is initially measured at cost, being the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests, and any previous interest held, over the net identifiable assets acquired and liabilities assumed. If the fair value of the net assets acquired is in excess of the aggregate consideration transferred, the Group reassesses whether it has correctly identified all of the assets acquired and all of the liabilities assumed, and reviews the procedures used to measure the amounts to be recognized at the acquisition date. If the reassessment still results in an excess of the fair value of net assets acquired over the aggregate consideration transferred, then the gain is recognized in profit or loss.

After initial recognition, goodwill is measured at cost less any accumulated impairment losses. For the purpose of impairment testing, goodwill acquired in a business combination is, from the acquisition date, allocated to each of the Group's cash-generating units that are expected to benefit from the combination, irrespective of whether other assets or liabilities of the acquiree are assigned to those units.

Where goodwill has been allocated to a cash-generating unit and part of the operation within that unit is disposed of, the goodwill associated with the disposed operation is included in the carrying amount of the operation when determining the gain or loss on disposal. Goodwill disposed in these circumstances is measured based on the relative values of the disposed operation and the portion of the cash-generating unit retained.

	2023	2022
Cost	1,902	1,702
Accumulated changes	—	—
	<hr/>	<hr/>
Net book value at January 1	1,902	1,702
Additions	—	—
Foreign currency translation difference	(57)	200
Impairments	—	—
	<hr/>	<hr/>
Net change	(57)	200
Cost	1,845	1,902
Accumulated changes	—	—
	<hr/>	<hr/>
Net book value at December 31	1,845	1,902

In-Process R&D

Accounting policy: The cost of in-process R&D acquired in a business combination is the fair value at the date of acquisition.

Following initial recognition of the development expenditure as an asset, the asset is carried at cost less any accumulated amortization and accumulated impairment losses. Amortization of the asset begins when development is complete and the asset is available for use. It is amortized over the period of expected future benefit. Amortization is recorded in operating expenses. During the period of development, the asset is tested for impairment annually.

	2023	2022
Cost	6,025	6,261
Accumulated changes	(152)	(152)
Net book value at 1 January	5,873	6,109
Foreign currency translation difference	(175)	334
Additions	—	—
Reclassification	—	(570)
Amortization for the year	—	—
Impairments	—	—
Net change	(175)	(236)
Cost	5,850	6,025
Accumulated changes	(152)	(152)
Net book value at 31 December	5,698	5,873

License Fees

Accounting policy: License fees for the exclusive right to certain patents, critical in the development of the ARC Therapies, are capitalized and measured at cost on initial recognition.

Following initial recognition of the license fees as an asset, the asset is carried at cost less any accumulated amortization and accumulated impairment losses. Amortization of the asset begins when development of the ARC Therapies (ONWARD R&D) is complete, and the asset is available for use. It is amortized over the period of expected future benefit. Amortization is recorded in operating expenses. During the period of development, the asset is tested for impairment annually.

	2023	2022
Cost	2,383	2,218
Accumulated changes	—	—
Net book value at 1 January	2,383	2,218
Additions	—	31
Foreign currency translation difference	(72)	134
Reversals	(50)	—
Amortization for the year	—	—
Impairments	—	—
Net change	(122)	165

	2023	2022
Cost	2,261	2,383
Accumulated changes	—	—
Net book value at 31 December	2,261	2,383

In 2023, the Company reassessed the capitalization of the annual license fee component and reversed amounts previously capitalized (EUR 50k) to profit and loss.

Impairment Assessment

The in-process R&D was acquired through the acquisition of GTX Medical SA (now ONWARD Medical SA) and the business combination with NRT Inc.(now ONWARD Medical Inc.). The value of the in-process R&D is contingent on the success of the FDA approval of the NRT product. In terms of the NRT acquisition agreement, ONWARD also received and assumed responsibility for the exclusive license agreements with the Regents of the University of California (“UCLA”) and the California Institute of Technology (“Caltech”). In terms of these agreements, the occurrence of the IPO triggered the change in ownership clauses and resulted in additional payments to be made. These payments, as well as the annual license fee payments, are recognized as a separate class of intangible assets.

As per the accounting policies above goodwill, in-process R&D and license fees are tested for impairment annually. ONWARD performed its annual impairment test at year-end (consistent with the prior year) based on the most recent budgets and forecast calculations.

Significant Estimates:

Key assumptions used in the impairment test was the growth rate and the rate for discounting the projected cash flows.

- Cash flows are based on the expectation of receiving FDA approval. Revenue is only expected to occur towards the end of 2024. This is a one-year delay from previous expectations because of delayed submission of the Company’s first De Novo product application for clearance to the FDA. Upon FDA clearance, sales will start in the US focusing on patients with Veterans Affairs (VA) coverage, and home use will follow. CE marking is expected in 2025, after which, sales in Europe will follow. Operating costs increase to support sales and marketing efforts, as well as to maintain ongoing development and clinical research, including the next pivotal trial. Based on management’s estimate, EBITDA is not expected to be positive prior to 2027.
- Cash generating unit: As stated in the Annual Report, ONWARD has developed two targeted, programmable neurostimulation platforms: an implantable system, ARC^{IM}, and a non-invasive, transcutaneous system, ARC^{EX}. Both systems contain the same basic elements: an electrical impulse generator, electrodes placed in proximity to the spinal cord, and a programmer that enables clinicians to set stimulation therapy parameters and allows users to control their therapy within those parameters. The two ARC Therapy platforms share common components and have a similar user interface. This optimizes the use of development resources while providing users with a consistent, easy-to-use experience. Based on the aforementioned, in the pre-commercial phase the Company is viewed as one cash generating unit.
- Growth rate estimate: Rate is based on published industry research.
- Discount rate: Discount rates represent the current market assessment of the risks specific to ONWARD. The discount rate calculation is based on the specific circumstances of the Group and is derived from its weighted average cost of capital (WACC). The WACC measures the expected returns required by both debt and equity investors of a company, weighted by their respective contributions of capital.

The cash flow projections were determined using management’s internal forecasts that cover an initial period from 2024 to 2031, after which a terminal value was calculated. Using projected cash flows covering a period of more than five years is not considered unusual for pre-commercial lifescience

companies. Due to long development timelines and regulatory approval requirements, it is not atypical for Companies in the industry to use a period that extends beyond five years. The values assigned to the key assumptions represent management's assessment of future expectations. ONWARD performed a sensitivity analysis and noted that a reasonable change in either the discount rate (to 20%) or terminal growth rate (to 0%), or both the discount rate (to 20%) and terminal growth rate (to 0%), would not cause the carrying amount to exceed its recoverable amount. As shown by recent history, should the expected revenues move out by another year, this would not cause the carrying amount to exceed its recoverable amount.

	2023	2022
Discount rate	13.4%	14.3%
Terminal value growth rate	1.70%	1.70%

3.1 Property, Plant and Equipment

Accounting policy: Property, plant, and equipment is stated at cost, net of accumulated depreciation and accumulated impairment losses, if any. Such costs includes the cost of replacing part of the property, plant, and equipment and borrowing costs for long-term construction projects if the recognition criteria are met. When significant parts of property, plant and equipment are required to be replaced at intervals, the Group recognizes such parts as individual assets with specific useful lives and depreciates them accordingly. Likewise, when a major inspection is performed, its cost is recognized in the carrying amount of the plant and equipment as a replacement if the recognition criteria are satisfied. All other repair and maintenance costs are recognized in profit or loss as incurred.

Property, plant, and equipment transferred from customers is initially measured at the fair value at the date on which control is obtained.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets as follows:

- Office equipment 3 years
- Leasehold improvements 5 years

The useful life of leasehold improvements is the same or less than the lease term.

An item of property, plant, and equipment and any significant part initially recognized is derecognized upon disposal or when no future economic benefits are expected from its use or disposal. Any gain or loss arising from derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the income statement when the asset is derecognized.

The residual values, useful lives, and methods of depreciation of property, plant, and equipment are reviewed at each financial year end and adjusted prospectively, if appropriate.

Cost

	Office equipment	Leasehold improvements	TOTAL
At January 1, 2022	802	–	802
Additions	121	265	386
At December 31, 2022	923	265	1,188
Additions	352	70	422
Disposals	–	–	–
At December 31, 2023	1,275	335	1,610

Accumulated Depreciation

	Office equipment	Leasehold improvements	TOTAL
At January 1, 2022	(612)	–	(612)
Depreciation for the year	(135)	(26)	(161)
At December 31, 2022	(747)	(26)	(773)
Depreciation for the year	(141)	(87)	(228)
At December 31, 2023	(888)	(113)	(1001)

Net book value

	Office equipment	Leasehold improvements	TOTAL
At December 31, 2022	176	239	415
At December 31, 2023	387	222	609

3.2 Right of Use Assets and Lease Liabilities

Accounting policy: The Group assesses at contract inception whether a contract is, or contains, a lease. That is, if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

Group as a lessee

The Group applies a single recognition and measurement approach for all leases, except for short-term leases and leases of low-value assets. The Group recognizes lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets.

Right-of-Use Assets

The Group recognizes right-of-use assets at the commencement date of the lease (i.e., the date the underlying asset is available for use). Right-of-use assets are measured at cost, less any accumulated depreciation and accumulated impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the initial measurement amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date, less any lease incentives received.

Right-of-use assets are depreciated on a straight-line basis over the shorter of the lease term and the estimated useful lives of the assets.

If ownership of the leased asset transfers to the Group at the end of the lease term or the cost reflects the exercise of a purchase option, depreciation is calculated using the estimated useful life of the asset.

Lease Liabilities

At the commencement date of the lease, the Group recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. The lease payments include fixed payments (including in-substance fixed payments) less any lease incentives receivable, variable lease payments that depend on an index or a rate, and amounts expected to be paid under residual value guarantees. The lease payments also include the exercise price of a purchase option reasonably certain to be

exercised by the Group and payments of penalties for terminating the lease, if the lease term reflects the Group exercising the option to terminate.

Variable lease payments that do not depend on an index or a rate are recognized as expenses (unless they are incurred to produce inventories) in the period in which the event or condition that triggers the payment occurs.

In calculating the present value of lease payments, the Group uses its incremental borrowing rate at the lease commencement date because the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the lease payments (e.g., changes to future payments resulting from a change in an index or rate used to determine such lease payments), or a change in the assessment of an option to purchase the underlying asset. The Group's lease liabilities are included in lease liabilities.

Short-Term Leases and Leases of Low-Value Assets

The Group applies the short-term lease recognition exemption to its short-term leases of office space (i.e., those leases that have a lease term of 12 months or less from the commencement date and do not contain a purchase option). It also applies the lease of low-value assets recognition exemption to leases of office equipment that are considered to be low value. Lease payments on short-term leases and leases of low-value assets are recognized as expense on a straight-line basis over the lease term.

Right-of-use assets

The Group entered into a five-year lease for offices in Lausanne, Switzerland in November 2021. This lease is classified as a right-of-use asset. The office lease in Eindhoven, in the Netherlands, ended in October 2023 and was classified as a short-term office lease. In November 2023, a new lease was entered into for the Eindhoven office for one year.

Key movements relating to right-of-use assets are presented below:

	2023	2022
Net book value at January 1	1,681	2,190
Additions	299	90
Depreciation for the year	(497)	(575)
Onerous lease contract	–	(24)
Net book value at December 31	1,483	1,681

The office buildings are leased for office space. The lease in Lausanne includes an extension option exercisable up to one year before the end of the non-cancellable lease term. The lease in Eindhoven includes an extension option for an additional one year; the extension was included in the calculation of the right-of-use asset recognized over a full period of two years.

Lease liabilities

The maturity of the lease liability in relation to the office building is as follows:

	2023	2022
Less than one year	568	427
One to five years	1,051	1,294
More than five years	–	–
Total lease liability	1,619	1,721

Movement of the lease liability:

	2023	2022
Balance as at January 1	1,721	2,214
Additions	299	90
Onerous lease contract	–	(26)
Interest accretion	69	84
Repayments	(548)	(641)
Foreign currency impact	78	–
Total lease liability	1,619	1,721

The incremental borrowing rate applied is 4% for the Lausanne office and is 7.4% for the Eindhoven office.

On 1 November 2022, the Group entered into a short-term office lease for 12 months for which the Group elected not to recognize a right-of-use asset and lease liability. Amount recognized in relation to this short-term lease amounted to EUR 8.8k.

For the maturity analysis of the undiscounted cash flows, refer to note 4.3.

3.3 Indirect Tax Receivables

The tax receivables consist of refundable VAT and are collectable within 12 months. The decrease in the receivable is a direct result of quarterly filing of VAT returns and claims received throughout the year.

3.4 Other Current Assets

	2023	2022
Advance payments	936	905
Grants and other receivables	260	266
Rental guarantee	305	285
	1,501	1,456

The Group provided a guarantee of EUR 305k (2022: EUR 285k) to fulfill collateral requirements relating to the Lausanne office rental agreement. This guarantee places no restriction on the cash position and is payable on demand if the Company fails to meet its commitments. Advance payments mostly relate to prepaid D&O insurance for which the premium decreased in 2023.

3.5 Cash and Cash Equivalents and Fixed Term Deposits

Accounting policy: Cash and short-term deposits in the statement of financial position comprise cash at banks and on hand, and short-term deposits with a maturity of three months or less, that are readily convertible to a known amount of cash and subject to an insignificant risk of change in value.

For the purpose of the consolidated statement of cash flows, cash and cash equivalents consist of cash and short-term deposits as defined above, net of outstanding bank overdrafts, as they are considered an integral part of the Group's cash management.

	2023	2022
Cash at bank	3,568	21,760
Short-term deposits	26,200	20,000
Cash and cash equivalents	29,768	41,760
Fixed term deposits	-	20,000
	-	20,000
Cash and cash equivalents and fixed term deposits	29,768	61,760

Cash at banks earns interest at floating rates based on daily bank deposit rates. Short-term deposits are made for varying periods of between one day and three months, depending on the immediate cash requirements of the Group, and earn interest at the respective short-term deposit rates.

Fixed term deposits represent deposits made for varying periods exceeding three months but less than 12 months from inception.

At 31 December 2023, the Group had no bank overdrafts. All cash is freely at the disposal of the company.

3.6 Trade Payables

Trade payables and accrued expenses are non-interest bearing and are normally settled on 30-90 day terms. The decrease is a direct result of delay in ARCEX and the timing of settlement.

3.7 Other Payables

The other payables can be broken down as follows:

	2023	2022
Wage tax and social security	485	466
Grants received in advance	473	1,328
Bonus	1,243	1,856
Invoices to be received	538	732
Other	425	1,284
Grant-related payabl	1,358	-
	4,522	5,666

The decrease in Other Payables is due to decrease in the bonus accrual and amounts that were due to subcontractors (on grants) paid in early 2023. An accrual was raised in response to the pending grant amendment with EISMEA, refer to Note 2.1 EISMA, and is the estimated amount the Company may be required to repay for grant amounts received in advance in 2022.

4. Financing, Financial Risk Management and Financial Instruments

4.0 Issued Capital and Reserves

Share capital and share premium

Accounting Policy: Ordinary Shares are classified as **share capital**. Equity instruments are recorded at the proceeds received, net of direct issue costs.

The **share premium** represents the amount by which the fair value of the consideration received exceeds the nominal value of shares issued. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds.

The authorized share capital (“maatschappelijk kapitaal”) amounts to EUR 12,225,000 divided into 50,937,500 Ordinary Shares and 50,937,500 Preferred Shares with a nominal value of EUR 0.12 each.

At 31 December 2023, 30,184,388 Ordinary Shares were issued (31 December 2022: 30,184,388 shares). All of the issued Ordinary Shares are fully paid-up and represent capital in the Company. No shareholders have any voting rights different from any other shareholder.

Other Reserves

	Currency translation differences	Stock compensation reserve	Total other reserves
Balance at 1 January 2022	(283)	69	(214)
Share-based payment expense: LTIP	–	1,691	1,691
Currency translation differences	602	–	602
Balance at 31 December 2022	319	1,760	2,079
Share-based payment expense: LTIPS	–	2,564	2,564
Currency translation differences	(155)	–	(155)
Balance at 31 December 2023	164	4,324	4,488

Currency translation reserve

Exchange gains and losses arising from the translation of the functional currency of foreign operations to the reporting currency of the parent are accounted for in this legal reserve. In the case of the sale of a participating interest, the associated accumulated translation differences are transferred to the profit and loss account and presented therein as part of the result on the sale.

The foreign currency translation reserve relates to the investment in United States.

Stock compensation reserve

The stock compensation reserve is used to recognize the value of equity-settled share-based payments provided to employees, including key management personnel, as part of their remuneration.

4.1 Earnings Per Share (EPS)

Accounting Policy: Basic EPS is calculated by dividing the profit for the year attributable to ordinary equity holders of the parent by the weighted average number of Ordinary shares outstanding during the year.

Diluted EPS is calculated by dividing the profit attributable to ordinary equity holders of the parent (after adjusting for interest on the convertible Preference shares) by the weighted average number of Ordinary shares outstanding during the year plus the weighted average number of Ordinary shares that would be issued on conversion of all the dilutive potential Ordinary shares into Ordinary shares. The objective of determining diluted EPS is to reflect the maximum possible dilutive effect arising from potential Ordinary shares outstanding during the period. The Group is currently loss-making and there are currently no anti-dilutive potential Ordinary shares to be considered. Therefore, diluted EPS is disregarded for 2023. The share options granted under the LTIP (refer to Note 2.9) could have a potential dilutive effect in the future, but had no impact in 2023.

There have been no other transactions involving Ordinary shares or potential Ordinary shares between the reporting date and the date of authorization of these financial statements.

The following tables reflect the income and share data used in the EPS calculation:

Profit (loss) attributable to ordinary shareholders

	2023	2022
Profit (loss) for the year, attributable to equity holders of the parent	(36,181)	(32,772)

Weighted-average number of ordinary shares

	2023 Thousands	2022 Thousands
Weighted average number of ordinary shares for basic EPS	30,184	30,184

4.2 Financial Liabilities

Accounting Policy:

Financial Instruments – Initial Recognition and Subsequent Measurement

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity. Financial assets and financial liabilities are initially recognized when the Company becomes a party to the contractual provisions of the instrument.

Financial Liabilities

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings, payables, or as derivatives designated as hedging instruments in an effective hedge, as appropriate. A financial liability is classified as FVPL if it is classified as held-for-trading, it is a derivative or it is designated as such on initial recognition. Financial liabilities at FVPL are measured at fair value and net gains and losses, including any interest expense, are recognized in profit or loss. Other financial liabilities are subsequently measured at amortized cost using the effective interest method. Interest expense and foreign exchange gains and losses are recognized in profit or loss. Any gain or loss on derecognition is also recognized in profit or loss.

All financial liabilities are recognized initially at fair value and, in the case of liabilities at amortized cost, net of directly attributable transaction costs.

The Group's financial liabilities include trade payables, other payables, loans, and borrowings.

For purposes of subsequent measurement, financial liabilities are classified in two categories:

- Financial liabilities at fair value through profit and loss
- Financial liabilities at amortized cost

Financial liabilities at fair value through profit or loss (FVPL)

Financial liabilities at fair value through profit or loss include financial liabilities held for trading and financial liabilities designated upon initial recognition as at fair value through profit or loss.

Financial liabilities are classified as held for trading if they are incurred for the purpose of repurchasing in the near term. This category also includes derivative financial instruments entered into by the Group that are not designated as hedging instruments in hedge relationships as defined by IFRS 9. Separated embedded derivatives are also classified as held for trading unless they are designated as effective hedging instruments.

Gains or losses on liabilities held for trading are recognized in the statement of profit or loss.

Financial liabilities designated upon initial recognition at fair value through profit or loss are designated at the initial date of recognition, and only if the criteria in IFRS 9 are satisfied. The Group has not designated any financial liability as at fair value through profit or loss.

Financial Liabilities at Amortized Cost

This is the category most relevant to the Group. After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortized cost using the effective interest rate ("EIR") method. Gains and losses are recognized in the profit or loss when the liabilities are derecognized, as well as through the EIR amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the EIR. The EIR amortization is included as finance costs in the statement of profit or loss.

Derecognition

A financial liability is derecognized when the obligation under the liability is discharged or cancelled or expires. When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as the derecognition of the original liability and the recognition of a new liability at fair value. The difference in the respective carrying amounts is recognized in the statement of profit or loss.

Offsetting of Financial Instruments

Financial assets and financial liabilities are offset and the net amount is reported in the consolidated statement of financial position if there is a currently enforceable legal right to offset the recognized amounts and there is an intention to settle on a net basis, to realize the assets and settle the liabilities simultaneously. No offsetting is currently applied.

	2023	2022
Balance as at 31 December	15,255	12,656
Innovation loan		
Balance as per 1 January 2022	11,451	
Loan amount received	–	
Interest/cumulative dividend accrued during the year	1,205	
Balance as per 31 December 2022	12,656	
Loan amount received	1,292	
Interest accrued during the year	1,307	
Balance as per 31 December 2023	15,255	

Innovation loan

On 5 February 2016, the Group was granted a loan from RVO NL (Dutch Government) of EUR 10M payable according to a set payment scheme. The loan is advanced in installments based on progress. In 2023, two installments were received amounting to EUR 1.3M.

The loan carries interest at 10% per annum and is accrued on a yearly basis.

The current redemption plan for the loan is as presented below:

<i>Date</i>	% of Loan amount
1 January 2026	15.0
1 April 2026	15.0
1 July 2026	17.5
1 October 2026	17.5
1 January 2027	17.5
1 April 2027	17.5
1 July 2027	All due interest

Certain Intellectual Property (patents registered), have been pledged to the RVO NL in case of default of repayment of the loan. These patents have not been capitalized as at 31 December 2023.

4.3 Financial Risk Management Objectives and Policies

The Group's principal financial liabilities comprise of loans and borrowings and trade and other payables. The main purpose of these financial liabilities is to finance the Group's operations and to provide guarantees to support its operations.

The Group is responsible for implementing and evaluating policies which govern the funding, investments, and any use of derivative financial instruments. The Group is exposed to various risks. The Group monitors risk exposure on an ongoing basis, as summarized below:

Capital management

Capital includes issued capital, share premium, and all other equity reserves attributable to the equity holders of the parent. The primary objective of the Group's capital management is to continue as a going concern while maximizing shareholder value. The Group manages its capital structure and will consider adjustments in light of changes in economic conditions. To maintain or adjust the capital structure, the Group may issue new shares.

Liquidity risk

The Group manages liquidity risk by continuously monitoring forecast and actual cash flows. The Group's objective is to maintain a balance between continuity of funding and flexibility through the use of subsidies and grants, and sufficient progress towards regulatory approval, which is related to future financing rounds.

Cash is invested in low-risk investments such as short-term bank deposits or savings accounts. The Group mainly makes use of liquid investment in current accounts (in Euros) or short-term deposit accounts. The ability of the Group to maintain adequate cash reserves to support its activities in the medium term is highly dependent on the Group's ability to raise additional funds.

The following table details the undiscounted remaining contractual maturity for the Group's financial liabilities with agreed repayment periods, including both interest and principal cash flows:

As at 31 December 2023:

	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Innovation loan	–	6,500	14,295	–	20,795
Lease liability	615	1,084	–	–	1,699
Trade payables	1,369	–	–	–	1,369
Total	1,984	7,584	14,295	–	23,863

As at 31 December 2022:

	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Innovation loan	–	–	19,298	–	19,298
Lease liability	512	1,452	–	–	1,964
Trade payables	1,909	–	–	–	1,909
Total	2,421	1,452	19,298	–	23,171

Market risk

Market risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in market prices. The Group's activities may expose it to changes in foreign currency exchange rates and interest rates. The Group is not exposed to any equity price risk or commodity price risk, as it does not invest in these classes of investments.

Credit risk

Because of the absence of sales to third parties and therefore trade receivables, credit risk arises mainly from cash and cash equivalents and deposits with banks and financial institutions. The Group only works with international reputable commercial banks and financial institutions when investing surplus funds. Short- and fixed-term deposits are subject to approval in line with internal policy. The Group holds accounts with ING, Belfius, UBS, First American Bank, Deutsche Bank and Banque Cantonale Vaudoise (BCV). The number of banks and financial institutions is to minimize concentration risk and therefore mitigate financial loss through a counterparty's potential failure to make payments.

Currency risk

Currency risk is the risk that reported financial performance, or the fair value or future cash flows of a financial instrument, will fluctuate because of changes in foreign exchange rates. The Group is exposed to currency risk for the activities mainly in the US, as the accounting is performed in US dollars, whereas the functional currency of the Group is the euro. The risk is currently managed by replenishing the US bank account at regular intervals to account for both the positive and negative changes.

4.4 Fair Value and Fair Value Hierarchy of the Financial Statements

Accounting policy: All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level input that is significant to the fair value measurement as a whole:

- Level 1 — Quoted (unadjusted) market prices in active markets for identical assets or liabilities
- Level 2 — Valuation techniques for which the lowest level input that is significant to the fair value measurement is directly or indirectly observable
- Level 3 — Valuation techniques for which the lowest level input that is significant to the fair value measurement is unobservable.

The carrying amounts and fair values of the Group's financial instruments are as follows, including its fair value hierarchy:

	Carrying amount	Estimated fair value
2023		
Financial liabilities		
Innovation credit loan (Level 2)	15,255	15,460
Total financial liabilities	15,255	15,460
2022		
Financial liabilities		
Innovation credit loan (Level 2)	12,656	13,689
Total financial liabilities	12,656	13,689

Management has assessed that the fair values of cash and cash equivalents and accounts payable approximate to their carrying amounts largely due to the short-term maturities of these instruments.

The fair values of the financial assets and liabilities are included at the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced or liquidation sale. The following methods and assumptions were used to estimate the fair values:

The fair value of Innovation credit loan and due interest have been calculated by discounting the expected future cash flows using rates currently available for instruments with similar terms, credit risk and remaining maturities.

During the period, there were no transfers of fair value measurements between Level 1 and Level 2 and no transfers into or out of Level 3 for both financial assets and financial liabilities.

4.5 Financial Income and Expense

Accounting policy: Interest income is recognized by applying the effective interest rate, except for short-term receivables when the effect of discounting is immaterial. The Company's financial assets include cash and cash equivalents and other long term and current receivables.

Borrowing costs directly attributable to the acquisition, construction, or production of an asset that necessarily takes a substantial period of time to get ready for its intended use or sale are capitalized as part of the cost of the asset. All other borrowing costs are expensed in the period in which they occur. Borrowing costs consist of interest and other costs that an entity incurs in connection with the borrowing of funds.

	2023	2022
Interest income from deposits	972	62
Interest on loans	(1,307)	(1,205)
Interest post-employment benefits	–	–
Interest banks	–	(226)
Interest on lease liabilities	(69)	(84)
Exchange losses	(190)	(24)
Bank charges	(17)	(33)
Net Finance expense	(611)	(1,510)

5. Other Disclosures

5.0 Post-Employment Benefits: Defined Benefit Obligation

Accounting Policy: Group companies operate various pension schemes. The schemes are funded through payments to insurance companies or trustee-administered funds, determined by periodic actuarial calculations. The Group has both defined benefit and defined contribution plans.

Defined Benefit Plan

The Group operates a defined benefit pension plan in Switzerland, which requires contributions to be made to a separately administered fund. The cost of providing benefits under the defined benefit plan is determined using the projected unit credit method.

Remeasurements, comprising of actuarial gains and losses, are recognised in the statement of financial position with a corresponding debit or credit to retained earnings through OCI in the period in which they occur. Remeasurements are not reclassified to profit or loss in subsequent periods.

Past service costs are recognized in profit or loss on the earlier of:

- The date of the plan amendment or curtailment, and
- The date that the Group recognizes related restructuring costs

Net interest is calculated by applying the discount rate to the net defined benefit liability or asset. The Group recognizes the changes in the net defined benefit obligation due to service costs comprising current service costs, past-service costs, gains and losses on curtailments and non-routine settlements as part of operating expenses, and the net interest expense or income as part of net finance costs in the consolidated statement of profit and loss.

	2023	2022
Plan assets	4,289	3,879
Obligation	(6,370)	(5,001)
Net liability	2,081	1,121

A defined benefit plan is a pension plan that is not a defined contribution plan. Typically, defined benefit plans specify an amount of pension benefit that an employee will receive upon retirement, typically dependent on one or more factors such as age, years of service, and compensation. The benefits paid to employees in Switzerland qualify as a defined benefit plan.

The pension plan for Swiss employees (“the Pension Fund”) is a defined benefit plan. The Pension Fund provides benefits for retirement, disability, and surviving dependents that meet or exceed the minimum benefits required under the Federal Law on Occupational Retirement, Survivors’ and Disability Insurance (“BVG”), including the legal coordination charge, which is also insured. The monthly premium to fund the Pension Fund’s benefits is split equally between the employer and the employees. Contributions, which vary by the age of the employees, range from 6-13% of the covered salary and are credited to the employees’ individual retirement savings accounts. The Pension Fund is responsible for capital investments and pursues an investment strategy with a prescribed investment policy. The Group assumes an average retirement age of 64 (female) and 65 (male), respectively. Upon retiring (including early and partial retirement), insured persons are entitled to a lifelong retirement pension if employees do not choose to withdraw the entire balance, or portion thereof, of their individual retirement savings accounts in the form of a capital payment.

The Pension Fund is administered by Allianz Suisse, Switzerland, which is legally separate from the Group and is governed by a foundation board. In addition, there is a pension fund commission comprised of two employee and two employer representatives. The duties of the foundation board, as well as the pension fund commission, are laid out in the BVG and the specific pension fund rules. They are required by law to act in the best interest of the participants and are responsible for setting certain policies (e.g. investment, contribution, and indexation policies) for the Pension Fund. At least four times a year, the foundation board, as well as the pension fund commission, meet to analyze consequences and decide on adjustments in the investment strategy.

Pursuant to the BVG, additional employer and employee contributions may be imposed whenever a significant funding deficit arises in accordance with the BVG. In addition to investment risk, the Pension Fund is exposed to actuarial risk, longevity risk, currency risk, and interest rate risk. In addition to the pension plan for Swiss employees, a defined benefit plan for Swiss management also provides retirement benefits and risk insurance for death and disability for components of remuneration in excess of the maximum insurable amount of salary under the plan described above.

Movement of net defined-benefit liability

	2023	2022
Balance as at 1 January	1,121	1,388
Service costs	652	562
Admin costs	45	43
Past service costs	23	–
Employee benefit expenses	720	605
Net interest costs/(income)	15	3
Included in statement of profit and loss	735	608
Actuarial gains/(losses)		
- Financial assumptions	932	(1,956)
- Demographic assumptions	–	–
- Experience adjustment	(449)	1,286
- Return on assets excluding interest income	321	184
	804	(486)
Exchange rate differences	80	65
Included in statement of comprehensive income*	884	(421)
Contributions by employer	(659)	(454)
Balance as at 31 December	2,081	1,121

* Excluding tax impact

The principal assumptions used in determining post-employment (pension) benefit obligations for the plan are shown below:

	2023	2022
Discount rate	1.35%	2.30%
Salary increase	2.50%	2.50%
Interest credit rate	1.00%	1.00%
Mortality base table	BVG2020	BVG2020
Longevity improvement	CMI2018; 1.25%	CMI2018; 1.25%

A quantitative sensitivity analysis for significant assumptions as at 31 December is shown below:

	2023	2022
Discount rate		
+ 25bps	(271)	(190)
- 25bps	292	203
Salary increase		
+ 25bps	119	84
- 25bps	(113)	(80)
Interest credit rate		
+ 25bps	101	76
- 25bps	(98)	(73)
Mortality base table		
Life expectancy + 1 year	44	27
Life expectancy - 1 year	(42)	(26)

The sensitivity analyses have been determined based on a method that extrapolates the impact on the defined benefit obligation as a result of reasonable changes in key assumptions occurring at the end of the reporting period. The sensitivity analyses are based on a change in a significant assumption, keeping all other assumptions constant. The sensitivity analyses may not be representative of an actual change in the defined benefit obligation as it is unlikely that changes in assumptions would occur in isolation from one another.

The following are the expected payments or contributions to the defined benefit plan in future years:

	2023	2022
Within the next 12 months	350	281
Between 2 and 5 years	1,702	1,426
Beyond 5 years	3,172	2,540
Total expected payments	5,223	4,247

The average duration of the defined benefit plan obligation at the end of the reporting period is 18 years (2022: 16 years).

Plan assets allocation

The asset allocation in the Swiss pension plan at 31 December was as follows:

	2023	2022
Bonds	2,709	2,309
Equities	–	–
Loans	93	134
Mortgages	507	504
Real Estate	922	872
Cash, derivatives and funds	58	60
	4,289	3,879

Plan assets in 2023 and 2022 do not include property occupied by or financial instruments issued by ONWARD.

5.1 Commitments and Contingencies

Legal claim contingencies

As at 31 December 2023, the Group had no legal claim contingencies.

Guarantees

The Group has provided a guarantee to Wincasa for EUR 305k as collateral for the lease of the office space in Lausanne and paid a deposit of EUR 8k to SPACES for the lease of the office space in Eindhoven.

Royalties

The Group has entered into three license agreements with EPFL that will pay out royalties in case the Company is able to generate revenues in the future for products directly linked to these licenses. The royalty scheme with EPFL is based on net sales. To date, no royalties have been paid as there is no product generating revenue.

On 27 September 2019, Neurorecovery Technologies Inc. (now ONWARD Medical Inc.) entered into a license agreement with the Regents of the University of California acting through Technology Development Group UCLA campus granting an exclusive license on certain patents in certain fields of neuromodulation and spinal cord stimulation, and a non-exclusive license on certain other patent rights. Various revenue milestone payments are due under the exclusive license and royalty payments are due under the non-exclusive license. The agreement contains various milestone and diligence obligations ranging from USD 10k to USD 50k payable upon entering a phase III clinical trial, regulatory approval, and/or first commercial sale. To date, none of the milestones triggering the obligations have occurred.

On 8 October 2019, Neurorecovery Technologies Inc. (now ONWARD Medical Inc.) entered into a license agreement with the California Institute of Technology ("Caltech"), the latter on behalf of various intellectual property owners, including UCLA, University of Louisville, DEI and USC, granting an exclusive license on certain technology in certain fields of epidural and transcutaneous neuromodulation and a non-exclusive license of certain other intellectual property. Various revenue milestone payments, diligence obligations, and royalty payments are due under the license. These payments range from USD

20k to USD 75k payable upon FDA approval, CE Mark, and/or first commercial sale. To date, no payments are outstanding for requirements that have been met.

5.2 Related Party Transactions

Note 1.1 provides the information about the Group's structure including the details of the subsidiaries. Transactions between the Company and its subsidiaries have been eliminated on consolidation and are not disclosed in the notes.

The Group considers the Board and the Management Team to be key management as defined in IAS 24 'Related parties.' Full details of the remuneration of the board (CEO and non-executives) are included in the Remuneration report.

	Salary, bonuses and other (short-term employee benefits)	Pension premiums (post-employment benefits)	Share-based payment	Total
2023				
Management Team, excluding CEO	2,827	98	643	3,568
CEO	703	64	916	1,683
Non-Executive Directors	445	–	441	886
	3,975	162	2,000	6,137

	Salary, bonuses and other (short-term employee benefits)	Pension premiums (post-employment benefits)	Share-based payment	Total
2022				
Management Team, excluding CEO	2,574	105	596	3,275
CEO	917	44	469	1,430
Non-Executive Directors	364	–	256	621
	3,855	149	1,321	5,326

5.3 Events After the Reporting Period

On 25 March 2024, ONWARD issued a total of 4,444,444 new Ordinary shares at a price per share of EUR 4.50 as part of an accelerated bookbuild offering through a private placement with institutional investors, certain founders, management, and members of the Board of Directors (4,307,641 shares) and a separate public offering with retail investors in France (136,803 shares). The total capital raised was EUR 20 million.

On 15 January 2024, the Group granted 710,975 stock options to the Management Team, including the CEO, CTO, and CSO with an exercise price of EUR 2.94. The conditions of the existing plan as explained in Note 2.9 apply to this grant.

Company financial statements

Company statement of income

For the year ended 31 December

All amounts in EUR '000

	Notes	2023	2022
Grants		532	2,076
Total operating income	B	532	2,076
Operating expenses		(29,679)	(31,003)
Total operating expenses	C	(29,679)	(31,003)
Operating result for the period		(29,147)	(28,927)
Net finance expense	D	(392)	(1,453)
Result before tax		(29,539)	(30,380)
Income tax expense	E	–	–
Share in result from participating interests	F	(6,642)	(2,392)
Result after tax		(36,181)	(32,772)

The notes on pages F-62 to F-68 are an integral part of these separate financial statements.

Company balance sheet

(Before appropriation on result)

All amounts in EUR '000

	Notes	31 December 2023	31 December 2022
ASSETS			
Non-current assets			
Tangible fixed assets	G	118	61
Financial fixed assets	H	807	1,139
		<u>925</u>	<u>1,200</u>
Current assets			
Trade and other receivables	I	26,748	16,900
Fixed term deposits	J	–	20,000
Cash at bank and in hand	J	13,854	31,501
		<u>40,602</u>	<u>68,401</u>
		<u>41,527</u>	<u>69,601</u>
EQUITY AND LIABILITIES			
Equity and reserves			
Issued capital	K	3,622	3,622
Share premium		155,248	155,249
Other reserves		4,199	1,760
Legal reserve: Currency translation differences		165	319
Retained earnings		(109,122)	(75,547)
Result for the year		(36,181)	(32,772)
Total equity		<u>17,931</u>	<u>52,631</u>
Provisions	L	5,233	256
Non-current liabilities	M	15,297	12,656
Current liabilities	N	3,066	4,058
		<u>41,527</u>	<u>69,601</u>

The notes on pages F-62 to F-68 are an integral part of these separate financial statements.

Notes to the Company financial statements

A. PRESENTATION OF FINANCIAL STATEMENTS AND RECOGNITION AND MEASUREMENT PRINCIPLES

The description of the activities of ONWARD Medical NV (the company) and the company structure, as included in the notes to the consolidated financial statements, also applies to the company financial statements.

The company is the sole shareholder of the following subsidiaries:

- ONWARD Medical SA, based in Switzerland
- ONWARD Medical Inc, based in the United States of America

These separate financial statements have been prepared in accordance with Title 9, Book 2 of the Dutch Civil Code. For setting the principles for the recognition and measurement of assets and liabilities and determination of results for its separate financial statements, the Company makes use of the option provided in section 2:362(8) of the Dutch Civil Code. This means that the principles for the recognition and measurement of assets and liabilities and determination of the result (hereinafter referred to as principles for recognition and measurement) of the separate financial statements of the Company are the same as those applied for the consolidated EU-IFRS financial statements. These principles also include the classification and presentation of financial instruments, being equity instruments or financial liabilities. In case no other principles are mentioned, refer to the accounting principles as described in the consolidated financial statements. For an appropriate interpretation of these statutory financial statements, the separate financial statements should be read in conjunction with the consolidated financial statements.

Information on the use of financial instruments and on related risks for the group is provided in the notes to the consolidated financial statements of the group.

B. OPERATING INCOME

Operating income relates to grant and other income received. Government subsidies have been received for the research and development of several development projects. There are no unfulfilled conditions or contingencies attached to these subsidies.

	2023	2022
Government subsidies (EU)	464	1,972
Other income	68	104
Total revenues and other income	532	2,076

<i>(In EUR 000)</i>	Total Grant	Recognized as Grant Income 2023	Recognized as Grant Income 2022	Recognized as Grant Income cumulative before 2022	Grant received in advance as per 31-12-2023
Grants					
PREP2GO	362	15	104	243	—
DARPA	3,004	419	1,412	1,173	—

ZonMW	250	83	83	83	–
EISMEA – Reverse Paralysis	292	(237)	273	–	183
EISMEA – NEMO BMI	144	(85)	85	–	108
Eurostars Impulse	500	160	14	–	–
Rewire	347	56	–	–	122
SH-ARC	500	53	–	–	60
Total		464	1,972	1,499	473

C. OPERATING EXPENSES

Operating expenses by nature are as follows:

	2023	2022
Wages and salaries	(1,242)	(1,797)
Social security costs (includes WBSO benefit)	54	32
Pension costs – other	(69)	(82)
Share-based benefit expenses	(148)	(1,691)
Other labor costs	(724)	(1,739)
Other operating expenses	(27,492)	(25,515)
Depreciation and amortization	(58)	(211)
	(29,679)	(31,003)

The increase in Other operating expenses is driven by Research and Development expenses due to advancements made on our ARCEX and ARCIM platforms (mainly in Switzerland) which increased the charge from Switzerland to the Netherlands under the existing agreement.

During 2023, the Company had on average 15.9 full-time equivalents located in the Netherlands (2022: 16.3), 74.2 full-time equivalents located in Switzerland (2022: 68.3) and 14.5 (2022: 11.5) full-time equivalents located in the United States.

D. NET FINANCE EXPENSE

	2023	2022
Interest income	891	52
Interest on loans	(1,307)	(1,434)
Interest banks	–	–
Interest on lease liabilities	(5)	–
Exchange losses	35	(48)
Bank charges	(6)	(23)
Net Finance expense	(392)	(1,453)

The decrease is the result of interest income earned from positive cash balances in 2023.

E. INCOME TAX EXPENSE

	2023	2022
Current income tax	–	–
Deferred income tax	–	–
Total corporate income tax in profit and loss	–	–
Current income tax charge at tax rate of 25.8%	7,621	7,838
Non-deductible expenses	(38)	(436)
Non-recognized deferred tax asset on temporary differences	66	(111)
Non-recognized deferred tax asset on permanent differences	(203)	–
Net operating losses not recognized	(7,446)	(7,291)
	–	–

The effective tax rate was 0% in 2023 (2022: 0%), which is lower than the statutory income tax rate of 25.8% (2022: 25.8%) in the Netherlands. The difference is primarily due to non-deductible expenses relating to share-based compensation and the net operating losses for which no deferred tax asset can be recognized. The uncertainty is based on insufficient evidence of future sources of income to support the realization of a deferred tax asset due to the Company being loss-making with limited tax planning opportunities.

For the unused operating losses of EUR 120M (2022: EUR 91M) no deferred tax is recognized. These losses can be carried forward indefinitely subject to local tax rules.

F. SHARE IN RESULTS FROM PARTICIPATING INTERESTS

An amount of EUR 6.642M (2022: EUR 2.392M) of share in results from participating interests relates to Group companies.

G. TANGIBLE FIXED ASSETS

Cost

	Office equipment	Right-of-use- asset	TOTAL
At 1 January , 2022	1,171	–	1,171
Additions	18	–	10
Disposal	(465)	–	(465)
At 31 December , 2022	716	–	716
Additions	18	97	114
Disposal	–	–	–
At 31 December , 2023	734	97	830

Accumulated Depreciation

	Office equipment	Right-of-use- asset	TOTAL
At 1 January , 2022	(974)	–	(974)
Depreciation for the year	(102)	–	(102)
Disposal	421	–	421
At 31 December , 2022	(655)	–	(655)
Depreciation for the year	(49)	(9)	(58)
Disposal	–	–	–
At 31 December , 2023	(704)	(9)	(713)

Net book value

	Office equipment	Right-of-use- asset	TOTAL
At 31 December 2022	61	–	61
At 31 December 2023	30	88	118

H. FINANCIAL FIXED ASSETS

Financial fixed assets consist of participating interests in Group companies. Financial fixed assets are accounted for in the Company financial statements at net asset value. They are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount.

	2023	2022
Cost	1,139	2,459
Accumulated impairments	–	–
Net book value at 1 January	1,139	2,459
Revaluations through OCI	(928)	858
Exchange differences	(155)	172
Group share-based payment scheme	2,416	–
Share in result of participating interests	(6,642)	(2,392)
Addition: license fees paid on behalf of subsidiary	–	–
Provision: negative participating interest	4,977	42
Net change	(332)	(1,320)
Cost	807	1,139
Accumulated impairments	–	–
Net book value at 31 December	807	1,139

The Company has the firm intention to support its subsidiary, ONWARD Medical Inc, to meet its obligations to third parties. A provision has been recognized for the negative value of the investment to the amount of EUR 4,977k (2022: 42k).

I. TRADE AND OTHER RECEIVABLES

Amounts due from Group companies are recognized initially at fair value and subsequently at amortized cost. Amortized cost is determined using the effective interest rate. The Company recognizes a credit loss for financial assets (such as a loan) based on an expected credit loss (ECL), which will occur in the coming twelve months or – after a significant decrease in credit quality or when the simplified model can be used – based on the entire remaining loan term.

For intercompany receivables, the ECL would be applicable as well, however this could cause differences between equity in the consolidated and separate financial statements. For this reason, the Company elected to eliminate these differences through the respective receivable account in the separate financial statements.

	2023	2022
Indirect tax receivable	76	458
Receivables from related parties – group companies	25,596	15,174
Receivables from related parties - other	37	190
Other	239	257
Advance payments made	800	821
	26,748	16,900

The Company funds the operations of the subsidiaries. The increase in the receivable is a result of the increase in operations in 2023.

J. CASH AT BANK, IN HAND AND FIXED TERM DEPOSITS

	2023	2022
Cash at bank	2,654	21,501
Short-term deposits	11,200	10,000
Cash at bank and in hand	13,854	31,501
Fixed term deposits	–	20,000
	–	20,000
Cash at bank, in hand, and fixed term deposits	13,854	51,501

Cash at banks earns interest at floating rates based on daily bank deposit rates. Short-term deposits are made for varying periods of between one day and three months, depending on the immediate cash requirements of the Group, and earn interest at the respective short-term deposit rates. Fixed term deposits are made for period exceeding three months but less than one year and earn interest at the respective fixed term deposit rates. At 31 December 2023, the Group had no bank overdrafts. All cash is freely at the disposal of the company.

K. SHAREHOLDERS' EQUITY

For the statement of changes in equity for the year ended 31 December 2023, please refer to consolidated statement of changes in equity in the consolidated financial statements. Additional information on the shareholders' equity is disclosed in note 4.0 of the consolidated financial statements.

L. PROVISIONS

	2023	2022
Opening balance as at 1 January	256	214
Negative participating interest	4,977	42
Balance as at 31 December	5,233	256

The Company has the firm intention to support its subsidiary, ONWARD Medical Inc, to meet its obligations to third parties. A provision has been recognized for the negative participating interest to the amount of EUR 5,233k (2022: 256k).
The amount is considered current.

M. NON-CURRENT LIABILITIES

	2023	2022
Balance as at 31 December	15,297	12,656
		2023
		Innovation loan
Loan as at 1 January		12,656
Loan amount received		1,292
Interest/cumulative dividend accrued during the year		1,307
Long term lease liability		42
Net book value as at 31 December		15,297

N. CURRENT LIABILITIES

Amounts due to Group companies recognized as financial liabilities at amortized cost as per the policy in the consolidated financial statements.

	2023	2022
Trade payables	734	1,899
Tax liabilities	4	63
Payables from related parties	–	–
Other payables	970	2,096
Grant-related payables	1,358	–
	3,066	4,058

O. COMPENSATION OF THE BOARD OF DIRECTORS

The members of the Board and the Management Team are considered key management personnel as defined in IAS 24 'Related party disclosures.' For details on their remuneration, reference is made to note 5.2 of the consolidated financial statements. Full details of the remuneration of the board (CEO and non-executives) are included in the Remuneration report.

P. FEES FOR AUDIT AND OTHER SERVICES

In accordance with article 382.a of Part 9, Book 2, of the Netherlands Civil Code, the total audit cost can be specified as follows:

	Ernst & Young Accountants LLP	
	2023	2022
Audit of financial statements	259	478
Audit of special purpose financial statements	–	–
Other assurance services	–	8
	<hr/>	<hr/>
	259	486

Q. SUBSEQUENT EVENTS

For subsequent events, please refer to Note 5.3 of the Consolidated Financial Statements.

R. PROPOSED APPROPRIATION OF RESULT

The Board of Directors proposes to deduct the net loss in full to the retained earnings.

Independent auditor's report

To: the shareholders and board of directors of ONWARD Medical N.V.

Report on the audit of the financial statements 2023 included in the annual report

Our opinion

We have audited the financial statements 2023 of ONWARD Medical N.V. based in Amsterdam, the Netherlands.

The financial statements comprise the consolidated and company financial statements.

In our opinion:

- The accompanying consolidated financial statements give a true and fair view of the financial position of ONWARD Medical N.V. as at 31 December 2023 and of its result and its cash flows for 2023 in accordance with International Financial Reporting Standards as adopted in the European Union (EU-IFRSs) and with Part 9 of Book 2 of the Dutch Civil Code
- The accompanying company financial statements give a true and fair view of the financial position of ONWARD Medical N.V. as at 31 December 2023 and of its result for 2023 in accordance with Part 9 of Book 2 of the Dutch Civil Code

The consolidated financial statements comprise:

- The consolidated statement of financial position as at 31 December 2023
- The following statements for 2023: the consolidated statement of profit and loss, comprehensive income, changes in equity and cash flows
- The notes comprising material accounting policies and other explanatory information

The company financial statements comprise:

- The company balance sheet as at 31 December 2023
- The company statement of income for 2023
- The notes comprising a summary of the accounting policies and other explanatory information

Basis for our opinion

We conducted our audit in accordance with Dutch law, including the Dutch Standards on Auditing. Our responsibilities under those standards are further described in the *Our responsibilities for the audit of the financial statements* section of our report.

We are independent of ONWARD Medical N.V. ('the company') in accordance with the EU Regulation on specific requirements regarding statutory audit of public-interest entities, the Wet toezicht accountantsorganisaties (Wta, Audit firms supervision act), the Verordening inzake de onafhankelijkheid van accountants bij assurance-opdrachten (ViO, Code of Ethics for Professional Accountants, a regulation with respect to independence) and other relevant independence regulations in the Netherlands. Furthermore we have complied with the Verordening gedrags- en beroepsregels accountants (VGBA, Dutch Code of Ethics).

We believe the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Information in support of our opinion

We designed our audit procedures in the context of our audit of the financial statements as a whole and in forming our opinion thereon. The following information in support of our opinion and any findings were addressed in this context, and we do not provide a separate opinion or conclusion on these matters.

Our understanding of the business

ONWARD Medical N.V. and its subsidiaries (the 'group') are developing both an Implantable Neurostimulation Systems (INS) and a non-invasive system for electrical stimulation of specific areas of the spinal cord.

We determined materiality and identified and assessed the risks of material misstatement of the financial statements, whether due to fraud or error in order to design audit procedures responsive to those risks and to obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion.

Materiality

Materiality	€1,100,000 (2022: €890,000)
Benchmark applied	3% of operating expenses
Explanation	R&D companies such as ONWARD Medical N.V. which are in the start-up phase, report no or modest revenues. The stakeholders expect the entity to operate at a loss during the R&D phase. The value that owners or others generally attribute to these entities is primarily based on the promise of future success of the products. Based on these factors we deem operating expenses to be a suitable basis, as it is one of the most important measures of the company's performance.

We have also taken into account misstatements and/or possible misstatements that in our opinion are material for the users of the financial statements for qualitative reasons.

We agreed with the audit committee of the board of directors that misstatements in excess of €55,000, which are identified during the audit, would be reported to them, as well as smaller misstatements that in our view must be reported on qualitative grounds.

Scope of the group audit

ONWARD Medical N.V. is at the head of a group of entities. The financial information of this group is included in the consolidated financial statements.

Because we are ultimately responsible for the opinion, we are also responsible for directing, supervising and performing the group audit. In this respect we have determined the nature and extent of the audit procedures to be carried out for group entities. Decisive were the size and/or the risk profile of the group entities or operations. As the processes of ONWARD Medical are highly centralized and all transactions are initiated, recorded, processed and reported on central level we have applied a centralized audit approach on the full group consisting of 3 components in which all audit procedures are performed by the same team.

In total these procedures represent 100% of the group's total assets, operating expenses and net loss.

By performing the centralized procedures mentioned above at all components of the group, together with additional procedures at group level, we have been able to obtain sufficient and appropriate audit evidence about the group's financial information to provide an opinion on the consolidated financial statements.

Teaming and use of specialists

We ensured that the audit team included the appropriate skills and competences which are needed for the audit of a listed client in the medical technology industry. We included specialists in the areas of IT audit, forensics, share based payments, valuation of intangible assets and income tax.

Our focus on fraud and non-compliance with laws and regulations

Our responsibility

Although we are not responsible for preventing fraud or non-compliance and we cannot be expected to detect non-compliance with all laws and regulations, it is our responsibility to obtain reasonable assurance that the financial statements, taken as a whole, are free from material misstatement, whether caused by fraud or error. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

Our audit response related to fraud risks

We identified and assessed the risks of material misstatements of the financial statements due to fraud. During our audit we obtained an understanding of the company and its environment and the components of the system of internal control, including the risk assessment process and management's process for responding to the risks of fraud and monitoring the system of internal control and how the board of directors exercises oversight, as well as the outcomes.

We refer to section "Risk Management and Control" of the board of director's report for management's (fraud) risk assessment.

We evaluated the design and relevant aspects of the system of internal control and in particular the fraud risk assessment, as well as the code of conduct. We evaluated the design and the implementation of internal controls designed to mitigate fraud risks.

As part of our process of identifying fraud risks, we evaluated fraud risk factors with respect to financial reporting fraud, misappropriation of assets and bribery and corruption in close co-operation with our forensic specialists. We evaluated whether these factors indicate that a risk of material misstatement due to fraud is present.

We incorporated elements of unpredictability in our audit. We also considered the outcome of our other audit procedures and evaluated whether any findings were indicative of fraud or non-compliance.

We addressed the risks related to management override of controls, as this risk is present in all companies. For these risks we have performed procedures among other things to evaluate key accounting estimates for management bias that may represent a risk of material misstatement due to fraud, in particular relating to important judgment areas and significant accounting estimates as disclosed in Note 1.6 to the financial statements including research & development, share-based payments, impairment of intangible assets, post-employment benefits and income taxes. We have also used data analysis to identify and address high-risk journal entries and evaluated the business rationale (or the lack thereof) of significant extraordinary transactions, including those with related parties. We considered available information and made enquiries of relevant executives and directors.

The fraud risks, we identified, enquiries and other available information did not lead to specific indications for fraud or suspected fraud potentially materially impacting the view of the financial statements.

Our audit response related to risks of non-compliance with laws and regulations

We performed appropriate audit procedures regarding compliance with the provisions of those laws and regulations that have a direct effect on the determination of material amounts and disclosures in the financial statements. Furthermore, we assessed factors related to the risks of non-compliance with laws and regulations that could reasonably be expected to have a material effect on the financial statements from our general industry experience, through discussions with the board of directors, reading minutes, and performing substantive tests of details of classes of transactions, account balances or disclosures.

We also inspected internal lawyers' letters and correspondence with regulatory authorities. We remained alert to any indication of (suspected) non-compliance throughout the audit. Finally we obtained written representations that all known instances of non-compliance with laws and regulations have been disclosed to us.

Our audit response related to going concern

The board of directors made a specific assessment of the company's ability to continue as a going concern and to continue its operations for the foreseeable future. As disclosed in Note 1.4 to the financial statements, as a result of the completed private placement and French retail public offering in March 2024, the Company believes that its cash position will be sufficient to meet the Company's capital requirements and fund its operations for at least 12 months as from the date of preparing the financial statements. Furthermore is stated that to continue development and reach commercialization as planned the Company will need to attract additional funds in the future and that the Company's long term existence is contingent on achieving FDA approval and CE mark on its products. The financial statements have been prepared on a going concern basis.

We discussed and evaluated the specific assessment with the board of directors exercising professional judgment and maintaining professional skepticism. We considered whether the board of director's going concern assessment, based on our knowledge and understanding obtained through our audit of the financial statements or otherwise, contains all relevant events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion.

Based on our procedures performed, we did not identify material uncertainties about going concern. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company to cease to continue as a going concern.

Our key audit matters

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements. We have communicated the key audit matter to the board of directors. The key audit matter is not a comprehensive reflection of all matters discussed.

The nature of this key audit matter did not change in comparison with previous year.

Valuation of intangible fixed assets	
Note 3.0 intangible assets	
Risk	<p>At year-end 2023, ONWARD Medical N.V. carried an intangible asset balance of € 9.8 million, consisting of goodwill (€ 1.8 million), capitalized in-process R&D (€ 5.7 million) and capitalized license fees (€ 2.3 million). The goodwill as well as the capitalized in-process R&D and license fees relate to the acquisition of ONWARD Medical Inc in 2019. In accordance with EU-IFRS, ONWARD Medical N.V. is required to perform an impairment test on an annual basis. The impairment test is significant to our audit because the assessment process is complex, requires management judgement and is based on assumptions that are affected by expected future market conditions. For these reasons, we consider this a key audit matter.</p>
Our audit approach	<p>As part of our audit procedures we audited the assumptions and methodologies used by the company, and also the robustness of the planning process to evaluate whether the company is able to prepare reliable estimates.</p> <p>The value of the in-process R&D is contingent on the success of the US Food and Drug Association (FDA) approval and CE mark of the company's products, as well as successfulness of bringing the products to the market.</p> <p>In order to assess the reasonability of input data, the valuation model and the discount rate we have, among other procedures:</p> <ul style="list-style-type: none"> • verified the appropriateness and consistent application of the impairment model and related inputs; • compared the data with external data such as expected inflation rate, external market growth expectations and market capitalization of the Company; • analyzed the sensitivities in the company's impairment testing model. <p>We specifically focused on the risk of not achieving regulatory approvals and whether a reasonable possible change in the assumptions could trigger an impairment.</p> <p>We also evaluated the adequacy of the company's disclosure in note 3.0 of the annual report, including disclosures regarding assumptions and sensitivities as well as consistency between the going concern forecasts as disclosed in Note 1.4 and the inputs in the company's impairment testing model.</p>
Key observations	<p>We have evaluated management's key assumptions and estimates to be within an acceptable range. We agree with management's conclusion that no impairment of intangible assets is required and conclude that the disclosures in note 3.0 of the annual report are in accordance with EU-IFRS.</p>

Report on other information included in the annual report

The annual report contains other information in addition to the financial statements and our auditor's report thereon.

Based on the following procedures performed, we conclude that the other information:

- is consistent with the financial statements and does not contain material misstatements
- contains the information as required by Part 9 of Book 2 of the Dutch Civil Code for the Board of Director's report and the other information as required by Part 9 of Book 2 of the Dutch Civil Code and as required by Sections 2:135b and 2:145 sub-section 2 of the Dutch Civil Code for the remuneration report.

We have read the other information. Based on our knowledge and understanding obtained through our audit of the financial statements or otherwise, we have considered whether the other information contains material misstatements. By performing these procedures, we comply with the requirements of Part 9 of Book 2 and Section 2:135b sub-Section 7 of the Dutch Civil Code and the Dutch Standard 720. The scope of the procedures performed is substantially less than the scope of those performed in our audit of the financial statements.

The board of directors is responsible for the preparation of the other information, including the Board of Directors' report in accordance with Part 9 of Book 2 of the Dutch Civil Code and other information required by Part 9 of Book 2 of the Dutch Civil Code. The board of directors is responsible for ensuring that the remuneration report is drawn up and published in accordance with Sections 2:135b and 2:145 sub-section 2 of the Dutch Civil Code.

Report on other legal and regulatory requirements and ESEF

Engagement

We were engaged by the general meeting as auditor of ONWARD Medical N.V. on 11 October 2021, as of the audit for the year 2021 and have operated as statutory auditor ever since that date.

No prohibited non-audit services

We have not provided prohibited non-audit services as referred to in Article 5(1) of the EU Regulation on specific requirements regarding statutory audit of public-interest entities.

European Single Electronic Reporting Format (ESEF)

ONWARD Medical N.V. has prepared the annual report in ESEF. The requirements for this are set out in the Delegated Regulation (EU) 2019/815 with regard to regulatory technical standards on the specification of a single electronic reporting format (hereinafter: the RTS on ESEF).

In our opinion the annual report prepared in the XHTML format, including the partially marked-up consolidated financial statements as included in the reporting package by ONWARD Medical N.V., complies in all material respects with the RTS on ESEF.

The board of directors is responsible for preparing the annual report, including the financial statements, in accordance with the RTS on ESEF, whereby the board of directors combines the various components into a single reporting package.

Our responsibility is to obtain reasonable assurance for our opinion whether the annual report in this reporting package complies with the RTS on ESEF.

We performed our examination in accordance with Dutch law, including Dutch Standard 3950N, "Assurance-opdrachten inzake het voldoen aan de criteria voor het opstellen van een digitaal verantwoordingsdocument" (assurance engagements relating to compliance with criteria for digital reporting). Our examination included amongst others:

- Obtaining an understanding of the company's financial reporting process, including the preparation of the reporting package
- Identifying and assessing the risks that the annual report does not comply in all material respects with the RTS on ESEF and designing and performing further assurance procedures responsive to those risks to provide a basis for our opinion, including:
 - Obtaining the reporting package and performing validations to determine whether the reporting package containing the Inline XBRL instance document and the XBRL extension taxonomy files, has been prepared in accordance with the technical specifications as included in the RTS on ESEF

- Examining the information related to the consolidated financial statements in the reporting package to determine whether all required mark-ups have been applied and whether these are in accordance with the RTS on ESEF.

Description of responsibilities regarding the financial statements

Responsibilities of the board of directors for the financial statements

The board of directors is responsible for the preparation and fair presentation of the financial statements in accordance with EU-IFRSs and Part 9 of Book 2 of the Dutch Civil Code. Furthermore, the board of directors is responsible for such internal control as the board determines is necessary to enable the preparation of the financial statements that are free from material misstatement, whether due to fraud or error.

As part of the preparation of the financial statements, the board of directors is responsible for assessing the company's ability to continue as a going concern. Based on the financial reporting framework mentioned, the board of directors should prepare the financial statements using the going concern basis of accounting unless the board of directors either intends to liquidate the company or to cease operations, or has no realistic alternative but to do so. The board of directors should disclose events and circumstances that may cast significant doubt on the company's ability to continue as a going concern in the financial statements.

The non-executive board members of the board of directors are responsible for overseeing the company's financial reporting process.

Our responsibilities for the audit of the financial statements

Our objective is to plan and perform the audit engagement in a manner that allows us to obtain sufficient and appropriate audit evidence for our opinion.

Our audit has been performed with a high, but not absolute, level of assurance, which means we may not detect all material errors and fraud during our audit.

Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements. The materiality affects the nature, timing and extent of our audit procedures and the evaluation of the effect of identified misstatements on our opinion.

We have exercised professional judgment and have maintained professional skepticism throughout the audit, in accordance with Dutch Standards on Auditing, ethical requirements and independence requirements. The Information in support of our opinion section above includes an informative summary of our responsibilities and the work performed as the basis for our opinion.

Our audit further included among others:

- Performing audit procedures responsive to the risks identified, and obtaining audit evidence that is sufficient and appropriate to provide a basis for our opinion
- Obtaining an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control
- Evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the board of directors
- Evaluating the overall presentation, structure and content of the financial statements, including the disclosures

- Evaluating whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation

Communication

We communicate with the audit committee of the board of directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant findings in internal control that we identify during our audit.

In this respect we also submit an additional report to the audit committee of the board of directors in accordance with Article 11 of the EU Regulation on specific requirements regarding statutory audit of public-interest entities. The information included in this additional report is consistent with our audit opinion in this auditor's report.

We provide the audit committee of the board of directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the audit committee of the board of directors, we determine the key audit matters: those matters that were of most significance in the audit of the financial statements. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, not communicating the matter is in the public interest.

Eindhoven, 24 April 2024

Ernst & Young Accountants LLP

Signed by J.C.F. Lemmens

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