



(Onward Medical B.V., a private company with limited liability (besloten vennootschap met beperkte aansprakelijkheid), incorporated under the laws of the Netherlands, with its statutory seat (statutaire zetel) in Amsterdam, the Netherlands)

Initial Public Offering of up to 5,900,000 ordinary shares and admission to listing and trading on Euronext Brussels and Euronext Amsterdam

This prospectus (this "**Prospectus**") has been prepared in connection with the Offering (as defined below) and the admission to listing and trading of all ordinary shares in the issued share capital of Onward Medical N.V. (the "**Company**") with a nominal value of EUR 0.12 each (the "**Ordinary Shares**") with a primary listing on Euronext in Brussels, a regulated market operated by Euronext Brussels SA/NV ("**Euronext Brussels**") and a secondary listing on Euronext in Amsterdam (the "**Admission**"), a regulated market operated by Euronext Amsterdam N.V. ("**Euronext Amsterdam**", and together with Euronext Brussels, "**Euronext**"). At the date of this Prospectus, the Company is a private limited liability company (*besloten vennootschap met beperkte aansprakelijkheid*) incorporated under the laws of the Netherlands named Onward Medical B.V. The Company will be converted into a public limited liability company (*naamloze vennootschap*) and will be renamed Onward Medical N.V. ultimately on the First Trading Date (as defined below).

The Company is offering up to 5,900,000 newly issued Ordinary Shares (the "**Offer Shares**"), which excludes, unless the context indicates otherwise, any Ordinary Shares issued pursuant to the Increase Option or Over-Allotment Option (both as defined below). The aggregate number of Offer Shares may be increased by up to 20% of the aggregate number of Offer Shares (or up to 1,180,000 Ordinary Shares) initially offered to a number of 7,080,000 Ordinary Shares (the "**Increase Option**"). Any decision to exercise the Increase Option will be communicated, at the latest, on the date of the announcement of the Offer Price (as defined below).

The Offer Shares, when issued, will be fully fungible with all Ordinary Shares in the share capital of the Company as of the date hereof and rank *pari passu* in all respects. Assuming no exercise of the Increase Option and Over-Allotment Option (as defined below), the Offer Shares will constitute not more than 20% of the Company's total issued share capital. Assuming the Increase Option and the Over-Allotment Option are fully exercised, the Offer Shares will constitute not more than 25% of the Company's total issued share capital. See "*The Offering*".

The offering of the Offer Shares (the "**Offering**") consists of (i) an initial public offering to retail investors in Belgium and an offering to qualified investors ("**Qualified Investors**") within the meaning 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**"), (ii) a private placement in (a) the European Economic Area (the "**EEA**") (other than in Belgium) to certain Qualified Investors, (b) the United Kingdom to "Qualified Investors" within the meaning of Article 2(e) of the UK version of Regulation (EU) 2017/1129 as amended by The Prospectus (Amendment etc.) (EU Exit) Regulations 2019, which forms part of UK law by virtue of the European Union (Withdrawal) Act 2018 (the "**UK Prospectus Regulation**"), who are also persons with professional experience in matters relating to investments falling within the definition of "investment professionals" in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "**Order**"), or high net worth companies, unincorporated associations and other persons falling within Articles 49(2)(A) to (D) of the Order or other persons to whom the Offering may lawfully be communicated, and (c) Switzerland, to investors that qualify as "professional clients" within the meaning of the Swiss Financial Services Act (*Finanzdienstleistungsgesetz*) of 15 June 2018, as amended (the "**FinSA**") and (iii) a private placement in the United States of America (the "**United States**" or "**US**") to persons reasonably believed to be "qualified institutional buyers" ("**QIBs**") as defined in, and pursuant to, Rule 144A ("**Rule 144A**") under the US Securities Act of 1933, as amended (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. The Offering outside of the United States will be made in accordance with Regulation S ("**Regulation S**") under the US Securities Act (those qualified, professional and/or institutional investors together with the QIBs are collectively referred to as the "**Institutional Investors**").

There is no minimum amount for the Offering.

LSP V Coöperatieve U.A., Stichting Depositary INKEF Investment Fund, Gimv Investments H&C Netherlands 2016 B.V. and Wellington Partners Nominee Ltd. (the "**Participating Shareholders**") have irrevocably

committed to subscribe for an aggregate amount representing up to 15% of the Offer Shares in the Offer at the Offer Price (as defined below), subject to the closing of the Offering (the "**Subscription Commitments Shareholders**") such commitment capped at an offer size of EUR 100 million, in which case the Subscription Commitments Shareholders shall be EUR 15 million.

Dave Marver, Jan Øhrstrøm, John Murphy, Hendrik Lambert and a group of smaller lenders that do not qualify for disclosure under the Prospectus Regulation have made use of their pro rata subscription rights under the Convertible Loan Agreement, (the "**Participating Lenders**"), and have, by way of subscription commitments, irrevocably and conditional only on closing of the Offering, committed themselves to subscribe for an aggregate amount representing up to 2.4% of the Offer Shares in the Offer at the Offer Price (as defined below) (the "**Subscription Commitments Lenders**").

In addition AXA Investment Managers Paris (EUR 5.7 million), Öhman Fonder (EUR 5 million), Belfius Insurance NV/SA (EUR 5 million) and a smaller investor that does not qualify for disclosure under the Prospectus Regulation (each a "**Cornerstone Investor**" together: the "**Cornerstone Investors**" and together with the Participating Shareholders and the Participating Lenders: the "**Participating Investors**") severally and not jointly, have irrevocably agreed to purchase Offer Shares in the aggregate amount of EUR 16.2 million at the Offer Price (as defined below) (the "**Subscription Commitments Cornerstones**" and together with the Subscription Commitments Shareholders, and the Subscription Commitments Lenders (the "**Subscription Commitments**").

As there is no minimum amount of the Offering, if not all of the Offer Shares are subscribed for in the Offering, the net proceeds from the Offering could be limited, all or in part, to the net proceeds from the Subscription Commitments.

Prior to the Offering, there has been no public market for the Ordinary Shares. Application has been made to list and admit all of the Ordinary Shares to trading under the symbol "ONWD" with international securities identification number ("**ISIN**") NL0015000HT4 on Euronext. Subject to extension of the timetable for the Offering, trading on an "as-if-and-when-issued" basis in the Ordinary Shares on Euronext is expected to commence at 9:00 a.m. Central European Time ("**CET**") on or about 21 October 2021 (the "**First Trading Date**").

INVESTING IN THE OFFER SHARES INVOLVES RISKS. SEE "RISK FACTORS" BEGINNING ON PAGE 26 OF THIS PROSPECTUS FOR A DESCRIPTION OF THE RISK FACTORS THAT SHOULD BE CAREFULLY CONSIDERED BEFORE INVESTING IN THE OFFER SHARES.

The price of the Offer Shares (the "Offer Price") is expected to be in the range of EUR 11.75 to EUR 13.75 per Offer Share (the "Offer Price Range").

The Offering will take place from 9:00 a.m. CET on 12 October 2021 until 4:00 p.m. CET on 19 October 2021 (the "**Offering Period**"), subject to extension of the timetable for the Offering. The Offer Price Range is indicative. The Offer Price (in euro) and the exact number of Offer Shares offered in the Offering will be determined by the Company, after consultation with the Joint Global Coordinators (as defined below), after the end of the Offering Period on the basis of the book-building process and taking into account the conditions and factors described in "*The Offering*". The Offer Price and the exact numbers of Offer Shares to be sold will be stated in a pricing statement (the "**Pricing Statement**") which will be filed with the Dutch Authority for the Financial Markets (*Stichting Autoriteit Financiële Markten*, the "**AFM**"), submitted to the Belgian Financial Services and Markets Authority (the "**FSMA**") and announced through a press release that will be posted on the Company's website (<https://ir.onwd.com>).

The Company, after consultation with the Joint Global Coordinators, reserves the right to change the Offer Price Range, to decrease the number of Offer Shares or to increase the number of Offer Shares by exercise of the Increase Option, prior to the allocation of the Offer Shares (the "**Allocation**"). In the event the lower limit of the Price Range is decreased or the Offer Price is set below the lower end of the Price Range, or in the event the higher limit of the Price Range is increased or the Offer Price is set above the top end of the Price Range, this will be published in a supplement to the Prospectus. In the event of publication of a supplement to this Prospectus, and if required by law, investors will have the right to withdraw their orders made prior to the publication of the supplement. Such withdrawal must be done within the time period set forth in the supplement (which shall not be shorter than three business days after publication of the supplement). Any change in the number of Offer Shares and/or the Offer Price Range and/or the Offering Period will be announced in a press release that will be posted on the Company's website (www.onwd.com).

Bank Degroof Petercam SA/NV and Belfius Bank NV/SA are acting as joint global coordinators for the Offering (in such and any other capacity, the "**Joint Global Coordinators**" and the "**Underwriters**").

Subject to extension of the timetable for the Offering, payment (in euro) for, and delivery of, the Offer Shares ("**Settlement**") is expected to take place on or about 22 October 2021 (the "**Settlement Date**") through the book-entry systems of the Netherlands Central Institute for Giro Securities Transactions (*Nederlands Centraal Instituut voor Giraal Effectenverkeer B.V.*) ("**Euroclear Nederland**"). If Settlement does not take place on the Settlement Date as planned or at all, the Offering may be withdrawn, in which case all subscriptions for Offer Shares will be disregarded, any allotments made will be deemed not to have been made and any subscription payments made will be returned without interest or other compensation and transactions in the Offer Shares on Euronext may be annulled. Any transactions in Offer Shares prior to Settlement are at the sole risk of the parties concerned. The Company, the Underwriters, Bank Degroof Petercam SA/NV as the Company's listing agent (the "**Listing Agent**") and Belfius Bank NV/SA as the Company's settlement agent (the "**Settlement Agent**"), and Euronext do not accept any responsibility or liability towards any person as a result of the withdrawal of the Offering or the (related) annulment of any transactions in the Offer Shares. For more information regarding the conditions of the Offering and the consequences of any termination or withdrawal of the Offering, see "*The Offering*".

The Company will grant the Joint Global Coordinators an option (the "**Over-Allotment Option**"), exercisable within 30 calendar days after the First Trading Date, pursuant to which Belfius Bank NV/SA, as the stabilization manager (the "**Stabilization Manager**"), acting on behalf of the Underwriters, may require the Company to issue and sell at the Offer Price up to 885,000 additional Ordinary Shares (or 1,062,000 additional Ordinary Shares in the event the Increase Option is exercised in full (the "**Over-Allotment Shares**")), comprising up to 15% of the total number of Offer Shares sold in the Offering, to cover over-allotments or short positions, if any, in connection with the Offering or to facilitate stabilization transactions.

The Offering is only made in those jurisdictions in which, and only to those persons to whom, the Offering may be lawfully made. The Offering and the distribution of this Prospectus, any related materials and the offer, acceptance, delivery, transfer, exercise, purchase of, subscription for, or trade in, Ordinary Shares may be restricted by law in jurisdiction and therefore persons into whose possession this Prospectus comes should inform themselves and observe any restrictions. The Offer Shares have not been, and will not be, registered under the US Securities Act or with any securities regulatory authority of any state in the United States and may not be offered or sold directly or indirectly in the United States absent such registration, 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. The Offer Shares are being offered and sold outside the United States in accordance with Regulation S and within the United States to persons reasonably believed to be QIBs pursuant to Rule 144A. 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. Each purchaser of and subscriber for Offer Shares, in making a purchase or subscription, will be deemed to have made certain acknowledgments, representations and agreements as set out in "*Selling and Transfer Restrictions*". Prospective investors in the Offer Shares should carefully read "*Selling and Transfer Restrictions*". Neither the Company nor any Underwriter is taking any action to permit a public offering of the Offer Shares in any jurisdiction outside Belgium.

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 AFM, as competent authority under the Prospectus Regulation. This Prospectus has, following its approval thereof by the AFM, been notified to the FSMA in Belgium 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. Investors should make their own assessment as to the suitability of investing in the Ordinary Shares.

Joint Global Coordinators

**Bank Degroof Petercam
SA/NV**

Belfius Bank NV/SA

This Prospectus is dated 11 October 2021

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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 Offering (as defined below) and the admission to listing and trading of all ordinary shares in the issued share capital of Onward Medical N.V. (the "**Company**"), which is currently a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) named Onward Medical B.V. and which will be converted into a public limited liability company (*naamloze vennootschap*) and renamed Onward Medical N.V. ultimately on the First Trading Date (as defined below), with a nominal value of EUR 0.12 per share (the "**Ordinary Shares**") with a primary listing on Euronext in Brussels, a regulated market operated by Euronext Brussels SA/NV ("**Euronext Brussels**") and a secondary listing on Euronext in Amsterdam, a regulated market operated by Euronext Amsterdam N.V. ("**Euronext Amsterdam**", and together with Euronext Brussels, "**Euronext**") (the "**Admission**"). The Company is offering newly issued Ordinary Shares (the "**Offer Shares**") which excludes, unless the context indicates otherwise, any Ordinary Shares issued pursuant to the Increase Option or Over-Allotment Option (both as defined below).

The Company's statutory seat (*statutaire zetel*) is in Amsterdam, the Netherlands, and its registered office is at High-Tech Campus 32, 5656 AE 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 11 October 2021 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**") 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 Offer 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, at the date of this Prospectus, a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) incorporated and domiciled in the Netherlands. The Company's LEI is 9845007A2CC4C8BFSB80. The Company will be converted into a public limited liability company (*naamloze vennootschap*) ultimately on 21 October 2021 (the "**First Trading Date**"). The Company together with its subsidiaries is a group within the meaning of article 2:24b of the Dutch Civil Code (*Burgerlijk Wetboek*) ("**DCC**") (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 is a medical technology company developing innovative therapies to enable functional recovery for people with 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. ARCEX and ARCIM, 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 the First Trading Date, the Company's authorized share capital will comprise Ordinary Shares, which will be admitted to listing and trading on Euronext, and preferred shares having a nominal value of EUR 0.12 (the "**Preferred Shares**"). As an anti-takeover measure, the Company's general meeting of shareholders shall authorize the Board (as defined below) prior to the First Trading Date 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, after the First Trading Date.

Immediately prior to the Settlement Date (assuming the conversion of all amounts under the convertible loan agreement dated 20 April 2021, between the Company and among others Invest-NL Capital N.V., LSP V Coöperatieve U.A., Stichting Depository INKEF Investment Fund Gimv Investments, Wellington Partners Nominee Ltd. and Olympic Investments Inc. (the "**Convertible Loan Agreement**")) at the midpoint of the price range of the offer price per Offer Share ("**Offer Price**") the following holders of Ordinary Shares (each a "**Shareholder**") hold either directly or indirectly a substantial interest (*substantiële deelneming*, i.e. a holding of at least 3% of the share capital or voting rights in the Company): (i) LSP V Coöperatieve U.A., (ii) Stichting Depository INKEF Investment Fund, (iii) Wellington Partners Nominee Ltd., (iv) Gimv Investments H&C Netherlands 2016 B.V., (v) G-Therapeutics Founders S.a.r.l., (vi) Stichting G-Therapeutics Participaties, (vii) G-Therapeutics Participaties B.V., (viii) NRT Holdings LLC, and (ix) InvestNL.

As of the First Trading Date, the Company will have 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 will be the Executive Director, and Jan Øhrstrøm, Roel Bulthuis, Fredericus Colen, Grégoire Courtine, Ian Curtis, John de Koning, Regina Hodits and Patrick Van Beneden the Non-Executive Directors. The Company's independent auditor is Ernst & Young Accountants LLP ("**EY**").

What is the key financial information regarding the issuer?

Special purpose consolidated financial statements as of 31 December 2020

The following tables set out information from the special purpose consolidated financial statements as at 31 December 2020 and for the year then ended, including comparative information as at 31 December 2019 and 2018 and for the years then ended, which have been

prepared in accordance with International Financial Reporting Standards as adopted by the European Union ("IFRS", and the "Financial Statements"). EY has audited the Financial Statements and has issued an unqualified independent auditor's report thereon, with an emphasis of matter paragraph on the special purpose nature of the Financial Statements disclosed in Note 2 of the Financial Statements and restriction on use and an emphasis of matter paragraph on the material uncertainty with respect to the going concern assumption disclosed in Note 4 of the Financial Statements. The auditor's opinion is not modified in respect of these matters:

Emphasis on the special purpose and restriction on use

We draw attention to note 2, which describes the special purpose of the special purpose consolidated financial statements. The special purpose consolidated financial statements do not represent ONWARD Medical B.V.'s financial statements in accordance with Section 2:361 of the Dutch Civil Code and its articles of association and are prepared for the purpose of including in the prospectus in order for ONWARD Medical B.V. to comply with the requirements for historical financial information by, or pursuant to, Regulation (EU) 2017/1129. As a result, the special purpose consolidated financial statements may not be suitable for another purpose. Our independent auditor's report is required by the Commission Delegated Regulation (EU) 2019/9 80 and is issued for the purpose of complying with that Delegated Regulation. Therefore, the Company's auditor's report should not be used for another purpose.

Material uncertainty with respect to the going concern assumption

We draw attention to note 4 Continuity of the Group in the special purpose consolidated financial statements, which indicates that the Company's cash position would be negative as of 30 September 2022 based on the assumptions made by the board of directors regarding expected cash inflows and outflows over the next 12 months. These forecasts do not include financing alternatives currently under consideration by the board of directors. In this context, the board of directors is aware that the continuity of Company's operations depends on its ability to obtain these new sources of funding and that there are material uncertainties in this regard. Please note that the Company's long-term success is contingent on achieving FDA approval and CE mark of its products. These conditions indicate the existence of a material uncertainty which may cast significant doubt on the company's ability to continue as a going concern. We draw attention to these disclosures.

Our opinion is not modified in respect of these matters.

Unaudited condensed consolidated interim financial statements as at 30 June 2021

The following tables furthermore set out information from the unaudited condensed consolidated interim financial statements as at 30 June 2021 and for the six-months then ended have been prepared in accordance with IAS 34 Interim Financial Reporting (the "Interim Financial Statements"). The Interim Financial Statements have been reviewed by EY which has issued an unqualified independent auditor's review report thereon, including an emphasis of matter paragraph on the material uncertainty with respect to the going concern assumption disclosed in Note 3 of the Interim Financial Statements and an emphasis matter paragraph stating that the condensed consolidated interim financial information, including the corresponding figures included in the condensed consolidated interim statements of profit or loss, comprehensive income, changes in equity and cash flows and the related notes, for the period from 1 January 2020 to 30 June 2020 have not been audited nor reviewed:

Material uncertainty with respect to the going concern assumption

We draw attention to note 3 Continuity of the Group in the condensed consolidated interim financial statements, which indicates that the company's cash position would be negative as of 30 September 2022 based on the assumptions made by the board of directors regarding expected cash inflows and outflows over the next twelve months. These forecasts do not include financing alternatives currently under consideration by the board of directors. In this context, the board of directors is aware that the continuity of Company's operations depends on its ability to obtain these new sources of funding and that there are material uncertainties in this regard. Please note that the Company's long-term success is contingent on achieving FDA approval and CE mark of its products. These conditions indicate the existence of a material uncertainty which may cast significant doubt on the company's ability to continue as a going concern. We draw attention to these disclosures.

Corresponding figures neither audited nor reviewed

We have not audited nor reviewed the condensed consolidated interim financial statements for the period from 1 January 2020 to 30 June 2020. Consequently, we have not audited nor reviewed the corresponding figures included in the condensed consolidated interim statements of profit or loss, comprehensive income, changes in equity and cash flows and the related notes.

Condensed consolidated Statement of profit and loss

(In EUR 000)	Audited			Unaudited	
	For the year ended 31 December			For the six-month period ended 30 June	
	2020	2019	2018	2021	2020
Grants	800	554	474	586	211
Total Revenues and Other Income	800	554	474	586	211
Science expenses	(1,123)	(313)	(586)	(569)	(542)
Research and Development expenses	(5,823)	(5,356)	(4,722)	(3,280)	(2,804)
Clinical & Regulatory expenses	(2,770)	(1,239)	(654)	(1,944)	(1,232)
Market and Market Access expenses	(394)	(261)	(98)	(353)	(167)
Patent and related expenses	(1,186)	(525)	(455)	(786)	(455)
General and administrative expenses	(5,016)	(3,632)	(2,364)	(3,478)	(1,691)
Total operating expenses	(16,312)	(11,326)	(8,879)	(10,410)	(6,891)
Operating Loss for the period	(15,512)	(10,772)	(8,405)	(9,824)	(6,680)
Financial Income	-	6	3	-	-
Financial expenses	(4,482)	(2,678)	(1,492)	(2,931)	(2,096)
Loss for the period before taxes	(19,994)	(13,444)	(9,894)	(12,755)	(8,776)
Income tax expenses	(20)	(39)	(18)	(16)	(28)
Net loss for the period	(20,014)	(13,483)	(9,912)	(12,771)	(8,804)

Condensed consolidated statement of financial position

(In EUR 000)	Audited			Unaudited
	As at 31 December			As at 30 June
	2020	2019	2018	2021
ASSETS				
Intangible fixed assets	6,825	7,382	25	6,745

Property, plant and equipment	248	215	179	222
Right of use assets	149	254	360	96
Non-current assets	7,222	7,851	564	7,063
Indirect tax receivables	93	131	190	176
Receivable from related parties	57	51	49	58
Other current assets	436	183	92	463
Cash and cash equivalents	6,382	15,129	8,665	25,894
Current assets	6,968	15,494	8,996	26,591
Total assets	14,190	23,345	9,560	33,654
EQUITY AND LIABILITIES				
Equity and reserves				
Shareholders' equity	-	-	-	-
Share premium	3,083	3,083	83	3,083
Other reserves	18,465	15,217	9,117	20,473
Other comprehensive income	(710)	(304)	(33)	(772)
Retained Earnings	(52,933)	(32,919)	(19,436)	(65,704)
Total equity attributable to shareholders	(32,095)	(14,923)	(10,269)	(42,920)
LIABILITIES				
Interest bearing loans	41,817	33,479	17,144	69,311
Deferred tax liability	1,343	1,448	-	1,327
Other financial liabilities	-	-	-	2,480
Lease liability	61	198	324	-
Post-employment benefits	399	429	356	550
Non-current liabilities	43,620	35,554	17,824	73,668
Income tax liabilities	27	39	11	44
Lease liability	137	126	95	130
Trade payables	911	1,306	852	1,007
Other payables	1,590	1,243	1,047	1,725
Currents liabilities	2,665	2,714	2,005	2,906
Total Equity and Liabilities	14,190	23,345	9,560	33,654

Condensed consolidated Statement of Cash Flows

(In EUR 000)	Audited			Unaudited	
	For the year ended		31 December	For the six-month period ended 30 June	
	2020	2019	2018	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES					
Loss for the period before taxes	(19,994)	(13,444)	(9,894)	(12,755)	(8,776)
Adjusted for:					
Depreciation and impairment of property, plant and equipment and right-of-use assets	271	229	234	124	123
Share based payment transaction expense	2,700	289	361	2,007	558
Post-employment benefits	(5)	(105)	(4)	169	(2)
Net finance costs	4,482	2,672	1,489	2,931	2,096
Other non-cash items	(7)	-	-	(14)	(17)
Changes in working capital					
Increase (-)/Decrease (+) in Trade and other receivables	(221)	(24)	(118)	(112)	82
Increase (+)/Decrease (-) in Trade and other payables	(48)	575	852	230	(630)
Interest received	-	1	-	-	-
Interest paid	(37)	(20)	(26)	(23)	(7)
Bank changes paid	(11)	(7)	(5)	(6)	(5)
Income tax paid	(31)	(11)	(45)	-	(31)
Net cash generated/(used) from operating activities	(12,901)	(9,845)	(7,156)	(7,449)	(6,609)
CASH FLOWS FROM INVESTING ACTIVITIES					
Investment in fixed assets	(173)	(124)	(103)	(45)	(112)
Acquisitions of a subsidiary, net of cash acquired	-	25	-	-	-
Net cash generated/(used) from investment activities	(173)	(99)	(103)	(45)	(112)
CASH FLOWS FROM FINANCING ACTIVITIES					
Proceeds from interest-bearing loans	3,946	11,743	5,489	27,106	553
Payment of principal portion of lease liabilities	(126)	(95)	(49)	(68)	(62)
Proceeds from issuance of shares	548	4,755	3,207	-	-
Net cash generated/(used) from financing activities	4,368	16,403	8,647	27,038	491
Net change in cash and cash equivalents	(8,706)	6,459	1,388	19,544	(6,231)
Effect of exchange rates on cash and cash equivalents	(41)	5	3	(32)	(12)

Cash and cash equivalents at 1 January	15,129	8,665	7,274	6,382	15,129
Cash and cash equivalents at the end of the period	6,382	15,129	8,665	25,894	8,886

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

Working Capital Statement

On the date of this Prospectus, the Company is of the opinion that it does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this Prospectus. In case the Company would not be able to attract new funds (beyond its existing cash and cash equivalents), it expects to run out of working capital by end of September 2022. In the event the Company is not able to attract any such additional funds and the Company maintains its current strategy and development activities, its 12 month working capital shortfall is projected to be approximately EUR 1.5 to EUR 2 million at the end of September 2022.

The Company has decided to initiate the Offering to secure adequate funding for working capital needs for a period of at least 12 months. Although the net proceeds from the issue of the Offer Shares will allow the Company to fund its operations for at least the next 12 months, there is no assurance the Company will have sufficient working capital to fund its operations in the future.

In the event that the Offering is withdrawn, the Company would be required to raise additional funding in order to meet the funding requirements for the ARC^{IM} Blood pressure and ARC^{IM} Mobility trial, research and development activities and part of the marketing strategy and commercialization efforts. Such additional funding could be a combination of (non-dilutive) external financing and further shareholders' financing, for which the Company would need to initiate financing discussions after the date of the Prospectus. The likelihood of success of such discussions is unclear and, if the Company would be unable to raise additional funding for a sufficient amount or at all, it would not be able to fund its activities and efforts as currently planned.

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 26 of this Prospectus before making a decision to invest in the Offer 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 may require additional capital to finance its planned operations, which may not be available to it on acceptable terms or at all. This may adversely affect the Company's sales and marketing plan, its ongoing research and development efforts and have a material adverse effect on its business, financial condition, and result of operations;
- The Company may face substantial competition, which may result in others discovering, developing, or commercializing products before or more successfully than it does;
- Enrollment and retention of patients in clinical trials, including its Up-LIFT pivotal clinical trial for ARC^{EX}, is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside its control, which could cause significant delays in the completion of such trials or may cause it to abandon one or more clinical trials;
- The Company must obtain FDA clearance or approval before it can sell any of its products in the United States and CE Certification before it can sell any of its products in the European Union. Approval of similar regulatory authorities in countries outside the United States and the European Union is required before it can sell its products in countries that do not accept FDA clearance or approval or CE Certification. The Company may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of its products if such clearance or approval is denied or delayed;
- If the Company obtains clearance or approval for its products, their commercial success will depend in part upon the level of reimbursement it receives from third parties for the cost of its products to users;
- If its investigational devices are cleared or approved, the Company will need to receive access to hospital facilities and clinics, or its sales may be negatively impacted;
- The Company may not receive the necessary approvals, granted de novo classifications, or clearances for its ARC^{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;
- Part of the Company's assets, including intellectual property is pledged to Rijksdienst voor Ondernemend Nederland (RvO part of Dutch ministry of Economic Affairs), and the enforcement of such pledge could substantially harm the future development and operations of the Company; and
- The Company licenses certain technology underlying the development of its investigational devices and the loss of the license would result in a material adverse effect on its business, financial position, and operating results and cause the market value of its Ordinary Shares to decline.

Section C – Key Information on the Securities

What are the main features of the securities?

The Ordinary Shares are 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 will trade in euro on Euronext. The Company will offer up to 5,900,000 Ordinary Shares (the "Offer

Shares") which excludes, unless the context indicates otherwise, any Ordinary Shares issued pursuant to the Increase Option or Over-Allotment Option (as defined below). The aggregate number of Offer Shares may be increased by up to 20% of the aggregate number of Offer Shares (or up to 1,180,000 Ordinary Shares) initially offered to a number of 7,080,000 Ordinary Shares (the **"Increase Option"**). Assuming full exercise of the Over-Allotment Option and the Increase Option, the Offer Shares will constitute up to 25% of the Company's issued share capital. The ISIN of the Ordinary Shares is NL0015000HT4.

The Ordinary Shares will rank *pari passu* with each other and Shareholders will be 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 as they will read immediately after the conversion into a public limited liability company on the First Trading Date (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 may be limited or excluded by a resolution of the General Meeting, ultimately on the First Trading Date, authorizing the Board to issue Ordinary Shares or grant rights to subscribe for Ordinary Shares for a period of 18 months following the First Trading Date and to limit or exclude the pre-emptive rights pertaining to such Ordinary Shares and rights. This authorization of the Board will be limited to: (i) up to a maximum of 10% of the Ordinary Shares issued and outstanding as at close of business on the Settlement Date (as defined below) or, in case the Over-Allotment Option is exercised after the Settlement Date, at close of business on the date of the issuance of the Over-Allotment Shares, for general purposes; and, in addition, (ii) up to a maximum of 10% of the Ordinary Shares issued and outstanding on the Settlement Date or, in case the Over-Allotment Option is exercised after the Settlement Date, at close of business on the date of the issuance of the Over-Allotment Shares, in connection with takeovers, mergers, demergers and strategic alliances. Such designations may be revoked at any time by the General Meeting. These general authorizations granted to the Board expire after a period of 18 months following the First Trading Date.

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 and Belgium and the transfer of Offer Shares into jurisdictions other than the Netherlands and Belgium 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?

Prior to the Offering, there has been no public market for the Ordinary Shares. Application has been made to list all Ordinary Shares under the symbol "ONWD" on Euronext Brussels (primary listing) and Euronext Amsterdam (secondary listing). Subject to extension of the timetable for the Offering, trading in the Ordinary Shares on Euronext is expected to commence, on an "as-if-when-issued-and/or-delivered" basis, on or about the First Trading Date.

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

Section D – Key Information on the Offering

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

The Offering. The offering of the Offer Shares (the **"Offering"**) consists of (i) an initial public offering to retail investors in Belgium and an offering to qualified investors (**"Qualified Investors"**) within the meaning of the Prospectus Regulation, (ii) a private placement in (a) the European Economic Area (the **"EEA"**) (other than in Belgium) to certain Qualified Investors, (b) the United Kingdom to "Qualified Investors" within the meaning of Article 2(e) of the UK version of Regulation (EU) 2017/1129 as amended by The Prospectus (Amendment etc.) (EU Exit) Regulations 2019, which forms part of UK law by virtue of the European Union (Withdrawal) Act 2018 who are also persons with professional experience in matters relating to investments falling within the definition of "investment professionals" in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the **"Order"**), or high net worth companies, unincorporated associations and other persons falling within Articles 49(2)(A) to (D) of the Order or other persons to whom the Offering may lawfully be communicated, and (c) Switzerland, to investors that qualify as "professional clients" within the meaning of the Swiss Financial Services Act (*Finanzdienstleistungsgesetz*) of 15 June 2018, as amended (the **"FinSA"**) and (iii) a private placement in the United States of America (the **"United States"** or **"US"**) to persons reasonably believed to be "qualified institutional buyers" (**"QIBs"**) as defined in, and pursuant to, Rule 144A (**"Rule 144A"**) under the US Securities Act of 1933, as amended (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. The Offering outside of the United States will be made in accordance with Regulation S ("**Regulation S**") under the US Securities Act (those qualified, professional and/or institutional investors together with the QIBs are collectively referred to as the "**Institutional Investors**").

Over-allotment option. The Company will grant the Joint Global Coordinators an option (the "**Over-Allotment Option**"), exercisable within 30 calendar days after the First Trading Date, pursuant to which the Belfius Bank NV/SA, as the stabilization manager (the "**Stabilization Manager**"), acting on behalf of Bank Degroof Petercam SA/NV and Belfius Bank NV/SA act as Joint Global Coordinators for the Offering (in such and any other capacity, the "**Joint Global Coordinators**" and the "**Underwriters**"), may require the Company to issue and sell at the Offer Price up to 885,000 additional Ordinary Shares Shares (or 1,062,000 additional Ordinary Shares in the event the Increase Option is exercised in full)(the "**Over-Allotment Shares**"), comprising up to 15% of the total number of Offer Shares sold in the Offering, to cover over-allotments or short positions, if any, in connection with the Offering or to facilitate stabilization transactions.

Offering period. Prospective investors may subscribe for Offer Shares during the period commencing at 9:00 a.m. Central European Time ("**CET**") on 12 October 2021 and ending at 4:00 p.m. CET on 19 October 2021 (the "**Offering Period**") and prospective Retail Investors (as defined below) may subscribe for Offer Shares in the period commencing 12 October 2021 and ending at 4:00 p.m. CET on 19 October 2021. This timetable is subject to extension. There is no early closing of the Offering Period for retail investors.

Offer price and number of Offer Shares. The Offer Price is expected to be in the range of EUR 11.75 to EUR 13.75 per Offer Share (the "**Offer Price Range**"). The Offer Price and the exact number of Offer Shares will be determined on the basis of a book-building process in which only institutional investors can participate. The Offer Price Range is an indicative price range. The Offer Price, the exact numbers of Offer Shares to be sold and the maximum number of Over-Allotment Shares will be stated in a pricing statement which will be filed with the AFM, submitted to the FSMA, and announced through a press release that will be posted on the Company's website. The Company, after consultation with the Joint Global Coordinators, reserves the right to change the Offer Price Range, to decrease the number of Offer Shares or to increase the number of Offer Shares prior to the allocation of the Offer Shares (the "**Allocation**"). In the event the lower limit of the Price Range is decreased or the Offer Price is set below the lower end of the Price Range, or in the event the higher limit of the Price Range is increased or the Offer Price is set above the top end of the Price Range, this will be published in a supplement to the Prospectus. In the event of publication of a supplement to this Prospectus, and if required by law, investors will have the right to withdraw their orders made prior to the publication of the supplement. Such withdrawal must be done within the time period set forth in the supplement (which shall not be shorter than three business days after publication of the supplement). Upon a change of the number of Offer Shares, references to Offer Shares in this Prospectus should be read as referring to the amended number of Offer Shares and references to Over-Allotment Shares should be read as referring to the amended number of Over-Allotment Shares.

Allocation. The Allocation is expected to take place after termination of the Offering Period on or about 20 October 2021, subject to extension of the timetable for the Offering. Allotment to investors who applied to subscribe for Offer Shares will be determined by the Company in agreement with the Underwriters (as defined below), and full discretion will be exercised as to whether or not and how to allot the Offer Shares. There is no maximum or minimum number of Offer Shares for which prospective investors may subscribe and multiple (applications for) subscriptions are permitted (except for retail investors – see below). In the event that the Offering is over-subscribed, investors may receive fewer Offer Shares than they applied to subscribe for. In the event of over-subscription of the Offering, in principle the Subscription Commitments Shareholders in cash can be reduced in line with the allocation principles that will apply to the other investors that will subscribe in the Offering, while the Subscription Commitments Cornerstones and the Subscription Commitments Lenders shall not be reduced but be allocated entirely.

Retail Investors. Retail Investors must indicate in their subscription orders the number of Offer Shares they are committing to subscribe for. Every order must be expressed in number of Offer Shares with no indication of price and shall be deemed placed at the Offer Price. Only one application per Retail Investor will be accepted. If the Underwriters determine, or have reason to believe, that a single Retail Investor has submitted several subscription orders, through one or more intermediaries, they may disregard such subscription orders. There is no minimum or maximum amount or number of Offer Shares that may be subscribed for in one subscription order.

Subscription orders are subject to a possible reduction Retail Investors in Belgium can only acquire the Offer Shares at the Offer Price and are legally bound to acquire the number of Offer Shares indicated in their subscription order at the Offer Price, unless (i) the Offering has been withdrawn in which case the subscription orders will become null and void, or (ii) in the event of the publication of a supplement to this Prospectus, and if required by law, in which case the Retail Investors will have the right to withdraw their orders made prior to the publication of the supplement exercisable within at least three business days after the publication of the supplement.

Payment. Payment for and delivery of the Offer Shares will take place on the settlement date, which is expected to be 22 October 2021 (the "**Settlement Date**"). Taxes and expenses, if any, must be borne by the investor. Investors must pay the Offer Price in immediately available funds in full in euro on or before the Settlement Date.

Delivery of Shares. The Offer Shares will be delivered in book-entry form through the facilities of Euroclear Nederland. If Settlement does not take place on the Settlement Date as planned or at all, the Offering may be withdrawn, in which case all subscriptions for Offer Shares will be disregarded, any allotments made will be deemed not to have been made and any subscription payments made will be returned without interest or other compensation. Any dealings in Ordinary Shares prior to Settlement are at the sole risk of the parties concerned.

Pre-commitments. LSP V Coöperatieve U.A., Stichting Depositary INKEF Investment Fund, Gimv Investments H&C Netherlands 2016 B.V. and Wellington Partners Nominee Ltd. have irrevocably and conditional only on closing of the Offering, committed themselves to subscribe for Offer Shares in the Offering for an aggregate amount representing up to 15% of the Offered Shares such commitment capped at an offer size of EUR 100 million, in which case the Subscription Commitments Shareholders shall be EUR 15 million.

Dave Marver, Jan Øhrstrøm, John Murphy, Hendrik Lambert and a group of smaller lenders that do not qualify for disclosure under the Prospectus Regulation have irrevocably and conditional only on closing of the Offering, committed themselves to subscribe for Offer Shares in the Offering for an aggregate amount representing up to 2.4% of the Offer Shares in the Offer at the Offer Price

AXA Investment Managers Paris, Öhman Fonder, Belfius Insurance and a smaller investor that does not qualify for disclosure under the Prospectus Regulation, jointly the Cornerstone Investors, have irrevocably and conditional only on closing of the Offering, committed themselves to subscribe for Offer Shares in the Offering for an aggregate amount of EUR 16.2 million at the Offer Price

Lock-up. The Directors, Managers, Current Shareholders of the Company (including for these purposes at least the lenders representing a majority of the principal amount loaned to the Company under the Convertible Loan Agreement) have entered into a lock-up arrangement with the Company in respect of their Shares in the Company held immediately prior to the Offering.

Underwriters. Bank Degroof Petercam SA/NV and Belfius Bank NV/SA are acting as Joint Global Coordinators for the Offering (in such and any other capacity, the "Joint Global Coordinators" and the "Underwriters").

Settlement Agent. Belfius Bank NV/SA is the paying agent with respect to the Ordinary Shares on Euronext.

Retail Coordinator. Belfius Bank NV/SA is the retail coordinator with respect to the Preferential Retail Allocation

Listing Agent: Bank Degroof Petercam SA/NV is the listing agent with respect to the Admission.

Stabilization Manager: Belfius Bank NV/SA is the stabilization manager with respect to the Ordinary Shares on Euronext.

Timetable. Subject to extension of the timetable for, or withdrawal of, the Offering, the timetable below sets forth certain expected key dates for the Offering.

Event	Expected Date	Time CET
Expected start of the Offering Period	12 October 2021	9:00 a.m.
Expected end of the Offering Period for Retail Investors.....	19 October 2021	4:00 p.m.
Expected end of the Offering Period for Institutional Investors.....	19 October 2021	4:00 p.m.
Expected publication of the Offer Price and results of the Offering and communication of allocations	20 October 2021	
Expected First Trading Date (listing and start of "if-and-when-issued-and/or-delivered" trading).....	21 October 2021	
Expected Closing Date (payment, settlement and delivery of the Offer Shares).....	22 October 2021	
Expected last possible exercise date of the Over-allotment Option...	20 November 2021	

The Company, in consultation with the Joint Global Coordinators, reserves the right to extend the Offering Period. In the event of an extension of the Offering Period, these dates will be amended and published through a press release, which will also be posted on the Company's website and (if required) in a supplement to this Prospectus that is subject to the approval of the AFM.

Any extension of the timetable for the Offering will be published in a press release at least three hours before the end of the original Offering Period, provided that any extension will be for a minimum of one full business day. In any event, the Offering Period will be at least six business days.

Dilution. The issuance of the Offer Shares will result in the Company's share capital (taking into account the Shares issued upon conversion of the Convertible Loan Agreement at the Offer Price minus 25% and the share issuance to EPFL and the effectuation of the Reverse Stock Split increasing by approximately 25%. Accordingly, the Current Shareholders will suffer an immediate dilution as a result of the Offering of approximately 0.75%, assuming the full placement issuance of the Offer Shares (including the exercise in full of the Increase Option and Over-Allotment Option) and no participation of the Current Shareholders in the Offering.

Estimated expenses. Assuming that the Offering is fully subscribed and the Offer Price is at the mid-point of the Offer Price Range (as at the date of this Prospectus), the estimated expenses, commissions and taxes payable by the Company related to the Offering amount to approximately EUR 5,5 million. No expenses have been or will be charged to the investors by the Company in relation to the Offering. Assuming placement of the maximum number of Offer Shares (including the full exercise of the Increase Option), that the Offer Price is at the mid-point of the Price Range and that the Over-Allotment Option is exercised in full, the underwriting fees and expenses will be approximately EUR 4,4 million.

Why is this prospectus being produced?

Reasons for the offering and use of proceeds. The Company believes that the Admission and the Offering is a logical next step in its development and that its timing is appropriate, given the Company's current profile and level of maturity.

The Company believes that the Offering will provide the Company with additional capital support (i) for product development and research and development activities, (ii) to conduct clinical trials, and (iii) for overall commercial development. The Admission further provides the Company with access to capital markets, which it may use to support and develop further growth of the Company and to finance further research and/or strategic M&A transactions, as they become available.

The Company expects the Admission and the Offering to create a new long-term shareholder base as well as liquidity for the existing and future Shareholders. It is the intention of the Company to create a meaningful free float in the Ordinary Shares on Admission.

Underwriting agreement. The Company and the Underwriters have entered into an underwriting agreement as with respect to the Offering (the "**Underwriting Agreement**"). The Underwriting Agreement is conditional on, among others, the entry into a pricing agreement between the Company and the Underwriters setting the Offer Price per Offer Share. Under the terms and subject to the conditions set forth in the Underwriting Agreement, the Underwriters will severally (and not jointly, nor jointly and severally) agree to subscribe for all the Offer Shares, less those Offer Shares subscribed for by the Participating Shareholders and the Participating Lenders pursuant to a Subscription Commitment (the "**Underwritten Shares**"), in their own name but for the account of the relevant subscribers in the Offering to whom those Underwritten Shares have been allocated. The Underwriters shall have no obligation to underwrite any of the Underwritten Shares prior to the execution of the pricing agreement. In the event that no pricing agreement is executed or the Underwriting Agreement is terminated in respect of all parties, a supplement to this Prospectus shall be published. After publication of the supplement, the subscriptions for the Offer Shares will automatically be cancelled and withdrawn, and subscribers will not have any claim to delivery of the Offer Shares or to any compensation.

Most material conflicts of interest. As of the date of this Prospectus, the only contractual relationships between the respective Underwriters and the Company relate to this Offering. One or more of the Underwriters and/or their respective affiliates may in the future, from time to time, engage in commercial banking, investment banking and financial advisory and ancillary activities in the ordinary course of their business with the Company or any parties related to it, in respect of which they may, in the future, receive customary compensation, fees and/or commission. Additionally, the Underwriters and/or their affiliates, may, in the ordinary course of their business, hold the Company's securities for investment purposes. Belfius Insurance NV/SA, a member of the Belfius group, has entered into a Subscription Agreement with the Company for an amount of EUR 5 million with guaranteed allocation (see also under *Pre-commitments*). In such relationships the relevant parties may not be obliged to take into consideration the interests of the investors. In respect of the aforementioned, the sharing of information is generally restricted for reasons of confidentiality by internal procedures or by rules and regulations. As a result of acting in the capacities described above, the Underwriters may have interests that may not be aligned, or could potentially conflict with the interests of (potential) investors, or the Company's interests. The investors should be aware of the fact that the Underwriters, when they act as lenders to the Issuer (or when they act in any other capacity whatsoever), have no fiduciary duties or other duties of any nature whatsoever vis-à-vis the investors and that they are under no obligation to take into account the interests of the investors.

SAMENVATTING

Dit hoofdstuk bevat een Nederlandse vertaling van de Engelstalige samenvatting van het prospectus gedateerd 11 oktober 2021. In geval van mogelijk verschillend gedefinieerde begrippen primeert de Engelstalige samenvatting van het prospectus.

Sectie A – Inleiding en Waarschuwingen

Deze samenvatting moet worden gelezen als een inleiding op het prospectus (het "**Prospectus**") opgesteld in verband met de Aanbieding (zoals hieronder gedefinieerd) en de Toelating (zoals hieronder gedefinieerd) tot notering en verhandeling van alle gewone aandelen in het geplaatst aandelenkapitaal van Onward Medical N.V. (de "**Vennootschap**"), die momenteel een besloten vennootschap met beperkte aansprakelijkheid is onder de naam Onward Medical B.V. en die zal worden omgevormd tot een naamloze vennootschap onder de naam Onward Medical N.V. uiterlijk op de Eerste Handelsdag (zoals hieronder gedefinieerd), met een nominale waarde van EUR 0,12 per aandeel (de "**Gewone Aandelen**") met een primaire notering op Euronext in Brussel, een gereguleerde markt die wordt beheerd door Euronext Brussels SA/NV ("**Euronext Brussels**") en een secundaire notering op Euronext in Amsterdam, een gereguleerde markt die wordt beheerd door Euronext Amsterdam N.V. ("**Euronext Amsterdam**"), en samen met Euronext Brussels, "**Euronext**") (de "**Toelating**"). De Vennootschap biedt nieuw uitgegeven Gewone Aandelen aan (de "**Aangeboden Aandelen**"), met uitsluiting, tenzij uit de context anders blijkt, van enige Gewone Aandelen die zijn uitgegeven ingevolge de Verhogingsoptie of Overtoewijzingsoptie (beide zoals hieronder gedefinieerd).

De statutaire zetel van de Vennootschap is gevestigd in Amsterdam, Nederland, en de maatschappelijke zetel is High-Tech Campus 32, 5656 AE Eindhoven, Nederland. Het telefoonnummer van de Vennootschap is + 31 40 288 2830 en haar website is (www.onwd.com). De Vennootschap is ingeschreven in het Handelsregister van de Kamer van Koophandel onder nummer 64598748 en haar *legal entity identifier* ("**LEI**") is 9845007A2CC4C8BFSB80. Het internationale identificatienummer voor effecten ("**ISIN**") van de Gewone Aandelen is NL0015000HT4.

Dit Prospectus is op 11 oktober 2021 goedgekeurd als prospectus voor de toepassing van artikel 3 van Verordening (EU) 2017/1129 van het Europees Parlement en de Raad van 14 juni 2017 (met inbegrip van alle relevante gedelegeerde verordeningen) (de "**Prospectusverordening**") door de Stichting Autoriteit Financiële Markten (de "**AFM**"), als bevoegde autoriteit onder de Prospectusverordening. Dit Prospectus is, na goedkeuring door de AFM, bekendgemaakt aan de Autoriteit voor Financiële Diensten en Markten in België (de "**FSMA**") en dit voor het paspoorten in overeenstemming met artikel 25 van de Prospectusverordening. Het adres van de AFM is Vijzelgracht 50, 1017 HS Amsterdam, Nederland. Haar telefoonnummer is +31 (0)20 797 2000 en haar website is www.afm.nl.

Elke beslissing om te beleggen in de Gewone Aandelen dient door de belegger steeds gebaseerd te zijn op een volledige bestudering van het gehele Prospectus en niet enkel van de Samenvatting. Een belegger loopt het risico zijn geïnvesteerd kapitaal geheel of gedeeltelijk te verliezen, en wanneer de aansprakelijkheid van de belegger niet beperkt is tot het bedrag van de belegging, kan de belegger meer dan het geïnvesteerd kapitaal verliezen. Wanneer een vordering met betrekking tot de informatie die in dit Prospectus is vervat of door verwijzing erin is opgenomen voor de rechter wordt gebracht, is het mogelijk dat de belegger krachtens, die als eiser optreedt, de relevante nationale wetgeving de kosten voor de vertaling van dit Prospectus moet dragen voordat de gerechtelijke procedure kan worden ingeleid. Civiele aansprakelijkheid rust uitsluitend op de personen die de samenvatting, met inbegrip van een vertaling ervan, hebben ingediend, maar enkel voor zover de samenvatting misleidend, onjuist of inconsistent is, wanneer zij samen met de andere delen van dit Prospectus wordt gelezen, of indien deze, wanneer zij samen wordt gelezen met de andere delen van dit Prospectus, niet de essentiële informatie bevat die voor de belegger ter ondersteuning bij zijn overweging om al dan niet in de Aangeboden Aandelen te investeren.

Sectie B – Essentiële Informatie over de Uitgevende Instelling

Welke uitgevende instelling geeft de effecten uit?

De uitgevende instelling van de Gewone Aandelen is de Vennootschap. De Vennootschap is, op de datum van dit Prospectus, een besloten vennootschap met beperkte aansprakelijkheid, gevestigd en kantoorhoudend in Nederland. De LEI van de Vennootschap is 9845007A2CC4C8BFSB80. De Vennootschap zal worden omgevormd tot een naamloze vennootschap uiterlijk op 21 oktober 2021 (de "**Eerste Handelsdag**"). De Vennootschap vormt samen met haar dochtervennootschappen een groep in de zin van artikel 2:24b van het Burgerlijk Wetboek ("**BW**") (elk een "**Groepsmaatschappij**"), en samen met de Vennootschap, de "**Groep**"). De Vennootschap is een medisch technologiebedrijf dat innovatieve therapieën ontwikkelt en commercialiseert om functioneel herstel mogelijk te maken voor mensen met een dwarslaesie. Het innovatieve technologieplatform van de Vennootschap is gebaseerd op ONWARD ARC™ Therapie ("**ARC Therapie**"), een gerichte, geprogrammeerde elektrische stimulatie van het ruggenmerg om beweging, onafhankelijkheid en gezondheid te herstellen bij mensen met een dwarslaesie. ARC Therapie bestaat uit twee platformen een implantaerbaar platform ("**ARC^{IM}**") en een uitwendig platform ("**ARC^{EX}**") die beide gericht zijn op verschillende niveaus van een dwarslaesie en die mogelijk ook kunnen worden gebruikt voor andere ziekten/aandoeningen, zoals de ziekte van Parkinson en een beroerte. Sinds haar oprichting heeft de Vennootschap nog geen inkomsten of netto kasstromen gegenereerd uit de verkoop van haar producten. ARC^{EX} en ARC^{IM}, de meest geavanceerde producten van de Vennootschap en haar enige producten in klinische ontwikkeling, zijn nog niet goedgekeurd voor commercialisatie.

Vanaf de datum van de Eerste Handelsdag zal het maatschappelijk kapitaal van de Vennootschap bestaan uit Gewone Aandelen, die zullen worden toegelaten tot de notering en verhandeling op Euronext, en preferente aandelen met een nominale waarde van EUR 0,12 (de "**Preferente Aandelen**"). Als beschermingsmaatregel zal de algemene vergadering van aandeelhouders van de Vennootschap het Bestuur (zoals hierna gedefinieerd) voorafgaand aan de Eerste Handelsdag machtigen om een call-optie toe te kennen aan een onafhankelijke stichting naar Nederlands recht (indien en wanneer deze wordt geïncorporeerd), om Preferente Aandelen te verwerven krachtens een call-optieovereenkomst die kan worden aangegaan tussen de Vennootschap en de Beschermende Stichting, indien deze op dat moment bestaat, na de Eerste Handelsdag.

Onmiddellijk voorafgaand aan de Afwikkelingsdatum (uitgaande van de conversie van alle bedragen onder de converteerbare leningovereenkomst van 20 april 2021, tussen de Vennootschap en onder andere Invest-NL Capital N.V., LSP V Coöperatieve U.A., Stichting Depositary INKEF Investment Fund Gimv Investments, Wellington Partners Nominee Ltd. en Olympic Investments Inc. (de "**Converteerbare Leningovereenkomst**")) tegen het midden van de prijsvork van de aanbiedingsprijs per Aangeboden Aandeel ("**Aanbiedingsprijs**") de volgende houders van Gewone Aandelen (elk een "**Aandelehouder**") over een rechtstreeks of onrechtstreeks substantieel belang (*substantiële deelneming*, d.w.z. een participatie van ten minste 3% van het aandelenkapitaal of de stemrechten in de Vennootschap): (i) LSP V Coöperatieve U.A., (ii) Stichting Depositary INKEF Investment Fund, (iii) Wellington Partners Nominee Ltd., (iv) Gimv Investments H&C Netherlands 2016 B.V., (v) G-Therapeutics Founders S.a.r.l, (vi) Stichting G-Therapeutics Participaties, (vii) G-Therapeutics Participaties B.V., (viii) NRT Holdings LLC, en (ix) InvestNL.

Vanaf de Eerste Handelsdag zal de Vennootschap een one-tier bestuur hebben die bestaat uit één of meer uitvoerende bestuurders en één of meer niet-uitvoerende bestuurders (samen het "Bestuur" en elk een "Bestuurder"). Dave Marver zal de uitvoerende bestuurder zijn, en Jan Øhrstrøm, Roel Bulthuis, Fredericus Col-en, Grégoire Courtine, Ian Curtis, John de Koning, Regina Hodits en Patrick Van Beneden de niet-uitvoerende bestuurders. De onafhankelijke auditor van de Vennootschap is Ernst & Young Accountants LLP ("EY").

Wat is de essentiële financiële informatie over de uitgevende instelling?

Geconsolideerde financiële overzichten voor bijzondere doeleinden per 31 december 2020

In de volgende tabellen wordt informatie uit de geconsolideerde financiële overzichten voor speciale doeleinden per en voor het jaar eindigend op 31 december 2020 weergegeven, inclusief vergelijkende cijfers per en voor de jaren eindigend op 31 december 2019 en 2018, die zijn opgesteld in overeenstemming met de International Financial Reporting Standards zoals aanvaard binnen de Europese Unie ("IFRS", en de "Financiële Overzichten"). EY heeft de Financiële Overzichten gecontroleerd en heeft daarover een goedkeurende verklaring afgegeven, met een paragraaf ter benadrukking van het bijzondere doel van de Financiële Overzichten zoals toegelicht in Toelichting 2 van de Financiële Overzichten en de beperking in het gebruik en een paragraaf ter benadrukking van de materiële onzekerheid in verband met de continuïteitsveronderstelling toegelicht in Toelichting 4 van de Financiële Overzichten. Het oordeel van de accountant is niet gewijzigd ten aanzien van deze aangelegenheden:

Benadrukking van het speciale doel en gebruiksbeperking

Wij vestigen uw aandacht op Toelichting 2 waarin het speciale doel van de geconsolideerde financiële overzichten voor speciale doeleinden wordt beschreven. De geconsolideerde financiële overzichten voor speciale doeleinden zijn niet de jaarrekening van ONWARD Medical B.V. in overeenstemming met artikel 361 van Titel 9 Boek 2 BW en de statuten en is opgesteld met het doel om in het prospectus op te nemen opdat ONWARD Medical B.V. kan voldoen aan de vereisten voor historische financiële informatie bij of krachtens Verordening (EU) 2017/1129. Als gevolg hiervan zijn de geconsolideerde financiële overzichten voor speciale doeleinden mogelijk niet geschikt voor een ander doel. Onze controleverklaring is vereist op grond van Gedelegeerde Verordening (EU) 2019/980 van de Commissie en is verstrekt om te voldoen aan die Gedelegeerde Verordening. Daarom dient de controleverklaring niet voor een ander doel te worden gebruikt.

Materiële onzekerheid met betrekking tot de continuïteitsveronderstelling

Wij vestigen uw aandacht op Toelichting 4 "Continuïteit van de Groep" in de geconsolideerde financiële overzichten voor speciale doeleinden waarin wordt uiteengezet dat de kaspositie van de entiteit op 30 september 2022 negatief zou zijn op basis van de veronderstellingen gemaakt door de raad van bestuur met betrekking tot de verwachte kasstromen over de komende 12 maanden. Deze prognoses omvatten geen financieringsalternatieven die momenteel door de raad van bestuur worden overwogen. In deze context is de raad van bestuur zich ervan bewust dat de continuïteit van de activiteiten van de Vennootschap afhangt van haar vermogen om deze nieuwe financieringsbronnen te verkrijgen en dat er in dit opzicht materiële onzekerheden bestaan. De Vennootschap wijst erop dat het succes van de Vennootschap op lange termijn afhankelijk is van het behalen van FDA-goedkeuring en CE-markering van haar producten. Deze condities duiden op het bestaan van een onzekerheid van materieel belang die gereede twijfel kan doen ontstaan over de mogelijkheid van de entiteit om haar continuïteit te handhaven. Wij vestigen uw aandacht op deze toelichting.

Ons oordeel is niet aangepast als gevolg van deze aangelegenheden.

Niet gecontroleerde verkorte geconsolideerde tussentijdse financiële overzichten per 30 juni 2021

In de volgende tabellen wordt ook informatie uit de niet-gecontroleerde verkorte geconsolideerde tussentijdse financiële overzichten per 30 juni 2021 en voor de zes maanden eindigend op die datum weergegeven, die zijn opgesteld in overeenstemming met IAS 34 Tussentijdse Financiële Overzichten (de "Tussentijdse Financiële Overzichten"). De Tussentijdse Financiële Overzichten zijn beoordeeld door EY, die daarover een goedkeurende beoordelingsverklaring heeft verstrekt, inclusief een paragraaf ter benadrukking van het bestaan van een onzekerheid van materieel belang die gereede twijfel kan doen ontstaan over de mogelijkheid van de Vennootschap om haar continuïteit te handhaven zoals toegelicht in Toelichting 3 van de Tussentijdse Financiële Overzichten en een paragraaf ter benadrukking die stelt dat de verkorte tussentijdse financiële informatie, met inbegrip van de overeenkomstige cijfers in de verkorte geconsolideerde tussentijdse winst-en-verliesrekening, gerealiseerde en niet-gerealiseerde resultaten, vermogensmutaties en kasstromen en de bijbehorende toelichtingen, voor de periode van 1 januari 2020 tot en met 30 juni 2020 niet is gecontroleerd of beoordeeld:

Materiële onzekerheid met betrekking tot de continuïteitsveronderstelling

In Toelichting 3 "Continuïteit van de Group" in de verkorte geconsolideerde tussentijdse financiële overzichten wordt uiteengezet dat de kaspositie van de entiteit op 30 september 2022 negatief zou zijn op basis van de veronderstellingen gemaakt door de raad van bestuur met betrekking tot de verwachte kasstromen over de komende 12 maanden. Deze prognoses omvatten geen financieringsalternatieven die momenteel door de raad van bestuur worden overwogen. In deze context is de raad van bestuur zich ervan bewust dat de continuïteit van de activiteiten van de entiteit afhangt van haar vermogen om deze nieuwe financieringsbronnen te verkrijgen en dat er in dit opzicht materiële onzekerheden bestaan. De Vennootschap wijst erop dat het succes van de entiteit op lange termijn afhankelijk is van het behalen van FDA-goedkeuring en CE-markering van haar producten. Deze condities duiden op het bestaan van een onzekerheid van materieel belang die gereede twijfel kan doen ontstaan over de mogelijkheid van de entiteit om haar continuïteit te handhaven. Wij vestigen uw aandacht op deze toelichting.

Vergelijkende cijfers niet gecontroleerd of beoordeeld

Wij hebben de verkorte geconsolideerde tussentijdse financiële overzichten voor de periode van 1 januari 2020 tot 30 juni 2020 niet gecontroleerd of beoordeeld. Bijgevolg hebben wij de vergelijkende cijfers opgenomen in de verkorte geconsolideerde tussentijdse winst-en-verliesrekening, het overzicht van gerealiseerde en niet-gerealiseerde resultaten, het mutatieoverzicht eigen vermogen en het kasstroomoverzicht en de gerelateerde toelichtingen niet gecontroleerd of beoordeeld.

Verkorte Geconsolideerde Winst-en-verliesrekening

(In EUR 000)	Gecontroleerd			Niet gecontroleerd	
	Voor het jaar afgesloten op 31 december			Voor de periode van zes maanden eindigend op 30 juni	
	2020	2019	2018	2021	2020
Subsidies	800	554	474	586	211
Totaal inkomsten en overige baten	800	554	474	586	211
Wetenschapskosten	(1.123)	(313)	(586)	(569)	(542)
Onderzoeks- en ontwikkelingskosten	(5.823)	(5.356)	(4.722)	(3.280)	(2.804)
Klinische en reglementaire uitgaven	(2.770)	(1.239)	(654)	(1.944)	(1.232)

Markt- en markttoegangskosten	(394)	(261)	(98)	(353)	(167)
Octrooi- en aanverwante uitgaven	(1.186)	(525)	(455)	(786)	(455)
Algemene en administratieve kosten	(5.016)	(3.632)	(2.364)	(3.478)	(1.691)
Totaal bedrijfskosten	(16.312)	(11.326)	(8.879)	(10.410)	(6.891)
Bedrijfsverlies voor de periode	(15.512)	(10.772)	(8.405)	(9.824)	(6.680)
Financiële opbrengsten	-	6	3	-	-
Financiële kosten	(4.482)	(2.678)	(1.492)	(2.931)	(2.096)
Verlies van de periode vóór belasting	(19.994)	(13.444)	(9.894)	(12.755)	(8.776)
Belastingen	(20)	(39)	(18)	(16)	(28)
Netto verlies voor de periode	(20.014)	(13.483)	(9.912)	(12.771)	(8.804)

Verkorte Geconsolideerde Balans

	Gecontroleerd			Niet gecontroleerd
	2020	Per 31 december 2019	2018	Per 30 juni 2021
<i>(In EUR 000)</i>				
ACTIVA				
Immateriële vaste activa	6.825	7.382	25	6.745
Materiële vaste activa	248	215	179	222
Activa waarop een gebruiksrecht rust	149	254	360	96
Vaste activa	7.222	7.851	564	7.063
Vorderingen uit hoofde van indirecte belastingen	93	131	190	176
Vorderingen op verbonden partijen	57	51	49	58
Andere vlottende activa	436	183	92	463
Geldmiddelen en kasequivalenten	6.382	15.129	8.665	25.894
Vlottende activa	6.968	15.494	8.996	26.591
Totaal activa	14.190	23.345	9.560	33.654
EIGEN VERMOGEN EN PASSIVA				
Eigen vermogen				
Eigen vermogen	-	-	-	-
Uitgiftepremie	3.083	3.083	83	3.083
Overige reserves	18.465	15.217	9.117	20.473
Niet-gerealiseerde resultaten	(710)	(304)	(33)	(772)
Overgedragen resultaat	(52.933)	(32.919)	(19.436)	(65.704)
Totaal eigen vermogen toerekenbaar aan aandeelhouders	(32.095)	(14.923)	(10.269)	(42.920)
PASSIVA				
Rentedragende leningen	41.817	33.479	17.144	69.311
Uitgestelde belastingverplichting	1.343	1.448	-	1.327
Overige financiële verplichtingen	-	-	-	2.480
Leaseverplichting	61	198	324	-
Vergoedingen na uitdiensttreding	399	429	356	550
Langlopende verplichtingen	43.620	35.554	17.824	73.668
Belastingenschulden	27	39	11	44
Leaseverplichting	137	126	95	130
Handelscrediteuren	911	1.306	852	1.007

Overige schulden	1.590	1.243	1.047	1.725
Kortlopende schulden	2.665	2.714	2.005	2.906
Totaal eigen vermogen en schulden	14.190	23.345	9.560	33.654

Verkort Geconsolideerd Kasstroomoverzicht

(In EUR 000)	Gecontroleerd			Niet gecontroleerd	
	Voor het jaar afgesloten op 31 december			Voor de periode van zes maanden eindigend op 30 juni	
	2020	2019	2018	2021	2020
KASSTROMEN UIT BEDRIJFSACTIVITEITEN					
Verlies over de periode vóór belastingen	(19.994)	(13.444)	(9.894)	(12.755)	(8.776)
Aangepast voor:					
Afschrijvingen en bijzondere waardeverminderingen op materiële vaste activa en gebruiksrechten	271	229	234	124	123
Kosten van op aandelen gebaseerde betalingen	2.700	289	361	2.007	558
Vergoedingen na uitdiensttreding	(5)	(105)	(4)	169	(2)
Netto financieringskosten	4.482	2.672	1.489	2.931	2.096
Overige niet-geldelijke posten	(7)	-	-	(14)	(17)
Wijzigingen in het bedrijfskapitaal					
Toename (-)/afname (+) van handelsvorderingen en overige vorderingen	(221)	(24)	(118)	(112)	82
Toename (+)/afname (-) van handelsschulden en overige te betalen posten	(48)	575	852	230	(630)
Ontvangen rente	-	1	-	-	-
Betaalde rente	(37)	(20)	(26)	(23)	(7)
Betaalde bankmutaties	(11)	(7)	(5)	(6)	(5)
Betaalde inkomstenbelasting	(31)	(11)	(45)	-	(31)
Netto kasstroom gegenereerd/(gebruikt) uit bedrijfsactiviteiten	(12.901)	(9.845)	(7.156)	(7.449)	(6.609)
KASSTROMEN UIT INVESTERINGSACTIVITEITEN					
Investerings in vaste activa	(173)	(124)	(103)	(45)	(112)
Verwerving van een dochteronderneming, na aftrek van de verworven liquide middelen	-	25	-	-	-
Netto kasstroom gegenereerd/(gebruikt) uit investeringsactiviteiten	(173)	(99)	(103)	(45)	(112)
KASSTROMEN UIT FINANCIERINGSACTIVITEITEN					
Opname van rentedragende leningen	3.946	11.743	5.489	27.106	553
Betaling van de hoofdsom van leaseverplichtingen	(126)	(95)	(49)	(68)	(62)
Opbrengsten uit de uitgifte van aandelen	548	4.755	3.207	-	-
Netto kasstroom gegenereerd/(gebruikt) uit financieringsactiviteiten	4.368	16.403	8.647	27.038	491
Nettowijziging in geldmiddelen en kasequivalenten	(8.706)	6.459	1.388	19.544	(6.231)
Effect van wisselkoersen op geldmiddelen en kasequivalenten	(41)	5	3	(32)	(12)
Geldmiddelen en kasequivalenten op 1 januari	15.129	8.665	7.274	6.382	15.129
Geldmiddelen en kasequivalenten aan het einde van de periode	6.382	15.129	8.665	25.894	8.886

Het Prospectus bevat geen pro forma financiële informatie.

Verklaring over het Werkkapitaal

Op de datum van dit Prospectus is de Vennootschap van mening dat zij niet over voldoende werkkapitaal beschikt om aan haar huidige behoeften te voldoen en om de werkkapitaalbehoeften te dekken voor een periode van ten minste 12 maanden vanaf de datum van dit Prospectus. Indien de Vennootschap niet in staat zou zijn om nieuwe financiële middelen aan te trekken (buiten de bestaande geldmiddelen en kasequivalenten), verwacht zij eind september 2022 zonder werkkapitaal te zitten. In het geval dat de Vennootschap niet in staat is om dergelijke additionele financiële middelen aan te trekken en de Vennootschap haar huidige strategie en ontwikkelingsactiviteiten handhaaft,

zal haar tekort aan werkkapitaal op 12 maanden naar verwachting ongeveer EUR 1,5 tot EUR 2 miljoen bedragen aan het einde van september 2022.

De Vennootschap heeft besloten om de Aanbieding te initiëren om voldoende financiering te verzekeren voor haar werkkapitaalbehoefte voor een periode van ten minste 12 maanden. Hoewel de netto-opbrengst van de uitgifte van de Aangeboden Aandelen de Vennootschap in staat zal stellen om haar activiteiten gedurende ten minste de volgende 12 maanden te financieren, bestaat er geen zekerheid dat de Vennootschap over voldoende werkkapitaal zal beschikken om haar activiteiten in de toekomst te financieren.

In het geval dat de Aanbieding wordt ingetrokken, zal de Vennootschap additionele financiering moeten ophalen om te voldoen aan de financieringsvereisten voor de ARC^{IM} Bloeddruk- en ARC^{IM} Mobiliteitsstudie, onderzoeks- en ontwikkelingsactiviteiten en een deel van de marketingstrategie en commercialiseringsinspanningen. Dergelijke additionele financiering zou een combinatie kunnen zijn van (niet-verwaterende) externe financiering en verdere financiering van de aandeelhouders, waarvoor de Vennootschap financieringsgesprekken zal moeten opstarten na de datum van het Prospectus. De kans van slagen van dergelijke besprekingen is onbekend en, indien de Vennootschap niet in staat zou zijn om enige of voldoende additionele financiering te verkrijgen, zal zij haar activiteiten en inspanningen niet kunnen financieren zoals momenteel gepland.

Wat zijn de voornaamste risico's specifiek voor de uitgevende instelling?

De volgende belangrijke risico's houden verband met de activiteiten, bedrijfsresultaten, financiële toestand en vooruitzichten van de Groep. Bij de selectie en rangschikking van de risicofactoren heeft de Groep rekening gehouden met omstandigheden zoals de waarschijnlijkheid dat het risico zich voordoet op basis van de huidige stand van zaken, de mogelijke impact die de verwezenlijking van het risico zou kunnen hebben op de activiteiten, de financiële toestand, de bedrijfsresultaten en de vooruitzichten van de Groep, en de aandacht die het management van de Groep op basis van de huidige verwachtingen zou moeten besteden aan deze risico's indien ze zich zouden voordoen. Beleggers dienen alle risicofactoren, die van wezenlijk belang zijn en in hun geheel dienen te worden gelezen, te lezen, te begrijpen en in overweging te nemen, zoals uiteengezet onder "Risk Factors" beginnend op pagina 26 van dit Prospectus, alvorens een beslissing te nemen om in de Aangeboden Aandelen te beleggen.

- De Vennootschap is volledig afhankelijk van het succes van twee experimentele apparaten, de ARCIM- en ARCEX-platformen. Zelfs als de Vennootschap in staat is om de klinische ontwikkeling te voltooien en gunstige klinische resultaten te verkrijgen voor de eerste indicaties die het nastreeft, is het mogelijk dat ze niet in staat is om voor haar ARCIM- en ARCEX-platformen een wettelijke vergunning of goedkeuring te verkrijgen of om die met succes te commercialiseren;
- De Vennootschap heeft sinds haar oprichting aanzienlijke operationele verliezen geleden en verwacht ook in de toekomst operationele verliezen te zullen lijden, en het is mogelijk dat zij niet in staat is winstgevendheid te bereiken of te handhaven. Dat kan een negatieve invloed hebben op de marktprijs van haar Gewone Aandelen en op haar vermogen om kapitaal te aan te trekken en haar activiteiten voort te zetten;
- De Vennootschap kan extra kapitaal nodig hebben om haar geplande activiteiten te financieren, dat mogelijk niet onder aanvaardbare voorwaarden of helemaal niet beschikbaar is. Dat kan het verkoop- en marketingplan van de Vennootschap, haar lopende onderzoeks- en ontwikkelingsinspanningen negatief beïnvloeden en een wezenlijk negatief effect hebben op haar activiteiten, financiële positie en bedrijfsresultaat;
- De Vennootschap kan te maken krijgen met aanzienlijke concurrentie, wat ertoe kan leiden dat anderen eerder of met meer succes producten ontdekken, ontwikkelen of commercialiseren dan de Vennootschap;
- Inclusie en retentie van patiënten in klinische studies, met inbegrip van het centrale klinische Up-LIFT-onderzoek voor ARC^{EX}, is een duur en tijdrovend proces en kan moeilijker of onmogelijk worden gemaakt door meerdere factoren die zich buiten haar controle om voordoen. Dat kan aanzienlijke vertragingen bij de voltooiing van dergelijke studies veroorzaken of kan ertoe leiden dat ze één of meer klinische studies gestaakt/afgebroken worden;
- De Vennootschap moet een vergunning of goedkeuring van de FDA krijgen voor het haar producten in de Verenigde Staten kan verkopen. Het moet ook een CE-certificaat krijgen voor het haar producten in de Europese Unie kan verkopen. De goedkeuring van regelgevende instanties in landen buiten de Verenigde Staten en de Europese Unie is vereist voordat de Vennootschap haar producten kan verkopen in landen die geen vergunning of goedkeuring van de FDA of CE-certificaat accepteren. De Vennootschap kan bijkomende kosten of vertraging oplopen bij het voltooien, of uiteindelijk niet kunnen voltooien van de ontwikkeling en commercialisering van haar producten, indien deze goedkeuring geweigerd of vertraagd wordt;
- Indien de Vennootschap de vergunning of goedkeuring van haar producten verkrijgt, zal haar commerciële succes gedeeltelijk afhangen van het niveau van terugbetaling dat zij van derden ontvangt voor de kosten van haar producten voor gebruikers;
- Als haar onderzoekapparaten een vergunning hebben gekregen of zijn goedgekeurd, moet de Vennootschap toegang krijgen tot ziekenhuisfaciliteiten en klinieken, of anderszins kan de verkoop van de onderzoekapparaten negatief worden beïnvloed;
- Mogelijk ontvangt de Vennootschap niet de nodige goedkeuringen, de novo-classificaties of vergunningen voor haar ARC^{EX}- en ARC^{IM}-platformen of toekomstige apparaten en uitgebreide indicaties. Als het er niet in slaagt deze reglementaire vergunning of goedkeuring tijdig te verkrijgen, kan dat een nadelige invloed hebben op haar vermogen om haar activiteiten uit te breiden;
- Het klinische ontwikkelingsproces om de wettelijke vergunningen of goedkeuringen te verkrijgen is lang en duur en heeft onzekere resultaten. De gegevens die in deze klinische studies zijn ontwikkeld, zijn ook onderworpen aan interpretatie door de FDA en buitenlandse regelgevende instanties. Indien klinische studies van het huidige ARCEX-platform, het ARCIM-platform en toekomstige producten niet de resultaten opleveren die nodig zijn om wettelijke toestemming of goedkeuring te ondersteunen, of in de Verenigde Staten geen toegekende de novo-classificatie of goedkeuring opleveren of, met betrekking tot de huidige of toekomstige producten van de Vennootschap, elders, dan zal de Vennootschap niet in staat zijn om deze producten te commercialiseren. Ze kan ook bijkomende kosten oplopen of vertragingen bij de voltooiing ervaren, of uiteindelijk niet in staat zijn om de commercialisering van deze producten te voltooien;
- Een deel van de activa van de Vennootschap, met inbegrip van de intellectuele eigendom, wordt verpand aan de Rijksdienst voor Ondernemend Nederland (de RvO is onderdeel van het Nederlandse ministerie van Economische Zaken) en de afdwinging van dit pand kan de toekomstige ontwikkeling en activiteiten van de Vennootschap aanzienlijk schaden; en
- De Vennootschap beschikt over bepaalde licenties voor bepaalde technologie die ten grondslag ligt aan de ontwikkeling van haar onderzoek hulpparaten. Het verlies van de licentie zou een wezenlijk negatief effect hebben op haar activiteiten, financiële positie en bedrijfsresultaten, en zou ervoor zorgen dat de marktwaarde van haar gewone aandelen daalt.

Sectie C – Essentiële Informatie over de Effecten

Wat zijn de hoofdkenmerken van de effecten?

De Gewone Aandelen zijn gewone aandelen in het geplaatst kapitaal van de Vennootschap met een nominale waarde van EUR 0,12 per aandeel. De Gewone Aandelen worden uitgedrukt en zullen worden verhandeld in euro op Euronext. De Vennootschap zal maximaal 5.900.000 Gewone Aandelen aanbieden (de "**Aangeboden Aandelen**"), exclusief, tenzij uit de context anders blijkt, enige Gewone Aandelen die zijn uitgegeven ingevolge de Verhogingsoptie of Overtoewijzingsoptie (zoals hieronder gedefinieerd). Het totaal aantal Aangeboden Aandelen kan worden verhoogd met maximaal 20% van het totale aantal Aangeboden Aandelen (of maximaal 1.180.000 Gewone Aandelen) dat aanvankelijk wordt aangeboden tot een aantal van 7.080.000 Gewone Aandelen (de "**Verhogingsoptie**"). Uitgaande van volledige uitoefening van de Overtoewijzingsoptie en de Verhogingsoptie, zullen de Aangeboden Aandelen maximaal 25% van het geplaatst aandelenkapitaal van de Vennootschap vormen. Het ISIN van de Gewone Aandelen is NL0015000HT4.

De Gewone Aandelen zullen allen dezelfde rang hebben (*pari passu*) en Aandeelhouders zullen recht hebben op dividenden en andere uitkeringen die worden toegewezen na de vaststelling van de jaarrekening waaruit blijkt dat een dergelijke uitkering is toegestaan en uitgekeerd. Het Bestuur kan ook besluiten om tussentijdse uitkeringen te doen in overeenstemming met de statuten van de Vennootschap zoals deze zullen luiden onmiddellijk na de omvorming tot een naamloze vennootschap op de Eerste Handelsdag (de "**Statuten**"). Elk Gewoon Aandeel geeft recht op uitkeringen en geeft de houder ervan het recht om de algemene vergadering van de Vennootschap, zijnde het vennootschapsorgaan, of waar de context dit vereist, de algemene vergadering van Aandeelhouders (de "**Algemene Vergadering**") bij te wonen en er één stem uit te brengen. Er zijn geen beperkingen op het stemrecht verbonden aan de Gewone Aandelen.

Bij de uitgifte van Gewone Aandelen of het verlenen van rechten tot het inschrijven op Gewone Aandelen, behoudens uitzonderingen (d.w.z. in het geval van een uitgifte van Gewone Aandelen aan werknemers van de Vennootschap of een Groepsmaatschappij, tegen een inbreng anders dan in geld of ingevolge de uitoefening van een eerder verkregen recht tot inschrijving op Gewone Aandelen), heeft iedere Aandeelhouder een voorkeursrecht naar evenredigheid van het aantal Gewone Aandelen dat hij reeds bezit. Er zijn geen voorkeursrechten verbonden aan Preferente Aandelen en er zijn geen voorkeursrechten van toepassing in het geval van een uitgifte van Preferente Aandelen. De voorkeursrechten kunnen worden beperkt of uitgesloten door een besluit van de Algemene Vergadering, uiterlijk op de Eerste Handelsdag, waarbij het Bestuur wordt gemachtigd om Gewone Aandelen uit te geven of rechten te verlenen om in te schrijven op Gewone Aandelen voor een periode van 18 maanden na de Eerste Handelsdag en om het voorkeursrecht met betrekking tot dergelijke Gewone Aandelen en rechten te beperken of uit te sluiten. Deze machtiging van het Bestuur zal beperkt zijn tot: (i) tot een maximum van 10% van de uitgegeven en uitstaande Gewone Aandelen zoals op de Afwikkelingsdatum (zoals hieronder gedefinieerd) of, in geval van uitoefening van de Overtoewijzingsoptie na de Afwikkelingsdatum, bij sluiting van de handel op de datum van de uitgifte van de Overtoewijzingsaandelen, voor algemene doeleinden; en, daarnaast, (ii) tot een maximum van 10% van de uitgegeven en uitstaande Gewone Aandelen op de Afwikkelingsdatum of, in geval van uitoefening van de Overtoewijzingsoptie na de Afwikkelingsdatum, bij sluiting van de handel op de datum van de uitgifte van de Overtoewijzingsaandelen, in verband met overnames, fusies, splitsingen en strategische allianties. Dergelijke aanwijzingen kunnen te allen tijde door de Algemene Vergadering worden herroepen. Deze aan het Bestuur verleende algemene machtigingen vervallen na een periode van 18 maanden na de Eerste Handelsdag.

In geval van een insolventieprocedure zijn de vorderingen van de Aandeelhouders achtergesteld op die van de schuldeisers van de Vennootschap. Dit betekent dat een belegger mogelijk zijn geïnvesteerd kapitaal geheel of gedeeltelijk kan verliezen. Indien en voor zover er Preferente Aandelen uitstaan, zullen deze Preferente Aandelen een relatieve voorkeur hebben boven de Gewone Aandelen bij het uitkeren van dividenden of in verband met een uitkering die wordt gedaan bij de vereffening van de Vennootschap.

Er zijn geen beperkingen op de overdraagbaarheid van de Gewone Aandelen in de Statuten. De Aanbieding aan personen die gevestigd of woonachtig zijn in, of onderdaan zijn van, of een geregistreerd adres hebben in andere landen dan Nederland en België en de overdracht van Aangeboden Aandelen naar andere rechtsgebieden dan Nederland en België kan echter onderworpen zijn aan specifieke voorschriften of beperkingen.

De Vennootschap heeft in het verleden nooit dividenden in contanten uitgekeerd of toegewezen en verwacht niet dat zij in de nabije toekomst dividenden in contanten zal uitkeren. De Vennootschap heeft de intentie om alle beschikbare fondsen en eventuele toekomstige winsten te behouden om de verdere ontwikkeling en uitbreiding van de activiteiten van de Vennootschap te financieren.

Waar zullen de effecten worden verhandeld?

Voorafgaand aan de Aanbieding is er geen publieke markt geweest voor de Gewone Aandelen. Er is een aanvraag gediend voor de notering van alle Gewone Aandelen onder het symbool "ONWD" op Euronext Brussels (primaire notering) en Euronext Amsterdam (secundaire notering). Behoudens een eventuele verlenging van het tijdschema voor de Aanbieding, zal de verhandeling van de Gewone Aandelen op Euronext naar verwachting aanvangen, op een 'alsof-wanneer-uitgegeven-en/of-geleverd'-basis, op of omstreeks de Eerste Handelsdag.

Wat zijn de voornaamste risico's specifiek voor de effecten?

De volgende belangrijke risico's hebben betrekking op de Gewone Aandelen, de bedrijfsresultaten, de financiële toestand en de vooruitzichten. Bij de selectie en rangschikking van de risicofactoren heeft de Groep rekening gehouden met omstandigheden zoals de waarschijnlijkheid dat het risico zich voordoet op basis van de huidige stand van zaken, de mogelijke impact die het materialiseren van het risico zou kunnen hebben op de activiteiten, de financiële toestand, de bedrijfsresultaten en de vooruitzichten van de Groep, en de aandacht die het management van de Groep op basis van de huidige verwachtingen zou moeten besteden aan deze risico's indien ze zich zouden materialiseren. Beleggers dienen alle risicofactoren, die van wezenlijk belang zijn en in hun geheel dienen te worden gelezen, te lezen, te begrijpen en in overweging te nemen, zoals uiteengezet onder "*Risk Factors*" beginnend op pagina 26 van dit Prospectus, alvorens een beslissing te nemen om in de Aangeboden Aandelen te beleggen:

- De betaling van toekomstige dividenden zal afhangen van de financiële toestand en bedrijfsresultaten van de Groep, alsook van de uitkeringen van operationele dochterondernemingen aan de Vennootschap;
- Het feit dat er voor de Aanbieding geen minimumbedrag is vastgesteld, kan invloed hebben op het beleggingsplan van de Vennootschap en de liquiditeit van de Aandelen; en
- Bepaalde belangrijke aandeelhouders van de Vennootschap na de Aanbieding kunnen een ander belang dan de Vennootschap hebben en kunnen de Vennootschap, met inbegrip van de uitkomst van aandeelhoudersstemmen, controleren.

Sectie D – Essentiële Informatie over de Aanbieding van Effecten aan het Publiek

Onder welke voorwaarden en welk tijdschema kan ik in dit effect beleggen?

De Aanbieding. De Aanbieding van de Aangeboden Aandelen (de "**Aanbieding**") bestaat uit (i) een openbare aanbieding aan particuliere beleggers in België en een aanbieding aan gekwalificeerde beleggers ("**Gekwalificeerde Beleggers**") in de zin van de Prospectusverordening, (ii) een onderhandse plaatsing in (a) de Europese Economische Ruimte (de "**EER**") (anders dan in België) aan bepaalde Gekwalificeerde Beleggers, (b) het Verenigd Koninkrijk aan "Gekwalificeerde Beleggers" in de zin van artikel 2(e) van de Britse versie van Verordening (EU) 2017/1129, zoals gewijzigd door The Prospectus (Amendment etc.) (EU Exit) Regulations 2019, die deel

uitmaakt van de Britse wetgeving krachtens de European Union (Withdrawal) Act 2018 en die ook personen zijn met professionele ervaring in zaken die betrekking hebben op beleggingen die vallen onder de definitie van "investment professionals" in artikel 19, lid 5, van de Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, zoals gewijzigd (de "**Order**"), of vermogende vennootschappen, verenigingen zonder rechtspersoonlijkheid en andere personen die onder artikel 49, lid 2, onder A tot en met D, van de Order vallen of andere personen aan wie de Aanbieding op wettelijke wijze kan worden medegegeeld, en (c) Zwitserland, aan beleggers die kwalificeren als "professionele cliënten" in de zin van artikel 4 van de Zwitserse wet op de financiële diensten (*Finanzdienstleistungsgesetz*) van 15 juni 2018, zoals gewijzigd (de "**FinSA**") en (iii) een onderhandse plaatsing in de Verenigde Staten van Amerika (de "**Verenigde Staten**" of "**VS**") aan personen van wie redelijkerwijs mag worden aangenomen dat zij "gekwalificeerde institutionele kopers" ("**QIB's**") zijn, zoals gedefinieerd in, en overeenkomstig *Rule 144A* ("**Rule 144A**") onder de US Securities Act van 1933, zoals gewijzigd (de "**US Securities Act**"), of overeenkomstig een andere vrijstelling van, of in een transactie die niet onderworpen is aan, de registratievereiste onder de US Securities Act en de toepasselijke effectenwetten van de staten. De Aanbieding buiten de Verenigde Staten zal worden gedaan in overeenstemming met Regulation S ("**Regulation S**") onder de US Securities Act (deze gekwalificeerde, professionele en/of institutionele investeerders worden samen met de QIB's gezamenlijk de "**Institutionele Investeerders**" genoemd).

Overtoewijzingsoptie. De Vennootschap zal aan de Joint Global Coördinatoren (zoals hieronder gedefinieerd) een optie toe te kennen (de "**Overtoewijzingsoptie**"), die uitoefenbaar is tot 30 kalenderdagen na de Eerste Handelsdag, op grond waarvan Belfius Bank NV/SA, als stabilisatiemanager (de "**Stabilisatiemanager**"), handelend in naam van Bank Degroof Petercam SA/NV en Belfius Bank NV/SA optredend als Joint Global Coordinators voor de Aanbieding (in die en enige andere hoedanigheid, de "**Joint Global Coordinators**" en de "**Underwriters**"), kan eisen dat de Vennootschap tot 885.000 bijkomende Gewone Aandelen uitgeeft en verkoopt tegen de Aanbiedingsprijs (of 1.062.000 bijkomende Gewone Aandelen in het geval de Verhogingsoptie volledig wordt uitgeoefend) (de "**Overtoewijzingsaandelen**"), die tot 15% omvatten van het totale aantal Aangeboden Aandelen dat in de Aanbieding wordt verkocht, om eventuele overtoewijzingen of shortposities in verband met de Aanbieding te dekken of om stabilisatietransacties te vergemakkelijken.

Aanbiedingsperiode. Potentiële beleggers kunnen inschrijven op de Aangeboden Aandelen tijdens de periode die aanvangt om 9.00 uur Centrale Europese Tijd ("**CET**") op 12 oktober 2021 en eindigt om 16.00 uur CET op 19 oktober 2021 (de "**Aanbiedingsperiode**") en potentiële Particuliere Beleggers (zoals hieronder gedefinieerd) kunnen inschrijven op Aangeboden Aandelen in de periode die aanvangt op 12 oktober 2021 en eindigt om 16.00 uur CET op 19 oktober 2021. Dit tijdschema is onderhevig aan verlenging. Er is geen vervroegde afsluiting van de Aanbiedingsperiode voor particuliere beleggers.

Aanbiedingsprijs en aantal Aangeboden Aandelen. De Aanbiedingsprijs zal naar verwachting liggen tussen EUR 11,75 en EUR 13,75 per Aangeboden Aandeel (de "**Prijsvork van de Aanbieding**"). De Aanbiedingsprijs en het exacte aantal Aangeboden Aandelen zullen worden vastgesteld op basis van een *book-building* proces waaraan alleen institutionele beleggers kunnen deelnemen. De Prijsvork van de Aanbieding is indicatief. De Aanbiedingsprijs, het exacte aantal te verkopen Aangeboden Aandelen en het maximumaantal Overtoewijzingsaandelen zullen worden vermeld in een prijsopgave die zal worden neergelegd bij de AFM, ingediend bij de FSMA, en aangekondigd via een persbericht dat zal worden geplaatst op de website van de Vennootschap. De Vennootschap behoudt zich het recht voor om, na overleg met de Joint Global Coördinatoren, de Prijsvork van de Aanbieding te wijzigen, het aantal Aangeboden Aandelen te verlagen of het aantal Aangeboden Aandelen te verhogen voorafgaand aan de toewijzing van de Aangeboden Aandelen (de "**Toewijzing**"). In het geval dat de ondergrens van de Prijsvork van de Aanbieding wordt verlaagd of de Aanbiedingsprijs wordt vastgesteld onder de ondergrens van de Prijsvork van de Aanbieding, of in het geval dat de bovengrens van de Prijsvork van de Aanbieding wordt verhoogd of de Aanbiedingsprijs wordt vastgesteld boven de bovengrens van de Prijsvork van de Aanbieding zal dit worden gepubliceerd in een aanvulling op het Prospectus. In het geval van publicatie van een aanvulling op dit Prospectus, en indien wettelijk vereist, zullen beleggers het recht hebben om hun orders, gemaakt vóór de publicatie van de aanvulling, in te trekken. Een dergelijke intrekking moet gebeuren binnen de termijn die in de aanvulling vermeld staat (die niet korter mag zijn dan drie dagen na de publicatie van de aanvulling). Bij een wijziging van het aantal Aangeboden Aandelen moeten verwijzingen naar Aangeboden Aandelen in dit Prospectus worden gelezen als verwijzingen naar het gewijzigde aantal Aangeboden Aandelen en moeten verwijzingen naar Overtoewijzingsaandelen worden gelezen als verwijzingen naar het gewijzigde aantal Overtoewijzingsaandelen.

Toewijzing. De Toewijzing zal naar verwachting plaatsvinden na de beëindiging van de Aanbiedingsperiode op of omstreeks 20 oktober 2021, behoudens verlenging van het tijdschema voor de Aanbieding. De Toewijzing aan beleggers die hebben verzocht om in te schrijven op de Aangeboden Aandelen zal worden bepaald door de Vennootschap in overeenstemming met de Underwriters, en er zal volledige discretie worden uitgeoefend over de toewijzingsmethode en over het al dan niet toewijzen van de Aangeboden Aandelen. Er is geen maximum- of minimumaantal Aangeboden Aandelen waarop potentiële beleggers kunnen inschrijven en meerdere (aanvragen tot) inschrijvingen zijn toegestaan (behalve voor retailbeleggers – zie onder). In het geval van overinschrijving op de Aanbieding, kunnen de Inschrijvingsverplichtingen Aandeelhouders (zoals hieronder gedefinieerd) in contanten in principe worden verminderd in overeenstemming met de toewijzingsprincipes die zullen gelden voor de andere investeerders die zullen inschrijven op de Aanbieding, terwijl de Inschrijvingsverplichtingen Cornerstone Investeerders en Inschrijvingsverplichtingen Kredietverstrekkers (beide zoals hieronder gedefinieerd) niet zullen worden verminderd, maar volledig zullen worden toegewezen.

Particuliere Beleggers. Particuliere Beleggers moeten in hun inschrijvingsorders het aantal Aangeboden Aandelen vermelden waarvoor zij zich ertoe verbinden om in te schrijven. Elk order dient te worden uitgedrukt in aantal Aangeboden Aandelen zonder aanduiding van de prijs en wordt geacht te zijn geplaatst tegen de Aanbiedingsprijs. Slechts één aanvraag per Particuliere Belegger zal worden aanvaard. Indien de Underwriters vaststellen, of reden hebben om aan te nemen, dat één Particuliere Belegger meerdere inschrijvingsorders heeft ingediend, via één of meerdere tussenpersonen, mogen zij deze inschrijvingsorders negeren. Er is geen minimum- of maximumbedrag of -aantal van Aangeboden Aandelen waarop in één inschrijvingsorder kan worden ingeschreven.

Inschrijvingsorders zijn onderhevig aan een mogelijke vermindering. Particuliere Beleggers in België kunnen de Aangeboden Aandelen alleen verwerven tegen de Aanbiedingsprijs en zijn wettelijk verplicht om het aantal Aangeboden Aandelen te verwerven dat in hun inschrijvingsorder is aangegeven tegen de Aanbiedingsprijs, tenzij (i) de Aanbieding is ingetrokken, in welk geval de inschrijvingsorders nietig worden, of (ii) in geval van publicatie van een aanvulling op dit Prospectus, in welk geval de Particuliere Beleggers het recht hebben om hun orders die vóór de publicatie van de aanvulling zijn geplaatst, in te trekken, hetgeen binnen ten minste drie werkdagen na de publicatie van de aanvulling kan worden uitgeoefend.

Betaling. Betaling voor en levering van de Aangeboden Aandelen zal plaatsvinden op de afwikkelingsdatum, die naar verwachting 22 oktober 2021 zal zijn (de "**Afwikkelingsdatum**"). Belastingen en kosten, indien van toepassing, zijn voor rekening van de belegger. Beleggers moeten de Aanbiedingsprijs volledig in onmiddellijk beschikbare fondsen in euro betalen op of vóór de Afwikkelingsdatum.

Levering van Aandelen. De Aangeboden Aandelen worden geleverd in girale vorm via de faciliteiten van Euroclear Nederland. Indien de Afwikkeling niet plaatsvindt op de Afwikkelingsdatum zoals gepland of helemaal niet, kan de Aanbieding worden ingetrokken, in welk geval alle inschrijvingen voor Aangeboden Aandelen buiten beschouwing worden gelaten, eventuele toewijzingen worden geacht niet te zijn gedaan en eventuele inschrijvingsbetalingen worden geretourneerd zonder rente of andere vergoeding. Enige transacties in Gewone Aandelen voorafgaand aan de Afwikkeling zijn geheel op risico van de betrokken partijen.

Voorafgaande toezeggingen: LSP V Coöperatieve U.A., Stichting Depositary INKEF Investment Fund, Gimv Investments H&C Netherlands 2016 B.V. en Wellington Partners Nominee Ltd. hebben zich onherroepelijk en uitsluitend op voorwaarde van voltooiing van de Aanbieding verbonden om in te schrijven op Aangeboden Aandelen in de Aanbieding voor een totaal bedrag dat maximaal 15% van de Aangeboden Aandelen vertegenwoordigt (de "**Inschrijvingsverplichtingen Aandeelhouders**"), een dergelijke verbintenis begrensd tot een omvang van de Aanbieding van EUR 100 miljoen, in welk geval de Inschrijvingsverbintenissen Aandeelhouders EUR 15 miljoen zullen bedragen.

Dave Marver, Jan Øhrstrøm, John Murphy, Hendrik Lambert en een groep van kleinere kredietverschaffers die niet in aanmerking komen voor openbaarmaking op basis van de Prospectusverordening, hebben zich onherroepelijk en uitsluitend op voorwaarde van voltooiing van de Aanbieding verbonden om in te schrijven op Aangeboden Aandelen in de Aanbieding voor een totaalbedrag van EUR dat maximaal 2,4% van de Aangeboden Aandelen in de Aanbieding tegen de Aanbiedingsprijs vertegenwoordigt (de "**Inschrijvingsverplichtingen Kredietverstrekkers**").

AXA Investment Managers Paris, Öhman Fonder, Belfius Insurance en een kleinere investeerder die niet in aanmerking komt voor openbaarmaking op basis van de Prospectusverordening, gezamenlijk de Cornerstone Investeerders, hebben zich onherroepelijk en uitsluitend op voorwaarde van afsluiting van de Aanbieding verbonden om in te schrijven op Aangeboden Aandelen in de Aanbieding voor een totaalbedrag van EUR 16,2 miljoen tegen de Aanbiedingsprijs (de "**Inschrijvingsverplichtingen Cornerstone**").

Lock-up. De Bestuurders, Managers en Huidige Aandeelhouders van de Vennootschap (met inbegrip van voor deze doeleinden ten minste de kredietverstrekkers die een meerderheid vertegenwoordigen van de hoofdsom die aan de Vennootschap is geleend in het kader van de Converteerbare Leningsovereenkomst) zijn een lock-up verbintenis aangegaan met de Vennootschap met betrekking tot hun Aandelen in de Vennootschap die zij onmiddellijk voorafgaand aan de Aanbieding aanhielden.

Underwriters. Bank Degroof Petercam SA/NV en Belfius Bank NV/SA treden op als Joint Global Coördinatoren voor de Aanbieding (in die en enige andere hoedanigheid, de "**Joint Global Coördinatoren**" en de "**Underwriters**").

Betaalkantoor. Belfius Bank NV/SA is het betaalkantoor met betrekking tot de Gewone Aandelen op Euronext.

Noteringsagent. Bank Degroof Petercam SA/NV is het noteringsagent met betrekking tot de Toelating.

Retail Coördinator. Belfius Bank NV/SA is de retail coördinator met betrekking tot de Preferente Toewijzing aan Particuliere Beleggers.

Stabilisatiemanager. Belfius Bank NV/SA is de stabilisatiemanager met betrekking tot de Gewone Aandelen op Euronext.

Tijdschema. Behoudens verlenging van het tijdschema voor, of intrekking van, de Aanbieding, worden in het onderstaande tijdschema bepaalde verwachte belangrijke data voor de Aanbieding uiteengezet.

Gebeurtenis	Verwachte datum	Tijd CET
Verwachte start van de Aanbiedingsperiode	12 oktober 2021	9:00 uur
Verwacht einde van de Aanbiedingsperiode voor Particuliere Beleggers	19 oktober 2021	16:00 uur
Verwacht einde van de Aanbiedingsperiode voor Institutionele Beleggers	19 oktober 2021	16:00 uur
Verwachte publicatie van de Aanbiedingsprijs en de resultaten van de Aanbieding en mededeling van de toewijzing	20 oktober 2021	
Verwachte Noteringsdatum (notering en start van de "as-if-and-when-issued-and/or-delivered"-handel)	21 oktober 2021	
Verwachte Afwikkelingsdatum (betaling, afwikkeling en levering van de Aangeboden Aandelen)	22 oktober 2021	
Verwachte laatst mogelijke uitoefendatum van de Overtoewijzingsoptie...	20 november 2021	

De Vennootschap behoudt zich, in overleg met de Joint Global Coördinatoren, het recht voor om de Aanbiedingsperiode te verlengen. In geval van een verlenging van de Aanbiedingsperiode, zullen deze data worden aangepast en bekendgemaakt via een persbericht, dat ook zal worden gepubliceerd op de website van de Vennootschap en (indien vereist) in een aanvulling op dit Prospectus dat onderworpen is aan de goedkeuring van de AFM.

Elke verlenging van het tijdschema voor de Aanbieding zal ten minste drie uur voor het einde van de oorspronkelijke Aanbiedingsperiode in een persbericht worden gepubliceerd, met dien verstande dat elke verlenging ten minste één volledige werkdag bedraagt. In elk geval zal de Aanbiedingsperiode ten minste zes werkdagen bedragen.

Verwatering. De uitgifte van de Aangeboden Aandelen zal leiden tot een verhoging van het maatschappelijk kapitaal van de Vennootschap (rekening houdend met de Aandelen uitgegeven bij de conversie van de Converteerbare Leningsovereenkomst tegen de Aanbiedingsprijs verminderd met 25% en de uitgifte van de aandelen aan École polytechnique fédérale de Lausanne en de effectuering van de Omgekeerde Aandelensplitsing) van ongeveer 25%. Overeenkomstig zullen de Huidige Aandeelhouders als gevolg van de Aanbieding een onmiddellijke verwatering ondergaan van ongeveer 0,75%, uitgaande van de volledige plaatsing van de Aangeboden Aandelen (met inbegrip van de volledige uitoefening van de Verhogingsoptie en de Overtoewijzingsoptie) en geen deelname van de Huidige Aandeelhouders aan de Aanbieding.

Geschatte kosten. In de veronderstelling dat volledig op de Aanbieding wordt ingeschreven en dat de Aanbodprijs zich in het midden van de Prijsvork van de Aanbieding bevindt (op de datum van dit Prospectus), bedragen de geschatte kosten, commissies en belastingen die door de Vennootschap moeten worden betaald in verband met de Aanbieding bedragen ongeveer EUR 5,5 miljoen. Er zijn of zullen door de Vennootschap geen kosten in verband met de Aanbieding aan de beleggers in rekening worden gebracht. Ervan uitgaande dat het maximumaantal Aangeboden Aandelen wordt geplaatst (met inbegrip van de volledige uitoefening van de Verhogingsoptie), dat de Aanbiedingsprijs zich in het midden van de Prijsvork van de Aanbieding bevindt en dat de Overtoewijzingsoptie volledig wordt uitgeoefend, zullen de Underwriting vergoedingen en -kosten ongeveer EUR 4,4 miljoen bedragen.

Waarom wordt dit prospectus opgesteld?

Redenen voor de Aanbieding en gebruik van de opbrengst. De Vennootschap is van mening dat de Toelating en de Aanbieding een logische volgende stap is in haar ontwikkeling en dat de timing ervan gepast is, gelet op het huidige profiel en het maturiteitsniveau van de Vennootschap.

De Vennootschap meent dat de Aanbieding de Vennootschap zal voorzien van bijkomende kapitaalsteun (i) voor productontwikkeling en onderzoeks- en ontwikkelingsactiviteiten, (ii) om klinische studies uit te voeren, en (iii) voor de algemene commerciële ontwikkeling. De Toelating verschaft de Vennootschap verder toegang tot de kapitaalmarkten, die ze kan gebruiken om de verdere groei van de

Vennootschap te ondersteunen en te ontwikkelen en om verder onderzoek en/of strategische M&A-transacties te financieren, wanneer deze beschikbaar worden.

De Vennootschap verwacht dat de Toelating en de Aanbieding een nieuwe lange termijn aandeelhoudersbasis zal creëren, evenals liquiditeit voor de bestaande en toekomstige Aandeelhouders. Het is de bedoeling van de Vennootschap om bij de Toelating een betekenisvolle *free float* in de Gewone Aandelen te creëren.

Underwriting Overeenkomst. De Vennootschap en de Underwriters hebben een Underwriting Overeenkomst afgesloten met betrekking tot de Aanbieding (de "**Underwriting Overeenkomst**"). De Underwriting Overeenkomst is onder meer afhankelijk van het afsluiten van een pricing overeenkomst tussen de Vennootschap en de Underwriters waarin de Aanbiedingsprijs per Aangeboden Aandeel wordt vastgelegd. Onder de voorwaarden en bepalingen uiteengezet in de Underwriting Overeenkomst, zullen de Underwriters hoofdelijk (en niet gezamenlijk, noch gezamenlijk en hoofdelijk) instemmen om in te schrijven op alle Aangeboden Aandelen, verminderd met de Aangeboden Aandelen waarop is ingeschreven door de Deelnemende Investeerders ingevolge een Inschrijvingsverbintenis (de "**Underwriting Aandelen**"), in hun eigen naam maar voor rekening van de relevante inschrijvers in de Aanbieding aan wie die Underwriting Aandelen zijn toegewezen. De Underwriters zijn niet verplicht om enige van de Underwriting Aandelen over te nemen vóór de uitvoering van de pricing overeenkomst. Indien geen pricing overeenkomst wordt uitgevoerd of de Underwriting Overeenkomst wordt beëindigd ten aanzien van alle partijen, zal er een aanvulling op dit Prospectus worden gepubliceerd. Na publicatie van de aanvulling zullen de inschrijvingen op de Aangeboden Aandelen automatisch worden geannuleerd en ingetrokken, en de inschrijvers zullen geen aanspraak kunnen maken op de levering van de Aangeboden Aandelen of op enige vergoeding.

Meest wezenlijke belangenconflicten. Op de datum van dit Prospectus, hebben de enige contractuele relaties tussen de Underwriters en de Vennootschap betrekking op deze Aanbieding. Eén of meer Underwriters en/of hun respectievelijk verbonden ondernemingen kunnen in de toekomst, van tijd tot tijd, commerciële bank-, investeringsbank-, financiële advies- en nevenactiviteiten uitoefenen in het kader van hun gewone bedrijfsuitoefening met de Vennootschap of met ieder van haar verbonden partijen, in het kader waarvan zij in de toekomst gebruikelijke vergoedingen, honoraria en/of provisies kunnen ontvangen. Bovendien kunnen de Underwriters en/of hun verbonden ondernemingen, in het kader van hun normale bedrijfsuitoefening, de effecten van de Vennootschap aanhouden voor beleggingsdoeleinden. Belfius Insurance NV/SA, een lid van de Belfius groep, heeft een Inschrijvingsovereenkomst gesloten met de Vennootschap voor een bedrag van EUR 5 miljoen met gegarandeerde toewijzing (zie ook onder *Voorafgaande toezeggingen*). In dergelijke relaties zijn de betrokken partijen mogelijk niet verplicht rekening te houden met de belangen van de beleggers. Met betrekking tot het voornoemde wordt het delen van informatie doorgaans vanwege vertrouwelijkheidsredenen beperkt door interne procedures of door regels en voorschriften. Als gevolg van het optreden in de hierboven beschreven hoedanigheden, kunnen de Underwriters belangen hebben die mogelijk niet op één lijn liggen, of mogelijk in strijd zijn met de belangen van (potentiële) beleggers, of de belangen van de Vennootschap. De beleggers dienen zich bewust te zijn van het feit dat de Underwriters, wanneer zij optreden als kredietverstrekkers aan de uitgevende instelling (of wanneer zij optreden in welke andere hoedanigheid dan ook), geen fiduciaire of andere verplichtingen van welke aard dan ook hebben ten aanzien van de beleggers en dat zij niet verplicht zijn om rekening te houden met de belangen van de beleggers.

RÉSUMÉ

La traduction française du résumé ci-dessous n'a pas été soumise au processus d'approbation de l'AFM (tel que défini ci-dessous). Ce chapitre contient une traduction française du résumé anglais du prospectus daté du 11 octobre 2021 (le "Prospectus"). En cas de divergence d'interprétation des termes, le résumé anglais du Prospectus prévaudra

Section A - Introduction et Avertissements

Ce résumé doit être lu comme une introduction au Prospectus préparé dans le cadre de l'Offre (telle que définie ci-dessous) et de l'admission à la cotation et à la négociation de toutes les actions ordinaires représentatives du capital social d'Onward Medical N.V. (la "**Société**"), qui est actuellement une société privée à responsabilité limitée (*besloten vennootschap met beperkte aansprakelijkheid*) dénommée Onward Medical B.V. et qui sera transformée en société anonyme (*naamloze vennootschap*) et renommée Onward Medical N.V. au plus tard à la Date de la Première Négociation (telle que définie ci-dessous), d'une valeur nominale de 0,12 EUR par action (les "**Actions Ordinaires**") avec une cotation primaire sur Euronext à Bruxelles, un marché réglementé géré par Euronext Brussels SA/NV ("**Euronext Brussels**") et une cotation secondaire sur Euronext à Amsterdam, un marché réglementé géré par Euronext Amsterdam N.V. ("**Euronext Amsterdam**"), et ensemble avec Euronext Brussels, "**Euronext**") ("**Admission**"). La Société offre des Actions Ordinaires nouvelles (les "**Actions Offertes**") qui excluent, sauf si le contexte indique le contraire, toute Action Ordinaire émise en vertu de l'Option d'Augmentation ou de l'Option de Surallocation (toutes deux définies ci-dessous).

Le siège statutaire (*statutaire zetel*) de la Société est situé à Amsterdam, aux Pays-Bas, et son siège social est situé à High-Tech Campus 32, 5656 AE 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 inscrite 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 d'identification international des titres ("**ISIN**") des Actions Ordinaires est NL0015000HT4.

Le Prospectus a été approuvé le 11 octobre 2021 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. Ce Prospectus a, suite à son approbation par l'AFM, été notifié à l'Autorité des Services et Marchés Financiers en Belgique (la "**FSMA**") aux fins de bénéficiaire 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 Offertes.

Section B - Informations clés sur l'Emetteur

Qui est l'émetteur des valeurs mobilières ?

L'émetteur des Actions Ordinaires est la Société. La Société est, à la date du Prospectus, une société privée à responsabilité limitée (*besloten vennootschap met beperkte aansprakelijkheid*) constituée et ayant son siège aux Pays-Bas. Le LEI de la Société est 9845007A2CC4C8BFSB80. La Société sera convertie en une société anonyme (*naamloze vennootschap*) au plus tard le 21 octobre 2021 (la "**Date de la Première Négociation**"). La Société et ses filiales constituent un groupe au sens de l'article 2:24b du Code civil néerlandais (*Burgerlijk Wetboek*) ("**DCC**") (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 de la Date de la Première Négociation, le capital autorisé de la Société comprendra des Actions Ordinaires, qui seront admises à la cotation et à la négociation sur Euronext, et des actions privilégiées d'une valeur nominale de 0,12 EUR (les "**Actions Privilégiées**"). En tant que mesure anti-OPA, l'assemblée générale des actionnaires de la Société autorisera le Conseil (tel que défini ci-dessous) avant la Date de la Première Négociation à accorder 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, après la Date de la Première Négociation.

Immédiatement avant la Date de Règlement (en supposant la conversion de tous les montants en vertu de la convention de prêt convertible datée du 20 avril 2021, conclue entre la Société et, entre autres, Invest-NL Capital N.V., LSP V Coöperatieve U.A., Stichting Depositary INKEF Investment Fund Gimv Investments, Wellington Partners Nominee Ltd. et Olympic Investments Inc. (la "**Convention de Prêt Convertible**") au point médian de la fourchette du prix de l'offre par Action Offerte (le "**Prix de l'Offre**"), les détenteurs d'Actions Ordinaires suivants (chacun étant un "**Actionnaire**") détiendront directement ou indirectement une participation substantielle (*substantiële deelneming*, c'est-à-dire une participation d'au moins 3% du capital social ou des droits de vote dans la Société) : (i) LSP V Coöperatieve U.A., (ii) Stichting Depositary INKEF Investment Fund, (iii) Wellington Partners Nominee Ltd., (iv) Gimv Investments H&C Netherlands 2016 B.V., (v) G-Therapeutics Founders S.a.r.l, (vi) Stichting G-Therapeutics Participaties, (vii) G-Therapeutics Participaties B.V., (viii) NRT Holdings LLC, et (ix) InvestNL.

À compter de la Date de la Première Négociation, la Société disposera 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 sera l'Administrateur Exécutif, et Jan Øhrstrøm, Roel Bulthuis, Fredericus Colen, Grégoire Courtine, Ian Curtis, John de Koning, Regina Hodits et Patrick Van Beneden, les Administrateurs Non Exécutifs. Le commissaire indépendant de la Société est Ernst & Young Accountants LLP ("EY").

Quelles sont les informations financières clés concernant l'émetteur?

États financiers consolidés à usage spécifique au 31 décembre 2020

Les tableaux suivants présentent les informations provenant des états financiers consolidés à usage spécifique au 31 décembre 2020 et pour l'exercice clos à cette date, y compris les informations comparatives au 31 décembre 2019 et 2018, et pour les exercices clos à cette date, qui ont été préparés conformément aux International Financial Reporting Standards tels qu'adoptés par l'Union européenne ("IFRS", et les "États Financiers"). EY a vérifié les États financiers et a émis un rapport d'audit indépendant sans réserve sur ceux-ci, avec un paragraphe d'observation relatif à la nature spécifique des États Financiers divulgués dans la Note 2 des États Financiers et à la restriction d'utilisation et un paragraphe d'observation relatif à l'incertitude matérielle concernant l'hypothèse de continuité d'exploitation divulguée dans la Note 4 des États Financiers. L'opinion de l'auditeur n'est pas modifiée en ce qui concerne ces questions :

Accent mis sur l'usage spécifique et la restriction d'utilisation

Nous attirons l'attention sur la Note 2 décrit l'objet particulier des états financiers consolidés à usage spécifique. Les états financiers consolidés à usage spécifique ne représentent pas les états financiers de ONWARD Medical B.V. conformément à la section 2:361 du Code civil néerlandais et à ses statuts et sont préparés dans le but d'être inclus dans le prospectus afin que ONWARD Medical B.V. se conforme aux exigences en matière d'informations financières historiques prévues par le Règlement (UE) 2017/1129 ou en vertu de celui-ci. Par conséquent, les états financiers consolidés à usage spécifique peuvent ne pas convenir à un autre usage. Le rapport de notre commissaire indépendant est requis par le Règlement Délégué (UE) 2019/980 de la Commission et est émis dans le but de se conformer à ce Règlement Délégué. Par conséquent, le rapport du commissaire de la Société ne doit pas être utilisé à d'autres fins.

Incertitude significative concernant l'hypothèse de continuité d'exploitation

Nous attirons l'attention sur la Note 4, Continuité du Groupe dans les états financiers consolidés à usage spécifique indique que la trésorerie de la Société serait négative au 30 septembre 2022 sur la base des hypothèses formulées par le Conseil concernant les entrées et sorties de trésorerie prévues au cours des 12 prochains mois. Ces prévisions ne tiennent pas compte des alternatives de financement actuellement envisagées par le Conseil. Dans ce contexte, le Conseil est conscient que la continuité des opérations de la Société dépend de sa capacité à obtenir ces nouvelles sources de financement et qu'il existe des incertitudes importantes à cet égard. Veuillez noter que le succès à long terme de la société est subordonné à l'obtention de l'approbation de la FDA et de la marque CE de ses produits. Ces conditions indiquent l'existence d'une incertitude significative qui peut jeter un doute important sur la capacité de la Société à poursuivre son activité en continuité. Nous attirons l'attention sur ces divulgations.

Notre opinion n'est pas modifiée en ce qui concerne ces questions.

États financiers intermédiaires consolidés condensés non vérifiés au 30 juin 2021

Les tableaux suivants présentent en outre des informations issues des états financiers intermédiaires consolidés condensés non vérifiés au 30 juin 2021 et pour le semestre clos à cette date ont été préparés conformément à la norme IAS 34 Interim Financial Reporting (les "États Financiers Intermédiaires"). Les États Financiers Intermédiaires ont été examinés par EY qui a émis un rapport d'examen indépendant sans réserve sur ceux-ci, y compris un paragraphe d'observation sur l'incertitude significative concernant l'hypothèse de la continuité de l'exploitation présentée à la Note 3 des États Financiers Intermédiaires et un paragraphe d'observation indiquant que les informations financières intermédiaires consolidées condensées, y compris les chiffres correspondants inclus dans les états intermédiaires consolidés résumés du compte de résultats, du résultat global, des variations des capitaux propres et des flux de trésorerie et les notes connexes, pour la période du 1er janvier 2020 au 30 juin 2020, n'ont pas été vérifiées ni examinées :

Incertitude significative concernant l'hypothèse de continuité d'exploitation.

Nous attirons l'attention sur la Note 3, Continuité du Groupe dans les états financiers intermédiaires consolidés condensés indique que la trésorerie de la Société serait négative au 30 septembre 2022 sur la base des hypothèses formulées par le Conseil concernant les entrées et sorties de trésorerie prévues au cours des douze prochains mois. Ces prévisions ne tiennent pas compte des alternatives de financement actuellement envisagées par le Conseil. Dans ce contexte, le Conseil est conscient que la continuité des opérations de la Société dépend de sa capacité à obtenir ces nouvelles sources de financement et qu'il existe des incertitudes importantes à cet égard. Veuillez noter que le succès à long terme de la Société est subordonné à l'obtention de l'approbation de la FDA et de la marque CE pour ses produits. Ces conditions indiquent l'existence d'une incertitude significative qui peut jeter un doute important sur la capacité de la société à poursuivre son activité. Nous attirons l'attention sur ces divulgations.

Chiffres correspondants ni vérifiés ni révisés

Nous n'avons pas vérifié ni examiné les états financiers intermédiaires consolidés condensés pour l'exercice du 1er janvier 2020 au 30 juin 2020. Par conséquent, Nous n'avons pas vérifié ni examiné les chiffres correspondants inclus dans les états intermédiaires consolidés condensés du compte de résultats, du résultat global, des variations des capitaux propres et des flux de trésorerie et les notes connexes.

États consolidés condensés du compte de résultats

	Vérfié			Non vérifié	
	Pour l'exercice clos au 31 décembre			Pour le semestre clos au 30 juin	
	2020	2019	2018	2021	2020
<i>(en milliers d'€)</i>					
Subventions	800	554	474	586	211
Total des Revenus et Autres Revenus	800	554	474	586	211
Frais scientifiques	(1.123)	(313)	(586)	(569)	(542)
Frais de recherche et de développement	(5.823)	(5.356)	(4.722)	(3.280)	(2.804)
Frais cliniques et réglementaires	(2.770)	(1.239)	(654)	(1.944)	(1.232)
Frais de marketing et d'accès au marché	(394)	(261)	(98)	(353)	(167)
Frais de brevet et dépenses connexes	(1.186)	(525)	(455)	(786)	(455)
Frais généraux et administratifs	(5.016)	(3.632)	(2.364)	(3.478)	(1.691)
Total des frais d'exploitation	(16.312)	(11.326)	(8.879)	(10.410)	(6.891)
Perte d'exploitation pour l'exercice	(15.512)	(10.772)	(8.405)	(9.824)	(6.680)

Produits financiers	-	6	3	-	-
Charges financières	(4.482)	(2.678)	(1.492)	(2.931)	(2.096)
Perte de l'exercice avant impôts	(19.994)	(13.444)	(9.894)	(12.755)	(8.776)
Charges d'impôts sur le revenu	(20)	(39)	(18)	(16)	(28)
Perte nette pour l'exercice	(20.014)	(13.483)	(9.912)	(12.771)	(8.804)

État consolidé condensé de la situation financière

(en milliers d'€)	Vérfié			Non vérifié
	2020	Au 31 décembre 2019	2018	Au 30 juin 2021
ACTIF				
Immobilisations incorporelles	6.825	7.382	25	6.745
Immobilisations corporelles	248	215	179	222
Droit d'utilisation d'actifs	149	254	360	96
Actifs immobilisés	7.222	7.851	564	7.063
Créances d'impôts indirects	93	131	190	176
Créance sur les parties liées	57	51	49	58
Autres actifs circulants	436	183	92	463
Trésorerie et équivalents de trésorerie	6.382	15.129	8.665	25.894
Actifs circulants	6.968	15.494	8.996	26.591
Total de l'actif	14.190	23.345	9.560	33.654
CAPITAUX PROPRES ET PASSIF				
Fonds propres et réserves				
Capitaux propres	-	-	-	-
Prime d'émission	3.083	3.083	83	3.083
Autres réserves	18.465	15.217	9.117	20.473
Autres éléments du résultat global	(710)	(304)	(33)	(772)
Résultats non distribués	(52.933)	(32.919)	(19.436)	(65.704)
Total des capitaux propres attribuables aux actionnaires	(32.095)	(14.923)	(10.269)	(42.920)
PASSIF				
Emprunts portant intérêt	41.817	33.479	17.144	69.311
<u>Impôts différés</u>	1.343	1.448	-	1.327
Autres dettes financières	-	-	-	2.480
Dettes de location	61	198	324	-
Avantages postérieurs à l'emploi	399	429	356	550
Passifs immobilisés	43.620	35.554	17.824	73.668
Dettes d'impôts sur le revenu	27	39	11	44
Dettes de location	137	126	95	130
Dettes commerciales	911	1.306	852	1.007
Autres dettes	1.590	1.243	1.047	1.725
Passifs Courants	2.665	2.714	2.005	2.906
Total des Fonds Propres et du Passif	14.190	23.345	9.560	33.654

Etats consolidés condensés des Flux de Trésorerie

(en milliers d'€)	Vérfié			Non vérifié	
	2020	2019	2018	Pour le semestre clos au 30 juin 2021	2020
FLUX DE TRÉSorerIE PROVENANT DES ACTIVITÉS D'EXPLOITATION					
Perte de l'exercice avant impôts	(19.994)	(13.444)	(9.894)	(12.755)	(8.776)

Corrigé pour :					
Amortissement et dépréciation des immobilisations corporelles et des droits d'utilisation d'actifs	271	229	234	124	123
Charges liées aux transactions de paiements en actions	2.700	289	361	2.007	558
Avantages postérieurs à l'emploi	(5)	(105)	(4)	169	(2)
Coûts financiers nets	4.482	2.672	1.489	2.931	2.096
Autres éléments non décaissés	(7)	-	-	(14)	(17)
Variations du fonds de roulement :					
Augmentation (-)/Diminution (+) des créances commerciales et autres créances	(221)	(24)	(118)	(112)	82
Augmentation (-)/Diminution (+) des dettes commerciales et autres dettes	(48)	575	852	230	(630)
Intérêts reçus	-	1	-	-	-
Intérêts payés	(37)	(20)	(26)	(23)	(7)
Frais bancaires payés	(11)	(7)	(5)	(6)	(5)
Impôt sur le revenu payé	(31)	(11)	(45)	-	(31)
Trésorerie nette générée / (utilisée) par les activités opérationnelles	(12.901)	(9.845)	(7.156)	(7.449)	(6.609)
FLUX DE TRÉSORERIE PROVENANT DES ACTIVITES D'INVESTISSEMENT					
Investissements dans des actifs immobilisés	(173)	(124)	(103)	(45)	(112)
Acquisition d'une filiale, nette de la trésorerie acquise	-	25	-	-	-
Trésorerie nette générée/(utilisée) par les activités d'investissement	(173)	(99)	(103)	(45)	(112)
FLUX DE TRÉSORERIE PROVENANT DES ACTIVITÉS DE FINANCEMENT					
Produits des emprunts portant intérêts	3.946	11.743	5.489	27.106	553
Paiement de la partie principale des dettes de location	(126)	(95)	(49)	(68)	(62)
Produit de l'émission d'actions	548	4.755	3.207	-	-
Trésorerie nette générée/(utilisée) par les activités de financement	4.368	16.403	8.647	27.038	491
Variation nette de la trésorerie et des équivalents de trésorerie	(8.706)	6.459	1.388	19.544	(6.231)
Effet des taux de change sur la trésorerie et les équivalents de trésorerie	(41)	5	3	(32)	(12)
Trésorerie et équivalents de trésorerie au 1er janvier	15.129	8.665	7.274	6.382	15.129
Trésorerie et équivalents de trésorerie à la fin de l'exercice	6.382	15.129	8.665	25.894	8.886

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

Déclaration sur le Fonds de Roulement

À la date du présent Prospectus, la Société est d'avis qu'elle ne dispose pas 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. Dans le cas où la Société ne serait pas en mesure d'attirer de nouveaux fonds (au-delà de sa trésorerie et de ses équivalents de trésorerie existants), elle prévoit d'épuiser son fonds de roulement d'ici fin septembre 2022. Dans le cas où la Société ne serait pas en mesure d'attirer de tels fonds supplémentaires et où la Société maintiendrait sa stratégie et ses activités de développement actuelles, son fonds de roulement manquant sur 12 mois devrait être d'environ 1,5 à 2 millions d'EUR à la fin du mois de septembre 2022.

La Société a décidé de lancer l'Offre afin de garantir un financement adéquat pour les besoins en fonds de roulement pour une période d'au moins 12 mois. Bien que le produit net de l'émission des Actions Offertes permette à la Société de financer ses opérations pendant au moins les 12 prochains mois, rien ne garantit que la Société disposera d'un fonds de roulement suffisant pour financer ses opérations à l'avenir.

Dans l'éventualité où l'Offre serait retirée, la Société serait tenue de réunir des fonds supplémentaires afin de répondre aux exigences de financement de l'essai ARC^{IM} sur la pression Artérielle et ARC^{IM} sur la Mobilité, des activités de recherche et de développement et d'une partie de la stratégie de marketing et des efforts de commercialisation. Ce financement supplémentaire pourrait être une combinaison de financement externe (non dilutif) et de financement supplémentaire par les actionnaires, pour lequel la Société devrait entamer des discussions de financement après la date du Prospectus. La probabilité de succès de ces discussions n'est pas claire et, si la Société ne parvenait pas à lever des fonds supplémentaires pour un montant suffisant ou pas du tout, elle ne serait pas en mesure de financer ses activités et ses initiatives comme prévu actuellement.

Quels sont les risques clés 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 26 du Prospectus avant de prendre la décision d'investir dans les Actions Offertes.

- 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 ;
- 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, y compris son essai clinique pivot Up-LIFT pour l'ARC^{EX}, 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 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 ;
- Une partie des actifs de la Société, y compris la propriété intellectuelle, est mise en gage auprès du Rijksdienst voor Ondernemend Nederland (RVO, partie du Ministère Néerlandais des Affaires Economiques), et la réalisation de ce gage pourrait nuire considérablement au développement et aux opérations futures de la Société ; 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 important 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 de la Société d'une valeur nominale de EUR 0,12 chacune. Les Actions Ordinaires sont exprimées et seront négociées en euros sur Euronext. La Société offrira jusqu'à 5.900.000 Actions Ordinaires (ci-après dénommées les "**Actions Offertes**"), ce qui exclut, sauf indication contraire du contexte, toute Action Ordinaire émise en vertu de l'Option d'Augmentation ou de l'Option de Surallocation (telles que définies ci-dessous). Le nombre total d'Actions Offertes peut être augmenté jusqu'à 20% du nombre total d'Actions Offertes (ou jusqu'à 1.180.000 Actions Ordinaires) initialement offertes à un nombre de 7.080.000 Actions Ordinaires ("**Option d'Augmentation**"). En supposant l'exercice intégral de l'Option de Surallocation et de l'Option d'Augmentation, les Actions Offertes constitueront jusqu'à 25 % du capital social de la Société. L'ISIN des Actions Ordinaires est NL0015000HT4.

Les Actions Ordinaires seront de rang égal entre elles (*pari passu*), 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 tels qu'ils seront rédigés immédiatement après la transformation en société anonyme à la Date de la Première Négociation (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*) ("**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 aux Actions Ordinaires, sous réserve d'exceptions (c'est-à-dire en cas d'émission d'Actions Ordinaires au profit des employés de la Société ou d'une Société du Groupe, contre un apport autre qu'en espèces ou suite à l'exercice d'un droit de souscription d'Actions Ordinaires précédemment acquis), chaque Actionnaire dispose 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 peuvent être limités ou exclus par une résolution de l'Assemblée Générale, au plus tard à la Date de la Première Négociation, autorisant le Conseil à émettre des Actions Ordinaires ou à accorder des droits de souscription aux Actions Ordinaires pendant une période de 18 mois suivant la Date de la Première Négociation et à limiter ou exclure les droits de préemption relatifs à ces Actions ordinaires et droits. Cette autorisation

du Conseil sera limitée : (i) à un maximum de 10 % des Actions Ordinaires émises et en circulation à la clôture à la Date de Règlement (telle que définie ci-dessous) ou, dans le cas où l'Option de Surallocation est exercée après la Date de Règlement, à la clôture à la date de l'émission des Actions de Surallocation à des fins générales ; et, en outre, (ii) à un maximum de 10 % des Actions Ordinaires émises et en circulation à la Date de Règlement ou, dans le cas où l'Option de Surallocation est exercée après la Date de Règlement, à la clôture à la Date de Règlement des Actions de Surallocation, dans le cadre d'OPA, fusions, scissions et alliances stratégiques. Ces désignations peuvent être révoquées à tout moment par l'Assemblée Générale. Ces autorisations générales accordées au Conseil expirent après une période de 18 mois suivant la Date de la Première Négociation.

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 et la Belgique, 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 et la Belgique 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 ?

Avant l'Offre, il n'y avait pas de marché public pour les Actions Ordinaires. Une demande de cotation de toutes les Actions Ordinaires sous le symbole "ONWD" a été déposée auprès de Euronext Brussels (cotation primaire) et d'Euronext Amsterdam (cotation secondaire). Sous réserve d'une prolongation du calendrier de l'Offre, la négociation des Actions Ordinaires sur Euronext devrait commencer, sur une base "as-if-when-issued-and/or-delivered", à la Date de la Première Négociation ou aux alentours de cette date.

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 26 du présent Prospectus avant de prendre la décision d'investir dans les Actions Offertes :

- 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 ;

- Le fait qu'aucun montant minimum ne soit fixé pour l'Offre peut affecter le plan d'investissement de la Société et la liquidité des Actions ; et

- Certains actionnaires importants de la Société après l'Offre 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'Offre

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

L'Offre. L'offre des Actions Offertes (l' "**Offre**") consiste en (i) une offre publique initiale aux investisseurs particuliers en Belgique et une offre aux investisseurs qualifiés ("**Investisseurs Qualifiés**") au sens du Règlement Prospectus, (ii) un placement privé dans (a) l'Espace économique européen ("**EEE**") (autre qu'en Belgique) auprès de certains Investisseurs Qualifiés, (b) au Royaume-Uni auprès d'Investisseurs qualifiés au sens de l'article 2(e) de la version britannique du Règlement (UE) 2017/1129 tel que modifié par le Prospectus (Amendment etc.) (EU Exit) Regulations 2019, qui fait partie du droit britannique en vertu de la loi de 2018 de (retrait de) l'Union européenne, qui sont également des personnes ayant une expérience professionnelle en matière d'investissements relevant de la définition des "professionnels de l'investissement" de l'Article 19(5) du Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, tel que modifié (l' "**Ordonnance**"), ou des sociétés à valeur nette élevée, des associations non constituées en société et d'autres personnes relevant de l'Article 49(2)(A) à (D) de l'Ordonnance ou d'autres personnes auxquelles l'Offre peut être légalement communiquée, et (c) en Suisse, à des investisseurs qualifiés de "clients professionnels" au sens de l'Article 4 de la Loi Suisse sur les Services Financiers (*Finanzdienstleistungsgesetz*) du 15 juin 2018, telle que modifiée (la "**FinSA**") et (iii) un placement privé aux États-Unis d'Amérique (les "**États-Unis**" ou "**US**") à des personnes dont on peut raisonnablement penser qu'elles sont des "acheteurs institutionnels qualifiés" ("**QIBs**") tels que définis dans, et conformément à la Rule 144A (la "**Rule 144A**") du US Securities Act de 1933, tel que modifié (le "**US Securities Act**"), ou conformément à une autre exemption de l'obligation d'enregistrement prévue par le US Securities Act et les lois étatiques sur les valeurs mobilières applicables, ou dans le cadre d'une transaction non soumise à cette obligation. L'Offre en dehors des États-Unis sera réalisée conformément à la Regulation S (la "**Regulation S**") du US Securities Act (ces investisseurs qualifiés, professionnels et/ou institutionnels, ainsi que les QIBs, sont collectivement désignés comme les "**Investisseurs Institutionnels**").

Option de Surallocation. La Société accordera aux Joint Global Coordinators une option (l' "**Option de Surallocation**"), exerçable dans les 30 jours calendriers après la Date de la Première Négociation, en vertu de laquelle Belfius Banque NV/SA en sa qualité de Gestionnaire de Stabilisation (le "**Gestionnaire de Stabilisation**"), agissant pour le compte de Banque Degroof Petercam SA/NV et Belfius Banque NV/SA agissant en leur qualité de *Joint Global Coordinators* dans le cadre de l'Offre (en cette et tout autre qualité, les "**Joint Global Coordinators**" et les "**Underwriters**"), peut exiger de la Société qu'elle émette et vende au Prix de l'Offre jusqu'à 885.000 Actions Ordinaires supplémentaires (ou 1.062.000 Actions Ordinaires additionnelles si l'Option d'Augmentation est entièrement exercée) (les "**Actions de Surallocation**"), comprenant jusqu'à 15 % du nombre total d'Actions Offertes vendues dans le cadre de l'Offre, afin de couvrir les surallocations ou les positions courtes, le cas échéant, dans le cadre de l'Offre ou de faciliter les opérations de stabilisation.

Période d'offre. Les investisseurs potentiels peuvent souscrire aux Actions Offertes au cours de la période commençant à 9h00, heure d'Europe centrale ("**CET**"), le 12 octobre 2021 et se terminant à 16h00 CET le 19 octobre 2021 (la "**Période d'Offre**") et les Investisseurs Particuliers potentiels (tels que définis ci-dessous) peuvent souscrire aux Actions Offertes au cours de la période commençant le 12 octobre

2021 et se terminant à 16h00 CET le 19 octobre 2021. Ce calendrier est susceptible d'être prolongé. Il n'y a pas de clôture anticipée de la Période d'offre pour les investisseurs particuliers.

Prix de l'offre et nombre d'Actions Offertes. Le Prix de l'Offre devrait se situer dans une fourchette de 11,75 EUR à 13,75 EUR par Action Offerte (la "**Fourchette de Prix de l'Offre**"). Le Prix de l'Offre et le nombre exact d'Actions Offertes seront déterminés sur la base d'un processus de book building auquel seuls les investisseurs institutionnels peuvent participer. La Fourchette de Prix de l'Offre est une fourchette de prix indicative. Le Prix de l'Offre, le nombre exact d'Actions Offertes à vendre et le nombre maximum d'Actions de Surallocation seront indiqués dans une déclaration de prix qui sera déposée auprès de l'AFM, soumise à la FSMA, et annoncée par un communiqué de presse qui sera publié sur le site internet de la Société. La Société, après consultation des Joint Global Coordinators, se réserve le droit de modifier la Fourchette de Prix de l'Offre, de diminuer le nombre d'Actions Offertes ou d'augmenter le nombre d'Actions Offertes avant l'allocation des Actions Offertes ("**Allocation**"). Si la limite inférieure de la fourchette de prix est réduite ou si le Prix de l'Offre est fixé en dessous de la limite inférieure de la fourchette de prix, ou si la limite supérieure de la fourchette de prix est augmentée ou si le Prix de l'Offre est fixé au-dessus de la limite supérieure de la fourchette de prix, cela sera publié dans un supplément au Prospectus. En cas de publication d'un supplément au Prospectus, et si légalement requis, les investisseurs auront le droit de retirer leurs ordres passés avant la publication du supplément. Ce retrait doit intervenir dans le délai fixé dans le supplément (qui ne doit pas être inférieur à trois jours ouvrables après la publication du supplément). En cas de modification du nombre d'Actions Offertes, les références aux Actions Offertes dans le Prospectus doivent être lues comme faisant référence au nombre modifié d'Actions Offertes et les références aux Actions de Surallocation doivent être lues comme faisant référence au nombre modifié d'Actions de Surallocation.

Allocation. L'Allocation devrait avoir lieu après la fin de la Période d'Offre le ou vers le 20 octobre 2021, sous réserve de l'extension du calendrier de l'Offre. L'attribution aux investisseurs qui ont demandé à souscrire à des Actions Offertes sera déterminée par la Société en accord avec les Underwriters (tels que définis ci-dessous), et une entière discrétion sera exercée quant à l'allocation ou non et à la manière d'allouer les Actions Offertes. Il n'y a pas de nombre maximum ou minimum d'Actions Offertes pour lesquelles les investisseurs potentiels peuvent souscrire et les (demandes de) souscriptions multiples sont autorisées (sauf pour les investisseurs particuliers – voir ci-dessous). Dans le cas où l'Offre serait sursouscrite, les investisseurs pourraient recevoir moins d'Actions Offertes que celles auxquelles ils ont demandé de souscrire. En cas de sursouscription de l'Offre, les Engagements de Souscription des Investisseurs Fondamentaux (Cornerstone Investors) en espèces peuvent être réduits en ligne avec les principes d'allocation qui s'appliqueront aux autres investisseurs qui souscriront à l'Offre, alors que les Engagements de Souscription Fondamentaux et les Engagements de Souscription des Prêteurs ne seront pas réduits mais entièrement alloués.

Investisseurs Particuliers. Les Investisseurs Particuliers doivent indiquer dans leurs ordres de souscription le nombre d'Actions Offertes qu'ils s'engagent à souscrire. Chaque demande doit être exprimée en nombre d'Actions Offertes sans indication de prix et sera considérée comme placée au Prix de l'Offre. Une seule demande par Investisseur Particulier sera acceptée. Si les Underwriters déterminent, ou ont des raisons de croire, qu'un même Investisseur Particulier a soumis plusieurs demandes de souscription, par le biais d'un ou plusieurs intermédiaires, ils se réservent le droit de ne pas tenir compte de ces demandes de souscription. Il n'y a pas de montant ou de nombre minimum ou maximum d'Actions Offertes pouvant être souscrites dans une demande de souscription.

Les ordres de souscription sont sujets à une éventuelle réduction. Les Investisseurs Particuliers en Belgique ne peuvent acquérir les Actions Offertes qu'au Prix de l'Offre et sont légalement tenus d'acquérir le nombre d'Actions Offertes indiqué dans leur ordre de souscription au Prix de l'Offre, sauf (i) si l'Offre a été retirée, auquel cas les demandes de souscription deviendront nulles et non avenues, ou (ii) en cas de publication d'un supplément au Prospectus, et si légalement requis, auquel cas les Investisseurs Particuliers auront le droit de retirer leurs ordres placés avant la publication du supplément, exerçable dans un délai d'au moins trois jours ouvrables après la publication du supplément.

Paiement. Le paiement et la livraison des Actions Offertes auront lieu à la date de règlement, qui devrait être le 22 octobre 2021 (la "**Date de Règlement**"). Les taxes et les frais, le cas échéant, doivent être pris en charge par l'investisseur. Les investisseurs doivent payer le Prix de l'Offre en fonds immédiatement disponibles en totalité en euros au plus tard à la Date de Règlement.

Livraison des Actions. Les Actions Offertes seront livrées sous forme d'inscription en compte par l'intermédiaire des services d'Euroclear Nederland. Si le Règlement n'a pas lieu à la Date de Règlement comme prévu ou pas du tout, l'Offre peut être retirée, auquel cas toutes les souscriptions d'Actions Offertes ne seront pas prises en compte, toutes les attributions effectuées seront réputées ne pas avoir été faites et tous les paiements de souscription effectués seront restitués sans intérêt ni autre compensation. Toute transaction d'Actions Ordinaires avant le Règlement est effectuée au seul risque des parties concernées.

Pré-engagements. LSP V Coöperatieve U.A., Stichting Depositary INKEF Investment Fund, Gimv Investments H&C Netherlands 2016 B.V. et Wellington Partners Nominee Ltd. se sont engagés irrévocablement et seulement sous la condition de la clôture de l'Offre, à souscrire aux Actions Offertes de l'Offre pour un montant total représentant jusqu'à 15% des Actions Offertes, cet engagement étant plafonné à une taille d'offre de 100 millions EUR, auquel cas les Engagements de Souscription des Actionnaires seront de 15 millions EUR.

Dave Marver, Jan Øhrstrøm, John Murphy, Hendrik Lambert et un groupe de plus petits prêteurs qui ne remplissent pas les conditions requises en matière de divulgation en vertu du Règlement Prospectus se sont engagés de manière irrévocable et sous réserve uniquement de la clôture de l'Offre, à souscrire à des Actions Offertes dans le cadre de l'Offre pour un montant total représentant jusqu'à 2,4% des Actions Offertes dans le cadre de l'Offre au Prix de l'Offre.

AXA Investment Managers Paris, Öhman Fonder, Belfius Insurance et un plus petit investisseur qui ne remplit pas les conditions requises en matière de divulgation en vertu du Règlement Prospectus, ensemble les Investisseurs Fondamentaux, se sont engagés irrévocablement

et seulement sous condition de la clôture de l'Offre à souscrire des Actions Offertes de l'Offre pour un montant total de 16,2 millions EUR au Prix de l'Offre.

Lock-up. Les Administrateurs, les Managers, les Actionnaires Actuels de la Société (en ce compris à cette fin au moins les prêteurs représentant une majorité du montant en principal prêté à la Société en vertu de la Convention de Prêt Convertible) ont conclu un engagement de "lock-up" avec la Société en ce qui concerne leurs Actions dans la Société détenues immédiatement avant l'Offre.

Souscripteurs. La Banque Degroof Petercam SA/NV et Belfius Banque NV/SA agissent en tant que Joint Global Coordinators pour l'Offre (en cette qualité et en toute autre qualité, les "**Joint Global Coordinators**" et les "**Underwriters**").

Coordinateur pour les Particuliers. Belfius Banque SA est le coordinateur pour les investisseurs particuliers en ce qui concerne l'Allocation Préférentielle pour les Particuliers.

Agent de Cotation : La Banque Degroof Petercam SA/NV est l'agent de cotation pour l'Admission.

Gestionnaire de la Stabilisation. Belfius Banque SA est le gestionnaire de stabilisation pour les Actions Ordinaires sur Euronext.

Calendrier. Sous réserve d'une extension du calendrier de l'Offre, ou d'un retrait de celle-ci, le calendrier ci-dessous présente certaines dates clés prévues pour l'Offre.

Événement	Date Prévue	Heure CET
Début prévu de la Période d'Offre	12 octobre 2021	9:00
Fin prévue de la Période d'Offre pour les Investisseurs Particuliers.....	19 octobre 2021	16:00
Fin prévue de la Période d'Offre pour les Investisseurs Institutionnels	19 octobre 2021	16:00
Publication prévue du Prix de l'Offre et des résultats de l'Offre et communication des allocations	20 octobre 2021	
Date prévue de Cotation (cotation et début de la négociation sur une base "if-and-when-issued-and/or-delivered"	21 octobre 2021	
.....		
Date prévue de Clôture (paiement, règlement et livraison des Actions Offertes).....	22 octobre 2021	
.....		
Dernière date d'exercice prévue pour l'Option de Surallocation.....	20 novembre 2021	

La Société, en consultation avec les Joint Global Coordinators, se réserve le droit de prolonger la Période d'Offre. En cas d'extension de la Période d'Offre, ces dates seront modifiées et publiées par le biais d'un communiqué de presse, qui sera également publié sur le site internet de la Société et (si nécessaire) dans un supplément au Prospectus soumis à l'approbation de l'AFM.

Toute prolongation du calendrier de l'Offre sera publiée dans un communiqué de presse au moins trois heures avant la fin de la Période d'Offre initiale, à condition que toute prolongation soit d'au moins un jour ouvrable complet. En tout état de cause, la Période d'Offre sera d'au moins six jours ouvrables.

Dilution. L'émission des Actions Offertes entraînera une augmentation du capital social de la Société (en tenant compte des Actions émises lors de la conversion de la Convention de Prêt Convertible au Prix de l'Offre moins 25 % et de l'émission d'actions à l'EPFL et de la réalisation du *Reverse Stock Split*, augmentant d'environ 25 %. Par conséquent, les Actionnaires Actuels subiront une dilution immédiate du fait de l'Offre d'environ 0,75 %, en supposant le placement total des Actions Offertes (en ce compris l'exercice intégral de l'Option d'Augmentation et de l'Option de Surallocation) et aucune participation des Actionnaires Actuels à l'Offre.

Frais estimés. En supposant que l'Offre soit entièrement souscrite et que le Prix de l'Offre se situe au milieu de la Fourchette de Prix de l'Offre (à la date du Prospectus) les dépenses, commissions et taxes estimées payables par la Société en rapport avec l'Offre s'élèvent à environ 5,5 millions EUR. Aucune dépense n'a été ou ne sera facturée aux investisseurs par la Société dans le cadre de l'Offre. En supposant le placement du nombre maximal d'Actions Offertes (y compris l'exercice intégral de l'Option d'Augmentation), que le Prix de l'Offre se situe au point médian de la Fourchette de Prix et que l'Option de Surallocation est exercée en totalité, les commissions et dépenses de souscription s'élèveront à environ 4,4 millions EUR.

Pourquoi ce prospectus est-il établi ?

Raisons de l'offre et utilisation du produit. La Société estime que l'Admission et l'Offre constituent une prochaine étape logique de son développement et que son calendrier est approprié, compte tenu du profil actuel et du niveau de maturité de la Société.

La Société estime que l'Offre lui apportera un soutien financier supplémentaire (i) pour le développement de produits et les activités de recherche et développement, (ii) pour la réalisation d'essais cliniques et (iii) pour le développement commercial global. L'Admission permet en outre à la Société d'accéder aux marchés de capitaux, qu'elle pourra utiliser pour soutenir et développer la croissance de la Société et pour financer de nouvelles recherches et/ou des opérations stratégiques de fusion et d'acquisition, lorsqu'elles seront disponibles.

La Société s'attend à ce que l'Admission et l'Offre créent une nouvelle base d'actionnaires à long terme ainsi que des liquidités pour les Actionnaires existants et futurs. La Société a l'intention de créer un flottant significatif dans les Actions Ordinaires lors de l'Admission.

Underwriting Agreement. La Société et les Underwriters ont conclu une convention de prise ferme concernant l'Offre (l'"**Underwriting Agreement**"). L'Underwriting Agreement est conditionnée, entre autres, à la conclusion d'un accord sur le prix entre la Société et les Underwriters fixant le prix de l'Offre par Action Offerte. Aux termes et sous réserve des conditions énoncées dans l'Underwriting Agreement, les Underwriters s'engagent individuellement (et non conjointement, ni conjointement et solidairement) à souscrire à la totalité des Actions Offertes, à l'exception des Actions Offertes souscrites par les Investisseurs Participants en vertu d'un Engagement de Souscription (les "**Actions Souscrites**"), en leur propre nom mais pour le compte des souscripteurs concernés de l'Offre auxquels ces Actions Souscrites ont été attribuées. Les Underwriters n'ont aucune obligation de souscrire à des Actions Souscrites avant la signature de la convention de fixation du prix. Dans le cas où aucune convention de fixation de prix n'est signée ou si l'Underwriting Agreement est résilié à l'égard de toutes les parties, un supplément au Prospectus sera publié. Après la publication du supplément, les souscriptions aux Actions Offertes seront automatiquement annulées et retirées, et les souscripteurs ne pourront prétendre à la livraison des Actions Offertes ou à une quelconque compensation.

Conflits d'intérêts les plus importants. À la date du Prospectus, les seules relations contractuelles entre les Underwriters respectifs et la Société concernent la présente Offre. Un ou plusieurs des Underwriters et/ou leurs affiliés respectifs peuvent à l'avenir, de temps à autre, s'engager dans des activités de banque commerciale, de banque d'investissement et de conseil financier et des activités auxiliaires dans le cours normal de leurs affaires avec la Société ou toute partie liée à celle-ci, à l'égard desquelles ils peuvent, à l'avenir, recevoir une rémunération, des honoraires et/ou une commission habituels. En outre, les Souscripteurs et/ou leurs affiliés peuvent, dans le cadre de leurs activités ordinaires, détenir des valeurs mobilières de la Société à des fins d'investissement. Belfius Insurance NV/SA, un membre du groupe Belfius, a conclu une convention de souscription (*Subscription Agreement*) avec la Société pour un montant de 5 millions EUR avec une allocation garantie (voir aussi "*Pré-engagements*"). Dans ces relations, les parties concernées peuvent ne pas être obligées de prendre en considération les intérêts des investisseurs. En ce qui concerne ce qui précède, le partage d'informations est généralement limité pour

des raisons de confidentialité par des procédures internes ou par des règles et règlements. En raison de leur action dans les rôles décrits ci-dessus, les Underwriters peuvent avoir des intérêts qui peuvent ne pas être alignés, ou qui pourraient potentiellement entrer en conflit avec les intérêts des investisseurs (potentiels), ou avec les intérêts de la Société. Les investisseurs doivent être conscients du fait que les Underwriters, lorsqu'ils agissent en tant que prêteurs de l'Émetteur (ou lorsqu'ils agissent en toute autre qualité), n'ont aucune obligation fiduciaire ou autre obligation de quelque nature que ce soit vis-à-vis des investisseurs et qu'ils n'ont aucune obligation de prendre en compte les intérêts des investisseurs.

RISK FACTORS

Before investing in the Offer Shares, prospective investors should carefully consider the risks and uncertainties 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 Offer 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") (each a "Group Company", and together with the Company, the "Group") may face a number of these risks described below simultaneously, and one or more risks described below may be interdependent. 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 and uncertainties described below are the material risks and uncertainties concerning the Group's business and the Offer Shares, they are not the only risks and uncertainties relating to the Group and the Offer 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 Offer 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 Offer Shares. Furthermore, before making an investment decision with respect to any Offer 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 Offer 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 activities prior to 2020 have consisted of developing its technology and conducting preclinical studies and clinical trials. As a result, the Company has recorded net losses of EUR 12.8 million for the six-month period ended 30 June, 2021 and EUR 20.0 million, EUR 13.5 million, and EUR 9.9 million for the years ended 31 December 2020, 2019, and 2018, respectively (totaling EUR 56.2 million over this aggregate period). As of 30 June 2021, the Company's retained earnings balance amounts to negative EUR 65.7 million. To date, the Company has financed its operations primarily through equity financings and interest-bearing loans financing.

The current or future clinical trials of any of its current or future investigational devices are, and the manufacturing and marketing of any such investigational devices will be, subject to extensive and rigorous review and regulation by the FDA and other government authorities in the United States and in other countries where the Company intends to test and, if cleared or approved, market such investigational devices. The Company expects that its operating expenses will continue to increase as it (i) continues research and development activities for its ARC^{IM} and ARC^{EX} technology platforms and related technologies, (ii) seeks US Food and Drug Administration ("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 2 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 does not currently have sufficient working capital to fund its operations for at least the next 12 months following the date of this Prospectus.

Based on a working capital assessment, the Company expects that it will have a shortfall of approximately EUR 1.5 to EUR 2 million at the end of September 2022 in relation to its present working capital requirements. See *Capitalization and indebtedness* under *Working capital statement*. Although the net proceeds from the issue of the Offer Shares will allow the Company to fund its operations for at least the next 12 months, there is no assurance the Company will have sufficient working capital to fund its operations in the future.

In the event that the Offering is withdrawn, the Company would be required to raise additional funding in order to meet the funding requirements for the ARC^{IM} Blood pressure and ARC^{IM} Mobility trial, research and development activities and part of the marketing strategy and commercialization efforts.

Such additional funding could be a combination of (non-dilutive) external financing and further shareholders' financing, for which the Company would need to initiate financing discussions after the date of the Prospectus. The likelihood of success of such discussions is unclear and, if the Company would be unable to raise additional funding for a sufficient amount or at all, it would not be able to fund its activities and efforts as currently planned.

The Company may 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 the years 2018 to 2020 amounts to EUR 30.3 million, primarily due to its research and development activities and conducting clinical trials for its investigational devices. The Company's expenses will also 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, costs and expenses incidental to being a public company, and general operations. In addition, other unanticipated costs may arise.

As of 30 June 2021, the Company had cash and cash equivalents of EUR 25.9 million, and interest-bearing loans in the aggregate of EUR 69.3 million.

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 and applying for (i) de novo classification granting marketing authorization for ARC^{EX} for use in clinics, and subsequent to such de novo classification, 510(k) clearance is expected for ARC^{EX} for use in the home and (ii) 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 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 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.

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 the Covid-19 pandemic, 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 two companies with similar technology, Cosyma LTD and SpineX, Inc., both of which are pursuing similar indications to the Company and with similar technologies to ARC^{EX}. Though the Company believes its IP rights would prevent either Cosyma LTD and SpineX from being able to commercialize similar devices utilizing the Company's IP-protected waveform, there can be no guarantee that the Company will be able to enforce its IP rights. The outcome of any potential IP dispute 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 many 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, including its Up-LIFT pivotal clinical trial for ARC^{EX}, is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside its control, which could cause significant delays in the completion of such trials or may cause it to abandon one or more clinical trials.

The Company may encounter delays or difficulties in enrolling, or be unable to enroll, a sufficient number of patients to complete any of its clinical trials on its current timelines, or at all, and even once enrolled, it may be unable to retain a sufficient number of patients to complete any of its trials. For example, as a result of the COVID-19 pandemic, the Company had slower than expected enrollment for its Up-LIFT pivotal clinical trial for ARC^{EX}. 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 small 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 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.

The development, manufacture, and marketing of the Company's products are 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. Subsequent to obtaining such de novo classification, the Company intends to pursue additional regulatory clearances for ARC^{EX}, including use in the 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 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 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.

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 by physicians, physical therapists, occupational therapists, neurologists, and physiatrists who work in the rehabilitation clinic setting, functional neurosurgeons, patients, third-party payors such as health insurance companies, and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments, including therapeutic options offered by rehabilitation centers for people with spinal cord injury. Physicians, physical therapists, hospitals, and rehabilitation clinics will need to establish training and procedures to utilize and implement the ARC^{IM} and ARC^{EX} platforms, and there can be no assurance that these parties will adopt the use of these devices or develop sufficient training and procedures to properly utilize them. Market acceptance of, and demand for, any product that the Company may develop and commercialize will depend on many factors, both within and outside of its control. 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. Payors 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 loss of any members of senior management or key scientific personnel could harm its business and significantly delay or prevent the achievement of research, development, or business objectives. Competition for qualified employees and consultants is intense among medical device companies, and the loss of qualified employees or consultants, or an inability to attract, retain, and motivate additional highly skilled employees or consultants could hinder its ability to successfully develop marketable products.

The Company's future success also depends on its ability to identify, attract, hire, train, retain, and motivate other highly skilled scientific, technical, marketing, managerial, and financial personnel, as well as sales personnel once commercialization may begin. 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.

The Company relies on third-party suppliers and contract manufacturers, the most significant and strategic ones among which are Osypka and Oscor Inc., for the raw materials and components used in its ARC^{EX} and ARC^{IM} platforms and to manufacture and assemble its products. 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 72.8 full-time equivalents employed that includes both employees and contractors, including 36.7 working out of its headquarters location in Eindhoven, the Netherlands, 27.6 in Switzerland working out of its Lausanne office, and 8.5 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 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^{IM} 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 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 consumers, 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.

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 after the Offering.

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 has 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, recently 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. It is also possible that additional governmental action is taken to address the COVID-19 pandemic. 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. In December 2019, a novel strain of coronavirus, SARS-CoV-2, was identified in Wuhan, China. Since then, SARS-CoV-2, and the resulting disease, COVID-19, has spread to most countries around the globe. The COVID-19 pandemic has negatively impacted the Company's business, financial condition and results of operations by delaying first patient enrollment in its Up-LIFT Study from September 2020 to January 2021. Additionally, research and development of its ARC[™] System has been impacted by work-from-home requirements that have limited its ability to test and debug hardware and software systems, processes reliant on laboratory and other equipment housed in its facilities.

Numerous federal, state and local jurisdictions have imposed, and others in the future may impose, "shelter-in-place" orders, quarantines, executive orders and similar government orders and restrictions for their residents to control the spread of COVID-19. Other 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.

The extent to which the COVID-19 pandemic impacts the Company's business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity and spread of COVID-19 and the actions to contain COVID-19 or treat its impact. While the potential economic impact brought by and the duration of any pandemic, epidemic or outbreak of an infectious disease, including COVID-19, may be difficult to assess or predict, the widespread COVID-19 pandemic has resulted in, and may continue to result in, significant disruption of global financial markets, reducing the Company's ability to access capital, which could

in the future negatively affect its liquidity. For example, a planned financing that was originally scheduled to close in late 2020 was delayed when a lead investor unexpectedly withdrew in order to divert funds into portfolio companies needing cash infusions due to COVID-19. The Company subsequently completed a convertible note financing in April 2021 of a similar size. In addition, a recession or market correction resulting from the spread of an infectious disease, including COVID-19, could materially affect its business. Such economic recession could have a material adverse effect on its long-term business as hospitals curtail and reduce capital and overall spending. To the extent the COVID-19 pandemic 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, including its Up-LIFT pivotal clinical trial for ARC^{EX}, 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. 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 May 25, 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 January 31, 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 December 31, 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. 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 May 1, 2021, and low risk devices requiring registration later in 2021 and early 2022 (Class IIb and IIa devices from September 1, 2021 and Class I devices from January 1, 2022). European CE marks will continue to be recognized in UK until June 30, 2023, following which a UK Conformity Assessed ("UKCA") mark will be 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 UKNI mark (although devices bearing the CE UKNI marking will not be accepted on the EU market).

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, it 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 you 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 ARC^{EX} platform for hand/arm function, and in May 2020, granted a Breakthrough Device Designation for ARC^{IM} platforms 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.

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} and ARC^{IM}, 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[™] 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, such as based on information contained in its HDE periodic reports, that the HUD designation no longer applies to the device, 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[™] 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

Part of the Company's assets, including intellectual property is pledged to Rijksdienst voor Ondernemend Nederland (RvO, part of Dutch ministry of Economic Affairs), and the enforcement of such pledge could substantially harm the future development and operations of the Company.

The Company has secured a EUR 10 million deferred, risk-bearing 'innovation loan' from the Rijksdienst voor Ondernemend Nederland ("**RvO**"), part of Dutch ministry of Economic Affairs, to support the project "Spinal Implant with Motion-feedback for ParapLEgics" ("**Simple**"). In a letter dated 2 February 2021 from the RVO the date to satisfy the last milestone of the project was set at 30 September 2023.

The first repayment under this loan is not due before 1 January 2026 and the loan and the accrued interest need to be fully repaid by latest 1 July 2027. The loan is secured by a pledge on all material and immaterial assets of the Company, including intellectual property, that has been co-financed with this loan. Should the Company default on repayment of the loan, RVO 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, California Institute for Technology ("**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.

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.

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.

The Company's current patent portfolio will begin to naturally expire in 2031. However, given the amount of time required for the development, testing and regulatory review of new products, patents protecting its future products 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 uncertainties 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^{IM} 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 and the Offering

The fact that no minimum amount is set for the Offering may affect the Company's investment plan and the liquidity of the Shares.

The Company has the right to proceed with the Offering in a reduced amount, corresponding to a number of Offer Shares that is lower than the maximum number of Offer Shares in the Offering. Since there is no minimum amount of the Offering, if not all of the Offer Shares are subscribed for in the Offering, the net proceeds from the Offering could be limited, all or in part, to the net proceeds from Subscription Commitments (as described "*The Offering — Pre-commitments by the Participating Investors*"). The actual number of Ordinary Shares subscribed for, or placed, will be confirmed on the Company's website and by way of a press release together with the Offer Price. As a result, a number of Shares that is lower than the maximum number of Offer Shares in the Offering could be available for trading on the market, which could limit the liquidity of the Ordinary Shares. Furthermore, the Company's financial means in view of the uses of proceeds would in such case also be reduced. If this were to be the case, the Company may have to reduce its level of investments or look for further external funding. Reduced investment may lead to fewer product introductions, the conduct of fewer clinical studies, and deployment of a smaller commercial organization. Each of these limitations may lead to diminished financial performance.

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 pursuant to a resolution of 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 as they will read immediately after the conversion into a public limited liability company on the First Trading Date (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 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.

Pursuant to a resolution to be adopted by the General Meeting ultimately on the First Trading Date, the Board will be authorized to issue Ordinary Shares or grant rights to subscribe for Ordinary Shares for a period of 18 months following the First Trading Date and to limit or exclude the pre-emptive rights pertaining to such Ordinary Shares and rights. This authorization of the Board will be limited to: (i) up to a maximum of 10% of the Ordinary Shares issued and outstanding at the close of business on the Settlement Date or, in case the Over-Allotment Option is exercised after the Settlement Date, at close of business on the date of the issuance of the Over-Allotment Shares, for general purpose; and in addition, (ii) up to a maximum of 10% of the Ordinary Shares issued and outstanding on the Settlement Date or, in case the Over-Allotment Option is exercised after the Settlement Date, at close of business on the date of the issuance of the Over-Allotment Shares, , in connection with takeovers, mergers, demergers and strategic alliances. Such designations may be revoked at any time by the General Meeting.

The Company has agreed with the Joint Global Coordinators, pursuant to the Underwriting Agreement, to restrictions, subject to customary exceptions, on their ability to issue, sell or transfer Ordinary Shares or interests therein for a period ending 365 days after the First Trading Date.

The Directors, Managers and Current Shareholders (including for these purposes at least the lenders representing a majority of the principal amount loaned to the Company under the Convertible Loan Agreement) have agreed with the Company, to restrictions, subject to customary exceptions, on their ability to issue, sell or transfer Ordinary Shares or interests therein for a period ending 180 days (365 days for the Directors and Managers) after the First Trading Date. The lock-up restrictions apply to (a) any shares held immediately prior to the Offering (including for the avoidance of doubt for these purposes at least the Shares of the lenders representing majority of the principal amount loaned to the Company under the Convertible Loan Agreement) and (b) newly issued securities of an identical type, nominal value, description, rights and quantity to the ordinary Shares that would be loaned by the Lender to Belfius Bank SA/NV (acting as stabilization manager), but do not apply to any shares acquired by them under the Subscription Commitment or otherwise acquired in the Offering.

After the expiration of the applicable lock-up period, the Directors, Managers and Current Shareholders may sell their Ordinary Shares or the Company may issue Ordinary Shares or securities linked to them. None of the Shares issued pursuant to the Subscription Commitments are subject to a lock-up arrangement.

The Company may also 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.

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

In addition, the Joint Global Coordinators, acting together, have full discretion to waive the lock-up in connection with the Directors, Current Shareholders and the Company at any time before its expiry. This could also result in the Directors, Managers and Current Shareholders or the Company selling or issuing Ordinary Shares before expiry of the applicable lock-up periods. In addition, there could also be a perception in the market that such sales could occur due to the expiry of the relevant lock-up period or its waiver. For further information on such lock-up arrangements, see "*Plan of Distribution—Lock-up arrangements*".

The market price of the Ordinary Shares could decline if, following the Offering and after the expiration of the lock-up period, 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.

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. Any additional offering or issuance of Ordinary Shares by the Company, or the perception that an offering or issuance may occur, could also 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.

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). Ultimately on the First Trading Date, the Board will be designated by the General Meeting for a period of 18 months from the First Trading Date to limit or exclude pre-emptive rights subject to limits as set out in this Prospectus. However, 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. In such cases, Shareholders resident in such non-Dutch jurisdictions 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 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.

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. Any action to contest any of the Company's corporate actions 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 Offering may have different interest from the Company and may be able to control the Company, including the outcome of shareholder votes.

Following the closing of the Offering and listing of its Ordinary Shares, the Company will have a number of significant shareholders. For an overview of the Company's current significant shareholders (see also "*Shareholder Structure and Related Party Transactions*"). Currently, the Current Shareholders and the Company have entered into a shareholders' agreement (the "**Shareholders' Agreement**"), containing, among others, terms regarding the Company's business and governance, as well as pre-emptive rights and transfer restrictions regarding the Shares (see also "*Shareholder Structure and Related Party Transactions—Related Party Transactions—Shareholders' Agreement*"). The Shareholders' Agreement will be terminated effective as of the closing of the Offering. The Company is not aware of shareholders entering into a new shareholders' agreement or agreeing to act in concert following the closing of the Offering (other than certain lock-up arrangements as described above). Nevertheless, 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.

There is currently no public trading market for the Ordinary Shares and there is a risk that no active and liquid market for the Ordinary Shares will develop and that the price of the Ordinary Shares may be volatile.

Until trading on Euronext commences on an "as-if-and-when-issued" basis, which is expected on 21 October 2021, but is subject to Settlement taking place, there is no public trading market for the Ordinary Shares. There can be no assurance that an active trading market for the Ordinary Shares

will develop after the Offering or, if it does develop, that it will be sustained or liquid. If such market fails to develop or be sustained, this could negatively affect the liquidity and price of the Ordinary Shares, as well as increase their price volatility. Investors may not be in a position to sell their Ordinary Shares quickly or at the market price if there is no active trading in Ordinary Shares. In addition, an illiquid market for the Ordinary Shares may result in lower market prices and increased volatility, which could materially adversely affect the value of an investment in the Ordinary Shares.

The Offer Price may not be indicative of the market price for the Ordinary Shares after the Offering has completed. The market price of the Ordinary Shares could also 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 prices significantly below the Offer Price. The Company cannot guarantee that the market price of the Ordinary Shares will not decline, or that the Ordinary Shares will not trade at prices significantly below the Offer Price, regardless of the Company's actual performance.

Risks related to Taxation

The Company's ability to use its net operating losses and research and development credit carryforwards 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 ("**NOL**") and its research and development credit carryforwards to offset future taxable income. The Company's existing NOLs and research and development credit carryforwards 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, even if it attains profitability.

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 2020 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 (as defined below under "*Taxation—Certain United States Federal Income Tax Considerations*") 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. For further discussion of the PFIC rules and the adverse US federal income tax consequences in the event the Company is classified as a PFIC, see the section of this Prospectus titled "*Taxation—Certain United States Federal Income Tax Considerations*."

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 11 October 2021. This Prospectus has, following the approval thereof by the AFM, been notified to the FSMA 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 Dutch and French. The Company is responsible for the consistency between the English, Dutch and French versions of the summary of this Prospectus. Without prejudice to the responsibility of the Company for inconsistencies between the different language versions of the summary of this Prospectus, in the case of discrepancies between the 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 quality of the issuer or the securities that are the subject of this Prospectus and the Company. Investors should make their own assessment as to the suitability of investing in the Offer 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, the Underwriters or any of their respective representatives that any recipient of this Prospectus should subscribe for or purchase any Offer Shares. Prior to making any decision whether to purchase the Offer 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 Offer 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 Offer Shares. In making an investment decision, prospective investors must rely on their own examination and analysis of the Company, the Offer Shares and the terms of the Offering, including the merits and risks involved.

Prospective investors should rely only on the information contained in this Prospectus, the Pricing Statement 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 Offering, 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, the Settlement Agent, the Underwriters 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 Offer 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 Offer Shares. A prospective investor should not invest in Offer Shares unless it has the expertise (either alone or with a financial adviser) to evaluate how the Offer Shares will perform under changing conditions, the resulting effects on the value of the Offer 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 Offer Shares.

No representation or warranty, express or implied, is made or given by the Listing Agent, the Settlement Agent, the Underwriters or any of their affiliates or any of their 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, the Settlement Agent, the Underwriters or any of their respective affiliates or representatives as to the past or future. None of the Listing Agent, the Settlement Agent or the Underwriters 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 Offering or the Offer Shares. Accordingly, the Listing Agent, the Settlement Agent and the Underwriters 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.

Although the Underwriters are party to various agreements pertaining to the Offering and the Underwriters have entered or might enter into a financing arrangement with the Company or any of its affiliates, this should not be considered as a recommendation by any of them to invest in the Offer Shares.

The Underwriters are 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 their respective clients in relation to the Offering and will not be responsible to anyone other than to the Company for giving advice in relation to the Offering and for the listing and trading of the Ordinary Shares and/or any other transaction or arrangement referred to in this Prospectus.

In connection with the Offering, the Underwriters and any of their respective affiliates, acting as an investor for its own account, may take up Offer Shares in the Offering and in that capacity may retain, purchase or sell for its own account such securities and any Offer Shares or related investments and may offer or sell such Offer Shares or other investments otherwise than in connection with the Offering. Accordingly, references in this Prospectus to Offer Shares being offered or placed should be read as including any offering or placement of Offer Shares to the Underwriters or any of their respective affiliates acting in such capacity. The Underwriters do not intend to disclose the extent of any such investment or transactions otherwise than pursuant to any legal or regulatory obligation to do so. In addition the Underwriters or their affiliates may enter into financing arrangements (including swaps) with investors in connection with which the Underwriters (or their affiliates) may from time to time acquire, hold or dispose of Offer Shares.

The distribution of this Prospectus and the Offering 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 Offer Shares in any jurisdiction in which such offer or invitation would be unlawful. The Company and the Underwriters require persons into whose possession this Prospectus comes to inform themselves of and observe all such restrictions. None of the Company, the Underwriters 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 Offer Shares, of any such restrictions. The Company and the Underwriters reserve the right in their own absolute discretion to reject any offer to purchase Offer Shares that the Company, the Underwriters 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 contains no omission likely to affect its import.

Information to distributors

Solely for the purposes of the product governance requirements contained within: (a) EU Directive 2014/65/EU on markets in financial instruments, as amended ("**MiFID II**"); (b) articles 9 and 10 of Commission Delegated Directive (EU) 2017/593 supplementing MiFID II; and (c) local implementing measures (together, the "**MiFID II Product Governance Requirements**"), and disclaiming all and any liability, whether arising in tort, contract or otherwise, which any "manufacturer" (for the purposes of the MiFID II Product Governance Requirements) may otherwise have with respect thereto, the Offer Shares have been subject to a product approval process, which has determined that the Offer Shares are: (i) compatible with an end target market of retail investors and investors who meet the criteria of professional clients and eligible counterparties, each as defined in MiFID II; and (ii) eligible for distribution through all distribution channels as are permitted by MiFID II (the "**Target Market Assessment**"). Notwithstanding the Target Market Assessment, "distributors" (for the purposes of the MiFID II Product Governance Requirements) should note that: the price of the Offer Shares may decline and investors could lose all or part of their investment; the Offer Shares offer no guaranteed income and no capital protection; and an investment in the Offer Shares is compatible only with investors who do not need a guaranteed income or capital protection, who (either alone or in conjunction with an appropriate financial or other adviser) are capable of evaluating the merits and risks of such an investment and who have sufficient resources to be able to bear any losses that may result therefrom. The Target Market Assessment is without prejudice to the requirements of any contractual, legal or regulatory selling restrictions in relation to the Offering.

For the avoidance of doubt, the Target Market Assessment does not constitute: (a) an assessment of suitability or appropriateness for the purposes of MiFID II; or (b) a recommendation to any investor or group of investors to invest in, or purchase, or take any other action whatsoever with respect to the Offer Shares.

Each distributor is responsible for undertaking its own target market assessment in respect of the Offer Shares and determining appropriate distribution channels.

Presentation of financial and other information

IFRS information

The special purpose consolidated financial statements of ONWARD Medical B.V., as of and for the year ended 31 December 2020 including comparative information as of and for the years ended 31 December 2019 and 31 December 2018 have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union ("**IFRS**") (the "**Financial Statements**"). Ernst & Young Accountants LLP, independent auditor, has audited the Financial Statements and has issued an unqualified independent auditor's report thereon, with the following emphasis of matter paragraphs:

Emphasis on the special purpose and restriction on use

We draw attention to note 2, which describes the special purpose of the special purpose consolidated financial statements. The special purpose consolidated financial statements do not represent ONWARD Medical B.V.'s financial statements in accordance with Section 2:361 of the Dutch Civil Code and its articles of association and are prepared for the purpose of including in the prospectus in order for ONWARD Medical B.V. to comply with the requirements for historical financial information by, or pursuant to, Regulation (EU) 2017/1129. As a result, the special purpose consolidated financial statements may not be suitable for another purpose. Our independent auditor's report is required by the Commission Delegated Regulation (EU) 2019/9 80 and is issued for the purpose of complying with that Delegated Regulation. Therefore, our auditor's report should not be used for another purpose.

Material uncertainty with respect to the going concern assumption

We draw attention to Note 4 Continuity of the Group in the special purpose consolidated financial statements, which indicates that the Company's cash position would be negative as of 30 September 2022 based on the assumptions made by the board of directors regarding expected cash inflows and outflows over the next 12 months. These forecasts do not include financing alternatives currently under consideration by the board of directors. In this context, the board of directors is aware that the continuity of Company's operations depends on its ability to obtain these new sources of funding and that there are material uncertainties in this regard. Please note that the Company's long-term success is contingent on achieving FDA approval and CE mark of its products. These conditions indicate the existence of a material uncertainty which may cast significant doubt on the company's ability to continue as a going concern. We draw attention to these disclosures.

Our opinion is not modified in respect of these matters.

The unaudited condensed consolidated interim financial statements of ONWARD Medical B.V. as of and for the six months ended 30 June 2021 have been prepared in accordance with IAS 34 Interim Financial Reporting (the "**Interim Financial Statements**"). The Interim Financial Statements have been reviewed by Ernst & Young Accountants LLP which has issued an unqualified independent auditor's review report thereon, including the following emphasis of matter paragraphs:

Material uncertainty with respect to the going concern assumption

We draw attention to Note 3 Continuity of the Group in the condensed consolidated interim financial statements, which indicates that the company's cash position would be negative as of 30 September 2022 based on the assumptions made by the board of directors regarding expected cash inflows and outflows over the next twelve months. These forecasts do not include financing alternatives currently under consideration by the board of directors. In this context, the board of directors is aware that the continuity of Company's operations depends on its ability to obtain these new sources of funding and that there are material uncertainties in this regard. Please note that the Company's long-term success is contingent on achieving FDA approval and CE mark of its products. These conditions indicate the existence of a material uncertainty which may cast significant doubt on the company's ability to continue as a going concern. We draw attention to these disclosures.

Corresponding figures neither audited nor reviewed

We have not audited nor reviewed the condensed consolidated interim financial statements for the period from 1 January 2020 to 30 June 2020. Consequently, we have not audited nor reviewed the corresponding figures included in the condensed consolidated interim statements of profit or loss, comprehensive income, changes in equity and cash flows and the related notes.

Selected financial information

The financial data set forth below as at and for the six month period then ended 30 June 2021 and as at and for the years ended 31 December, 2020, 2019 and 2018 have been extracted from the Financial Statements and Interim Financial Statements and should be read in conjunction with other information contained in this Prospectus, including the alternative performance measures.

<i>(In EUR 000)</i>	Audited			Unaudited	
	For the year ended 31 December			For the six-month period ended 30 June	
	2020	2019	2018	2021	2020
Total Revenues and Other Income	800	554	474	586	211
Operating loss for the period	(15,512)	(10,772)	(8,405)	(9,824)	(6,680)
Loss for the period before taxes	(19,994)	(13,444)	(9,894)	(12,755)	(8,776)
Net Loss for the period	(20,014)	(13,483)	(9,912)	(12,771)	(8,804)

<i>(In EUR 000)</i>	Audited			Unaudited	
	For the year ended 31 December			For the six-month period ended 30 June	
	2020	2019	2018	2021	2020
Net cash generated / (used) from operating activities	(12,901)	(9,845)	(7,156)	(7,449)	(6,609)
Net cash generated / (used) from investing activities	(173)	(99)	(103)	(45)	(112)
Net cash generated / (used) from financing activities	4,368	16,403	8,647	27,038	491
Cash and cash equivalents at end of period	6,382	15,129	8,665	25,894	8,886

<i>(In EUR 000)</i>	Audited			Unaudited
	As at 31 December			As at 30 June
	2020	2019	2018	2021
Total assets	14,190	23,345	9,560	33,654
Total equity attributable to shareholders	(32,095)	(14,923)	(10,269)	(42,920)
Financial debt <i>(Not audited or reviewed)</i>	43,757	35,680	17,919	73,798
Net financial Debt <i>(Not audited or reviewed)</i>	37,375	20,551	9,254	47,904

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**"). The Company has included the following APMs in this Prospectus:

- capital expenditure;
- working capital;
- financial debt; and,
- net financial debt.

The APMs presented are not measures of financial performance under IFRS, but measures used by management to monitor the underlying performance of the Group's business and operations and, accordingly, they have not been audited or reviewed. Further, they may not be indicative of the Group's historical operating results, nor are such measures meant to be predictive of the Group's future results. The APMs have not been audited or reviewed by the independent auditor.

The Company has included the APMs in this Prospectus because they represent key measures used by management to evaluate the Group's operating performance. Further, management believes that the presentation of the APMs is helpful to prospective investors because these and other similar measures and related ratios are widely used by certain investors, securities analysts and other interested parties as supplemental measures of performance and liquidity. Management also believes that the APMs facilitate 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, each of these APMs have 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, these measures and ratios may not be comparable to measures used by other companies under the same or similar names.

Prospective investors should not consider the APMs 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 APMs contained in this Prospectus and they 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.

Each of the APMs is described below.

- "Capital expenditure" is defined as investments in fixed assets, part of the net cash flows used in investing activities as included in the consolidated statement of cash flows in the Financial Statements and Interim Financial Statements. The Group considers capital expenditure as a useful indicator to measure of the expenditure incurred in investments in its products and in the growth of its business. Management believes that capital expenditure is also useful for analysts and investors to understand how the Group monitors and assesses its ongoing expenditure on a consistent basis.

<i>(In EUR 000)</i>	Unaudited			
	As at 31 December			As at 30 June
	2020	2019	2018	2021
Investment in Laboratory equipment	150	22	66	-
Investment in Computer equipment	23	75	34	45
Investment in Furniture	-	27	3	-
Capital expenditure	173	124	103	45

- "working capital" is defined as the sum of receivables and other current assets minus the sum of trade and other payables as included in the consolidated statement of financial position in the Financial Statements and Interim Financial Statements.

<i>(In EUR 000)</i>	Unaudited			
	As at 31 December			As at 30 June
	2020	2019	2018	2021
Indirect tax receivables	93	131	190	176
Receivable from related parties	57	51	49	58
Other current assets	436	183	92	463
Trade payables	(911)	(1,306)	(852)	(1,007)
Other payables	(1,590)	(1,243)	(1,047)	(1,725)
Working Capital	(1,915)	(2,184)	(1,568)	(2,035)

- "financial debt" is defined as the sum of the non-current liabilities and the short term position of the non-current liabilities included in the current liabilities as included in consolidated statement of financial position in the Financial Statements and Interim Financial Statements.

<i>(In EUR 000)</i>	Unaudited			
	As at 31 December			As at 30 June
	2020	2019	2018	2021
Non-current liabilities				
Interest bearing loans	41,817	33,479	17,144	69,311
Deferred tax liability	1,343	1,448	-	1,327
Other financial liabilities	-	-	-	2,480
Lease liability	61	198	324	-
Post-employment benefits	399	429	356	550
Current Liabilities				
Lease Liability	137	126	95	130
Financial Debt	43,757	35,680	17,919	73,798

- "net financial debt" is defined as the financial debt minus the cash and cash equivalents as included in the consolidated statement of financial position in the Financial Statements and Interim Financial Statements.

<i>(In EUR 000)</i>	Unaudited			
	As at 31 December			As at 30 June
	2020	2019	2018	2021
Financial Debt	43,757	35,680	17,919	73,798
Cash and cash equivalents	(6,382)	(15,129)	(8,665)	(25,894)
Net financial debt	37,375	20,551	9,254	47,904

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 Interim Financial Statements and 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 Interim Financial Statements or 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 Interim Financial Statements and the Financial Statements. Such percentages may be computed using the numerical figures expressed in thousands of euros in the

Interim Financial Statements and 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 Bloomberg L.P. This exchange rate information is solely provided for convenience purposes. The exchange rate of the euro on 11 October 2021 (the latest practicable date before publication of this Prospectus) was USD 1.1574 = EUR 1.00.

Year	Euro	US dollar (High)	US dollar (Low)	US dollar (Average)	US dollar (Period end)
2021	1	1.2327	1.1552	1.1948	1.1574
2020	1	1.2298	1.0688	1.1419	1.2216
2019	1	1.1543	1.0899	1.1194	1.1213
2018	1	1.2510	1.1218	1.1809	1.1467
2017	1	1.2036	1.0405	1.1300	1.2005
2016	1	1.1534	1.0388	1.1069	1.0517

Month	Euro	US dollar (High)	US dollar (Low)	US dollar (Average)	US dollar (Period end)
Aug-21	1	1.1870	1.1675	1.1768	1.1809
July-21	1	1.1887	1.1771	1.1825	1.1870
Jun-21	1	1.2213	1.1858	1.2040	1.1858
May-21	1	1.2250	1.2005	1.2148	1.2227
Apr-21	1	1.2126	1.1759	1.1971	1.2020
Mar-21	1	1.2091	1.1717	1.1900	1.1730
Feb-21	1	1.2175	1.1964	1.2095	1.2075
Jan-21	1	1.2327	1.2077	1.2174	1.2136

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, Elías 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) Johnson RL, Wilson CG. A review of vagus nerve stimulation as a therapeutic intervention. *J Inflamm Res*, (v) NSCISC Annual Report, and (vi) 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 Offer 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. In case a significant new factor, material mistake or material inaccuracy relating to the information included in this Prospectus, which may affect the assessment of the Offer Shares, arises after the end of the Offering Period and the start of trading of the Offer Shares on Euronext, the Company will not supplement this Prospectus.

Investors who have already agreed to purchase or subscribe for the Offer Shares before the supplement is published shall, if required by law, have the right, exercisable within three business days following the publication of a supplement, to withdraw their acceptances. Investors are not allowed to withdraw their acceptance in any other circumstances.

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. For the avoidance of doubt, references in this paragraph to any supplement being published by the Company do not include the Pricing Statement.

Notice to Investors

The distribution of this Prospectus and the offer, acceptance, delivery, transfer, exercise, purchase of, subscription for, or trade in the Offer Shares may, in certain jurisdictions other than the Netherlands and Belgium, including, but not limited to, the United States, 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 Offer 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 Underwriters or any of their respective affiliates or representatives, is making any representation to any offeree, purchaser or subscribers of the Offer Shares regarding the legality of an investment in the Offer Shares by such offeree, purchaser or subscriber under the laws applicable to such offeree, purchaser or subscriber.

Investors who purchase Offer Shares will be deemed to have acknowledged that: (i) they have not relied on the Listing Agent, the Settlement Agent or the Underwriters or any person affiliated with any of them 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 Offer 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, the Listing Agent, the Settlement Agent or any of the Underwriters.

EXCEPT AS OTHERWISE SET OUT IN THIS PROSPECTUS, THE OFFERING DESCRIBED IN THIS PROSPECTUS IS NOT BEING MADE TO INVESTORS IN THE UNITED STATES, CANADA, AUSTRALIA SOUTH-AFRICA OR JAPAN.

This Prospectus does not constitute or form part of any offer or invitation to sell, or any solicitation of any offer to acquire, Offer 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 Offer Shares, is restricted by law in certain jurisdictions. This Prospectus may only be used where it is legal to offer, solicit offers to purchase or sell Offer Shares. Persons who obtain this Prospectus must inform themselves about and observe all such restrictions. None of the Company or the Underwriters accept any legal responsibility for any violation by any person, whether or not a prospective purchaser or subscriber of Ordinary Shares, of any such restrictions. The Company and the Underwriters reserve the right in their own absolute discretion to reject any offer to purchase Ordinary Shares that the Company, the Underwriters or their respective agents believe may give rise to a breach or violation of any laws, rules or regulations.

No action has been or will be taken to permit a public offer or sale of Offer Shares, or the possession or distribution of this Prospectus or any other material in relation to the Offering, in any jurisdiction outside the Netherlands or Belgium where action may be required for such purpose. 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. See "*Selling and Transfer Restrictions*". 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 Offer 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 Offer Shares will be sold only to persons reasonably believed to be QIBs as defined in, and pursuant to, Rule 144A 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. All offers and sales of the Offer Shares outside the United States will be 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 Offer 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. See "*Selling and Transfer Restrictions*".

THE OFFER 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 Offer Shares which are the subject of the Offering contemplated by this Prospectus have not and will not be offered to the public other than in Belgium, except that the Offer 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) subject to obtaining the prior consent of the Joint Global Coordinators for any such offer; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

No such offer of Offer Shares shall require the Company or any of the Joint Global Coordinators 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 Offer Shares or to whom any offer is made will be deemed to have represented, warranted and agreed to the Company and the Underwriters, that it is a Qualified Investor.

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

In the case of any Offer 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 Offer Shares acquired by it in the Offering 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 Offer Shares to the public other than their offer or resale in a Relevant Member State to Qualified Investors or in circumstances in which the prior consent of the Underwriters has been obtained to each such proposed offer or resale. The Company, the Underwriters and their affiliates and others, will rely upon the truth and accuracy of the foregoing representation, acknowledgement and agreement. Notwithstanding the above, a person who is not a Qualified Investor and who has notified the Underwriters of such fact in writing may, with the prior consent of the Underwriters, be permitted to acquire Offer Shares in the Offering.

Notice to prospective investors in the United Kingdom

No offer of the Offer Shares which are the subject of the Offering contemplated by this Prospectus may be made to the public in the United Kingdom except that an offer may be made in the United Kingdom:

- (a) at any time 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 "EUWA");
- (b) at any time to fewer than 150 natural or legal persons (other than qualified investors as defined in Article 2 of Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the EUWA) in the United Kingdom subject to obtaining the prior consent of the relevant Joint Global Coordinators nominated by the Group for any such offer; or
- (c) at any time in any other circumstances falling within section 86 of the Financial Services and Markets Act 2000,

provided that no such offer of Offer Shares referred to in paragraphs (a) and (c) above shall require the Group or any Joint Global Coordinator 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 Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the EUWA.

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

Notice to prospective investors in Switzerland

In Switzerland, the Offer Shares may only be offered to "professional clients" within the meaning of the FinSA by way of a private placement. The Offer 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 Offer 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 Offer Shares constitutes a prospectus pursuant to the FinSA, and neither this Prospectus nor any other offering or marketing material relating to the Offer 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. 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 or Executive Officers, may be limited under law. In addition, substantially all of the Company's assets are located outside the United States.

As a result, it may be impossible or difficult for investors to effect service of process within the United States upon such persons or the Company or to enforce against them in United States courts a judgment obtained in such courts. In addition, there is doubt as to the enforceability, in the Netherlands, of original actions or actions for enforcement based on the federal or state securities laws of the United States or judgments of United States courts, including judgments based on the civil liability provisions of the United States federal or state securities laws.

The United States and the Netherlands do not currently have a treaty providing for reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. With respect to choice of court agreements in civil or commercial matters, it is noted that the Hague Convention on Choice of Court Agreements entered into force for the Netherlands, but has not entered into force for the United States. It should be noted that the Hague Convention on Choice of Court Agreements does not apply to one-sided exclusive jurisdiction clauses. Accordingly, a judgment rendered by a court in the United States would not automatically be recognized and enforced by the 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 his claim with the competent Dutch court, the Dutch court will in principle to recognize and give effect to such foreign judgment insofar as it finds that (i) the jurisdiction of the United States court has

been based on grounds which are internationally acceptable, (ii) proper legal procedures have been observed (*behoorlijke rechtspleging*), (iii) the judgment does not contravene Dutch public policy (*openbare orde*), and (iv) the judgment is not incompatible with a judgment of a Dutch court or an earlier judgment of a foreign court that is capable of being recognized in the Netherlands. However, even if such a foreign judgment is given binding effect, a claim based on that foreign judgment may still be rejected if the foreign judgment is not or no longer formally enforceable.

Based on the lack of a treaty as described above, US investors may not be able to enforce against the Company or its directors, representatives or certain experts named herein who are residents of the Netherlands or countries other than the United States any judgments obtained in US courts in civil and commercial matters, including judgments under the US federal securities laws.

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*", "*Operating and Financial Review*" 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*", "*Business*" and "*Operating and Financial Review*" 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

This Prospectus is available to retail investors in Belgium. The Summary of this Prospectus will be made available in Dutch and French. This Prospectus will be made available to investors at no cost at the Company's registered office, located at High-Tech Campus 32 5656 AE Eindhoven, the Netherlands, and can be obtained by retail investors in Belgium at Bank Degroof Petercam SA/NV and Belfius Bank NV/SA upon request by phone: +32 2 287 95 52 (Bank Degroof Petercam SA/NV) and +32 222 12 01 (French) and +32 222 12 02 (Dutch) (Belfius Bank NV/SA).

Subject to certain country restrictions, this Prospectus and the Summary of this Prospectus are also available to investors, on the following websites: <https://ir.onwd.com/prospectus>, <https://www.degroofpetercam.com/en-be/Onward-2021>, <https://www.degroofpetercam.com/nl-be/Onward-2021> and <https://www.degroofpetercam.com/fr-be/Onward-2021> and www.belfius.be/Onward2021.

The posting of this Prospectus on the internet does not constitute an offer to sell or a solicitation of an offer to buy any of the Offer Shares to or from any person in any jurisdiction in which it is unlawful to make such offer or solicitation to such person. The electronic version may not be copied, made available or printed for distribution. Information on the website of the Company (www.onwd.com) or any other website does not form part of this Prospectus and has not been scrutinized or approved by the AFM.

For so long as any Ordinary Shares of the Company are "restricted securities" within the meaning of Rule 144(a)(3) under the US Securities Act, the Company will, during any period in which it is neither subject to Section 13 or 15(d) of the US Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), nor exempt from reporting pursuant to Rule 12g3-2(b) thereunder, provide to any holder or beneficial owner of such restricted securities or to any prospective purchaser of such restricted securities designated by such holder or beneficial owner, upon the request of such holder, beneficial owner or prospective purchaser, the information required to be provided by Rule 144A(d)(4) under the US Securities Act.

The Company is not currently subject to the periodic reporting and other information requirements of the Exchange Act.

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 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. Investors should make their own assessment as to the suitability of investing in the securities.

The validity of this Prospectus shall expire on the First Trading 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.

REASONS FOR THE OFFERING AND USE OF PROCEEDS

Reasons for Offering and Admission

The Company believes that the Admission and the Offering is a logical next step in its development and that its timing is appropriate, given the Company's current profile and level of maturity.

The Company believes that the Offering will provide the Company with additional capital support (i) for product development and research and development activities, (ii) to conduct clinical trials, and (iii) overall commercial development, (as also further described under "*Use of Proceeds*" below). The Admission further provides the Company with access to capital markets, which it may use to support and develop further growth of the Company and to finance further research and/or strategic M&A transactions, as they become available.

The Company expects the Admission and the Offering to create a new long-term shareholder base as well as liquidity for the existing and future Shareholders. It is the intention of the Company to create a meaningful free float in the Ordinary Shares on Admission.

Use of Proceeds

The commissions due to the Underwriters, and expenses (up to an agreed cap), will be borne by the Company. Assuming that the Offering is fully subscribed (excluding Increase Option and Over-allotment Option) and the Offer Price is at the mid-point of the Offer Price Range (as at the date of this Prospectus), the expenses, commissions and taxes related to the Offering payable by the Company are estimated to amount to approximately EUR 5.5 million.

The Company expects the net proceeds from the Offering (based on an Offer Price at the mid-point of the Offer Price Range and assuming the sale of the maximum number of Offer Shares by the Company), after deduction of expenses, commissions and taxes (estimated to amount to approximately EUR 5.5 million¹), to amount to approximately EUR 69.8 million. Net proceeds will be approximately EUR 97.2 million in case of a placement of the maximum number of Offered Shares in the Offering, including the exercise in full of the Increase Option and the Over-allotment Option (after deduction of expenses, commissions and taxes (estimated to amount to approximately EUR 6.6 million)).²

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

- approximately 20% to fund product development and research and development activities, more specifically the development of the commercial ARC^{EX} device and the ARC^{IM} system including the associated lead portfolio;
- approximately 30% to conduct clinical trials in the United States and Europe including but not limited to:
 - Feasibility and pivotal trials for the ARC^{IM} Blood pressure and trunk control indications;
 - Feasibility and pivotal trials for the ARC^{IM} Mobility indication; and,
 - Pilot and pivotal trials for the ARC^{EX} Upper limbs indication, including evaluation of the therapy's effective use in the clinic and the home.
- approximately 30% to build the Company's commercial capabilities in both the United States and Europe in order to begin marketing the Company's therapies. This is expected to include hiring and training of field-based sales and engineering staff, office-based customer service and technical support staff, marketing and market access staff, and the systems and

¹ In addition to these expenses the Company is required to pay an IPO fee amounting to USD 1 million to UCLA and an IPO fee amounting to USD 1.5 million to Caltech upon the settlement of the Offering (see "License Agreements with EPFL, NeuroRestore and CHUV and other Parties").

² In addition to these expenses the Company is required to pay an IPO fee amounting to USD 1 million to UCLA and an IPO fee amounting to USD 1.5 million to Caltech upon the settlement of the Offering (see "License Agreements with EPFL, NeuroRestore and CHUV and other Parties").

infrastructure required to support those hires and to conduct commerce in the Group's target markets; and,

- approximately 20% for general corporate purposes, including corporate staff, facilities, insurance, and other items.

While the Company does not expect to change the allocation of the use of proceeds, it is entitled to do so.

The Company cannot predict with certainty all of the particular uses for the proceeds from the issuance of the Offer Shares, or the amounts that it will actually spend on the uses set forth above. The amounts and timing of the Company's actual expenditures will depend upon numerous factors, including the progress, costs, timing and results of its further development of the ARC^{IM} and ARC^{EX} platforms, ARC^{EX} developments, the net proceeds actually raised by it in the Offering, amounts received by way of revenues and the Company's operating costs and expenditures. As such, the Company's Board assumes significant flexibility in applying the net proceeds from the issue of the Offer Shares and may change the allocation of these proceeds as a result of these and other contingencies.

Furthermore, the Company has the right to proceed with a capital increase in a reduced amount, corresponding to a number of Offer Shares lower than the maximum number of Offer Shares in the Offering. In the event that the Company would proceed with the capital increase in a reduced amount, it may be required to raise additional capital in order to meet the funding requirements of the above proposed uses. Furthermore, as no minimum amount is set with respect to the Offering, see "*Risk Factor—Risks related to the Ordinary Shares and the Offering—The fact that no minimum amount is set for the Offering may affect the Company's investment plan and the liquidity of the Shares*" and "*The Offering—Offer Price and Number of Offer Shares*", the Company has the right to proceed with a capital increase in a reduced amount, corresponding to a number of Offer Shares lower than the maximum number of Offer Shares in the Offering.

In the event that the Company would proceed with the capital increase in a reduced amount, (i) in a worst case scenario, the net proceeds of the Offering would be equal to the net proceeds from the Subscription Commitments of the Participating Investors, and (ii) it may be required to raise additional capital in order to meet the funding requirements of the above uses. In the event that the net proceeds from the Offering are limited to the net proceeds from the Subscription Commitments of the Participating Investors (i.e. EUR 16.2 million for the Subscription Commitments Cornerstones plus an amount equal to 15% of the Offer Shares in the Offer at the Offer Price for the Subscription Commitments Shareholders plus the Subscription Commitments Lenders), the Company would use these proceeds to (i) complete research and development initiatives (ii) conduct clinical trials, and (iii) fund commercialization efforts, albeit at a less fulsome and lower pace. The Company is entitled to optimize its priorities based on prevailing circumstances, but it is likely to prioritize investments and activities that lead to the most streamlined path to revenue and cash flow generation. The spending by category is likely to be in alignment with the percentages outlined in this section above. At present, that would include completing the Up-LIFT study in order to apply for authorization to market ARC^{EX} and pursuing authorization to market ARC^{IM} for blood pressure and trunk control. Other activities could be curtailed or deferred, and spending reduced. In addition, the Company could pursue the raising of additional capital in the private markets, something it has done successfully in the past.

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. The Board may, subject to Dutch law and the Articles of Association, resolve to pay a dividend on the Ordinary Shares from one or more of the reserves which do not need to be maintained pursuant to Dutch law.

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 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. 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.

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 and the Offering—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 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*").

See "*Taxation*" for an overview of the material Dutch, Belgian and US 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 as of 31 July 2021 on an actual basis and as adjusted to give effect to (i) the sale of the Offer Shares and the receipt of the net proceeds of the Offer Shares, assuming that the maximum number of Offer Shares (including the exercise in full of the Increase Option and the Over-Allotment Option) are issued at the mid-point of the Offer Price Range, (ii) the full conversion of the convertible preference shares and (iii) the full conversion of the Convertible Loan Agreement, (iv) the issuance of the EPFL shares and (v) the Reverse Stock Split and the increase of the nominal value of each ordinary share to EUR 0.12. The actual information has been derived from the unaudited management accounts as at 31 July 2021. These tables should be read in conjunction with the Group's Financial Statements, the Interim Financial Statements and the notes thereto included elsewhere in this Prospectus and "Operating and Financial Review". See "Description of Share Capital" for information concerning the Company's share capital.

Capitalization

	As at 31 July, 2021		
	Actual	Adjustment <i>(in EUR thousands)</i>	As adjusted
Total current debt (including current portion of non-current debt).....	115	-	115
Guaranteed	-	-	-
Secured.....	115 ⁽¹⁾	-	115
Unguaranteed/unsecured.....	-	-	-
Total non-current debt (excluding current portion of non-current debt).....	74,389	(61,427)	12,962
Guaranteed	-	-	-
Secured.....	10,982 ⁽²⁾	-	10,982
Unguaranteed/unsecured.....	63,407 ⁽³⁾	(61,427) ⁽⁴⁾	1,980
Shareholder's equity	(45,521)	158,597	113,076
Share capital	-	3,845 ^{(7), (9)}	3,845
Share premium	3,083	159,657 ^{(4),(5),(6), (7),(9)}	162,740
Other reserves	20,102 ⁽⁶⁾	(14,795) ⁽⁶⁾	5,307
Retained earnings	(68,706) ⁽⁸⁾	9,890 ⁽⁵⁾	(58,816)
.....			
Total	28,983	97,170	126,153

- (1) Total current debt of EUR 115k comprises lease liabilities from the Group's unaudited management accounts as at 31 July 2021 and represents amounts payable to the landlord of the office building in the Netherlands that is partly secured by a bank guarantee for an amount up to EUR 41k.
- (2) The secured portion of non-current interest-bearing loans from the Group's unaudited management accounts as at 31 July 2021, represents amounts payable to the RVO NL (Dutch government). Certain Intellectual Property (patents registered), have been pledged to the RVO NL in case of default of repayment of the loan.
- (3) Unguaranteed/unsecured portion of the non-current interest-bearing loans from the Group's unaudited management accounts as at 31 July 2021 consist of the convertible preference A shares liability, the convertible loan, the convertible loan conversion option, the post-employment benefits from the Swiss Pension Plan and the deferred tax liability on the acquired NRT intangible assets.
- (4) The convertible loan and the convertible loan conversion option with a total non-current debt value of EUR 27,681k as at 31 July, 2021 are, in case of a successful Offering, anticipated to convert into Ordinary shares based on the Offer Price and a discount of 25%. The convertible cumulative preference A shares with a total non-current debt value of EUR 33,746k as at 31 July, 2021 are, in case of a successful Offering, anticipated to convert into Ordinary shares, at the conversion rate of 5:2.
- (5) The accumulated accrued interest of EUR 9,890k included in the total non-current debt value will not convert at IPO and will be adjusted against historical incurred losses.
- (6) The Other reserves as at 31 July, 2021 consist of reserves for share-based payments, conversion option preference shares and other comprehensive income from the Group's unaudited management accounts as at 31 July 2021. The conversion option preference shares with a total value of EUR 14,795k as at 31 July, 2021 are, in case of a successful Offering, anticipated to convert into Ordinary shares, at the conversion rate of 5:2.

- (7) As result of the conversion of Corporate Conversion, the nominal share capital of the shares will be increased to EUR 0.12. As result of this part of share premium has been converted into nominal value.
- (8) Retained earnings includes the result for the seven month period ended 31 July 2021 as derived from the unaudited management accounts.
- (9) Total net proceeds from the Offering of EUR 97,171k minus the nominal value of the Offering Shares of EUR 977k is added to the share premium.

Indebtedness

	As at 31 July, 2021		
	Actual	Adjustment (in EUR thousands)	As adjusted
A Cash	24,435 ⁽¹⁾	95,015 ⁽⁴⁾	119,450
B Cash equivalents	-	-	-
C Other current financial assets	-	-	-
D Liquidity (A + B + C).....	24,435	95,015	119,450
E Current financial debt (including debt instruments, but excluding current portion of non-current financial debt).....	115 ⁽²⁾	-	115
F Current portion of non-current financial debt.....	-	-	-
G Current financial indebtedness (E + F).....	115	-	115
H Net current financial indebtedness (G – D)	(24,320)	(95,015)	(119,335)
I Non-current financial debt (excluding current portion and debt instruments).....	74,389 ⁽³⁾	(61,427)	12,962
J Debt instruments	-	-	-
K Non-current trade and other payables	-	-	-
L Non-current financial indebtedness (I + J + K)	74,389	(61,427)	12,962
M Total financial indebtedness (H + L).....	50,069	(156,442)	(106,373)

- (1) Cash from the Group's unaudited management accounts as at 31 July 2021.
- (2) Total current debt of EUR 115k comprises lease liabilities from the Group's unaudited management accounts as at 31 July 2021 and represents amounts payable to the landlord of the office building in the Netherlands that is partly secured by a bank guarantee for an amount up to EUR 41k.
- (3) The secured portion of non-current interest-bearing loans from the Group's unaudited management accounts as at 31 July 2021, represents amounts payable to the RVO NL (Dutch government), Certain Intellectual Property (patents registered), have been pledged to the RVO NL in case of default of repayment of the loan. Unguaranteed/unsecured non-current debt consist of the convertible preference A shares liability, the convertible loan, the convertible loan conversion option, the post-employment benefits from the Swiss Pension Plan and the deferred tax liability on the acquired NRT intangible assets.
- (4) Total net proceeds from the Offering of EUR 97,171k adjusted for EUR 2,156k related to IPO fees to UCLA and Caltech.

As at 31 July 2021, the Company has no indirect indebtedness. For contingencies refer to note 34 Commitments and contingencies in the Financial Statements and also refer to "*License Agreements with EPFL, NeuroRestore and CHUV and other Parties – Caltech*".

Working capital statement

On the date of this Prospectus, the Company is of the opinion that it does not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this Prospectus. See also the paragraph Risk Factors, with specific reference to "*The Company may require additional capital to finance its planned operations, which may not be available to it on acceptable terms or at all*". In case the Company would not be able to attract new funds (beyond its existing cash and cash equivalents), it expects to run out of working capital by end of September 2022. In the event the Company is not able to attract any such additional funds and the Company maintains its current strategy and development activities, its 12 month working capital shortfall is projected to be approximately EUR 1.5 to EUR 2 million at the end of September 2022.

The Company has decided to initiate the Offering to secure adequate funding for working capital needs for a period of at least 12 months. Assuming that the Offer Price is at the lower end of the Price Range, the gross proceeds from the issue of the Offer Shares, based on the existing Subscription Commitments only are estimated to be approximately EUR 19.6 million, which considerably exceeds the working capital shortfall referred to above.

In the event that the Offering is withdrawn, the Company would be required to raise additional funding in order to meet the funding requirements for the ARC[™] Blood pressure and ARC[™] Mobility trial, research and development activities and part of the marketing strategy and commercialization efforts. Such additional funding could be a combination of (non-dilutive) external financing and further shareholders' financing (see also "*Use of Proceeds*" in the paragraph "*Reasons for the Offering and use of proceeds*"), for which the Company would need to initiate financing discussions after the date of the Prospectus. The likelihood of success of such discussions is unclear and, if the Company would be unable to raise additional funding for a sufficient amount or at all, it would not be able to fund its activities and efforts as currently planned.

OPERATING AND FINANCIAL REVIEW

The following discussion and analysis should be read in conjunction with the rest of this Prospectus, including the Interim Financial Statements, including the independent auditor's review report thereon, as well as the Financial Statements, including the independent auditor's reports thereon, which are included elsewhere in this Prospectus.

Except as otherwise stated, this Operating and Financial Review is based on the Interim Financial Statements which have been prepared in accordance with IAS 34 Interim Financial Reporting and the Financial Statements, which have been prepared in accordance with IFRS. 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 following discussion contains forward-looking statements that involve risks and uncertainties. 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.

Overview

The Company is a medical technology company developing innovative therapies to enable functional recovery for people with SCI. The Company's technology platforms are based on 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.

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.

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.

The Company has incurred significant losses in each year of operations, as it has devoted a significant amount of its resources to research and product and clinical development. During the six-months period ended 30 June 2021, the Company recorded net losses of EUR 12.8 million and aggregated with the recorded net losses for the years ended 31 December 2020, 2019 and 2018, the Company incurred aggregate net losses of EUR 56.2 million. It expects to continue to incur substantial operating losses in the future. The Company will not receive any revenues or net cash flows from sales of its products unless they have been approved by the European Medicines Agency ("EMA"), the FDA or similar regulatory authorities in other countries and commercialized successfully, which the Company does not expect to be before 2023, if at all.

Material Factors Affecting Results of Operations

The Group's results of operations have been affected in the periods under review, and are expected to continue to be affected, by the following factors.

COVID-19

In March 2020, the World Health Organization characterized the novel coronavirus outbreak, COVID-19, as a pandemic. This has affected the course of business of the Company and has required exceptional measures. Governmental safety guidelines have been implemented in the offices in Eindhoven and Lausanne as well as guidelines on travel for all employees. The restrictions to limit

travel and to work from home have impacted the development capacity as well as the ability to perform clinical activities at hospitals and rehab centers. For example, first patient enrolment in the Company's Up-LIFT Study was delayed by several months. Planned first enrolment was initially September 2020, whereas actual first enrolment was January 2021. The Company is monitoring the results of the vaccination programs in the countries where it is active and continues to follow the changing and re-opening safety guidelines in the individual countries. The impact of COVID-19 on the Company's activities, however, remains uncertain at this time and will depend on the future developments that cannot be predicted.

Regulatory approvals and reimbursement

The commercialization of both ARC Therapy platforms depends on receiving regulatory approval in the regions where the Company intends to generate revenues in the coming years following the approval of the notified bodies, including FDA. Both the ARC^{EX} (upper extremities) and the ARC^{IM} (mobility and blood pressure and trunk control) platforms have received breakthrough designation from the FDA. Upon successful completion of the Up-LIFT trial and if the Company is granted regulatory approvals, it expects to commercialize its initial product, the ARC^{EX} platform, in the US and Europe in 2023. It then expects to launch the ARC^{IM} platform, if approved, commercially in the US and EU in 2024 to restore normal blood pressure and trunk control. In 2025, it expects to pursue HDE for the commercialization of ARC^{IM} for mobility (walking) in the US.

If the Medicare Coverage of Innovative Technology ("**MCIT**") pathway is implemented in the US (it is currently being deliberated by the Centers for Medicare and Medicaid Services whether to finalize and implement MCIT and a date of 15 December 2021 has been set to make a final determination), the Company expects to receive reimbursement in the US for both the ARC^{EX} and ARC^{IM} platforms for at least the first four years if FDA approval is obtained in 2023 (ARC^{EX}) and 2024 (ARC^{IM}). Should MCIT for some reason not be implemented by the time the Company's therapies are approved for commercial sale in the US or should MCIT not be applicable to the Company's therapies, the Company expects that providers can use existing codes to seek payment for purchase or use of the Company's therapies.

The Company expects to initially commercialize in the below markets:

- United Kingdom
- Germany
- France
- Netherlands

These countries have initially been selected based on the reimbursement environment for new medical technologies and the sophistication of their SCI rehabilitation infrastructure. Countries in Europe typically require submission of a dossier of clinical and health economic data prior to providing reimbursement coverage and payment.

Expected increase in research and development expenses as well as clinical and regulatory expenses

Research and development expenses as well as the clinical and regulatory expenses are expected to increase in 2021 to further develop the commercial ARC^{EX} platform as well as the ARC^{IM} platform and lead portfolio. The Company expects to capitalize its development expenses once the approval for commercial use by the European Medicines Agency ("**EMA**"), the FDA or similar regulatory authorities in other countries has become more certain.

The Company expects its clinical and regulatory expenses to more than double in 2021 compared to 2020 and further increase in future years as result of the increase in clinical study activity for both ARC^{EX} and ARC^{IM}. The increase in the clinical and regulatory expenses is related to the Up-LIFT study activity for ARC^{EX} to obtain regulatory approval and feasibility study activities for ARC^{IM}.

Description of Key Line Items

Set forth below is a brief description of the composition of certain line items of the consolidated statement of profit and loss. This description should be read in conjunction with the Financial Statements and the Interim Financial Statements and the summary of significant accounting policies elsewhere in this section and in the Financial Statements and the Interim Financial Statements.

Total Revenues and Other Income

As the Company remains in a clinical state of development and started its first pivotal study in January 2021, none of its products have been approved and commercialized yet, and therefore the Company did not generate revenues from commercial activities in the financial statements under review, nor has it generated any income under partnership or collaboration agreements. The Company has received several grants throughout the years that are reported as Revenue and Other Income in the consolidated statement of profit and loss.

Science expenses

The Company's science expenses consist primarily of the cost of sponsored research activities that are undertaken by universities with which it collaborates. Since its inception, the Company has had a close working relationship with two of the founders of the Company, Gregoire Courtine, Professor at EPFL and Jocelyne Bloch, Neurosurgeon at CHUV and Professor at Université de Lausanne.

The activities between the Company and EPFL are formalized in research agreements which govern the activities of Professor Courtine sponsored by the Company.

The relationship with the CHUV consists primarily of the research activities of Professor Bloch that are enumerated in an agreement between the Company and the CHUV. In 2018 and earlier years, the Company also sponsored part of the physiotherapist and study nurse costs for one of the first feasibility studies.

Research and development expenses

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^{IM} platform as well as the employee related expenses for research and development, including salaries and benefits.

The Company expects its research and development expenses to increase in 2021 as result of the development of the commercial ARC^{EX} platform and the completion of the ARC^{IM} lead portfolio. The Company has not capitalized any of its research and development expenses in the financial statements under review as, in line with market practice, the Company has not obtained product approval yet to commercialize its products. As a result, all research and development expenses to date have been recognized in the consolidated statement of profit and loss.

Clinical and regulatory expenses

The Company's clinical and regulatory expenses in the period under review consist of the employee related expenses including salaries and benefits for employees working on clinical trials, and as of 1 January 2020 also includes costs relating to the Contract Research Organization ("**CRO**") and compensation to research sites for the Up-LIFT study.

The Company expects its clinical and regulatory expenses to more than double in 2021 compared to 2020 and further increase in future years as result of the increase in clinical study activity for both ARC^{EX} and ARC^{IM}.

Marketing and market access expenses

The Company's marketing and market access expenses in the period include rebranding activities relating to the introduction of the ONWARD brand as well as reimbursement analyses performed by third party consultants.

Patent and related expenses

The Company's patent 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 as well as related employee expenses, including salary and benefits in the area of business development.

General and administrative expenses

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, quality assurance and supply chain. The latter two functions are expected to be reported separately in the future once the Company starts commercialization. The other components in the general and administrative expenses are the costs related to travel, information technologies, lease and rental of office spaces, insurance and general maintenance expenses.

Operating Loss

The Operating Loss is the result of the Revenue and Other Income for the period adjusted for the operating expenses.

Loss before tax

The loss before tax is a combination of the Company's operating loss adjusted for the net finance costs, including interest expenses on loans, bank administration costs as well as foreign exchange gains and losses for transactions in currencies other than the euro.

Tax on result

As per the Company's structure the Company is subject to filing tax returns in the Netherlands, Switzerland and, since 2019, in the United States.

In the Netherlands, the Company has not made profits since its inception, and as a result no corporate income taxes have been paid. Currently, the accumulated tax losses can be carried forward for a maximum of six years to offset part of future tax profits. Under new legislation effective as of 1 January 2022, the carryforward period will be unlimited and the amount of the tax losses utilization will be limited to 50 per cent of taxable income (in excess of EUR 1 million). The Company is currently in the development stage, and it is uncertain when in the future the Company will generate taxable profits. Therefore, no carry forward tax losses have been recognized as deferred tax assets in the Company's financial statements.

The Swiss subsidiary, Onward Medical S.A. has a cost-plus agreement with the Dutch parent company and therefore the Swiss entity files an annual tax profit resulting in an annual corporate income tax expense in Switzerland.

For the US assets that were acquired through the merger with NRT in 2019, the former tax losses are likely not going to be carried forward due to the change in ownership. Tax losses since the transaction date can be carried forward indefinitely. For the 2020 tax loss no deferred tax asset has been recognized as it is still uncertain when the US activities will generate taxable profits.

In the future, the Company intends seeking advice on the most effective tax structure considering the regimes for tax losses carry forward and corporate income tax rates on tax profits.

Operating Loss for the periods

The following table sets out the Group's operating loss for the periods indicated.

<i>(In EUR 000)</i>	Audited			Unaudited	
	For the year ended 31 December			For the six-month period ended 30 June	
	2020	2019	2018	2021	2020
Grants	800	554	474	586	211
Total Revenue and other income	800	554	474	586	211
Science expenses	(1,123)	(313)	(586)	(569)	(542)
Research and development expenses	(5,823)	(5,356)	(4,722)	(3,280)	(2,804)
Clinical and Regulatory expenses	(2,770)	(1,239)	(654)	(1,944)	(1,232)
Marketing and Market Access expenses	(394)	(261)	(98)	(353)	(167)
Patent and related expenses	(1,186)	(525)	(455)	(786)	(455)
General and administrative expenses	(5,016)	(3,632)	(2,364)	(3,478)	(1,691)
Total operating expenses	(16,312)	(11,326)	(8,879)	(10,410)	(6,891)
Operating loss for the period	(15,512)	(10,772)	(8,405)	(9,824)	(6,680)
Financial Income	-	6	3	-	-
Financial expenses	(4,482)	(2,678)	(1,492)	(2,931)	(2,096)
Loss for the period before taxes	(19,994)	(13,444)	(9,894)	(12,755)	(8,776)
Income tax expenses	(20)	(39)	(18)	(16)	(28)
Net loss for the period	(20,014)	(13,483)	(9,912)	(12,771)	(8,804)

Comparison Operating loss for the six-month periods ended 30 June 2021 and 2020

The Group's Operating loss for the six-month period ended 30 June 2021 compared with the six-month period ended 30 June 2020 is discussed below.

Total Revenues and Other Income

In the periods under review, the Company did not market nor sell any products. The Company started a first pivotal study in January 2021 in order to obtain its first product approval. The Company has accordingly not yet manufactured any stimulation device for commercial purposes resulting in the cost of goods sold being zero.

The Company did however receive grants in The Netherlands and Switzerland to support research and development activities, whereby these grants are coming from US, European and local grant programs. The grants are qualified as Revenue and Other Income.

Total revenues and other income for the six-month period ended 30 June 2021 more than doubled to EUR 586k from EUR 211k in the six-month period ended 30 June 2020. This is predominantly the result of a new grant from the US Department of Defense Advanced Research Projects Agency (the "**DARPA grant**"), a grant from the Eurostars Programme of EUREKA together with the European Community, named Prep2Go (the "**Eurostar Grants**") and a grant from ZonMw (the "**ZonMw grant**").

Science expenses

Science expenses for the six-month period ended 30 June 2021 increased by 5% to EUR 569k from EUR 542k in the six-month period ended 30 June 2020. This is a result of the planned scientific research agreements with EPFL that are not formalized as of 30 June 2021 combined with the increase in share based payment expenses.

Research and Development expenses

Research and development expenses for the six-month period ended 30 June 2021 increased by 17% to EUR 3.3 million from EUR 2.8 million in the six-month period ended 30 June 2020. This is a combination of increased spend with the hardware supplier of the ARC^{IM} main controller, the ARC^{EX} platform and increased employee cost including increased share-based payment expenses, while only partly off- set by less money being spent with the hardware suppliers of the ARC^{IM} stimulator in the six-month period ended 30 June 2021.

Clinical and regulatory expenses

Clinical and regulatory expenses for the six-month period ended 30 June 2021 increased by 58% to EUR 1.9 million from EUR 1.2 million in the six-month period ended 30 June 2020. The increase is mainly due to the start of the Up-LIFT Study in January 2021 where the Company hired additional employees and incurred the costs from the Up-LIFT Study through its CRO.

Marketing and market access expenses

Marketing and market access expenses for the six-month period ended 30 June 2021 increased by 111% to EUR 353k from EUR 167k in the six-month period ended 30 June 2020. This increase is the result of the ONWARD rebranding spending combined with the market access investigative activities in both Europe and the United States.

Patent and related expenses

Patent and related expenses for the six-month period ended 30 June 2021 increased by 73% to EUR 786k from EUR 455k in the six-month period ended 30 June 2020. The increase is mainly caused by the due diligence work by both European and US patent counsels in relation to the latest Convertible Loan Agreement financing round and the preparation for this prospectus.

General and administrative expenses

General and administrative expenses for the six-month period ended 30 June 2021 increased by 106% to EUR 3.5 million from EUR 1.7 million in the six-month period ended 30 June 2020. This is a combination of the increase in employee related costs, including the share-based payment expense increase, as a result of a change in management with the hire of a new CEO, plus increased finance and legal costs in relation to the preparation of the Convertible Loan Agreement financing round and the preparation of this prospectus.

Comparison Operating loss for the Years Ended 31 December 2020, 2019 and 2018

The Group's Operating loss for the year ended 31 December 2020 compared with the year ended 31 December 2019 and the Group's Operating loss for the year ended 31 December 2019 compared with the year ended 31 December 2018 are discussed below.

Total Revenues and Other Income

In the three years under review, the Company did not market nor sell any products. The Company started a first pivotal study in January 2021 to obtain its first product approval. The Company has accordingly not yet manufactured any stimulation device for commercial purposes resulting in the cost of goods sold being zero as well.

The Company did however receive grants in The Netherlands and Switzerland to support research and development activities, whereby these grants are coming from US, European and local grant programs. The grants are qualified as Total revenues and other income.

Total revenues and other income increased in 2020 by 44%, from EUR 554k in 2019 to EUR 800k in 2020. This is a result of a new grant from the US Department of DARPA, and the Eurostar Grants.

Total revenues and other income increased in 2019 by 17%, from EUR 474k in 2018 to EUR 554k in 2019. This is a result of completion of the LEAP grant and receiving a couple of new grants including Eurostar Grants, and other local grants as explained in the Liquidity and Capital resources chapter.

Science expenses

Science expenses predominantly relate to the scientific collaboration with EPFL and the CHUV.

Science expenses increased in 2020 by 259%, from EUR 313k in 2019 to EUR 1.1 million in 2020. This is a result of the scientific work expansion in relation to the additional indications for the ARC^{IM} platform plus an increase in the share-based payment expense in 2020

Science expenses decreased in 2019 by 47%, from EUR 586k in 2018 to EUR 313k in 2019 as a result of the limited activities in the STIMO-1 locomotion study in 2019.

Research and Development

Research and development expenses, increased in 2020 by 9% from EUR 5.3 million in 2019 to EUR 5.8 million in 2020. This is a combination of less money spent with the hardware suppliers of the ARC^{IM} stimulator in 2020, offset by increased spend with the hardware supplier of the ARC^{IM} patient controller and the ARC^{EX} platform and increased employee cost, including an increase in the share-based payment expense in 2020.

Research and development expenses increased by 13% in 2019, from EUR 4.7 million in 2018 to EUR 5.3 million in 2019. This is a combination of the increased spend on the ARC^{IM} stimulator, partly offset by a decrease in spending on the first ARC^{IM} Paddle Lead.

Clinical and regulatory expenses

Clinical and regulatory expenses increased by 124% in 2020, from EUR 1.2 million in 2019 to EUR 2.8 million in 2020. The increase is mainly due to the preparation of the Up-LIFT Study where the Company hired additional employees and incurred the CRO costs for the study start-up.

Clinical and regulatory expenses increased by 89% in 2019, from EUR 654k in 2018 to EUR 1.2 million in 2019. The main driver for the increase is the hiring of employees and spending on the STIMO-2 study that was ultimately postponed.

Marketing and market access expenses

Marketing and market access expenses increased by 51% in 2020, from EUR 261k in 2019 to EUR 394k in 2020. This increase is the result of the rebranding spending with third party suppliers as the Vice President Marketing left the Company in 2020 and was not directly replaced.

The increase in marketing and market access expenses by 166% in 2019, from EUR 98k in 2018 to EUR 261k in 2019, is mainly the result of the difference of a full year employment of the Vice President Marketing in 2019 versus a couple of months in 2018.

Patent and related expenses

Patent and related expenses increased by 126%, from EUR 525k in 2019 to EUR 1.2 million in 2020, mainly due to added maintenance costs of the ARC^{EX} patent portfolio as part of the acquisition of NRT as well as the due diligence work by both European and US patent counsels in relation to the latest Convertible Loan Agreement financing round.

The increase in Patent and related expenses by 15% in 2019, from EUR 455k in 2018 to EUR 525k in 2019, is related to the added maintenance costs of the ARC^{EX} patent portfolio in the last quarter of 2019.

General and administrative expenses

General and administrative expenses increased by 38% in 2020 from EUR 3.6 million in 2019 to EUR 5.0 million in 2020. This is a combination of a decrease in employee related costs as a result of a

change in management and employee resources, offset by increased employee related costs for share based payment expenses plus increased head-hunter costs, to recruit two executive management team members and a number of development engineers, as well as increased legal counsel support.

General and administrative expenses increased by 54% in 2019, from EUR 2.4 million in 2018 to EUR 3.6 million in 2019, driven by the advisory cost for the acquisition of NRT, the expansion of the office footprint and increase in employee cost.

Liquidity and Capital Resources

General

As of 31 December 2020, the Company's Financial Statements include cash and cash equivalents balance of EUR 6.4 million and negative retained earnings of EUR 52.9 million. As of 30 June 2021, the Company's Interim Financial Statements include cash and cash equivalents of EUR 25.9 million and negative retained earnings of EUR 65.7 million.

The Company's principal resources of capital until 30 June 2021 have been from equity investments by leading European venture capitalists in life science, the issuance of interest bearing loans including convertible notes and the issuance of non-dilutive grants from the Dutch government (the latter are reported as revenue and other income per the above paragraph):

- EUR 36.0 million from convertible preference A shares issued in private placements to LSP, Inkef, GIMV, Wellington, NRT Holdings and management and founders;
- EUR 0.1 million from ordinary shares issued in private placements to management and founders;
- EUR 6.0 million split in EUR 3.0 million from convertible preference A shares issuance and EUR 3.0 million from ordinary shares issuance, both through a contribution in kind for the assets of NeuroRecovery Technologies Inc;
- EUR 30 million from convertible loans received from Invest-NL, LSP, Inkef, GIMV, Wellington, and various private investors;
- EUR 8.5 million from a subordinated innovation loan from RVO (Dutch Government); and
- EUR 2.5 million from various non-dilutive government subsidies since 2016.

As the Company continues to grow its business, it expects to fund its operations through multiple sources, including the funds raised in this Offering, cash flow from operations and non-dilutive financings such as reimbursable cash advances or subsidies.

Equity

On the date of this Prospectus, the Company's issued and paid-up capital is as reflected below:

Share Capital

Ordinary O shares and Ordinary E shares

Issued and fully paid shares (Number of shares)	Ordinary EUR 1	Ordinary E EUR 0.000003	Ordinary O EUR 0.000003	Ordinary R EUR 0.0000001	Total
Opening balance as at 20 November 2015	82,584	-	-	-	82,584
Series A Financing (april '16)	-82,584	977,778	2,306,221	2,500,001	5,701,416
As at 31 December 2016	-	977,778	2,306,221	2,500,001	5,784,000
Series A Financing (dec '17)	-	694,444	-	-	694,444
As at 31 December 2017	-	1,672,222	2,306,221	2,500,001	6,478,444
Series A Financing (sept. '18)	-	861,111	-	-	861,111
As at 31 December 2018	-	2,533,333	2,306,221	2,500,001	7,339,555
Series A Financing – NRT (oct. '19)	-	1,222,222	2,500,000	-2,500,001	1,222,221
As at 31 December 2019	-	3,755,555	4,806,221	-	8,561,776
Series A Financing – NRT (oct. '19)	-	1,018,519	-	-	1,018,519
As at 31 December 2020	-	4,774,074	4,806,221	-	9,580,295
E-share issuance	-	3,727,098	-	-	3,727,098
As at 30 June 2021	-	8,501,175	4,806,221	-	13,307,393
<i>Share Capital value</i>	EUR -	25.50	14.42	-	39.92

Ultimately on the First Trading Date, the issued non-voting ordinary shares E and ordinary shares O will convert 1:1 into Ordinary Shares and thereafter shall be subject to the 5:2 Reverse Stock Split. The Ordinary R shares were cancelled on 27 September 2019, by means of a written resolution of the general meeting.

Convertible preference A shares

On the date of this prospectus there were also 37,666,666 convertible preference A shares in issue (2019: 35,583,332; 2018: 20,000,001). These convertible preference A shares are separated into liability and equity components based on the terms of the contract. Reference is made to the note 24 and note 29 in the Financial Statements and note 8 and note 9 in the Interim Financial Statements.

The convertible preference A shareholders can upon their request and in case of a liquidation event (including an IPO) convert their shares at the conversion rate of one ordinary O share for every one preference share held. The preference shares carry a dividend of 6% per annum. The dividend rights are cumulative. The preference shares rank ahead of the ordinary shares in the event of a liquidation. Ultimately on the First Trading Date all convertible preference A shares will convert 1:1 into Ordinary Shares and thereafter shall be subject to the 5:2 Reverse Stock Split.

EPFL Options

The Ecole Polytechnique Fédérale de Lausanne ("EPFL") has the right to acquire 197,511 Ordinary Shares with nominal value EUR 0.12 (493,778 ordinary shares prior to the Reverse Stock Split in respect of the use of EPFL's intellectual property rights (the "EPFL Option 1"). The EPFL Option 1 can be exercised by EPFL until an IPO or an exit transaction ("Exit"). An "Exit" shall mean: (i) the sale of all or substantially all of the Company's assets, or (ii) the sale of more than fifty per cent (50%) of the Company's issued and outstanding capital stock, to any company, entity or person, or (iii) the liquidation, dissolution or winding up of the Company including, without limitation, any merger or consolidation where the Company is not the surviving company.

In addition, EPFL has the right to acquire 0.3% of the total Ordinary shares of the Company at zero consideration at the time of an IPO as set forth in the terms of the license agreement in respect of the use of EPFL's intellectual property rights (the "EPFL Option 2").

Under this agreement EPFL also has a right to receive the cash value equivalent to the number of shares representing 0.3% of the total capital stock of the Company existing, on a fully diluted basis, at the time of an Exit not being an IPO. An Exit, not being an IPO, is not considered to be the most probable outcome. The rights are non-cumulative and shall only apply once according to the earliest event.

For the accounting treatment and valuation of the EPFL Option 1 and EPFL Option 2 reference is made to note 29 in the Financial Statements and note 9 in the Interim Financial Statements.

EPFL has indicated that it want to exercise EPFL Option 1 and EPFL Option 2 as part of the IPO.

The Convertible Loan Agreement

On 20 April 2021 the Company entered into a Convertible Loan Agreement of EUR 30 million (EUR 27.1 million (the "**Principal Amount**") furnished per 30 June 2021, with an additional EUR 2.9 million executed in July 2021). The outstanding portion of the Principal Amount shall bear interest at a rate of 8% per year. Under the Convertible Loan, there are several situations that would trigger a conversion of the loan into shares:

- Upon closing of a qualified financing event
- Upon closing of a financing round not qualifying as a qualified financing event
- Upon entering into of a liquidity event prior to conversion or repayment
- Upon a milestone event
- Upon election by the option holder

In terms of the agreement no assets may be pledged by the Company without consent from the majority of lenders.

The Convertible Loan includes the following conversion options. These conversion options are mutually exclusive:

Conversion Option	Option Holder/ Lender/ Mandatory upon contingent event	Fixed or Variable Number of Shares	Cap or Floor to Share Price
Qualified Financing Series A	Mandatory upon contingent event	Variable depending on price per share per financing	Cap at original subscription price per share in case actual IPO price is higher.
Qualified Financing Senior Shares	Mandatory upon contingent event	Variable depending on price per share per financing.	Floor if price is below original subscription price.
Non-Qualified Financing Series A	Option Holder (by majority) upon contingent event	Variable depending on price per share per financing	Cap at original subscription price per share in case actual IPO price is higher.
Non-Qualified Financing Senior Shares	Option Holder (by majority) upon contingent event	Variable depending on price per share per financing.	Floor if price is below original subscription price.
Milestone Event	Mandatory upon contingent event	Fixed, converted at the original subscription price, as accrued interest is not converted	None
Liquidity Event	Option holder (individually) upon contingent event	Fixed converted at the original subscription price (as accrued interest is not converted) or variable depending on the latest round of financing, as elected by holder	None
Election	Option holder (only if the above contingencies do not occur)	Fixed number of Series A shares (as accrued interest is not converted), or variable depending on last round of financing for Senior Shares	None

For the accounting treatment and valuation of the Convertible loan reference is made to note 6 and note 8 in the Interim Financial Statements.

An IPO, such as the Offering, being one of the conversion options, is considered a qualified financing event, whereby the loan, plus the accrued interest (at an interest rate of 8%) convert into ordinary shares at the Offer Price minus a 25% discount (see also "*Shareholder Structure and Related Party Transactions— Related Party Transactions—Convertible Loan Agreement*").

The Innovation loan

There is a 10% interest-bearing loan from the Dutch government (RVO) to support innovation. The loan will need to be repaid in seven instalments with the first instalment to be repaid on 1 January 2026, and the last payment on July 1st, 2027. Certain assets, including IP, have been pledged to the RVO in the case of default of repayment of the loan, see also "*Risk Factors—Risks Related to the Company's Intellectual Property—Part of the Company's assets, including intellectual property is pledged to Rijksdienst voor Ondernemend Nederland (RvO, part of Dutch ministry of Economic Affairs), and the enforcement of such pledge could substantially harm the future development and operations of the Company.*" As per 30 June 2021, a loan amount of EUR 8.5 million has been received from RVO and the accrued interest amounts to EUR 2.4 million. The loan is milestone based and to date the Company has received 85% (EUR 8.5 million) of the granted loan amount of EUR 10 million. The remaining 15%, or EUR 1.5 million, is expected to be received in the next 18-months.

Government subsidies

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 and grants. The following funding agreements are included as grants as part of total revenues and other income in the (condensed) consolidated (interim) statement of profit and loss included in the Financial Statements and Interim Financial Statements:

<i>(In EUR 000)</i>	Total Grant	Allocated for the year ended 31 December			Allocated for six-month period ended 30 June
		2020	2019	2018	2021
LEAP	376	-	-	113	-
RESTORE	370	37	100	133	-
DISPERSE	311	36	93	93	-
WALKAGAIN	500	185	180	135	-
CONFIRM	416	197	81	-	69
BESTABLE	100	25	59	-	8
SWISS LOCAL	79	24	41	-	14
PREP2GO	348	104	-	-	69
DARPA	1,152	192	-	-	384
ZonMw	250	-	-	-	42
Total		800	554	474	586

The total grant income is recognized on a straight-line basis over the active running period of the grant, therefore not matching the actual incoming grant payments. The income therewith aligns with the expenses, as these can only be incurred during the running period of the grants.

LEAP

This Eurostars funding agreement with the Swiss Innovation Agency Innosuisse for a total amount of EUR 376,154 started in April 2016 and ended in September 2018. The total grant has been received and has become unconditional. In this project, ONWARD collaborated with Motek Medical B.V, the Technical University of Delft, the Clinique Romande de Readaptation and EPFL to develop Rysen,

an innovative body weight support system for neurorehabilitation. The system is now CE marked and commercialized by Motek.

RESTORE

This Eurostars funding agreement with the Netherlands enterprise agency RVO for a total amount of EUR 370,213 started in April 2017 and ended in September 2019, with follow up reporting resulting in the additional 10% granting of the allocated amount in 2020. The total grant amount has been received and has become unconditional. In this project, ONWARD collaborated with Zurich Medtech A.G., IT'IS Foundation, Universitair Medisch Centrum Utrecht and EPFL to develop a simulation framework supporting the pre-operative planning for ARC Therapy, using patient imagery data to generate patient personalized models of the spine to infer *a priori* optimal implant location and stimulation configurations.

DISPERSE

This Penta funding agreement with the Netherlands enterprise agency RVO for a total amount of EUR 310,867 started in March 2017 and ended in March 2020, with follow up reporting resulting in the additional 10% granting of the allocated amount. The total grant amount has been received and has become unconditional. In this project, ONWARD collaborated with Phillips and a large consortium of medical device development companies to investigate the influence of the coexistence of multiple implants on MRI safety.

Walkagain

This Eurostars funding agreement with the Netherlands enterprise agency RVO for a total amount of EUR 499,912 started in April 2018 and ended in September 2020, with follow up reporting resulting in the additional 10% granting of the allocated amount. The total grant amount has been received and has become unconditional. In this project, ONWARD collaborated with Gait-UP S.A. and EPFL to develop algorithms for closed-loop control of spinal cord stimulation based on motion sensor data.

CONFIRM

This Eurostars funding agreement with the Swiss Innovation Agency Innosuisse for a total amount of EUR 416,293 started in May 2019 and ends in October 2021, with follow up reporting resulting in the additional 25.75% granting of the allocated amount. At 31 December 2020, 74.25% of the total grant amount has been received and the remainder is expected in 2021 after submission of the final report which will trigger the payment of the last tranche. In this project, ONWARD is collaborating with Inomed A.G., Universitätsklinikum Heidelberg and EPFL to develop an intra-operative neuromonitoring system and algorithms facilitating the surgical implantation of ARC^{IM}.

BESTABLE

This Eurobench funding agreement with PKF ATTEST INNCOME S.L. and the Spanish National Research Council CSIC for a total amount of EUR 100,000 started in September 2019 and ends in December 2021. An amount equal to 85% of the grant is paid during the grant period in tranches in 2019, 2020 and 2021. The remaining 15% of the total grant amount will be paid after submission of the final report. In this project, ONWARD is collaborating with the Technical University of Delft, the Agencia Estatal Consejo Superior De Investigaciones Cientificas (CSIC) and the University Rehabilitation Institute to develop a benchmarking system for assessment of balance performance.

PREP2GO

This Eurostars funding agreement with the Netherlands enterprise agency RVO for a total amount of EUR 347,802 started in April 2020 and ends 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 being paid after submission of the final report. In this project, ONWARD is collaborating 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

This US Department of Defense funding agreement for phase 1 for a total amount of EUR 1,152,000 (or USD 1,354,000) started in October 2020 and ends in March 2022. The grant amounts are being

charged on a monthly basis over the 18 months period based on actual incurred costs. The agreement with the DOD provides for additional funding beyond March 2022. 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 correspond to a roadmap development of ARC^{IM} to be used in the hours following SCI. See "*Business—License Agreements with EPFL, NeuroRestore and CHUV and other Parties*".

ZonMw

This Dutch funding agreement with the Netherlands Organisation for Health Research and Development for a total amount of EUR 250,000 started in April 2021 and ends in March 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 ARC^{IM} and evaluating its use to alleviate locomotor deficits in Parkinson disease.

Cash flows

The following table presents primary components of the Group's cash flows for each of the periods indicated for the six-month periods ended June 30, 2021, and 2020 and the years ended 31 December 2020, 2019 and 2018.

(In EUR 000)	Audited			Unaudited	
	For the year ended 31 December			For the six-month period ended 30 June	
	2020	2019	2018	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES					
Loss for the period before taxes	(19,994)	(13,444)	(9,894)	(12,755)	(8,776)
Adjusted for:					
Depreciation and impairment of property, plant and equipment and right-of-use assets	271	229	234	124	123
Share based payment transaction expense	2,700	289	361	2,007	558
Post-employment benefits	(5)	(105)	(4)	169	(2)
Net finance costs	4,485	2,672	1,489	2,931	2,096
Other non-cash items	(7)	-	-	(14)	(17)
Changes in working capital					
Increase (-)/Decrease (+) in Trade and other receivables	(221)	(24)	(118)	(112)	82
Increase (+)/Decrease (-) in Trade and other payables	(48)	575	852	230	(630)
Interest received	-	1	-	-	-
Interest paid	(37)	(20)	(26)	(23)	(7)
Bank changes paid	(11)	(7)	(5)	(6)	(5)
Income tax paid	(31)	(11)	(45)	-	(31)
Net cash generated/(used) from operating activities	(12,901)	(9,845)	(7,156)	(7,449)	(6,609)
CASH FLOWS FROM INVESTING ACTIVITIES					
Investment in fixed assets	(173)	(124)	(103)	(45)	(112)
Acquisitions of a subsidiary, net of cash acquired	-	25	-	-	-
Net cash generated/(used) from investment activities	(173)	(99)	(103)	(45)	(112)
CASH FLOWS FROM FINANCING ACTIVITIES					
Proceeds from interest-bearing loans	3,946	11,743	5,489	27,106	553
Payment of principal portion of lease liabilities	(126)	(95)	(49)	(68)	(62)
Proceeds from issuance of shares	547	4,755	3,207	-	-
Net cash generated/(used) from financing activities	4,368	16,403	8,647	27,038	491
Net change in cash and cash equivalents	(8,706)	6,459	1,388	19,544	(6,231)
Effect of exchange rates on cash and cash equivalents	(41)	5	3	(32)	(12)
Cash and cash equivalents at 1 January	15,129	8,665	7,274	6,382	15,129
Cash and cash equivalents at the end of the period	6,382	15,129	8,665	25,894	8,886

Cash flows from operating activities

Cash flows used in operating activities increased from EUR 6.6 million for the six-month period ended 30 June 2020, to EUR 7.4 million for the six-month period ended 30 June 2021. The increase is a mainly the result of the increase of EUR 4 million in the loss for the period before taxes, offset by the increase in the share based payment transaction expense and the increase in net finance costs of combined EUR 2.3 million. The remaining effect is the result of the difference in working capital changes in the comparable periods.

Cash flows used in operating activities increased from EUR 9.8 million in 2019 to EUR 12.9 million in 2020. The increase is a combination of the increase in the loss for the period before taxes from EUR 13.4 million in 2019 to EUR 20 million in 2020, offset by the increase in the share based payment transaction expense and increase in net finance costs for combined EUR 4.5 million, plus an increase working capital of EUR 0.3 million. For an explanation of what the Company considers working capital, please refer to "*Important Information—Presentation of financial and other information—Alternative performance measures*".

Cash flows used in operating activities increased from EUR 7.2 million in 2018 to EUR 9.9 million in 2019, which is in line with the overall increase in the loss for the period before taxes from EUR 9.9 million in 2018 to EUR 13.4 million in 2019, offset by an increase in net finance costs of EUR 1.2 million and a decrease in working capital of EUR 0.5 million. For an explanation of what the Company considers working capital please refer to "*Important Information—Presentation of financial and other information—Alternative performance measures*".

Cash flows used in investing activities

Cash flows used in investing activities decreased from EUR 0.1 million for the six-month period ended 30 June 2020, to EUR 45k for the six-month period ended 30 June 2021. The laboratory equipment purchased in the first six-months in 2020 did not recur in the first six months in 2021.

Cash flows used in investing activities increased from EUR 0.1 million in 2019 to EUR 0.2 million in 2020 due to increased investments in computer equipment, laboratory equipment and furniture offset by the net cash incurred from the NRT acquisition.

Cash flows used in investing activities remained constant at EUR 0.1 million from 2018 to 2019 as the level of investments in laptops, laboratory equipment and furniture were fairly stable in both years. Reference is also made to the Capital expenditure definition refer to "*Important Information—Presentation of financial and other information—Alternative performance measures*".

Cash flows from financing activities

Cash flows from financing activities increased from EUR 0.5 million for the six-month period ended 30 June 2020, to EUR 27.0 million for the six-month period ended 30 June 2021. The main driver for the cash flow increase is the execution of the Convertible Loan Agreement in April 2021.

Cash flows from financing activities dropped from EUR 16.4 million in 2019 to EUR 4.4 million in 2020. The decrease is the result of a decrease of EUR 11 million in milestone payments of the Series A Financing plus a decrease of EUR 1.0 million in milestone payments of the Innovation Loan facility.

Cash flows from financing activities increased from EUR 8.7 million in 2018 to EUR 16.4 million in 2019. The increase is the result of an increase of EUR 5.8 million in milestone payments of the Series A Financing plus an increase of EUR 2.0 million in milestone payments of the Innovation Loan facility.

Capital expenditures

The Company has, to date, invested in laboratory equipment, computer equipment and furniture, whereby these investments are capitalized at the time of acquisition and depreciated over three years. Capital expenditures totaled EUR 103k in 2018, EUR 124k in 2019 and EUR 173k in 2020. For an explanation of what the Company considers capital expenditure please refer to refer to "*Important Information—Presentation of financial and other information—Alternative performance measures*".

Acquisitions

In 2019, the Company merged with NRT, a company located in Los Angeles, California (United States). The Company acquired 100% of the shares of NRT on a share for share basis, whereby the former shareholders of NRT received shares in the Company. The NRT merger brought several important assets to the merged entity:

- an external spinal cord stimulation platform that delivers therapy transcutaneously (through the skin);
- Intellectual Property licensed from the University of California at Los Angeles, Caltech, and the University of Louisville;
- a shareholder relationship with the Christopher & Dana 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.

Off-Balance-Sheet Arrangements and Contingent Liabilities

The Company does not have any off-balance sheet liabilities, other than the items mentioned in note 34 of the Financial Statements.

Significant Accounting Policies

- The preparation of the Financial Statements and Interim Financial Statements require the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Company's accounting policies as disclosed in note 5 of the Financial Statements and in note 2 of the Interim Financial Statements.
- The areas involving a higher degree of judgement or complexity, are areas where assumptions and estimates are significant to the Financial Statements. They are disclosed in note 7 of the Financial Statements and in note 2 of the Interim Financial Statements.

Financial Risk Management

Liquidity risk

The Company manages liquidity risk by monitoring forecast and actual cash flows on a regular basis.

The remaining contractual maturity for the Company's financial liabilities with agreed upon repayment schedule, including both the principal and interest cash flows as of 30 June 2021 is included in the below table:

<i>(in EUR 000)</i>	< 1 year	1-3 years	3-5 years	> 5 years	Total
Innovation Loan	-	-	2,535	16,763	19,298
Convertible preference A shares	-	-	60,541	-	60,541
Convertible loan	-	-	31,693	-	31,693
Other financial liabilities - conversion option	-	-	2,480	-	2,480
Lease Liability	130	-	-	-	130
Trade & other payables	2,732	-	-	-	2,732
Total	2,862	-	97,249	16,763	116,874

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 Company's activities may expose it to changes in foreign currency exchange rates and interest rates. The Company 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 Company only works with international reputable commercial banks and financial instruments.

Interest rate risk

The Company is exposed to interest rate risk in respect of surplus funds held on deposit. The risk is considered to be insignificant. The Company is not exposed to interest rate risk in respect of its financial instrument liabilities as the interest rate on its innovation loan and convertible loan are fixed.

Foreign exchange risk

The Company 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 Company 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. To date the incurred exchange rate effects are insignificant.

BUSINESS

Overview

The Company is a medical technology company developing innovative therapies to enable functional recovery for people with SCI. The Company's technology platforms are based on 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.

Market Opportunity – Unmet Need

The spinal cord contains neural circuits that control specific neurological functions, including sensation, movement, bladder, bowel, sexual, hemodynamic, and immune responses. These circuits are under the continuous control of the brain. An SCI suddenly disrupts or completely interrupts the flow of information between the brain and the spinal cord, with potential dramatic consequences. The circuits in the spinal cord below the injury are disconnected from the brain, resulting in the alteration or complete loss of sensory, motor and autonomic functions.^{3 4} Injuries can occur at any level of the spinal cord, which determines the specific neurological functions affected by the injury; and can be classified as an incomplete injury – some nervous signals remain and are able to travel past the lesion, to a functionally complete injury – a total loss of sensory and motor functions.

There is no cure for SCI. For all of human history, people with SCI have been forced to contend with paralysis, impaired movement, and several other challenges and complications, often including urinary tract infection, urinary and/or fecal incontinence, poor blood pressure regulation, spasticity, loss of sexual function, pressure sores, and difficult breathing or swallowing. In addition, people with SCI commonly experience sleep problems, fatigue, and depression, restrictions on jobs and social activities, and requirements for attendant care.

In the US and Europe, there are approximately 650,000 people with SCI and the annual incidence is approximately 50,000, consisting of 31,000 in the Europe⁵ and 18,000 in the US.⁶ Globally, the prevalence exceeds 7,000,000 and the annual incidence exceeds 768,000.⁷

Patient Journey

Typically after someone suffers an SCI, they undergo emergency surgery ("**Acute Phase**") and remain in intensive care for approximately one week ("**Sub-Acute Phase**"). Thereafter they undergo three to six months of rehabilitation ("**Intermediate Phase**") at which point they typically plateau ("**Chronic Phase**"), making no further progress in recovery of function. In fact, rehabilitation is often focused on adapting to limitations in daily life rather than restoring function. People with SCI therefore face a lifetime of challenges that include secondary complications, further declines in quality of life, high levels of dependency on outside care, and high healthcare system utilization.⁸

³ M.W.G. Brinkhof et al., "Health conditions in people with spinal cord injury: Contemporary evidence from a population-based community survey in Switzerland," *J. Rehabil. Med.*, vol. 48, no. 2, pp. 197–209, Feb. 2016, doi: 10.2340/16501977-2039.

⁴ M. Walter and A. V. Krassioukov, "Autonomic Nervous System in Paralympic Athletes with Spinal Cord Injury," *Phys. Med. Rehabil. Clin. N. Am.*, vol. 29, no. 2, pp. 245–266, May 2018, doi: 10.1016/j.pmr.2018.01.001.

⁵ 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.

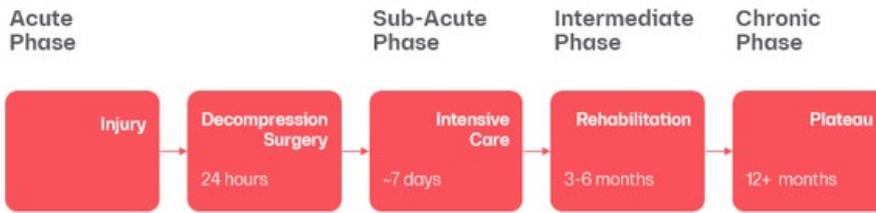
⁶ National Spinal Cord Injury Statistical Center, *Facts and Figures at a Glance*. Birmingham, AL: University of Alabama at Birmingham, 2019.

⁷ 2020 NSCISC Annual Statistical Report Complete Public Version

⁸ NSCISC Annual Report, US only, World Health Organization Fact Sheet, November 2013, estimate 40-80 cases per million. 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.

Little or no progress after Intermediate Phase

Patient Journey



Long-Term Challenges:

- Secondary complications
- Decline in quality of life
- High healthcare system utilization, dependent care

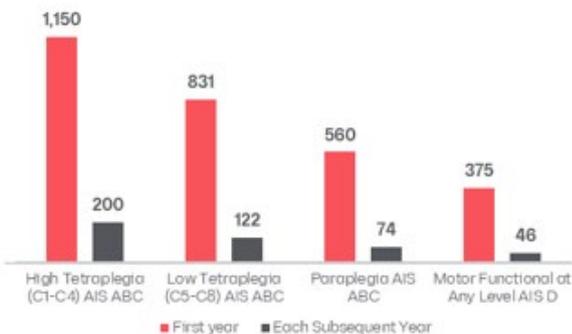
People with SCI often require expensive assistance to support routine activities of daily life, and the quality of their lives can be poor. It is estimated that the lifetime cost to support someone with paraplegia can exceed EUR 2.1 million (USD 2.5 million) and the cost to support someone with high tetraplegia can exceed EUR 4.2 million (USD 5.0 million).⁹

The Company seeks to fill that void, introducing therapies during the Acute, Sub-Acute, Intermediate, and Chronic Phases that can result in functional improvement even years after an injury.

SCI creates expensive dependence on attendant care and healthcare system utilization

Average Lifetime Costs

Average Yearly Expenses (in \$k)



Estimated Lifetime Costs by Age at Injury (in \$k)



Costs are highest for people with most common injury location (cervical spine)

Source: 2020 NSCISC Annual Statistical Report Complete Public Version

Vision

"Empowered by movement, people with spinal cord injury will enjoy life in every way that matters to them."

SCI can lead to paralysis as well as a number of other challenges, including infection, incontinence, and poor blood pressure regulation. ARC Therapy has been observed in clinical trials to not only

⁹ 2020 NSCISC Annual Report, US

restore the ability to walk following SCI, but also the potential to help people with SCI in a variety of other ways.¹⁰

The Company's vision is to develop and commercialize therapies that address all of the major challenges faced by people with SCI, leveraging the Company's ARC^{IM} and ARC^{EX} platforms to deliver spinal cord stimulation for SCI patients across a broad spectrum of injury locations and impairment severities.

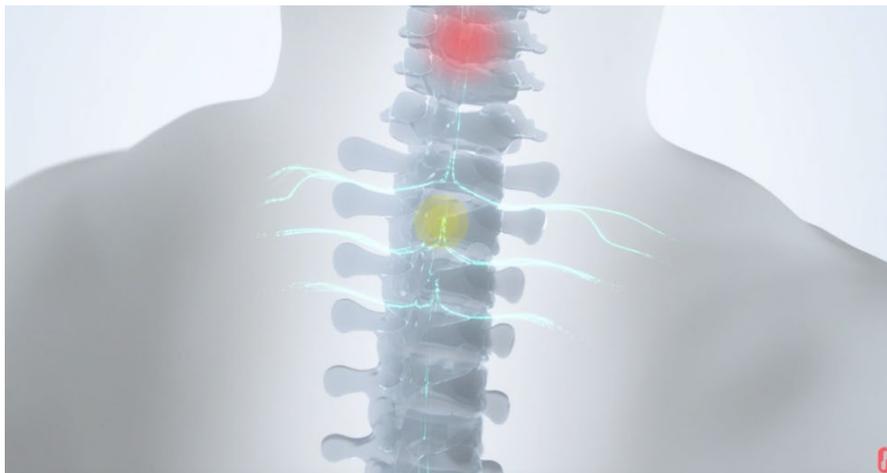
By varying the location of spinal cord stimulation and optimizing output parameters based on the scientific insights of the Company's research and development team and the Company's academic research partners, the Company expects to leverage its ARC^{IM} and ARC^{EX} platforms to restore movement and autonomic functions throughout the body.

The Company's primary target will be serving the needs of people with SCI, but the Company envisions its therapies may also provide benefit to other populations with similar challenges, such as people who have suffered strokes or have Parkinson's or Parkinson's-like symptoms.

ONWARD ARC Therapy

The Company's solution

The Company's solution is ARC Therapy. ARC Therapy is a targeted, programmed, electrical stimulation of the spinal cord designed to restore movement, independence, and health in people with SCI. ARC Therapy applies programmed electrical stimulation to the intact, dormant spinal cord anatomy downstream from the lesion, at locations specifically associated with particular movements or functions using stimulation parameters optimized to restore those movements or functions.



The Company delivers ARC Therapy via two proprietary investigational platforms, ARC^{IM} and ARC^{EX}, both of which have been awarded FDA Breakthrough Device Designation: (i) ARC^{EX} for restoration of strength and function of the upper extremities, (ii) ARC^{IM} for walking, and (iii) ARC^{IM} for blood pressure and trunk control, in recognition of their potential to address significant patient needs with a truly innovative solution.¹¹ This will be further explained under "*The Company's solution*".

The Company's technology and products are protected by a strong and growing portfolio of intellectual property rights, including 121 granted utility and design patents and 171 pending applications, across 15 countries. In total, the Company owns 14 trademarks registered and pending around the globe.

The Company continuously invests in research and development. 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

¹⁰ GTX Medical, "Supportive Clinical Data for ARC^{IM} and ARC^{EX} Therapies", 18 November 2020.

¹¹ FDA Letter of 3 June 2021, Q210843, FDA Letter of 29 May 2020, Q200272/S001 and FDA Letter of 5 October 2017, Q171397.

revenue generation. The Company also plans to explore the use of ARC Therapy to treat people with diseases beyond SCI, such as Parkinson's disease and stroke.

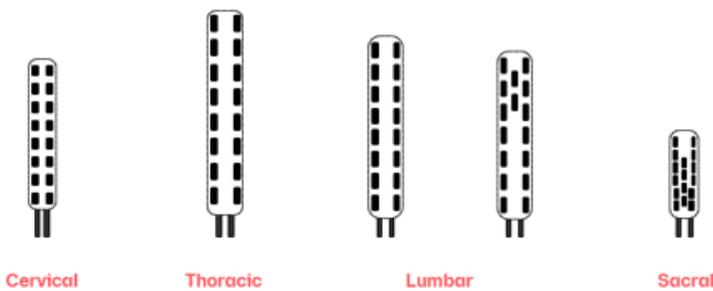
ARC^{IM} platform

ARC^{IM} consists of a proprietary implantable pulse generator ("IPG") and a family of five paddle leads, each optimized for placement along the spinal cord in an area thought to be responsible for restoring a particular movement or function, for instance, the cervical lead is designed for upper limb function, the thoracic lead is designed for blood pressure and trunk, the lumbar leads are designed for locomotion with two different sizes accommodating for differences in patient anatomy, and the sacral lead is designed for bowel, bladder and sexual function.

The IPG is controlled by a small, wireless external unit that is programmed and/or controlled by a tablet programmer or voice-activated smartwatch. The IPG is purpose-built for SCI indications. It offers several capabilities not currently found in IPGs used for spinal cord stimulation ("SCS") for pain, such as ARC^{IM}'s ability to wirelessly send high volumes of information at very low latency and its capability to recharge from a distance 2-3X further than current devices.

ARC^{IM} IPG is paired with a family of leads rigorously designed and optimized for deployment along different areas of the spinal cord with electrode spacing and configuration designed to optimally stimulate the desired movement or function. While similar leads are offered by companies marketing spinal cord stimulation systems for pain management, pain management leads are designed to deliver current to the spinal cord itself, whereas the Company's leads are designed to deliver current to the dorsal roots which lay along the lateral aspects of the spinal cord. The Company's leads are generally larger than leads designed for pain management, and more importantly they incorporate electrodes in locations not generally offered in those leads. (Note: The graphic renderings of the leads below are illustrative and do not necessarily reflect the actual electrode placement on each lead paddle shown.)

Broad family of leads, rigorously designed and optimized for specific deployment along spinal column



Lead Platform Provides Flexibility

Paddle geometry and electrode placement

Allow for variation in spinal segment anatomy while providing the specificity required to modulate targeted dorsal roots

Designed specifically for ONWARD therapies, targeting spinal roots vs. the dorsal column

Difficult to replicate without proprietary computational models and deep understanding of anatomy

Design patent applications have been filed to protect our designs

Design process and resources leveraged

1. Leveraged published human data on spinal segments and nerve root locations to establish initial norms
2. Constructed proprietary 3D atlas of human spinal anatomy through structural MRI mapping using specialized targeted scan sequences
3. Derived computational models based on these data with realistic biophysical material properties and geometries
4. Used computational models to optimize tradeoff between selectivity and anatomic variation



The initial planned indication for ARC^{IM} is restoration of normal blood pressure and enhanced trunk control in people with SCI. In June 2021, the Company commenced a clinical trial ("STIMO HEMO") sponsored by one of its research partners with the intention of gaining experience and gleaning clinical insights prior to beginning a planned pivotal trial for this indication in the US and Europe. A later planned indication for ARC^{IM} is restoration of mobility (walking) in the spinal cord injury population - see "Regulatory framework—Clinical and Regulatory".

ARC^{IM} is designed to address clinical indications for which precise stimulation parameters are required or 24/7 availability is important. These include movement-related functions such as walking and autonomic functions such as bladder and bowel control, and blood pressure regulation.

In addition to blood pressure, trunk control, and mobility (walking), other potential indications currently in pre-clinical or research phases for ARC^{IM} include but are not limited to bladder and bowel control, restoration of sexual function, restoration of arm and hand function. The Company intends to gain regulatory approval for ARC^{IM} indications in the US and Europe – see "*Regulatory framework—Clinical and Regulatory*".

ARC^{EX} platform

ARC^{EX} is an external device, consisting of a small stimulator that connects to adhesive leads that are placed on the skin near the area of the spinal cord responsible for the movement or function targeted for restoration. The stimulator is designed to be programmed and/or controlled by a tablet and/or smartwatch.

External stimulation is applied via two separate currents. The first desensitizes nerves near the skin so that the second current can be comfortably delivered with sufficient intensity to reach the spinal cord.

ARC^{EX} is designed to restore function in conjunction with rehabilitation. It is intended to be used periodically during 20-30 minute sessions delivered in the clinic or home. The initial planned indication for ARC^{EX} is improvement or restoration of upper extremity (hand and arm) strength and function via therapy delivered in the clinic. In January 2021 the Company commenced a pivotal trial ("**Up-LIFT**") with the intention of gaining regulatory clearances and approvals for this indication in the US and Europe - see "*Regulatory framework—Clinical and Regulatory*". The Company expects to receive FDA clearance for the initial in-clinic indication in 2023. It plans to pursue a home use indication with planned US regulatory clearance in late 2023 or early 2024. Medical device companies do not yet have practical experience with Europe's new MDR framework. While it is possible regulatory authorization to market in Europe may precede US clearance, at this time the Company is assuming similar timelines.

Commercial operations

The Company does not currently offer any products for commercial sale. Following the expected successful completion of Up-LIFT, the Company expects to commercialize ARC^{EX}, in the US and Europe in 2023 for the improvement of strength and function of the upper extremities. The Company then expects to launch ARC^{IM} commercially in the US and Europe in 2024 to restore normal blood pressure and trunk control. In 2025, the Company expects to commercialize ARC^{IM} in the US for mobility (walking) via HDE from the FDA. The European authorization process for ARC^{IM} for the mobility indication is not yet determined. The Company's plans to commercialize its products and the associated timelines are dependent on the Company's ability to demonstrate safety and effectiveness as may be required by regulatory authorities in the Company's respective target markets. Those details are explained in "*Regulatory framework*".

People with SCI are typically cared for by a limited number of specialty rehabilitation clinics in the US and Europe. The Company estimates the total number of these clinics in these target markets at 188, of which 105 are located in the US and 83 in Europe.¹² In addition to rehabilitation clinics, the Company also plans to market to specialized trauma centers where emergency surgeries are performed following SCI. These specialized trauma centers are also limited in number. The Company estimates there are 342 such centers in the US and Europe. Lastly, the Company expects to support implant procedures for its ARC^{IM} systems, which are expected to be performed in hospitals and ambulatory surgery centers by functional neurosurgeons. Given the overall modest number of call points and clinicians responsible for managing SCI patients and performing accompanying surgeries, the Company plans to deploy its own direct sales and service organization in both geographies. The Company will support its field organization with marketing professionals who will focus on developing and executing plans to drive adoption of the Company's therapies.

The Company's commercial organization will consist of sales and clinical support professionals who will focus on initiatives to raise awareness for the Company's products and services and drive

¹² FDA Letter of 3 June 2021, Q210843, FDA Letter of 29 May 2020, Q200272/S001 and FDA Letter of 5 October 2017, Q171397.

adoption thereof. They will also provide support for use of the Company's products in clinics, hospitals, and other settings.

The Company expects to focus its commercial efforts on physical therapists, occupational therapists, neurologists, and psychiatrists who work in the rehabilitation clinic setting. These clinicians will manage patients using ARC^{EX}, refer patients for implants of ARC^{IM} and will also care for patients following implant of ARC^{IM}. The Company also expects to focus on functional neurosurgeons, whom the Company expects to perform the implant procedure for ARC^{IM}. Because the implant procedure is substantially similar to that which functional neurosurgeons are already performing for SCS for pain indication, the Company expects the training burden for functional neurosurgeons to be minimal.

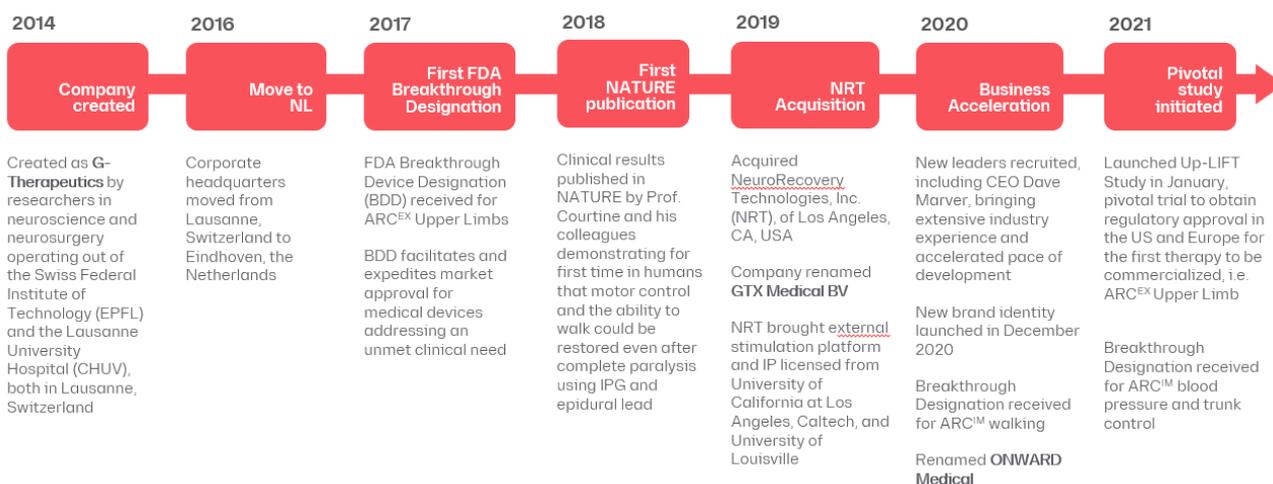
The Company intends to utilize digital marketing tools, leveraging its website and social media channels, and email campaigns. It is widely known that the SCI community spends considerable time online and the Company intends to communicate directly with potential patients and their caregivers through these means.

In the United States, the Company is well positioned to benefit from reimbursement for its therapies, either through the MCIT pathway that may be available to devices with FDA Breakthrough Device Designation or the use of existing codes for pain management and other devices similar to those the Company plans to commercialize. Given the innovative nature of the Company's technologies, validated by Breakthrough Device Designations, the Company believes its therapies will also be eligible for new technology add-on payments. The Company is currently exploring reimbursement pathways in Europe and will pursue similar opportunities to seek enhanced payments for innovative technologies that address unmet needs.

History

Progress accelerated in 2020 as company entered pivotal trial phase

History



The Company was formed in 2014 by Professor Courtine, Professor Bloch and other researchers in neuroscience and neurosurgery operating out of EPFL and CHUV. 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., 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.¹³ These results were obtained using an implantable platform consisting of an IPG and epidural lead. That same year the Company was renamed GTX Medical B.V.

In 2019, GTX Medical B.V. acquired NRT. 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 institutional shareholders participated in the 2021 financing and the Company recruited several additional investors, including the Dutch impact investment fund, Invest-NL, and Olympic Investments, the private investment arm of the Onassis Foundation.

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 who are currently conducting the Up-LIFT Study. 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.

Strengths

Large, underserved patient population

There is no cure for SCI. For all of human history, people with SCI have been forced to contend with paralysis, impaired movement, and several other challenges and complications, often including urinary tract infection, urinary and/or fecal incontinence, poor blood pressure regulation, spasticity, loss of sexual function, pressure sores, and difficult breathing or swallowing.

In the US and Europe, there are approximately 650,000 people with SCI and the annual incidence is approximately 50,000, including 31,000 in Europe¹⁴ and circa 18,000 in US¹⁵. Globally, the prevalence exceeds 7,000,000 and the annual incidence exceeds 768,000.

¹³Wagner, 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.

¹⁴ 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.

¹⁵ National Spinal Cord Injury Statistical Center, Facts and Figures at a Glance. Birmingham, AL: University of Alabama at Birmingham, 2019.

The Company's therapies are among the first to offer the potential to help people with spinal cord injury regain movement and other functions, improving quality of life for a large group of people for whom life is a true struggle. In addition to the large number of people with SCI that can potentially be helped by the Company's therapies, large populations of stroke sufferers and those with Parkinson's disease can also be potentially aided by the Company's technology.

Two proprietary, synergetic technology platforms

The Company is developing and intends to market two proprietary platforms, ARC^{EX} and ARC^{IM}. These platforms are highly proprietary, backed by scientific knowledge, intellectual property, and know-how. Together, these two platforms allow the Company to address a broad range of indications across SCI, stroke, and Parkinson's disease in the hospital, rehabilitation clinic, and home.

ARC^{EX} and ARC^{IM} are highly synergistic, sharing common components, hardware, and software systems. They are developed by the same development organization, will be studied by the same clinical and regulatory organization, and will be marketed by the same commercial organization targeting the same specialty rehabilitation clinics in the US and Europe.

Three FDA Breakthrough Device Designation awards

The Company has already been granted three Breakthrough Device Designations by the FDA. This program is intended to streamline the authorization process to develop, assess, and review truly innovative technologies that address an unmet need. Each of the Company's indications intended for marketing in the next four years has been awarded this designation, including restoration of upper extremity strength and function for ARC^{EX}, regulating blood pressure and restoring trunk control for ARC^{IM}, and restoration of walking for ARC^{IM}.

Multiple potential indications and robust research pipeline

The Company's therapies can be applied to multiple potential indications and populations, enlarging the total available market. These potential indications and populations can be accessed using the Company's hardware technology, adapted for each indication via modest changes in software and firmware. The Company's opportunities are further broadened by a robust research pipeline at its principal research partner, NeuroRestore, which plans to conduct several clinical (human) proof of concept studies over the next 18 months. The Company will select and commercialize the most promising of these opportunities, providing a rich pipeline and promising a steady flow of new indications for which it expects to seek regulatory approval to market over the next several years.

Deep and comprehensive intellectual property portfolio

The Company has more than 290 issued or pending patents worldwide, half developed and owned by the Company and half licensed exclusively from the world's leading global neuroscience research laboratories. As pioneer in the field of electrical spinal cord stimulation for mobility and autonomic function, the Company has amassed an intellectual property position it believes constitutes a significant obstacle for potential competitive entrants. As first-mover and by virtue of its deep relationships with academic research centers worldwide, the Company has also established fortifications in scientific knowledge, know-how, and trade secrets it believes provide a very strong and sustainable advantage.

Seasoned, international management team

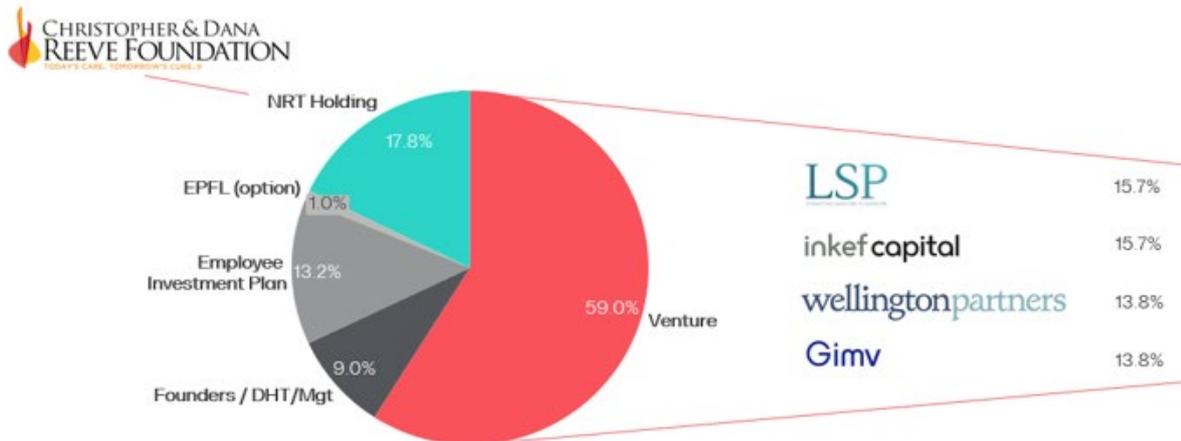
The Company's management team consists of individuals with long-held experience in medical technology, extensive international experience, and backgrounds working at relevant companies private and public, large and small. The Company believes its management team can scale with the Company as it grows and has the experience needed to complete required development initiatives, gain regulatory approval to market its products globally, and successfully commercialize them in order to realize financial returns.

Strong validation from leading life science investors

Since 2016, the Company has been financially supported by investment capital from some of the world's leading life science investors and government funds. These include Life Sciences Partners, Wellington Partners, Gimv, and INKEF. In the Company's most recent financing, transacted April 2021, new investors included Dutch impact fund, Invest-NL, and Olympic Investments, the private investment arm of the Onassis Foundation.

Backed by respected life science investors and the leading SCI patient advocacy group

Shareholders



Ownership as per June 8, 2021 Basis: Cap Table incl. EPFL option

Deep relationships with leading patient associations

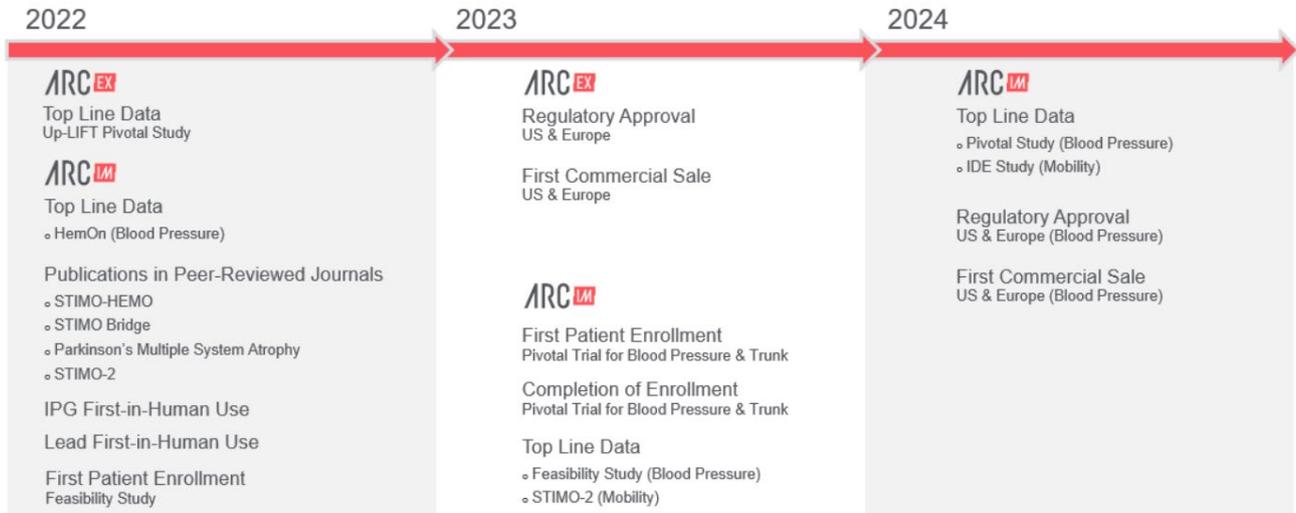
The Company enjoys excellent relationships with the world's leading patient advocacy groups for people with spinal cord injury. The world's largest such organization, the Christopher and Dana Reeve Foundation ("**Reeve Foundation**"), is an investor in the Company. The Company has embarked on shared media affairs initiatives with the Reeve Foundation in the US and they share a common Board Director, Ian Curtis. Wings for Life, another leading patient advocacy and research organization based in Europe, has provided financial support to NeuroRestore (CHF 720,000) for studies conducted by the Company's research partner, principally for walking, i.e. STIMO trial, and is in the contract phase to provide additional funding to the same research partner for a future walking trial. The Company also has a relationship with the Praxis Foundation in Canada and International Spinal Research Trust.

Robust opportunities for news flow

As an entity with two technology platforms and plans to target multiple indications, the Company has the potential to generate significant news flow related to its therapies. Before the end of 2022, findings from the STIMO Bridge, Parkinson's Multiple System Atrophy and STIMO-HEMO clinical trials are likely to be published in peer reviewed scientific or medical journals. The Company also expects to announce first-in-human use of its IPG and lead, completion of enrollment in its Up-LIFT Study, and first enrollment in its ARC^{IM} feasibility study. Top line data from the Up-LIFT pivotal study may also be shared. It is expected that 2023 will bring news of regulatory approvals for ARC^{EX} in the US and Europe and first commercial sale on both continents. The Company also expects first enrollment and completion of enrollment for its ARC^{IM} pivotal trial for the blood pressure and trunk indications. Lastly, the Company may share top line data in 2023 from its ARC^{IM} blood pressure feasibility study and STIMO-2 mobility study. Other newsworthy events may include regulatory milestones and approvals, additional Breakthrough Device Designations, quarterly update PR and conference calls, congress and investor conference participation, grant announcements, new hires and research partnerships. Further events that may contribute to news flow are detailed in the chart below.

Multiple platforms and indications expected to fill news flow pipeline

Numerous Milestones to Drive Value



Commercial and marketing strategy

Commercialization efforts

The Company does not currently offer any products for commercial sale. It expects to begin marketing its ARC^{EX} system in 2023 and its ARC^{IM} system in 2024. The Company's plans to commercialize its products and the associated timelines are dependent on the Company's ability to demonstrate safety and effectiveness as may be required by regulatory authorities in the Company's respective target markets. Those details are explained in the "Regulatory framework".

Patients are concentrated in specialized rehabilitation facilities and trauma centers

Commercial Strategy

Approach

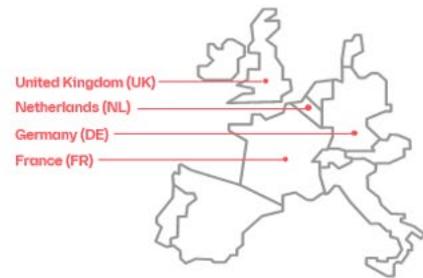
- Generate referrals to functional neurosurgeons for ARC^{IM} implants and prescriptions for home use of ARC^{EX}
- Engage with functional neurosurgeons, neurologists and therapists in trauma centers and specialized rehabilitation facilities
- Target same clinics for ARC^{IM} and ARC^{EX} therapies
- Focus on US and select European markets with attractive reimbursement environment for new medical technologies and sophisticated SCI rehabilitation infrastructure

US



Country	Level 1 Trauma Centers	SCI Rehab Clinics
US	190	105

Select European Markets



Country	Level 1 Trauma Centers	SCI Rehab Clinics
DE	91	27
UK	27	10
NL	11	8
FR	23	38

Geographical focus and commercial objectives

The Company plans to market its products in the United States and Europe, where people with SCI are typically cared for by a limited number of trauma and rehabilitation centers. When people suffer a spinal cord injury, they typically undergo emergency surgery in a trauma center. Thereafter, they typically spend a week in intensive care before starting rehabilitation training that can last up to one

year, but typically lasts 3-6 months, depending on the market. Rehabilitation training typically occurs in a specialty rehabilitation clinic with the equipment and expertise to help people with spinal cord injury.

Rehabilitation Clinics

The majority of the Company's selling efforts are expected to focus on clinicians managing SCI patients in specialty rehabilitation clinics. These clinics manage patients undergoing rehabilitation training in the months following injury and provide ongoing support to those who are chronically injured. The latter constitute the large prevalence pool of SCI patients globally.

The Company expects clinicians at these clinics (neurologists, rehabilitation physicians, physical therapists, and occupational therapists) to use the Company's therapies as follows:

- Apply ARC Therapy using ARC^{EX} in the clinic
- Prescribe ARC^{EX} for use in the home
- Refer patients to functional neurosurgeons for implantation of ARC^{IM} and subsequent use of ARC Therapy in the clinic and home

There are a limited number of specialty rehabilitation clinics in the US and Europe. In the US, the Company expects to primarily target the 105 SCI rehabilitation clinics in the US certified by the Commission of Accredited Rehabilitation Facilities (CARF). CARF certification demonstrates a clinic has a comprehensive integrated inpatient rehabilitation program, outpatient medical rehabilitation program, home and community services, residential rehabilitation, and vocational services.¹⁶ These certified centers provide a robust referral base for the Company's products and will serve as focused and fertile marketing targets.

In the selected European markets the Company expects to initially target, there are 27 SCI specialty rehab centers in Germany¹⁷, 10 in the United Kingdom¹⁸, 8 in the Netherlands¹⁹, and 38 in France.²⁰

Neurologists & Rehabilitation Physicians will prescribe ARC^{EX} for clinic/home use and refer patients for ARC^{IM} implants

Referral Pathway



Decider
Neurologists & Rehabilitation Physicians



Hospitals and Ambulatory Surgery Centers

When patients are referred for an implant of ARC^{IM}, these implants will typically be performed in hospitals or ambulatory surgery centers. The Company expects implant procedures to be performed

¹⁶ CARF Provider Search- United States Find a Provider - Advanced (carf.org).

¹⁷ Deutsche Behandlungszentren (dmgp.de).

¹⁸ Medical Management Advice :: Royal National Orthopaedic Hospital (rnoh.nhs.uk).

¹⁹ PHM50279 93..95 (inSCI.network).

²⁰ Table 3 Regional distribution of the number of rehabilitation units, their capacities (number of beds) and the number of patients admitted (nature.com) 148 specialty rehab clinics, but only 38 treated 6 or more SCI in the past year.

by functional neurosurgeons. This subspecialty of surgeons is familiar with device therapy and neuromodulation, commonly performing implants for deep brain stimulation and spinal cord stimulation for pain therapy. The implant procedure for ARC^{IM} is substantially similar to the procedure functional neurosurgeons are currently performing for spinal cord stimulation for pain, so the Company expects little resistance to adoption and a minimal training burden.

Trauma Centers

The Company plans to target trauma centers to provide its therapies that may be appropriate for people shortly after injury. Level 1 trauma centers provide total care for all aspects of an injury, and prompt availability of relevant specialists such as neurosurgeons.²¹ Therefore, they provide an access point to Acute and Subacute SCI patients and neurosurgeons who can implant ARC^{IM} devices. It is envisioned that the Company's blood pressure management indication may be well suited for this acute environment, helping to stabilize blood pressure and promote spinal cord perfusion.

In the US, most SCI patients are treated at just 190 Level 1 or major trauma centers.²² In Europe, the Company plans to target four markets: Germany, France, UK and the Netherlands, selected based on their attractive reimbursement environment for new medical technologies and sophisticated SCI rehabilitation infrastructure. There are 27 major trauma centers in the UK²³, 11 in the Netherlands²⁴, 91 in Germany²⁵, and 23 in France²⁶.

Given the small number of facilities the Company must target in order to market its therapies and support surgical interventions, the Company plans to deploy a direct sales and service organization. Details on the planned organization are provided below.

In the initial period following launch, the Group's focus will be solely on the US and large European markets. If FDA clearance or approval or CE certification permits the Group's entry into other large markets, the Group will likely pursue entry via a relationship with a distribution partner. The Group also expects to enter certain Asian markets such as Japan via partnership.

Marketing strategy

The Company intends to primarily target specialty rehabilitation clinics, where clinicians manage SCI patients in the Intermediate and Chronic phases. The clinicians working in these facilities generally determine the course of therapy for SCI patients.

Building relationships

In the US, the Company is well positioned to penetrate the approximately 105 SCI specialty rehabilitation clinics because it expects to establish relationships with many of those clinics participating in the Up-LIFT study and will further broaden its network as it commences a planned pivotal trial for ARC^{IM} in 2023.

Current US Up-LIFT study sites	9
Expected US ARC^{IM} pivotal study sites	10
Other current or expected research sites*	6
Total	25

*Transcutaneous therapy pilot sites, DARPA-related collaborations, other collaborations

²¹ American Trauma Society <https://www.amtrauma.org/page/TraumaLevels>, retrieved 09AUG2021.

²² MacKenzie EJ, Hoyt DB, Sacra JC, et al. National Inventory of Hospital Trauma Centers. JAMA. 2003;289(12):1515–1522. doi:10.1001/jama.289.12.1515.

²³ National Health Services A4_map (www.nhs.uk) Retrieved 09AUG2021.

²⁴ PHM50279 93..95 (inisci.network).

²⁵ Orthopedic Trauma Association Development of trauma systems in Europe—reports from England: OTA International (lww.com) Retrieved 09AUG2021.

²⁶ France does not have official criteria for trauma center levels as the above countries, however Traumabase is a registry of 23 top trauma hospitals in that country. Traumabase Registry https://www.traumabase.eu/en_US.

By the time ARC^{EX} is expected to be authorized for commercial sale in the US in 2023, the Company expects to have already established relationships with approximately 25% (25/105) of the existing specialty rehabilitation centers.

A similar approach will be employed in Europe, with initial emphasis on the four countries mentioned above and broadening thereafter. In these countries, the Company expects to build relationships with thought-leading SCI clinics and hospitals in each market through collaboration on clinical research. Once authorized for commercial sale in these markets, those SCI clinics will become reference centers that can be leveraged for training and awareness building. Already, two Up-LIFT sites are enrolling subjects in the UK and Europe with additional centers planned to study ARC^{IM} indications for safety and effectiveness in 2022 and beyond.

Digital Marketing

The Company intends to use marketing strategies commonly employed in the medical device industry to raise awareness for its therapies. However, there are several unique strategies planned that leverage the Company's strengths and positioning. It is well accepted that the SCI community spends considerable time online. The Company intends to emphasize digital marketing to reach patients and their loved ones directly, leveraging its web presence, social media channels, email marketing, and influencer marketing.

Patient Advocacy Groups

The Company enjoys strong relationships with major patient advocacy groups worldwide. The most significant of such relationships is with the Reeve Foundation. The Reeve Foundation is a shareholder in the Company and they share a common Director. The Company expects to use its relationship with Reeve and similar advocacy organizations across the globe such as Wings for Life, Praxis, and Spinal Research to help drive awareness for its therapies, collaborate on government and market access initiatives, and as potential sources of data and non-dilutive funding, chiefly to support research and clinical trials.

Media

The Company's therapies and the activities of its research partners have been featured in major media outlets globally. Given the breakthrough nature of its work, the Company expects media interest to persist and grow as it begins to commercialize its therapies and patients are positively impacted. The Company has engaged Finn Partners, a leading life sciences media relations firm, to help it drive awareness for its therapies in the media.

Sales and Marketing Organization

Given the small number of facilities the Company must target in order to market its therapies and support surgical interventions, the Company plans to deploy a direct sales and service organization in both the US and Europe. This organization is expected to consist of experienced medical technology and rehabilitation professionals and will include vice presidents of sales, regional managers, sales representatives and field engineers.

The Company expects to deploy its field organization cautiously, beginning with five individuals in each of the US and Europe, and growing as conditions dictate in order to capture growth opportunities assertively.

The Company will support the Company's field organization with marketing professionals who will develop and execute plans to drive adoption of the Company's therapies. The marketing organization is expected to include vice presidents of marketing, product managers, marketing managers and market access professionals.

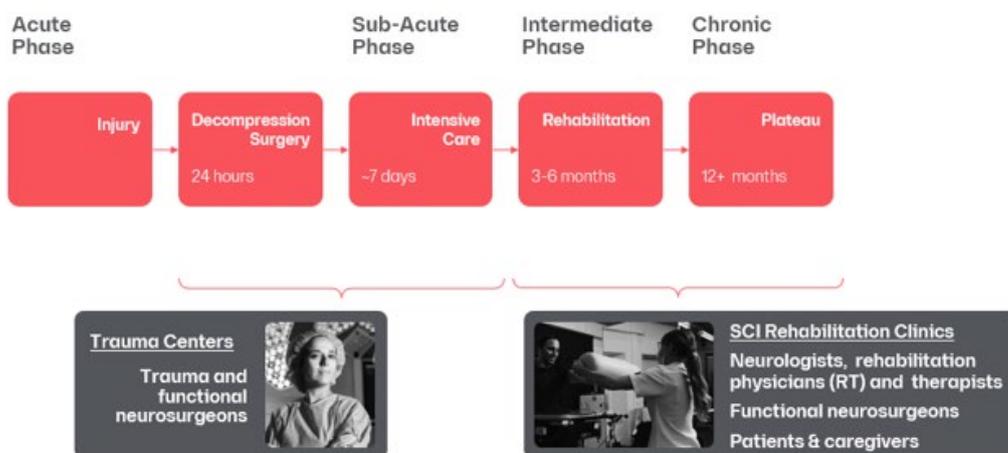
The Company's sales professionals are expected to primarily target two groups of decision-makers: trauma surgeons and rehabilitation clinicians. Trauma surgeons may be targeted for the Company's therapies that may provide benefit during decompression surgery or the Sub-Acute Phase, such as blood pressure regulation. Rehabilitation physicians will be targeted for the Company's therapies

expected to provide benefit during the Intermediate and Chronic Phases, such as blood pressure regulation, trunk control, mobility, and other indications currently in development. The Company's sales professionals will focus on generating awareness for the Company's therapy among target clinicians and the facilities where they practice, while the Company's field engineers will focus on training and education and implant support.

In the future, the Company may also target self-pay gyms, where chronically injured SCI patients sometimes seek care.

Specific customer targets at each stage in patient journey

Clinician Customers in Patient Journey



Reimbursement landscape

Reimbursement in the United States

As described above, if ARC Therapy is authorized to be marketed in the United States, ARC^{IM} will be sold to hospitals and ambulatory surgery centers for use by trauma and functional neurosurgeons. It is expected that ARC^{EX} will be sold to specialty rehabilitation clinics and directly to SCI patients for use in the home.

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 (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 its 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 international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Furthermore, many international 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 their currently cleared or approved products, the Company can give 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.

Third-party payors 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. Additionally, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. 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. 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.

The Company has been granted FDA Breakthrough Device Designation for three indications – ARC^{EX} for restoration of strength and function of the upper extremities, ARC^{IM} for walking, and ARC^{IM} for blood pressure and trunk control. For an elaboration on the FDA Breakthrough Device Designation see "Regulatory framework".

Three FDA Breakthrough Device Designation awards (BDD), providing fast pathway to market and reimbursement via MCIT¹ pathway

Breakthrough Device Designation

BDD Grant dates



Description

- Voluntary FDA program to facilitate and expedite market approval for medical devices addressing an unmet clinical need
- First criterion: Provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions
- Second criterion (one of several needs to be met):
 - Breakthrough technology
 - No approved or cleared alternative exists
 - Offers significant advantages over existing approved or cleared alternatives
 - Device availability is in the best interest of patients

Benefits

- Shorter review times and prioritized review
- Potential for guaranteed reimbursement from CMS via MCIT¹ Pathway (final decision in December)
- Opportunity to interact directly with FDA
- Less strict requirements for clinical study design (e.g. only "reasonable assurance of safety and effectiveness" is required, resulting in lower confidence interval and smaller sample size)

1 MCIT = Medicare Coverage of Innovative Technology

FDA's Breakthrough Devices Program is a voluntary program for certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and healthcare providers with timely access to these medical devices by speeding up their development, assessment, and review. It offers manufacturers an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely manner. Manufacturers can also expect a prioritized review of their submission.

The US Medicare program, for the elderly and disabled, responded to FDA's Breakthrough Devices Program by utilizing the breakthrough designation to facilitate improved payment and provide an alternative pathway to coverage called MCIT.

The MCIT Pathway

On 3 October 2019, an Executive Order was signed to bring new and innovative technologies to beneficiaries sooner under a new Medicare coverage pathway, the MCIT, for FDA-designated breakthrough medical devices. This new coverage is intended to offer patients expanded access to new, breakthrough devices.

The MCIT program will provide national Medicare coverage for breakthrough devices. Coverage under MCIT lasts for four years, and is approved as early as when FDA market authorization is obtained.

Manufacturers will elect to participate in MCIT and will be able to choose a start date for coverage at any point within two years from the date FDA market authorization is provided. The breakthrough device designation is reserved for devices that meet certain criteria from the 21st Century Cures Act, including providing for more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition, and must meet a second requirement, such as being a "breakthrough technology".

At the end of the four-year period of MCIT coverage, manufacturers will have all current coverage options available such as a National Coverage Determination ("**NCD**"), one or more Local Coverage Determinations ("**LCD**"), and claim by claim decisions.

To receive improved payment, a device must be deemed clinically significant. While this is typically determined through the published literature, receiving a breakthrough designation fulfils this requirement, which is the case for both products. Medicare's alternative pathway to coverage is scheduled to be issued on December 15, 2021. It provides for immediate coverage for four years, while additional data is being gathered.

All three of the indications the Company currently plans to commercialize have been awarded Breakthrough Device Designation and should MCIT be enacted in December 2021, these indications would benefit. There is a 2003 Medicare National Coverage Decision (160.2) which dictates that electrical stimulation for motor function disorders should not be reimbursed. This is a nearly 20 year old determination that is not based on the Company's technology but is worded broadly and may present an obstacle to the Company's use of the MCIT pathway for its ARC^{IM} Therapy for mobility. CMS has an expedited process to remove National Coverage Decisions that are older than 10 years. The Company intends to pursue this removal sometime prior to expected launch of ARC^{IM} for walking in 2025. The initial planned indication for ARC^{IM}, blood pressure, remains eligible for MCIT and is unaffected by the 2003 determination.

In September 2021, CMS issued a proposed rule to repeal MCIT. This proposal rule initiates a public comment period and states CMS' intent "to conduct future rulemaking to explore an expedited coverage pathway that provides access to innovative beneficial technologies."²⁷ Should MCIT not be enacted, the Company believes CMS, based on statements in its proposed rule to repeal, will take measures to explore and implement a similar mechanism to provide expedited coverage to innovative therapies such as those being developed by the Company. Moreover, the Company's therapies can leverage existing codes and new technology add-on payments, where applicable, for coverage as detailed below.

Coding and payment

Because the implant procedure for ARC^{IM} is substantially similar to what is currently used to implant spinal cord stimulation devices for pain management, existing codes may be used. This decreases the evidence requirements for launch, and shortens the period of time to revenue.

Medicare Physician Payment 2021

Physician Payment Code	Procedure	Payment
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²⁷ CMS Proposed Rule, September 2021, Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary"

63655	Lead Implantation	\$800
63685	Generator Implantation	\$346

Medicare Facility Payment 2021

Facility	Procedure	Payment
Hospital Outpatient Department	Full system implant	\$29,445
Ambulatory Surgery Center	Full system implant	\$40,654

Facility payments include the cost of the device, but not physician services which are billed separately. Medicare pays the Hospital Outpatient Department a single amount for the full system implant, while the Ambulatory Surgery Center is paid separately for the lead and generator implantation resulting in a higher payment amount. Private payers tend to pay 25% more than Medicare.

Medicare payment systems lag behind new technology. The systems are prospective, meaning that payment amounts, for a given procedure, are determined in advance based on historical claims data. The established payments are then applied to a combination of diagnosis and procedure codes. Because they use predetermined fixed-payment amounts, the systems can underpay for a new, more-expensive technology. As a result, Medicare created a new-technology payment process for the hospital outpatient setting.

For the hospital outpatient setting, the new-technology payment process is called Transitional-Pass-Through ("**TPT**") payment. To qualify, a technology must be too new to be represented in Medicare's historical claims data. It must be clinically significant based on the literature, and "not insignificantly" more expensive. TPT status is granted quarterly and can be applied for prior to FDA approval. Acceptance to the program results in two to three years of market-price data gathering, before a payment amount is established. Having an FDA-designated Breakthrough product satisfies the "clinically significant" criterion. The Company has not yet initiated pursuit of a TPT payment for its therapies but expects to do so pending the outcome of MCIT and once it initiates its pivotal trial for ARC^{IM} in the US.

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 3 years). Similar to the TPT payment process for outpatient described in the preceding paragraph, the FDA Breakthrough Device Designation awarded to ARC^{IM} increases the likelihood the device will qualify for NTAP. With NTAP, a hospital would receive a 65% add on payment for the incremental cost of the device and procedure in addition to the Diagnosis Related Group ("**DRG**") payment associated with the procedure. The current payment rate for DRG 030 (spinal procedures without complications and comorbidities) is \$15,150, though DRG 029 or 028 have higher payment rates of \$21,178 and \$37,408 respectively and could be applicable if the patient has complications and comorbidities under DRG 029 or major complications and comorbidities under DRG 028. For illustrative purposes, with NTAP and an ARC^{IM} list price of \$35,000, a hospital would receive \$15,150 under DRG 030 and 65% of the \$35,000 hypothetical device price for a total payment of \$37,900. Under DRGs 029 or 028, the total payments would be \$43,928 and \$60,158 respectively.

There are existing provider-payment codes for physical therapy, which include the use of the ARC^{EX}. Here too, this decreases the evidence requirements for a US launch, and shortens the period of time to revenue.

ARC^{EX}, because it is external and long-lasting, is considered Durable Medical Equipment ("**DME**"), and is categorized under a different set of codes. The applicable DME code is one used to allow

immediate post FDA clearance launch of the product. Because this code is for new technology, it has no set price, allowing ONWARD to establish its desired price in the marketplace before receiving a product-specific code.

The Company has engaged a leading reimbursement consulting firm, Comprehensive Reimbursement Solutions® of Minneapolis, MN, USA, to assist with navigating the reimbursement landscape and optimizing the Company's path forward.

Reimbursement in Europe

The path forward in Europe is more varied than in the US. The Company expects to initially commercialize in the following markets, based on the attractiveness of their reimbursement environment for new medical technologies and the sophistication of their SCI rehabilitation infrastructure:

- United Kingdom
- Germany
- France
- Netherlands

Below please find a description of the reimbursement environment and coverage pathway for each of the Company's initial target markets in Europe.

United Kingdom

In England, the National Health Service ("**NHS**") has typically routed non-invasive neurostimulators through two pathways: i) clinical commissioning group ("**CCG**") block contracts, and ii) national funding via Part IX of the drug tariff. Traditionally, CCGs have issued block contracts for some hospitals and home-based services, including durable equipment such as CPAP. Recent NHS changes will consolidate local payers into 42 integrated care systems ("**ICS**"), which are likely to rely on a combination of fixed price/volume agreements for home-use products, as well as bundled payments where appropriate. To be reimbursed through Part IX of the drug tariff, a neurostimulator will need to be cost-effective and appropriate for prescription by a general practitioner, which is unlikely for ARC^{EX}. For either pathway, it is likely that ARC^{EX} will need to receive a positive NICE appraisal.

For ARC^{IM}, NHS operates the healthcare resource groups ("**HRG**"), a national DRG-style payment system for inpatient and day case hospital care, under which the implantation, revision, replacement, and removal of ARC^{IM} would fall. In addition, high-cost spinal cord stimulators are also eligible for add-on payment through the High Cost Tariff Exclusion Device ("**HCTED**") list, which will supplement the tariff for the implantation procedures. The new ICS structure will still rely on HRG tariff values as a cost basis for new 'blended' payments, and the national HCTED add-on payment will likely become a fixed element of the blended payment.

Once sufficient evidence has been generated, reimbursement for ARC^{EX} and ARC^{IM} will occur within roughly 12 to 18 months, after positive NICE appraisal. In total, the Company's reimbursement consultants estimate a timeline of 24 to 30 months for reimbursement.

Germany

Medical devices in the outpatient and physician clinic setting require a new EBM 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, ARC^{EX} will likely need a new HMV category. In order to achieve a new product category, a positive evaluation by G-BA will be necessary. Once contained within the HMV, reimbursement will be negotiated through individual contracts with statutory health insurances ("**SHI**"). The timeline for ARC^{EX} reimbursement would be two to four years from CE marking.

For implantable devices, Germany operates a DRG-based system to compensate hospital inpatient admissions. Among the selected markets, Germany may offer the most accessible pathway for inpatient add-on payment. The "**NUB**" innovation payment (*Neue Untersuchungs- und Behandlungsmethoden*) affords locally negotiated payment for up to four years. Following the NUB, a permanent DRG assignment or permanent add-on payment in the form of (*Zusatzentgelt, ZE*) for high-cost services, may be provided.

A new OPS code would be required to establish NUB funding or NUB payment. NUB funding would temporarily supplement DRG payment until it could be incorporated into the DRG system. Two neurostimulators have achieved NUB approval in the last three years.

NUB funding in Germany could be achieved for ARC^{IM} within as little as 11 months from CE marking.

France

Home-use devices in France are reimbursed through the *Liste de Produits et Prestations Reduit* ("**LPPR**"), which contains a list of generic, non-brand specific products that are reimbursable, as well as a list of brand name specific products. Though a formal HTA assessment is not required for inclusion into a generic category, a new or brand-specific category will be needed for ARC^{EX} and would require a positive HTA assessment of ARC^{EX}. Products related to a procedure performed by a healthcare professional at a physician's office are included in the procedure tariff.

Implantable devices are eligible for supplemental payment through the *Liste en Sus*, paid in addition to DRG-style bundled payment through the *Groupe Homogenes du Sejours* ("**GHS**"). To achieve reimbursement through the *Liste en Sus*, a dossier for HTA review will be required, and clinical evidence will likely be required to demonstrate superiority to existing "gold standard" treatment. While the process is intended to last only 90 days, the publication of new tariffs can take two or more years.

The Netherlands

External home-use devices are covered under the *Hulpmiddelenzorg* ("**HMZ**"). Once covered under the HMZ, each insurance company creates specific criteria for reimbursement of a product, and each may restrict the choice of brands for a covered category. However, as HMZ categories are indication-specific, it is likely that ARC^{EX} will require a new category, which will require positive evidence evaluation by the *Zorginstituut Nederland* ("**ZIN**").

Implantable neurostimulators are included in the Basic Benefits Portfolio and are reimbursed through bundled DBC "Care Products" (similar to DRGs). As with HMZ categories, DBC Care Products are often based on a specific indication, according to Care Activity Codes, which may require ARC^{IM} to achieve a novel procedure code; however, it may be possible for the device itself to leverage existing coding. Due to its novel indications, ARC^{IM} may require a novel DBC Care Product category, which would require evidence review.

Among the target markets, the Netherlands has the most flexibility in its ability to reimburse new products. Once sufficient evidence has been gathered, reimbursement is likely to occur more rapidly than in other markets.

Countries in Europe generally require submission of clinical and health economic data prior to providing reimbursement coverage and payment. The Company has engaged an international market access and health policy consultant, Herb Riband, to assist the Company with this process. Mr. Riband built and led international market access teams for Medtronic and Amgen. He oversaw a Phase I project to help the Company assess the value propositions of the Company's therapies and prepare for future reimbursement/health technology assessment ("**HTA**") discussions in Europe. The Company has also engaged Hull Associates LLC of Boston, MA, US, to assist the Company with Phase II in Europe, which is providing a targeted reimbursement landscape assessment for the Company's selected and prioritized European markets.

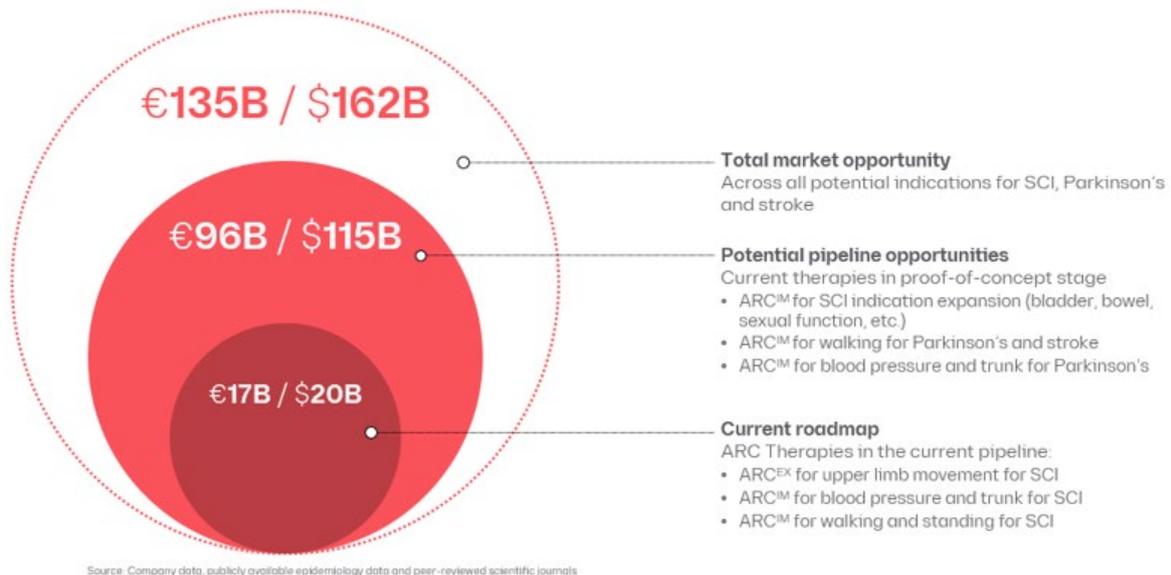
Market overview

Market Opportunity

The total addressable market for the Company's therapies currently in development and for which the Company aims to seek regulatory clearances and approvals in the US and Europe in the next five years is EUR 17 billion. The market expands considerably, to nearly EUR 100 billion, when considering other potential indications for ARC Therapy which are already in preclinical and clinical proof-of-concept stage, including some that may have application beyond SCI, helping people with stroke and Parkinson's disease (see table below).

Realistic and significant expansion opportunities

Total Addressable Market



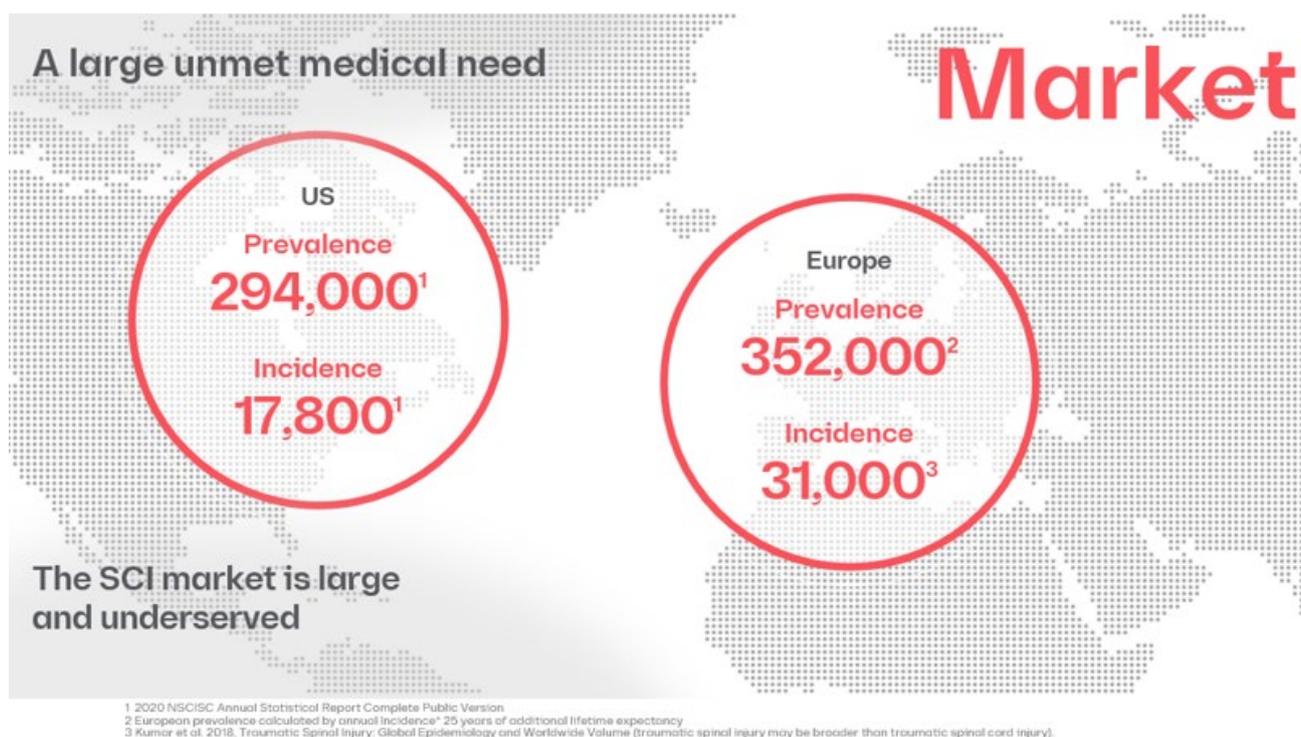
- Phase 1: **Near-term target markets** include ARC^{EX} Upper Limb, ARC[™] for Blood pressure and trunk, and ARC[™] for Mobility (EUR 17.4 billion market opportunity).
- Phase 2: **Additional indications include** ARC[™] for Bowel, Bladder and Sexual functions, ARC[™] for Parkinson (Blood Pressure and Mobility), and ARC[™] for Mobility in Stroke (EUR 95.5 billion market opportunity).
- Phase 3: **Long-term opportunities** include all above-listed market opportunities (EUR 135.4 billion market opportunity).

Indication	Therapy	Phase 1	Phase 2	Phase 3
SCI	ARC-EX Upper Limbs	€ 2.1	€ 2.1	€ 2.1
	ARC-EX Trunk			€ 0.3
	ARC-EX Mobility			€ 0.1
	ARC-IM Hemo/Trunk	€ 7.6	€ 7.6	€ 7.6
	ARC-IM Mobility	€ 7.7	€ 7.7	€ 7.7
	ARC-IM Upper Limbs			€ 9.7
	ARC-IM Autonomics		€ 11.7	€ 11.7
Parkinson's	ARC-IM Hemo/Trunk		€ 20.2	€ 20.2
	ARC-IM Mobility		€ 26.8	€ 26.8
Stroke	ARC-EX Upper Limbs			€ 5.9
	ARC-EX Mobility			€ 6.6
	ARC-IM Mobility		€ 19.5	€ 19.5
	ARC-IM Upper Limbs			€ 17.3
Total		€ 17.4	€ 95.5	€ 135.4

Total Addressable Market by phase, in EUR billions

Spinal Cord Injury

Each year, approximately 768,000 people suffer a traumatic SCI globally, including approximately 31,000 people in Europe²⁸ and approximately 18,000 in the US.²⁹



To estimate the European market opportunity, the Company included European countries requiring CE mark to allow marketing of medical technologies. These countries constitute approximately 66% of the total European population as defined by the World Health Organization (WHO), thus 66% of the total European population of 914 million. To estimate European prevalence, the Company extrapolated the European TSI incidence (34 per million) over a 25 year period as determined in

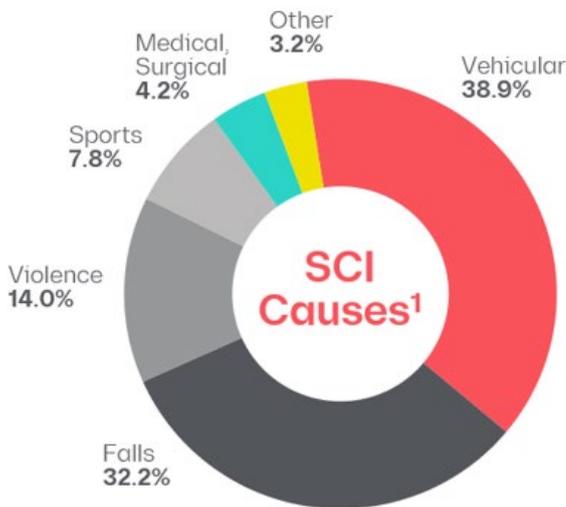
²⁸ Kumar et al. 2018, "Traumatic Spinal Injury: Global Epidemiology and Worldwide Volume", World Neurosurg., vol. 113, pp. e345-e363, May 2018, doi: 10.1016/j.wneu.2018.02.033.

²⁹ 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, Table 2.

Kumar et al. 2018. This result was averaged with a lower bound estimate derived using the incidence reported for the France Rhones-Alpes Region (12.7 per million) from Singh et al. 2014.

SCI is caused primarily by automobile accidents and falls, with young males disproportionately affected.

Damage to the spinal cord resulting in loss of function



¹2020 NSCISC Annual Statistical Report Complete Public Version

SCI Causes & Patient Profile

Profile of SCI Patient

- Nearly half of the injuries occur between the ages of 16 and 30 years¹
- 78% of new SCI cases are male¹

The current neuromodulation market is comprised primarily of revenues from spinal cord stimulation for pain management and deep brain stimulation ("DBS") for epilepsy and Parkinson's disease. Market revenues totaled USD 8.2 billion in 2019 and were projected to grow at more than 15% over the next five years.

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

Opportunity to create new segment, stimulating the spinal cord for movement and autonomics

Neurostimulation has emerged as a dynamic field for treatment of a range of clinical conditions

\$8.2B (2019) **15.4% CAGR** (2020-2026)

Spinal cord stimulation and DBS are most well developed current applications

\$2.9B (2019) **8.0% CAGR** (2020-2026)

Growth trends:

- Rising prevalence of neurological disorders
- Increasing capital availability
- Emergence of minimally invasive approaches

Neurostimulation Market

FDA approved

Deep brain stim
Dystonia, epilepsy, essential tremor, obsessive-compulsive disorder, depression, Parkinson's disease

Hypoglossal nerve stim
Sleep apnea

Vagus nerve stim
Depression, epilepsy

Spinal cord stim
Pain management

Sacral nerve stim
Urinary incontinence, fecal incontinence

Emerging

Deep brain stim
Addiction, chronic pain, cluster headache, dementia, depression (major), Huntington's disease, MS, stroke, Tourette, traumatic brain injury, sleep disorder, autism

Vagus nerve stim
Alzheimer's, Obesity, Lung injury, Cardiovascular disease, stroke, diabetes, anxiety, pain management

Spinal cord stimulation
Mobility, blood pressure control, bladder and bowel control, trunk control, upper limb function, sexual function, spasticity

Sacral nerve stim:
Interstitial Cystitis



Sources: Global Market Insights Neurostimulation Devices Market; Fortune Business Insights Spinal Cord Stimulation Market; Horroen 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 | Johnson RL, Wilson CG. A review of vagus nerve stimulation as a therapeutic intervention. J Inflamm Res. 2018;11:203-213, Mayo Clinic

The spinal segment level of an SCI determines which body functions are impacted, while the lesion severity (as determined by the ASIA impairment scale ("**AIS**"), developed by the American Spinal Injury Association ("**ASIA**")) indicates the extent to which those functions are affected.³⁰ Elements of the AIS-scale include:

- **Grade A:** the impairment is complete. There is no motor or sensory function left below the level of injury;
- **Grade B:** the impairment is incomplete. Sensory function, but not motor function, is preserved below the neurologic level (the first normal level above the level of injury) and some sensation is preserved in the sacral segments S4 and S5;
- **Grade C:** the impairment is incomplete. Motor function is preserved below the neurologic level, but more than half of the key muscles below the neurologic level have a muscle grade less than 3 (i.e., they are not strong enough to move against gravity);
- **Grade D:** the impairment is incomplete. Motor function is preserved below the neurologic level, and at least half of the key muscles below the neurologic level have a muscle grade of 3 or more (i.e., the joints can be moved against gravity); and,
- **Grade E:** the patient's functions are normal. All motor and sensory functions are unhindered.

After decades of progress in clinical management and immediate care after SCI in the past century, morbidity has decreased, and outcomes improved. However, no efficient repair strategy to improve recovery after an SCI is yet available. Rehabilitation therapy focuses on issues affecting quality of life and community participation teaching the patient the skills needed in daily life to adjust to his condition.³¹ The average duration of stay for inpatient functional rehabilitation depends on the level and severity of the injury based on the AIS. In the United States, the average rehabilitation stay is 55 (± 37) days (tetraplegic C5-C6 level: 65 (± 38); paraplegic: 45 (± 29)), during which a patient receives about 24 (± 5) hours of treatment per week.³² It is expected that the patient reaches his or her maximal recovery within the first year post injury. As of today, no restorative or curative treatment for SCI is yet available.³³

After an SCI, while disconnected from the brain, the circuits that control sensory and motor functions remain anatomically intact. The neurons located in the dorsal root ganglia still encode sensory information arising from peripheral organs and transmit this information through their afferent fibers to the spinal cord. These afferents enter the spinal cord through a continuum of posterior roots.

People with spinal cord injury confront a litany of health challenges and limitations to daily life activities as described above. For example, a majority of SCI individuals experience poor blood regulation (i.e. hemodynamic) instability after their injury.^{34 35} These cardiovascular dysfunctions are life threatening and greatly reduce quality of life.³⁶

³⁰ Madonna Rehabilitation Hospital, 'Asia Impairment Scale (AIS) Score', <https://www.madonna.org/spinal-cord-injury/asia-impairment-scale-ais-score>, retrieved 21SEPT2021; S.C. Kirshblum et al., 'International Standards for Neurological Classification of Spinal Cord Injury', *J. Spinal Cord Med.*, vol. 34, no. 6, pp. 535-546, doi: 10.1179/204577211X13207446293695.

³¹ N. Gómara-Toldrà, M. Sliwinski, and M. P. Dijkers, "Physical therapy after spinal cord injury: a systematic review of treatments focused on participation," *J. Spinal Cord Med.*, vol. 37, no. 4, pp. 371–379, Jul. 2014, doi: 10.1179/2045772314Y.0000000194.

³² G. Whiteneck et al., "Inpatient treatment time across disciplines in spinal cord injury rehabilitation," *J. Spinal Cord Med.*, vol. 34, no. 2, pp. 133–148, 2011, doi: 10.1179/107902611X12971826988011.

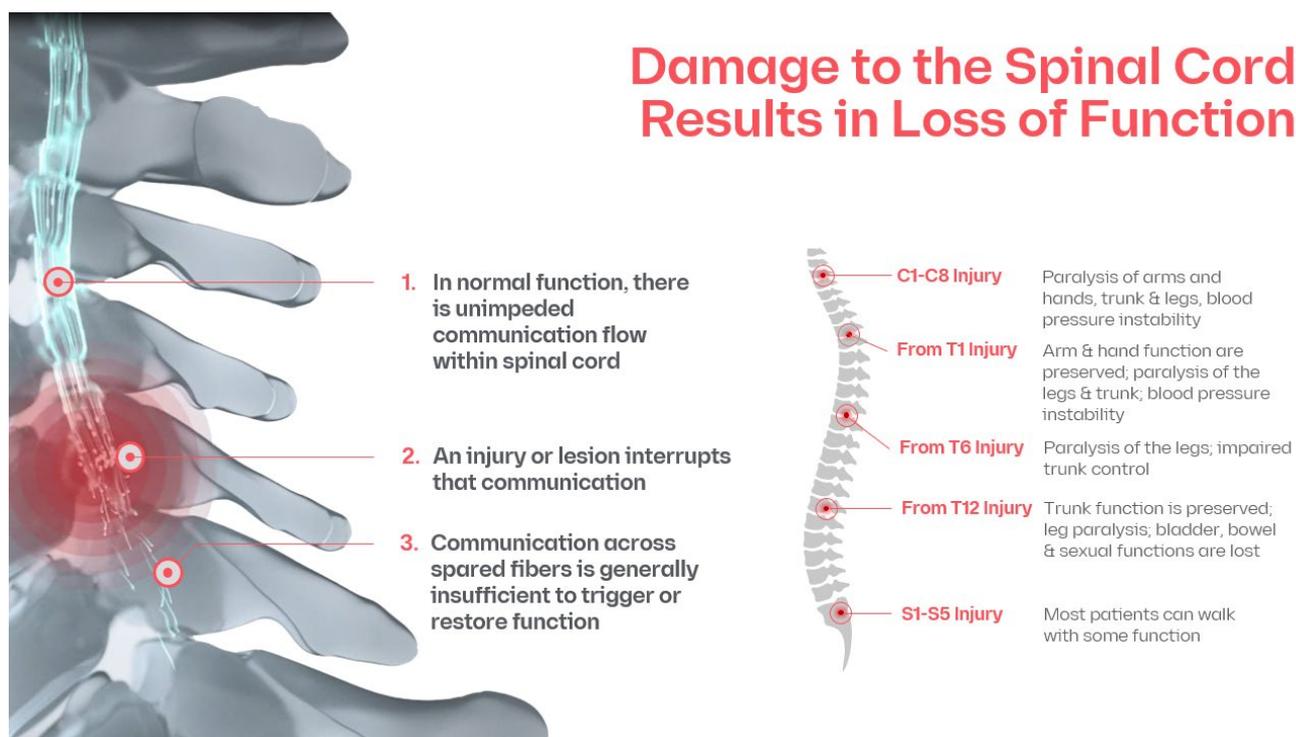
³³ K. Nas, L. Yazmalar, V. Şah, A. Aydın, and K. Öneş, "Rehabilitation of spinal cord injuries," *World J. Orthop.*, vol. 6, no. 1, pp. 8–16, Jan. 2015, doi: 10.5312/wjo.v6.i1.8.

³⁴ M. Rath et al., "Trunk Stability Enabled by Noninvasive Spinal Electrical Stimulation after Spinal Cord Injury," doi: 10.1089/neu.2017.5584.

³⁵ A. Crawford, K. Armstrong, K. Loparo, M. Audu, and R. Triolo, "Detecting destabilizing wheelchair conditions for maintaining seated posture," *Disabil. Rehabil. Assist. Technol.*, vol. 13, no. 2, pp. 178–185, Feb. 2018, doi: 10.1080/17483107.2017.1300347.

³⁶ G. Desroches, D. Gagnon, S. Nadeau, and M. R. Popovic, "Effects of sensorimotor trunk impairments on trunk and upper limb joint kinematics and kinetics during sitting pivot transfers in individuals with a spinal cord injury," *Clin. Biomech.*, vol. 28, no. 1, pp. 1–9, Jan. 2013, doi: 10.1016/j.clinbiomech.2012.11.001.

Specific health impacts are in large part determined by the location and severity of the SCI. As explored below, certain regions of the spinal cord are responsible for controlling specific movements and/or functions. Functions below the lesion site are generally impacted.



The disruption of supraspinal control leads to a life-threatening blood pressure instability leading to, dysrhythmias and bradycardia, low resting blood pressure, high and low pressure among others, occurring multiple times per day.³⁷³⁸³⁹⁴⁰ The lack of descending control induces autonomic dysreflexia linked to an over-excitation of the sympathetic nervous system below the injury level in response to an input caudal to the lesion. Autonomic dysreflexia is described as a massive uncontrolled sympathetic activation and severe hypertension resulting from extreme vasoconstriction.⁴¹ This can lead to myocardial infarction, cerebral hemorrhage, and death.⁴² Another major concern and frequent cardiovascular dysfunction experienced by SCI individuals is orthostatic hypotension.⁴³ This dysfunction is caused by a lack of supraspinal control and provokes a severe and rapid drop in blood pressure during a change of posture. This sudden drop in blood pressure can lead to loss of consciousness and, over long-term, has been associated with declined cerebrovascular and cardiovascular health.⁴⁴⁴⁵⁴⁶ Medical management is generally not considered effective in treating blood pressure dysregulation in people with SCI.

³⁷ C. Sinderby, P. Ingvarsson, L. Sullivan, I. Wickström, and L. Lindström, "The role of the diaphragm in trunk extension in tetraplegia," *Paraplegia*, vol. 30, no. 6, pp. 389–395, Jun. 1992, doi: 10.1038/sc.1992.88.

³⁸ J. L. Minkel, "Seating and mobility considerations for people with spinal cord injury," *Phys. Ther.*, vol. 80, no. 7, pp. 701–709, Jul. 2000.

³⁹ J. J. Cragg, V. K. Noonan, A. Krassioukov, and J. Borisoff, "Cardiovascular disease and spinal cord injury Results from a national population health survey," *Neurology*, vol. 81, no. 8, pp. 723–728, Aug. 2013, doi: 10.1212/WNL.0b013e3182a1aa68.

⁴⁰ A. A. Phillips, A. V. Krassioukov, P. N. Ainslie, and D. E. R. Warburton, Baroreflex function after spinal cord injury, vol. 29. *J Neurotrauma*, 2012.

⁴¹ J. C. Wu et al., "Increased risk of stroke after spinal cord injury: A nationwide 4-year follow-up cohort study," *Neurology*, vol. 78, no. 14, pp. 1051–1057, Apr. 2012, doi: 10.1212/WNL.0b013e31824e8eaa.

⁴² K. C. Eldahan and A. G. Rabchevsky, "Autonomic dysreflexia after spinal cord injury: Systemic pathophysiology and methods of management," *Auton. Neurosci. Basic Clin.*, vol. 209, pp. 59–70, Jan. 2018, doi: 10.1016/j.autneu.2017.05.002.

⁴³ M. Manogue, D. S. Hirsh, and M. Lloyd, "Cardiac electrophysiology of patients with spinal cord injury," *Heart Rhythm*, vol. 14, no. 6, pp. 920–927, Jun. 2017, doi: 10.1016/j.hrthm.2017.02.015.

⁴⁴ J. M. Wecht and W. A. Bauman, "Implication of altered autonomic control for orthostatic tolerance in SCI," *Auton. Neurosci. Basic Clin.*, vol. 209, no. August 2016, pp. 51–58, 2018, doi: 10.1016/j.autneu.2017.04.004.

⁴⁵ J. M. Wecht, J. P. Weir, S. Martinez, M. Eraifej, and W. A. Bauman, "Orthostatic hypotension and orthostatic hypertension in American veterans," *Clin. Auton. Res. Off. J. Clin. Auton. Res. Soc.*, vol. 26, no. 1, pp. 49–58, Feb. 2016, doi: 10.1007/s10286-015-0328-4.

⁴⁶ A. A. Phillips and A. V. Krassioukov, Contemporary cardiovascular concerns after spinal cord injury: Mechanisms, maladaptations, and management, vol. 32. *Mary Ann Liebert Inc.*, 2015.

Physical Comorbidities

- Pain
- Loss of sensation
- Sexual dysfunction
- Bladder and bowel dysfunction
- Urinary tract infection
- Respiratory problems
- Heart rate variability
- Poor blood pressure regulation
- Bone density loss
- Spasticity (muscle spasms)
- Pressure sores (skin ulcer)

Mental / Quality of Life Effects

- Sleep problems
- Fatigue
- Depression
- Dependence on attendant care
- Restrictions on jobs and social activities

The recovery of normal autonomic cardiovascular function is reported to be of higher priority by SCI people.^{47,48,49,50,51} However, it is currently less studied than restoring motor function in SCI research.

Sensory-motor impairments induced by SCI commonly affect the trunk. As a result, daily tasks can become very difficult and more dangerous to perform for the patient.⁵² Postural stability cannot be sustained, increasing the risk of falls and injuries.⁵³ Daily tasks such as transferring from a wheelchair to bed⁵⁴ or reaching around from the wheelchair to lift an object can become very difficult or impossible leading to a reduced quality of life and independence level for the person with SCI. Restoring trunk stability and control has been shown to improve health and quality of life such as better breathing and diaphragmatic movement,⁵⁵ as well as relief pressure from switching positions leading to a decrease in the risk of developing pressure ulcers.⁵⁶

The spinal segment level of an SCI determines which body functions are impacted, while the lesion severity (as determined by the AIS score, A-D, with A the most severe and D the least severe) indicates the extent to which those functions are affected. The NSCISC Annual Statistical Report 2020 provides the distribution of spinal segment level and injury severity for more than approximately 32,000 patients over 35 years.⁵⁷ The following patient populations are limited only to Europe and the US.

⁴⁷ J. C. Wu et al., "Increased risk of stroke after spinal cord injury: A nationwide 4-year follow-up cohort study," *Neurology*, vol. 78, no. 14, pp. 1051–1057, Apr. 2012, doi: 10.1212/WNL.0b013e31824e8eaa.

⁴⁸ K. C. Eldahan and A. G. Rabchevsky, "Autonomic dysreflexia after spinal cord injury: Systemic pathophysiology and methods of management," *Auton. Neurosci. Basic Clin.*, vol. 209, pp. 59–70, Jan. 2018, doi: 10.1016/j.autneu.2017.05.002.

⁴⁹ M. Ueno, Y. Ueno-Nakamura, J. Niehaus, P. G. Popovich, and Y. Yoshida, "Silencing spinal interneurons inhibits immune suppressive autonomic reflexes caused by spinal cord injury," *Nat. Neurosci.*, vol. 19, no. 6, pp. 784–787, Apr. 2016, doi: 10.1038/nn.4289.

⁵⁰ J. W. Squair, A. A. Phillips, M. Harmon, and A. V. Krassioukov, "Emergency management of autonomic dysreflexia with neurologic complications," *CMAJ*, vol. 188, no. 15, pp. 1100–1103, Oct. 2016, doi: 10.1503/cmaj.151311.

⁵¹ K. D. Anderson, "Targeting Recovery: Priorities of the Spinal Cord-Injured Population," *J. Neurotrauma*, vol. 21, no. 10, pp. 1371–1383, 2004, doi: 10.1089/neu.2004.21.1371.

⁵² D. Wan and A. V. Krassioukov, "Life-threatening outcomes associated with autonomic dysreflexia: a clinical review," *J. Spinal Cord Med.*, vol. 37, no. 1, pp. 2–10, Jan. 2014, doi: 10.1179/2045772313Y.0000000098.

⁵³ V. E. Claydon and A. V. Krassioukov, "Orthostatic hypotension and autonomic pathways after spinal cord injury," *J. Neurotrauma*, vol. 23, no. 12, pp. 1713–1725, Dec. 2006, doi: 10.1089/neu.2006.23.1713.

⁵⁴ K. M. Rose et al., "Orthostatic hypotension and the incidence of coronary heart disease: the Atherosclerosis Risk in Communities study," *Am. J. Hypertens.*, vol. 13, no. 6 Pt 1, pp. 571–578, Jun. 2000, doi: 10.1016/s0895-7061(99)00257-5.

⁵⁵ M. L. Eigenbrodt, K. M. Rose, D. J. Couper, D. K. Arnett, R. Smith, and D. Jones, "Orthostatic hypotension as a risk factor for stroke: the atherosclerosis risk in communities (ARIC) study, 1987-1996," *Stroke*, vol. 31, no. 10, pp. 2307–2313, Oct. 2000, doi: 10.1161/01.str.31.10.2307.

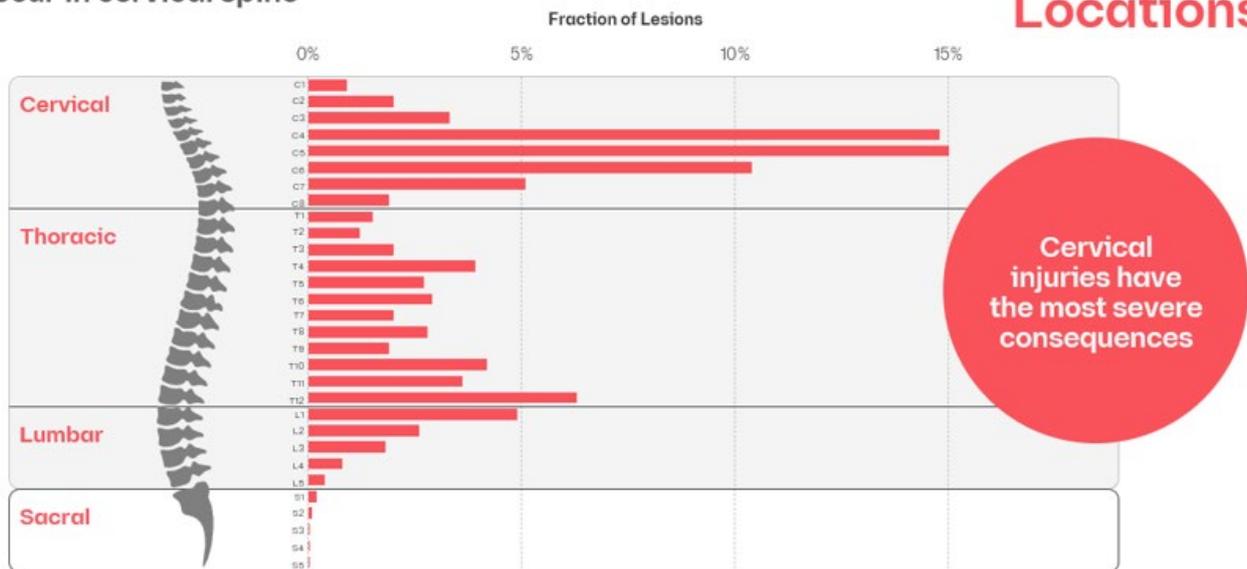
⁵⁶ K. M. Rose et al., "Orthostatic hypotension predicts mortality in middle-aged adults: the Atherosclerosis Risk In Communities (ARIC) Study," *Circulation*, vol. 114, no. 7, pp. 630–636, Aug. 2006, doi: 10.1161/CIRCULATIONAHA.105.598722.

⁵⁷ National Spinal Cord Injury Statistical Center. 2020 Annual Statistical Report for the Spinal Cord Injury Model Systems. University of Alabama at Birmingham: Birmingham, Alabama.

The NSCISC Annual Statistical Report, published in 2020, showed the distribution of injury locations for 30,000 individuals with SCI. The most common injury location was the cervical spinal cord, vertebrae C5 and C6.

Data from 30,000 SCIs show most occur in cervical spine

Injury Locations



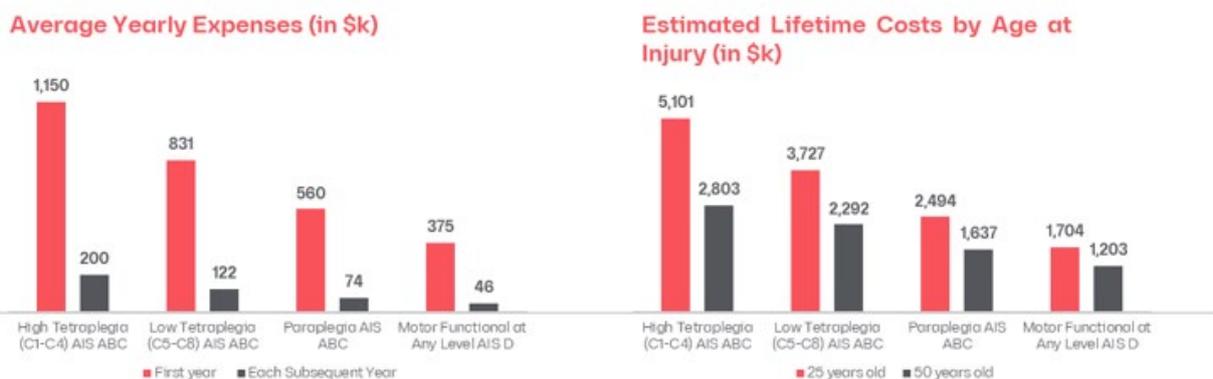
Source: 2020 NSCISC Annual Statistical Report Complete Public Version Note: N = 30k SCI patients

Market segmentation for ARC^{IM} and ARC^{EX} follows the distribution of spinal cord injury anatomical level and severity.

Injuries to the cervical spinal cord generally lead to the most severe functional impairment, with paraplegia and commonly tetraplegia. Dependence on outside care following an SCI can be extremely costly. Below please see lifetime costs by injury severity.

SCI creates expensive dependence on attendant care and healthcare system utilization

Average Lifetime Costs



Costs are highest for people with most common injury location (cervical spine)

Source: 2020 NSCISC Annual Statistical Report Complete Public Version

Following is a detailed explanation of the Company's cumulative total addressable market opportunity.

The initial targeted indication for ARC^{EX} is improvement in hand and arm strength and function for people with a cervical lesion with severity AIS B to D. Within the Up-LIFT Study, subjects with lesions

C2-C8 are eligible. However, for that group includes 16,783 new patients every year and counts a total population of 216,839 individuals. Based on an analysis that considered the pricing and relative utility of similar medical technologies, the Company estimates the ARC^{EX} market opportunity is EUR 153 million annually, with a total market potential of EUR 1.9 billion.

The initial indication for which the Company expects to pursue regulatory approval for ARC^{IM} is to stabilize blood pressure and improve trunk control in people with a cervical lesion with severity AIS A to C and lesion between C1-C8, and for people with an AIS A lesion above the thoracic level T6. That group includes 20,308 new patients every year and a total population of 262,381 individuals. Based on an analysis that considered the pricing and relative utility of similar medical technologies, the Company estimates the ARC^{IM} market opportunity for blood pressure and trunk control is EUR 545 million annually, with a total market potential of EUR 7.5 billion.

The Company also expects to pursue regulatory approval to use ARC^{IM} to improve mobility for people with an AIS B to D lesion above the thoracic level T11. That group includes 20,494 new patients every year and a total population of 264,779 individuals. Based on an analysis that considered the pricing and relative utility of similar medical technologies, the Company estimates the market opportunity for ARC^{IM} for mobility is EUR 550 million annually, with a total market potential of EUR 7.6 billion. This analysis limits the eligibility for mobility to those with AIS B-D. However, it was observed in the STIMO trial that subjects with AIS A also benefitted thus the eligible patient population for mobility could expand in the future to include patients with severity AIS A.

The largest potential market opportunities for ARC^{IM} are for restoration of arm and hand function, as well as the sacral indications – bowel, bladder and sexual function. Restoration of arm and hand function will benefit people with any cervical lesion, a group including 25,900 new patients every year and a total population of 334,628 individuals. Restoration of sacral functions will be indicated for people with any lesion above lumbar level L5, a group including 29,106 new patients every year and a total population of 376,053 individuals.⁵⁸ Based on an analysis that considered the pricing and relative utility of similar medical technologies, the Company estimates the ARC^{IM} market opportunity for arm and hand function is EUR 696 million annually, with a total market potential of EUR 8.9 billion. The ARC^{IM} market opportunity for sacral functions is EUR 842 million annually, with a total market potential of EUR 10.8 billion.

The total annual market opportunity for ARC^{IM} for people with SCI is EUR 2.6 billion, with a total market (cumulative) potential of EUR 34 billion.

Parkinson's disease

Parkinson's disease is a neurodegenerative disorder interrupting normal communication flow between the brain and the rest of the body, eventually leading to paralysis. This interruption of communication is due to neuronal death in deep cerebral structures, which normally relay information to lower body parts, and therefore results in effects comparable to those observed with SCI.

For instance, 26% to 40% of Parkinsonian patients suffer from severe orthostatic hypotension,⁵⁹ a debilitating condition that can be addressed with electrical stimulation of pressor circuits in the spinal cord. That group includes 22,476 new patients every year and a total population of 707,927 individuals. Based on an analysis that considered the pricing and relative utility of similar medical technologies, the Company estimates the ARC^{IM} market opportunity for blood pressure in Parkinson's Disease is EUR 1.1 billion annually, with a total market potential of EUR 19 billion.

Parkinson's patients typically suffer from impaired mobility and 40% are subject to freezing-of-gait,⁶⁰ a condition impeding step initiation. The Company has observed the potential for ARC^{IM} technology to restore mobility in preclinical experiments in non-human primate models of Parkinson's disease.⁶¹ The Company estimates that there are 56,493 new Parkinson's patients affected with freezing-of-gait every year, and an estimated total population of 941,543 individuals. Based on an analysis that

⁵⁸ Excluding eligible patients for ARC^{IM}® Mobility, which Lead implant area overlap with that of ARC^{IM}® for Sacral functions.

⁵⁹ Kim et al. 2015; Tyberghein et al. 2013; Velsehoer et al. 2011

⁶⁰ Ge et al. 2020

⁶¹ Unpublished data based on EPFL work. Paper currently under review by NATURE

considered the pricing and relative utility of similar medical technologies, the Company estimates that the ARC^{IM} market opportunity for mobility in Parkinson's disease is EUR 1.5 billion annually, with a total market potential of EUR 25.2 billion.

The total annual market opportunity for ARC^{IM} for Parkinson's disease is EUR 2.6 billion, with a total market potential of EUR 44.3 billion cumulative.⁶²

Stroke

Stroke is a very common disorder resulting in a multitude of potential impairments, including paralysis and impaired mobility. ARC Therapy is the first solution observed in clinical trials to restore movement even after years of paralysis and it has the potential to improve the function and quality of life in stroke patients.

Limiting the addressable population of stroke survivors to patients of working age⁶³ and without cognitive impairment,⁶⁴ 66,073 people will suffer from long lasting impairments of arm and hand function every year,⁶⁵ with a total population of 578,140 individuals. Based on an analysis that considered the pricing and relative utility of similar medical technologies, the Company estimates the ARC^{IM} market opportunity for arm and hand function for stroke survivors is EUR 1.8 billion annually, with a total market potential of EUR 17.3 billion. Based on an analysis that considered the pricing and relative utility of similar medical technologies, the Company estimates the ARC^{EX} market opportunity for arm and hand function for Stroke survivors is EUR 601 million annually, with a total market potential of EUR 5.9 billion.

74,332 people who suffer a stroke will not recover walking function every year, including a total population of 650,408 individuals. Based on an analysis that considered the pricing and relative utility of similar medical technologies, the Company estimates the ARC^{IM} market opportunity for mobility for stroke survivors is EUR 2.0 billion annually, with a total market potential of EUR 19.5 billion. Based on an analysis that considered the pricing and relative utility of similar medical technologies, the Company estimates the ARC^{EX} market opportunity for mobility for Stroke survivors is EUR 676 million annually, with a total market potential of EUR 6.6 billion.

The total annual market opportunity for ARC^{EX} and ARC^{IM} for stroke survivors is EUR 1.2 billion and EUR 3.7 billion respectively, with corresponding total market potential of EUR 12.4 billion and EUR 36.8 billion.

Competitive Landscape

As was discussed in the "*Market Opportunity—Unmet Need*" section above, there is no current therapy known to the Company that can predictably improve strength and function in people with SCI following the initial Intermediate Phase. Indeed, often the goal of rehabilitation following SCI is to adapt to limitations in daily life activities rather than restore lost function because conventional rehabilitation approaches are often ineffective.

Typically after someone suffers an SCI, they undergo emergency surgery and remain in intensive care for approximately one week. Thereafter they undergo three to six months of rehabilitation at which point they typically plateau, making no further progress in recovery of function. They therefore face a lifetime of challenges that include secondary complications (i.e. urinary tract infection, spasticity and pressure sores), further declines in quality of life, high levels of dependency on outside care, and high healthcare system utilization. The Company seeks to fill that void, introducing therapies during

⁶² These are estimations from the Company based on various scientific publications. Ovbiagele et al. 2011 is used to calculate US incidence and prevalence for stroke. An estimation of 774 Million inhabitants in total was made for the population of the US + EU and applied US stroke incidence and prevalence fraction to determine the total EU + US stroke population. Dobkin 2005 and Hendricks et al. 2002 is used to calculate the fraction of stroke survivors unable to walk and Sun et al. 2014 and Rist et al. 2013 is used to calculate the fraction of those without cognitive impairment. NHS Digital. (2015) is used to calculate the fraction of those in working age. See Stroke Market Size Estimate spreadsheet for all the calculations and references, *Cell A20 and B20*.

⁶³ NHS Digital. (2015). Bespoke requested data, https://www.stroke.org.uk/sites/default/files/state_of_the_nation_2017_final_1.pdf

⁶⁴ Sun et al. 2014; Rist et al. 2013

⁶⁵ Aqueveque et al. 2017; Rumping et al. 1999

the Acute, Sub-Acute, Intermediate, and Chronic phases that can result in functional improvement even years after an injury.

Below is a description of current therapeutic options offered by rehabilitation centers for people with SCI and other technological approaches intended to improve the condition of people with SCI. Thereafter is a description of therapeutic options in development that may offer future promise, but are not yet viable, and a description of current pharmacologic options that are not currently sufficiently effective.

Conventional Rehabilitation



The Company is not aware of a predictably restorative or curative treatment available for people with SCI. In the absence of an effective therapy, the focus of SCI rehabilitation has shifted from medical management to optimizing quality of life and community participation.⁶⁶ Rehabilitation programs typically consist of physical and occupational therapy, nursing, and counselling. Mobility training is an important part of rehabilitation, including learning to use assistive devices such as wheelchairs, walkers, crutches or braces.⁶⁷ Conventional rehabilitation yields limited recovery with results that are highly dependent on patient motivation and capacity to train.

Exoskeletons



Exoskeletons have been commercially available for several years, marketed globally by ReWalk Robotics, Ekso Bionics, Cyberdyne, and other companies. Adoption has lagged primarily due to high cost, lack of reimbursement in the US and other major markets, and limited availability of clinical data. Exoskeletons are heavy and typically require support from caregivers to apply, a process that can require 10-15 minutes. While time spent in a vertical position and enhanced mobility have been shown to positively affect autonomic functions such as bowel movements, exoskeletons do not generally offer improved autonomic function as a primary benefit. In addition, most exoskeletons do not offer volitional or "thought triggered" movement, an important feature of ARC^{IM}.

Functional Electrical Stimulation

⁶⁶ GómGómara-Toldrà et al., Physical therapy after spinal cord injury: a systematic review J. Spinal Cord Med 2014.

⁶⁷ GómGómara-Toldrà et al., Physical therapy after spinal cord injury: a systematic review J. Spinal Cord Med 2014.

FES has been commercially available for over 30 years, marketed globally by Bioness, Hasomed, Restorative Therapies, and others. It uses low-energy electrical pulses to artificially generate body movements in individuals who have been paralyzed due to SCI. Once electrode patches have been positioned on the muscles targeted for activation, FES can be used to generate muscle contraction in otherwise paralyzed limbs and to initiate grasping, walking, bladder voiding, standing, and certain other functions. There are several challenges associated with FES:

- complex set-up is generally required before each use;
- each muscle needs to be driven by an individual electrode, resulting in poor stimulation resolution or very complex control modalities, especially for the realization of functional tasks;
- muscles fibers are recruited in the opposite order of natural muscle-fiber recruitment, causing early fatigue during training;⁶⁸ and,
- stimulation needs to be externally triggered.

As a result of these challenges and despite its use over 30 years, FES has not been widely adopted by rehabilitation centers following SCI. Instead, FES is used primarily for rehabilitation after stroke or for patients with drop foot, a condition in which patients have difficulty lifting the front part of their foot.

Neurostimulation

Electrical Epidural Stimulation

Multiple academic groups in the US have reported benefits of Electrical Epidural Stimulation ("**EES**") after SCI. Reported results include recovery of voluntary control of paralyzed muscles,⁶⁹ improvement of cardiovascular function,⁷⁰ and restoration of bowel, bladder and sexual function.⁷¹ The Company has relationships or on-going collaborations with most active pioneering researchers in this field and has in-licensed relevant IP from their respective academic institutions. Though there are several academic initiatives ongoing, it is the Company's understanding that it is the only company actively developing EES-based products for people with neuromotor disorders as of the time of this Prospectus.

⁶⁸ Esquanazi et al., The ReWalk Powered Exoskeleton to Restore Ambulatory Function to Individuals with Thoracic-Level Motor-Complete Spinal Cord Injury. American J. of Physical Medicine & Rehabilitation 2012

⁶⁹ Lynch and Popovic, Functional Electrical Stimulation, <http://dept.me.umn.edu/labs/hmd/lab/docs/04472378.pdf>

⁷⁰ University of Arizona (2002-2004), Louisville University (Kentucky 2011-2018), Mayo Clinic (Minnesota 2018), University of Minnesota (Minnesota 2018)

⁷¹ ClinicalTrials.gov, Neuromodulation: Bladder Bowel and Sexual Function in SCI, Identifier: NCT04604951.

Current EES systems are designed for pain management and lack certain capabilities optimized for SCI indications

Existing Spinal Cord Stimulation Platforms

			
<p>Medtronic markets the Intelis™ platform for both Spinal Cord Stimulation (SCS) and Peripheral Nerve Stimulation (PNS) as an aid in the management of certain type of chronic pain.</p> <p>CE Mark approval in 2017 / FDA approval in 2017</p> <p>Lacks true closed-loop capabilities</p>	<p>Abbott markets the Proclaim series including devices designed to deliver spinal cord stimulation (SCS) for the treatment of chronic pain, and dorsal root ganglion (DRG) stimulation</p> <p>Abbott's latest Proclaim device (Proclaim XR) received FDA approval in 2019</p> <p>Lacks closed-loop capabilities, ability to stimulate from different electrodes at different frequencies, and rechargeable battery</p>	<p>Neuro markets the Senza Omnia system, which is the first and only SCS system designed to deliver Neuro's proprietary HF10 therapy in addition to all other available SCS frequencies</p> <p>CE Mark approval in 2020 / FDA approval in 2019</p> <p>Lacks closed-loop capabilities, ability to stimulate from different electrodes at different frequencies; battery capacity has been a concern</p>	<p>Boston Scientific's latest portfolio of SGS Systems is the WaveWriter Alpha™. The portfolio, consisting of four MRI conditional, Bluetooth-enabled implantable pulse generators (IPGs)</p> <p>FDA approval in 2020</p> <p>Lacks true closed-loop capabilities</p>

Sources: Clingan J. A., Patel A. & Maher D. P. (2020) Survey of Spinal Cord Stimulation Hardware Currently Available for the Treatment of Chronic Pain in the United States. Front. Pain Res. 1:572907. doi: 10.3388/fpain.2020.572907. Company data.

Several large medical technologies currently market spinal cord stimulation platforms for pain management, including Medtronic, Boston Scientific, St. Jude Medical, and Neuro. These platforms are optimized for pain and lack some of the key capabilities the Company believes are required for stimulation of the spinal cord for SCI-related indications:

- High speed wireless communications: Current pain devices employ Bluetooth or lack wireless communications capabilities altogether. The ARC^{IM} platform utilizes both Bluetooth Low Energy (BLE), used to connect to external sensors and programmers, and a Near Field Magnetic Inductive (NFMI) link between the IPG and the Hub. The NFMI link provides an exceptionally low latency, high-speed, low-power communication bridge between these two system components. This enables ARC^{IM} to incorporate data from external or implantable sensors and adjust stimulation parameters in near real-time. The Company views its NFMI link to be a competitive advantage and it believes this capability positions it as the best potential option for a host of indications optimized for closed-loop, such as blood pressure regulation, walking, and any indication requiring an implantable brain-spine interface, for example those leveraging implanted brain sensors from Neuralink or Blackrock Neurotech.
- Advanced recharging: Some current pain devices are non-rechargeable or consume power at high rates while delivering stimulation. These platforms would be challenged to deliver stimulation in a closed-loop context, when it is necessary to harvest sensory data and continually adjust stimulation parameters to optimize therapy. The Company's ARC^{IM} device is also capable of wirelessly recharging from a distance 2-3X further than current devices, improving patient convenience and extending the availability of the therapy to obese patients.
- Purpose-designed leads: The Company's ARC^{IM} IPG is paired with a family of leads rigorously designed and optimized for deployment along different areas of the spinal cord with electrode spacing and configuration designed to optimally stimulate the desired movement or function. While similar leads are offered by companies marketing spinal cord stimulation systems for pain management, those leads are designed to optimally deliver current to the spinal cord, whereas the Company's leads are designed to optimally deliver current to the dorsal spinal cord roots which reside along the lateral spinal cord. The Company's leads are generally larger and incorporate electrodes in areas not currently found in leads designed for pain management.
- The Company maintains a significant intellectual property estate (owned or licensed) now encompassing more than 290 issued or pending patents worldwide. Many of these patents

result from longstanding and in most cases exclusive IP licensing arrangements with most of the leading academic researchers active in spinal cord stimulation for SCI. The Company's status as pioneer has enabled the Company to gain a deep scientific understanding of where and how to stimulate to optimize effect. This advantage would be difficult to quickly replicate.

Notwithstanding the protective impact of this IP, the Company, in addition, believes the technical capabilities of its ARC[™] system could not be easily replicated by companies currently offering similar platforms for pain management. Matching the Company's real-time closed-loop capabilities, continuous low-latency, low power consumption communication capabilities, and recharging performance would be expected to require significant investments in time and resources.

Peripheral Nerve Stimulation

Multiple approaches based on PNS have been explored for people with SCI. PNS can be performed with a FES system using electrodes positioned above targeted nerves or with an implanted system. Though set-up can be simplified with the use of an implantable system, PNS has comparable performance limitations to FES.

Vagus nerve stimulation is an FDA approved approach for treating epilepsy and depression. It is under preclinical investigation by academic groups to drive improvement of motor and cardiovascular function after SCI. The vagus nerve is the longest nerve of the autonomic nervous system. It influences parasympathetic control of the heart, lungs, and digestive tract, and comprises sensory and motor fibers. It is not yet clear how this approach can be used to target patient-specific neural circuits that need to be re-activated after SCI. No human data is yet available.

Transcutaneous Spinal Cord (tSCS) Stimulation

Unlike ARC[™] which currently does not have any direct commercial competitors, ARC^{EX} faces two small companies with similar technology – Cosyma and SpineX. ARC^{EX} and similar technologies transcutaneously (through the skin) deliver current to the spinal cord. The amount of current required to reach spinal circuits through the skin is far higher than what is required by conventional non-invasive neurostimulation devices like FES or TENS devices described above. Without the use of the Company's IP protected waveform, the required current level would be uncomfortable for patients. This waveform uses a 5 to 10 kHz carrying frequency on top of the applied stimulation, enabling the therapeutic current to cross the skin and activate spinal cord circuits without excess discomfort.

Cosyma – Cosyma is a Russian company that markets a device for research purposes. It is not currently commercially marketed in the US or Europe. The Company is not aware of any US or European IP owned or licensed by Cosyma.

SpineX – SpineX is a spinout of UCLA that raised USD 250,000 in funding in late 2019, per Pitchbook.

Several academic researchers now involved with Cosyma and SpineX were affiliated with the University of California Los Angeles and were involved with NRT, the Company acquired by the Company in late 2019. The IP associated with transcutaneous spinal cord stimulation resulting from research performed by these individuals and produced while they were affiliated with UCLA and NRT is now exclusively licensed to the Company. To progress toward commercialization, it cannot be excluded that both companies would infringe on the UCLA IP licensed exclusively to the Company, unless they have another technique to transcutaneously deliver current to the spinal cord. In those conditions and given the lack of apparent funding and IP controlled by these companies, the Company holds skepticism about their respective abilities to successfully scale and commercialize, and thus emerge as credible competitors to the Company.

Biotechnological approaches

Scaffolds

Several initiatives are exploring implantation of bio-resolvable scaffolds into the lesion site to promote the regrowth of nerve fibers across the lesion. InVivo Therapeutics, a NASDAQ listed company received HUD designation from the FDA for their Neuro-Spinal Scaffold, and development is on-going.

Importantly, scaffolds and biological approaches are only expected to offer clinical utility when deployed in the Acute Phase. This means they are unlikely to benefit the huge prevalence pool of chronically injured SCI patients.

Stem cells

Stem cell implants for repairing damaged spinal cords have received significant research attention, but thus far failed to reliably heal injuries in human subjects. They will likely reveal their full potential for recovery in combination with other training modalities, especially neuromodulation, which will enable and facilitate the functional wiring of newly implanted cells with endogenous spinal circuits that is required to promote clinical recovery. The Company believes stem cells, like scaffolds, are more complementary than competitive.

Pharmacology

Numerous pharmacological treatments are available for people with SCI, for addressing symptoms of associated comorbidities such as spasticity, blood pressure, and mood disorders. None of these available treatments has been shown to promote recovery.

Currently, the most promising pharmacological approach is the use of growth factors to enhance regrowth of nerve fibers across the lesion site. Research remains at a preclinical stage. Similar to scaffolds and stem cells, growth factors' effectiveness may be empowered if used in combination with neurostimulation.

Some medications can be used to help manage orthostatic hypotension and chronic hemodynamic instabilities. Unfortunately, they are limited, and their effect is not optimal. They require a certain amount of time to be active and their effect can persist for hours with significant side effects such as severe hypertension. While hemodynamic dysfunctions such as orthostatic hypotension is transient and most of the time unexpected^{72,73,74}. The administration of long-acting pressor agents (e.g. midodrine) and anti-hypertensives (e.g. nifedipine and prazosin) have shown to acutely improve blood pressure and cerebrovascular functions but are not optimal to manage chronic hemodynamic instability induced by SCI^{75,76,77}.

The Company's blood pressure therapy is designed to be turned on and off by the patient with voice commands. This ability to initiate and terminate therapy within seconds contrasts to the slow-acting nature of current pharmacologic agents and the inability to voluntarily stop their effects.

The Company's solution

ARC Therapy

The Company's solution is ARC Therapy – targeted, programmed, electrical stimulation of the spinal cord designed to restore movement, independence, and health in people with SCI.

When someone suffers an SCI, the conduction of signals across the lesion are impacted. The spinal cord and nervous system "downstream" from the lesion are intact and dormant, awaiting signals from

⁷² A. Krassioukov, J. J. Eng, D. E. Warburton, and R. Teasell, A Systematic Review of the Management of Orthostatic Hypotension After Spinal Cord Injury, vol. 90. Arch Phys Med Rehabil, 2009.

⁷³ A. Krassioukov, D. E. Warburton, R. Teasell, J. J. Eng, and Spinal Cord Injury Rehabilitation Evidence Research Team, "A systematic review of the management of autonomic dysreflexia after spinal cord injury," Arch. Phys. Med. Rehabil., vol. 90, no. 4, pp. 682–695, Apr. 2009, doi: 10.1016/j.apmr.2008.10.017.

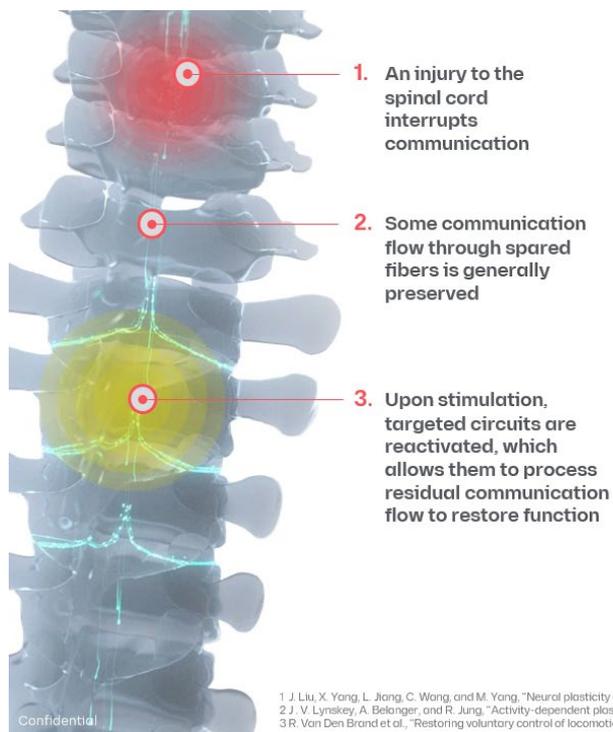
⁷⁴ M. Hubli, C. M. Gee, and A. V. Krassioukov, "Refined assessment of blood pressure instability after spinal cord injury," Am. J. Hypertens., vol. 28, no. 2, pp. 173–181, Feb. 2015, doi: 10.1093/ajh/hpu122.

⁷⁵ A. A. Phillips, A. V. Krassioukov, P. N. Ainslie, and D. E. R. Warburton, "Perturbed and spontaneous regional cerebral blood flow responses to changes in blood pressure after high-level spinal cord injury: The effect of midodrine," J. Appl. Physiol., vol. 116, no. 6, pp. 645–653, Mar. 2014, doi: 10.1152/jappphysiol.01090.2013.

⁷⁶ A. A. Phillips, D. E. R. Warburton, P. N. Ainslie, and A. V. Krassioukov, "Regional neurovascular coupling and cognitive performance in those with low blood pressure secondary to high-level spinal cord injury: Improved by alpha-1 agonist midodrine hydrochloride," J. Cereb. Blood Flow Metab., vol. 34, no. 5, pp. 794–801, 2014, doi: 10.1038/jcbfm.2014.3.

⁷⁷ A. A. Phillips, S. L. Elliott, M. M. Z. Zheng, and A. V. Krassioukov, "Selective alpha adrenergic antagonist reduces severity of transient hypertension during sexual stimulation after spinal cord injury," J. Neurotrauma, vol. 32, no. 6, pp. 392–396, Mar. 2015, doi: 10.1089/neu.2014.3590.

the brain that cannot cross the lesion site with adequate strength to trigger normal movement or function. ARC Therapy applies programmed electrical stimulation to the intact, dormant spinal cord anatomy downstream from the lesion, at locations specifically associated with particular movements or functions using stimulation parameters optimized to restore those movements or functions.



ARC Therapy Mechanism of Action

Activating and enlivening dormant pathways to restore movement and function^{1,2,3}

- Epidural Electrical Stimulation (EES) is applied to the spinal cord below the injury site, reactivating dormant neuronal pathways to restore function
- When stimulated, the spinal cord can process signals from the brain transmitted through spared fibers to restore function
- When used in combination with neurorehabilitation, function may be restored even in absence of stimulation
- The growth of new neural connections is termed neuroplasticity
- EES is designed to exploit the neurobiological principles of neuroplasticity to reverse paralysis and promote recovery after SCI

1 J. Liu, X. Yang, L. Jiang, C. Wang, and M. Yang, "Neural plasticity after spinal cord injury," *Neural Regen Res*, vol. 7, no. 5, pp. 386-391, Feb. 2012, doi: 10.3969/j.issn.1673-5374.2012.05.010.
2 J. V. Lynskey, A. Belanger, and R. Jung, "Activity-dependent plasticity in spinal cord injury," *J Rehabil Res Dev*, vol. 45, no. 2, pp. 229-240, 2008, doi: 10.1682/JRRD.2007.03.0047.
3 R. Van Den Brand et al., "Restoring voluntary control of locomotion after paralyzing spinal cord injury," *Science*, vol. 336, no. 6085, pp. 1182-1185, 2012, doi: 10.1126/science.1217416

The Company's research partners at EPFL (NeuroRestore) and elsewhere have uncovered these locations and stimulation parameters, showing success in preclinical and clinical research that has been published in *NATURE* and other leading peer-reviewed scientific and medical journals. In fact, the Company has exclusive licensing agreements to commercialize these breakthroughs from several leading neuroscience research institutions globally, including Caltech, University of California at Los Angeles, University of Minnesota, University of Louisville, University of Calgary, University of British Columbia, and EPFL.

The Company delivers ARC Therapy via two proprietary investigational platforms, ARC^{IM} and ARC^{EX}, both of which have been awarded FDA Breakthrough Device Designation in recognition of their potential to address significant patient needs with a truly innovative solution.

The ARC^{IM} Platform

The ARC^{IM} platform is implantable, consisting of an implantable pulse generator and a family of paddle leads, each optimized for placement along the spinal cord in an area thought to be responsible for restoring a particular movement or function.



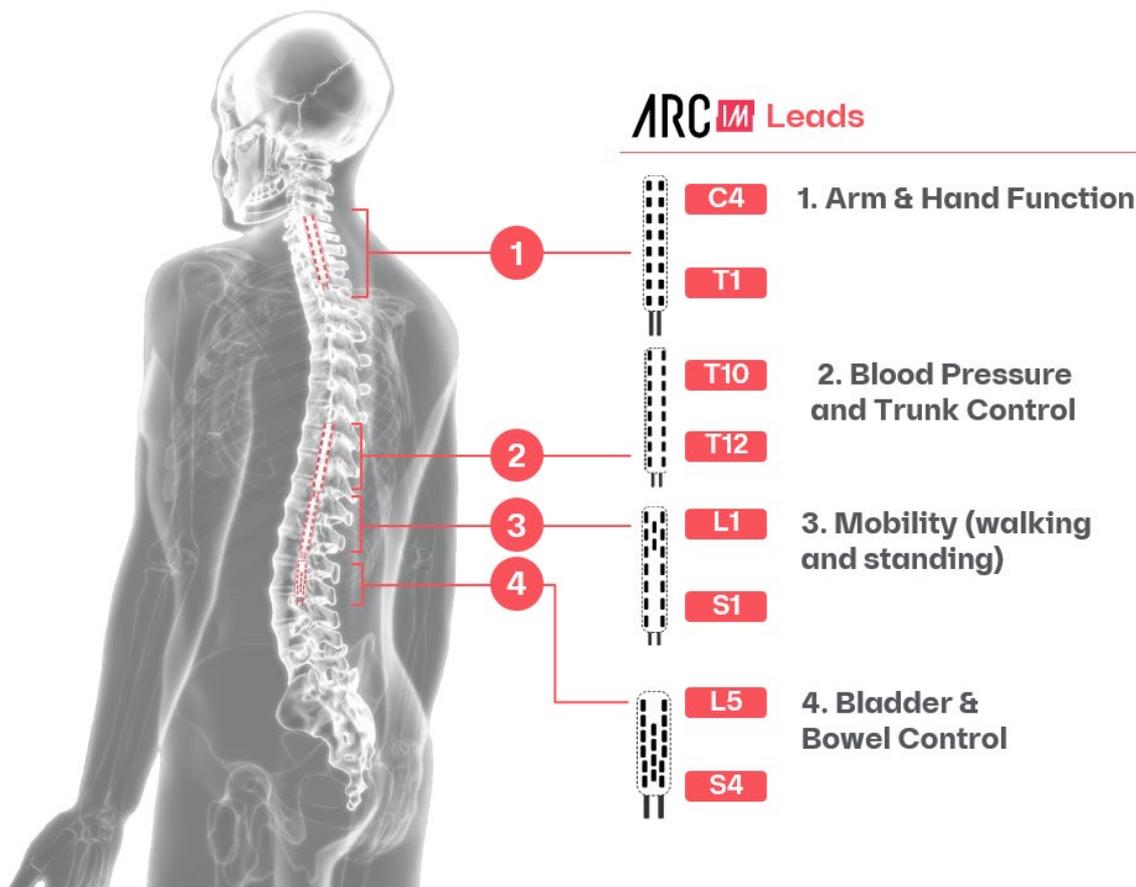
The IPG is controlled by a small, wireless external unit that is programmed and/or controlled by a tablet programmer or voice-activated smartwatch.

The ONWARD IPG is purpose-built for SCI indications. It offers several capabilities not currently found in IPGs used for SCS for pain:

- Designed for closed-loop operation, with the ability to assimilate large volumes of wireless data from sensors and other devices with reduced latency and low power consumption.
- The parameters of delivered stimulation can be adjusted in real time based on external inputs or sensor inputs; sensors can either be implanted, wearable, or integrated within the IPG.
- There are 16 independent current sources and independent stimulation frequencies.
- Proprietary stimulation waveforms, including biomimetic waveforms, burst stimulation mode to preserve natural proprioception during high intensity stimulation, and a ramping mode to deliver a smooth activation function.
- Equipped with advanced battery recharging capabilities, able to wirelessly charge through the skin at greater distances than current SCS devices.

The ARC^{IM} IPG is paired with a family of leads rigorously designed and optimized for deployment along different areas of the spinal cord with electrode spacing and configuration designed to optimally stimulate the desired movement or function. The leads are placed not on the spinal cord itself, but on the dura, a fibrous layer surrounding the spinal cord. The leads the Company expects to commercialize as part of the ARC^{IM} system have been redesigned and differ from the Go-2 leads used in the STIMO study, detailed below. The redesigned leads are further optimized to capture the spinal cord anatomy responsible for controlling or triggering the desired movement or function.

The Hub functions as a central connection and processing point for ARC^{IM} and ARC^{EX} (to be described later) and includes several wireless and wired interfaces. It also includes the necessary microprocessors for hosting wireless protocols and running the algorithms used to adjust stimulation in real-time in support of closed-loop functionality. The Hub permits a multitude of sensors to be connected directly to the ARC^{IM} system and provides real-time feedback for therapy optimization. The Hub is also used to recharge the ARC^{IM} IPG wirelessly.



The implant procedure for ARC^{IM} is similar to that which is currently performed for devices that stimulate the spinal cord for pain management. These procedures are most commonly performed by functional neurosurgeons and require approximately two hours. Patients typically remain in the hospital for one day following implant and subsequently require one week of recovery prior to initiation of post-operative mapping and rehabilitation training.

Surgical procedure expected to require <120 minutes skin to skin

ARC^{IM} Implantation Surgery

1 Patient preparation

Before surgery, perform MRI scan to pre-determine ideal location of paddle lead on the spinal cord

2 Incision



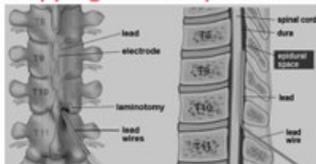
Make small skin incision at the appropriate incision site

3 Laminotomy



Perform laminotomy to place the leads

4 Mapping and lead placement



Position lead in the epidural space above the spinal cord

Measure muscle response or autonomic activity using EMG to assure proper lead placement
Secure leads with sutures

5 Pulse generator insertion



Make small skin incision below the waistline

Create a pocket for generator beneath the skin and attach it with the lead wire

6 Wound closure

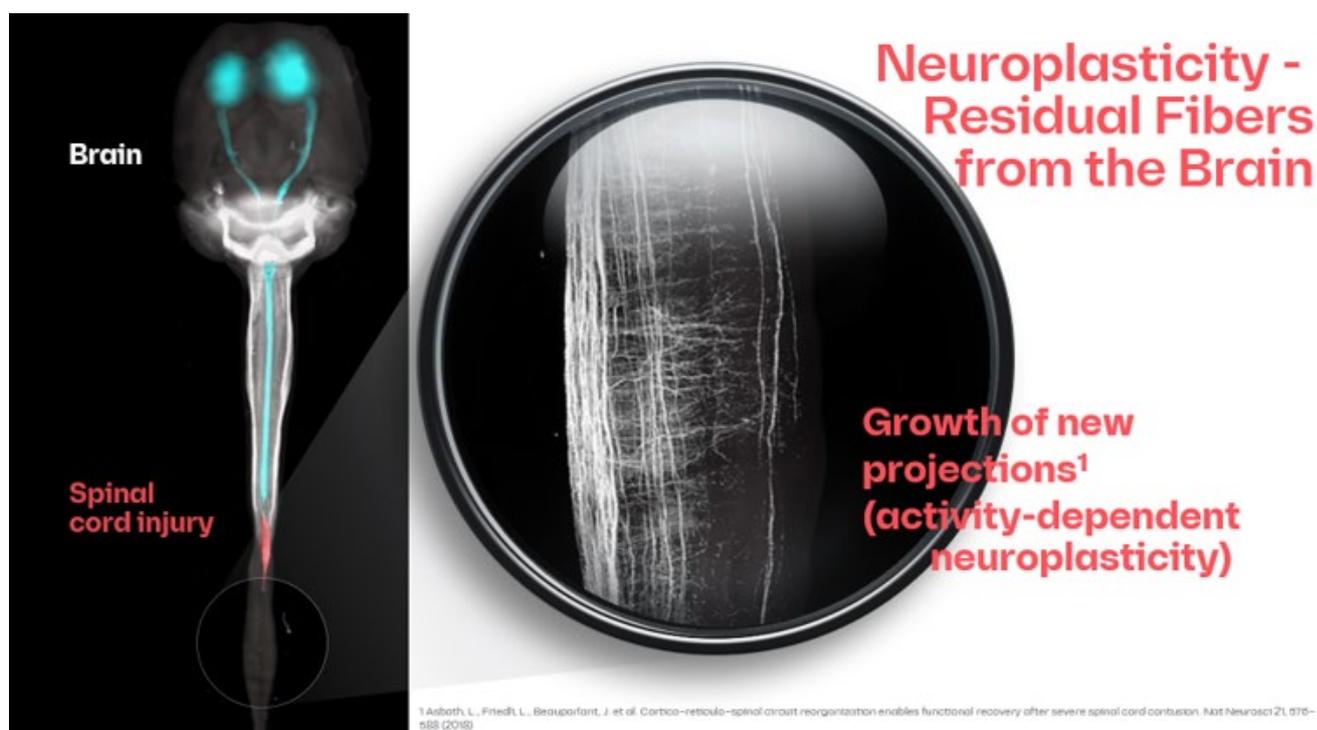


Close incisions with sutures and skin glue

ARC^{IM}

ARC Therapy recruits large-diameter afferent fibers where they enter in the spinal cord from the dorsal roots.⁷⁸ These fibers primarily innervate proprioceptive organs. Consequently, their depolarization with electrical currents leads to the activation of proprioceptive feedback circuits. These circuits are the elementary building blocks of movement. Consequently their recruitment reactivates hypoactive spinal circuits and increases the functional impact of anatomically intact yet functionally silent or poorly active descending pathways below the lesion. The engagement of residual descending pathways during neurorehabilitation supported by the ARC therapy will trigger neural circuit reorganization – also known as neuroplasticity – both at supraspinal and spinal levels. This neuroplasticity which happens after weeks/months of training, promotes functional recovery in the absence of stimulation,^{79,80} but will be significantly enhanced when supported by ARC Therapy.

In the graphic below an image of a rodent brain and spinal cord is shown, with the spinal cord injury identified in red. Moving from left to right, the images telescope until they magnify and uncover the growth of new nerve projections across the injury site. This is visual microscopic evidence of neuroplasticity.



The chart below demonstrates the typical care pathway for SCI patients selected for ARC Therapy.

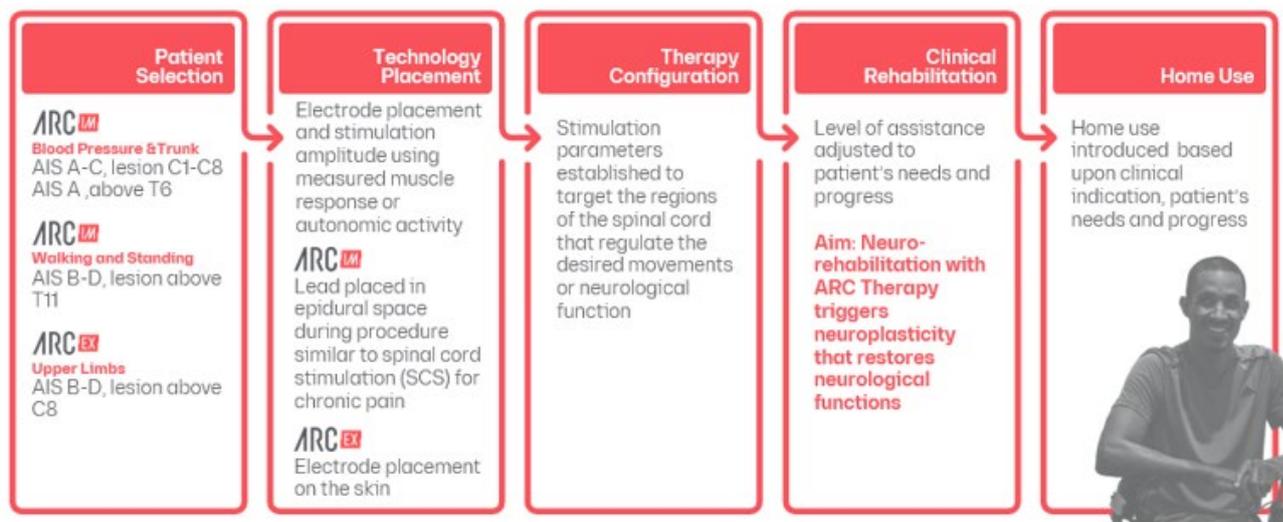
⁷⁸ E. M. Moraud *et al.*, "Mechanisms Underlying the Neuromodulation of Spinal Circuits for Correcting Gait and Balance Deficits after Spinal Cord Injury," *Neuron*, vol. 89, no. 4, pp. 814–828, 2016, doi: 10.1016/j.neuron.2016.01.009.

⁷⁹ L. Asboth *et al.*, "Cortico-reticulo-spinal circuit reorganization enables functional recovery after severe spinal cord contusion," *Nat. Neurosci.*, vol. 21, no. 4, pp. 576–588, Apr. 2018, doi: 10.1038/s41593-018-0093-5.

⁸⁰ R. Van Den Brand *et al.*, "Restoring voluntary control of locomotion after paralyzing spinal cord injury," *Science*, vol. 336, no. 6085, pp. 1182–1185, 2012, doi: 10.1126/science.1217416.

ARC Therapy and long-term neurorehabilitation promotes neuroplasticity and restores function

ARC Therapy Continuum



Mechanism of Action

The ARC^{IM} platform is designed to address clinical indications for which precise stimulation parameters are required and/or 24/7 availability is important. These include movement-related functions such as mobility and trunk control, as well as autonomic functions such as blood pressure regulation, and bladder and bowel control.

The initial planned indications for the ARC^{IM} platform include mobility, blood pressure regulation, and trunk control for the SCI population, but several other potential indications are possible. New indications can generally be targeted with modest adjustments to firmware and software. The specific stimulation parameters and mechanism of action differ depending on the indication. Below is more information about the first two indications for ARC^{IM} for which the Company intends to seek authorization to market – Blood pressure and trunk control and mobility.

ARC^{IM} Blood Pressure and Trunk Control

Therapy Description

The Company's initial target indication for ARC^{IM} is the stabilization of hemodynamic function and restoration of trunk control and stability.

Although an SCI interrupts most or all descending inputs from supraspinal centers in the brain, the neural circuits located below the lesion site are still intact but remain in a hypoactive state due to the lack of excitatory and modulatory inputs from the brain and brainstem. The therapy objective is to stabilize blood pressure and support trunk stability below the level of the lesion. Using an implanted electrode array located over the dorsal aspect of the thoracic spinal cord, EES can reactivate the neural circuits located below the electrodes. Lead implantation is similar to that used for SCS for chronic pain.⁸¹

EES recruits large-diameter afferent fibers where they enter in the spinal cord through the dorsal roots.⁸² These fibers primarily innervate proprioceptive organs. Consequently, their depolarization with electrical currents leads to the activation of proprioceptive feedback circuits. These circuits are the elementary building blocks of movement. Consequently, their recruitment reactivates hypoactive spinal circuits and increases the functional impact of anatomically intact yet functionally silent or poorly

⁸¹ Bedder & Bedder, 2009

⁸² E. M. Moraud *et al.*, "Mechanisms Underlying the Neuromodulation of Spinal Circuits for Correcting Gait and Balance Deficits after Spinal Cord Injury," *Neuron*, vol. 89, no. 4, pp. 814–828, 2016, doi: 10.1016/j.neuron.2016.01.009.

active descending pathways below the lesion. This engagement during rehabilitation training will trigger neural circuit reorganization – also known as neuroplasticity – both at supraspinal and spinal levels. This neuroplasticity which happens after weeks/months of training, promotes functional recovery in the absence of stimulation,^{83,84} but will be significantly enhanced when supported by EES. ARC^{IM} Therapy was developed based on the understanding of the physiological mechanisms underlying the therapeutic effect of EES. ARC^{IM} Therapy stimulation protocols are delivered using an implantable neurostimulation system, consisting of an IPG and an electrode array (lead) placed over the dura on the posterior aspect of the spinal cord.

The key concept of the therapy is the activation of the dorsal roots with spatiotemporal ARC^{IM} Therapy stimulation protocols. The delivery of the stimulation needs to be targeted to precise spatial locations according to the functional anatomy of the patient's spinal cord. ARC^{IM} Therapy is significantly more effective than continuous stimulation as it provides a biomimetic stimulation that reinstates the natural dynamic of spinal circuit activation: stimulation is delivered at the right place, with the right timing, and at the right intensity.⁸⁵

Hemodynamic instability post-SCI is due to the interruption of supraspinal excitatory drive to the sympathetic circuitry, disrupting the sympathetic division of the natural baroreflex. A series of experiments were conducted to understand the mechanisms underlying the improvement in blood pressure induced by epidural electrical stimulation over the lumbosacral spinal cord. The precise dorsal roots responsible for addressing hypotension by increasing cardiac output and vascular resistance, termed hemodynamic hotspots, were identified by the Company's research partners at EPFL, who published this ground breaking work in *Nature*, January 2021.⁸⁶ The Company's research partners at EPFL recently dissected the anatomical topology and physiological dynamics of the sympathetic circuitry to understand how hemodynamic ARC^{IM} Therapy can target these physiological processes and modulate blood pressure. This research identifies a clear anatomical and functional enrichment within the three caudal thoracic spinal segments which the researchers termed the hemodynamic hotspots. The ARC^{IM} Therapy protocol immediately stabilized hemodynamics in rodent and non-human primate models of SCI. The researchers also validated the features of hemodynamic ARC^{IM} Therapy in one human patient.⁸⁷ The patient reports dramatic reduction in episodes of orthostatic hypotension, cessation of pharmaceutical management, and greater vertical motor neurorehabilitation. In addition, spinal segments associated with trunk stability almost certainly overlap with the hemodynamic hotspots.^{88 89 90}

Current clinical practice in SCI rehabilitation

In current clinical practice, management of cardiovascular instabilities is addressed differently following clinical practice guidelines such as for the management of acute SCI.⁹¹ Pharmacological treatment can be implemented. Apart from medications, the patient is asked to manage his lifestyle and make some changes that can help to support cardiovascular function. Non-pharmacological and pharmacological options for managing cardiovascular dysfunctions post-SCI are limited. To this day

⁸³ L. Asboth *et al.*, "Cortico-reticulo-spinal circuit reorganization enables functional recovery after severe spinal cord contusion," *Nat. Neurosci.*, vol. 21, no. 4, pp. 576–588, Apr. 2018, doi: 10.1038/s41593-018-0093-5.

⁸⁴ R. Van Den Brand *et al.*, "Restoring voluntary control of locomotion after paralyzing spinal cord injury," *Science*, vol. 336, no. 6085, pp. 1182–1185, 2012, doi: 10.1126/science.1217416.

⁸⁵ J. W. Squair *et al.*, "Neuroprosthetic baroreflex controls haemodynamics after spinal cord injury," *Nature*, pp. 1–7, Jan. 2021, doi: 10.1038/s41586-020-03180-w.

⁸⁶ J. W. Squair *et al.*, "Neuroprosthetic baroreflex controls haemodynamics after spinal cord injury," *Nature*, pp. 1–7, Jan. 2021, doi: 10.1038/s41586-020-03180-w.

⁸⁷ J. W. Squair *et al.*, "Neuroprosthetic baroreflex controls haemodynamics after spinal cord injury," *Nature*, pp. 1–7, Jan. 2021, doi: 10.1038/s41586-020-03180-w.

⁸⁸ S. Sprigle, C. Maurer, and M. Holowka, "Development of Valid and Reliable Measures of Postural Stability," *J. Spinal Cord Med.*, vol. 30, no. 1, pp. 40–49, 2007.

⁸⁹ J. Quinzaños, A. R. Villa, A. A. Flores, and R. Pérez, "Proposal and validation of a clinical trunk control test in individuals with spinal cord injury," vol. 52, no. 6, pp. 449–454, doi: 10.1038/sc.2014.34.

⁹⁰ J. T. Hachmann, J. S. Calvert, P. J. Grahm, D. I. Drubach, K. H. Lee, and I. A. Lavrov, "Review of Epidural Spinal Cord Stimulation for Augmenting Cough after Spinal Cord Injury," *Front. Hum. Neurosci.*, vol. 11, no. March, pp. 1–10, Mar. 2017, doi: 10.3389/fnhum.2017.00144.

⁹¹ M. G. Fehlings *et al.*, "A Clinical Practice Guideline for the Management of Acute Spinal Cord Injury: Introduction, Rationale, and Scope," *Glob. Spine J.*, vol. 7, no. 3 Suppl, pp. 84S-94S, Sep. 2017, doi: 10.1177/2192568217703387.

there is no existing therapy allowing restoration of autonomic functions and hemodynamic stability following an SCI. It is crucially needed to improve the quality of life of patients.

Mechanism of Action

Preclinical and clinical research from the past two decades shows that EES can promote the recovery of motor and autonomic functions after SCI. The mechanism is that EES recruits large-diameter afferent fibers where they enter the spinal cord through the dorsal roots. The recruitment of these fibers leads to the modulation of specific neuronal populations that are involved in the regulation of motor and autonomic functions. Therefore, EES utilizes large-diameter afferent fibers as a gateway to modulate specific neuronal circuits, and thus provides the potential to normalize neurological functions after SCI.⁹²

The neuronal populations engaged by EES logically depend on the location of the stimulation. For example, many studies have delivered EES over lumbar spinal segments to modulate motor circuits involved in the control of leg muscles. EES targeting the lumbar dorsal roots restored standing and walking in people with paralysis due to an SCI.

In turn, the application of EES over the low-thoracic spinal cord enables the regulation of blood pressure. Indeed, EES targeting the low-thoracic dorsal roots leads to the modulation of sympathetic neurons, which result in a proportional increase in blood pressure.^{93 94 95 96 97} It was reported in several clinical trials that arterial blood pressure could be modulated acutely when delivering EES. It was also shown that with specific optimized stimulation parameters, blood pressure could be maintained within a normal range during resting and orthostatic stress^{98 99 100 101 102}. Daily use of EES using optimized parameters was shown to improve cardiovascular regulation during an orthostatic stress test as well as improve orthostatic hypotension, and these effects persisted even in the absence of stimulation.^{103 104 105}

⁹² J. C. Wu et al., "Increased risk of stroke after spinal cord injury: A nationwide 4-year follow-up cohort study," *Neurology*, vol. 78, no. 14, pp. 1051–1057, Apr. 2012, doi: 10.1212/WNL.0b013e31824e8eaa.

⁹³ N. Wenger et al., "Spatiotemporal neuromodulation therapies engaging muscle synergies improve motor control after spinal cord injury," *Nat. Med.*, vol. 22, no. 2, pp. 138–145, 2016, doi: 10.1038/nm.4025.

⁹⁴ R. Van Den Brand et al., "Restoring voluntary control of locomotion after paralyzing spinal cord injury," *Science*, vol. 336, no. 6085, pp. 1182–1185, 2012, doi: 10.1126/science.1217416.

⁹⁵ M. Capogrosso et al., "A brain-spine interface alleviating gait deficits after spinal cord injury in primates," *Nature*, vol. 539, no. 7628, pp. 284–288, 2016, doi: 10.1038/nature20118.

⁹⁶ S. Harkema et al., "Effect of epidural stimulation of the lumbosacral spinal cord on voluntary movement, standing, and assisted stepping after motor complete paraplegia: a case study," *Lancet Lond. Engl.*, vol. 377, no. 9781, pp. 1938–1947, Jun. 2011, doi: 10.1016/S0140-6736(11)60547-3.

⁹⁷ Y. P. Gerasimenko et al., "Noninvasive Reactivation of Motor Descending Control after Paralysis," *J. Neurotrauma*, vol. 32, no. 24, pp. 1968–1980, Dec. 2015, doi: 10.1089/neu.2015.4008.

⁹⁸ C. R. West et al., Association of epidural stimulation with cardiovascular function in an individual with spinal cord injury, vol. 75. American Medical Association, 2018.

⁹⁹ S. C. Aslan et al., "Epidural spinal cord stimulation of lumbosacral networks modulates arterial blood pressure in individuals with spinal cord injury-induced cardiovascular deficits," *Front. Physiol.*, vol. 9, no. MAY, pp. 1–11, 2018, doi: 10.3389/fphys.2018.00565.

¹⁰⁰ S. J. Harkema et al., "Normalization of Blood Pressure with Spinal Cord Epidural Stimulation After Severe Spinal Cord Injury," *Front. Hum. Neurosci.*, vol. 12, no. March, pp. 1–11, 2018, doi: 10.3389/fnhum.2018.00083.

¹⁰¹ J. W. Squair et al., "Neuroprosthetic baroreflex controls haemodynamics after spinal cord injury," *Nature*, pp. 1–7, Jan. 2021, doi: 10.1038/s41586-020-03180-w.

¹⁰² D. Darrow et al., "Epidural Spinal Cord Stimulation Facilitates Immediate Restoration of Dormant Motor and Autonomic Supraspinal Pathways after Chronic Neurologically Complete Spinal Cord Injury," *J. Neurotrauma*, vol. 12, p. neu.2018.6006, 2019, doi: 10.1089/neu.2018.6006.

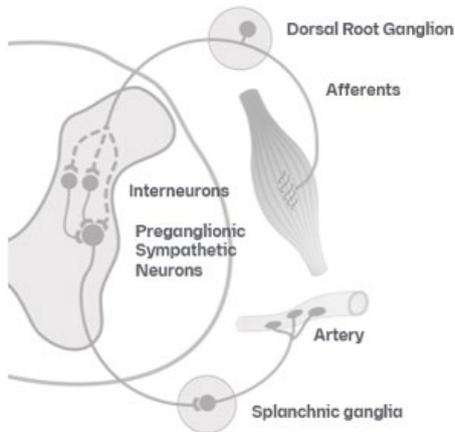
¹⁰³ S. C. Aslan et al., "Epidural spinal cord stimulation of lumbosacral networks modulates arterial blood pressure in individuals with spinal cord injury-induced cardiovascular deficits," *Front. Physiol.*, vol. 9, no. MAY, pp. 1–11, 2018, doi: 10.3389/fphys.2018.00565.

¹⁰⁴ B. E. Legg Ditterline et al., "Beneficial Cardiac Structural and Functional Adaptations After Lumbosacral Spinal Cord Epidural Stimulation and Task-Specific Interventions: A Pilot Study," *Front. Neurosci.*, vol. 14, p. 554018, 2020, doi: 10.3389/fnins.2020.554018.

¹⁰⁵ S. J. Harkema et al., Epidural Spinal Cord Stimulation Training and Sustained Recovery of Cardiovascular Function in Individuals with Chronic Cervical Spinal Cord Injury, vol. 75. American Medical Association, 2018.

Stimulation recruits the sympathetic circuits that regulate blood pressure

ARC^{IM} Blood Pressure Detailed Mechanism of Action



1 Squair et al., nature 2021.

Activation of sympathetic circuits

The recruitment of large-diameter afferent fibers also activates sympathetic preganglionic neurons through the recruitment of excitatory interneurons.¹

This activation of sympathetic preganglionic neurons activates sympathetic neurons located in the splanchnic ganglia.

This activation leads to the vasoconstriction of arteries, which increases blood pressure.

There is an enrichment of sympathetic preganglionic neurons in the low thoracic spinal cord (T10-T12). Consequently, targeting the last three segments with epidural electrical stimulation leads to the most effective modulation of blood pressure.

These last thoracic segments are called **hemodynamic hotspot**.

Travelling waves over these hemodynamic hotspots mimic the natural dynamics of blood pressure regulation, thus leading to a more robust and more physiological modulation of blood pressure.

Adjusting the amplitude of the stimulation allows real-time control over blood pressure in closed-loop.

EES has also shown positive effects on improving trunk musculature and stability. A study from the Mayo clinic¹⁰⁶ reported that EES delivered over the lumbar spinal cord allowed improved trunk control. Unpublished data from the STIMO clinical trial on the three participants with complete sensorimotor paralysis who exhibited moderate to pronounced deficits of lower trunk muscles, showed improved control of their trunk using EES (publication submitted to a top-tier journal).¹⁰⁷ These participants were implanted with a clinical lead developed by the Company, called the Go-2 Lead. This lead was implanted over the thoracolumbar region allowing the stimulation of the last thoracic dorsal roots that project onto the region of the spinal cord wherein circuits controlling the trunk musculature are located. Trunk-specific stimulation programs allowed all three participants to improve a broad range of trunk movements while seated. Motor neurons innervating trunk muscles are distributed within all the thoracic segments. Therefore, EES targeting the thoracic dorsal roots will further improve the recovery of trunk motor function compared to the first evaluations in those three STIMO participants in which stimulation was restricted to one pair of dorsal roots. The new ARC^{IM} Lead may provide significant benefit in targeting these dorsal roots, resulting in benefits across the spectrum of potential indications for ARC^{IM}.

Intended Treatment Population

This therapy is expected to initially be studied for individuals with SCI with an injury located between C3 and T6. These individuals should have confirmed hemodynamic instability such as orthostatic hypotension and/or autonomic dysreflexia. Once commercialized, we expect the target population to expand to people with spinal cord injuries characterized as AIS-A with lesions above T6 and AIS A-C with lesions C1-C8.

Translating ARC^{IM} Therapy into Humans: Proof of Concept

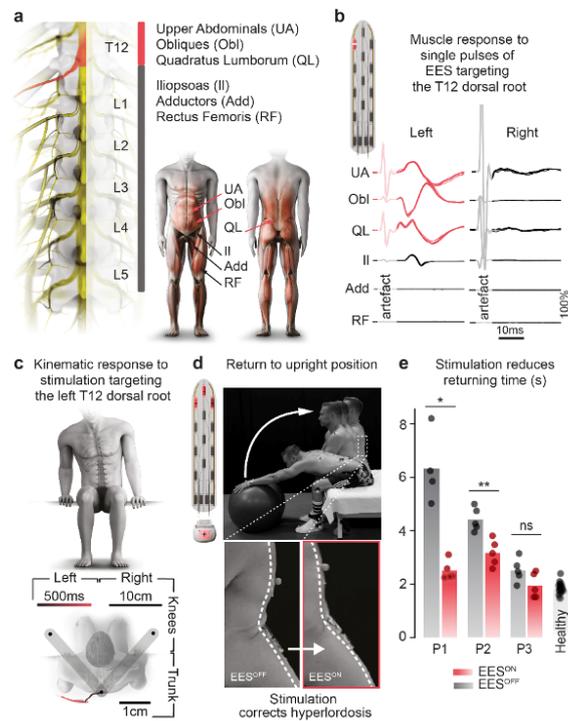
The evolutionary conservation of the sympathetic circuitry enabled a rapid translation of ARC^{IM} Therapy protocols from rats to non-human primates to humans. The Company's research partners at EPFL (NeuroRestore) validated the Company's approach for hemodynamic ARC^{IM} Therapy in three rhesus monkeys with complete upper thoracic SCI.¹⁰⁸ This research demonstrated the ability of ARC^{IM}

¹⁰⁶ M. Gill et al., "Epidural Electrical Stimulation of the Lumbosacral Spinal Cord Improves Trunk Stability During Seated Reaching in Two Humans With Severe Thoracic Spinal Cord Injury," *Front. Syst. Neurosci.*, vol. 14, p. 79, 2020, doi: 10.3389/fnsys.2020.569337.

¹⁰⁷ A. Rowald et al., "Immediate recovery of trunk and leg motor functions after complete paralysis", Accepted for publication in *Nature Medicine*.

¹⁰⁸ J. W. Squair et al., "Neuroprosthetic baroreflex controls haemodynamics after spinal cord injury," *Nature*, pp. 1–7, Jan. 2021, doi: 10.1038/s41586-020-03180-w.

Therapy to control hemodynamic function during well-controlled simulated orthostatic challenges in a negative pressure chamber (see the figure below, under a). Then, the main features of hemodynamic ARC^{IM} Therapy were verified in one patient with cervical SCI who suffered severe orthostatic hypotension for many years (see the figure below, under b).¹⁰⁹ The epidural leads were implanted over the cardiovascular hotspots in the lower thoracic spinal cord (see the figure below, under c), which activated sympathetic circuits (see the figure below, under d). When tilted upright to provoke an orthostatic challenge, the severe drop in blood pressure was monitored by a proportional controller that adjusted the amplitude of ARC^{IM} Therapy waves to rapidly normalize blood pressure (see the figure below, under e). For these reasons, the Company believes that ARC^{IM} Therapy foreshadows a new era in the hemodynamic management of both acute and chronic SCI. The Company envisions that ARC^{IM} Therapy will become the first-line treatment for hemodynamic instability in people with chronic SCI, where vasopressor agents and compression garments will become second-line treatments behind the precise control of blood pressure achieved with ARC^{IM} Therapy.



a) Trunk and leg musculature, spinal cord and implanted stimulating Lead over thoracic (T12) and lumbosacral roots.

b) Electrophysiological experiments were used to determine targeted trunk and leg spinal cord regions. Circular plots report EMG amplitude (in grey scale) when delivering single-pulse EES at increasing amplitudes (radial axis) for selected muscles of the trunk (UA: Upper Abdominals, Obl: Obliques, and QL: Quadratus Lumborum) and the legs (IL: Iliopsoas, RF: Rectus Femoris, and Add: Adductors). c) Participant performing repeated front pull movement on a medicine ball in the absence of stimulation (black) and in the presence of targeted trunk stimulation (red). Curve radius (in mm) of the cervical, thoracic and lumbar regions are measured at four different steps of the performed exercise (numbered snapshots 1-4). Positive and negative values respectively reflect kyphosis and lordosis movements. Exercises were repeated 4-5 times in each condition (stim off/on).

Based on the promise of the clinical research described above, the Company expects to conduct a series of additional studies culminating in a pivotal trial to commence in 2023 in the US and Europe. Should that trial proceed as expected, the Company expects to submit applications for marketing approvals and subsequently commercializing the ARC^{IM} platform for blood pressure and trunk control

¹⁰⁹ J. W. Squair *et al.*, "Neuroprosthetic baroreflex controls haemodynamics after spinal cord injury," *Nature*, pp. 1–7, Jan. 2021, doi: 10.1038/s41586-020-03180-w.

in the US and Europe, if authorized, in 2024. This is an aggressive timeline that could be extended based on discussions with FDA and TÜV SÜD, and/or other developments.

Potential Improvement of Autonomic Dysreflexia and Preventing Secondary Health Conditions

ARC^{IM} Therapy aims to support stabilization of hemodynamic function as well as trunk stability leading to better patient outcomes. EES triggers reversible increases in blood pressure in a well-controlled way.¹¹⁰ These pressor responses must be distinguished from uncontrolled, life-threatening episodes of hypertension, known as autonomic dysreflexia.

The Company believes long-term use of EES does not increase the incidence of autonomic dysreflexia. Non-public data in a rodent model from the lab of Professor Courtine shows that autonomic dysreflexia is caused by the aberrant sprouting of neural pathways from the sacral region onto the sympathetic circuits in the low-thoracic spinal cord. ARC^{IM} Therapy prevents this sprouting, which reduces or even eliminates autonomic dysreflexia in rodent models.

Improvements of autonomic functions in general will lead to an increase in the patient's quality of life and reduce associated healthcare costs. Similar therapies in the field of SCI rehabilitation have shown that neuroplasticity induced by stimulation can improve, for example, bladder function, in turn leading to a reduction of medication use for bladder control.¹¹¹ ¹¹² Some positive outcomes have also been reported that prevent, reduce or alleviate SCI-related secondary health conditions such as pressure ulcer formation and improved bowel function.¹¹³¹¹⁴

As more scientific data becomes available, specific stimulation programs may be developed to promote recovery of specific autonomic functions

ARC^{IM} Mobility/Walking

Therapy Description

The spinal cord contains neural circuits that control specific neurological functions, including sensation, movement, bladder, bowel, sex, hemodynamic and immune responses. These circuits are under the continuous control of the brain. An SCI partially or completely disrupts the flow of information between the brain and the spinal cord, with potentially dramatic consequences. The circuits in the spinal cord below the injury are disconnected from the brain, resulting in the alteration or complete loss of sensory, motor and autonomic functions. Injuries can occur at any level of the spinal cord, which determines the specific neurological functions affected by the injury; and can be classified as incomplete injury – some nervous signals remain and are able to travel past the lesion, to functionally complete injury – a total loss of sensory and motor functions.

While disconnected from the brain, the circuits that control movement remain anatomically intact. For example, the neurons located in the dorsal root ganglions still encode sensory information arising from peripheral organs and transmit this information through their afferent fibers to the spinal cord. These afferents enter the spinal cord through a continuum of posterior roots. To control the movement, the ensemble of sensory information is then translated into motor commands that are delivered to the muscles via efferent nerves located in the ventral roots. These segmental circuits, also called reflex circuits, are the elementary building blocks of motor control, which can be recruited and modulated with epidural electrical stimulation, as explained below. Concerning the muscles of the lower extremities of the body, these circuits are located within the lumbar segments, at the level of the conus of the spinal cord (see the figure below, under A and B).

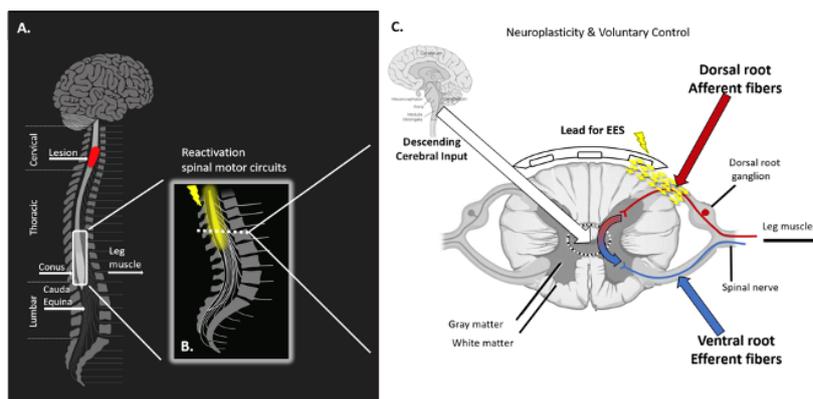
¹¹⁰ J. W. Squair *et al.*, "Neuroprosthetic baroreflex controls haemodynamics after spinal cord injury," *Nature*, pp. 1–7, Jan. 2021, doi: 10.1038/s41586-020-03180-w.

¹¹¹ N. Herrity, C. S. Williams, C. A. Angeli, S. J. Harkema, and C. H. Hubscher, "Lumbosacral spinal cord epidural stimulation improves voiding function after human spinal cord injury," *Sci. Rep.*, vol. 8, no. 1, pp. 1–11, 2018, doi: 10.1038/s41598-018-26602-2

¹¹² C. H. Hubscher *et al.*, "Improvements in bladder, bowel and sexual outcomes following task-specific locomotor training in human spinal cord injury," *PLoS ONE*, vol. 13, no. 1, pp. 1–26, 2018, doi: 10.1371/journal.pone.0190998.

¹¹³ A. Esquenazi, M. Talaty, A. Packel, and M. Saulino, "The Rewalk powered exoskeleton to restore ambulatory function to individuals with thoracic-level motor-complete spinal cord injury," *Am. J. Phys. Med. Rehabil.*, vol. 91, no. 11, pp. 911–921, 2012, doi: 10.1097/PHM.0b013e318269d9a3.

¹¹⁴ A. J. Kozlowski, T. N. Bryce, and M. P. Dijkers, "Time and effort required by persons with spinal cord injury to learn to use a powered exoskeleton for assisted walking," *Top. Spinal Cord Inj. Rehabil.*, vol. 21, no. 2, pp. 110–121, 2015, doi: 10.1310/sci2102-110.



A. Overview of spinal anatomy. **B.** Zoom of stimulation in conus region and reactivation of spinal motor circuits. **C.** Schematic overview explaining the physiology and therapy reactivation principle. EES: Epidural Electrical Stimulation.

Although an SCI interrupts most or all descending inputs from supraspinal centers in the brain, the neural circuits located below the lesion site are still intact but remain in a hypoactive state due to the lack of excitatory and modulatory inputs from the brain and brainstem. The therapy objective is to support recovery of voluntary motor control and neurological controls below the level of the lesion.

Using an implanted electrode array located over the dorsal aspect of the lumbosacral spinal cord, EES can reactivate the neural circuits located below the electrodes. Lead implantation is similar to that used for SCS for chronic pain.¹¹⁵

EES recruits large-diameter afferent fibers at their entry into the spinal cord from the posterior roots (see the figure above, under C).¹¹⁶ These fibers primarily innervate proprioceptive organs. Consequently, their depolarization with electrical currents leads to the activation of proprioceptive feedback circuits. This reactivates hypoactive spinal circuits and increases the functional impact of anatomically intact yet functionally silent or poorly active descending pathways below the lesion. This engagement during rehabilitation training will trigger neural circuit reorganization – also known as neuroplasticity – both at supraspinal and spinal levels. This neuroplasticity which happens after weeks/months of training, promotes functional recovery in the absence of stimulation,¹¹⁷ but will be significantly enhanced when supported by EES. In order to modulate motor functions in a more efficient manner, ARC[™] was developed based on the understanding of the physiological mechanisms underlying the therapeutic effect of EES.

The key concept of the therapy is the activation of the dorsal roots with spatiotemporal EES stimulation protocols. The delivery of the stimulation needs to be targeted to precise spatial locations according to the functional anatomy of the patient's spinal cord and the timing of these pulses should not be continuous but temporally synchronous with the intended motor command of the patient.

Organization of Acute SCI care

Immediately after an SCI, patients are admitted to a trauma center in order to be surgically stabilized. On average ten days later, patients are transferred to an SCI rehabilitation center for primary rehabilitation. In this rehabilitation center they will undergo in-patient rehabilitation (duration: three to six months depending on severity and functional goals). During this in-patient rehabilitation they receive (not limited to) medical, psychological and social care, occupational therapy and physiotherapy. Usually a patient's daily program consists of short timeslots (30-60 minutes) of different rehabilitation activities. Depending on the country, patients can continue rehabilitation in an out-patient setting after discharge (frequency: two to three days/week for as long as deemed appropriate).

¹¹⁵ Bedder & Bedder, 2009.

¹¹⁶ Moraud et al., 2016.

¹¹⁷ Asboth et al., 2018; Van Den Brand et al., 2012

Recently, the EMSCI network documented the relative content of physiotherapy interventions in patients with acute/subacute SCI. The main components of physiotherapy are strength training and locomotor/mobility training, for approximately 28% (\pm 20%) and 15% (\pm 18%) of the total physiotherapy time respectively. Patients undergo 2.1 (\pm 0.7) sessions of physical therapy per day, with a median duration of 45 (\pm 30) minutes. Whereas training sessions are initially provided in individual settings, over time patients integrate more group training sessions.

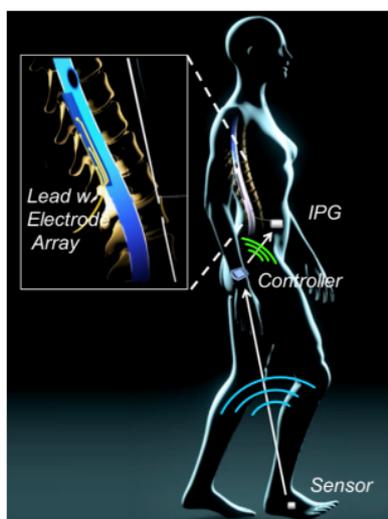
The aim of the rehabilitation training is to support the spontaneous recovery after SCI. Indeed, spinal cord damage opens a time-restricted temporal window during which the potential for neuroplasticity is enhanced. The vast majority of neurological recovery occurs during the first three months, but to a smaller degree can continue for up to 18 months or longer. Currently, there is no intervention that effectively augments the spontaneously occurring neurological recovery.

Epidural Electrical Stimulation

The therapy consists of delivering time-related electrical stimulation protocols that are synchronized with the person's activities during intensive rehabilitation training when the subject actively engages in certain motor tasks such as standing, walking, balancing, climbing a staircase, or other motor tasks involving the legs.

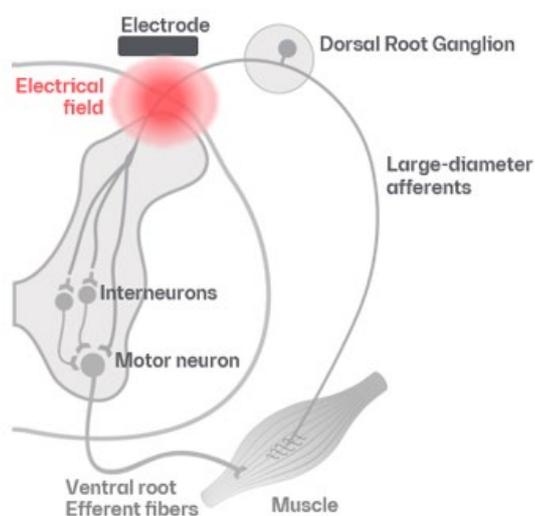
To engage motoneurons at the appropriate time, trains of spatially selective electrical pulses are delivered with a temporal sequence that matches the natural flow of proprioceptive information and/or coincides with the intended motor command from the brain.

ARCTM stimulation protocols are delivered using an implantable neurostimulation system, consisting of an IPG and an electrode array (lead) placed over the dura on the posterior aspect of the lumbosacral region of the spinal cord after which stimulation timing is synchronized with activity information from movement sensors on the feet or shank.



Schematic representation of ARCTM therapy, an implantable neurostimulation system (INS) with real-time motion feedback

Stimulation recruits well-defined neuronal circuits in the spinal cord



1 Maroufi et al., *neuron* 2016 | 2 Formento et al., *nature neuroscience* 2018 | 3 Wenger et al. *nature medicine* 2016, Capogrosso et al., *Nature* 2016

ARCTM Mobility Detailed Mechanism of Action

Epidural Electrical Stimulation

An electrode array is placed over the dorsal aspect of the spinal cord to deliver electrical currents.

The electrical current does not penetrate the spinal cord but flows on the side where it recruits the neural structures with the least resistance to current: large-diameter afferent fibers located in the dorsal roots¹.

Large-diameter afferent fibers (dorsal roots) carry information about the length of muscles. Their recruitment leads to the activation of neuronal circuits associated with the muscle that they innervate^{1,2}.

Consequently, targeting an individual dorsal root enables the modulation of specific muscles.

The recruitment of specific dorsal roots (spatial selectivity) with a temporal structure that coincides with the intended movement reproduce the natural activation of muscles².

This mechanism of action enables the configuration of spatiotemporal stimulation programs to support any activities, including standing, walking, biking, swimming, etc.

This approach, unlike the more commonly used FES in which muscle fibers are directly stimulated, engages motor circuits through the sensory pathways that are naturally engaged in motor control.¹¹⁸ This paradigm does not lead to muscle exhaustion, which is one of the key limitations of FES.

This stimulation, based on replicating native neurophysiologic signalling also stands in contrast to other empirical (non-modulated) stimulation approaches such as continuous EES. ARCTM is significantly more effective than continuous stimulation to facilitate movement as it provides a biomimetic stimulation that reinstates the natural dynamic of spinal circuit activation: stimulation is delivered at the correct location and appropriate moment in the movement cycle.¹¹⁹ Moreover, continuous stimulation disrupts proprioception, which limits the relevance of this stimulation paradigm for the facilitation of dynamic movements.¹²⁰

These spatiotemporal stimulation protocols strongly enhance the amplitude and potency of leg movements compared to those of continuous stimulation. In rodent and non-human primate models of leg paralysis it was shown to enable sustained weight-bearing activity.¹²¹ This concept directly translates into a therapy for humans with SCI that was evaluated in humans in the STIMO study described below.

ARCTM therapy induced the following effects improving leg motor function:

- Immediate prosthetic function through a facilitation of the intended leg movement via "immediate" motor control of the legs. Spatiotemporal EES directly improves the quality and quantity of active leg movements and allows patients to sustain training for extended periods.
- Improvement of motor functions and physical independence linked to the activity-dependent neuroplasticity in the long-term.

ARCTM Therapy can either be performed in closed-loop, by triggering the stimulation using real-time motion feedback from external motion sensors or by teaching the patient to initiate the intended motor

¹¹⁸ Hofstoetter et al., 2015; Danner et al., 2015; Karen Minassian, Hofstoetter, Dzeladini, Guertin, & Ijspeert, 2017.

¹¹⁹ Courtine et al., 2009.

¹²⁰ Formento et al., 2018.

¹²¹ Capogrosso et al., 2013; Wenger et al., 2016.

command in synchrony with a pre-programmed stimulation pattern configured for the intended motor task (open-loop).

Intended Treatment Population

ARC^{IM} Therapy for mobility is intended for supporting recovery of leg motor functions and neurological controls through the use of ARC^{IM} Therapy in adults with SCI who have a lesion both higher than vertebrae and spinal cord neurological levels T10 with preserved conus medullaris containing the circuits involved in the control of leg muscles. The lead is positioned over this region. Previous studies have applied ARC^{IM} Therapy to people with SCI or spinal cord compression, neither related to oncological causes nor to a neurodegenerative disease. In the future, the Company expects to explore use of ARC^{IM} Therapy to facilitate mobility or prevent freezing of gait in people with neurodegenerative disorders.

Potential Improvement in Mobility

ARC^{IM} Therapy for mobility has been shown in the STIMO study¹²² to restore standing, improve walking quality as well as result in increased endurance and higher activity during locomotor training. In the STIMO study, the first results of three participants, see table below, with cervical lesion have been published in Wagner et al., (Nature, 2018) while analyses for the following participants are still on-going. Enrollment is now complete and publications detailing the results for the remaining participants are expected in the next 12 months.

One of the important results observed post-rehabilitation for the three patients is a significant improvement in leg motor score (LMS, part of ASIA evaluation protocol), as well as an increase in isometric joint torque production even in the absence of ARC^{IM} Therapy. Such an increase in LMS after therapy in patients with chronic SCI has not been reported until now. This result demonstrates the ability of ARC^{IM} Therapy to mediate an important neuroplasticity of spared circuits and residual connections.

	Leg Motor Score		6 Min Walk Test (m)		Isometric Joint Torque Left leg (Nm)		Isometric Joint Torque Right Leg (Nm)	
	Pre-Implant	Post-Rehab	Pre-Implant	Post-Rehab EES	Pre-Implant	Post-Rehab	Pre-Implant	Post-Rehab
P1	16	30	64	150	0	3	8	16
P2	25	36	13	60	30	48	27	44
P3	2	4	0	0	2	4	2	5

Each of the study participants who completed the main study showed significant improvement in their walking parameters and also in their ASIA Score. The two most recent, and also most severe patients, both with motor complete injury (AIS-A) did not show any residual motor function at study enrollment. Therefore, all three functionalities of gait (swing, weight acceptance and propulsion) needed to be fully re-enabled by the stimulation, which was established in both participants within 2 weeks after the start of the ARC^{IM} Therapy configuration. After intensive training, but prior to the end of the five-month rehabilitation training, both participants were able to walk with only the support of a walker and/or a physiotherapist.

In conclusion, both hypothesized effects of ARC^{IM} Therapy have been observed in this pilot study:

- Immediate effects through the neuroprosthetic support (improvement in walking quality including high activity and increased endurance)
- Long-term effects through neuronal remodeling and neuroplasticity (e.g. improved muscle force, voluntary control against gravity without stimulation).

¹²² ClinicalTrials.gov Identifier: NCT02936453.

Overall, these results demonstrate the feasibility and success in translating the therapy, which combines spatiotemporal ARC^{IM} Therapy with body weight support overground rehabilitation, in humans.

Potential Improvements for Secondary Health Conditions

The aim of ARC^{IM} Therapy for mobility is to support recovery of leg motor function and neurological controls that will positively impact quality of life. Spatiotemporal ARC^{IM} Therapy for mobility would first support improved capacity for physical activity which in turn positively impacts cardiovascular metabolism and leads to better patient outcomes. Improving capacity for physical activity induced by ARC^{IM} Therapy could lead to a reduction in pain, and spasticity. Moreover, ARC^{IM} Therapy for mobility has the potential to influence and ameliorate symptoms of autonomic dysfunctions by promoting the reorganization of neural circuits regulating those functions. Improvements of autonomic functions have the potential to increase patients' quality of life and to reduce associated healthcare costs.

Similar therapies in the field of SCI rehabilitation have shown that neuroplasticity induced by stimulation can improve, for example, bladder function, in turn leading to reduced medication use for bladder control.¹²³ Some positive outcomes have also been reported to prevent or alleviate SCI-related secondary health conditions such as a reduced probability of pressure ulcer formation and improved bowel function.¹²⁴

Though neuroplasticity has been observed for mobility and movement related indications, long-term restoration of function in the absence of stimulation may not be achievable for all autonomic functions such as bladder control.

A variety of secondary health conditions improvements was observed in the STIMO participants. These yet unpublished improvements were observed for cardiovascular function, thermoregulation, bladder and bowel function, sexual function, sleep, spasticity and pain. As more scientific data becomes available, specific stimulation programs may be developed to promote recovery of specific autonomic functions.

ARC^{IM} Clinical and Regulatory Matters

The Company is preparing to conduct future clinical trials to seek regulatory approval to market its ARC^{IM} platform in the US and Europe. The Company believes ARC^{IM} is a Class III device that will require PMA approval in order to be lawfully marketed in the United States, but the Company may pursue approval to legally market at least one indication via HDE.

In the next five years, the Company expects to seek regulatory approval to use ARC^{IM} 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^{IM}. Those are discussed in the "*Research and Development*" section.

Mobility / Walking

The Company was founded in 2014 to commercialize technology that would restore the ability to walk in people with SCI. The STImulation Movement Overground ("**STIMO**") study (ClinicalTrials.gov identifier: NCT 02936453), conducted by CHUV with the Company as a research partner, showed that the ability to walk could be restored in people with clinically incomplete SCI. Later, the study was modified to also include subjects with clinically complete injury. This study enrolled chronically-injured subjects with a wide range of injury classifications (AIS A-D, most severe to least severe) and with injuries suffered as long as 14 years prior to enrollment.

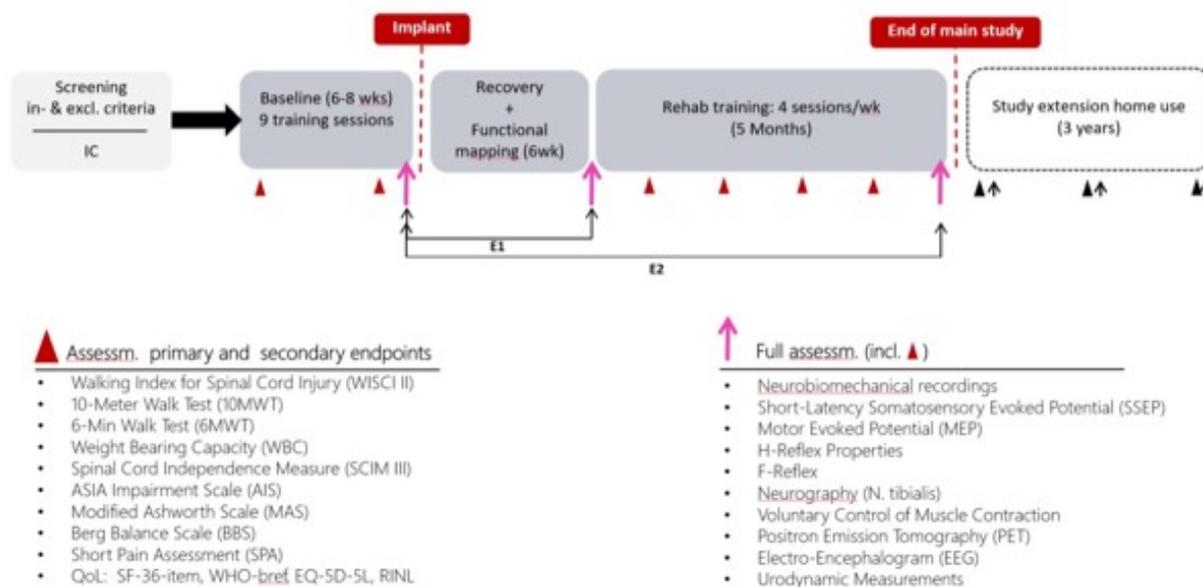
¹²³ Herrity et al., 2018; Hubscher et al., 2018.

¹²⁴ Esquenazi, Talaty, Packel, & Saulino, 2012; Kozlowski, Bryce, & Dijkers, 2015.

STIMO was a single center, non-randomized interventional trial, conducted at CHUV, enrolling a total of ten paraplegic adults with a chronic (>12 months post injury) clinically complete or incomplete SCI injury with a neurological severity classification going from AIS-A to D. Eligible candidates had a focal lesion at the level of T11 or above, due to trauma or bleeding, and a stable medical condition. The first patient was enrolled in July 2016, and the main study ended in March 2021. In addition, patients were given the option to continue the use of the neuromodulation system at home, during an optional follow-up study of two times three years (see the figure below for overall flowchart of the study phases and endpoints measurements). Eight participants opted to continue the use of the neuromodulation system at home.

The Company was a research partner to the project and as such it had access to the clinical data (see section 4.3.2) but was not the sponsor. Also, in three patients, the Company's clinical epidural lead (called Go-2 lead) was implanted.

The primary objective of the study was to demonstrate the safety and feasibility of the ARC Therapy. The secondary objectives were to investigate the immediate effects of the stimulation (as a neuroprosthetic effect), as well as the long-term training effects (neuroplasticity). For a full list of study endpoints and measures, see the figure below.



Spatiotemporal targeted electrical spinal cord stimulation was delivered using a combination of market approved devices that were used off label, or fully investigational devices (mainly software and an implantable epidural lead). For the implantable epidural lead, either a Medtronic Specify® 5-6-5 paddle lead (FDA approved for the indication of "chronic pain") or an ONWARD lead, previously called "Go-2 Lead" (investigational device) were placed epidurally over the lumbar spinal cord. The lead was connected to a Medtronic Activa RC implantable pulse generator (FDA approved for the indication 'Deep Brain Stimulation') with adapted firmware that allows real-time triggering. Specific events in the gait cycle during walking (e.g. leg swing phase, weight bearing, and propulsion) were derived from motion sensors on the patient's feet, and were linked wirelessly to the pulse generator that activated the required stimulation protocols to stimulate the correct spinal roots at the correct time during the gait cycle, thereby using short trains of stimuli with defined intensities and frequencies.¹²⁵ A commercially available Body Weight Support (BWS) system provided multidirectional body-weight assistance within a large and safe rehabilitation environment.¹²⁶

When the patient progressed in his rehabilitation and gained sufficient muscle strength, BWS could be limited to a walker or crutches. The investigational system also supported physical activity outside

¹²⁵ Wenger et al., 2016, 2014.

¹²⁶ Mignardot et al., 2017; Vallery et al., 2013.

the rehabilitation center. It allowed control of the stimulator (selection of stimulation sequences, switching stimulation on and off) using a tablet that could be combined with a voice-controlled smartwatch. This included stimulation for specific activities such as walking or cycling which could be used on a daily basis by the subjects using the therapy at home or in out-patient rehabilitation.

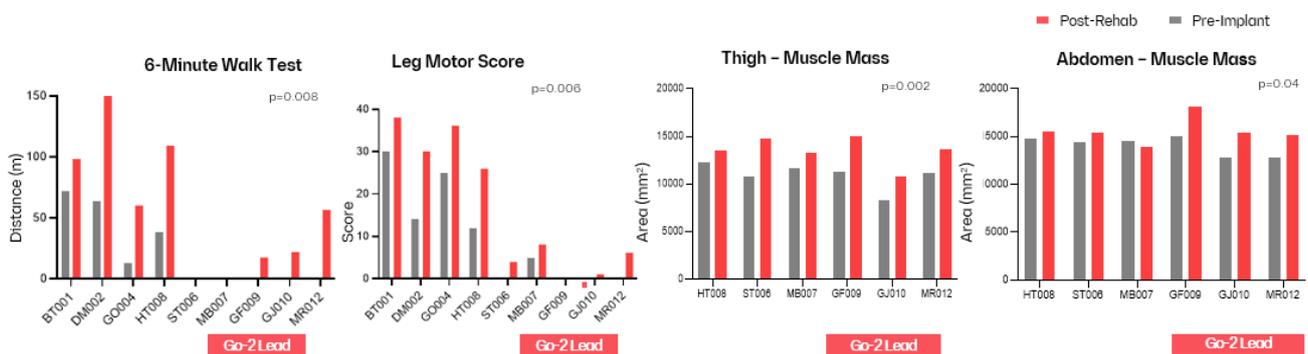
This investigational system allowed the performance of locomotion that would be impossible otherwise for this category of patients, i.e. independent overground walking under partial body weight support, and more importantly, promoted the active volitional engagement of the patients during each step throughout the rehabilitation training, resulting in durable neuroplasticity.

The study, which enrolled ten subjects, demonstrated statistically significant improvement in 6-Minute Walk Test, Leg Motor Score, Thigh Muscle Mass, and Abdominal Muscle Mass, an unprecedented result.

	6 Minutes Walk Test		Leg Motor Score		Thigh Muscle Mass		Abs Muscle Mass	
	Pre-Implant (Meters)	Post-Rehab Stim (Meters)	Pre-Implant	Post-Rehab	Pre-Implant (mm ²)	Post-Rehab (mm ²)	Pre-implant (mm ²)	Post-Rehab (mm ²)
BT001	72	98	30	38	n.a.	n.a.	n.a.	n.a.
DM002	64	150	14	30	n.a.	n.a.	n.a.	n.a.
GO004	13	60	25	36	n.a.	n.a.	n.a.	n.a.
HT008	38	109	12	26	12276	13536	14790	15583
ST006	0	0	0	4	10835	14777	14427	15369
MB007	0	0	5	8	11653	13262	14577	13941
GF009	0	17	0	0	11238	14956	15008	18130
GJ010	0	22	0	1	8279	10742	12856	15356
MR012	0	56	0	6	11212	13619	12813	15120

Clinical proof of concept, showing statistically significant improvement in movement and muscle mass

STIMO Study Results for Mobility



Breakthrough: STIMO demonstrated for the first time that people with complete SCI could walk again¹

ST006, MB007, GF009, GJ010, MR012 could not walk at all prior to their implants

GF009, GJ010 and MR012, all motor complete injuries, all walked post-rehab

The group with some pre-existing function responded strongly

STIMO study has been conducted by NeuroRestore with implants performed at Centre Hospitalier Universitaire Vaudois (CHUV) in collaboration with researchers from the Swiss Federal Institute of Technology (EPFL), both in Lausanne, Switzerland.



Sources: 1Wagner et al. Nature 2018; unpublished STIMO Data - Competitive academic studies claiming locomotion but not showing clinically relevant data.

In collaboration with the Company's research partners, the Company next plans to study the impact of spinal cord stimulation on injured subjects in the Sub-Acute phase (1 to 6 months post-injury) in a study called STIMO 2. These sub-acute subjects are likely to have endured less loss of muscle mass and overall fitness and may respond even more robustly.

Depending on their severity of injury, subjects can sometimes stand and walk soon after surgery, but others require several months of rehabilitation to regain the required muscle mass, strength, and overall coordination. Because a significant commitment to rehabilitation is required by the subject to restore the walking function, enrollment in a large-scale clinical trial may be prolonged and commercial uptake may be measured. For these reasons, the Company intends to commercialize other indications before walking. The Company's intent is to postpone significant clinical or commercialization efforts until 2022 at the earliest, at which time the Company would support the Company's research partners in conducting STIMO 2. Thereafter, the Company expects to commence a study to obtain evidence required to gain approval to market ARC^{IM} for the walking indication in the United States via HDE and in Europe.

Current plan is to seek FDA approval via Humanitarian Device Exemption (HDE)

Mobility Regulatory Pathway

2020	2021	2022	2023	2024	2025	
STIMO			STIMO-2	IDE	F/U	HDE
n=10 Single Center - Switzerland Chronic SCI patients Initiated by NeuroRestore			n=20 Multicenter - Germany, Netherlands, Switzerland Sub-acute SCI patients Initiated by NeuroRestore	n=25 Multicenter - US & EU Chronic vs. Acute TBD		FDA CE

HDE as an initial step, followed by later PMA

IDE = Investigational Device Exemption
F/U = Follow-up

The Company believes an HDE is the fastest and most effective way to offer this important therapy to people with SCI who would like to restore their ability to walk. Later, the Company expects to pursue approval to market this indication via a traditional PMA pathway. The timing for a PMA approval is not presently defined, but it is likely to follow the HDE by 12-24 months.

Blood Pressure and Trunk Control

The initial planned commercial indication for ARC^{IM} is restoration of normal blood pressure and enhanced trunk control in people with SCI. Successful preclinical studies were performed on over 100 rodents and non-human primates by the Company's research partners at EPFL. In June 2021 the STIMO HEMO study sponsored by CHUV was initiated with the first patient enrollment with the intent to gain experience and glean clinical insights prior to beginning a planned pivotal trial for this indication in the US and Europe.

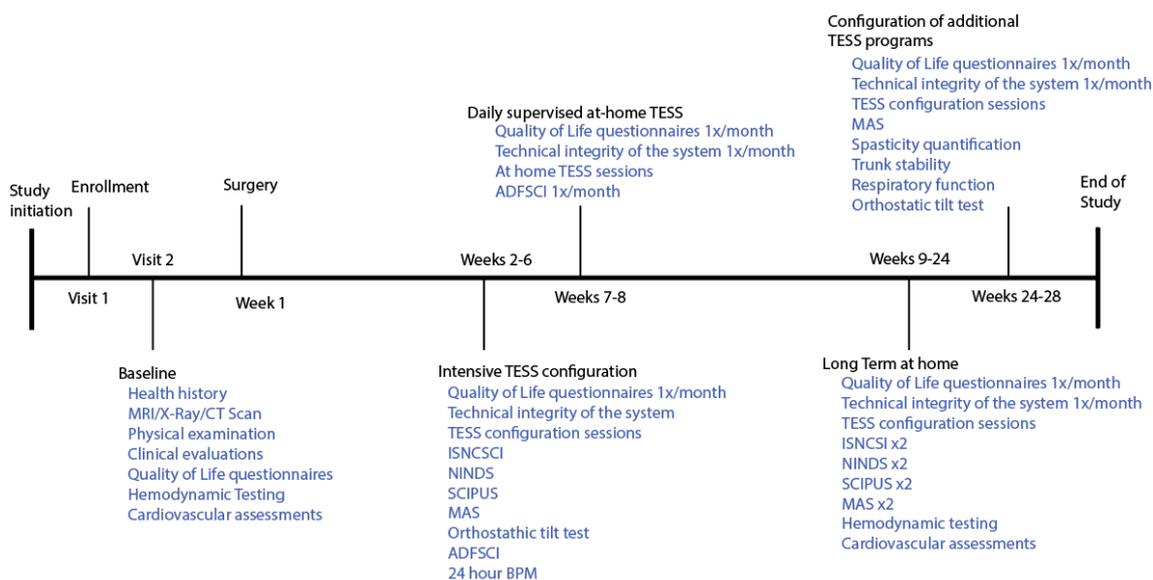
STIMO HEMO study – Clinical Proof of Concept

The STIMO HEMO feasibility study will implant 8 patients with chronic (>12 months) SCI located between C3 and T6 who have confirmed severe orthostatic hypotension and autonomic dysreflexia. In this study, the Company proposes to stimulate the circuits in the spinal cord that are directly responsible for the regulation of blood pressure and trunk stability in patients with chronic SCI located between C3 and T6 and who suffer from severe orthostatic hypotension and autonomic dysreflexia.

Enrolled patients will be implanted with the investigational system by a neurosurgeon experienced in epidural implants for chronic pain, which require a similar surgical technique. This feasibility study is monocentric, single arm, non-blinded, non-randomized and will take place at the CHUV.

A total of 8 participants will be implanted with commercially available systems used off-label. Patients will then proceed to one month of an intensive device configuration protocol to configure the epidural spinal cord stimulation (eSCS) settings of their investigational device to regain hemodynamic stability. After the intensive device configuration phase, daily supervised at-home hemodynamic stimulation will be tested for 5 sessions per week for two weeks. Thereafter, during the long-term at-home hemodynamic stimulation phase (until the end of the study - 6 months), patients will have a minimum of 5 stimulation supported at-home sessions per week and one laboratory visit per month. During the laboratory visits, several clinical evaluations will be assessed to evaluate the patient's cardiovascular and neurological status and quality of life.

Finally, patients will have to undergo additional testing during configuration of additional stimulation programs. During this phase stimulation configurations for hemodynamic stability, respiratory function, trunk stability and spasticity will be tested.



The primary outcome of this study is the safety and feasibility of the therapy and will report on the occurrence of Adverse Events and Serious Adverse Events that are deemed related or possibly related to the study procedure or the study investigational system. The secondary outcome will report on the efficacy measure and will quantify the immediate ability of the stimulation to manage blood pressure instability during orthostatic challenges. Exploratory outcomes will also focus on the following:

- Potential changes in cardiac, cerebrovascular and systemic vascular health and function using echocardiography, vascular ultrasound and ECG.
- Evaluation of the at-home hemodynamic stimulation sessions and better characterization of the use of the investigational system using a Daily Stimulation Log filled out by the patient
- Immediate and long-term effect of the at-home hemodynamic stimulation on incidence and severity of orthostatic hypotension and autonomic dysreflexia assessed by laboratory evaluations, urodynamics assessments, orthostatic challenge, beat-by-beat blood pressure monitoring, ECG, 14-hr ABPM (Ambulatory Blood Pressure Monitoring) and ADFSCI (Autonomic dysreflexia following spinal cord injury) questionnaire.
- Effect of the stimulation on trunk control using a spasticity questionnaire, the Modified Ashworth Scale assessment as well as measurements using electrophysiology, and kinematic sensors.
- Potential effect of the stimulation on the respiratory function using a spirometry assessment.
- Effect of the stimulation on renin-angiotensin-aldosterone system (RAAS) and on markers of its activity using blood samples.
- Quality of life. Patients will fill-out monthly questionnaires specifically designed to evaluate quality of life and other questionnaires focusing on other specific aspects and functions that SCI might affect (sexual, bladder and bowel functions, mental health, spasticity, autonomic functions, pain, sleep).

HemON Study – First-in-Human

The HemON study is a First-in-Human study sponsored by EPFL and will be the first time the ARC^{IM} technology is used in a trial. The aim of the study is to provide therapy for blood and trunk stabilization in patients with sub-acute to chronic SCI. Eight participants will be enrolled in the study and implanted with the ARC^{IM} device to assess the feasibility and preliminary safety of ARC^{IM} Therapy.

This feasibility study is single-center, prospective, single arm, non-blinded, non-randomized and will take place at the CHUV (Lausanne, Switzerland). A total of 8 participants will be implanted with ARC^{IM} Investigational System.

The study duration is 24 months per participant. The enrollment period is estimated to last 8 months (enrollment of 1 participant per month) and the total study duration is expected to be 32 months. It is expected first patient enrollment will occur in late 2021.

The primary outcome of this study is the safety measure and will report on the occurrence of Adverse Events and Serious Adverse Events that are deemed related or possibly related to the study procedure or to the ARC^{IM} Investigational System. The secondary outcomes will focus on both clinical impact and technical impact. The secondary outcomes with technical impact will cover the following topics:

- Evaluation of the home-use of ARC^{IM} Investigation System assessed via weekly questionnaires and a stimulation usage log.
- Evaluation of the robustness of ARC^{IM} Investigational System using the occurrence of Device Deficiencies, and the automatic logs recorded by the devices.
- Evaluation of the usability and clinical procedures of the ARC^{IM} investigational System by the different users assessed by questionnaires
- Evaluation of ARC^{IM} Investigational System requirements and specifications assessed with lead design tests, biomimetic stimulation tests, and ramping tests of the ARC^{IM} IPG during optimization sessions.

The secondary outcomes with clinical impact will focus on the following:

- Preliminary efficacy of ARC^{IM} Therapy at supporting management of hemodynamic instability assessed during an orthostatic head-up tilt test, via continuous blood pressure monitoring and the MART (Mapping of Rehab Training) form
- Effect of ARC^{IM} Therapy on trunk control and mobility assessed with the Wheelchair Performance test, the Trunk Control Test (Quinzaños 2014), trunk stability measurements and CT scans.
- Effect of ARC^{IM} Therapy on spasticity and muscle tone via the use of questionnaires and the Modified Ashworth Scale (MAS)
- Effect of ARC^{IM} Therapy on daily life performance assessed with the SCIM III score (Spinal Cord Independence Measure) and with the Canadian Occupational Performance Measure (COPM).
- Respiratory functions will be evaluated using spirometry assessment and cough test
- Autonomic dysreflexia will be evaluated with urodynamic assessment
- Pressure sores prevention, will be evaluated with sitting assessment, occurrence of adverse events related to pressure sores, specific participant recorded outcomes measures and CT scans
- Participant's quality of life and other questionnaires focusing on other specific aspects and functions that SCI might affect (bladder, bowel and sexual functions, mental health, sleep) assessed with weekly and monthly questionnaires, and via semi-structured interviews

Feasibility – Pivotal study

The study leading to market approval in US and EU will be a combined feasibility-pivotal design during which the Company expects to implant 90 patients with sub-acute to chronic SCI located between C3 and T6 who have confirmed severe orthostatic hypotension. This pivotal study will be multicentric, multinational (EU and US), single arm, non-blinded and non-randomized. This study will occur in US and Europe and will involve 12-15 sites.

The purpose of this pivotal study is to evaluate the safety and effectiveness of electrical spinal stimulation administered by the implantable ARC^{IM} system for stabilizing blood pressure to avoid SCI-associated hemodynamic instability and control of trunk stability to improve SCI patients' posture in adults with SCI. During this study, prospective data on quality of life and autonomic function improvements will be captured as secondary and/or observational endpoints.

The objectives of this study are multiple:

- Safety: Provide confirmatory evidence that use of the ARC^{IM} Thoracic device, inclusive of all components and accessories, is safe.
- Effectiveness: Provide confirmatory evidence that use of the ARC^{IM} Thoracic device provides an effective treatment for the stabilization of Blood Pressure in patient suffering from SCI and control of the trunk stability.
- Observational: Provide data regarding the potential benefits of the ARC^{IM} Thoracic device to achieve other secondary outcomes such as improvement in Quality of Life (QoL) tone normalization, respiratory functions and other autonomic functions (Bowel & bladder management, sexual function).

The Company has not yet met with the FDA regarding this study design so it is possible these objectives may change.

Multicenter pivotal trial planned for 2023

Blood Pressure & Trunk Regulatory Pathway

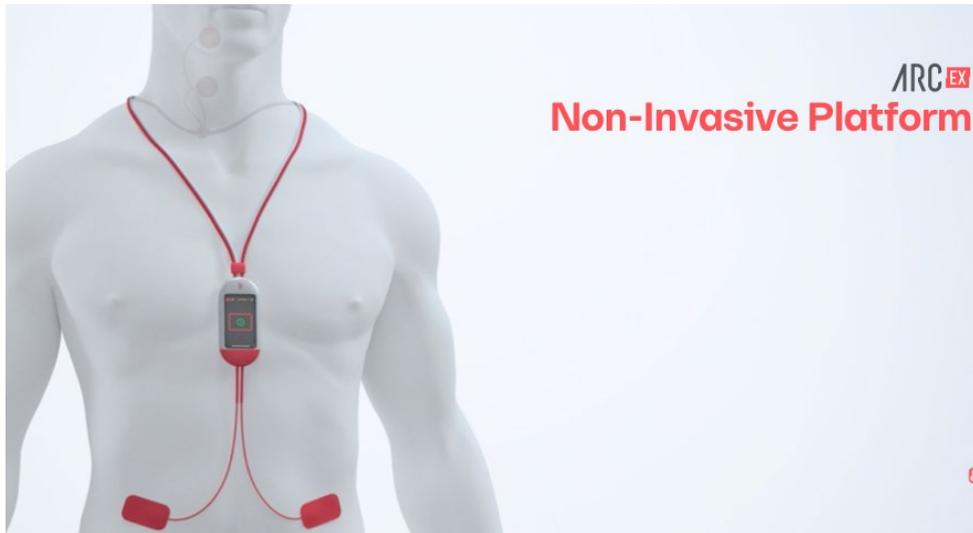
The Road to FDA Approval and CE Mark

2021	2022	2023	2024
cPoC STIMO HEMO		Feasibility	Pivotal
n=8	FiH HemON - Early Feasibility	n=15	n=75-100
Lausanne and Calgary	n=8	5 sites in EU+US First multicenter study with ONWARD technology	15 sites in EU+US Large multicenter prospective
	Lausanne FiH for ONWARD IPG & apps	ONWARD Complete tech, incl. lead	
			F/U Closing / Report / PMA
			FDA CE

cPoC = Clinical Proof of Concept
 FiH = First in Human
 Feos = Feasibility
 F/U = Follow-up

Note we expect the STIMO-HEMO study to continue into 2022, concurrent with the conduct of the HeMon study.

The ARC^{EX} Platform



The ARC^{EX} platform is external, consisting of a small stimulator that connects to adhesive leads that are placed on the skin near the area of the spinal cord responsible for the movement or function targeted for restoration. The stimulator can be programmed and/or controlled by a tablet or smartwatch.

Transcutaneous Spinal Cord Stimulation (tSCS) - Mechanism of Action

ARC^{EX} Components & Mechanism of Action

Components

ARC^{EX} platform consists of small stimulator that connects to adhesive leads placed on skin near spinal cord area responsible for the movement or function targeted for restoration

Stimulator can be programmed and/or controlled by tablet or smartwatch



Smart Phone/Watch



Electrodes & Leads



Programmer



Stimulator

Mechanism of Action

External stimulation is applied using a proprietary frequency modulated waveform:

- o High frequency component enables painless flow of current
- o Lower frequency signal designed to activate the spinal neural circuits

Therapy

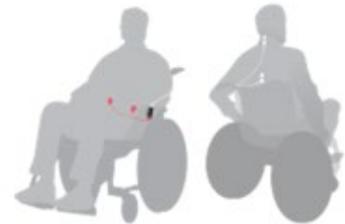
ARC^{EX} platform is designed to restore function in conjunction with rehabilitation.

Intended to be used periodically during 20-30 minute sessions delivered in the clinic or home

Initial planned indication for ARC^{EX} is improvement or restoration of upper extremity (hand and arm) strength and function

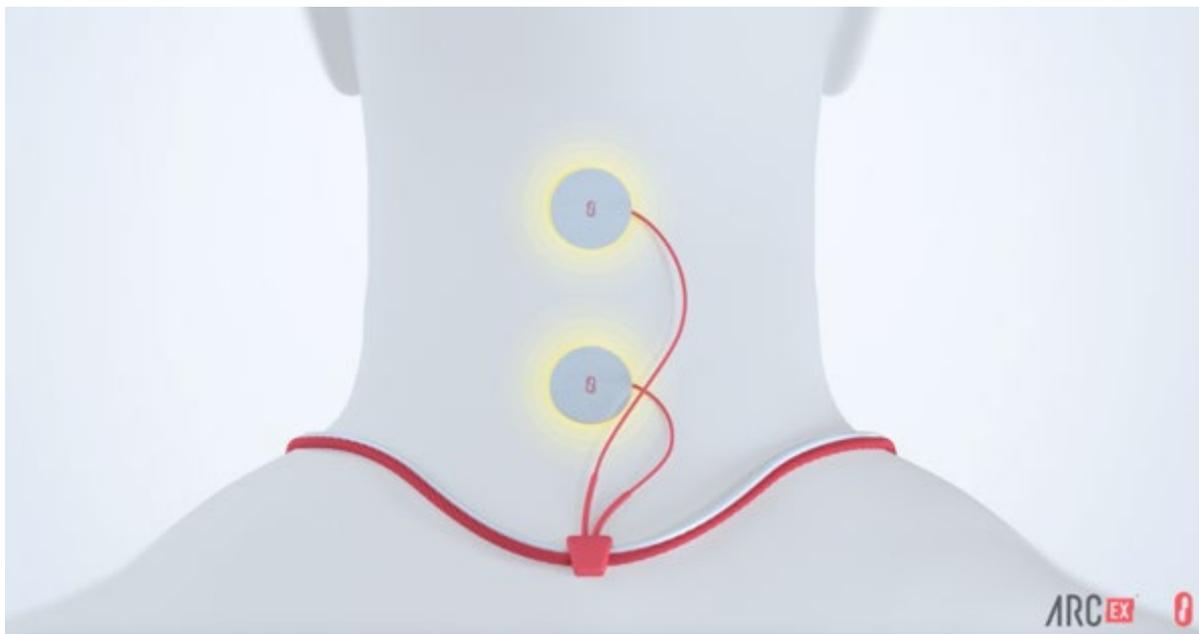
Highly synergistic with ARC^M platform; offers leading rehab clinics opportunity to directly observe benefits of ARC therapy

Some underlying therapy, some FDA reviewers, some customers, some ONWARD clinical organization and salesforce



ARC^{EX} consists of a stimulator that is connected directly to leads that are placed on the skin. The stimulator contains Hub functionality as described in the ARC^M section above, though since the ARC^{EX} system is wired, the wireless capabilities are not embodied.

External stimulation is applied using a proprietary frequency modulated waveform. The high frequency component enables painless flow of current, while the lower frequency signal is designed to activate the spinal neural circuits.



The ARC^{EX} platform is designed to restore function in conjunction with rehabilitation. It is intended to be used periodically during 20-30 minute sessions delivered in the clinic or home.

The initial planned indication for ARC^{EX} is improvement or restoration of upper extremity (hand and arm) strength and function when delivered in the clinic. Current standard-of-care is functional task

practice ("FTP"), which is repetitive practice of functional tasks, such as placing balls into a bucket. In fact, in January 2021 the Company commenced a pivotal trial with the intent to gain regulatory clearances and approvals for this indication in the US and Europe, expected in 2023.

ARC^{EX} Clinical and Regulatory

The Company believes non-invasive electrical spinal cord stimulation may be used in conjunction with conventional rehabilitation therapy in patients with SCI to improve the recovery of physiological function following injury. ARC^{EX} is designed to help people experiencing paralysis due to injury to help regain mobility, independence, and an improved quality of life. ARC^{EX} is a transcutaneous spinal cord stimulator that is externally connected to the patient using body surface electrodes. Stimulation pulses are provided to the patient to reactivate damaged and dormant neural circuits through neuromodulation of the spinal cord. The patients are able to relearn patterns of activation associated with pre-injury function. ARC^{EX} is designed to be used at home, in the hospital and in rehabilitation therapy clinics.

Beginning in May 2017, a series of physician-sponsored, small-scale clinical trials were undertaken using the LIFT System (predecessor to ARC^{EX}, then referred to as the NeuroEnabling Stimulator System). ARC^{EX} and LIFT deliver the same current, but ARC^{EX} will offer improvements in user interface, usability, industrial design, and programmability. The clinical data derived from these feasibility studies suggest that the device has a favorable tolerability profile and the potential to provide significant clinical benefit to patients with SCI.

Early feasibility studies showed promising results across multiple indications

52 subjects
8 studies
ASIA class A-D
Ages 18-66 years
Cervical and thoracic injuries
1-23 years post injury

Activity-based training combined with ARC^{EX} therapy for an average of 2 months

Meaningful gains in voluntary control of the lower and upper extremities, trunk control, cardiovascular function, thermoregulation, independent standing, activities of daily living, and quality of life

Pilot Studies

Best practices emerged which informed design of the Up-LIFT pivotal clinical study

Observations

- No device-related serious adverse events and no unanticipated adverse device effects were reported
- Every subject demonstrated improved performance in one or more of the outcome measures tested
- New functional gains were noted such as the ability to pick up, hold and use objects or perform new tasks

Overview of Clinical Pilot Studies with LIFT

Beginning in May of 2017, a series of investigator-sponsored, small-scale clinical studies using ARC^{EX} Therapy with a clinical version of the device called LIFT were undertaken, some of which have resumed post-Covid. Eight (8) studies were conducted at the following seven sites:

1. Strides SCI Functional Fitness (San Juan Capistrano, CA, USA)
2. Rancho Los Amigos National Rehabilitation Center (Downey, CA, USA)
3. University of Washington (Seattle, WA, USA)
4. Queen Elizabeth Spinal Unit (Glasgow, Scotland, UK)
5. Neurokinex Rehab Centers (London, England, UK)
6. Craig Hospital (Englewood, CO, USA)
7. Kessler Rehabilitation Center (West Orange, NJ, USA)

Under IRB approval and after patient informed consent, a total of 52 subjects in eight studies were enrolled, as of 1 May, 2021. Subjects with total or partial loss of motor and/or sensory function due to spinal cord injury participated in these studies. To a varying degree, each study enrolled patients with different sites of injury ranging in classification and age from AIS-A to AIS-D and 18-66, respectively. Subjects were 1-23 years post-injury. Each subject was subjected to a type of activity-based training along with ARC^{EX} therapy for an average of two months.

Clinically meaningful gains in motor and sensory function were assessed using a combination of metrics derived from established neurological and physical medicine and rehabilitation practices. Gains include recovery or improvement in voluntary control of the lower and upper extremities, hand, trunk control, cardiovascular function, thermoregulation, independent standing, activities of daily living ("ADL"), and quality of life. Over the course of these studies, a set of best practices have emerged which formed the basis of the ongoing pivotal clinical study.

The following table lists all clinical studies performed to date using the LIFT System (as summarized in the table below with LIFT Feasibility Studies) arranged chronologically by start date. These studies were single-arm feasibility studies of subjects with spinal cord injury ranging in classification from AIS-A through D, in which proof of concept, preliminary safety and effectiveness of ARC^{EX} in treating spinal cord injury were evaluated in various protocols.

Date	No. of Subjects	Study Site	Injury Site	Area of Focus
May 2017	13	Strides	C3-C7, C4-T11	Restoring Hand Function, Standing, Stepping
Aug 2017	7	University Washington	C3-C5	Restoring Hand Function
Oct 2017	7	Rancho Los Amigos	T11 and above	Restoring bladder Function
March 2018	4	University Washington	C3-C7	Locomotion and Autonomic Function
June 2018	4	Queen Elizabeth	C2-C6	Determining Safety and Efficacy
July 2018	2	Neurokinex	C4	Determining Safety and Efficacy
Nov 2019	6	Neurokinex	T5-T12	Restoring Hand Function, Standing, Stepping
July 2018	7	Craig	C5-C6	Restoring Hand Function NRS with Neurorecovery Network Protocol
July 2018	2	Kessler	C5-C8	Restoring Hand-Function, Standing, Stepping
Total	52	7	C2-C8, T5-T12	

Upper Extremity Studies

Four of these feasibility studies included 20 patients who followed a treatment protocol focused on upper extremities that is similar to what has been implemented in the pivotal study. Although there were differences in the study protocols, the data from this subset are generally homogenous with outcomes that are suggestive of the results expected from Up-LIFT. The aim of these studies was three-fold: 1) test run a study design that will be used as a basis for the pivotal study; 2) identify the optimum endpoints to target; and 3) investigate the effectiveness of ARC^{EX} therapy to improve hand and arm function in individuals with significant deficit due to chronic cervical SCI.

After a period of baseline assessment, the upper extremity studies followed a sequential design of alternating blocks of intervention. For example, one month of functional training alone was followed by one month of training plus ARC^{EX} therapy; typically, 3 sessions per week for 1-2 hours per session. In some cases, patients received continued therapy in a randomization scheme over an additional period of time. Functional testing at prescribed intervals was used to assess treatment effects and safety including some or all of the following assessments: International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI), pinch and grip force measurements using force transducers, Graded Redefined Assessment of Strength Sensation and Prehension (GRASSP), Capabilities of Upper Extremity – Question/Test (CUE-Q/T), Spinal Cord Independent Measure (SCIM III), Neurogenic Bowel Questionnaire, Neurogenic Bladder Symptom Score, Patient Health Questionnaires (PHQ-9), and SF-Qualiveen Instrument.

The demographics of those enrolled in the upper extremity pilot studies were 80% male, age 34.4 ± 14.1 yr, post-chronic non-progressive cervical injury 5.0 ± 5.3 yr, classified as AIS-A to AIS-D (see the table below).

Study ID	N	% Male	Age in Yr. (Range)	AIS	Injury Level	Time Since Injury (Yr.)	Duration of Study (Mo.)
1	5	100	34.8 (25-61)	B (1), C (4)	C3-C7	7.8 (1.5-23)	2
2	7	71	40.6 (28-62)	B (3), C (2), D (2)	C3-C5	4.3 (1.5-12)	4
7	7	71	27.0 (18-55)	A (2), B (2), C (2), D (1)	C5-C6	1.9 (1-4)	1-4
8	1	100	39.0	A (1)	C5	15.0	12
Total	20	80	34.4 (18-62)	A (3), B (6), C (8), D (3)	C3-C7	5.0 (1-23)	3.3 (1-12)

Demographics of upper extremity SCI subjects enrolled in the LIFT System feasibility studies

Prior Clinical Studies Conclusions

The pilot studies demonstrated performance gains in every individual enrolled with improvement in one or more of the various outcome measures that were tested. In addition, new functional gains were also noted such as the ability to pick up and hold objects, manage the use of an object like a utensil, or perform a new task. Adverse events (AEs) were recorded throughout the studies and reported to the responsible IRB committees. There were no reported serious adverse events (SAEs) related to the use of the device and no unanticipated adverse device effects (UADEs).

The clinical data derived from the feasibility evaluations of 20 subjects using the LIFT System for restoration of hand/arm function described above suggests that the LIFT System has the potential to provide significant clinical benefit to patients with cervical SCI. Clinically meaningful improvement in functional performance and quality of life after training with ARC^{EX} therapy were noted in every study. These studies have provided important insight regarding best practices for delivering therapy with the LIFT System.

Additionally, the results show that the combination of the LIFT System with activity-based training can lead to sustained long-term improvement in function years after the injury. The presence of no device-related serious adverse events after several hundred hours of stimulation over an average of over three months suggests a positive safety profile for the device.

Up-LIFT FDA Pivotal Trial

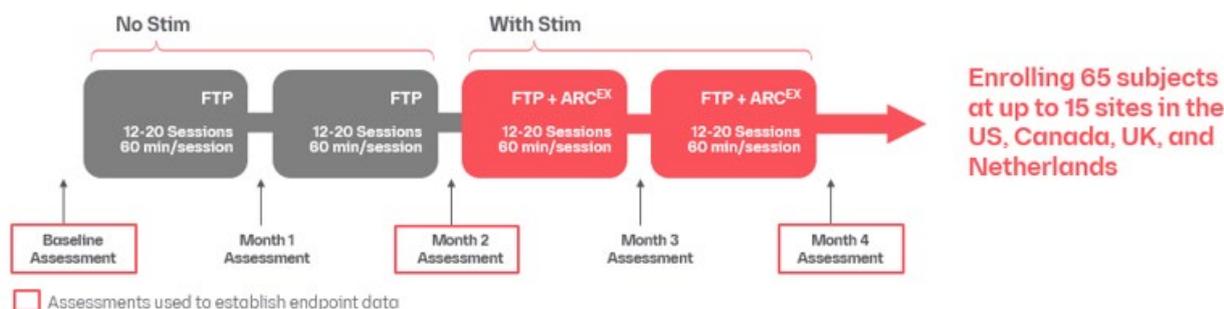
Based on the results of these studies, the Company commenced a pivotal study for this technology. The Company is currently conducting Up-LIFT, a study intended to support submissions for regulatory clearances and approvals to market and offer the ARC^{EX} platform for commercial sale in the US and Europe. In the US, the Company expects to first pursue de novo classification for ARC^{EX} for use in

the clinic. After obtaining authorization to market the device for use in the clinic, the Company expects to pursue 510(k) clearance for ARC^{EX} for use in the home. Authorization to market ARC^{EX} in Europe will be pursued via the newly implemented MDR regulation with TÜV-SÜD as Notified Body.

The Up-LIFT Study is a prospective, single-arm study designed to evaluate the safety and effectiveness of non-invasive electrical spinal cord stimulation (ARC Therapy) administered by a clinical version of ARC^{EX} to treat upper extremity functional deficits in people with chronic tetraplegia.

Two months of training followed by two months of ARC^{EX} stimulation

UP LIFT
FDA Pivotal Trial



The first large-scale trial of non-invasive spinal cord stimulation technology

Initial Indication: Improvement in upper extremity strength and function

Commenced January 2021, expected to complete enrollment this year

Primary Endpoint: Clinically relevant improvement in at least one strength and one function measure



FTP = Functional Task Practice

Details for the Up-LIFT study can be found on ClinicalTrials.gov, under identifier NCT04697472. The Company expects to enroll up to 65 subjects at up to 15 sites in the US, Canada, the UK, and the Netherlands. Study Principal Investigators are Edelle Field-Fote, PT, PhD of the Shepherd Center, Atlanta, GA, USA, and Chet Moritz, PT, PhD of University of Washington, USA.

To ensure that the benefits realized in the study are directly attributable to the ARC Therapy, all enrolled subjects first undergo a guided, in-clinic conventional functional task practice (FTP) program lasting approximately two months to regain their upper extremity (UE) function. Performance gains realized during this wash-in period provide a subject specific control that reflects the limits of conventional functional task practice without stimulation (standard of care). At the conclusion of the wash-in period, subjects complete pre-stimulation testing of UE function.

To test the additive benefit of training with stimulation, combined functional task practice and ARC Therapy will then be administered over a period of approximately two months using a clinical version of the ARC^{EX} device, currently called LIFT. Functional task practice will follow established rehabilitation protocols that are specific to the individual subject's specific needs and capabilities.¹²⁷ Training will be graded to accommodate performance improvement over time, thus maximizing the potential benefit to subjects. Subjects will participate in up to 20 in-clinic training sessions per month. At the end of the two-month training period the improvement in UE function will be measured and used to assess the progress of primary study endpoints.

All performance metrics will be assessed at enrollment, at the completion of the wash-in period and at the end of the ARC Therapy assessment period. Subjects with clinically meaningful gains in multiple performance domains resulting from use of ARC Therapy will be considered responders. Additionally, gains during the wash-in (control) period will be compared to gains during the ARC Therapy (test)

¹²⁷ Beekhuizen & Field-Fote, Functional Task Practice versus Functional Task Practice with Stimulation: Effects on Upper Extremity Function and Cortical Plasticity in Individuals with Incomplete Cervical Spinal Cord Injury, 2005

period. Safety will be evaluated throughout the entire study through periodic monitoring and analysis of all reported adverse events.

Key Inclusion Criteria:

Subjects must meet all the following criteria:

1. At least 22 years old and no older than 75 years old at the time of enrollment
2. Non-progressive cervical spinal cord injury from C2 to C8 inclusive.
3. American Spinal Injury Association (ASIA) Impairment Scale (AIS) classification B, C, or D.
4. Indicated for upper extremity training procedures by subject's treating physician or a physical therapist.
5. Minimum 12 months post-injury.
6. Capable of providing informed consent.

Key Exclusion Criteria:

Subjects must not meet any of the following criteria:

1. Has uncontrolled cardiopulmonary disease or cardiac symptoms as determined by the Investigator.
2. Has any unstable or significant medical condition that is likely to interfere with study procedures or likely to confound study endpoint evaluations like severe neuropathic pain, depression, mood disorders or other cognitive disorders.
3. Has been diagnosed with autonomic dysreflexia that is severe, unstable, and uncontrolled.
4. Requires ventilator support.
5. Has an autoimmune etiology of spinal cord dysfunction/injury.
6. Spasms that limit the ability of the subjects to participate in the study training as determined by the Investigator.
7. Breakdown in skin area that will come into contact with electrodes.
8. Has any active implanted medical device.
9. Pregnant, planning to become pregnant or currently breastfeeding.
10. Concurrent participation in another drug or device trial that may interfere with this study.
11. In the opinion of the investigators, the study is not safe or appropriate for the participant.



Primary Endpoints

Primary

Efficacy

Subjects with clinically meaningful gains* in multiple performance domains resulting from the ARC Therapy with LIFT will be considered responders:



Safety

Incidence of all procedure and device related serious adverse events

*Minimal important difference (MID) based on Cohen's Effect Size and validated against Global Impression of Change (GIC); Cohen, J. (1988). Statistical Power Analysis for the Behavioral Sciences. New York: Lawrence Erlbaum Associates.



Secondary Endpoints

Hierarchical testing (in order of importance):

Superiority of FTP* + ARCEX therapy compared to FTP alone (responder rates)

Superiority of FTP + ARCEX therapy compared to FTP alone (quantitative comparison):

- Pinch force
- GRASSP-Prehension
- GRASSP-Strength
- ISNCSCI-UEMS
- ISNCSCI-Total sensory score
- EQ-5D-5L
- SCIM
- WHOQOL-BREF

Observational – numerous descriptive statistics on assessments impacting quality of life and long-term consequences of SCI (e.g., pain, spasticity, sleep, bladder/bowel & sexual function)

*Functional Task Practice

Rationale for the Selection of Study Endpoints

The choice of study endpoints for this pivotal study was guided by multiple factors:

1. Safety.
2. Relevance to upper extremity function.
3. Capture improvements in both strength and function.
4. Magnitude of changes that are clinically meaningful.

To align on specific outcome variables, the recommendations for SCI common data elements (CDE) proposed by National Institute of Neurological Disorders and Stroke (NINDS) were reviewed. The SCI CDE Working Group is supported by the NINDS CDE Team. This group recommended standardized, validated instruments for SCI research. The International Spinal Cord Society (ISCoS) and the

American Spinal Injury Association (ASIA) have since collaborated to incorporate the International SCI data sets into the NINDS CDEs. Next, the findings from stakeholder groups like North American Spinal Cord Injury Consortium (NASCI), Praxis Spinal Cord Institute and Neurotech Network were reviewed to identify the priorities of those suffering from the condition. Lastly, discussions with thought leaders in SCI research were also solicited. Based on these inputs, it was determined that a single composite primary endpoint that includes ISNCSCI, GRASSP, CUE-T, pinch and grasp strengths would be ideal to capture hand/arm improvements in both strength and function dimensions. To get a complete picture of the improvements with ARC Therapy, additional measures that reflect functional recovery, quality of life, and autonomic function will be captured as secondary and observational endpoints as reported in the following sections.

Study Outcomes Measures

1. International Standard Neurological Classification of Spinal Cord Injury (ISNCSCI)

The International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) or more commonly referred to as the ASIA Impairment Scale (AIS), was developed by the American Spinal Injury Association (ASIA) as a universal classification tool for Spinal Cord Injury based on a standardized sensory and motor assessment, with the most recent revised edition published in 2019. The impairment scale involves both a motor and sensory examination to determine the sensory and motor levels for the right and left side, the overall neurological level of the injury and completeness of the injury.

ISNCSCI motor and sensory scores are derived from four sub-scores: upper and lower extremities and left and right sides. Upper extremity and lower extremity motor scores (UEMS, LEMS) are derived from grading five muscles each in the upper and lower extremities on a scale of 0 (total paralysis) to 5 (normal active movement, full range of motion against gravity and sufficient resistance). Sensory scores are derived similarly for upper and lower extremities by grading pin prick and light touch sensation on a scale of 0 (absent) to 2 (normal or intact).

Scoring and range: Motor score: 0-100, sensory score (light touch and pinprick: 0-112 each)

2. Graded Refined Assessment of Strength, Sensibility and Prehension (GRASSP)

The GRASSP is a clinical impairment measure specific to the upper limb for use after tetraplegia. It is a multimodal test that measures sensorimotor and prehension function in three domains important in describing arm and hand function (strength, sensibility and prehension) comprising five subtests for each upper limb: strength, dorsal sensation, palmar sensation, prehension ability and prehension performance. These numerical scores provide a comprehensive profile of upper-limb function.

GRASSP Strength (strength) - assessed by testing for muscle contraction and range of motion with or without gravity and graded as 0 (no palpable muscle contraction) to 5 (full range of motion against gravity with maximum resistance).

GRASSP Sensibility (dorsal sensation and palmar sensation) - tested using Semmes-Weinstein 4 monofilament probes. The pressure applied and sensation elicited was represented by numeric values ranging from 0 (no response) to 4 (normal sensation).

GRASSP Prehension (prehension ability and performance) - divided into ability vs. performance. This domain represents the influence of sensation and strength on goal-oriented upper limb tasks like cylindrical grasp and lateral pinch along with six timed tasks.

Scoring: sensation (dorsal and palmar, 0-12 each), strength (Ten muscles per upper limb graded from 0-5 for a total 50 for each upper limb), prehension: ability (12) and performance (30)

3. Pinch and Grasp Force

Pinch and grasp force will be measured by the Commander Echo Console with the Pinch and Hand Dynamometer (JTech Medical, Salt Lake City, UT) to quantify finger and grasp strength.

Scoring: Up to 222N

4. *Capabilities of Upper Extremity Test (CUE-T)*

CUE-T is an assessment tool that measures functional limitation and assesses the amount of difficulty experienced in performing specific actions with one or both arms and hands in individuals with tetraplegia. Questions focus on the individuals' ability to reach or lift; pull and push with their arms; move and position their arm and wrist; use their hand and fingers; and press with the tip of the index finger.

Scoring and range: 1 – Totally limited, cannot do it at all to 7 – Not at all limited; 32 – 224

Recall period: Instantaneous

5. *Numerical Rating Scale for Pain*

An anchored 0 to 10 rating for pain where "0" represents no pain and 10 represents worst pain imaginable. The recall period can be adjusted based on how the question is phrased (e.g. in the last seven days, rate your average pain on a scale of 0 to 10). The score usually represents the average pain experienced by the subject in the recall period.

6. *International Spinal Cord Injury Pain Data Set (ISCIPDS)*

To standardize collection and reporting of pain in SCI, ISCIPDS was developed by an international consortium of pain and SCI experts. It collects pain interference with day-to-day activities, mood, and sleep over a seven-day recall period.

Scoring: Interference: 0 (no interference) to 10 (extreme interference)

7. *Medical Outcomes Study (MOS) Sleep Score*

This is a sleep scale developed for the Medical Outcomes Study (MOS), a two-year study of subjects with chronic conditions. MOS-Sleep contains ten self-rated questions on sleep duration, sleep disturbance, adequacy, and somnolence.

Scoring and range: 1 (all of the time) – 6 (none of the time); 1 – 60 points

8. *Spinal Cord Independence Measure (SCIM III)*

The SCIM has been developed to address three specific areas of function in subjects with spinal cord injuries (SCI): Self-care (feeding, grooming, bathing, and dressing), respiration and sphincter management, and mobility (bed and transfers and indoors/outdoors).

Domains: Self-care, respiration and sphincter management, mobility

Scoring: self-care: 20, respiration, and sphincter management: 40, mobility: 40

Range: 0 to 100

Anchor: 0 – total dependence, 100 – complete independence

9. *Penn Spasm Frequency Scale (PSFS)*

A two-component, self-reported measure of frequency and severity of spasms after spinal cord injury.

Scoring: Frequency (0 to 4), severity (1 to 3)

Anchor: Frequency (0 - No spasms to 4 - Spontaneous spasms occurring more than ten times per hour), severity (1 - Mild to 3 - Severe)

10. *5-Dimension, 5-Level European Quality of Life (EQ-5D-5L)*

EQ-5D instrument comprises a short descriptive system questionnaire to assess the health state of an individual. Each state is represented by a five-digit number ranging from 0 through 4 (e.g. 42311), where each number represents an individual domain. The number is then translated into an index score. The questionnaire also has a visual analogue scale (EQ VAS) to capture the health state.

Scoring and range: VAS: 0 (Worst health imaginable) – 100 (best health imaginable); EQ-5D-5L Index: 0.000 – 1.000

11. World Health Organization Quality of Life Measure (WHOQOL-BREF)

WHOQOL-BREF contains 26 questions in four domains with 24 of them assigned to the facets/areas relevant to quality of life. Two questions address overall quality of life and general health.

Scoring and range: Transformed scores (4 to 20 or 0 to 100)

12. International Standards to document remaining Autonomic Function after Spinal Cord Injury (ISAFSCI)

A semi-quantitative questionnaire on autonomic control including heart function, blood pressure, sweating, temperature regulation, broncho pulmonary system, bladder and bowel management and sexual function.

Scoring: Normal/abnormal (heart function, blood pressure, sweating, temperature regulation, broncho pulmonary system); 0 – Complete loss of control through 2 – Normal function (bladder and bowel management, sexual function)

13. 9-Item Patient Health Questionnaire

A nine-item, self-reported measure of depression.

Scoring and range: 0 (Not at all) – 3 (Nearly every day); 0-27

14. Patient/Clinician Global Impression of Change (PGIC/CGIC)

Global impression of change (GIC) is a nine-point Likert scale used to assess treatment-induced changes in a subject's clinical status (improvement or decline). The GIC will provide a general indication of changes related to activity limitations, symptoms, emotions, and overall quality of life. The questionnaire is completed both by the study subjects (Patient GIC) and the physicians (Clinician GIC) and may be used to validate the relative clinical benefit of treatment as quantified by other outcome measures used in the study.

Anchor: Very much improved, much improved, moderately improved, minimally improved, no change, minimally worse, moderately worse, much worse, very much worse.

Target Indication

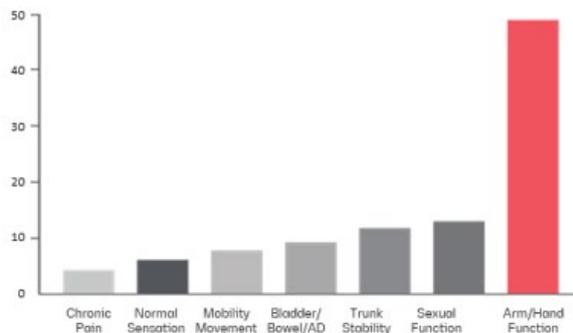
The Company has selected upper extremity deficit as its initial target indication in response to data showing this is the highest priority function SCI patients want restored:

Why select upper limbs as our initial indication?

Patients Prioritize Upper Extremity Function

Highest Priority for Individuals with Cervical Injury

Percent Response



~50% of participants indicated regaining arm and hand function would most improve their quality of life

ARC

Source: Candy Tefertiller, PT, DPT, PhD, NCS, Executive Director of Research, Craig Hospital, presented at Unite2Fight Paralysis Conference, 2020. Adapted from Anderson (2004). Targeting Recovery: Priorities of the Spinal Cord-Injured Population. J Neurotrauma. 21(10): 1371-83.

The following centers are expected to enroll subjects in the Up-LIFT study. The Company is authorized to add up to two additional sites in the US, Canada, UK, or Europe should that be necessary to reach enrollment objectives.

Enrollment on schedule for 2021 completion

Research Collaborators

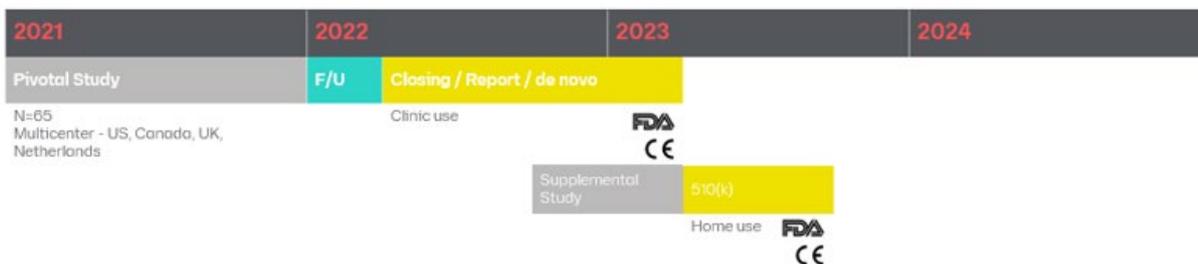
Site	Location	Investigator	Status
Shepherd Center	Shepherd Atlanta, GA	Field-Fote	Enrolling
U Washington	Seattle, WA	Moritz	Enrolling
CRAIG	Craig Denver, CO	Tefertiller	Enrolling
U Minnesota	Minneapolis, MN	Morse	Enrolling
SPAULDING. ADAPTIVE SPORTS CENTERS	Spaulding Cambridge, MA	Trumbower	Enrolling
Mayo	Rochester, MN	Zhao	Enrolling
VA	Bronx VA New York, NY	Murray	Enrolling

Site	Location	Investigator	Status
THE MIAMI PROJECT TO CURE PARALYSIS	Miami, FL	TBD	Pending
Jefferson	Thomas Jefferson Philadelphia, PA	Marino	Enrolling
MHRA	Queen Elizabeth Glasgow, SC	Purcell	Enrolling
Toronto Rehab	Toronto Rehab Toronto, CA	Kalsi-Ryan	Enrolling
UBC	ICORD Vancouver, CA	Krassioukov	Enrolling
ccmo	St. Maartenskliniek Nijmegen, NL	Van Ness	Enrolling

The Up-LIFT study commenced 8 January 2021 and is expected to complete enrollment during or before the first quarter of 2022. Should the study continue to proceed according to expectation, the Company expects the first regulatory clearance and approval sometime in early 2023 for use in the clinic and subsequent regulatory clearance and approval in late 2023 or early 2024 for use in the home. Similar dates are expected for market authorization in Europe. The Company has not yet consulted with the FDA about requirements for its home use study. We expect Up-LIFT Study results to be published in early 2023.

Multicenter pivotal trial already underway

ARC^{EX} Upper Limb Regulatory Pathway



de novo clearance for Clinic use:

- no predicate device
- non-significant risk determination by FDA (Feb 2021)
- no IDE required
- expected class II

510(k) clearance for Home use:

- de novo device becomes predicate
- must show comparable safety and efficacy profile
- modest data requirements
- minor modifications via letter to file

F/U = Follow-up

Platform Synergies

ARC^{IM} and ARC^{EX} share common hardware and software components, including stimulator electronics, voice activated smartwatch, programmer, and remote manager.

One technology platform with shared components provides opportunity to target multiple indications

Our Solution



- Targeted, programmed stimulation of the spinal cord to restore movement, independence, and health in people with spinal cord injury
- Implantable and external platforms leverage common components (circuits, processors, sensors, code, UI elements and testing assets) for efficiency
- Software adapts easily to address several indications
- OTS cloud solutions support big data and connected health

The Company expects to develop both platforms using the same R&D organization, to conduct clinical trials using the same clinical organization, and to market both platforms to the same SCI specialty rehabilitation clinics using the same sales and service organization.

Manufacturing and Supplier Relations

The Company's products have been developed in collaboration with and will be manufactured by third-parties with deep and longstanding experience in medical device manufacturing. These suppliers have been selected based on their expertise and longevity in the industry, as well as their experience

working with active implantables and other highly regulated devices. Outsourcing manufacturing activities reduces capital investment and operational expense for the Company.

These suppliers have undergone a rigorous selection process during which their capabilities were vetted by the Company's R&D, Quality, and Regulatory Affairs teams. The expertise underlying the Company's products is maintained within the Company. Suppliers are monitored regularly for their ability to meet demand, respond to design and process changes, and support investigations of production and testing issues. Products are inspected for quality and are tested to assure they meet specification, are properly packaged and sterilized, and are ready for use.

Key suppliers are subject to detailed supplier agreements that protect the Company's interests and assure products and components comply with medical device standards and are products according to rigorous specifications. In some cases, the Company's most critical suppliers are single-source. Given the Company's expected volumes and the level of collaboration required, it is not expected the Company will add second sources for some of these products and components. The Company will therefore seek to reduce risk by maintaining sufficient inventory and through regular supplier audits.

The Company's most critical suppliers are as follows:

- For the ARC^{IM} IPG 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 its IPG, including the header. This supplier is specialized in the manufacturing of IPGs and has a positive industry reputation.
- For the ARC^{IM} IPG development the Company entered into development, manufacturing and supply agreement on February 13, 2019 with a Swiss-headquartered supplier for the printed circuit board assembly ("**PCBA**"). This supplier is specialized in the manufacturing of PCBA's and has a positive industry reputation.
- 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 Oscor Inc. to develop and supply a range of different lead-paddles for the specific use indications mentioned earlier in this document.
- For the functional testing of the ARC^{IM} system the Company entered into a development, manufacturing and supply agreement on 1 March 2019 with a US-headquartered supplier to develop and manufacture specialized functional test systems to perform design verification testing.
- For the ARC^{IM} Patient 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 patient controller.
- For the ARC^{EX} platform the Company has entered into a specified statement of work with a US-headquartered supplier. This relationship is a result of the acquisition of NRT for whom the supplier developed the first version of the ARC^{EX} device. Since that contract ended, the Company is now requesting specific work packages from the supplier for updates to the existing device and supply of devices for use in the pivotal trial.
- For the Up-LIFT pivotal trial the Company entered into a master clinical services agreement on 30 July 2020 with a US-headquartered contract research organization to support the Company in the study management, monitoring, data management and reporting of the study.

More details on these suppliers and associated agreements can be found in "*Material Contracts*".

Research and Development

As of September 2021, the Company had 36.2 full-time equivalents employees on the Company's R&D-team. The team serves under the leadership of John Murphy, who has led similar Neuromodulation development projects at Abbott Laboratories, and LivaNova PLC. The team is

divided into subgroups focused on hardware, software, firmware, therapy development, and program management, each under leaders with relevant experience in engineering and/or medical technology.

The Company's R&D staff are currently located in Eindhoven, the Netherlands, Lausanne, Switzerland, and Florida, USA. The Company develops technologies and therapies internally and in collaboration with partners who bring required expertise in critical areas.

Current R&D priorities include completion of the Company's ARC[™] platform, completion of an updated version of ARC^{EX} in preparation for its submissions for regulatory clearances and approvals and subsequent planned commercial launch in 2023, and associated software, hardware, and patient management platforms.

The Company's primary R&D strategies are as follows:

- Development of purpose-built, proprietary systems.
- Creation of a robust pipeline via close collaboration with leading academic researchers.
- Leverage of shared components and approaches across technology platforms.

Three major components of R&D strategy drive efficiencies and sustainable advantage

R&D Strategy

Development of purpose-built, proprietary systems

Unlike many neuromodulation companies, **we have developed our own IPG and family of leads** for ARC[™]

Our **technologies are purpose-built** for our indications

We have the **flexibility to adapt our technology to planned and future indications** without dependence on larger firms

Creation of a robust pipeline via close collaboration with leading researchers

Our primary research partner is NeuroRestore in Lausanne, Switzerland; **much of their work is supported by non-dilutive funding**

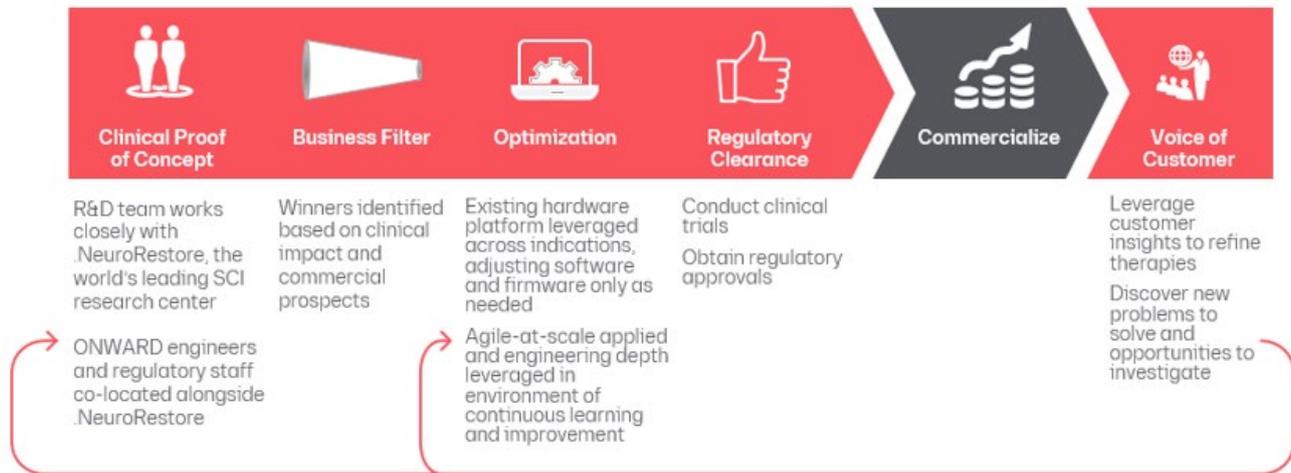
They have **extensive capabilities across the continuum of research activities**

We have developed a new **research platform to facilitate new insights and drive collaboration** with researchers across the globe

Leverage of shared components and approaches across technology platforms

Our technology platform can be **leveraged across applications and can be used to pursue multiple indications**, using shared development resources, staff, etc.





The Company is developing its own proprietary IPG, driven by the unique set of requirements necessarily to deliver therapies for people with spinal cord injury. In order to restore and optimize mobility and other autonomic functions, it is necessary to provide real-time adjustments of stimulation parameters in response to physiologic and motion sensors. For example, to restore mobility or walking, rapid adjustments are required. Human perception is variable, but generally perception of moving stimulus occurs eight to ten times per second or every 100 milliseconds. In order to create fluid motion, update intervals as brief as 50 milliseconds may be necessary, driving the following capabilities for ARC^{IM}:

- Collection of sensor data over a known time interval from multiple body-worn locations.
- Transmission of data from sensors to the system controller.
- Calculation of therapy adjustments in response to inputs.
- Transmission of adjustments to the stimulator.
- Application of new therapy parameters.
- Capable of abdominal implantation.

To enable these capabilities, ARC^{IM} incorporates a high speed, ultra-low power data link as well as higher processing capability than devices currently marketing spinal cord stimulation systems for pain management or IPGs being offered by contract design and manufacturing suppliers. Indeed, the Company is not aware of any currently marketed neuromodulation systems that offer this suite of capabilities.

Several neuromodulation devices offer some sort of closed-loop functionality, stimulating the spinal cord for pain management, providing deep brain stimulation for Parkinson's disease, or vagus nerve stimulation for epilepsy, but their data collection is performed over a far longer time period and the nature of the indications they target allow them to adjust output over seconds or even minutes rather than the milliseconds required for the Company's indications.

Saluda Medical and Medtronic offer systems that sense neural response to stimulation therapy, adjusting output amplitude briskly but these adjustments are made in response to IPG-based sensing circuits or an IMU; their algorithms are threshold based and easily calculated. Output adjustments are also made to accommodate for differences in electrode-spinal column spacing due to postural

changes, not to physiological parameters such as blood pressure or body worn motion sensors such as those used as part of the ARC^{IM} system.

The Company is only aware of one currently marketed system capable of closed-loop operation using a physiologic parameter - Inspire Medical's sleep apnea device, which incorporates an implanted sensor that connects directly to the IPG and is placed in the chest wall to detect inspiration. The stimulator uses this signal to apply hypoglossal nerve stimulation to clear the airway during inspiration. While similar in concept, Inspire's timing is slower than that of ARC^{IM} and the ARC^{IM} system demands cannot be met by Inspire or similar current technology.

To improve usability for wheelchair-bound SCI patients, the IPG is ideally placed in the abdomen. Generally, the abdomen has thicker fat layer, leading to deeper implant depth which can fluctuate and indeed increase over time with weight gain. ARC^{IM} features a rechargeable IPG to both meet stimulation output demands and support an inductive link to transfer power to the IPG for recharging. These two requirements require that recharging be effective at distance of up to 3cm. ARC^{IM} is designed to provide a charging zone of 3cm which translates to nearly 5cm of maximum separation, outperforming all other known neurostimulation platforms.

Closed-loop is essential for SCI indications to harvest sensor data and optimize stimulation parameters;^{1,2} leads and recharging are also important

Optimal Lead Designs

- Paddle leads longer and larger to cover spinal cord anatomy responsible for controlling targeted functions
- Electrodes located as laterally as possible on the lead

High Speed Wireless Communication

- High volumes of information
- Very low latency and low power consumption
- Allows for near real-time adjustments

Advanced Recharging

- Capable of recharging from a distance, 2-3x further
- Improves patient convenience
- Extends availability of the therapy to obese patients

Platform Advantages, Including Closed-Loop

Commercially available SCS paddle leads designed for pain and not optimized for SCI indications

Current pain devices employ Bluetooth or lack wireless communications capabilities altogether

Some current pain devices are non-rechargeable or consume power at high rates while delivering stimulation

Large IP portfolio, longstanding and exclusive IP licenses with leading academic institutions, and deep scientific understanding of spinal cord stimulation for SCI indications provide advantage

1 C. E. Bouton and C. J. Czura, Sensing and Decoding Neural Signals for Closed-Loop Neuromodulation and Advanced Diagnostics in Chronic Disease and Injury, Second Edn. Elsevier Ltd, 2018. doi:10.1016/b978-0-12-805303-8.00031-5.
2 J. W. Squire et al., "Neuroprosthetic baroreflex controls haemodynamics after spinal cord injury," Nature, pp. 1-7, Jan. 2021, doi:10.1038/s41586-020-02180-w.

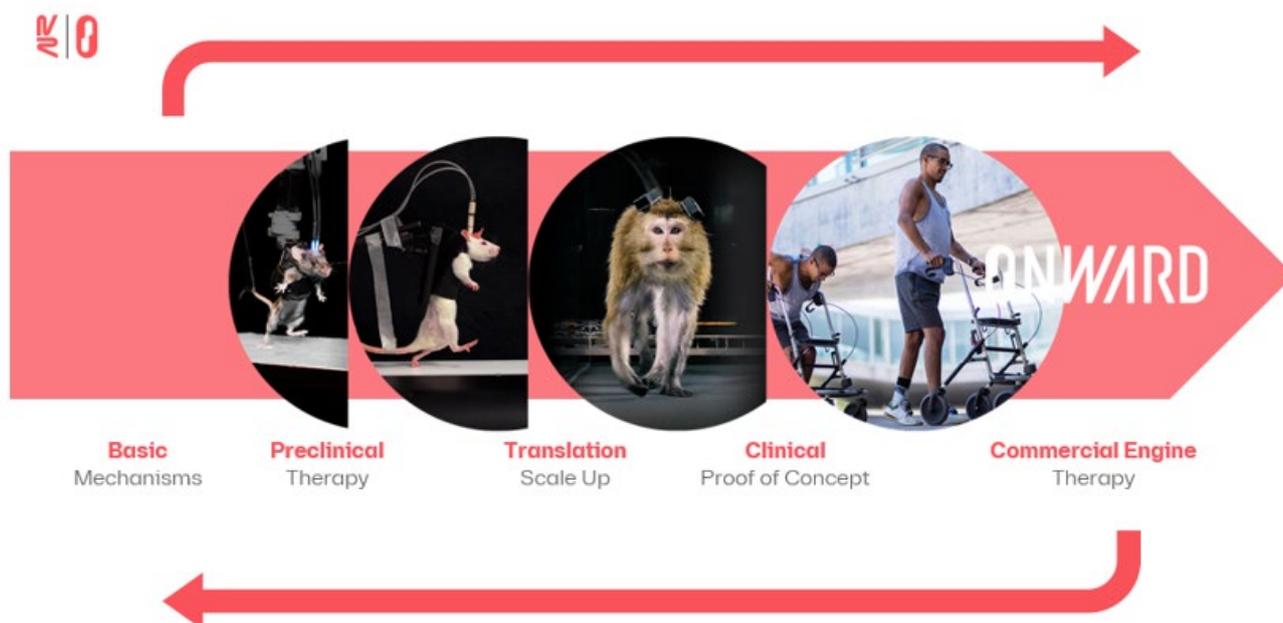
The Company is in the process of developing an updated version of ARC^{EX} that is expected to offer the following improvements vs the LIFT device being used in clinical trials. These updates reflect the Company's efforts to exploit R&D synergies between its implantable and external platforms, creating one technology platform that supports efficiencies in development resources and its supply chain:

- Updated industrial design shared with ARC™, leveraging shared hardware, firmware, and software.
- Updated tablet and patient programmers (smartwatch) shared with ARC™, hosting tailored clinician and patient apps.
- Bluetooth communication links are shared with ARC™.
- New stimulation engine to support higher therapy amplitudes and frequencies.
- New user interface (UI) and form factor for improved ease-of-use and support for clinic and home use.
- New connected health solution shared with ARC™ for monitoring therapy delivery and generating, aggregating, analyzing and developing insights from data.

Though the Company has invested robustly in its own R&D organization and development initiatives, it partners closely with leading academic research centers to identify and nurture emerging indications and technologies.

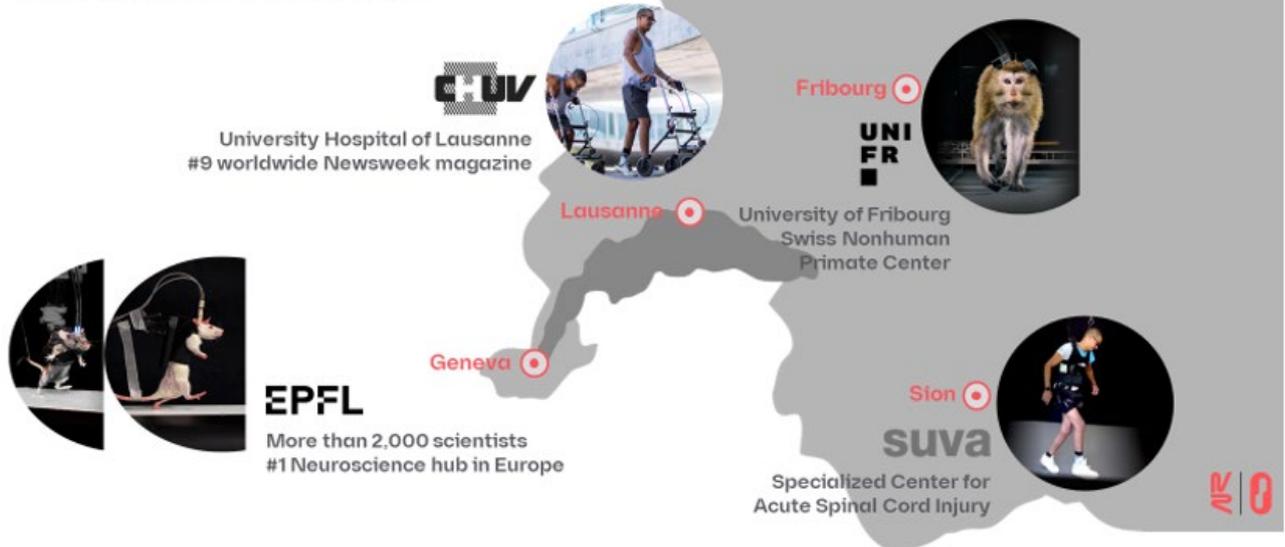
The Company's principal research relationship is with NeuroRestore, a joint research initiative involving the EPFL and CHUV. The Company has an exclusive IP and commercialization license agreement with these parties that is detailed under "*Material contracts*".

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 by the Company have shown sufficient promise to reach the human proof of concept stage. NeuroRestore plans to initiate several such proofs of concept in the next 18 months.



Technology, research, and medical expertise across continuum of research stages

Network of Advanced Research Facilities



The specific projects are subject to change based on scientific progress and priorities, but as of the date of this Prospectus, the projects are as shown in the chart below. Some of the clinical proof of concept studies have been submitted to competent authorities and have been approved to begin enrollment; others are in protocol design stage.

Exclusive relationship with the world's preeminent research lab drives rapid innovation

NeuroRestore collaboration

Relationship

- Several exclusive IP license agreements in place with company
- Gregoire Courtine, Head of .NeuroRestore is ONWARD co-founder and Chief Science Officer
- EPFL receives royalties and other financial incentives

Research pipeline

Indication	2021	2022
Brain Spine Interface	cPoC	
Mobility Parkinson's	cPoC	
DBS Interface	cPoC	
Blood Pressure	cPoC	
Cervical		cPoC
Mobility (STIMO-2)		cPoC

6 Clinical Proofs of Concept expected over next two years
 Much of this work is sponsored by grants and is non-dilutive

cPoC = Clinical Proof of Concept



Below are descriptions of the studies that have been submitted to competent authorities and have been approved to begin enrollment:

Brain Spine Interface

Called STIMO-BSI, this is a single site, single arm, non-blinded, non-randomized interventional study sponsored by NeuroRestore. The primary objective is to evaluate the safety of the approach in terms of tolerability of the cortical recording device. Secondary objectives are to assess preliminary effectiveness of the treatment in terms of motor performance with brain-controlled spinal cord

stimulation and long-term neurological recovery. This study has been registered on clinicaltrials.gov, NTC04632290.

Mobility Parkinson's

Called STIMO-PARK, this is a single site, single arm, non-blinded, non-randomized interventional study sponsored by NeuroRestore. The primary objective is to assess the safety of targeted electrical spinal stimulation to support rehabilitation in patients with Parkinson's disease. Secondary objectives are to assess the preliminary efficacy of targeted epidural spinal stimulation to induce selective modulations in leg muscle recruitment, to assess the preliminary efficacy of targeted epidural spinal stimulation-supported rehabilitation to improve leg motor performance, at the muscular level (single joint leg muscle strength and fatigue), and during gait (speed and endurance), to assess the preliminary efficacy of targeted epidural spinal stimulation-supported rehabilitation to alleviate deficits commonly associated with Parkinson's disease, including freezing of gait, posture and balance deficits and motor and non-motor scores, and to assess the complementarity of targeted epidural spinal stimulation with other standard neuromodulation therapies (i.e. dopaminergic medication and DBS). This study has been registered on clinicaltrials.gov, NTC04956770.

DBS Interface

Called HoT-DBS, this is a single site, single arm, non-blinded, non-randomized interventional study sponsored by NeuroRestore. The primary objective is to evaluate the safety of the approach in terms of tolerability of DBS of the lateral hypothalamus in patients with chronic spinal cord injury. The secondary objective is to assess the preliminary effectiveness of DBS of the lateral hypothalamus in terms of augmenting leg motor performance acutely and with rehabilitation. This study has been registered on clinicaltrials.gov, NTC04965727.

Blood Pressure

Called STIMO-HEMO, this study is described in detail in "*ARC^{IM} Clinical and Regulatory Matters*". It has been registered on clinicaltrials.gov, NTC04994886.

Mobility

Called STIMO 2, this is a multicenter, single-arm, non-blinded, non-randomized, interventional study sponsored by NeuroRestore. The primary objective is to assess the safety and feasibility of targeted epidural spinal stimulation to support mobility rehabilitation in the intensive rehabilitation phase in patients with spinal cord injury of less than 6 months (sub-acute). The secondary objective is to evaluate the preliminary effectiveness of mobility rehabilitation supported by targeted epidural spinal stimulation with regards to improvement of leg motor function and mobility recovery at 12 months after spinal cord injury. It has been registered on clinicaltrials.gov, NTC04196114.

The Company will select the most promising of these indications to develop and commercialize, based primarily on clinic results and commercial viability. Each of the potential indications can leverage the existing ARC^{IM} platform with minor software and firmware modifications. The Company therefore gains considerable leverage from its previous investment in the development of a proprietary neuromodulation platform and extensive accompanying IP estate.

Some of the planned research initiatives explore the use of ARC Therapy to treat people with Parkinson's disease and Stroke, advancing the potential for the Company's therapies to extend to large populations beyond SCI. Others include combination therapies pairing spinal cord stimulation with pharmaceutical agents or biological scaffolds.

Other planned research indications are dependent on outside technology development, such as the advancement of beat-to-beat blood pressure sensors that may enhance the accuracy and effectiveness of the Company's planned commercialization of ARC^{IM} to moderate blood pressure dysregulation in the SCI population. Another example is the continued advancement of brain implants (for example from NeuraLink and Blackrock Neurotech) that can sense a person's desire to move and transmit that desire wirelessly to ARC^{IM} which can then initiate movement. The Company's research

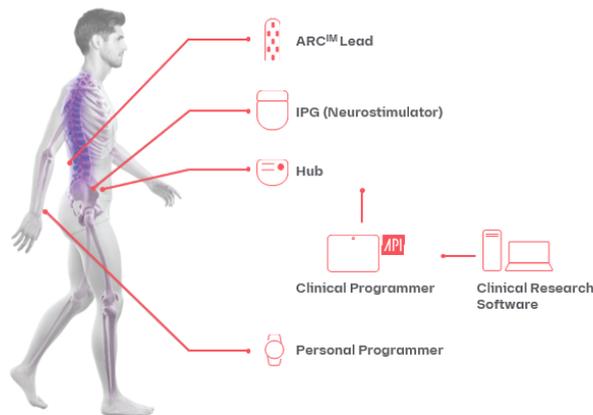
partners at NeuroRestore published proof of concept data in non-human primates for brain-controlled stimulation of the spinal cord in the scientific journal NATURE in 2016. This technology is applicable to people with complete SCI where no spared connection permits a volitional signal to navigate spared SCI circuits.

The Company plans to extend its research collaboration beyond NeuroRestore and the academic institutions such as Caltech and University of California with whom it already has IP licensing agreements. The Company has recently established relationships with many of the world's leading SCI rehabilitation clinics who are now participating in the Company's Up-LIFT Study (see "*The Company's solution—ARC^{EX} Clinical and Regulatory*"), which is intended to support a request for de novo classification to the FDA for marketing authorization of its ARC^{EX} platform described below in the Regulatory Matters section.

The Company has developed its ResearchGate platform to facilitate scientific exploration at the Company's research partner institutions.

Designed to facilitate experimentation and engagement with researchers

ResearchGate



The Company has developed a **research platform** to facilitate scientific exploration with leading SCI academic [centers](#)

ResearchGate permits researchers to **stimulate according to their own parameters** (beyond the confines of parameters used for existing therapies in development)

Designed to enable researchers to **identify new and different ways to stimulate the spinal cord** for the benefit of people with movement and functional challenges

Benefits

- Faster, easier collaboration with research partners
- Reduced dependency on core development resources
- Faster implementation of new paradigms and solutions
- Faster exploration and implementation of algorithms
- Rapid transfer of clinical findings to R&D

ResearchGate was designed to enable researchers to stimulate according to their own parameters (beyond the confines of parameters used for existing therapies) and to enable them to identify new and different ways of stimulating the spinal cord for the benefit of people with movement and functional challenges. ResearchGate opens the system up for researchers to use the full capability of the stimulator (within firmware programming limits) and incorporates sensors to explore closed loop investigational therapies and/or improvements. It is intended to be used solely within scientific or clinical setting and such use must be authorized by regulators as may be necessary.

The ResearchGate API allows a set of stimulation parameters to be uploaded to the stimulator from a source other than the ARC^{IM} application. After safety verification is completed (parameters are verified to be within limits) the file is loaded to the stimulator. The ResearchGate interface also allows the experimental stimulation parameters to be started, stopped and modified with low latency. Researchers can close the loop on stimulation by detecting a physiologic parameter and updating stimulation parameters based on this feedback.

ResearchGate has several intended benefits:

- Faster, easier collaboration with the Company's research partners.
- Reduced dependency on development resources.
- Faster implementation and exploration of new stimulation paradigms and closed-loop solutions.
- Faster implementation and exploration of algorithms.
- Rapid transfer of clinical findings to R&D for commercialization.

Regulatory framework

Clinical and Regulatory

As of September, 2021, the Company had 20.8 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 three groups: (i) Clinical, (ii) Regulatory, and (iii) Quality. 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^{IM} 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^{IM}, see "*Research and Development*".

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"¹²⁸. The Company's ISO 13485 certification has been in place since 2018 with the most recent audit conducted in late 2020 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 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

¹²⁸ ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes.

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 Premarket Clearance and Approval 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 Medical Device User Fee Amendments of 2017, or MDUFA IV, each 510(k), PMA, or de novo request must be accompanied by a user fee, although the fee may be waived under certain circumstances.

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 May 28, 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 ARCEX 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. However, there are similarities with the following Class II devices that suggest a similar classification will apply:

- Powered muscle stimulator (Section 890.5850 Class II) - Similar to 890.5850, the LIFT System passes electrical currents through electrodes attached to the skin at the affected body area.
- Transcutaneous electrical nerve stimulator for pain release (Section 882.5890 Class II) - Similar to 882.5890, the LIFT System is a transcutaneous electrical stimulator that delivers electrical current via external leads affixed to the patient's skin.
- Implanted spinal cord stimulator for pain relief (Section 882.5880 Class II) - Similar to 882.5880, the LIFT System applies electrical current to the spinal cord. The 882.5880 device consists of an implanted receiver with electrodes that are surgically placed on the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver. It differs from the Company's device in that the LIFT System uses an external stimulator and less invasive external electrodes affixed to the patient's skin.
- Cutaneous Electrodes (Section 882.1320 Class II) - Cutaneous electrodes that are utilized for FES are Class II devices per 882.1320. The Company's system utilizes a 510(k)-cleared

cutaneous electrode in accordance with the classification definition in 882.1320. The off-the-shelf electrode has been qualified for use with the Company's proprietary stimulator device.

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, ONWARD intends to submit a De Novo request for the ARC^{EX} System.

The Company is currently conducting Up-LIFT to seek regulatory approval to market and offer the ARC^{EX} platform for commercial sale in the US and Europe, see "*The Company's Solution—ARC^{EX} Clinical and Regulatory*". 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 May 28, 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 April 5, 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 May 26, 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 May 26, 2021 will continue to be valid for up to a period of 4 years. However, after May 26, 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

Now that 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 is a transitional period until 30 June 2023 during which EU CE marks will continue 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 May 1, 2021, and lower risk devices requiring registration later in 2021 and early 2022 (Class IIb and IIa devices from September 1, 2021 and Class I devices from January 1, 2022). After 30 June 2023, a UK Conformity Assessed ("**UKCA**") mark will be 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 November 30, 2020, U.S. Department of Health and Human Services Office of Inspector General, or OIG, published a final rule effective January 1, 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 January 29, 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 January 1, 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 Health Insurance Portability and Accountability Act, ("**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 processes is established or are otherwise subject to local privacy laws.

The GDPR became applicable on May 25, 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 June 17, 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*).

Intellectual property

Intellectual Property

The Company relies on varied intellectual property rights to protect exclusivity to its technological innovations and their therapeutic and commercial advantages. The Company also relies on registered designs to protect the distinctive look and feel of its products, as well as trademarks to establish brand recognition. These intellectual property rights confer valuable competitive advantages.

The Company's technology is protected by a large and growing portfolio of patent rights, both native to the Company and in-licensed. The Company continuously monitors its research and development activities as well as its commercialization strategy vis-à-vis its intellectual property. From time to time the Company has filed and may file patent applications on new inventions and ornamental or industrial designs, both to cover its contemplated commercial products and service, and to create enforceable assets against encroachment. As well, the Company benefits from relationships with licensing partners that from time to time may yield additional patents and patent applications.

As of May 2021, the Company's portfolio includes 121 granted utility and design patents and 171 pending applications, across 15 countries. The table below provides an overview of the Company's patents and patent applications which have been granted on a continuous basis since 2011.

	Patents	Applications
PCT	N/A	32
EP	43	56
US	37	53
China	11	10
Japan	5	7
Korea	2	1
Australia	13	4
Canada	4	5
Hong Kong	5	3
Israel	1	0
Total	122	171

Note: PCT = Patent Cooperation Treaty

The Company's selection of which countries to prosecute patent or design applications and/or to maintain granted patents or designs is based on the Company's commercialization strategy, which can change. The Company may, during the prosecution of any application in any jurisdiction employ strategies, in consultation with its attorneys, to amend, cancel or add claims or to abandon, continue or further prosecute pending applications. Further, in some instances and where possible, the

Company may or may not choose to pursue patent term extensions based on regulatory delay in the United States, or any other jurisdiction where such extensions are available.

In addition to the Company's native portfolio, the Company has various licenses from several leading global neuroscience academic research institutions including l'École Polytechnique Fédérale de Lausanne ("**EPFL**"), The University of California, Los Angeles ("**UCLA**"), The California Institute of Technology ("**Caltech**"), The University of Louisville, The University of Minnesota, The University of Calgary and The University of British Columbia. The Company is confident that the rights conferred by these licenses are sufficient, durable and valuable. The Company may, from time to time, review its licensing relationships with its licensors and modify, expand, reduce or drop the rights conferred.

The Company's ARC^{IM} and ARC^{EX} systems are protected by distinct but intersecting patent portfolios. Further, the various patents covering the Company's products and services are in many instances layered to provide varied and flexible scopes of coverage, from the system level down to specific product features and from the overall therapeutic method level down to specific uses. Therefore, the Company's IP protection is not reliant on any one patent but on a robust portfolio. The resulting patent portfolio aims to cover not only current but contemplated product and service offerings, but also protection against alternative architectures and solutions which could be pursued by competitors. The Company also benefits from first-mover advantage and has uniquely protected the Company's intended indications by means of various use, system, apparatus and method claims.

In addition to patents and designs, the Company also relies on a combination of trade secrets, copyrights, non-disclosure agreements, employment agreements and other contractual provisions and technical measures that help it preserve, maintain and develop its intellectual property position.

From time to time, the Company has and may review its intellectual property portfolio and, as a result of such review and in view of commercial and technical priorities, choose to abandon intellectual property owned by the Company. Further, in those instances where the Company's intellectual property assets have applicability outside of the Company's primary fields of interest and to the extent it is in the Company's interests to do so, the Company may license its intellectual property or sublicense in-licensed intellectual property.

The Company may also determine that it would be to its commercial or strategic benefit to enter into additional licensing agreements with existing licensing partners or other third parties.

As of the date of this Prospectus, the Company is in the process of finalizing an agreement with Neurosoft Bioelectronics. The Company licensed 4 patents and 2 patent applications from EPFL as part of the EPFL *License 1* in 2016. This licensed technology is no longer relevant to the Company's product roadmap and will be returned to EPFL for its subsequent license to Neurosoft Bioelectronics. Upon completion of the pending agreement, EPFL will issue a lump sum payment of EUR 50k to the Company. In addition, the Company will sub-license 2 patents from EPFL to Neurosoft Bioelectronics against royalty payments tied to Neurosoft Bioelectronics net sales. A fraction of the amount due in royalty payments will be paid to EPFL as determined by the *License 1* sub-licensing terms.

The Company, like all other holders of intellectual property, is exposed to the risks of third-party invalidation or nullity attacks against its patents both at the patent-granting authority level and in judicial and administrative courts. In such an event, the Company will mount an appropriate response in consultation with its attorneys.

Trademarks

The Company uses its corporate name, ONWARD, and the Company's associated logo and tagline, to generate awareness of the Company's activities and technologies in development. In total, the Company owns 19 trademarks registered and pending around the globe.

The Company uses the trademark ARC^{IM} to identify the Company's implantable solution, and the trademark ARC^{EX} to identify the Company's external system. The Company has either obtained or is pending registration for the ONWARD name and the ARC^{IM} and ARC^{EX} trademarks in 5 jurisdictions including Europe, US, United Kingdom, Japan and People's Republic of China.

The table below provides an overview of the Company's trademarks and trademark applications protecting the latest company branding as of 30th June 2021.

	Mark	Status
EUIPO	ONWARD	Pending
	EMPOWERING MOVEMENT	Pending
	ARC ^{EX}	Pending
	ARC ^{IM}	Pending
	O	Pending
UK	ONWARD	Pending
	EMPOWERING MOVEMENT	Pending
	ARC ^{EX}	Pending
	ARC ^{IM}	Pending
	O	Pending
US	ONWARD	Pending
	EMPOWERING MOVEMENT	Pending
	ARC ^{EX}	Pending
	ARC ^{IM}	Pending
	O	Pending
China	ONWARD	Pending
	O	Pending
Japan	ONWARD	Pending
	O	Pending
Total	19	19

Note: EUIPO = European Union Intellectual Property Office

Older marks include a total 26 items in EP, US, China, Japan and Switzerland, among which 10 marks are granted.

Domain names

The Company owns registrations for various domain names. The most important domain name is <onwd.com>. Other domain names of the Company redirect to this domain name and corresponding website.

Information technology

The Company relies on industry-standard, off-the-shelf ("**OTS**") information technology platforms to conduct its business. This includes commonly used desktop and smartphone applications, cloud-based application, and server-based applications and infrastructure. The Company maintains a company website and utilizes popular social media channels, such as LinkedIn, Twitter, and

Instagram. While applications and infrastructure are OTS, content and design are proprietary to the Company and in some cases protected by copyright.

Infrastructure

The Company's infrastructure--web, server and desktop applications and networks--is either hosted by cloud providers or administered by a third-party IT service provider. The Company's primary third-party hosting service provider for its network infrastructure is located in Tilburg, the Netherlands. For obvious reasons, the Company has adopted, in partnership with its providers, a range of measures to secure its internal and cloud-based applications and stored assets against various forms of cyber-attack, wrongful intrusion, data breaches, breakdown and data loss. The primary hosting provider has ISO 27001 certification for its information security management system. Contractual arrangements have been made by the Company with the hosting provider to ensure that sufficient technical and organizational measures are kept in place by the hosting provider to help ensure the continuity of the Company's and the platforms' operations, as well as their compliance with applicable law.

Platforms

The Company's platforms, both ARC[™] and ARC^{EX}, comprise part of a larger connected health platform. The Company understands that in the case of certain other digital health solutions (e.g. pacemakers) there have been multiple, successful attacks by malicious actors where access to both health data and control over actual implanted medical devices was gained. These attacks resulted in material losses through ransom schemes and negative effects that public knowledge of such events have on stock price and company valuation. The attacks have also resulted in undue risk of data compromise or in some high-risk healthcare applications, serious injury or death. While the safety risk profile of the Company's products is not of this magnitude, in order to protect itself from these risks and optimize its development speed, the Company has selected Google Cloud to host its connected health solution and leverages Google Firebase and Analytics for online hosting of data, visualization and analysis. This arrangement provides a secure interface, redundant hardened storage solutions and tools, storage facilities and portals that all meet stringent cybersecurity standards and relevant data protection standards.

The Company has also hardened and will continue to harden its in-house applications and devices against known types of penetration e.g. replay, denial of service, man-in-the-middle, random data. Methods such as code obfuscation, encryption, secure key exchange, regular operating system ("OS") updates, security patches, and timing and sequence-based monitoring are all used to guard against unwanted attacks. In addition, the Company has also partnered with a third-party firm with expertise in cybersecurity to perform fuzz and pen testing, and to assist with design patterns that help ensure Company applications are protected against known threats. Deployment of the application by persons is also controlled through the Google Play Store such that copies of the application can only be downloaded with permission and prescription, making it difficult for bad actors to obtain copies of the application for analysis and reverse engineering.

Environmental and health and safety

The Company is committed to providing a safe and healthy work environment for its employees, contractors and visitors. This commitment extends to ensuring its operations do not place local communities or the environment at risk. The Company has not been the subject of any significant environmental prosecutions for violating environmental regulations, licenses or other requirements during the past five financial years.

Insurance

The Company maintains insurance covering a range of business activities and exposures in accordance with standards and norms for a Company operating in the Company's industry and in the geographies in which the Company has a presence. The Company is in the process to renew or implement Key Man life insurance coverage on several critical executives, including Dave Marver and Professor Courtine.

The Company believes it is adequately insured and that it pays appropriate premiums for this coverage. The Company regularly evaluates its coverage and make adjustments as necessary. It cannot be ruled out that the Company could suffer damages that are not covered by existing policies or that exceed the coverage limits set in those policies.

Employees

As of the date of this Prospectus, the Company has 72.8 full-time equivalents employed that includes both employees and contractors. The following table presents a breakdown of the Company's full-time equivalents as at the date of the Prospectus, and as per the Financial Statements as of 31 December 2020, 2019, 2018.

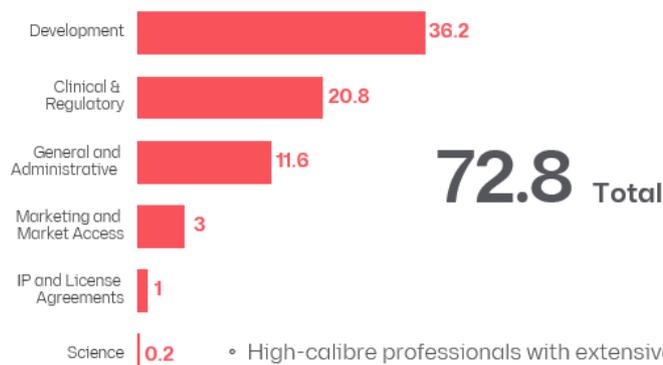
	Sep – 21	2020	2019	2018
Science	0.2	0.2	0.2	0.2
Development	36.2	28.1	38.4	29.2
Clinical & Regulatory	20.8	14.0	8.0	4.0
Marketing & Market Access	3	1.0	1.0	1.0
Patents & related	1	1.0	1.0	1.0
General & Administrative	11.6	10.7	9.9	7.1
Total	72.8	55.0	58.5	42.5

As of the date of this Prospectus, the Company had 36.7 full-time equivalents working out of the Company's headquarters location in Eindhoven, the Netherlands, 27.6 in Switzerland working out of the Company's Lausanne office, and 8.5 in the US, where the Company does not yet have an office location. These counts exclude open positions. The Company will continue recruiting talent and the headcount is expected to increase considerably in the next several years, primarily adding sales and marketing personnel to support commercialization in the US and Europe.

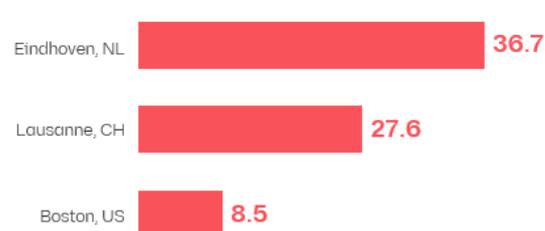
Experienced management and rapidly growing organization

Employees

Employee & full-time contractors by department as of September 2021¹², FTE #



Employee & full-time contractors by location as of September 2021¹², FTE #



- High-calibre professionals with extensive training, education, and experience in biomedical engineering, neuroscience, and other relevant fields
- Corporate culture based on patient-centricity, quality, innovation, openness and collaboration

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.

For the Up-LIFT pivotal study, the Company has entered into an agreement with a Contract Research Organization ("**CRO**") to coordinate the study on the Company's behalf. The CRO coordination includes the trial management, monitoring, data management, safety monitoring and reporting.

Supplier agreements

ARC^{IM} IPG agreements

For the ARC^{IM} IPG 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 is specialized in the manufacturing of IPG-cans and has a good reputation in the market. Since the IPG-can 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. 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 generated throughout the development services under the agreement 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 February 13, 2019 with a Swiss headquartered supplier for the development of the printed circuit board assembly ("**PCBA**"). This supplier is specialized in the manufacturing of PCBA's and has a good reputation in the market. Since the PCBA 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 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.

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 Oscor 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. 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 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, Go-2 paddle leads as well as an accessory kit to implant the paddle leads. Since the lead paddle is a key component of the ARC^{IM} platform this agreement can be considered as material. The part of the agreement relating to the packaging system and the paddle leads has been continued. The Company however still purchases accessory kits for the implant of the Oscor manufactured lead-paddles.

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 generated throughout the development services under the agreement are assigned to the Company.

The contract will end on 29 March 2023 and can be extended for additional one-year periods.

ARC^{IM} test system agreement

For the functional testing of the ARC^{IM} platform the Company entered into a development, manufacturing and supply agreement on 1 March 2019 with a US headquartered supplier to develop and manufacture specialized functional test systems to perform design verification testing. Since the ARC^{IM} platform is key to the ARC^{IM} Therapy 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 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 supplier has to-date built three systems, where in total two systems are placed at the suppliers of the ARC^{IM} IPG and ARC^{IM} PCBA supplier and one at the Company's laboratory in Eindhoven.

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 and has a good reputation in the market. 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 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.

LIFT device agreement

For the development of the LIFT device the Company has entered into a specified statement of work with a US headquartered supplier. This relationship is a result of its acquisition of NRT where the supplier developed the first version of the LIFT device. Since that contract ended, the Company is now requesting specific work packages from the supplier for updates to the existing device and supply

of devices for use in the pivotal trial. Since the LIFT device is the critical part for the success for the Up-LIFT trial, this contract can be considered material.

Up-LIFT trial CRO agreement

For the Up-LIFT pivotal trial the Company entered into a master clinical services agreement on 30 July 2020 with a US headquartered Contract Research Organization (CRO) to support the Company in the study management, monitoring, data management and reporting of the study. Since this a key role in the success towards approval of the product the 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 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.

License Agreements with EPFL, NeuroRestore and CHUV and other Parties

Contracts & Agreements EPFL	Status
PDWALK agreement	<i>*Signature Pending</i>
DARPA	Active
Innosuisse Agreement	Active
Cervical research agreement	Active
Blood pressure research agreement	Active
Bladder & Bowel research agreement	Active
PREP2GO Consortium agreement	Active
CONFIRM Consortium agreement	Active
STIMO bridge research agreement	Completed
WALKAGAIN Consortium agreement	Completed
RESTORE Consortium agreement	Completed
OptiStim Agreement	Completed
Cervical Industrial Grant	Completed
STIMO research Agreement	Completed
LEAP Consortium Agreement	Completed

Contracts & Agreements CHUV	Status
Consultancy agreement with Prof. Bloch	Active
In cash support for STIMO study nurse	Active
In cash support for STIMO physical therapists	Active
Costs for 2 implants	Completed

In cash support for STIMO bridge surgeries	Completed
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Contracts & Agreements .NeuroRestore (CHUV + EPFL)	Status
Framework Agreement Include an appendix for each NR studies supported by ONWD	Active
STIMO-HEMO	Active
STIMO-Pharma	*Signature Pending
STIMO-BSI	*Signature Pending
STIMO-Parkinson	*Signature Pending
HemON	*Signature Pending
Hot-DBS	*Signature Pending

Licenses	Status
EPFL – Neurostimulation	Active
EPFL – Rehabilitation Robotic	Active
EPFL/UBC, UCa, UMi – Autonomic functions	Active
UCLA – Neurostimulation	Active
Caltech/UCLA, UoL – Neurostimulation	Active

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 and US Defense Advanced Research Projects Agency ("**DARPA**") funding, require the Company to grant a fully paid-up royalty free license to certain public institutions, for research and education purposes only. In 2016, the Company applied for, and received an up to EUR 10 million Innovation Credit from RVO. As part of the related loan agreement, the Company pledged assets, including intellectual property that were developed with the loan, to RVO in the case of events of default (including but not limited to a Company bankruptcy). In such case, any in-licensed intellectual property would return to any of the Company's licensors.

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 EPFL has been granted an option to obtain 197,511 Ordinary Shares with nominal value EUR 0.12 (493,778 ordinary shares prior to the Reverse Stock Split), which option may be exercised until completion of the Offering or an exit. 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. EPFL has indicated that it wants to exercise the option as part of the IPO.

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 2% to 6% 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. In the case of an initial public offering, EPFL will get 0.3% of the Ordinary Shares of the Company. The agreement contains various milestone and diligence obligations. EPFL has indicated that it want to exercise the option as part of the IPO.

Caltech

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.

In addition the Company is required to pay an IPO fee to Caltech in the amount of USD 1.5 million upon completion of the Offering.

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.

In addition the Company will be required to pay a change of control/IPO fee of the higher of USD 1 million and the value of 2% of phantom stock (based on ordinary shares in existence prior to the merger of NRT with ONWARD).

The Convertible Loan Agreement

On 20 April 2021 the Company entered into a Convertible Loan Agreement of EUR 30 million (EUR 27.1 million (the "**Principal Amount**") furnished per 30 June 2021, with an additional EUR 2.9 million executed in July 2021). The outstanding portion of the Principal Amount shall bear interest at a rate of 8% per year. Under the Convertible Loan, there are several situations that would trigger a conversion of the loan into shares:

- Upon closing of a qualified financing event
- Upon closing of a financing round not qualifying as a qualified financing event
- Upon entering into of a liquidity event prior to conversion or repayment
- Upon a milestone event
- Upon election by the option holder

In terms of the agreement no assets may be pledged by the Company without consent from the majority of lenders.

The Convertible Loan Agreement includes the following conversion options. These conversion options are mutually exclusive:

Conversion Option	Option Holder/ Lender/ Mandatory upon contingent event	Fixed or Variable Number of Shares	Cap or Floor to Share Price
Qualified Financing Series A	Mandatory upon contingent event	Variable depending on price per share per financing	Cap at original subscription price per share in case actual IPO price is higher.
Qualified Financing Senior Shares	Mandatory upon contingent event	Variable depending on price per share per financing.	Floor if price is below original subscription price.
Non-Qualified Financing Series A	Option Holder (by majority) upon contingent event	Variable depending on price per share per financing	Cap at original subscription price per share in case actual IPO price is higher.
Non-Qualified Financing Senior Shares	Option Holder (by majority) upon contingent event	Variable depending on price per share per financing.	Floor if price is below original subscription price.
Milestone Event	Mandatory upon contingent event	Fixed, converted at the original subscription price, as accrued interest is not converted	None
Liquidity Event	Option holder (individually) upon contingent event	Fixed converted at the original subscription price (as accrued interest is not converted) or variable depending on the latest round of financing, as elected by holder	None
Election	Option holder (only if the above contingencies do not occur)	Fixed number of Series A shares (as accrued interest is not converted), or variable depending on last round of financing for Senior Shares	None

For the accounting treatment and valuation of the Convertible loan reference is made to note 6 and note 8 in the Interim Financial Statements.

An IPO, such as the Offering, being one of the conversion options, is considered a qualified financing event, whereby the loan, plus the accrued interest (at an interest rate of 8%) convert into ordinary shares at the Offer Price minus a 25% discount (see also "*Shareholder Structure and Related Party Transactions—Convertible Loan Agreement*").

The Innovation loan

There is a 10% interest-bearing loan from the Dutch government ("**RvO**") to support innovation. The loan will need to be repaid in seven installments with the first installment to be repaid on 1 January 2026, and the last payment on 1 July 2027. Assets, including IP, that were developed by the Company with the loan have been pledged to the RVO in the case of default of repayment of the loan. As per

June 30, 2021, a loan amount of EUR 8.5 million has been received from RVO and the accrued interest amounts to EUR 2.4 million. The loan is milestone based and to date the Company has received 85% (EUR 8.5 million) of the granted loan amount. The remaining 15%, or EUR 1.5 million, is expected to be received in the next 18 months.

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.

Facilities

The Company's headquarters and principal office is located at High Tech Campus, Building 32, 5656 AE, Eindhoven, the Netherlands, where the Company leases approximately 1,000 m² of office and laboratory space. The Company's current lease expires May 2022.

The Company has a second office located at EPFL Innovation Park, Building C, 1015 Lausanne, Switzerland, where the Company leases approximately 250 m² of office space. The Company's current lease of this facility is month-to-month and can be terminated with 90 days advance notice.

The Company intends to add new space or substitute space as may be necessary to accommodate the expansion or optimization of the Company's operations. It expects to open an office in the Boston, Massachusetts, USA area in the next several months.

Group structure

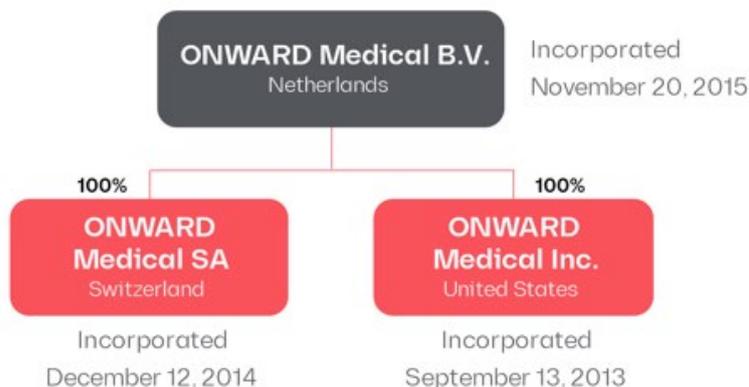
The Company is composed of ONWARD Medical B.V. (incorporated on 20 November 2015) and its wholly-owned subsidiaries:

- 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. The following chart represents the Company's structure as of the date of this Prospectus:

Headquarters in the Netherlands; two wholly owned subsidiaries

Corporate Structure



Grants and subsidies

The Company believes it is well positioned to benefit from grants and subsidies intended to support the development and commercialization of therapies for SCI, as well as grants available more generally to support emerging companies in the geographies in which it operates. Both Eindhoven and Lausanne regions provide small subsidies to foster the emergence of innovative companies. For instance, Lausanne region provides a small subsidy for every technical hire.

Historically, the Company has received grants and financial support from the EU, the US government, the Dutch government, and the Swiss government. It has also won several grants and awards tied to innovation. These grants have totaled nearly EUR 9 million for the period 2015 to 2023. European grants from various funding schemes such as Eurostar, ERA-NET, EuroBench, and PENTA, supported multiple research projects of two to three years in duration each, fostering the creation of new collaborations and promoting exchange of know-how and expertise within development partners and academic partners, and hence, providing support for the innovation behind the Company's technology.

DARPA Grant

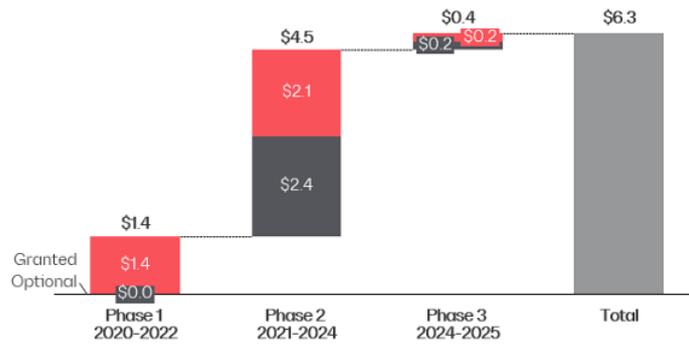
The DARPA grant funds a five-year-long project involving a consortium of research partners in the US, Canada and Switzerland, for a total of USD 36 million, with USD 6.3 million potentially granted to the Company. In response to the DARPA Bridging the Gap Plus¹²⁹ ("**BG+**") funding call, the consortium proposed the development of a new clinical intervention to modulate blood pressure and spinal cord perfusion and oxygenation in the hours following spinal cord injury. The intervention includes spinal cord stimulation using ARC^{IM}, combined with implanted sensors for blood pressure and spinal cord perfusion, as well as stem cells and scaffolds to be implanted in the lesion site to promote neural regrowth across the injury.

The Company and EPFL are collaborating to develop HEMO, an implantable spinal cord stimulation system to control blood pressure in the Acute phase which can operate in real-time closed-loop mode leveraging data from external blood pressure sensors. BG+ consortium partners in the US are working on scaffolds, stem cells and related pre-clinical experiments, with and without ARC^{IM}. Consortium partners are developing implantable sensors for blood pressure (MAP) and spinal cord perfusion and oxygenation (NIRS). Consortium partners in Canada are responsible for pre-clinical experiments to validate closed-loop control of HEMO using MAP and NIRS implanted sensors. A clinical study to evaluate HEMO in chronic patients will take place at partner sites in Switzerland and Canada, while the clinical study to evaluate closed-loop control of HEMO using MAP and NIRS implanted sensors will be conducted in Canada.

Every consortium partner will continue to own its IP, while the US government receives a free license solely for research and education purposes. Potential cases of joint-IP creation will be settled between co-inventing institutions. In case EPFL and the Company innovate jointly, those inventions will fall under the scope of existing licenses and agreements, with no further royalty stacking.

The five-year project started 1 October 2020, and is expected to end 30 September 2025. It consists of three phases as outlined below.

¹²⁹ Dr. Al Emondi, Bridging the Gap Plus (BG+), <https://www.darpa.mil/program/bridging-the-gap-plus>



There are several milestones the Company must meet to receive the outlined funding in full (USD million):

- Phase 1: System design, IPG software and firmware update for spinal cord stimulation for blood pressure control (already granted)
- Phase 2: System development completion (USD 2.1 million to be granted), development of a dedicated lead (USD 2.0 million contingent), and clinical validation in ten chronic patients in Switzerland and Canada (USD 0.4 million contingent)
- Phase 3: IDE from the FDA secured and clinical validation shown in five acute patients in Canada (USD 0.2 million to be granted and USD 0.2 million contingent)

The total amount that can be potentially granted to the Company: USD 3.6 million (assuming project the will go to Phases 2&3) and USD 2.6 million contingent on DARPA's determination to support those activities.

The Company believes its involvement in the DARPA consortium will contribute to its leadership and expertise in blood pressure management, paving the way for introduction of next generation systems that may follow ARC^{IM} for blood pressure.

Circa €8.3 M since inception, with more expected as we increase US presence

Grants and Subsidies

Period	Non-Dilutive Grant Funding, €'000s	Source
2015-2016	UK: 11	Wellcome Trust
	NL: 50	MIT Eindhoven Region
2015-2021	CH: 220	SPEI Lausanne Region
2016-2022	EU: 2,421	LEAP, Restore, Walkagain, Confirm Bestable, Disperse Prep to Go
2020-2025	US: 5,313	DARPA
2021-2024	NL: 250	ZonMW
Total Non-Dilutive Funding	8,265	

Going forward, expect to **continue benefiting from non-dilutive grant funding**, focus will expand to US, where Congress, Department of Defense, and VA have historically funded SCI research and clinical trials

The Company expects it will have an opportunity to continue benefiting from non-dilutive funding, particularly in the US where the US Congress, Department of Defense, and Department of Veteran's Affairs have historically funded research and clinical trials to advance therapies for SCI.

Historically, the Company has received grants and financial support from the European Union, the US government (Department of Defense), the Dutch government, and the Swiss government. It has also won several grants and awards tied to innovation.

The table below details grants and subsidies awarded to the Company since inception:

Award	Date	Duration	Amount
Wellcome Trust (UK). Innovation Award	Feb-15	12	EUR 11,000
SPEI (CH) – Lausanne Region	Jun-15	66	EUR 219,634
MIT (NL) – Eindhoven Region	Jun- 15	12	EUR 50,000
LEAP (EU) – Eurostar Project	Apr- 16	30	EUR 376,154
Disperse (EU) – EU PENTA Project	Feb-17	36	EUR 310,876
Restore (EU) – Eurostar Project	Apr-17	30	EUR 370,213
Walkagain (EU) – Eurostar Project	Apr-18	30	EUR 499,912
Confirm (EU) – Eurostar Project	May-19	30	EUR 416,293
Bestable (EU) – EuroBench Project	Sep-19	24	EUR 100,000
Prep to Go (EU) – Eurostar Project	Apr-20	30	EUR 347,802
DARPA – Phase 1 (US)	Oct-20	18	EUR 1,152,543
DARPA – Phase 2 (US)*	Apr-22	24	EUR 3,799,302
DARPA – Phase 3 (US)*	Apr-24	18	EUR 361,514
ZonMw (NL) – ERA NET Project	Jan-21	36	EUR 250,000
Total			EUR 8,265,243

**Contingent on demonstration of progress*

Covid-19 impact

While it appears impacts from Covid-19 are diminishing, the Company has experienced delays and challenges as a result of the pandemic.

First patient enrollment in the Company's Up-LIFT Study was delayed by several months. Planned first enrollment was initially scheduled for September 2020, whereas actual first enrollment was January 2021.

In addition, development of the ARC[™] System has been impacted by work-from-home requirements that have limited the Company's ability to test and debug hardware and software systems, processes reliant on laboratory and other equipment housed in the Company's facilities.

The Company successfully completed a convertible note financing through the Convertible Loan Agreement in April 2021. A financing of similar size was originally scheduled to close in late 2020, but was delayed when a lead investor unexpectedly withdrew in order to divert funds into portfolio companies needing cash infusions due to the pandemic.

Notwithstanding the above, despite Covid-19 the Company has been able to make strong and steady progress in its research and development initiatives and in the conduct of its clinical trials.

MANAGEMENT, EMPLOYEES AND CORPORATE GOVERNANCE

This section gives an overview of the material information concerning the Board, the Company's employees and its corporate governance as such will be reflected in the Articles of Association, the rules regarding the Board's functioning and internal organization (the "**Board Rules**"), each of which as they will be in effect ultimately on the First Trading Date. 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, each of which as they will be in effect ultimately on the First Trading Date. This overview does not reflect any temporary Covid-19 related rules or regulation. The full text of the Articles of Association (in Dutch, and an unofficial English translation thereof) and the Board Rules (in English) will be 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/documents/>) as of the First Trading Date.

Board Structure

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*).

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 will draw 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, which will be in effect ultimately on the First Trading Date.

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. 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 shareholders 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 (if any) 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 will adopt the Board Rules that will govern, among other things, its decision-making process and conduct of meetings. The Board Rules will be in effect ultimately on the First Trading Date and will on that date be published on the Company's website (www.onwd.com). The Board may amend the Board Rules 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 may 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 Roel Bulthuis and Patrick Van Beneden, at the end of the Annual General Meeting 2022;
- In respect of Grégoire Courtine and Regina Hodits, at the end of the Annual General Meeting 2023;
- In respect of Jan Øhrstrøm and John de Koning, at the end of the Annual General Meeting 2024; and
- In respect of Dave Marver, Ian Curtis and Fredericus Colen, at the end of the Annual General Meeting 2025.

Any directors to be appointed after the date of this Prospectus will be appointed for up to four years after which they may be reappointed for another two years.

Board Meetings and decisions

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 must, after having heard the relevant Director and without that relevant Director being present, 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 as well as on the First Trading Date, the Board is composed of the following Directors:

Name	Year of birth	Position	Initial Year of Appointment	Termination 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 2024
Grégoire Courtine	1975	Non-Executive Director and CSO	2016	End of the annual General Meeting to be held in 2023
Roel Bulthuis	1976	Non-Executive Director	2020	End of the annual General Meeting to be held in 2022
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
John de Koning	1968	Non-Executive Director	2016	end of the annual General Meeting to be held in 2024
Regina Hodits	1969	Non-Executive Director	2016	end of the annual General Meeting to be held in 2023
Patrick Van Beneden	1962	Non-Executive Director	2016	end of the annual General Meeting to be held in 2022

The Company's registered address, High Tech Campus 32, 5656 AE 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. Vincis 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 independent Chairman of (i) Blaze Bioscience Inc. (since 2015), specializing in injectables for fluorescence guided surgery, and (ii) Polyganixs B.V. (since 2016), specializing in polymer based surgical products Jan Øhrstrøm is the Chief Executive Officer of VarmX B.V. (since 2021), specializing in FXa reversal agent (blood clotting). 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.

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.

Mr. R. (Roel) Bulthuis (born 1976, The Netherlands) is a Non-Executive Director of the Company. Roel Bulthuis is a managing partner and head of the healthcare investment team at INKEF capital, which has backed more than 45 companies in healthcare and technology. Roel Bulthuis combines more than 15 years of experience across venture capital, pharma business development and investment banking. Roel Bulthuis previously was director of M Ventures (2009 to 2019), Canbex Therapeutics (2012 to 2018), Padlock Therapeutics (2014-2016), DNAscript (2018 to 2019), Aveni (2017 to 2019) and F-Star (2018 to 2019). Currently Roel Bulthuis is director of ten Biotech companies: Ambagon Therapeutics (2019), Comet Therapeutics (2019), Calypso Biotech (2020), Quralis (2020), Scenic Biotech (2019), NMD Pharma (2019), Salvia (2020), VarmX (2020), iOnctura (2020) and Draupnir Bio (2019). Roel Bulthuis holds an MSc. In Biopharmaceutical Sciences from Leiden University and an MBA in Finance from the Helsinki School of Economics.

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. Next to his position as director to the Company, Fredericus Colen is also Chief Executive Officer of Neovasc, a public medical device company developing, manufacturing and marketing products for the cardiovascular marketplace. Fredericus Colen held the position of Board Member at Mölnlycke Healthcare from 2012 to 2017 and as Board Member at Middle Peak Medical from 2015 to 2017. Fredericus Colen holds an MS at the RWTH Aachen, Germany.

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.

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 LSP (Life Sciences Partners), one of Europe's largest healthcare investment firms that supported the growth of hundreds of companies since its inception. John de Koning joined 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), Aelin Therapeutics (2017), VarmX (2020) and Visus Therapeutics (2021). John the 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.

Dr. Mrs. R. (Regina) Hodits (born 1969, Austria) is a Non-Executive Director since 2016. She has over 20 years of experience in venture capital, and is a managing partner at Wellington Partners Life Science ("WPLS") Venture Capital Consulting GmbH (2017), and as such is advising Wellington Partners IV Life Science Funds L.P. on investment decisions including the investment in Onward. Ms. R. Hodits currently represents the WPLS' funds on the Boards of Carisma, Sidekick, SNIPR Biome and STipe. She was a founding investor in Rigontec (acquired by MSD), Sapiens (acquired by Medtronic Inc.), Middle Peak Medical (acquired by Symetis / Boston Scientific), represented WPLS on the Board of Themis (acquired by MSD), and served as Spokesperson for the Board of the German PE and VC Association (BVK). Before joining WPLS, R. Hodits led the European life sciences efforts of Boston-based Atlas Venture. She was the founding investor in Bicycle Therapeutics, F-star and Jenavalve, and served on the Boards of U3 Pharma (acquired by Daiichi Sankyo), Nitec Pharma (now part of Horizon Pharma), Egalet and Novamed. Before, R. Hodits worked for Apax Partners and McKinsey. R. Hodits holds PhD in Biochemistry from the Technical University of Vienna, Austria and was as post-doctoral researcher at the MRC, Cambridge UK

Mr. P.F.Z. (Patrick) Van Beneden (born 1962, Belgium) is a Non-Executive Director since April 2016. Patrick Van Beneden is an associate partner at Gimv NV as of October 2020. Before that he was a partner at Gimv NV (1985 to 2020), a European investment company. Patrick Van Beneden has built a successful track record in life sciences, both in early and late stage investments and exits (Devgen, CropDesign, Plexxikon and Endosense,). Former board seats include Innogenetics, Crucell, Hypnion (acquired by Eli Lilly), CropDesign (acquired by BASF), Astex and Ablynx. Currently, Patrick Van Beneden is a board member of FIRE1 (2018), Biotalys (2013), and JenaValve Technology (2010). Patrick Van Beneden, holds a Master in financial sciences at the VLEKHO Business School Brussels, Belgium.

Management Team

The Company's Management Team consists of the following persons:

Name	Year of birth	Position	Member Since
Dave Marver	1968	CEO	2020
Marko Jansen	1970	CFO/COO	2017
John Murphy	1967	CTO	2020
Hendrik Lambert	1965	VP Clinical, Regulatory and Quality	2016

Biographies Management Team

Mr. D.L. (Dave) Marver (born 1968, United States), see above.

Mr. M. (Marko) Jansen (born 1970, The Netherlands) is the Company's Chief Financial Officer (2017). From January 2020 to July 2020 Marko Jansen was the Company's Chief Executive Officer. From 2016 to 2017 he was the Interim Chief Financial Officer of AudioNova International B.V. Marko Jansen started his career in public accounting with Arthur Andersen, followed by several (financial)

managerial roles in both large international operating organizations as well as start-up companies. Marko Jansen holds a Dutch auditor license with the NBA (as "*Accountant in Business*") and holds a PhD in business economics at the University of Tilburg, The Netherlands.

Mr. J.M. (John) Murphy (born 1967, United States) is the Company's Chief Technology Officer (2020). Before joining the Company John Murphy was the Chief Technology Officer of LivaNova Neuromodulation, a global medical technology company (2015 to 2020). John Murphy holds a PhD in Systèmes de production et robotique at EPFL, Switzerland.

Mr. H.L. (Hendrik) Lambert (born 1965, Belgium) is the Company's Vice President Clinical, Regulatory and Quality (2016). Before joining the Company, Hendrik Lambert was the Vice President for Clinical and Regulatory Affairs at Endosense (St. Jude Medical, now Abbott). Hendrik Lambert holds a PhD in Biomedical Engineering from the Ghent University, Belgium.

Board Committees

The board shall have three committees:

- a) the Audit Committee;
- b) the Compensation Committee; and,
- c) the Nomination and Corporate Governance Committee.

Each of these committees will have a charter on its role, responsibility and functioning, which charters will be in effect ultimately on the First Trading Date. These committees consist of Non-Executive Directors who are appointed to the committees by the Board. The committees report their findings to the Board, which is ultimately responsible for all decision-making.

Audit Committee

According to the charter of the Audit Committee, the Audit Committee is charged with, and shall be able to pass resolutions to, *inter alia* the following matters:

- a) monitoring the Board with respect to:
 - i. the relations with, and the compliance with recommendations and follow-up of comments made by, the internal audit function and the external auditor,
 - ii. the Company's funding,
 - iii. the application of information and communication technology by the Company, including risks relating to cybersecurity; and
 - iv. the Company's tax policy;
- b) issuing recommendations concerning the appointment and the dismissal of the head of the internal audit function, as relevant, and reviewing and discussing the performance of the internal audit function;
- c) reviewing and discussing the Company's audit plan, including with the internal audit function and the external auditor;
- d) reviewing and discussing the essence of the audit results, also with the internal audit function, including:
 - i. flaws in the effectiveness of the Company's internal risk management and control systems (the "**Internal Controls**");
 - ii. findings and observations with a material impact on the Company's risk profile; and

- iii. failings in the follow-up of recommendations made previously by the internal audit function;
- e) monitoring the audit of the Company's annual accounts and annual report and the Company's financial reporting processes, and making proposals to safeguard the integrity of such processes;
- f) reviewing and discussing the effectiveness of the design and operation of the Internal Controls with the Board, the CEO and the CFO, including:
 - i. identified material failings in the Internal Controls; and
 - ii. material changes made to, and material improvements planned for, the Internal Controls;
- g) reviewing and monitoring the independence of the external auditor, also considering any non-audit services rendered by the external auditor; and
- h) submitting proposals to the Board concerning the external auditor's engagement to audit the Company's financial statements, including the scope of the audit, the materiality standard to be applied and the external auditor's fees.

The members of the Audit Committee shall be appointed and dismissed by the Board. More than half of all its members, including the chairperson, shall be independent within the meaning of the Dutch Corporate Governance Code. At least one committee member must have competence in accounting and/or auditing. The Audit Committee shall meet as often as it determines is appropriate to carry out its responsibilities and each meeting shall be presided over by the chairperson and, in the absence of the chairperson, one of the other members shall be designated as the acting chairperson of the meeting.

The Audit Committee is expected to consist of three members, being: Ian Curtis, Patrick Van Beneden and Fredericus Colen. Ian Curtis will serve as chairperson of the Audit Committee.

Compensation Committee

According to the charter of the Compensation Committee, the Compensation Committee is charged with, and shall be able to pass resolutions relating to, *inter alia* the following matters:

- a) submitting proposals to the Board concerning changes to the Company's compensation policy, as relevant;
- b) submitting proposals to the Board concerning the compensation of individual Directors, at least covering:
 - i. the compensation structure,
 - ii. the amount of the fixed and variable compensation components,
 - iii. the applicable performance criteria,
 - iv. the scenario analyses that have been carried out,
 - v. the pay ratios within the Company's group,
 - vi. the views of the Director concerned with regard to the amount and structure of his own compensation; and
- c) the preparation of the Company's compensation report for the Board.

The members of the Compensation Committee shall be appointed and dismissed by the Board. More than half of all committee members shall be independent within the meaning of the Dutch Corporate Governance Code. The committee shall meet as often as it determines is appropriate to carry out its

responsibilities and each meeting shall be presided over by its chairperson and, in the absence of the chairperson, one of the other members shall be designated as the acting chairperson of the meeting.

The Compensation Committee is expected to consist of three members, being: Jan Øhrstrøm, Roel Bulthuis and Fredericus Colen. Jan Øhrstrøm will serve as chairperson of the Compensation Committee. In deviation from the Dutch Corporate Governance Code, the Compensation Committee shall be chaired by the Chairman of the Board. The Board considered that the experience and continuity of Jan Øhrstrøm being chairperson of the Compensation Committee outweighs the disadvantages of him also being the Chairperson of the Board.

Nomination and Corporate Governance Committee

According to the charter of the Nomination and Governance Committee, the Nomination and Governance Committee is charged with, and shall be able to pass resolution relating to, the following matters:

- a) drawing up selection criteria and appointment procedures for the Directors;
- b) reviewing the size and composition of the Board and submitting proposals for the composition profile of the Board;
- c) reviewing the functioning of individual Directors and reporting on such review to the Board;
- d) drawing up a plan for the succession of Directors;
- e) submitting proposals for (re)appointment of Directors; and
- f) supervising the policy of the Board regarding the selection criteria and appointment procedures for the Company's senior management and executive officers.

The committee members shall be appointed and dismissed by the Board. More than half of all members shall be independent within the meaning of the Dutch Corporate Governance Code. The committee shall meet as often as it determines is appropriate to carry out its responsibilities and each meeting shall be presided over by its chairperson and, in the absence of the chairperson, one of the other members shall be designated as the acting chairperson of the meeting.

The Nomination and Corporate Governance Committee is expected to consist of three members, being: Jan Øhrstrøm, John de Koning and Regina Hodits. Jan Øhrstrøm will serve as chairperson of the Nomination and Corporate Governance Committee. In deviation from the Dutch Corporate Governance Code, not more than half of the committee members is "independent" within the meaning of the Dutch Corporate Governance Code. The Board considered that the experience and continuity of John de Koning and Regina Hodits outweigh the disadvantages of them not being "independent".

Diversity

On 28 September 2021, a bill (*Wetsvoorstel inzake evenwichtige man vrouw verhouding in de top van het bedrijfsleven*) introducing stricter gender diversity measures was adopted by the Dutch Senate of the Dutch House of Representatives (*Eerste Kamer*). The bill is currently expected to enter into force on 1 January 2022. Once the bill enters into force, Dutch listed companies with a relevant listing, such as the Company, will have to comply with a quota of at least one-third for both women and men on supervisory boards. In a one-tier board, this one-third quota shall be applicable to non-executive directors. The quota will apply to new appointments, i.e., companies can reappoint a supervisory or non-executive director without complying with the one-third quota in respect of such re-appointment, but only where this happens within eight years after the year of the supervisory or non-executive director's first appointment. A new appointment not in accordance with the one-third quota will in principle be regarded as null and void (*nietig*). As a result, the person in question will not become a supervisory or non-executive director of the Company.

The Company would not be compliant with these rules as of the First Trading Date if the bill would be enacted in the form as it currently reads on the date of this Prospectus, as the Board would initially be comprised of 8 male Directors and 1 female Director as of the First Trading Date. The Company

has retained a leading medical technology search firm to assist in its efforts to recruit independent Directors with backgrounds that would help it satisfy independence and diversity measures within two years of the First Trading Date.

Diversity Policy

The Board will adopt a diversity policy with respect to the composition of the Board that will be effective ultimately on the First Trading Date. The policy will address concrete objectives relating to diversity and the diversity aspects relevant to the Company (e.g. nationality, age, gender, education and background). The Company will disclose 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 €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 at the Settlement Date, 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, 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 will have a direct or indirect beneficial interest in Ordinary Shares on the Settlement Date. 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
- Roel Bulthuis has been designated as Non-Executive Director by INKEF Capital, a major Shareholder of the Company at the date of the Prospectus.
- John de Koning has been designated as Non-Executive Director by LSP V Coöperatieve U.A., a major Shareholder of the Company at the date of the Prospectus.
- Ian Curtis has been designated as Non-Executive Director by NRT Holdings LLC, a major Shareholder of the Company at the date of the Prospectus. Mr Ian Curtis is a director of (i) the Christopher and Dana Reeve Foundation, (ii) the International Spinal Research Trust, and (iii) Neurokinex Charitable Trust. Ian Curtis is not a representative of NRT at the date of this Prospectus.
- Regina Hodits has been designated as Non-Executive Director by Wellington Partners Life Science Venture Capital Consulting GmbH, a major Shareholder of the Company at the date of the Prospectus.
- Patrick Van Beneden has been designated as Non-Executive Director by Gimv NV, 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.

Independency of Board members

At the date of this Prospectus the Board consists of nine members, eight of which are Non-Executive Directors. At the date of this Prospectus – and therefore prior to the closing of the Offering -, five 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 deemed "not independent" within the meaning of the Dutch Corporate Governance Code as he is the Chief Science Officer of the Company and receives personal compensation for such role. Regina Hodits and John de Koning, Roel Bulthuis and Patrick Van Beneden are deemed "not independent" within the meaning of the Dutch Corporate Governance Code as they are representatives of major shareholders (being Wellington, LSP, Inkef, NRT and GIMV) holding at least 10% of the shares in the Company at the date of this Prospectus. These four major Shareholders have a long-term interest in the Company and were willing to back this up by making senior partners/staff with relevant knowledge and experience available to the Company. The Board considers that Regina Hodits and John de Koning, Roel Bulthuis and Patrick Van Beneden fit the intended profile of the Supervisory 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. As a result of the closing of the Offering the shareholder interests of one or more of Wellington, LSP and/or GIMV could fall below 10%, in which case the representatives that such party has nominated to the Board would become "independent" within the meaning of the Code.

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 Ohrstrom), 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.

Board Remuneration

The remuneration of Directors shall be determined by the Board with due observance of the Company's compensation policy (the "**Compensation Policy**") and applicable statutory requirements. The Compensation Policy will be adopted on the First Trading Date by, and may only be amended by, the General Meeting.

The Compensation Committee shall prepare its recommendations relating to the Compensation Packages in accordance with the Compensation Policy and any such recommendation shall cover the compensation structure, the amount of the fixed and variable compensation components, the performance criteria used, the scenario analyses that have been carried out and the relevant internal pay ratio(s).

A proposal with respect to remuneration schemes in the form of Ordinary Shares or rights to Ordinary Shares in which Directors may participate is subject to approval by the General Meeting by simple majority of votes cast. Such a proposal must set out at least the maximum number of Ordinary Shares or rights to subscribe for Ordinary Shares to be granted to the Directors and the criteria for granting or amendment.

The Company's Compensation Policy will authorize the Board, at the recommendation of the Compensation Committee to determine the amount, level and structure of the remuneration packages of the Directors (the "**Compensation Packages**").

The Compensation Committee shall prepare its recommendations relating to the Compensation Packages in accordance with the Compensation Policy and any such recommendation shall cover the compensation structure, the amount of the fixed and variable compensation components, the performance criteria used, the scenario analyses that have been carried out and the relevant internal pay ratio(s). These Compensation Packages may consist of a mix of fixed and variable compensation

components, including base salary, short-term incentives, long-term incentives, fringe benefits, change of control benefits, severance pay and pension arrangements. The amount, level and structure of these Compensation Packages should contribute to the Company's strategy, long-term interests and sustainability by (i) attracting, retaining and motivating highly skilled individuals with the qualities, capabilities, profile and experience needed to support and promote the growth and sustainable success of the Company and its business, (ii) driving strong business performance, promoting accountability and incentivizing the achievement of short and long-term performance targets with the objective of furthering long-term value creation in a manner consistent with the Company's identity, mission and values, (iii) assuring that the interests of the Directors are closely aligned to those of the Company, its business and its stakeholders and (iv) ensuring overall market competitiveness of the Compensation Packages, while providing the Board sufficient flexibility to tailor the Company's compensation practices on a case-by-case basis, depending on the market conditions from time to time. In determining the amount, level and structure of Compensation Packages for the Directors, the Board shall consider, among other matters (i) the employment conditions of the employees of the Company and its subsidiaries, including their compensation and the development of relevant internal pay ratios, compared to those of the Directors, in order to strive for a balanced and fair remuneration, (ii) scenario analyses carried out in advance, (iii) the financial and non-financial performance indicators relevant to the Company's long-term strategy with due observance of the risks for the Company's business which may result from variable compensation and (iv) relevant market information such as industry standards and peer group data, pre-existing arrangements with the Directors, the respective positions which the Directors serve within the Company's organization and any remuneration payable by the Company or any of its subsidiaries to the Directors in any other capacity.

The Company must re-submit the remuneration policy to the General Meeting for approval at least once every four years as of the First Trading Date. Under the Dutch law, (re)approval of the remuneration policy is subject to a majority of at least 75% of the votes cast, unless a lower majority is required by the Articles of Association. Pursuant to the Articles of Association, the resolution to approve the remuneration policy is subject to approval by the General Meeting by simple majority of votes cast. In addition, the Company will submit the implementation of the remuneration policy over the relevant financial year, in the form of a remuneration report, to an advisory vote at each annual General Meeting. The aggregate annual amount or value of the variable compensation components shall not exceed 50% of the compensation components comprised in that Compensation Package.

Executive Director Remuneration

The remuneration of the Executive Director (and any other future Executive Directors) will be determined by the Board, at the recommendation of the Compensation Committee, in accordance with the Compensation Policy that is to be adopted prior to the First Trading Date.

Based on the Compensation Policy, the remuneration of Executive Directors may comprise the following components, providing for an appropriate balance between fixed and variable remuneration over the short and longer term, which is directly linked to business performance, shareholder value-creation and supporting the Company's strategy, including its long-term interests and its sustainability:

- Fixed annual base salary;
- Short-term variable compensation;
- Long-term variable compensation;
- Fringe benefits;
- Change of control benefits;
- Severance pay; and
- Pension.

The description below sets out the general aspects of the Compensation Policy applicable to Executive Directors; not all elements listed below are required to be part of the Compensation Package of an Executive Director.

*Fixed annual base salary ("**Annual Base Pay**")*

An Executive Director is entitled to an Annual Base Pay, including holiday allowance and other local statutory requirements (as applicable). The Annual Base Pay provides the main fixed element of the Compensation Package and is set at a level to attract and retain the caliber of the Executive Director required to devise and execute the Company's strategy.

*Short-term variable compensation ("**STI**") and long-term variable compensation ("**LTI**")*

An Executive Director is entitled to an STI and an LTI. The mix of STI and LTI in a Compensation Package should support both long-term value creation and the achievement of short-term Company objectives, including by (i) contributing to corporate social responsibility, (ii) rewarding the achievement of strategic milestones for the Company and its business, (iii) providing award opportunities in consideration for substantial contributions to the success of the Company and its business and/or (iv) promoting and incentivizing continued service of the Directors within the Company's organization.

With respect to all STI and LTI awards, subject to the terms of any existing contractual arrangements with the Executive Director concerned, the Board shall (i) set and, if appropriate, amend the applicable financial and/or non-financial metrics, targets, objectives and/or conditions, including corporate social responsibility metrics, and their respective weighting, in each case in accordance with the Compensation Policy, (ii) set and, if appropriate, amend the maximum amount for any cash incentive and the maximum number of securities underlying any equity incentive which may be awarded as part of an STI or LTI and (iii) determine the extent to which the applicable targets, objectives and/or conditions are achieved and the extent to which incentive awards vest, using clear, pre-defined, objective and verifiable methods.

Equity-based STI or LTI awards shall be subject to the following rules: (i) unvested and vested but unexercised awards shall expire no later than ten years after the date of grant, (ii) shares acquired by Executive Directors under such awards must be retained by them for a period of at least five years, provided that shares may be sold and transferred in order to facilitate a cashless exercise of such awards (also with respect to applicable taxes) and provided further that the Board may decide that no retention period applies to some or all of such awards.

Pension and fringe benefits

At the discretion of the Board (a) the Company shall (i) provide a pension arrangement for the Executive Directors with a pensionable salary that is based on their annual gross base salary and (ii) contribute to the pension premiums concerned up to an amount or percentage as determined by the Board (with the Executive Director concerned being obliged to pay the remaining part of such premiums) or (b) the Executive Directors shall be eligible to participate in the collective pension scheme that the Company has taken out for the benefits of its employees. Furthermore, an Executive Director is eligible to receive customary fringe benefits (other than the pension benefits described above).

Severance arrangements

The Executive Directors may be eligible for such severance payment upon termination of office as determined by the Board from time to time. An Executive Director's severance pay shall not exceed his annual gross base salary and shall not be paid if his service agreement is terminated early at the initiative of the Executive Director concerned, or in the event of seriously culpable or negligent behavior on the part of the Executive Director concerned.

Adjustment to variable remuneration

The Board may adjust the amount or value of an STI or LTI awarded to an Executive Director to a suitable level, if payment or satisfaction of that award would be unacceptable under the standards of reasonableness and fairness.

The Company may further reclaim payments made (in cash, in kind or in the form of securities) under an STI or LTI award, in whole or in part, to the extent that such payment was made on the basis of incorrect information regarding the achievement of the targets, objectives and/or conditions underlying the award or regarding the circumstances on which the award was dependent. The Non-Executive Directors, or a special representative designated by the General Meeting, may demand such repayment on the Company's behalf.

Remuneration for the Executive Director in 2020

The total amount of remuneration of Dave Marver for the financial year 2020 comprised of EUR 257,344 (including a bonus of EUR 50,000, holiday allowance and cost of living-, car- and housing-allowance). The Company paid EUR 4,808 as pension contribution for Dave Marver. In addition, the Company accounted for a share based payment expense of EUR 745,949 for Dave Marver in the financial year 2020.

Non-Executive Director Remuneration

The Compensation Packages of the Non-Executive Directors should reflect the time spent and responsibilities of their role on the Board.

Based on the Compensation Policy, the remuneration of Non-Executive Directors may comprise the following components, providing for an appropriate balance between fixed and variable remuneration over the short and longer term, which is directly linked to business performance, shareholder value-creation and supporting the Company's strategy, including its long-term interests and its sustainability:

- Annual fees (retainer fees, committee membership fees, chairperson fees and meeting attendance fees);
- STI;
- LTI; and
- Change of control benefits.

Remuneration for the Non-Executive Directors 2020

The total amount of remuneration for the Non-Executive Directors for the financial year 2020 comprised of EUR 326,071. In addition, the Company accounted for an amount of EUR 618,800 for shared based payment expenses in relation to the Non-Executive Directors in the financial year 2020.

Remuneration for the Management Team 2020

The total amount of remuneration for the Management team (for the avoidance of doubt excluding Dave Marver) for the financial year 2020 comprised EUR 776,997 (including holiday allowance and an aggregate bonus of EUR 141,211). The Company paid EUR 26,345 as pension contribution for the Management Team. In addition, the Company accounted for an amount of EUR 678,638 for share based payment expenses in relation to the Management Team in the financial year 2020.

Interests of the Directors and the Management Team

The table below provides an overview of the number of Shares each member of the Board and Management Team directly or indirectly holds immediately prior to the Settlement of the Offer (hence after the Reverse Stock Split has been effectuated). At the date of this Prospectus the Company does not have any Options issued to its Board or Management Team.

Name	Position	Number of shares	Number of Options
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Jan Øhrstrøm	Non-Executive Director and Chairperson	190,962	-
Fred Colen	Non-Executive Director	47,740	-
Grégoire Courtine	Non-Executive Director and CSO	763,850	-
Dave Marver	CEO	954,814	-
Marko Jansen	CFO/COO	210,962	-
John Murphy	CTO	381,926	-
Hendrik Lambert	VP Clinical Regulatory and Quality	191,674	-

Employment, Service and Severance Agreements

Ultimately on the First Trading Date, each of the Directors will enter into a services agreement (*overeenkomst van opdracht*) with the Company. The services agreement for the Executive Directors (or in case of Dave Marver in the employment agreement with Onward S.A.) may contain severance provisions which provide that upon termination of the agreement at the initiative of the Company (including situations where (i) the Board resolves not to nominate the Executive Director for reappointment by the General Meeting or (ii) the Executive Director is dismissed as Director by the General Meeting), except for urgent cause, such Executive Director shall be entitled to severance pay equal to 100% of the last earned gross fixed annual compensation, to be paid within one month following the termination of the services agreement. The Executive Director shall not be entitled to the aforementioned severance pay in case of a termination of the services agreement following a period of two years of illness.

The services agreements with the Non-Executive Directors do not contain any severance provisions.

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. No indemnification under the Articles of Association shall be given to an indemnified person:

- 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 person that led to the financial losses, damages, expenses, suit, claim, action or legal proceedings as described above 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 person);
- to the extent that his or her 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 person against the Company, except for proceedings brought to enforce indemnification to which he or she is entitled pursuant to the Articles of Association, pursuant to an agreement between such indemnified person 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 person; and

- for any financial losses, damages or expenses incurred in connection with a settlement of any proceedings effected without the Company's prior consent.

Under the Articles of Association, the Board may stipulate additional terms, conditions and restrictions in relation to the indemnification described above.

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 68. Contribution rates vary depending on age from 5.77% to 25.59% of pension base. Pensionable salary is maximized to EUR 110,111 (2020). Offset (franchise with respect to DC accrual) is EUR 14,167 (2020). 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 has not 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 partially taken as a lump sum, at an employee's discretion). 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.

Employees

The table below provides an overview of the total numbers of FTEs the Company employed, subdivided by functional category:

Segment	31 2020	December 2019	31 2018
Science	0.2	0.2	0.2
Development	28.1	38.4	29.2
Clinical and Regulatory	14.0	8.0	4.0
Marketing and Market Access	1.0	1.0	1.0
Patents and related	1.0	1.0	1.0
General and administrative	10.7	9.9	7.1
Total	55.0	58.5	42.5

Share incentive plan for employees

Long-Term Incentive Plan

In order to incentivize the Company's directors and employees, the Board will adopt the Long-Term Incentive Plan Onward Medical N.V. (the "**LTIP**") for employees, consultants, directors and officers of the Company and/or a Subsidiary prior to the completion of this offering. The LTIP will become effective upon the conversion from Onward Medical B.V. into Onward Medical N.V., which will occur ultimately on the First Trading Date. The LTIP will provide for the grant of options, SARs, Shares of Restricted Stock, RSUs, Performance Award, Other Awards, or a combination of the foregoing (all as defined in the LTIP, together the "**Awards**") intended to (i) attract, retain and motivate the participants of the LTIP with the qualities, skills and experience needed to support and promote the growth and sustainable success of the Company and its business; and (ii) incentivise the participants of the LTIP to perform at the highest level and to further the best interests of the Company, its business and its stakeholders.

Securities to be Offered

Shares underlying Awards ("**Plan Shares**") which are not Replacement Awards,¹³⁰ irrespective of whether such Awards have been exercised or settled, may not represent more than 10% of the Company's issued share capital immediately following the closing of the initial public offering of Shares by the Company.

The total number of ordinary shares reserved for issuance under the LTIP shall be increased annually on 1 January of each calendar year during the term of the LTIP, starting in 2022, by the lesser of (i) 5% of the Company's issued share capital on the last day of the immediately preceding calendar year or (ii) such lower number as may be determined by the Board (which number may also be nil). Plan Shares, except for Replacement Awards, which expire, which are cancelled or otherwise terminated, or which are exercised or settled in cash or assets in lieu of Plan Shares, shall again be available under the LTIP and shall not be counted towards the limit imposed.

Administration

The LTIP will be administered by the Board, except for all matters relating to the administration or operation of the LTIP, in which case the Compensation Committee will administer the LTIP (as applicable, the "**Committee**"). The Committee has broad discretion to administer the LTIP, including the power to determine the eligible individuals to whom Awards will be granted, the number and type of Awards to be granted and the terms and conditions of Awards.

Eligibility

The employees, consultants, directors and officers of the Company will be eligible to receive awards under the LTIP.

Types of Awards

Options and SARs. The Company may grant options to eligible persons. The Company may also grant stock appreciation rights ("**SARs**"). A SAR is the right to receive an amount equal to the excess of the fair market value of one Ordinary Share on the date of exercise over the grant price of the SAR, payable in shares of common stock, in cash, or in any combination of the two, as determined by the Committee. SARs may be granted in connection with, or independent of, other Awards. The exercise price of an option or SAR generally cannot be less than 100% of the fair market value of an Ordinary Share on the date on which the option or SAR is granted and the option or SAR must not be exercisable for longer than ten years following the date of grant. The Committee will have the discretion to determine other terms and conditions of an option or SAR award.

Restricted Stock Awards. A restricted stock award is a grant of ordinary shares subject to the restrictions on transferability and risk of forfeiture imposed by the Committee. As determined by the Committee and specified in the applicable award agreement, the holder of a restricted stock award may have rights as a shareholder, including the right to vote the Ordinary Shares subject to the restricted stock award or to receive dividends on the Ordinary Shares subject to the restricted stock

¹³⁰ A "**Replacement Award**" is an Award granted in assumption of, or in substitution or exchange for, long-term incentive awards previously granted by a person acquired (or whose business is acquired) by the Company or a Subsidiary or with which the Company or a Subsidiary merges or forms a business combination, as reasonably determined by the Committee.

award during the restriction period. At the discretion of the Committee, dividends distributed prior to vesting may be subject to the same restrictions and risk of forfeiture as the restricted shares with respect to which the distribution was made.

Restricted Stock Units ("RSU"). An RSU is a right to receive Ordinary Shares. However, RSUs may be settled in Ordinary Shares, their cash equivalent or any combination of the foregoing, as determined by the Committee. RSUs may be subject to the restrictions, including a risk of forfeiture, imposed by the Committee. Dividend equivalents may be granted in connection with RSUs and may entitle a participant to receive cash or Ordinary Shares equal in value to dividends or other distributions paid with respect to a specified number of Ordinary Shares. At the discretion of the Committee, such dividend equivalents may be paid currently or credited to an account for the participant, settled in cash or ordinary shares and subject to the same restrictions and risk of forfeiture as the RSU with respect to which the dividend equivalents are granted.

Other Awards. Other Awards are awards which do not take the form of an Option, SAR, Share of Restricted Stock or RSU, and which may be denominated or payable in, valued in whole or in part by reference to, or otherwise based on or related to Ordinary Shares or factors which may influence the value of Ordinary Shares, including cash-settled financial instruments and financial instruments which are convertible into or exchangeable for Plan Shares.

Performance Awards. Performance Awards are cash or stock awards that are payable, are granted, vested or may be exercised contingent upon the attainment of certain performance goals during a specified performance period.

Certain Transactions

If any change is made to the Company's capitalization, such as a share split, reverse share split, redenomination of the nominal value, or as a result of a dividend or other distribution, reorganization, acquisition, merger, demerger, business combination or other transaction involving the Company or a Subsidiary, appropriate adjustments will be made by the Committee to the LTIP and any shares subject to an award under the LTIP.

If long-term incentive awards are granted in assumption of, or in substitution or exchange for, outstanding Awards in connection with a change of control and the Committee has determined that such awards are sufficiently equivalent to the outstanding Awards concerned, then such outstanding Awards shall be cancelled and terminated upon the replacement awards being granted to the Participants concerned.

If, in connection with a Change of Control, outstanding Awards are not replaced by long-term incentive awards as described in the paragraph above, or are replaced by long-term incentive awards which the Committee does not consider to be sufficiently equivalent to such outstanding Awards, then such Awards shall immediately vest and, where relevant, settle in full, unless the Committee decides otherwise.

Repayment and/or recoupment

Any rights, payments and benefits under any Award shall be subject to repayment and/or recoupment by the Company in accordance with applicable law, stock exchange rules and such policies and procedures as the Company may adopt from time to time.

Plan Amendment and Termination

The Committee may amend or terminate any award, award agreement or the LTIP at any time; however, shareholder approval will be required for any amendment to the extent necessary to comply with applicable law or exchange listing standards. Notwithstanding the foregoing, no amendment of the LTIP will materially impair a participant's rights under an outstanding award unless (i) the Company requests the consent of the affected participant, and (ii) such participant consents in writing.

Corporate Resolutions

It is expected that ultimately on the First Trading Date, a General Meeting resolution and Board resolution will be adopted in order to issue up to 11,665,791 Ordinary Shares (which assumes full exercise of the Increase Option and Over-Allotment Option) and to exclude all pre-emptive rights accruing to Shareholders in relation to the issuance of these Ordinary Shares. The issuance and the delivery of the Offer Shares will take place on the Settlement Date. See also "*The Offering—Timetable*" and "*The Offering—Payment and taxes*".

In addition, ultimately on the First Trading Date, the Board will be authorized to issue Ordinary Shares or grant rights to subscribe for Ordinary Shares for a period of 18 months following the First Trading Date and to limit or exclude the pre-emptive rights pertaining to such Ordinary Shares and rights. This authorization of the Board will be limited to: (i) up to a maximum of 10% of the Ordinary Shares issued and outstanding at the close of business on the Settlement Date for general purposes or, in case the Over-Allotment Option is exercised after the Settlement Date, at close of business on the date of the issuance of the Over-Allotment Shares, ; and in addition, (ii) up to a maximum of 10% of the Ordinary Shares issued and outstanding on the close of business on the Settlement Date or, in case the Over-Allotment Option is exercised after the Settlement Date, at close of business on the date of the issuance of the Over-Allotment Shares, , in connection with takeovers, mergers, demergers and strategic alliances. Such designations may be revoked at any time by the General Meeting.

The Board will be further authorized for a period of 18 months following the First Trading Date to cause the repurchase of Ordinary Shares (or depository receipts for Ordinary Shares) by the Company of up to 10% of the Company's issued share capital (determined as at close of business on the Settlement Date or, in case the Over-Allotment Option is exercised after the Settlement Date, at close of business on the date of the issuance of the Over-Allotment Shares), 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). The Board will be authorized for a period of 18 months following the First Trading Date to cause the repurchase of Preferred Shares, for a price which is higher than nil and does not exceed the nominal value of the Preferred Shares concerned, and provided that such Preferred Shares are fully paid-up.

Finally, the General Meeting shall authorize the Board prior to the First Trading Date to grant a call option for a period of five years after the conversion into Onward Medical N.V., to an independent foundation under Dutch law (if and when incorporated) (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, after the First Trading Date. This call option, if and when granted, shall be continuous in nature and can be exercised repeatedly on multiple occasions (see also "*Description of Share Capital—Anti-Takeover measures*")

Dutch Corporate Governance Code

The Dutch Corporate Governance Code, as amended, entered into force on, and applies to any financial year starting on or after, 1 January 2017 and finds its statutory basis in Book 2 of the DCC (the "**Dutch Corporate Governance Code**" or "**Code**"). The Dutch Corporate Governance Code will apply to the Company as it has its registered office in the Netherlands and its Ordinary Shares will be listed on Euronext on the First Trading Date.

The Dutch Corporate Governance Code is based on a "comply or explain" (*pas toe of leg uit*) principle. Accordingly, companies are required to disclose in their board report whether or not they are complying with the various best practice principles of the Dutch Corporate Governance Code that are addressed to the Board. If a company deviates from a best practice principle in the Dutch Corporate Governance Code, the reason for such deviation must be properly explained in its board report.

Deviations from Best Practice Principles of the Dutch Corporate Governance Code

The Company acknowledges the importance of good governance and is committed to adhering to the best practices of the Code as much as possible. As of the First Trading Date, the Company does not

comply with all best practice provisions of the Code. As of the First Trading Date, the Company's main deviations from the Code are summarized below:

- Best practice provisions 2.1.7 and 5.1.1: At the date of this Prospectus the Board consists of nine members, eight of which are Non-Executive Directors. At the date of this Prospectus (i.e. prior to the closing of the Offering), six of the Non-Executive directors are deemed "not independent" within the meaning of the Code. Prof. Courtine, one of the Company's founders, is deemed "not independent" within the meaning of the Dutch Corporate Governance Code as he is the Chief Science Officer of the Company and receives personal compensation for this role. Regina Hodits and John de Koning, Roel Bulthuis, Ian Curtis and Patrick Van Beneden are deemed "not independent" within the meaning of the Code as they are representatives of major shareholders (i.e. Wellington, LSP, Inkef, NRT and GIMV) holding at least 10% of the shares in the Company at the date of this Prospectus. These five major Shareholders have a long-term interest in the Company and were willing to back this up by making senior partners/staff with relevant knowledge and experience available to the Company. The Board considers that Regina Hodits and John de Koning, Roel Bulthuis, Ian Curtis and Patrick Van Beneden fit the intended profile of the Supervisory 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. As a result of the closing of the Offering one or more shareholder interests of Wellington, LSP and/or GIMV could fall below 10%, in which case the representatives that such party has nominated to the Board would become "independent" within the meaning of the Code.
- Best practice 2.3.4: The Code provides that the chairperson of the Compensation Committee should not be chaired by the Chairperson of the Board. In deviation from Code, the Compensation Committee shall not be chaired by the Chairperson of the Board. The Board considered that the experience and continuity of Jan Øhrstrøm being chairperson of the Compensation Committee outweighs the disadvantages of him also being the Chairperson of the Board.
- Best practice provision 3.3.2: The Code recommends against providing equity awards as part of the compensation of a Non-Executive Director. However, the Company expects to deviate from this recommendation and grant equity awards to its Non-Executive Directors.
- Best practice provision 3.3.3: The Code recommends that shares held by a Non-Executive Director in the company on whose board of directors they serve should be held as a long term investment. The Company's Compensation Policy does not include such requirement, and therefore shares held by a Non-Executive Director may not necessarily be held as a long-term investment.
- Best practice provision 4.3.3: Under the Articles of Association, Directors are to be appointed on the basis of a binding nomination prepared by the Board. This means that the nominee will be appointed to the Board, unless the General Meeting overrules the binding nature of the nomination (in which case a new nomination will be prepared for a subsequent General Meeting). The Articles of Association provide that the General Meeting can only resolve to overrule a binding nomination by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital. However, the Code recommends that the General Meeting should be capable of passing such resolution by a simple majority of votes cast, representing no more than one-third of the issued share capital.
- Best practice provision 4.3.3: Under the Articles of Association, Directors can only be dismissed by the General Meeting by simple majority of votes cast, provided that the Board proposes the dismissal. In other cases, the General Meeting can only pass such resolution by a two-thirds majority representing more than half of the issued share capital. However, the Code recommends that the General Meeting should be capable of passing such by simple majority, representing no more than one-third of the issued share capital.

The Company cannot exclude the possibility of deviating from additional provisions of the Code after the First Trading Date, in which case it will explain any such deviations in its board report as noted above.

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 in effect on the date of this Prospectus and the Articles of Association and the Board Rules each of which as they will be in effect ultimately on the First Trading Date. 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) will be available free of charge on the Company's website (<https://ir.onwd.com/corporate-governance/documents/articles-of-association>) as of the First Trading Date. See also "Management, Employees 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 the First Trading Date the Company will be converted into a public company with limited liability (*naamloze vennootschap*) with its statutory seat (*statutaire zetel*) in Amsterdam, the Netherlands, and will be 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 Security Identification Number ("**ISIN**") is NL0015000HT4.

Corporate Purpose

Pursuant to its Articles of Association, the objects of the Company are:

- to development 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 the development of 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

As of the date of this Prospectus, the issued share capital of the Company comprises of 4,806,221 ordinary shares O and 8,501,172 non-voting ordinary shares E with a nominal value of EUR 0.000003 each and 37,666,666 preference shares A with a nominal value of EUR 0.000001 each. The net asset value (total assets minus total liabilities) per share (pre Reverse Stock Split) as at 30 June 2021, being the date of the Interim Financial Statements, and calculated using the 50,974,059 shares issued and outstanding at that time, is -/- EUR 0.84 per share (post Reverse Stock Split -/- EUR 0.34 per share). The Offer Price per share assuming it is at the mid-point of the price range EUR 12.75. As the Company is a company incorporated as a private limited liability company (*besloten vennootschap met beperkte aansprakelijkheid*) under the laws of the Netherlands, the Company is not required to have, and does not have, an authorized share capital at the date of this Prospectus.

As part of the Corporate Conversion, (i) all outstanding non-voting ordinary shares E, ordinary shares O and preferred shares A shall be converted into Ordinary Shares on a 1:1 ratio, (ii) such Ordinary Shares shall be subject to a 5:2 Reverse Stock Split and (iii) the nominal value of all Ordinary Shares shall be increased to EUR 0.12. This will take place by means of the execution of a notarial deed of conversion and amendment, which will take place ultimately on the First Trading Date. This deed will be executed following the delivery of a Dutch auditor's statement confirming that, on a day within five months prior to the conversion, the shareholders' equity (*eigen vermogen*) at least equaled the paid-in part of our issued share capital as set forth in the deed.

After the Corporate Conversion but prior to Settlement the Company will issue shares to EPFL and to the Lenders under the Convertible Loan Agreement (see "*Convertible Loan Agreement*" under "*Shareholder Structure and related party transactions*" and "*EPFL Options*").

On the Settlement Date, the Company's authorized (*maatschappelijk kapitaal*) share capital will amount 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. 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.

The below table shows the number of issued and outstanding shares at the prospectus date, and immediately following the issuances of the Offer Shares, assuming the Offering is fully subscribed:

Shares as of the Prospectus Date	Shares immediately prior to the issuance of the Offer Shares ⁽¹⁾	Shares immediately following the issuance of the Offer Shares				
		Without exercise of the Increase and Over-Allotment Options	With exercise of the Increase Option	With exercise of the Over-Allotment Option	With exercise of the Increase and Over-Allotment Options	
Shares	50,944,547	23,901,597	29,801,597	30,981,597	30,686,597	32,043,597

(1) Assumes the Offer Price being at the mid-point of the Price Range, full conversion of the amounts under the Convertible Loan Agreement, effectuation of the Reverse Stock Split and issuance of EPFL shares and cancellation of certain E shares and ordinary shares as set out in History of Share Capital. This will not have a dilutive impact on new investors.

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.

On the Settlement Date, all of the issued Ordinary Shares will be fully paid-up. On the Settlement Date, there will be no convertible securities, exchangeable securities or securities with warrants in the Company. 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 pursuant to the Call Option Agreement (as defined below) if and when entered into) and the Over-Allotment Option. All of the Ordinary Shares represent capital in the Company. 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 will have any voting rights different from any other Shareholder.

History of Share Capital

Since 1 January 2018 and prior to Settlement, the following changes to the Company's share capital have taken place in accordance with the provisions in the DCC:

Date	Transaction	Increase / reduction of share Capital (EUR)	Number of Shares issued / cancelled	Class of Shares issued	Par value per Share (EUR)	Total existing Shares
Issued share capital on 4 December 2017						2,306,221 ordinary shares class O 2,500,001 ordinary shares class R 12,250,000 pref. shares class A 1,672,222 ordinary shares class E
3 September 2018	Capital increase	7.75001	7,750,001	Pref. shares class A	0.000001	2,306,221 ordinary shares class O 2,500,001 ordinary shares class R 20,000,001 pref. shares class A 1,672,222 ordinary shares class E
3 September 2018	Capital increase	2.583333	861,111	Ordinary shares class E	0.000003	2,306,221 ordinary shares class O 2,500,001 ordinary shares class R 20,000,001 pref. shares class A 2,533,333 ordinary shares class E

11 October 2019	Capital increase	5.999999	5,999,999	Pref. shares class A	0.000001	2,306,221 ordinary shares class O 2,500,001 ordinary shares class R 26,000,000 pref. shares class A 2,533,333 ordinary shares class E
11 October 2019	Capital increase	2.000001	666,667	Ordinary shares class E	0.000003	2,306,221 ordinary shares class O 2,500,001 ordinary shares class R 26,000,000 pref. shares class A 3,200,000 ordinary shares class E
14 October 2019	Cancellatio n of ordinary shares class R	7.5000003	2,500,001	Ordinary shares class R	0.000003	2,306,221 ordinary shares class O 26,000,000 pref. shares class A 3,200,000 ordinary shares class E
14 October 2019	Capital increase	4.999999	4,999,999	Pref. shares class A	0.000001	2,306,221 ordinary shares class O 30,999,999 pref. shares class A 3,200,000 ordinary shares class E
14 October 2019	Capital increase	1.666665	555,555	Ordinary shares class E	0.000003	2,306,221 ordinary shares class O 30,999,999 pref. shares class A 3,755,555 ordinary shares class E
14 October 2019	Capital increase	7.5	2,500,000	Ordinary shares class O	0.000003	4,806,221 ordinary shares class O 30,999,999 pref. shares class A 3,755,555 ordinary shares class E
14 October 2019	Capital increase	4.583333	4,583,333	Pref. shares class A	0.000001	4,806,221 ordinary shares class O 35,583,332 pref. shares class A

						3,755,555 ordinary shares class E
15 July 2020	Capital increase	1.25	1,250,000	Pref. shares class A	0.000001	4,806,221 ordinary shares class O 36,833,332 pref. shares class A 3,755,555 ordinary shares class E
15 July 2020	Capital increase	2.777778	925,926	Ordinary shares class E	0.000003	4,806,221 ordinary shares class O 36,833,332 pref. shares class A 4,681,481 ordinary shares class E
14 October 2020	Capital increase	0.208334	208,334	Pref. shares class A	0.000001	4,806,221 ordinary shares class O 37,041,666 pref. shares class A 4,681,481 ordinary shares class E
12 November 2020	Capital increase	0.625000	625,000	Pref. shares class A	0.000001	4,806,221 ordinary shares class O 37,666,666 pref. shares class A 4,681,481 ordinary shares class E
12 November 2020	Capital increase	0.277779	92,593	Ordinary shares class E	0.000003	4,806,221 ordinary shares class O 37,666,666 pref. shares class A 4,774,074 ordinary shares class E
2 June 2021	Capital Increase	11.181294	3,727,098	Ordinary Shares class E	0.000003	4,806,221 ordinary shares class O 37,666,666 pref. shares class A 8,501,172 ordinary shares class E
11 October 2021	Cancellation of non-voting ordinary shares E	0.088536	29,512	Ordinary Shares class E	0.000003	4,806,221 ordinary shares class O 37,666,666 pref. shares class A

						8,471,660 ordinary shares class E
First trading date	Cancellation of shares for rounding purposes to prepare for Reverse Stock Split	0.000052	22 Pref. shares class A and 10 Ordinary Shares Class E	Pref. shares class A and Ordinary Shares Class E, respectively	0.000001 and 0.000003, respectively	4,806,221 ordinary shares class O 37,666,644 pref. shares class A 8,471,650 ordinary shares class E
First trading date	Corporate Conversion of all existing shares into ordinary shares, effectuation of the 5:2 Reverse Stock Split and increase of nominal value to EUR 0.12 per share	Issued share capital will be increased as a consequence of the reverse stock split to a total of EUR 2,445,336.72	N/A	Ordinary Shares	0.12	20,377,806 ordinary shares

As at the date of this Prospectus, all issued and outstanding shares have been fully paid-up.

Anti-Takeover Measures

The General Meeting shall authorize the Board prior to the First Trading Date to grant a call option for a period of five years after the conversion into Onward Medical N.V., 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, after the First Trading Date. 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. After the First Trading Date, 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 our 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 our issued share capital, unless the dismissal is proposed by the Board,
- (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, including the preparation of a binding nomination for Board members as discussed above,
- (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.

Furthermore, the Board, under circumstances invoke a reasonable period of up to 180 days to respond to certain shareholder proposals or a 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*".

Reverse stock split and amendment of Articles of Association

On the date of this Prospectus, the Company is a Dutch private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*). Ultimately on the First Trading Date, the Company shall complete a corporate conversion in the course of which it will be converted into a public company under Dutch law (*naamloze vennootschap*) and the legal name will change to Onward Medical N.V. Therefore, investors in the Offering will only acquire, and this prospectus only describes the offering of Ordinary Shares with a nominal value of EUR 0.12 of Onward Medical N.V. (the "**Corporate Conversion**").

As part of the Corporate Conversion, (i) all outstanding non-voting ordinary shares E and preferred shares A shall be converted into Ordinary Shares on a 1:1 ratio, (ii) such Ordinary Shares shall be subject to a 5:2 reverse stock split (the "**Reverse Stock Split**") and (iii) the nominal value of all Ordinary Shares shall be increased to EUR 0.12. This will take place by means of the execution of a notarial deed of conversion and amendment, which will take place ultimately on the First Trading Date. This deed will be executed following the delivery of a Dutch auditor's statement confirming that, on a day within five months prior to the conversion, the shareholders' equity (*eigen vermogen*) at least equaled the paid-in part of our issued share capital as set forth in the deed.

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 Offering—Delivery, Clearing and Settlement*" in relation to the delivery, clearing and settlement of 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 Offer 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.

Ultimately on the First Trading Date, the Board will be authorized to issue Ordinary Shares or grant rights to subscribe for Ordinary Shares for: (i) up to a maximum of 10% of the Ordinary Shares issued and outstanding at the close of business on the Settlement Date or, in case the Over-Allotment Option is exercised after the Settlement Date, at close of business on the date of the issuance of the Over-Allotment Shares for general purposes; and, in addition, (ii) up to a maximum of 10% of the Ordinary Shares issued and outstanding on the Settlement Date or, in case the Over-Allotment Option is exercised after the Settlement Date, at close of business on the date of the issuance of the Over-Allotment Shares, in connection with takeovers, mergers, demergers and strategic alliances. 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.

Ultimately on the First Trading Date, the General Meeting and the Board will further adopt resolutions to issue the Offer Shares.

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.

Ultimately on the First Trading Date, the Board will be authorized for a period of 18 months from the First Trading Date 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 (see 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 will be authorized for a period of 18 months following the First Trading Date to cause the repurchase of Ordinary Shares (or depository receipts for Ordinary Shares) by the Company of up to 10% of the Company's issued share capital (determined as at close of business on the Settlement Date or, in case the Over-Allotment Option is exercised after the Settlement Date, at close of business on the date of the issuance of the Over-Allotment Shares), 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).

The Board will be authorized for a period of 18 months following the First Trading Date to cause the repurchase of Preferred Shares, for a price which is higher than nil and does not exceed the nominal value of the Preferred Shares concerned, and provided that such Preferred Shares are fully paid-up.

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.

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 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 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 Prospectus, 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). 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 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.

Temporary COVID-19 Act

As of the date of this Prospectus, under temporary Dutch legislation relating to the outbreak of the COVID-19 pandemic, the Board may extend the six-month period within which the annual General Meeting must be held by up to four months. In addition, the Board may decide that a General Meeting will only be held virtually, without physical attendance, provided that certain requirements are met.

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 European Directive 2004/25/EC, 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 attaining 0.2% 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 0.2% 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. 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. CET 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 Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014 on market abuse, and the regulations promulgated thereunder (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 (www.afm.nl/en/professionals/registers). 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 May 17, 2017 amending Directive 2007/36/EC 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 (*bevoordering 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-EU (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 will be 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 immediately prior to and after Settlement

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, both immediately prior to Settlement and immediately after Settlement, without and with full exercise of the Over-Allotment Option, assuming that each Current Shareholder does not subscribe for the Offer Shares (other than as part of the Subscription Commitments) and taking into account the shares issued upon conversion of the Convertible Loan Agreement and the issuance of the EPFL shares at the Offer Price minus 25% ultimately on the First Trading Date. For the purposes of the below table it has also been assumed that (a) the 5:2 reverse stock split has been effectuated, (b) the Offer Price is at the mid-point of the Price Range, (c) the Participating Investors will not participate in the Offering in addition to the Subscription Commitments that were provided by the Participating Investors (see also "*The Offering—Pre-commitments by the Participating Investors*"), and (d) the Participating Investors will be allocated new Shares for the full amount of their Subscription Commitments.

Shareholders	Ordinary Shares owned immediately prior to Settlement			Ordinary Shares owned immediately after Settlement								
	Amount	Share capital	Voting rights	Without exercise of the Over-Allotment Option			With full exercise of the Over-Allotment Option			With exercise of the Increase and Over-Allotment Options		
				Amount	Share capital	Voting rights	Amount	Share capital	Voting rights	Amount	Share capital	Voting rights
LSP V Coöperatieve U.A. ⁽¹⁾	3,420,068	14.3%	14.3%	3,654,593	12.3%	12.3%	3,654,593	11.9%	11.9%	3,654,593	11.4%	11.4%
Stichting Depository INKEF Investment Fund ⁽²⁾	3,419,896	14.3%	14.3%	3,654,421	12.3%	12.3%	3,654,421	11.9%	11.9%	3,654,421	11.4%	11.4%
Wellington Partners Nominee Ltd. ⁽³⁾	3,049,999	12.8%	12.8%	3,258,859	10.9%	10.9%	3,258,859	10.6%	10.6%	3,258,859	10.2%	10.2%
Gimv Investments H&C Netherlands 2016 B.V. ⁽⁴⁾	3,017,745	12.6%	12.6%	3,224,835	10.8%	10.8%	3,224,835	10.5%	10.5%	3,224,835	10.1%	10.1%
G-Therapeutics Founders S.a.r.l.	787,700	3.3%	3.3%	789,777	2.7%	2.7%	790,089	2.6%	2.6%	790,566	2.5%	2.5%
Stichting G-Therapeutics Participaties	2,663,560	11.1%	11.1%	2,663,560	8.9%	8.9%	2,663,560	8.7%	8.7%	2,663,560	8.3%	8.3%
G-Therapeutics Participaties B.V.	725,100	3.0%	3.0%	725,100	2.4%	2.4%	725,100	2.4%	2.4%	725,100	2.3%	2.3%
NRT Holdings LLC	3,666,666	15.3%	15.3%	3,666,666	12.3%	12.3%	3,666,666	11.9%	11.9%	3,666,666	11.4%	11.4%
InvestNL	1,086,875	4.5%	4.5%	1,086,875	3.6%	3.6%	1,086,875	3.5%	3.5%	1,086,875	3.4%	3.4%

LSP Management Group B.V., Wellington Partners Management Limited, INKEF Capital B.V., and Gimv N.V. are several of Europe's leading life science venture capital funds, who led the Series A financing.

⁽¹⁾ LSP Management Group B.V. holds its interest via LSP V Coöperatieve U.A.

⁽²⁾ INKEF Capital B.V. holds its interest via Stichting Depository INKEF Investment Fund..

⁽³⁾ Wellington Partners Management Limited holds its interest via Wellington Partners Nominee Ltd.

⁽⁴⁾ Gimv N.V. holds its interest via Gimv Investments H&C Netherlands 2016 B.V.

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 following is a summary of transactions with related parties as defined in IAS 24 'Related Parties Disclosure', in accordance with IFRS. Transactions between related parties are effected on the same terms, conditions and amounts as transactions between unrelated parties. The Group is, and has been, a party to various agreements and other arrangements with certain related parties, the most significant of which are described below.

- The two independent non-executive directors Jan Øhrstrøm and Fredericus Colen both receive a fee for their Board membership and upon request of the Company Fredericus Colen can get compensated for additional advisory services.
- The intercompany payable balance of the Company to its Swiss subsidiary, ONWARD MEDICAL SA., amounts to EUR 1.3 million as per 31 December 2020. This balance is unsecured and non-interest bearing.
- The intercompany receivable balance of the Company from its US subsidiary, ONWARD MEDICAL Inc. amounts to EUR 2.5 million as per 31 December 2020. This balance is unsecured and non-interest bearing.
- Prof. Courtine, one of the Founders, who is employed by EPFL, entered into a consultancy agreement with the Company in 2016 whereby he provides services to the Company in the role of CSO for one day a week.

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 the Board and 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 all related party transactions met this standard at the time they occurred and were carried out on arm's length terms.

Shareholders' Agreement

The current Shareholders and the Company have entered in a shareholders' agreement on 5 April 2016 which has been amended and restated from time to time lastly on 14 October 2019. (the "**Shareholders' Agreement**").

Pursuant to the Shareholder's Agreement, the holders of preference shares are entitled to certain registration rights. This registration right only applies if, subsequent to the Offering, the Company decides to list its shares on a United States stock exchange or any other stock exchange where the sale of shares is subject to the registration of these shares. In most European jurisdictions, including the Netherlands, it is not mandatory to register shares before these shares can be sold to the public. If the Company decides to pursue a subsequent listing of its Ordinary Shares in the United States or any other jurisdiction requiring registration before the closing of the Offering, the costs and expenses relating to the registration of the shares will on the basis of the Shareholders' Agreement be borne by the Company.

The Shareholder's Agreement further grants certain shareholders a binding nomination right for the appointment of Non-Executive Directors to the Board.

The Shareholder's Agreement will terminate upon the closing of the Offering.

Convertible Loan Agreement

On 20 April 2021, the Company and *among others* Invest-NL Capital N.V., LSP V Coöperatieve U.A., Stichting Depository INKEF Investment Fund Gimv Investments, Wellington Partners Nominee Ltd. and Olympic Investments Inc. (the "**Lenders**") entered into a convertible loan agreement (the "**Convertible Loan Agreement**") as amended from time to time, pursuant to which the Lenders (including Maven Investment Partners Ltd., that acceded to the Convertible Loan Agreement at a later date) have, as per 30 June 2021, made available to the Company a convertible loan of EUR 30 million (the "**Principal Amount**") in the aggregate. The Company intends to apply the proceeds of the loan towards product development, clinical assessment, and commercial preparation for the Company's ARC Therapy in accordance with the Company's business plan and budget. This is consistent with the use of proceeds of the Offering, albeit that the breakdown of the use of proceeds from the convertible loan may be different than that of the Use of Proceeds of the Offering as set out in "*Reasons for the Offering and Use of Proceeds*".

The outstanding portion of the Principal Amount bears a cumulative and compounding interest at a rate of 8% per annum. Under the Convertible Loan Agreement, the Offering is one of the qualified financing events triggering a conversion. Upon completion of the Offering, the outstanding Principal Amount plus accumulated interest shall be converted in full into new Ordinary Shares in the Company by way of set-off against such amount against the subscription price for the new Ordinary Shares. The subscription per new Ordinary Share shall equal the Offer Price minus a discount of 25%.

Each Lender shall have the right to subscribe for its pro rata portion of Shares in connection with the Offering on the same terms and conditions including in the Underwriting and at the Offer Price or the offer price in such IPO, so without any discount. Said pro rata portion is to be determined by the total of number of shares that would be outstanding if the entire Loan including accrued interest would have been converted into Conversion Shares immediately prior to the closing of the Offering or the IPO. The pro rata subscriptions, if any, shall be allocated entirely (see also. "*Pre-commitments by the Participating Investors*" for details of the Subscription Commitments Lenders).

Shareholders' Loans

Other than the Convertible Loan Agreement, no shareholder has any outstanding loan to or from the Company.

THE OFFERING

Introduction

The Company is offering up to a total of 5,900,000 Offer Shares (excluding the Increase Option and the Over-Allotment Option within a price range of EUR 11.75 to EUR 13.75 per Offer Share – the Offer Price Range – to raise approximately up to EUR 75.2 million (assuming an Offer Price at the mid-point of the Offer Price Range on the Prospectus Date).

The Company reserves the right, after consultation with the Underwriters, to increase the total number of Offer Shares by up to 20% (the "**Increase Option**"). In the event that the Increase Option is exercised in full, the maximum number of Offer Shares amounts to 7,080,000 which would raise approximately up to EUR 90.3 million.

The Company will grant the Stabilization Manager, on behalf of the Underwriters, the option, exercisable up to 30 calendar days after the First Trading Date, pursuant to which the Underwriters may require the Company to issue at the Offer Price up to 885,000 Over-Allotment Shares (or up to 1,062,000 Over-Allotment Shares in the event that the Increase Option is exercised in full), comprising up to 15% of the total number of Offer Shares sold in the Offering, to cover short positions resulting from any over-allotments made in connection with the Offering and conduct stabilization transactions (if any) (the "**Over-Allotment Option**").

In the event that the Over-Allotment Option is exercised in full the maximum number of Offer Shares amounts to 6,785,000 which would raise approximately up to EUR 86.5 million (assuming an Offer Price at the mid-point of the Offer Price Range on the date of this Prospectus).

In the event that the Increase Option and the Over-Allotment Option are both exercised in full the maximum number of Offer Shares amounts to 8,142,000 which would raise approximately up to EUR 103.8 million (in each case assuming an Offer Price at the mid-point of the Offer Price Range on the date of this Prospectus).

The Offering consists of (i) an initial public offering to retail investors in Belgium and an offering to Qualified Investors within the meaning of the Prospectus Regulation, (ii) a private placement in (a) the EEA (other than in Belgium) to certain Qualified Investors, (b) the United Kingdom to persons with professional experience in matters relating to investments falling within the definition of "investment professionals" pursuant to Article 19(5) of the Order, (c) Switzerland, to investors that qualify as "professional clients" within the meaning of the FinSA, and (iii) a private placement in the United States, to persons reasonably believed to be QIBs as defined in, and pursuant to, 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. The Offering outside of the United States will be made in accordance with Regulation S under the US Securities Act.

Pre-commitments by the Participating Investors

The Participating Investors have, by way of Subscription Commitments, irrevocably and conditional only on closing of the Offering, committed themselves to subscribe for new Shares in the Offering:

- whereby the Participating Shareholders, being LSP V Coöperatieve U.A. (3.98%), Stichting Depository INKEF Investment Fund (3.98%), Gimv Investments H&C Netherlands 2016 B.V. (3.51%) and Wellington Partners Nominee Ltd. (3.54%) (the "**Participating Shareholders**"), have, by way of subscription commitments, irrevocably and conditional only on closing of the Offering, committed themselves to subscribe for Offer Shares in the Offering for an aggregate amount representing up to 15% of the Offered Shares (the "**Subscription Commitments Shareholders**") such commitment capped at an offer size of EUR 100 million, in which case the Subscription Commitments Shareholders shall be EUR 15 million;
- whereby the lenders who have made use of their pro rata subscription rights under the Convertible Loan Agreement, being Dave Marver, Jan Øhrstrøm, John Murphy, Hendrik

Lambert and a group of smaller lenders that do not qualify for disclosure under the Prospectus Regulation) (the "**Participating Lenders**"), have, by way of subscription commitments, irrevocably and conditional only on closing of the Offering, committed themselves for an aggregate amount representing up to 2.4% of the Offer Shares in the Offer at the Offer Price (as defined below) (the "**Subscription Commitments Lenders**");

- whereby the Cornerstone Investors, being Öhman Fonder (EUR 5 million), Belfius Insurance NV/SA (EUR 5 million), AXA Investment Managers Paris (EUR 5.7 million) and smaller investor that does not qualify for disclosure under the Prospectus Regulation (each a "**Cornerstone Investor**" and together: the "**Cornerstone Investors**" and together with the Participating Shareholders and the Participating Lenders (the "**Participating Investors**") have committed in aggregate EUR 16.2 million (the "**Subscription Commitments Cornerstones**" and together with the Subscription Commitments Shareholders and the Subscription Commitment Lenders the "**Subscription Commitments**").

Each Cornerstone Investment is conditional on *among others* (i) the full allocation of the relevant commitment, and (ii) the maximum valuation of all outstanding shares in the Company, calculated as the number of all outstanding shares in the Company before the Offering ("pre-money") multiplied by the final Offer Price, not exceeding EUR 325 million. If the Settlement Date has not occurred on or before 31 December 2021, each Cornerstone Investor is entitled to terminate its respective Cornerstone Investment.

In the event of over-subscription of the Offering, in principle the Subscription Commitments Shareholders can be reduced in line with the allocation principles that will apply to the other Investors that will subscribe in the Offering. The Subscription Commitments Cornerstones Investors and the Subscription Commitments Lenders shall not be reduced but be allocated entirely.

The Participating Investors may also subscribe for or purchase additional Ordinary Shares in the Offer. Allocation of any such additional Ordinary Shares shall be determined by the Company, after consultation with the Joint Global Coordinators, as described in "*Allocation*".

Timetable

Certain key dates in connection with the Offering are summarized in the following table. These are all anticipated dates, which are subject to any unforeseen circumstances and to an extension of the Offering Period.

Date	Event
12 October 2021, 9:00 a.m. CET	Expected start of the Offering Period
19 October 2021, 4:00 p.m. CET	Expected end of the Offering Period for Retail Investors
19 October 2021, 4:00 p.m. CET	Expected end of the Offering Period for Institutional Investors
20 October 2021	Expected publication of the Offer Price and results of the Offering and communication of allocations
21 October 2021	Expected First Trading Date (listing and start of "if-and-when-issued-and/or-delivered" trading)
22 October 2021	Expected Closing Date (payment, settlement and delivery of the Offer Shares)

20 November 2021	Expected last possible exercise date of the Over-allotment Option
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The Company, in consultation with the Joint Global Coordinators, reserves the right to extend the Offering Period. In the event of an extension of the Offering Period, these dates will be amended and published through a press release, which will also be posted on the Company's website and (if required) in a supplement to this Prospectus that is subject to the approval of the AFM.

Any extension of the timetable for the Offering will be published in a press release at least three hours before the end of the original Offering Period, provided that any extension will be for a minimum of one full business day. In any event, the Offering Period will be at least six business days.

Offer Price and Number of Offer Shares

The Offer Price will be a single price in euro, exclusive of the tax on stock exchange transactions, if applicable (see "*Taxation*"), and costs, if any, charged by financial intermediaries for the submission of applications, will apply to all investors, whether Retail Investors (as defined below) or Institutional Investors (as defined below).

The Offer Price will be determined within the Price Range on the basis of a book-building process in which only Institutional Investors can participate, taking into account various relevant qualitative and quantitative elements, including but not limited to the number of Offer Shares for which subscriptions are received, the size of subscription orders received, the quality of the investors submitting such subscription orders and the prices at which the subscription orders were made, as well as market conditions at that time.

The indicative Price Range has been determined by the Company in agreement with the Underwriters, taking into account market conditions and factors including but not limited to:

- the condition of the financial markets;
- the Company's financial position;
- qualitative assessment of the demand for the Offer Shares; and
- all other factors deemed relevant.

The actual number of Offer Shares issued by the Company in the Offering will only be determined after the Offering Period and will be published by way of a press release of the Company, simultaneously with the publication of the Offer Price and the allocation of Shares to Retail Investors. Such publication is currently expected to be made on or about 20 October 2021 and in any event no later than the first business day after the end of the Offering Period.

There is no minimum amount for the Offering. If not all of the Offer Shares are subscribed for in the Offering, the net proceeds from the Offering could be limited, all or in part, to the net proceeds from Subscription Commitments. The Company reserves the right to withdraw the Offering or suspend the Offering Period (see "*Withdrawal of the Offering or suspension of the Offering Period*" below) or to reduce the maximum number of Offer Shares at any time prior to the allocation of the Offer Shares. Any withdrawal of the Offering will be published by means of a press release. In the event of a withdrawal of the Offering, all orders received will automatically be cancelled and withdrawn, and investors will not have any claim to the delivery of the Offer Shares or any compensation.

Change of the Offer Price Range or Number of Offer Shares

The Offer Price Range is an indicative price range. The Company, after close consultation with the Joint Global Coordinators, reserves the right to change the Offer Price Range, to set the Offer Price

outside the Price Range and/or to increase or decrease the maximum number of Offer Shares prior to Allocation. In the event the lower limit of the Price Range is decreased or the Offer Price is set below the lower end of the Price Range, or in the event the higher limit of the Price Range is increased or the Offer Price is set above the higher end of the Price Range, this will be published in a supplement to the Prospectus. In the event of publication of a supplement to this Prospectus, and if required by law, investors will have the right to withdraw their orders made prior to the publication of the supplement. Such withdrawal must be done within the time period set forth in the supplement (which shall not be shorter than three business days after publication of the supplement). Any change in the number of Offer Shares and/or the Offer Price Range will be announced in a press release that will be posted on the Company's website. Upon a change of the number of Offer Shares, references to Offer Shares in this Prospectus should be read as referring to the amended number of Offer Shares and references to Over-Allotment Shares should be read as referring to the amended number of Over-Allotment Shares.

Retail Investors can only acquire the Offer Shares at the Offer Price and are legally bound to acquire the number of Offer Shares indicated in their subscription order at the Offer Price, unless (i) the Offering has been withdrawn in which case the subscription orders will become null and void, or (ii) in the event of the publication of a supplement to this Prospectus, and if required by law, in which case the Retail Investors will have the right to withdraw their orders made prior to the publication of the supplement exercisable within at least three business days after the publication of the supplement (see "*Right to withdraw*" below).

Offering Period

The Offering Period will begin on 12 October 2021 and is expected to close no later than 4:00 p.m. (CET) on 19 October 2021, subject to the possibility of an extension, provided that the Offering Period will in any event be open for at least six business days. This Prospectus will be made available as of the first calendar day of the Offering Period. The Offering Period can be closed, at the earliest, six business days after the start of the Offering Period and, hence, prospective investors can submit their orders at least during six business days after the start of the Offering Period.

The subscription period for the retail offering is expected to end at 4:00 p.m. on 19 October 2021, the same day as the end of the institutional book-building period.

Any extension of the Offering Period will be announced by means of a press release by the Company, and the dates for each of pricing, allocation, publication of the Offer Price and the results of the Offering, "as-if-and-when-issued-and/or-delivered" trading and closing of the Offering will in such case be adjusted accordingly.

In the event the Offering Period is extended with more than five business days, or 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 Offer Shares, arises or is noted between the date of this Prospectus and the First Trading Date, a supplement to this Prospectus will be published in accordance with relevant provisions under the Prospectus Regulation. Such a supplement will be subject to the approval by the AFM in accordance with the Prospectus Regulation, will be notified to the FSMA in Belgium for passporting in accordance with article 25 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, where necessary, to take into account new information included in the supplement.

Investors who have already agreed to subscribe for the Offer Shares before the supplement is published will have, if required by law, the right, exercisable within at least three business days after the publication of the supplement, to withdraw their subscription orders.. In the event the Offering Period is extended with five business days or less, this will only be announced by means of a press release by the Company. Prospective investors can submit their subscription orders during the Offering Period.

The timeline, validity and form of instructions to financial intermediaries in relation to the subscription for or purchase of Offer Shares will be determined by each financial intermediary in accordance with

its usual procedures or as otherwise notified to the investors. The Company is not liable for any action or failure to act by a financial intermediary in connection with any subscription or purchase, or purported subscription or purchase, of Shares.

Subscription orders by Retail Investors in Belgium may be submitted at the counters of Bank Degroof Petercam SA/NV and Belfius Bank NV/SA, at no cost to the investor or alternatively through banks or intermediaries other than the aforementioned intermediaries.

Investors wishing to place purchase orders for the Offer Shares through intermediaries other than Bank Degroof Petercam SA/NV and Belfius Bank NV/SA in Belgium should request details of the costs which these intermediaries may charge, which they will have to pay themselves. Applications are not binding upon the Company or the Underwriters as long as they have not been accepted (*See also: The Offering - Allocation*).

To be valid, the subscription orders must be submitted no later than 4:00 p.m. (CET) on 19 October 2021 (for Retail Investors) and no later than 4:00 p.m. (CET) on 19 October 2021 for Institutional Investors, unless the Offering Period is extended, in which case the subscription orders must be submitted no later than 4:00 p.m. (CET) at such extended closing date of the Offering Period.

Dilution resulting from the Offering

The issuance of the Offer Shares will result in the Company's share capital (taking into account the Shares issued prior to Settlement upon conversion of the Convertible Loan Agreement at the Offer Price minus 25% and the share issuance to EPFL and the effectuation of the Reverse Stock Split) increasing by approximately 25%. Accordingly, the existing Shareholders will suffer an immediate dilution as a result of the Offering of approximately 0.7%, assuming the issuance of 8,142,000 Offer Shares (including the exercise in full of the Increase Option and Over-Allotment Option) and no participation of the existing Shareholders in the Offering other than pursuant to the Subscription Commitments.

Retail Investors

A "**Retail Investor**" shall mean an individual person resident in Belgium or a legal entity located in Belgium that does not qualify as a qualified investor (*gekwalificeerde belegger*) as defined in article 2(e) of the Prospectus Regulation.

Retail Investors must indicate in their subscription orders the number of Offer Shares they are committing to subscribe for. Every order must be expressed in number of Offer Shares with no indication of price and shall be deemed placed at the Offer Price. Only one application per Retail Investor will be accepted. If the Underwriters determine, or have reason to believe, that a single Retail Investor has submitted several subscription orders, through one or more intermediaries, they may disregard such subscription orders. There is no minimum or maximum amount or number of Offer Shares that may be subscribed for in one subscription order. Subscription orders are subject to a possible reduction as described below in "*Allocation*".

Belfius Bank NV/SA will act as centralization agent for subscription orders by Retail Investors.

Institutional Investors

Institutional Investors must indicate in their subscription orders the number of Offer Shares or an amount they are committing to subscribe for, and the prices at which they are making such subscription orders during the book-building period. There is no minimum or maximum amount or number of Offer Shares that may be subscribed for in one subscription order. Subscription orders are subject to a possible reduction as described below in "*Allocation*". Only Institutional Investors can participate in the book-building process during the Offering Period.

Withdrawal of the Offering or suspension of the Offering Period

The Company reserves the right to withdraw the Offering or suspend the Offering Period should the pricing agreement not be signed. Furthermore, the Company reserves the right to withdraw or suspend the Offering if the Underwriting Agreement is terminated in the foreseen circumstances as described in the Underwriting Agreement (see "*Plan of Distribution—Underwriting*"). Such withdrawal of the Offering or the suspension of the Offering Period can occur up to the closing of the Offering. The Company also reserves the right to withdraw the Offering or suspend the Offering Period if the Board, following recommendations from the Underwriters, acknowledges that the quality and quantity of the subscriptions received is such that the Offering cannot be closed in the interest of the Company. Any withdrawal of the Offering or suspension of the Offering Period will be published by means of a press release. To the extent required, a supplement will also be published. In the event of a withdrawal of the Offering, all orders received will automatically be cancelled and withdrawn, and investors will not have any claim to the delivery of the Offer Shares or any compensation. The amounts already paid by the prospective investors will be reimbursed within three business days, without, however, being entitled to interest on this amount or to any form of compensation for any reason whatsoever. In the event of withdrawal of the Offering or suspension of the Offering Period, the Company will also be able to withdraw the application for admission to trading of all Ordinary Shares on the regulated markets of Euronext Brussels and Amsterdam, and will immediately notify Euronext of this.

Right to withdraw

Retail Investors and Belgium can only acquire the Offer Shares at the Offer Price and are legally bound to acquire the number of Offer Shares indicated in their subscription order at the Offer Price, unless (i) the Offering has been withdrawn in which case the subscription orders will become null and void, or (ii) in the event of the publication of a supplement to this Prospectus, in which case the Retail Investors will have, if required by law, the right to withdraw their orders made prior to the publication of the supplement, exercisable within at three business days after the publication of the supplement.

In accordance with article 23(1) of the Prospectus Regulation, in the event of a significant new development, or material mistake or inaccuracy relating to the information included in this Prospectus which is capable of affecting the assessment of the Offer Shares during the period between the date of approval of this Prospectus and the First Trading Date, a supplement to this Prospectus shall be published. Any supplement is subject to approval by the AFM, in the same manner as this Prospectus and must be made public in the same manner as this Prospectus.

Investors who have already agreed to subscribe for the Offer Shares before the supplement is published will have, if required by law, the right, exercisable within at least three business days after the publication of the supplement, to withdraw their subscription orders, provided that the significant new development, material mistake or inaccuracy referred to above arose before the closing of the Offering or the delivery of the Offer Shares. The financial intermediaries shall contact each investor individually at the latest at the end of the business day following the business day on which the supplement was published.

Allocation

The number of Offer Shares allotted to investors will be determined at the end of the Offering Period by the Company in agreement with the Underwriters on the basis of the respective demand of both Retail Investors and Institutional Investors and on the quantitative, and, for Institutional Investors only, the qualitative analysis of the order book.

The results of the Offering, the allocation for Retail Investors, the Offer Price, and the allocation criteria (in the case of over-subscription) will be announced by the Company on or about 20 October 2021 and in any event no later than the first business day after the end of the Offering Period.

In the event of the over-allotment of Offer Shares, the Underwriters will use reasonable efforts to deliver the newly issued Shares to individual persons residing in Belgium and to investors subject to Belgian income tax on legal entities (*rechtspersonenbelasting*), in this order of priority. No tax on stock exchange transactions is due on the subscription for newly issued Shares, but such tax could be due on the subscription for existing Shares (see "*Taxation—Material Belgian Tax Considerations*").

The manner for refunding amounts paid in excess by financial intermediaries in relation to the subscription for or purchase of Shares will be determined by each financial intermediary in accordance with its usual procedures or as otherwise notified to the investors.

In the event of over-subscription of the Offering, in principle the Subscription Commitments of the Participating Shareholders in cash can be reduced in line with the allocation principles that will apply to the other investors that will subscribe in the Offering, whereas the Subscription Commitments Cornerstones Investors and the Subscription Commitments Lenders shall not be reduced but be allocated entirely. See also "*Pre-commitments by the Participating Investors*" and "*Convertible Loan Agreement*" under "*Shareholder Structure and Related Party Transactions*".

Payment and taxes

The Offer Price must be paid by the investors in full, in euro, together with any applicable stock exchange taxes and costs. For further information about applicable taxes, see "*Taxation*".

The payment date for the Offer Shares, which is also the Settlement Date, is expected to be 22 October 2021 unless the Offering Period is extended. The Offer Price must be paid by investors by authorizing their financial institutions to debit their bank accounts with such amount for value on the Settlement Date.

Listing and Trading

Prior to the Offering, there has been no public market for the Ordinary Shares. Application has been made to list all of the Ordinary Shares on Euronext Brussels (primary listing) and Amsterdam (secondary listing) under the symbol "ONWD" with ISIN NL0015000HT4. Subject to extension of the timetable for the Offering, trading on an "as-if-and-when-issued" basis in the Offer Shares is expected to commence on or about 21 October 2021. The Ordinary Shares will trade in euro on Euronext Brussels and Euronext Amsterdam.

Delivery, Clearing and Settlement

The Ordinary Shares are registered shares which will be entered into the collective depot and giro depot on the basis of the Dutch Securities Giro Act. The Offer Shares will be delivered in book-entry form through the facilities of Euroclear Nederland. Application has been made for the Ordinary Shares to be accepted for clearance through the book-entry facilities of Euroclear Nederland. Euroclear Nederland has its offices at Herengracht 459-469, 1017 BS Amsterdam, the Netherlands.

Subject to extension of the timetable for the Offer, the Settlement Date is expected to be 22 October 2021, the business day following the First Trading Date (T+2). Delivery of the Offer Shares will take place on the Settlement Date, through the book-entry facilities of Euroclear Nederland, in accordance with its normal settlement procedures applicable to equity securities and against payment (in euros) for the Offer Shares and the Over-Allotment Shares, if applicable, in immediately available funds.

The closing of the Offering may not take place on the Settlement Date or at all if certain conditions or events referred to in the Underwriting Agreement are not satisfied or waived or occur on or prior to such date. See "*Plan of Distribution*".

If Settlement does not take place on the Settlement Date as planned or at all, the Offering may be withdrawn, in which case all subscriptions for Offer Shares will be disregarded, any allotments made will be deemed not to have been made and any subscription payments made will be returned without interest or other compensation. Any dealings in Ordinary Shares prior to Settlement are at the sole

risk of the parties concerned. Neither the Company, the Joint Global Coordinators, the Listing Agent, the Settlement Agent nor Euronext accepts any responsibility or liability for any loss incurred by any person as a result of a withdrawal of the Offering or the (related) annulment of any transactions in Ordinary Shares on Euronext Brussels and Euronext Amsterdam.

Restrictions on the transfer of Ordinary Shares are set out in "*Selling and Transfer Restrictions*".

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 Offer Shares and, if the Over-Allotment Option will be exercised, any Over-Allotment Shares will, upon issue, rank equally in all respects. The Offer Shares will carry dividend rights as of the date of issue. See "*Dividend Policy*".

Listing Agent

Bank Degroof Petercam SA/NV is the Listing Agent with respect to the Ordinary Shares on Euronext.

Settlement Agent

Belfius Bank NV/SA is the Settlement Agent with respect to the Ordinary Shares.

Stabilization Manager

Belfius Bank NV/SA is the Stabilization Manager with respect to the Ordinary Shares on Euronext.

Retail Centralization Agent

Belfius Bank NV/SA will act as centralization agent for subscription orders by Retail Investors.

Jurisdiction and Competent Courts

This Prospectus and the Offering are governed by Dutch Law. All disputes arising in connection with this Prospectus and the Offering shall be subject to the non-exclusive jurisdiction of the courts in Amsterdam, the Netherlands.

PLAN OF DISTRIBUTION

Underwriting

The Underwriters are Bank Degroof Petercam SA/NV, having its registered office at Rue de l'Industrie 44, 1040 Brussels (Belgium), registered with the Crossroad Bank for Enterprises under the number 0403.212.172 (Brussels) and Belfius Bank NV/SA, having its registered office at Place Charles Rogier 11, 1210 Brussels and registered with the Crossroad Bank for Enterprises under the number 0403.201.185 (Brussels).

On 11 October 2021, the Company and the Underwriters entered into an underwriting agreement with respect to the Offering (the "**Underwriting Agreement**"). The Underwriting Agreement is conditional on, among others, the entry into a pricing agreement between the Company and the Underwriters setting the Offer Price per Offer Share.

In the Underwriting Agreement, the Company makes customary representations and warranties and the Company agrees to indemnify each of the Underwriters against liabilities in connection with the Offering, including liability under the U.S. Securities Act.

The Underwriting Agreement provides that the obligations of the Underwriters to procure, as agent for the Company, subscribers or purchasers for the Offer Shares or, failing subscription by the procured subscribers or purchasers, to subscribe for or purchase the Offer Shares themselves at the Offer Price to be set forth in the pricing agreement to be entered into between the Company and the Underwriters on or around 20 October 2021 are subject to certain conditions precedent, including the following: (i) the pricing agreement having been entered into, (ii) representations and warranties made being true, accurate and not misleading; (iii) compliance by the Company with its obligations and undertakings under the Underwriting Agreement; (iv) this Prospectus having been approved by the AFM, passported for Belgium and no amendment or supplement having been published; (v) publication of the Launch Press Announcement and the Pricing Statement; (vi) the Offer Shares having been accepted for book-entry transfer by Euroclear; (vii) the Admission of the Offer Shares on Euronext; (viii) the stock lending agreement, lock-up agreements and certain subscription commitments having been entered into and (ix) no material adverse change or force majeure in the Company or its business having occurred since the date of this Prospectus.

Pursuant to, on the terms of, and subject to, the conditions set out in the Underwriting Agreement, the Underwriters will severally (and not jointly, or jointly and severally) agree to subscribe for the following percentage of the total number of Offer Shares less those Offer Shares subscribed for by the Participating Shareholders and the Participating Lenders pursuant to a Subscription Commitment (the "**Underwritten Shares**"), in their own name but for the account of the relevant subscribers in the Offering to whom those Underwritten Shares have been allocated:

Underwriters	Percentage of Underwritten Shares to be subscribed for
Bank Degroof Petercam SA/NV	50%
Belfius Bank NV/SA	50%
Total percentage of Underwritten Shares to be subscribed for	100%

The Underwriters shall have no obligation to underwrite any of the Underwritten Shares prior to the execution of the pricing agreement (and then only in accordance with the terms and subject to the conditions set forth therein and as described above). The Underwriters have not committed to

subscribe for any of the Shares that will not be subscribed for by investors in the Offering ('soft underwriting').

Immediately after receipt of the Underwritten Shares, the Underwriters will deliver such Underwritten Shares to the relevant subscribers in the Offering against payment of the Subscription Price therefor.

The Underwriting Agreement provides that each Underwriter shall have the right to terminate the Underwriting Agreement before the realization of the capital increase in relation to the Offering, among others if: (i) any material statement in any offering document is, or has become, or has been discovered to be, inaccurate or misleading in any respect, or any matter has arisen which would, if the offering documents were to be issued at such time, mean they would contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances in which they were made, not misleading; (ii) any matter has arisen which would, in the good faith opinion of the Joint Global Coordinators, require the publication of a supplement to this Prospectus; (iii) the approval for the admission of the Shares to listing and trading on Euronext has been withdrawn or refused; (iv) the representations and warranties given by the Company are not, or have ceased to be, true and accurate or there has been a material breach of any other provision of set forth in the Underwriting Agreement; (v) any of the Underwriters would default in performing its underwriting obligations under the Underwriting Agreement (it being specified that the termination rights in that case accrue to the non-defaulting Underwriter(s) only); (vi) any Joint Global Coordinator would terminate the Agreement in accordance with the termination events set forth in the Underwriting Agreement; (vii) in the good faith opinion of the Joint Global Coordinators and after consultation with the Company, there shall have been or it is likely that there will be a material adverse effect; (viii) any of the conditions precedent has not been satisfied; or (ix) there has been a force majeure event.

In the event that no pricing agreement is executed or that the Underwriting Agreement is terminated in respect of all parties, a supplement to this Prospectus shall be published. After publication of the supplement, the subscriptions for the Offer Shares will automatically be cancelled and withdrawn, and subscribers will not have any claim to delivery of the Offer Shares or to any compensation.

Assuming that the Offer Price is at the midpoint of the Price Range, the fees and commissions payable to the Underwriters by the Company are expected to be a maximum of (a) EUR 3.1 million, assuming a placement of the maximum number of Offer Shares in the Offering (excluding the exercise of the Over-allotment Option and the Increase Option), or (b) EUR 4.4 million, assuming a placement of the maximum number of Offer Shares in the Offering (including the exercise in full of the Over-allotment Option and the Increase Option).

Standstill

The Company has agreed pursuant to the Underwriting Agreement that it will not, and it will procure that none of its affiliates will, for a period as from the date of the Underwriting Agreement until 365 days after the Closing Date, otherwise than with the prior written consent of the Joint Global Coordinators (which will not be unreasonably withheld or delayed): (i) directly or indirectly, issue, offer, pledge, sell, contract to sell, sell or grant any option, right, warrant or contract to purchase, exercise any option to sell, purchase any option or contract to sell, or otherwise transfer, (attempt to) dispose of, lend, directly or indirectly, any Shares or securities of the Company that are substantially similar to the Shares, including but not limited to any securities that are convertible into or exchangeable for, or that represent the right to receive, Shares or any such substantially similar securities; (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of any Shares or otherwise has the same economic effect as (i), whether any such transaction in the case of (i) and (ii) is to be settled by delivery of Shares or such other securities, in cash or otherwise; (iii) publicly announce such an intention to effect any such transaction; or (iii) submit to its shareholders or any other body a proposal to effect any of the foregoing.

The foregoing shall not apply to (i) the issue of the Offer Shares, or (ii) the issue of share in connection to and the granting of awards in Ordinary Shares by the Company to the personnel, directors and consultants in the framework of an incentive plan, or (iii) the issue of Ordinary Shares as part of the pre-Offering corporate restructuring (including the conversion of the Convertible Loan), or (iv) the issue of shares up to 10% of the outstanding share capital in connection with an acquisition by the Company (stock or assets), which has been approved by competent corporate body of the Company or (v) the grant of a continuous and repeatedly exercisable right to subscribe for preferred shares in the share capital of the Company, to a protective foundation (when incorporated), which shall be laid down in call option agreement between the Company and the Protective Foundation, and the subsequent issuance(s) of such preferred shares.

Lock-up arrangements

The Directors, Managers, Current Shareholders of the Company (including for these purposes at least the lenders representing a majority of the principal amount loaned to the Company under the Convertible Loan Agreement) have entered into a lock-up arrangement with the Company in respect of their Shares in the Company held immediately prior to the Offering (together the "**Locked Securities**"). Any Shares that are acquired under the Subscription Commitments in the Offering are not subject to a lock-up arrangement.

Pursuant to the lock-up arrangement, the current holders of Locked Securities and lenders (including for these purposes at least the lenders representing a majority of the principal amount loaned to the Company under the Convertible Loan Agreement) under the Convertible Loan Agreement will not voluntarily do any of the following for a period of 180 days after the Closing Date for the Current Shareholders ("**Current Shareholders Lock-up Period**"), and for a period of 365 days after the Closing Date for the Directors and Managers ("**Directors and Managers Lock-up Period**") without the prior written consent of the Underwriters (i) offer, pledge, 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 Shares or any securities convertible into or exercisable or exchangeable for Shares or any other similar instrument that would give an equity-like economic interest in the Borrower to its holders, all to the extent such securities are (x) held immediately prior to the Offering (including for the avoidance of doubt any Shares issued upon conversion of the outstanding amount under the Convertible Loan Agreement) or (y) newly issued securities of an identical type, nominal value, description, rights and quantity to the ordinary Shares that would be loaned by the Lender to Belfius Bank SA/NV (acting as stabilization manager), 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 Shares (a) held immediately prior to the Offering (including for the avoidance of doubt any Shares issued upon conversion of the outstanding amount under the Convertible Loan) or (b) newly issued securities of an identical type, nominal value, description, rights and quantity to the ordinary Shares that would be loaned by the Lender to Belfius Bank SA/NV (acting as stabilization manager), whether any such transaction described in item (i) or (ii) above is to be settled by delivery of Shares or such other securities, in cash or otherwise.

The restrictions do not prohibit the holders of Locked Securities from: (i) accepting a public takeover or tender offer on all of the Shares or other securities of the Company, giving an irrevocable commitment to accept such an offer, or disposing of Locked 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 Locked Securities to the legal successor pursuant to the merger, liquidation, concursus, de-merger, transfer of a division or 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) transferring Locked Securities to the legal successors pursuant to (a) the death of such holder (in the event the holder is a natural person) or (b) the merger, liquidation, concursus, de-merger, 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; (v) lending a number of Locked Shares to one

of the Joint Global Coordinators in the framework of the Offering; (vi) acquiring Shares in the Offering (including pursuant to Subscription Commitments) or acquired thereafter in open market transactions or (vii) transfers of Locked Securities by a selling Shareholder in favor of any entity within such selling Shareholder's control or under common control with such selling Shareholder or to one or more persons, whether natural or legal, who are the ultimate beneficial owners of such Selling Shareholder, provided such transferee provides undertakings to the Joint Global Coordinators equivalent to those agreed by such selling Shareholder.

Over-allotment Option and price stabilization

In connection with the Offering, Belfius Bank NV/SA will act as Stabilization Manager on behalf of the Underwriters and may engage in transactions that stabilize, maintain or otherwise affect the price of the Shares or any options, warrants or rights with respect to, or other interest in, the Shares or other securities of the Company for up to 30 calendar days from the First Trading Date. These activities may support the market price of the Shares at a level higher than that which might otherwise prevail. Stabilization will not be executed above the Offer Price. Such transactions may be effected on the regulated market of Euronext, in the over-the-counter markets or otherwise. The Stabilization Manager and its agents are not required to engage in any of these activities and, as such, there is no assurance that these activities will be undertaken; if undertaken, the Stabilization Manager or its agents may discontinue any of these activities at any time and they must terminate at the end of the 30-calendar day period mentioned above.

Under the possible stabilization measures, investors may, in addition to the Offer Shares being offered, be allocated up to 15% of the Offer Shares subscribed for in the Offering as additional Shares as part of the allocation of the Shares to be placed.

The Participating Shareholders are expected to agree to lend (on a pro-rata basis) to the Stabilization Manager, acting on behalf of the Underwriters, a number of Shares equal to up to 15% of the number of Offer Shares subscribed for in the Offering, in order to enable the Stabilization Manager to settle any over-allotments.

The Company is expected to grant to the Stabilization Manager, acting on behalf of the Underwriters, an Over-allotment Option, in the form of an option, which will entitle the Stabilization Manager, acting on behalf of the Underwriters, to subscribe for additional Offer Shares for an aggregate number equal to up to 15% of the Offer Shares subscribed for in the Offering at the Offer Price to cover over-allotments or short positions, if any, in connection with the Offering.

The Stabilization Manager may elect to reduce any short position by exercising all or part of the Over-allotment Option. The Over-allotment Option will be exercisable for a period of 30 calendar days from the First Trading Date. The Over-allotment Option will be exercisable in whole or in part, and in one or in several times, to cover over-allotments or short positions, if any. The possibility to over-allot Shares in the Offering and to exercise the Over-allotment Option will exist whether or not the Offering is fully subscribed.

If the Stabilization Manager creates a short position in the Shares in connection with the Offering (i.e. over allot additional Shares), they may reduce that short position by purchasing Shares or by exercising all or part of the Over-allotment Option. Purchases of Shares to stabilize the trading price or to reduce a short position may cause the price of the Shares to be higher than it might be in the absence of such purchases. Neither the Company, nor the Underwriters make any representation or prediction as to the direction or the magnitude of any effect that the transactions described above may have on the price of the Shares.

During the Stabilization Period, the details of all stabilization transactions will be made public no later than the end of the seventh daily market session following the date of execution of such transactions, in accordance with Article 6.2 of the Commission Delegated Regulation (EU) 2016/1052 of 8 March

2016 supplementing Regulation (EU) No 596/2014 of the European Parliament and of the Council with regard to regulatory technical standards for the conditions applicable to buy-back programs and stabilization measures.

Within five business days of the end of the Stabilization Period, the following information will be made public in accordance with Article 5 of Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse and Article 6.3 of the Commission Delegated Regulation (EU) 2016/1052 of 8 March 2016 supplementing Regulation (EU) No 596/2014 of the European Parliament and of the Council with regard to regulatory technical standards for the conditions applicable to buy-back programs and stabilization measures: (i) whether or not stabilization was undertaken; (ii) the date at which stabilization started; (iii) the date on which stabilization last occurred; (iv) the price range within which stabilization was carried out, for each of the dates on which stabilization transactions were carried out; and (v) the final size of the Offering, including the result of the stabilization and the exercise of the Over-allotment Option, if any; and (vi) the place where the stabilization was undertaken including, where relevant, the name of the trading venue.

Increase Option

Depending on the volume of demand, the 5,900,000 initially offered Offer Shares sold in the Offering may be increased by up to 20% to 7,080,000 Offer Shares. Any decision to exercise the Increase Option will be communicated at the latest on the date of announcement of the Offer Price, which is currently expected to be on or around 20 October 2021.

Interests in the Offering

In connection with the Offering, each of the Underwriters and any of their respective affiliates, acting as an investor for its own account, may take up Offer Shares in the Offering and in that capacity may retain, purchase or sell for its own account such securities and any Shares or related investments and may offer or sell such Shares or other investments otherwise than in connection with the Offering. For more information on the fees and commissions of the Underwriters payable by the Company in connection with the Offering, see "*Plan of Distribution—Underwriting*". Accordingly, references in this Prospectus to Shares being offered or placed should be read as including any offering or placement of Offer Shares to any of the Underwriters or any of their respective affiliates acting in such capacity. None of the Underwriters intend to disclose the extent of any such investment or transactions otherwise than in accordance with any legal or regulatory obligation to do so. In addition, certain of the Underwriters or their affiliates may enter into financing arrangements (including swaps) with investors in connection with which such Underwriters (or their affiliates) may from time to time acquire, hold or dispose of Shares.

As of the date of this Prospectus, the only contractual relationships between the respective Underwriters and the Company relate to this Offering. The Underwriters and/or their respective affiliates may in the future, from time to time, engage in commercial banking, investment banking and financial advisory and ancillary activities in the ordinary course of their business with the Company or any parties related to it, in respect of which they may, in the future, receive customary compensation, fees and/or commission. Additionally, the Underwriters and/or their affiliates, may, in the ordinary course of their business, hold the Company's securities for investment purposes. Belfius Insurance NV/SA, a member of the Belfius group, has entered into a Subscription Agreement with the Company for an amount of EUR 5 million with guaranteed allocation. In such relationships the relevant parties may not be obliged to take into consideration the interests of the investors. In respect of the aforementioned, the sharing of information is generally restricted for reasons of confidentiality by internal procedures or by rules and regulations. As a result of acting in the capacities described above, the Underwriters may have interests that may not be aligned, or could potentially conflict with the interests of (potential) investors, or the Company's interests. The investors should be aware of the fact that the Underwriters, when they act as lenders to the Issuer (or when they act in any other capacity whatsoever), have no fiduciary duties or other duties of any nature whatsoever vis-à-vis the investors and that they are under no obligation to take into account the interests of the investors.

No public offering outside Belgium

No public offer is being made and no action has been or will be taken that would, or is intended to, permit a public offering of the Offer Shares, or the possession, circulation or distribution of this Prospectus or any other material relating to the Offer Shares, in any country or jurisdiction, other than Belgium, where any such action for that purpose is required. Accordingly, the Offer Shares may not be offered or sold, directly or indirectly, and neither this Prospectus nor any other offering material or advertisements in connection with the Offer Shares may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable rules and regulations of such country or jurisdiction. Purchasers of the Offer Shares may be required to pay stamp taxes and other charges in accordance with the laws and practices of the country of purchase in addition to the Offer Price.

SELLING AND TRANSFER RESTRICTIONS

No action has or will be taken by the Company or the Underwriters that would permit, other than pursuant to the Offering, an offer of the Offer Shares or possession or distribution of this Prospectus or any other offering material in any jurisdiction where action for that purpose is required. The distribution of this Prospectus and the offer of the Offer Shares in certain jurisdictions may be restricted by law. Accordingly, the Offer Shares may not be offered or sold, directly or indirectly, and neither this document nor any other offering material or advertisement in connection with the Offer Shares may be distributed or published in or from any jurisdiction except in circumstances that will result in compliance with any and all applicable rules and regulations of any such jurisdiction. Persons into whose possession this Prospectus comes should inform themselves about and observe any such restrictions, including those in the paragraphs that follow. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdictions. This document does not constitute an offer to subscribe for or purchase any of the Offer Shares to any person in any jurisdiction to whom it is unlawful to make such offer of solicitation in such jurisdiction.

United States

The Offer Shares have not been and will not be registered under the US Securities Act or with any securities regulatory authority of any state or other jurisdiction of the United States, and, subject to certain exceptions, may not be offered or sold, directly or indirectly, or otherwise transferred within the United States. In the United States, the Offer Shares will be sold only to persons reasonably believed to be QIBs in reliance on Rule 144A under the US Securities Act or under another exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act. All offers and sales of the Offer Shares outside the United States will be made to institutional investors in "offshore transactions" in compliance with Regulation S under the US Securities Act. In addition, until the end of the 40th calendar day after commencement of the offering, an offering or sale of Offer Shares within the United States by a dealer (whether or not participating in the offering) may violate the registration requirements of the US Securities Act if such offer or sale is made otherwise than in accordance with Rule 144A.

Rule 144A

Each purchaser of the Offer Shares within the United States pursuant to Rule 144A, by accepting delivery of this Prospectus, will be deemed to have represented, agreed and acknowledged that:

- (a) It is: (a) a QIB within the meaning of Rule 144A; (b) acquiring such Offer Shares for its own account or for the account of one or more QIBs; (c) acquiring Offer Shares for investment purposes, and not with a view to further distribution of such Offer Shares; and (d) aware, and each beneficial owner of such Offer Shares has been advised, that the sale of such Offer Shares to it is being made in reliance on Rule 144A or in reliance on another exemption from, or in a transaction not subject to, the registration requirements of the US Securities Act.
- (b) It understands that such Offer Shares have not been and will not be registered under the US Securities Act or with any securities regulatory authority of any state or other jurisdiction of the United States and may not be offered, sold, pledged or otherwise transferred except: (a) in accordance with Rule 144A to a person that the seller and any person acting on its behalf reasonably believes is a QIB purchasing for its own account or for the account of a QIB; (b) in an offshore transaction in accordance with Rule 903 or Rule 904 of Regulation S; or (c) pursuant to an exemption from registration under the US Securities Act provided by Rule 144 thereunder (if available), in each case in accordance with any applicable securities laws of any State of the United States.
- (c) The Offer Shares are "restricted securities" within the meaning of Rule 144(a)(3) under the US Securities Act and no representation is made as to the availability of the exemption provided by Rule 144 for resale of any Offer Shares.

- (d) It understands that such Offer Shares (to the extent they are in certificated form), unless otherwise determined by the Company in accordance with applicable law, will bear a legend substantially to the following effect:

THE OFFER SHARES REPRESENTED HEREBY 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 OF THE UNITED STATES AND MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED EXCEPT: (1) IN ACCORDANCE WITH RULE 144A UNDER THE US SECURITIES ACT ("**RULE 144A**") TO A PERSON THAT THE SELLER AND ANY PERSON ACTING ON ITS BEHALF REASONABLY BELIEVE IS A QUALIFIED INSTITUTIONAL BUYER WITHIN THE MEANING OF RULE 144A PURCHASING FOR ITS OWN ACCOUNT OR FOR THE ACCOUNT OF A QUALIFIED INSTITUTIONAL BUYER; (2) IN AN OFFSHORE TRANSACTION IN ACCORDANCE WITH RULE 903 OR RULE 904 OF REGULATION S UNDER THE US SECURITIES ACT; OR (3) PURSUANT TO AN EXEMPTION FROM REGISTRATION UNDER THE US SECURITIES ACT PROVIDED BY RULE 144 THEREUNDER (IF AVAILABLE), IN EACH CASE IN ACCORDANCE WITH ANY APPLICABLE SECURITIES LAWS OF ANY STATE OF THE UNITED STATES. NO REPRESENTATION CAN BE MADE AS TO THE AVAILABILITY OF THE EXEMPTION PROVIDED BY RULE 144 UNDER THE US SECURITIES ACT FOR REALES OF THE OFFER SHARES. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THE FOREGOING, THE ORDINARY SHARES REPRESENTED HEREBY MAY NOT BE DEPOSITED INTO ANY UNRESTRICTED DEPOSITARY RECEIPT FACILITY IN RESPECT OF THE OFFER SHARES ESTABLISHED OR MAINTAINED BY A DEPOSITARY BANK. EACH HOLDER, BY ITS ACCEPTANCE OF OFFER SHARES, REPRESENTS THAT IT UNDERSTANDS AND AGREES TO THE FOREGOING RESTRICTIONS.

- (e) The Company, the Underwriters and their affiliates, and others will rely upon the truth and accuracy of the foregoing acknowledgments, representations and agreements. If it is acquiring any Offer Shares for the account of one or more QIBs, it represents that it has sole investment discretion with respect to each such account and that it has full power to make the foregoing acknowledgments, representations and agreements on behalf of each such account.
- (f) The purchaser will not deposit or cause to be deposited such Offer Shares into any depositary receipt facility established or maintained by a depositary bank other than a Rule 144A-restricted depositary receipt facility, so long as such Offer Shares are "restricted securities" within the meaning of Rule 144(a)(3).
- (g) The Company shall not recognize any offer, sale, pledge or other transfer of the Offer Shares made other than in compliance with the above-stated restrictions. Prospective purchasers are hereby notified that sellers of the Offer Shares may be relying on the exemption from the provisions of Section 5 of the US Securities Act provided by Rule 144A.

Regulation S

Each purchaser of the Offer Shares outside of the United States pursuant to Regulation S, by its acceptance of delivery of this Prospectus, will be deemed to have represented, agreed and acknowledged as follows:

- (a) The purchaser is authorized to consummate the purchase of the Offer Shares in compliance with all applicable laws and regulations.
- (b) The purchaser is, or at the time the Offer Shares are purchased will be, the beneficial owner of such Offer Shares and: (i) is, and the person, if any, for whose account it is acquiring the Offer Shares is, outside the United States; (ii) is not an affiliate of the Company or a person

acting on behalf of such an affiliate; and (iii) is not in the business of buying or selling securities or, if it is in such business, it did not acquire such Offer Shares from the Company or an affiliate thereof in the initial distribution of such Offer Shares.

- (c) The purchaser is aware that such Offer Shares: (i) have not been and will not be registered under the US Securities Act or with any securities regulatory authority of any state or other jurisdiction within the United States; (ii) are being sold in accordance with Rule 903 or 904 of Regulation S and is purchasing such Offer Shares in an "offshore transaction" in reliance on Regulation S; and (iii) subject to certain exceptions, may not be offered or sold within the United States.
- (d) The Offer Shares have not been offered to it by means of any "direct selling efforts" as defined in Regulation S.
- (e) The purchaser acknowledges that the Underwriters and their respective affiliates will rely upon the truth and accuracy of the acknowledgments, representations and agreements in the foregoing paragraphs.
- (f) The purchaser is aware of the restrictions on the offer and sale of the Offer Shares pursuant to Regulation S described in this Prospectus.
- (g) The Company shall not recognize any offer, sale, pledge or other transfer of the Offer Shares made other than in compliance with the above-stated restrictions.

European Economic Area

In relation to each state other than Belgium which is a party to the agreement relating to the European Economic Area (a "**Relevant Member State**"), with effect from and including the date on which the Prospectus Regulation enters into effect in that Relevant Member State, an offer to the public of any Offer Shares which are the subject of the Offering contemplated by this Prospectus may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any Offer Shares may be made at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined in the Prospectus Regulation; or to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation) per Relevant Member State, subject to obtaining the prior consent of the Joint Global Coordinators; or
- (b) in any other circumstances falling under the scope of Article 1(4) of the Prospectus Regulation; provided that no such offer of Offer Shares shall require the Company or any Underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression "an offer to the public" in relation to any Offer Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the Offering and any Offer Shares to be offered so as to enable an investor to decide to purchase any Offer Shares, and the expression "**Prospectus Regulation**" means Regulation (EU) 2017/1129 and includes any relevant delegated regulations.

United Kingdom

In the United Kingdom, an offer to the public of any Offer Shares which are the subject of the Offering contemplated by this Prospectus may not be made without the publication of a prospectus in relation to the Offer Shares which has been approved by the FCA in accordance with the UK Prospectus

Regulation, except that an offer to the public in the United Kingdom of any Offer Shares may be made at any time under the following exemptions under the UK Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the Joint Global Coordinators for any such offer; or
- (c) in any other circumstances that do not require the publication of a prospectus pursuant to Article 3 of the UK Prospectus Regulation or Section 86 of the Financial Services and Markets Act 2000,

provided that no such offer of Offer Shares shall require the Company or the Underwriters to publish a prospectus pursuant to Article 3 of the UK Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

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

This Prospectus is being distributed only to, and is directed only at, persons who are outside the United Kingdom, or, if in the United Kingdom, who: (i) have professional experience in matters relating to investments falling within the definition of "investment professionals" in Article 19(5) of The Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "**Order**"); (ii) are high net worth bodies corporate, unincorporated associations and partnerships and the trustees of high value trusts, as described in Article 49(2) of the Order; (iii) the Company believes on reasonable grounds to be persons to whom Article 43(2) of the Order applies for these purposes; or (iv) are other persons to whom it may lawfully be communicated (all such persons referred to in paragraphs (i), (ii), (iii) and (iv) are defined as "**Relevant Persons**"). In the United Kingdom, any investment or investment activity to which this Prospectus relates is only available to and will only be engaged in with Relevant Persons. Any other persons who receive this Prospectus should not rely on or act upon it.

Switzerland

In Switzerland, the Offer Shares may only be offered to "professional clients" within the meaning of the FinSA by way of a private placement. The Offer 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 Offer 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 Offer Shares constitutes a prospectus pursuant to the FinSA, and neither this Prospectus nor any other offering or marketing material relating to the Offer Shares may be publicly distributed or otherwise made publicly available in Switzerland.

TAXATION

TAX WARNING

Potential investors and sellers of Ordinary Shares should be aware that they may be required to pay stamp taxes or other documentary taxes or 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 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, including the Offer Shares.

Prospective investors should carefully consider the tax consequences of investing in the Offer 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

The following is a general summary of certain material Dutch tax consequences of the acquisition, holding and disposal of the Ordinary Shares. This summary 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 general summary should be treated with corresponding caution.

This summary 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, and all of which are subject to change, possibly with retroactive effect. Where the summary refers to "the Netherlands" or "Dutch" it refers only to the part of the Kingdom of the Netherlands located in Europe.

This discussion is for general information purposes 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 advisers regarding the Dutch tax consequences relating to the acquisition, holding and disposal of the Ordinary Shares in light of their particular circumstances.

Please note that this summary does not describe the Dutch tax consequences for:

- (i) a holder of Ordinary Shares if such holder, and in the case of individuals, such holder's partner or certain of its relatives by blood or marriage in the direct line (including foster children), 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 speaking, a holder of securities in a company is considered to hold a substantial interest in such company, if such holder alone or, in the case of individuals, together with such holder's partner (as defined in the Dutch Income Tax Act 2001), directly or indirectly, holds: (i) an interest of 5% or more of the total issued and outstanding capital of that company or of 5% or more of the issued and outstanding capital of a certain class of shares of that company; or (ii) rights to acquire, directly or indirectly, such interest; or (iii) certain profit sharing rights in that company 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 a 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 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) pension funds, investment institutions (*fiscale beleggingsinstellingen*) and 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 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
- (iv) a holder of Ordinary Shares who 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 activities performed by such holder or certain individuals related to such holder (as defined in the Dutch Income Tax Act 2001).

Withholding tax

Dividends distributed by the Company generally are 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, among other things:

- 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 of redemption of Ordinary Shares, or proceeds of the repurchase of Ordinary Shares by the Company or one of its subsidiaries or other affiliated entities to the extent such proceeds exceed the average paid-in capital of those Ordinary Shares as recognized for purposes of Dutch dividend withholding tax;
- an amount equal to the par value of Ordinary Shares issued or an increase of the par value of Ordinary Shares, to the extent that it does not appear that a contribution, recognized for purposes of Dutch dividend withholding tax, has been made or will be made; and
- partial repayment of the paid-in capital, recognized for purposes of Dutch dividend withholding tax, if and to the extent that the Company has net profits (*zuivere winst*), unless (i) the general meeting 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 of the Company's articles of association.

Individuals and corporate legal entities who are resident or deemed to be resident of the Netherlands for Dutch tax purposes, generally are entitled to an exemption of or a credit for any Dutch dividend withholding tax against their income tax or corporate income tax liability and to a refund of any residual Dutch dividend withholding tax. The same generally applies to holders of Ordinary Shares that are neither resident nor deemed to be resident of the Netherlands if the Ordinary Shares are attributable to a Dutch permanent establishment of such non-resident holder.

A holder of Ordinary Shares, who is a resident of a country other than the Netherlands may, depending on such holder's specific circumstances, be entitled to exemptions from, reductions of, or full or partial

refunds of, Dutch dividend withholding tax under Dutch national tax legislation or a double taxation convention in effect between the Netherlands and such other country.

Dividend stripping

Pursuant to legislation to counteract "dividend stripping", a reduction, exemption, credit or refund of Dutch dividend withholding tax is denied if the recipient of the dividend is not the beneficial owner as described in the Dutch Dividend Withholding Tax Act 1965 (*Wet op de dividendbelasting 1965*). 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.

Taxes on income and capital gains

Dutch Resident Entities

Generally speaking, if the holder of Ordinary Shares is an entity that is a resident or deemed to be resident of the Netherlands for Dutch corporate income tax purposes (a "**Dutch Resident Entity**"), any payment on the Ordinary Shares or any gain or loss realized on the disposal or deemed disposal of the Ordinary Shares is subject to Dutch corporate income tax at a rate of 15% with respect to taxable profits up to EUR 245,000 and 25% with respect to taxable profits in excess of that amount (rates and brackets for 2021).

Dutch Resident Individuals

If the holder of Ordinary Shares is an individual resident or deemed to be resident of the Netherlands for Dutch income tax purposes (a "**Dutch Resident Individual**"), any payment on the Ordinary Shares or any gain or loss realized on the disposal or deemed disposal of the Ordinary Shares is taxable at the progressive Dutch income tax rates (with a maximum of 49.5% in 2021), 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 derives benefits from the Ordinary Shares that are taxable as benefits from other activities (*resultaat uit overige werkzaamheden*).

If the above-mentioned conditions (i) and (ii) do not apply to the individual holder of Ordinary Shares, such holder will be taxed annually on a deemed return (with a maximum of 5.69% in 2021) on the individual's net investment assets (*rendementsgrondslag*) for the year, insofar the individual's net investment assets for the year exceed a statutory threshold (*heffingvrij vermogen*). The deemed return on the individual's net investment assets for the year is taxed at a rate of 31%. Actual income, gains or losses in respect of the Ordinary Shares are as such not subject to Dutch income tax.

The net investment assets for the year are the fair market value of the investment assets less the allowable liabilities on 1 January of the relevant calendar year. The Ordinary Shares are included as investment assets. For the net investment assets on 1 January 2021, the deemed return ranges from 1.90% up to 5.69% (depending on the aggregate amount of the net investment assets of the individual on 1 January 2021). The deemed return will be adjusted annually on the basis of historic market

yields.

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 taxes on income or capital gains in respect of any payment on the Ordinary Shares or in respect of any gain or loss realized on the disposal or deemed disposal 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) 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 derive benefits from the Ordinary Shares that are taxable as benefits from other 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 a 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 of the Ordinary Shares.

Other taxes and duties

No Dutch registration tax, stamp duty or any other similar documentary tax or duty will be payable by a holder of Ordinary Shares in respect of any payment in consideration for the holding or disposal 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 Belgian 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. 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 800 (for income year 2021) per year and per taxpayer (Article 21, first subsection, 14^o, 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 800 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 increased with municipal 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 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% (as of assessment year 2021 linked to a tax year starting on or after 1 January 2020), except that a reduced corporate income tax rate of 20% (as of assessment year 2021 linked to a tax year starting on or after 1 January 2020) 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 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 au-thentique*"). 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.

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 800, per year and per taxpayer (for income year 2021). The liquidation and redemption bonuses cannot benefit from the exemption described above, even if the threshold of EUR 800 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 800 (for income year 2021) 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.

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 individuals who hold the Ordinary Shares for professional purposes are taxable at the ordinary progressive personal income tax rates (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.

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 (i) the Ordinary Shares represent at least 10% of the Company's share capital or a participation with an acquisition value of at least EUR 2.5 million (it being understood that only one out of the two tests must be satisfied), (ii) the Article 203 ITC Taxation Condition is satisfied and (iii) the Ordinary Shares have been held in full legal ownership for an uninterrupted period of at least one year immediately preceding the disposal.

If one of the above conditions is not met, the capital gains are taxable at the standard corporate tax rate of 25% (as of assessment year 2021 linked to a tax year starting on or after 1 January 2020), unless the reduced corporate income tax rate of 20% on the first EUR 100,000 of taxable profits applies (see 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 beheervenootschappen 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% (as of assessment year 2021 linked to a tax year starting on or after 1 January 2020). Capital losses on such shares are tax deductible. Internal transfers to and from the trading portfolio are assimilated to a realization.

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.

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 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).

Capital losses on Ordinary Shares incurred by Belgian resident legal entities are not tax deductible.

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*" / "*bordereel*"), 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. The Commission's Proposal regarding the FTT is still subject to negotiation between the Participating Member States and therefore may be changed at any time.

New annual tax on securities accounts

The Law of 17 February 2021 on the introduction of an annual tax on securities accounts, published in the Belgian Official Gazette on 25 February 2021, has introduced a new annual tax on securities accounts in the Belgian code of miscellaneous duties and taxes. The new tax entered into force on 26 February 2021.

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 of Belgian RD/ITC 1992, 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 25th 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.

Certain transactions relating to securities accounts performed as from 30 October 2020 will not be opposable to the Belgian tax authorities, in particular: (i) splitting a securities account into multiple securities accounts held with the same intermediary, or (ii) the conversion of taxable financial instruments held on a securities account into non-taxable nominative financial instruments. In addition, a general anti-abuse provision is also included to counter certain actions to avoid the application of the tax. The anti-abuse provision will apply retroactively as from 30 October 2020.

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.

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

On 6 July 2021, 111 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 ("**early adopters**"). More than 50 jurisdictions have committed to exchange information as from 2018, two jurisdictions as from 2019 and seven jurisdictions as from 2020. 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 and (iv) as from 2020 (for the 2019 financial year) a fourth list of six 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.

Certain United States Federal Income Tax Considerations

The following discussion is a general summary based on present law of certain US federal income tax consequences to US Holders, as defined below, of owning and disposing of Offer Shares acquired in the Offering. The summary is not a complete description of all tax considerations that may be relevant to a prospective investor; it is not a substitute for tax advice. It applies only to US Holders (as defined below) that purchase the Offer Shares in the Offering, will hold the Offer Shares as capital assets and use the US dollar as their functional currency. In addition, it does not describe all of the tax consequences that may be relevant in light of the US Holder's particular circumstances, including tax consequences applicable to US Holders subject to special rules, such as banks or other financial institutions, insurance companies, tax-exempt entities, dealers, traders in securities that elect to mark-to-market, regulated investment companies, real estate investment trusts, US expatriates, persons that directly, indirectly or constructively own 10% or more of the total combined voting power of the Company's voting stock or of the total value of the Company's shares, investors that will hold Offer Shares in connection with a permanent establishment or fixed base outside the United States, or investors that will hold Offer Shares as part of a hedge, straddle, conversion, constructive sale or other integrated financial transaction. This summary also does not address US federal taxes other than the income tax (such as estate or gift taxes) or US state and local, or non-US tax laws or considerations.

A "**US Holder**" is a beneficial owner of Offer 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.

This section is based on the Internal Revenue Code, its legislative history, final and proposed treasury regulations, published rulings and court decisions, all as currently in effect, as well as the United States Tax Convention with the Netherlands (the "**Treaty**"). These authorities are subject to change, possibly on a retroactive basis. The statements in this Prospectus are not binding on the US Internal Revenue Service (the "**IRS**") or any court, and thus the Group can provide no assurance that the US federal income tax consequences discussed below will not be challenged by the IRS or will be sustained by a court if challenged by the IRS.

The US federal income tax treatment of a partner in a partnership (or other entity or arrangement treated as a partnership for US federal income tax purposes) that holds Offer Shares generally will depend on the status of the partner and the activities of the partnership. Prospective purchasers that are partnerships should consult their own tax advisers regarding the specific US federal income tax consequences to their partners of the partnership's acquisition, ownership and disposition of Offer Shares.

Subject to the discussion below under "*Passive Foreign Investment Company Rules*", the gross amount of any distribution of cash or property with respect to the Offer Shares, including Netherlands tax withheld therefrom, if any, will be included in a US Holder's gross income as ordinary income from foreign sources when received. The dividends will not be eligible for the dividends-received deduction generally available to US corporations.

Dividends received by eligible non-corporate US Holders that satisfy a minimum holding period and certain other requirements should be taxed at the preferential rate applicable to qualified dividend income if the Company qualifies for the benefits of the Treaty and the Company is not a PFIC as to the US Holder in the year of distribution or the preceding year. Assuming that Offer Shares are traded on the Euronext exchanges in sufficient volume and the Company has a substantial presence in the

Netherlands for purposes of the Treaty, the Company believes it will qualify for benefits under the Treaty.

Dividends paid in a currency other than US dollars will be included in income in a US dollar amount based on the exchange rate in effect on the date of receipt, whether or not the currency is converted into US dollars at that time. A US Holder's tax basis in the non-US currency will equal the US dollar amount included in income. Any gain or loss on a subsequent conversion or other disposition of the non-US currency for a different US dollar amount generally will be US source ordinary income or loss. If dividends paid in a currency other than US dollars are converted into US dollars on the day they are received, the US Holder generally will not be required to recognize foreign currency gain or loss in respect of the dividend income.

A US Holder that is eligible for benefits under the Treaty may be able to claim a reduced rate of Netherlands withholding tax on dividends received on the Offer Shares. Each US Holder should consult its own tax adviser about its eligibility for reduction of Netherlands withholding tax. Subject to generally applicable limitations, a US Holder may claim a deduction or a foreign tax credit only for Netherlands tax withheld at the appropriate rate. However, a US Holder will not be allowed a foreign tax credit for withholding tax it could have reasonably avoided by claiming benefits under the US-Netherlands Treaty through appropriate procedures. In computing foreign tax credit limitations, non-corporate US Holders eligible for the preferential tax rate applicable to qualified dividend income may take into account only the portion of the dividend effectively taxed at the highest applicable marginal rate. For purposes of the US foreign tax credit limitation, dividends received with respect to the Offer Shares should generally constitute "passive category income." The rules governing foreign tax credits or deductions are complex and each prospective investor is urged to consult its own tax adviser regarding the availability of foreign tax credits or deductions under its particular circumstances.

Dividends received by certain non-corporate US Holders will generally be includible in "net investment income" for purposes of the Medicare contribution tax.

Dispositions

Subject to the discussion below under "*Passive Foreign Investment Company Rules*," a US Holder generally will recognize capital gain or loss on the sale or other disposition of Offer Shares equal to the difference between the US dollar value of the amount realized and the US Holder's adjusted tax basis in the Offer Shares. Any gain or loss generally will be treated as arising from US sources and will be long-term capital gain or loss if the US Holder's holding period exceeds one year. Deductions for capital loss are subject to significant limitations.

The initial tax basis of a US Holder's Offer Shares generally will be the US dollar value of the foreign currency denominated purchase price paid in the Offering determined on the date of purchase. If the Offer Shares are treated as traded on an "established securities market" at the time of the Offering, a cash basis US Holder (or, if it elects, an accrual basis US Holder) will determine the US dollar value of the cost of such Offer Shares by translating the amount paid at the spot rate of exchange on the settlement date of the purchase. A US Holder that receives a currency other than US dollars on the sale or other disposition of the Offer Shares will realize an amount equal to the US dollar value of the currency received at the spot rate on the date of sale or other disposition (or, if the Offer Shares are traded on an "established securities market" at the time of disposition, in the case of cash basis and electing accrual basis US Holders, the settlement date). A US Holder that does not determine the amount realized using the spot rate on the settlement date will recognize currency gain or loss if the US dollar value of the currency received at the spot rate on the settlement date differs from the amount realized. A US Holder will have a tax basis in the currency received equal to its US dollar value at the spot rate on the settlement date. Any currency gain or loss realized on the settlement date or on a subsequent conversion of the non-US currency for a different US dollar amount generally will be US source ordinary income or loss.

US Holders that are eligible for the benefits of the Treaty should not be subject to any Netherlands tax imposed on capital gains on the sale or other disposition of Offer Shares. Subject to applicable limitations, any Netherlands tax imposed on capital gains in respect of the sale or other disposition of

Offer Shares by a US Holder that is not eligible for the benefits of the Treaty will be creditable against such US Holder's federal income tax liability. However, since such capital gains will generally be income or loss from sources within the United States for foreign tax credit limitation purposes, a US Holder may not be able to credit all or a part of such tax against its federal income tax liability.

Capital gains from the sale or other disposition of the Offer Shares received by certain non-corporate US Holders will generally be includible in "net investment income" for purposes of the Medicare contribution tax.

Passive Foreign Investment Company Rules

The Company does not believe that it was classified as a PFIC for US federal income tax purposes for its most recent taxable year ending 31 December 2020 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. In general, a non-US corporation will be a PFIC for any taxable year in which, taking into account the income and assets of 25% or more owned subsidiaries, (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 or which do not produce income. For this purpose, passive income generally includes, among other things, dividends, interest, rents, royalties and gains from the disposition of passive assets (subject to various exceptions). Whether the Company is a PFIC is a factual determination made annually, and the Company's status could change depending upon, among other things, changes in the composition and relative value of its gross receipts and assets (including goodwill), which may be dependent on the market value of the Offer Shares, and the manner in which the Company otherwise conducts its business. Accordingly, no assurance can be given that the Company is not currently or will not become a PFIC in the current or any future taxable year.

If the Company were a PFIC for any taxable year during which a US Holder held the Offer Shares (whether or not the Company continued to be a PFIC), gain recognized by a US Holder on a sale or other taxable disposition (including certain pledges) of the Offer Shares would generally be allocated ratably over the US Holder's holding period for the Offer Shares. The amounts allocated to the taxable year of the sale or other taxable disposition and to any year before the Company became a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest rate in effect for individuals or corporations for that year, as appropriate, and an interest charge would be imposed. Further, to the extent that any distribution received by a US Holder on its Offer Shares exceeds 125% of the average of the annual distributions on the Offer Shares received during the preceding three years or the US Holder's holding period, whichever is shorter, that distribution would be subject to taxation in the same manner as gain, as described immediately above. In addition, if the Company were a PFIC for any taxable year and any subsidiaries of the Company were also a PFIC (any such entity, a "**Lower-tier PFIC**"), US Holders would be deemed to own a proportionate amount (by value) of the shares of each Lower-tier PFIC and would be subject to US federal income tax according to the rules just described on (i) certain distributions by a Lower-tier PFIC and (ii) dispositions of shares of Lower-tier PFICs, in each case, as if the US Holders held such shares directly.

A US Holder may be able to avoid some of the adverse impacts of the PFIC rules described above by electing to mark the Offer Shares to market annually. The election is available only if the Offer Shares are considered "marketable stock," which generally includes stock that is regularly traded in more than de minimis quantities on a qualifying exchange. If a US Holder makes the mark-to-market election, any gain from marking the Offer Shares to market or from disposing of them would be ordinary income. Any loss from marking the Offer Shares to market would be recognized only to the extent of unreversed gains previously included in income. Loss from marking the Offer Shares to market would be ordinary, but loss on disposing of them would be capital loss except to the extent of mark-to-market gains previously included in income. No assurance can be given that the Offer Shares will be traded in sufficient frequency and quantity to be considered "marketable stock" or whether the Euronext exchanges are or will continue to be considered qualifying exchanges for purposes of the

PFIC mark-to-market election. A valid mark-to-market election cannot be revoked without the consent of the IRS unless the Offer Shares cease to be marketable stock. US Holders will not be able to make mark-to-market elections with respect to Lower-tier PFICs.

The Group currently do not intend to provide information necessary for U.S. Holders to make qualified electing fund elections, which, if available, would result in a further alternative tax treatment.

US Holders should consult their own tax advisers concerning the Company's possible PFIC status and the consequences to them if the Company were classified as a PFIC for any taxable year.

Medicare Tax on Net Investment Income

Certain non-corporate US Holders whose income exceeds certain thresholds generally will be subject to a 3.8% surtax on their "net investment income" (which generally includes, among other things, dividends on, and capital gain from the sale or other disposition of, Offer Shares). Non-corporate US Holders should consult their own tax advisers regarding the possible effect of such tax on their ownership and disposition of Shares.

Information Reporting and Backup Withholding

Dividends on Offer Shares and proceeds from the sale or other disposition of Offer Shares may be reported to the IRS unless the holder establishes a basis for exemption. Backup withholding may apply to amounts subject to reporting. Any amount withheld may be credited against the holder's US federal income tax liability subject to certain rules and limitations. Prospective holders are urged to consult with their own tax advisers regarding the availability of the foreign tax credit under their particular circumstances.

Certain non-corporate US Holders are required to report information with respect to investments in Offer Shares not held through an account with a financial institution. US Holders that fail to report required information could become subject to substantial penalties. Potential investors are encouraged to consult with their own tax advisers about these and any other reporting obligations arising from their investment in Offer Shares.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PARTICULAR INVESTOR. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISER ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN OFFER SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

INDEPENDENT AUDITORS

Ernst & Young Accountants LLP, independent auditor, has audited the Financial Statements and has issued an unqualified independent auditor's report thereon, which is included in this Prospectus. The independent auditor's report includes emphasis of matter paragraphs, "*see Important Information—Presentation of financial and other information—IFRS information*".

The Interim Financial Statements have been reviewed by Ernst & Young Accountants LLP which has issued an unqualified independent auditor's review report thereon, which is included in this Prospectus. The independent auditor's review report includes emphasis of matter paragraphs, see "*Important Information—Presentation of financial and other information—IFRS information*".

Ernst & Young Accountants LLP is an independent registered audit firm with its principal place of business at Boompjes 258, 3011 XZ Rotterdam, The Netherlands. Ernst & Young Accountants LLP is registered at the Chamber of Commerce of Rotterdam in The Netherlands under number 24432944. The office address of the independent auditor of Ernst & Young Accountants LLP is Wassenaarseweg 80, 2596 CZ The Hague, The Netherlands. The auditor signing the auditor's reports on behalf of Ernst & Young Accountants LLP is a member of the Royal Netherlands Institute of Chartered Accountants (*Koninklijke Nederlandse Beroepsorganisatie van Accountants*).

GENERAL INFORMATION

Domicile, Legal Form and Incorporation

The Company's legal and commercial name is Onward Medical B.V., to be converted and renamed Onward Medical N.V. ultimately on the First Trading Date. The Company's registered office is at High Tech Campus 32, 5656 AE 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 9845007A2CC4C8BFSB80. The ISIN for the Ordinary Shares is NL0015000HT4. The Company's website is www.onwd.com.

No Significant Change

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 June 30, 2021.

Expenses of the Offering

Assuming that the Offering is fully subscribed and the Offer Price is at the mid-point of the Offer Price Range (as at the date of this Prospectus), the expenses related to the Offering are estimated at approximately EUR 5.5 million and include, among other items, the fees due to the AFM and Euronext, the commission for the Underwriters, and legal and administrative expenses, as well as publication costs and applicable taxes, if any. The expenses payable by the Company are estimated to amount to approximately EUR 5.5 million. See also "*Reasons for the Offering and Use of Proceeds*".

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/documents/>) from the date of this Prospectus (save for the Pricing Statement, which will be available after pricing of the Offering) until at least 12 months thereafter:

- this Prospectus;
- the Articles of Association;
- the Pricing Statement;
- the Board Rules;
- the charter of the Compensation Committee;
- the charter of the Audit Committee; and
- the charter of the Nomination Committee.

The Pricing Statement will be available after pricing of the Offering.

DEFINITIONS

The following definitions are used in this Prospectus:

510(k)	Clearance under Section 510(k) of the FDCA
Acute Phase	Phase starting at the moment of the spinal cord injury and covering the following first weeks until the start of the sub-acute phase. During this phase the patient reaches a status of medical stabilization needed to enter the following phase – the sub-acute phase.
ADL	Activities of Daily Living – Routine activities people do in their everyday life such as: showering, getting dressed, eating, toileting, mobility and continence.
Admission	The admission to listing and trading of all the Ordinary Shares on Euronext
ADN	Annual distribution number
AE	Adverse event – Unexpected medical occurrence after exposure to a treatment. It may be mild, moderate or severe.
Afferent fibers	Nerve fibers that carry signals from the periphery toward the central nervous system
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>)
AIS	ASIA impairment scale
AIMD	Active Implantable Medical Device – Device relying on electrical energy and intended to be introduced (partially or totally) into the human body.
Allocation	The allocation of the Offer Shares
Annual Accounts	The annual accounts referred to in article 2:391 DCC
Annual Base Pay	Fixed annual base salary
APMs	Alternative Performance Measures
ARC Therapy	ONWARD ARC™ Therapy
ARC^{EX}	The external platform of the ARC Therapy
ARC^{IM}	The implantable platform of the ARC Therapy
Articles of Association	The articles of association of the Company, which were adopted by the general shareholders' meeting of 11 October 2021, and which will enter into force subject to and effective as of the execution of a notarial deed of conversion and amendment, which will take place ultimately on the First Trading Date
ASIA	American Spinal Injury Association

Autoimmune etiology of spinal cord dysfunction/injury	Spinal cord dysfunction or injury caused by an autoimmune disease (for example: ankylosing spondylitis)
Autonomic	In relation to the autonomic nervous system regulating functions such as breathing, heart rate, digestion
Awards	options, SARs, Shares of Restricted Stock, RSUs, Performance Award, Other Awards, or a combination of the foregoing
Baroreceptor	Sensory nerve ending found in the walls of arteries such as the carotid sinus that is sensitive to changes in blood pressure.
Baroreflex	Reflex mechanism used to regulate blood pressure via the baroreceptors.
BDD	Breakthrough Device Designation - Designation given by the FDA to allow a timely access to devices providing a more effective treatment or diagnosis of life-threatening diseases by speeding-up their development, assessment and review
Belgian Investor	private individuals with habitual residence in Belgium, or legal entities for the account of their seat or establishment in Belgium
BG+	DARPA Bridging the Gap Plus
Biomimetic	Imitating a biological or physiological function
Board	The board of directors (<i>bestuur</i>) of the Company
Board Rules	The rules regarding the Board's functioning and internal organization
Bradycardia	Slower heart rate than normal range
Brain Spine Interface	Electrical signal produced by the brain is recorded and translated into a signal allowing the stimulation of the spine in a timely manner
BWS	Body Weight Support - overhead harness supporting a percentage of the body weight
Call Option Agreement	A call option agreement to be entered into between the Company and the Protective Foundation
Caltech	California Institute for Technology
Cardiovascular	Relating to the heart and blood vessels
CARF	Commission of Accredited Rehabilitation Facilities
Caudal	Opposite of rostral – towards the tail or posterior part of the body
CCG	clinical commissioning group
CE	Conformité Européene
CEO	The Company's Chief Executive Officer
Cerebral hemorrhage	Bleeding in the brain
Cerebrovascular	Relating to the blood flow in the brain
Cervical	Relating to the neck or located around the neck area

CET	Central European Time
Chairperson	The Chairperson of the Board
CHUV	Centre Hospitalier Universitaire Vaudois
Chronic Phase	Phase starting after the Sub-acute phase where the person reaches a plateau in his/her functional recovery
Commission's Proposal	the European Commission published a proposal
Committee	A committee designated by the Board for purposes of the LTIP
Comorbidity	A disease that is simultaneously present with another one
Company	Onward Medical N.V. (at the date of this prospectus still a private limited liability company (<i>besloten vennootschap met beperkte aansprakelijkheid</i>) named Onward Medical B.V., expected to be converted into a public limited liability company (<i>naamloze vennootschap</i>) pursuant to the Deed of Amendment and Conversion ultimately on the First Trading Date
Compensation Packages	The remuneration packages of the Directors
Compensation Policy	The Company's compensation policy
Convertible Loan Agreement	The convertible loan agreement, dated 20 April 2021, between the Company and <i>among others</i> Invest-NL Capital N.V., LSP V Coöperatieve U.A., Stichting Depository INKEF Investment Fund Gimv Investments, Wellington Partners Nominee Ltd. And Olympic Investments Inc.
Conus (medullaris)	The lower extremity of the spinal cord
COPM (Canadian Occupational Performance Measure)	Evidence-based outcome measure designed to capture a person's self-perception of performance in everyday living over time
Cornerstone Investors	AXA Investment Managers Paris, Öhman Fonder, Belfius Insurance NV/SA and a group of smaller investors that do not qualify for disclosure under the Prospectus Regulation
CRO	Contract research organisations
CSO	Chief Scientific Officer
CT Scan	Computerized tomography scan –medical imaging technique combining different X-ray images of the body
Current Shareholders	The holders of Shares at the date of this Prospectus
DAC2	Directive 2014/107/EU on administrative cooperation in direct taxation
DARPA	The US Department of Defense Advanced Research Projects Agency
DARPA grant	a grant from the US Department of Defense Advanced Research Projects Agency

DBC	Diagnose Behandeling Combinatie, also known as DTC – Diagnosis Treatment Combination. System for funding medical specialists and hospitals introduced in 2005 in the Netherlands.
DBS	Deep Brain Stimulation – Application of a current to specific structures in the brain via electrodes implanted in these brain areas.
DCC	Dutch Civil Code
Decompression surgery	Procedures relieving symptoms caused by pressure on the spinal cord
Deed of Amendment and Conversion	The notarial deed of amendment and conversion (<i>akte van statutenwijziging en omzetting</i>) of the Company, which will be executed ultimately on the First Trading Date
DFSA	The Dutch Financial Supervision Act (<i>Wet op het financieel toezicht</i>)
Diaphragmatic	Relating to the diaphragm
Director	an Executive Director or Non-Executive Director
DME	Durable Medical Equipment
Dorsal root	The sensory root of a spinal nerve
Dorsal root ganglia	Bundle of cell bodies of afferent sensory fibers in the dorsal root
DRG	Diagnosis Related Group
Dura	(Short for dura mater) Outermost membrane covering the spinal cord and the brain
Dutch Corporate Governance Code or "Code"	The Dutch corporate governance code issued on 8 December 2016
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>)
Dysreflexia (autonomic)	Overreaction of the autonomic nervous system to a stimulus below the spinal cord injury leading to different reactions including very high blood pressure possibly life-threatening diseases
Dysrhythmia	Disturbance of the normal rhythm heart rate
ECG	Electrocardiogram – measure the electrical activity of the heartbeat
EEA	European Economic Area

EES	Epidural Electrical Stimulation - application of a current to the spinal cord via an electrode implanted on the spinal cord.
Efferent nerves	Nerves carrying signals from the central nervous system to the peripheral nervous system
EMA	European Medicines Agency
Endogenous (spinal circuit)	Nerves carrying signals from the central nervous system to the peripheral nervous system
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
EPFL Option 1	a right by EPFL to acquire Ordinary shares at nominal value set forth in the terms of the license agreement in respect of the use of EPFL's intellectual property rights
EPFL Option 2	a right by EPFL to acquire Ordinary shares of the Company at the time of an IPO as set forth in in the terms of the license agreement in respect of the use of EPFL's intellectual property rights
Epidural	Placed or administered outside the dura mater
ESMA	The European Securities and Markets Authority
EU	European Union
EU Medical Devices Directive	Council Directive 93/42/EEC
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	means Euronext Amsterdam or Euronext Brussel individually or both of them
Euronext Amsterdam	Euronext in Amsterdam, a regulated market of Euronext Amsterdam N.V.
Euronext Brussels	Euronext in Brussel, a regulated market of Euronext Brussels SA/N.V.
Eurostar Grants	a grant from the Eurostars Programme of EUREKA together with the European Community, named Prep2Go
EUWA	the European Union (Withdrawal) Act 2018
Exchange Act	US Securities Exchange Act of 1934, as amended
Excitatory	The effect of a substance leading to excitation of a nerve cell
Executive Directors	Executive directors (<i>uitvoerend bestuurders</i>) of the Company
Exoskeleton	External rigid supportive structure
FCC	United States Federal Communications Commission

FCPA	Foreign Corrupt Practices Act
FDA	U.S. Food and Drug Administration
FDCA	U.S. 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 Statements	The audited consolidated financial statements of the Group for the year ended 31 December 2020, including the comparative historical financial information as of and for the years ended 31 December 2019 and 31 December 2018
FinSA	Swiss Financial Services Act (<i>Finanzdienstleistungsgesetz</i>) of 15 June 2018, as amended
First Trading Date	The date on which trading on an "as-if-and-when-issued" basis in the Shares on Euronext commences, which is expected to be 21 October 2021
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>)
FTEs	Full time equivalent personnel
FTT	financial transaction tax
FTP	Functional Task Practice
Financial Year	A financial year of the Company which ends on 31 December
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>)
GHS	Groupe Homogenes du Sejours
Group	The Company and its Group Companies
Group Companies	The Company's subsidiaries within the meaning of article 2:24b DCC
HCTED	High Cost Tariff Exclusion Device
HDE	Humanitarian Device Exemption
Hemodynamics	Forces involved in blood circulation in the body
Hemodynamic hotspots	Specific locations in the spinal cord that modulate the circuits responsible for blood pressure regulation.
HITECH Act	Health Information Technology for Economics and Clinical Health Act
HIPAA	Health Insurance Portability and Accountability

HMV	Hilfsmittelverzeichnis
HMZ	Hulpmiddelenzorg
HRG	Healthcare resource groups
HTA	Health technology assessment
HUD	Humanitarian use device
Hypertension	Higher blood pressure than normal range
Hypoactive	Related to a less active state than in normal range
Hypoglossal nerve stimulation	Stimulation of the hypoglossal nerve. The hypoglossal nerve is a cranial nerve innervating the muscles of the tongue.
Hypotension	Lower blood pressure than normal range
IAS	International Accounting Standards
ICS	Integrated care systems
IFRS	The International Financial Reporting Standards as adopted by the European Union
Increase Option	The option to increase the aggregate number of Offer Shares by up to 20% of the aggregate number Offer Shares
IMU	Inertial Measurement Unit
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
Innervate	To supply with nerves (can be applied to an organ, or a body part)
Interim Financial Statements	The condensed consolidated interim financial information of the Group as of and for the six months ended 30 June 2021 (including comparative numbers as of and for the six months ended June 30, 2020)
Intermediate Phase	3-6 months of rehabilitation after the Sub-Acute Phase
Internal Controls	the Company's internal risk management and control systems
Internal Revenue Code	The Internal Revenue Code of 1986, as amended
IPG	ONWARD implantable pulse generator
IRB	institutional review boards
ISIN	International securities identification number
Isometric joint torque	Assessment of an isometric torque of a joint against an external resistance.
ITC	the Belgian Income Tax Code
Joint Global Coordinators	Bank DeGroef Petercam SA/NV and Belfius Bank NV/SA in their capacity as joint global coordinators

Kyphosis	Excessive curvature of the spine leading to a hunched back posture
LCD	Local Coverage Determinations
Leg Motor Score (LMS)	Score calculated during the ASIA assessment to evaluate motor function in the lower limbs. This score is based on key muscles in the lower limbs on both sides. Highest possible score being 50
LEI	Legal Entity Identifier
Lenders	the Company and <i>among others</i> Invest-NL Capital N.V., LSP V Coöperatieve U.A., Stichting Depository INKEF Investment Fund Gimv Investments, Wellington Partners Nominee Ltd. and Olympic Investments Inc.
Lesion	A damaged region in the body
Listing Agent	Bank Degroof Petercam SA/NV
Locked Securities	Shares held by Directors, Managers, Current Shareholders of the Company (including for these purposes at least the lenders representing a majority of the principal amount loaned to LSP V Coöperatieve U.A., Stichting Depository INKEF Investment Fund, Gimv Investments H&C Netherlands 2016 B.V. and Wellington Partners Nominee Ltd under the Convertible Loan Agreement) immediately prior to the Offering, subject to a lock-up arrangement
Lordosis	Excessive inward curvature of the lumbar spine
LPPR	Liste de Produits et Prestations Réduit
LTI	Long-term variable compensation
LTIP	Long-Term Incentive Plan
Lumbar	Relating to the lumbar region of the back
Lumbosacral	Relating to the lumbar and sacral part of the back
MAP	Sensors for blood pressure
Market Abuse Regulation	Regulation (EU) No 596/2014 of the European Parliament and of the Council of April 16, 2014 on market abuse, and the regulations promulgated thereunder
MCAA	multilateral competent authority agreement
MCIT	Medicare Coverage of Innovative Technology
MDR	Medical Device Regulation
Medical Devices Regulation	Regulation (EU) 2017/745
MHRA	Medicines and Healthcare products Regulatory Agency
MiFID II	EU Directive 2014/65/EU on markets in financial instruments, as amended

MiFID II Product Governance Requirements	MiFID II, articles 9 and 10 of Commission Delegated Directive (EU) 2017/593 supplementing MiFID II, and local implementing measures
Modified Ashworth Scale	Clinical tool used to measure muscle tone
Modulatory	To regulate/adjust to a certain degree
Monophasic rectified waveform	Parameters of the waveform of a stimulation
Motoneuron	Nerve cell conducting impulse to a muscle or other effector
Myocardial infarction	Heart attack
NCD	National Coverage Determination
Nerve projections	Axons of neurons extending from the cell body to a more distant region of the body
Neurodegenerative	Characterized by the degeneration of the nervous system
Neuromodulation	Field of bioengineering implicating technologies impacting neural interfaces
Neuromotor	Relating to efferent nerve impulses toward motor effectors Ability of the nervous system to modify its connections and reorganize itself by creating new neural connections.
Neuroplasticity	Device used to restore function in the body via the interface of electrodes and the nervous system
Neuroprosthetic	Device used to restore function in the body via the interface of electrodes and the nervous system.
Neurostimulation	Application of an electrical stimulation inducing modulation or activation of the nervous system for a therapeutic effect
Neurorehabilitation	Supervised program of training to restore function to patients who suffered from a neurological disorder.
NHS	National Health Service – in the United Kingdom: refers to the publicly funded healthcare systems
NMES	Neuromuscular Electrical Stimulation
NICE	National Institute for Health and Care Excellence.
NIRS	Spinal cord perfusion and oxygenation
NOL	Net operating losses
NRT	NeuroRecovery Technologies, Inc.
NTAP	Medicare's New Technology Add-on Payment
NUB	Neue Untersuchungs- und Behandlungsmethoden
Offer Price	The offer price per Offer Share

Offer Price Range	The expected price range of EUR 11.75 to EUR 13.75 (inclusive) per Offer Share
Offer Shares	The Ordinary Shares that will be issued by the Company in the Offering, which excludes, unless the context indicates otherwise, the Over-Allotment Shares and any offer Shares issued pursuant to the Increase Option, if any
Offering	The offering of the Offer Shares
Offering Period	The period during which the Offering will take place, commencing on 9:00 a.m. CET on 12 October 2021 and ending on 4:00 p.m. CET on 19 October 2021, subject to extension of the timetable for the Offering
OPS	Operationen- und Prozedurenschlüssel – also known as Operation and Procedure Classification System. Official classification for the encoding of procedures, general medical measures and operations in Germany.
Order	The Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended
Ordinary Shares	Ordinary shares in the Company's share capital, with a nominal value of EUR 0.12 each
Orthostatic hypotension	Hypotension caused by transition to an upright position
OS	Operating system
OTS	Off-the-shelf
Over-Allotment Option	The option to be granted to the Stabilisation Manager (on behalf of the Joint Global Coordinators) exercisable within 30 calendar days from the First Trading Date, pursuant to which the Stabilisation Manager (on behalf of the Joint Global Coordinators) may require the Company to issue and sell additional Offer Shares at the Offer Price
Over-Allotment Shares	The Offer Shares that may be made available pursuant to the Over-Allotment Option
Paraplegic	Someone affected by paralysis (partial or complete) of the lower half of the body due to an injury or disease of the spinal cord.
Parkinson's Multiple System Atrophy	Multiple system atrophy parkinsonian type is a rare neurodegenerative condition causing symptoms similar to Parkinson's disease with more widespread damage to the nervous system controlling important functions such as blood pressure.
Participating Investors	Cornerstone Investors together with the Participating Shareholders and the Participating Lenders.

Participating Lenders	Certain lenders under the Convertible Loans Agreement who have made us of their pro rata subscription rights being Dave Marver, Jan Øhrstrøm, John Murphy, Hendrik Lambert and a group of smaller lenders that do not qualify for disclosure under the Prospectus Regulation
Participating Shareholders:	Certain existing shareholders of the company, being LSP V Coöperatieve U.A., Stichting Depositary INKEF Investment Fund, Gimv Investments H&C Netherlands 2016 B.V. and Wellington Partners Nominee Ltd
PBMs	pharmacy benefit managers
PCBA	Printed circuit board assembly
PDMR	Person discharging managerial responsibilities within the meaning of Article 3(25) of the Market Abuse Regulation
Perfusion	Passage of a fluid (blood, water..) through blood vessels, tissue or organ
PFIC	Passive foreign investment company
Pharmacological	Relating to the use, effects, and mechanism of actions of drugs.
PMA	Pre-market approval
PNS	Peripheral 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
Preganglionic neurons	Nerve fibers connecting the central nervous system to the ganglia in the autonomic nervous system
Prehension	Act of seizing
Pressor agents	Substances causing an increase in blood pressure.
Pricing Statement	The pricing statement detailing the Offer Price, the exact number of Offer Shares to be sold and the maximum number of Over-Allotment Shares, which will be filed with the AFM
Principal Amount	Means the principal amount under the Convertible Loan Agreement of EUR 30 million
Proprioception/proprioceptive	Perception of the position of the body or of a limb
Proprioceptive feedback circuit	Physical interactions with the environments allowing a person to build an awareness of their own body
Prospectus	This document or prospectus dated 11 October 2021
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

QIBs	Qualified institutional buyers as defined in Rule 144A of the US Securities Act
QSR	Quality System Regulations
Reeve Foundation	Christopher and Dana Reeve Foundation
Regulation S	Regulation S under the US Securities Act
Relevant Member State	Each member state of the EEA
Relevant Person	A relevant person within the meaning of the Order
Renin-Angiotensin-Aldosterone System (RAAS)	Hormone system playing an important role in the regulation of blood pressure
Replacement Award	A replacement awards is an Award granted in assumption of, or in substitution or exchange for, long-term incentive awards previously granted by a Person acquired (or whose business is acquired) by the Company or a Subsidiary or with which the Company or a Subsidiary merges or forms a business combination, as reasonably determined by the Committee
Retail Coordinator	Belfius Bank NV/SA
Retail Investor	an individual person resident in Belgium or a legal entity located in Belgium that does not qualify as a qualified investor (<i>gekwalificeerde belegger</i>) as defined in article 2(e) of the Prospectus Regulation
Rule 144A	Rule 144A under the US Securities Act
RVO	Rijksdienst voor Ondernemend Nederland
Sacral	Relating to the sacral region of the back
SAE	Serious adverse event - undesirable experience associated with the use of a medical product and the patient outcome is either death or life-threatening or disability/permanent damage or hospitalization.
SARs	stock appreciation rights
Scaffold (cellular)	Scaffolds engineered to induce cellular interactions contributing to the formation of new functional tissues
SCCs	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.
SCS	Spinal cord stimulation
Sensorimotor paralysis	Condition that decreases the ability of a person to feel and move due to a nerve damage
Settlement	Payment (in euro) for and delivery of the Offer Shares
Settlement Agent	Belfius Bank NV/SA

Settlement Date	The date on which Settlement occurs which is expected to be on or about 22 October 2021, subject to extension of the timetable for the Offering
Shareholder(s)	A holder of Shares
Shareholders Agreement	the shareholders agreement between the Company and the Current Shareholders dated 5 April 2016, which has been amended and restated from time to time lastly on 14 October 2019
Shareholders' Register	The shareholders' register of the Company with the last signed entry being dated 11 October 2021
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 as regards the encouragement of long-term shareholder engagement
Shares	The Ordinary Shares and the Preferred Shares
SHI	Statutory health insurances
Simple	Spinal Implant with Motion-feedback for ParapLEGics
Solidarity Contribution	The new annual tax on securities accounts
Somnolence	State of being drowsy
Spasticity	Abnormal increase in muscle tone usually caused by nerve damage and can be associated with pain
Spared circuit	Neuronal circuits (innervation) that were spared from injury
Spinal Cord Compression	Pressure on the spinal cord caused by a fracture, or a tumor or other conditions
Spinal Cord Independence Measure (SCIM III score)	Assessment used to evaluate the independence level of people with spinal cord injury in three specific areas: self-care, respiration and sphincter management, mobility
Spirometry assessment	a spirometer. The measure is based on the amount of inhaled and exhaled air
Stabilization Manager	Belfius Bank NV/SA
STI	Short-term variable compensation
STIMO	STImulation Movement Overground (title of clinical study)
STIMO HEMO	Clinical trial to gain experience and glean clinical insights prior to beginning a planned pivotal trial for this indication in the US and Europe
Stock Lending Agreement	The stock lending agreement to be entered between the Participating Shareholders and the Stabilization Manager
Sub-Acute Phase	Phase starting right after the Acute phase once the patient has reached a state of medical stabilization. This phase starts when the patient starts the rehabilitation phase.

Subscription Commitments	Means the Subscription Commitments Cornerstone together with the Subscription Commitments Shareholders and the Subscription Commitments Lenders
Subscription Commitments Cornerstone	the Cornerstone Investors having irrevocably agreed to purchase Offer Shares in the aggregate amount of EUR 16.2 million at the Offer Price
Subscription Commitments Lenders	the Participating Lenders having irrevocably agreed to purchase Offer Shares for an aggregate amount representing up to 2.4% of the Offer Shares in the Offer at the Offer Price (as defined below)
Subscription Commitments Shareholders	the Participating Shareholders having irrevocably committed to subscribe for an aggregate amount representing up to 15% of the Offer Shares in the Offer at the Offer Price , subject to the closing of the Offering such commitment capped at an offer size of EUR 100 million, in which case the Subscription Commitments Shareholders shall be EUR 15 million
Supraspinal	Placed or occurring above the spine – may refer to the brain
Supraspinal control	Neuronal control originating above the spine
Sympathetic (nervous system)	Part of the autonomic nervous system. The sympathetic nervous system innervates organs and regulates fundamental bodily functions such as heart rate
Target Market Assessment	A product approval process, which has determined that the Shares are: (i) compatible with an end target market of investors who meet the criteria of retail investors and professional clients and eligible counterparties, each as defined in MiFID II; and (ii) eligible for distribution through all distribution channels as are permitted by MiFID II
Tetraplegic (Quadraplegic)	Someone affected by paralysis (partial or complete) of upper and lower limbs due to injury or disease of the spinal cord.
Thermoregulation	Physiological process allowing the body to maintain its core temperature
The Netherlands	The part of the Kingdom of the Netherlands located in Europe
Thoracic	Related to the thoracic region of the back
Thoracolumbar	Related to the thoracic and lumbar regions of the back
Tonic stimulation	Continuous stimulation
Treaty	the United States Tax Convention with the Netherlands
TPT	Transitional-Pass-Through
tSCS	Transcutaneous spinal cord stimulation
Transcutaneous	Penetrating through the skin. For example: transcutaneous stimulation is stimulation delivered through the skin via electrodes placed on the skin

UADE	Unanticipated adverse device effects – serious adverse effect on health or safety or life-threatening problem or death caused by or associated with a device when that problem was not previously identified.
UCLA	University of California, Los Angeles
Underwriters	The Joint Global Coordinators
Underwriting Agreement	The underwriting agreement expected to be entered into on or about the date of this Prospectus between the Company and the Underwriters
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 UK version of Regulation (EU) 2017/1129 as it forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018, as amended from time to time;
Urodynamic assessment	Clinical test used to assess the bladder's ability to retain and release urine and diagnose urinary incontinence or other symptoms
US dollars or US\$ or USD or \$	The US Dollar, the lawful currency in the US
US Exchange Act	The United States Securities Exchange Act of 1934, as amended
US Securities Act	The United States Securities Act of 1933, as amended
Vascular	Relating to blood vessels
Vasoconstriction	Constriction of blood vessels inducing an increase in blood pressure
VAT	Value added tax
Ventral root	The motor root of a spinal nerve
Vice-Chairperson	The vice-chairperson
Waveform	Defined by the pulse shape, the amplitude, the frequency and burst
WPLS	Wellington Partners Life Science
ZIN	Zorginstituut Nederland
ZonMw grant	a grant from ZonMw

FINANCIAL STATEMENTS

Condensed consolidated interim financial information as of and for the six months ended June 30, 2021 (including comparative numbers per 30 June 2020, which are not 2020 interim financial statements) F-1

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ONWARD Medical B.V.

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the six months ended 30 June 2021

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Condensed Consolidated Interim statement of profit and loss

for the six-month period ended 30 June	2021	2020
	Notes	
<i>All amounts in EUR '000</i>		
Grants	586	211
Total Revenues and Other Income	586	211
Science expenses	(569)	(542)
Research and Development expenses	(3,280)	(2,804)
Clinical and Regulatory expenses	(1,944)	(1,232)
Marketing and Market Access expenses	(353)	(167)
Patent and related expenses	(786)	(455)
General and administrative expenses	(3,478)	(1,691)
Total operating expenses	(10,410)	(6,891)
Operating loss for the period	(9,824)	(6,680)
Financial income	–	–
Financial expense	(2,931)	(2,096)
Net finance costs	(2,931)	(2,096)
Loss for the period before tax	(12,755)	(8,776)
Income tax expense	11 (16)	(28)
Net loss for the period	(12,771)	(8,804)
Attributable to:		
Equity holders of the parent	(12,771)	(8,804)
Non-controlling interests	–	–
	(12,771)	(8,804)
Basic and diluted* earnings per share (€):		
Weighted average number of ordinary shares outstanding used for calculation (in thousands):	9,865	8,562
Basic earnings per ordinary share attributable to shareholders	(1,29)	(1,03)
Diluted earnings per ordinary share attributable to shareholders	(1,29)	(1,03)

* 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 therefore the effect of anti-dilutive potential ordinary shares is disregarded.

Condensed Consolidated Interim statement of comprehensive income

for the six-month period ended 30 June	2021	2020
	Notes	
<i>All amounts in EUR '000</i>		
Net loss for the period	(12,771)	(8,804)
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods	–	–
Other comprehensive income	–	–
Currency translation differences	(61)	33
Other comprehensive income that will be reclassified to profit or loss in subsequent periods	(61)	33
Total comprehensive result for the period, net of tax	(12,832)	(8,771)
Attributable to:		
Equity holders of the parent	(12,832)	(8,771)
Noncontrolling interests	–	–
	(12,832)	(8,771)

Condensed Consolidated Interim statement of financial position

<i>All amounts in EUR '000</i>	Notes	30 June 2021	31 December 2020
ASSETS			
Non-current assets			
Intangible fixed assets	7	6,745	6,825
Property, plant and equipment		222	248
Right of use assets		96	149
		<u>7,063</u>	<u>7,222</u>
Current assets			
Indirect tax receivables		176	93
Receivable from related parties		58	57
Other current assets		463	436
Cash and cash equivalents		25,894	6,382
		<u>26,591</u>	<u>6,968</u>
		<u><u>33,654</u></u>	<u><u>14,190</u></u>
EQUITY AND LIABILITIES			
Equity and reserves			
Shareholders' equity	9	–	–
Share premium	9	3,083	3,083
Other reserves	9, 10	20,473	18,465
Other Comprehensive Income		(772)	(710)
Retained earnings		(65,704)	(52,933)
Total equity attributable to shareholders		(42,920)	(32,095)
Non-current liabilities			
Interest-bearing loans	6, 8	69,311	41,817
Deferred tax liability		1,327	1,343
Other financial liabilities	6, 8	2,480	–
Lease liability		–	61
Post-employment benefits		550	399
		<u>73,668</u>	<u>43,620</u>
Current liabilities			
Income tax liabilities		44	27
Lease liability		130	137
Trade payables		1,007	911
Other payables		1,725	1,590
		<u>2,906</u>	<u>2,665</u>
		<u><u>33,654</u></u>	<u><u>14,190</u></u>

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 30th		Issued Capital*	Share Premium	Other reserves	Currency translation differences	Retained Earnings	Total Equity
<i>All amounts in EUR '000</i>	Notes						
As at January 1, 2021		-	3,083	18,287	(532)	(52,933)	(32,095)
Loss for the period		-	-	-	-	(12,771)	(12,771)
Other comprehensive income		-	-	-	(61)	-	(61)
Total comprehensive result		-	-	-	(61)	(12,771)	(12,832)
Share based payments		-	-	2,007	-	-	2,007
Issue of share capital		-	-	-	-	-	-
As at June 30, 2021	10	-	3,083	20,294	(593)	(65,704)	(42,920)

*) share capital amounts to EUR 39,92 as at 30 June 2021 (2020: EUR 25,69)

for the six-month period ended June 30th		Issued Capital*	Share Premium	Other reserves	Currency translation differences	Retained Earnings	Total Equity
<i>All amounts in EUR '000</i>	Notes						
As at January 1, 2020		-	3,083	15,004	(91)	(32,919)	(14,923)
Loss for the period		-	-	-	-	(8,804)	(8,804)
Other comprehensive income		-	-	-	33	-	33
Total comprehensive result		-	-	-	33	(8,804)	(8,771)
Share based payments		-	-	559	-	-	559
Issue of share capital		-	-	-	-	-	-
As at June 30, 2020	10	-	3,083	15,563	(58)	(41,723)	(23,135)

Condensed Consolidated Interim statement of cash flows

for the six-month period ended 30 June	2021	2020
	Notes	
<i>All amounts in EUR '000</i>		
Loss for the period before taxes	(12,755)	(8,776)
Adjusted for:		
• Depreciation and impairment of property, plant and equipment and right-of-use assets	124	123
• Share based payment transaction expense	2,007	558
• Post-employment benefits	169	(2)
• Net finance costs	2,931	2,096
• Other non-cash items	(14)	(17)
Changes in working capital:		
Increase (-) Decrease (+) in Trade and other receivables	(112)	82
Increase (+) Decrease (-) in Trade and other payables	230	(630)
Interests received	–	–
Interests paid	(23)	(7)
Income tax paid	–	(31)
Bank Charges paid	(6)	(5)
Net cash generated /(used) from operating activities	(7,449)	(6,609)
Cash flows from investing activities		
Investments in fixed assets	(45)	(112)
Net cash generated/(used) from investing activities	(45)	(112)
Cash flows from financing activities		
Proceeds from Borrowings	6, 8 27,106	553
Payment of principal portion of lease liabilities	(68)	(62)
Proceeds from issuance of shares	–	–
Net cash generated/(used) from financing activities	27,038	491
Movement in cash and cash equivalents		
Cash and cash equivalents at 1 January	6,382	15,129
Effect of exchange rates on cash and cash equivalents	(32)	(12)
Changes in cash and cash equivalents during the period	19,544	(6,231)
Cash and cash equivalents at 30 June	25,894	8,886

Notes to the Condensed Consolidated Interim Financial Statements

1. General information

ONWARD Medical B.V. (“ONWARD” or “The Company”) is a limited liability company, incorporated on November 20, 2015. The registered office is located at High Tech Campus 32, Eindhoven, the Netherlands. ONWARD Medical B.V. was formerly known as GTX medical B.V.

ONWARD and its subsidiaries (the “Group”) are developing both an Implantable Neuro-stimulation System (INS) and a non-invasive system (since the merger with NRT) for electrical stimulation of specific areas of the spinal cord.

The Company is not impacted by seasonality for its operations.

Information about subsidiaries

The consolidated financial statements of the Group include:

- ONWARD Medical SA, Switzerland; principal activities: the development and commercialization of an Implantable Neuro Stimulation System (INS) medical device solution to improve the lives of Spinal Cord Injured people. Holding 100%.
- Acquisition of NeuroRecovery Technologies, Inc (‘NRT’) in 2019; On October 14, 2019 the Group acquired 100% of the voting shares of NRT, a non-listed Delaware, USA based company, in exchange for the issuance of Company’s shares. NRT is involved in the development and commercialization of a non-invasive medical device solution to improve the lives of Spinal Cord Injured people. For the assets acquired and liabilities assumed see next paragraph.

Shareholders

At 30 June 2021, the shareholders of ONWARD Medical B.V. are:

- LSP V Coöperatieve U.A., the Netherlands
- Stichting Depositary INKEF Investment Fund, the Netherlands
- Wellington Partners Nominee Ltd., Jersey
- Gimv Investments H&C Netherlands 2016 B.V., the Netherlands
- G-Therapeutics Founders S.a.r.l., Switzerland
- Stichting G-Therapeutics Participaties, the Netherlands
- G-Therapeutics Participaties B.V., the Netherlands
- DHT Consultancy B.V., the Netherlands
- NRT Holdings LLC, USA
- GTX managers B.V., the Netherlands

None of these shareholders are considered an Ultimate Controlling party as none of the shareholders have more than 25% shares or voting rights in the company.

These Condensed Consolidated Interim Financial Statements were authorized for issue by Company’s Board of Directors on [date].

2. Basis of preparation

The Company’s condensed consolidated financial statements for the six month period ended June 30, 2021 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 special purpose financial statements as at and for the year ended 31 December 2020.

The significant accounting policies used in the preparation of the Condensed Consolidated Interim Financial Statements are consistent with those followed in the preparation of the Company’s Consolidated special purpose financial statements as of and for the year ended 31 December 2020.

The Condensed Consolidated Interim Financial Statements are presented in Euro (EUR) and all values are rounded to the nearest thousand (KEUR), except when otherwise indicated.

The preparation of the Condensed Consolidated 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 condensed consolidated 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 2020.

These Condensed Consolidated Interim Financial Statements were prepared for use in connection with a prospectus which the Company may issue in the foreseeable future.

3. Continuity of the Group

ONWARD Medical B.V. ("ONWARD") closed a Series A financing round of € 26 million in April 2016, with a group well-known European investors: LSP and Inkef Capital from Amsterdam, Wellington Partners from Munich and GIMV from Antwerp. In addition, the company secured an additional € 10 million Innovation loan from the Dutch ministry of economic affairs.

On October 14, 2019 ONWARD concluded a business combination with a US company named NeuroRecovery Technologies Inc. ("NRT"). The activities of NRT were brought in through an in-kind contribution of the NRT activities in exchange for shares in ONWARD Medical B.V. with a transaction value of € 6 million.

Prior to the NRT business combination, the Series A Funding was extended with an additional € 5 million to € 31 million. The open Funding Milestones of the initial Series A Funding were waived and the € 31 million was paid in full on October 14, 2019. After the NRT business combination the former NRT investors have also agreed to an additional investment of € 5 million into ONWARD that was fully paid as of November 2020.

On April 20, 2021 ONWARD closed an additional financing of € 27 million by means of a convertible loan agreement ("CLA") with several investors. The CLA allowed for a second close within 120 days to close an additional € 3 million that closed in July 2021.

The total new financing of € 30 million will be sufficient to fund the development and commercialization activities for the ARC Therapy thru at least September 2022.

Inherent uncertainties in these forecasts may have an impact on when the Company's cash position will actually become negative. To continue development and reach commercialization as planned after 30 September 2022, the Company has to attract additional funding. Please note that the Company's long-term success is contingent on achieving FDA approval and CE mark of its products.

The Company is actively involved in additional capital and financing discussions. The Board of Directors is aware that the continuity of Company's operations depends on its ability to find these new sources of funding and that there are material uncertainties in this regard. Considering the Company's history of successful attracting additional funding the Board of Directors have a reasonable expectation that ONWARD will be successful. As a result, the consolidated financial statements have been prepared on a going concern basis.

4. Standards issued but not yet effective

A number of new standards are effective from 1 January 2021 but they do not have a material effect on the Group's financial statements.

The policy for recognising and measuring income taxes in the interim period is described in note 11.

A number of new standards and amendments to standards are effective for annual periods beginning after 1 January 2022 and earlier application is permitted; however, the Group has not early adopted any of the forthcoming new or amended standards in preparing these condensed consolidated interim financial statements.

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.

6. Convertible loan

On 20 April 2021 the Company entered into a Convertible Loan Agreement of EUR 30 million (EUR 27.1 million (the "Principal Amount") furnished per 30 June 2021, with an additional EUR 2.9 million executed in July 2021). The outstanding portion of the Principal Amount shall bear interest at a rate of 8% per year. Under Convertible Loan, there are several situations that would trigger a conversion of the loan into shares:

- Upon closing of a qualified financing event
- Upon closing of a financing round not qualifying as a qualified financing event
- Upon entering into a liquidity event prior to conversion or repayment
- Upon a milestone event
- Upon election by the option holder

In terms of the agreement no assets may be pledged by the Company without consent from the majority of lenders.

The Convertible Loan includes the following conversion options. These conversion options are mutually exclusive:

Conversion Option	Option Holder/ Lender/ Mandatory upon contingent event	Fixed or Variable Number of Shares	Cap or Floor to Share Price
Qualified Financing Series A	Mandatory upon contingent event	Variable depending on price per share per financing	Cap at original subscription price per share in case actual IPO price is higher.
Qualified Financing Senior Shares	Mandatory upon contingent event	Variable depending on price per share per financing.	Floor if price is below original subscription price.
Non-Qualified Financing Series A	Option Holder (by majority) upon contingent event	Variable depending on price per share per financing	Cap at original subscription price per share in case actual IPO price is higher.
Non-Qualified Financing Senior Shares	Option Holder (by majority) upon contingent event	Variable depending on price per share per financing.	Floor if price is below original subscription price.
Milestone Event	Mandatory upon contingent event	Fixed, converted at the original subscription price, as accrued interest is not converted	None
Liquidity Event	Option holder (individually) upon contingent event	Fixed converted at the original subscription price (as accrued interest is not converted) or variable depending on the latest round of financing, as elected by holder	None
Election	Option holder (only if the above contingencies do not occur)	Fixed number of Series A shares (as accrued interest is not converted), or variable depending on last round of financing for Senior Shares	None

For recognition as equity all conversion options should meet the fixed-for-fixed requirement of IAS 32. This is not the case for each of the conversion options. Generally, multiple embedded derivatives in a single hybrid contract are treated as a single compound embedded derivative. These conversion options are considered a single compound embedded derivative as a) they relate to the same underlying risk

exposure (the valuation of the Company) and b) these conversion options are mutually exclusive and therefore not independent of each other. Based on the aforementioned, the option is considered an embedded derivative which is bifurcated and classified as a financial liability through profit and loss (“FVPL”).

Initial and subsequent measurement will be in line with the accounting policy as included in the Company’s Consolidated special purpose financial statements as of and for the year ended 31 December 2020. Interest related to the financial liability is recognised in profit and loss. On conversion at maturity, the financial liability is reclassified to equity and no gain or loss is recognised.

7. Intangible fixed assets

	30 June 2021	31 December 2020
Goodwill	1,588	1,607
In-Process R&D	5,157	5,218
Closing net book value	6,745	6,825

Goodwill

	30 June 2021
Cost	1,607
Accumulated amortization	–
Opening net book value	1,607
Additions	–
Foreign currency translation difference	(19)
Depreciation for the period	–
Impairments	–
Net change	(19)
Cost	1,588
Accumulated amortization	–
Closing net book value	1,588

In-Process R&D

	30 June 2021
Cost	5,370
Accumulated changes	(152)
Opening net book value	5,218
Acquisition of In-process R&D NRT	–
Foreign currency translation difference	(61)
Additions	–
Depreciation for the period	–
Impairments	–
Net change	(61)
Cost	5,309
Accumulated changes	(152)
Closing net book value	5,157

The group has not identified events during the six-month period ended June 30, 2021 that required an update of the impairment test that was performed at the end of 2020.

8. Financial liabilities

8.1 Interest bearing loans

Innovation loan

On February 5, 2016, the Group was granted a loan from RVO NL (Dutch Government) of € 10 million payable according a set payment scheme.

	30 June 2021
Loan opening balance	10,410
Loan amount received	–
Interest accrued during the period	488
Closing net book value	10,898

During the comparable six-month period ended 30 June, 2020 a loan amount of € 553k was received. The loan carries interest at 10%.

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 assets, including Intellectual Property and In-process R&D, have been pledged to the RVO NL in case of default of repayment of the loan.

Convertible preference A shares

On 3 June 2021, there were 37,666,666 convertible preference A shares in issue (2020: 37,666,666; 2019: 35,583,332; 2018: 20,000,001). The preference shares carry a dividend of 6% per annum. The dividend rights are cumulative. The preference shares rank ahead of the ordinary shares in the event of a liquidation. The preference A shares can be converted into Ordinary Shares of the company under different scenarios, where the rights and number of Ordinary Shares received differs. For the purpose of the valuation management assumed mandatory conversion upon IPO as the most likely scenario at a conversion rate of one ordinary share for one preference share as stated in the Company's last annual Consolidated special purpose financial statements as at and for the year ended 31 December 2020.

The equity portion is disclosed in Other Reserves.

	30 June 2021
Loan opening balance	31,407
Preference shares issued	–
Cumulative preference dividend (accrued)	1,992
Closing net book value	33,399

During the comparable six-month period ended 30 June, 2020 the accrued cumulative preference dividend amounted to € 1,670k.

Convertible loan

On 20 April 2021 the Company entered into a Convertible Loan Agreement of EUR 30 million (EUR 27.1 million (the “Principal Amount”) furnished per 30 June 2021, with an additional EUR 2.9 million executed in July 2021). The conversion option is considered an embedded derivative which is bifurcated and treated as a financial instrument at fair value through profit and loss. Based on the valuation performed this instrument has been reclassified, refer to Note 8.2.

	30 June 2021
Loan opening balance	–
Loan amount received	24,625
Interest accrued during the period	389
Closing net book value	25,014

The annual interest rate is 8%. The convertible loan is repayable within 36 months from date of signing the agreement. The repayment date is therefore 2024. In terms of the agreement no assets may be pledged by the Company without consent from the majority of lenders.

8.2 Other financial liabilities

Convertible loan – conversion option

The fair value of the embedded conversion options could not be measured reliably with reference to the terms and conditions as there is no active market. The fair value of the embedded conversion options is therefore equal to the difference between the fair value of the Convertible loan and the fair value of the debt portion.

At the Issue Date, the fair value of the debt portion and the fair value of the embedded derivatives together have a total fair value equal to the issue price of the Convertible Loan, given that the Convertible Loan was issued to market participants and therefore the total fair value should equal the transaction price. The expected cash flows are estimated per issue date based on the terms of the convertible loan agreement. This agreement specifies that an interest rate of 8.0% per annum is charged. The interest is accrued and repaid at maturity. As a result, there is one expected payment of principal and accrued interest at maturity date of the loan. For the discounting of the expected future interest and principal payments, an appropriate discount rate is determined using the (historic) debt spreads as determined by Aswath Damodaran, a renowned valuation practitioner. The applied debt spreads are based on the issue date of the Convertible Loan and the Preference Shares, as well as an indicative credit rating to incorporate the implied credit risk of Onward as at the valuation date.

Moody's rating methodology for pharmaceutical companies was used to estimate an indicative credit rating for Onward. This methodology not only considers financial metrics but also qualitative factors and the potential of Onward and its pipeline. Notching adjustments are included to incorporate the risk profile of the unsecured nature of the convertible bonds.

Based on the result of the valuation management used the mid-range of the outcome for the recognition of the embedded conversion option.

The table below includes a sensitivity analysis if the discount rate would increase or decrease with 1% or 2% respectively:

Sensitivity analysis - Convertible Loan					
Discount rate	9,52%	10,52%	11,52%	12,52%	13,52%
<i>(sensitivity on discount rate)</i>	<i>(2,0)%</i>	<i>(1,0)%</i>	-	1,0%	2,0%
Value debt portion	25.999	25.300	24.625	23.975	23.347
Implied option value	1.106	1.806	2.480	3.131	3.759
Total convertible loan value	27.106	27.106	27.106	27.106	27.106
<i>Option as % of notional</i>	<i>4,1%</i>	<i>6,7%</i>	<i>9,2%</i>	<i>11,6%</i>	<i>13,9%</i>

	30 June 2021
Opening balance	–
Conversion option at fair value	2,480
Closing balance	<u>2,480</u>

8.3 Financial risk management

The Group's financial risk management objectives and policies are consistent with those disclosed in the Consolidated special purpose financial statements for the year ended 31 December 2020.

Fair value hierarchy

The valuation techniques and inputs used to develop measurements for financial liabilities are consistent with those disclosed in the Consolidated special purpose financial statements for the year ended 31 December 2020.

The carrying amounts and fair values of the Group's financial instruments are as follows, including its fair value hierarchy:

Balance as at 30 June 2021	Carrying amount	Fair value
Financial liabilities		
Innovation credit loan (Level 2)	10,898	11,890
Convertible preference A shares (Level 3)	33,399	37,382
Convertible loan (Level 3)	25,014	25,014
Convertible loan – conversion option (Level 3)	2,480	2,480
Total financial liabilities	<u>71,791</u>	<u>76,766</u>
Balance as at 31 December 2020	Carrying amount	Fair value
Financial liabilities		
Innovation credit loan (Level 2)	10,410	11,393
Convertible preference A shares (Level 3)	31,407	35,549
Total financial liabilities	<u>41,817</u>	<u>46,942</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 except for the addition of the convertible loan and related conversion option. Refer to note 8 for details on the valuation including assumptions of the convertible loan and the conversion option. 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.

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:

As of 30 June 2021:

	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Innovation loan	–	–	2,535	16,763	19,298
Convertible preference A shares	–	–	60,541	–	60,541
Convertible loan	–	–	31,693	–	31,693
Other financial liabilities – conversion option	–	–	2,480	–	2,480
Lease liability	130	–	–	–	130
Trade & other payables	2,732	–	–	–	2,732
Total	2,862	–	97,249	16,763	116,874

As at 31 December 2020:

	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Innovation loan	–	–	–	19,298	19,298
Convertible preference A shares	–	–	–	60,541	60,541
Lease liability	137	61	–	–	198
Trade & other payables	2,501	–	–	–	2,501
Total	2,638	61	–	79,839	82,538

9. Issued capital and reserves

The authorized share capital is equal to the issued and paid capital

Share Capital

Issued and fully paid shares (Number of shares)	Ordinary € 1	Ordinary E € 0,000003	Ordinary O € 0,000003	Ordinary R € 0,0000001	Total
Opening balance as at 20 November 2015	82.584	-	-	-	82.584
Series A Financing (april '16)	-82.584	977.778	2.306.221	2.500.001	5.701.416
As at December 31, 2016	-	977.778	2.306.221	2.500.001	5.784.000
Series A Financing (dec '17)	-	694.444	-	-	694.444
As at December 31, 2017	-	1.672.222	2.306.221	2.500.001	6.478.444
Series A Financing (sept '18)	-	861.111	-	-	861.111
As at December 31, 2018	-	2.533.333	2.306.221	2.500.001	7.339.555
Series A Financing - NRT (oct '19)	-	1.222.222	2.500.000	-2.500.001	1.222.221
As at December 31, 2019	-	3.755.555	4.806.221	-	8.561.776
As at June 30, 2020	-	3.755.555	4.806.221	-	8.561.776
Series A Financing - NRT (oct '19)	-	1.018.519	-	-	1.018.519
As at December 31, 2020	-	4.774.074	4.806.221	-	9.580.295
E-share issuance	-	3.727.098	-	-	3.727.098
As at June 30, 2021	-	8.501.172	4.806.221	-	13.307.393
<i>Share Capital value</i>	€ -	€ 25,50	€ 14,42	€ -	€ 39,92

The Ecole Polytechnique Fédérale de Lausanne (EPFL) has the right to acquire 493,778 Ordinary shares at nominal value set forth in the terms of the license agreement in respect of the use of EPFL's intellectual property rights (the "**EPFL Option 1**"). The EPFL Option 1 can be exercised by EPFL until an initial public offering or an exit transaction. An "Exit" shall mean: (i) the sale of all or substantially all of the Company's assets, or (ii) the sale of more than fifty per cent (50%) of the Company's issued and outstanding capital stock, to any company, entity or person, or (iii) the liquidation, dissolution or winding up of the Company including, without limitation, any merger or consolidation where the Company is not the surviving company.

In addition EPFL has the right to acquire 0.3% of the total Ordinary shares of the Company at zero consideration at the time of an IPO as set forth in the terms of the license agreement in respect of the use of EPFL's intellectual property rights (the "**EPFL Option 2**"). Under this agreement EPFL also has a right to receive the cash value equivalent to the number of shares representing 0.3% of the total capital stock of the Company existing, on a fully diluted basis, at the time of an Exit not being an IPO. An Exit, not being an IPO, is not considered to be the most probable outcome. The rights are non-cumulative and shall only apply once according to the earliest event. Cash settlement is therefore not probable.

These rights are accounted for under IFRS 2 as equity settled share based payments. The fair value of the goods and services received on the respective grant dates were considered negligible mainly due to the lack of regulatory approvals.

Share Premium Reserve

	30 June 2021	30 June 2020
Opening balance	3,083	3,083
Issuance of shares, net of closing costs – in cash	–	–
Issuance of shares, net of closing costs – in kind (business combinations)	–	–
Closing balance	3,083	3,083

Other Reserves

	Convertible preference shares	Share-based payments	Total
Balance at January 1, 2020	14,246	971	15,217
Share based payment expense for the period	–	559	559
Balance at June 30, 2020	14,246	1,530	15,776
Balance at January 1, 2021	14,794	3,671	18,465
Share based payment expense for the period	–	2,007	2,007
Balance at June 30, 2021	14,794	5,678	20,473

10. Share-based payments

Employee Investment Plan

Under the Employee Investment Plan, eligible employees have the opportunity to subscribe for, indirectly via Stichting G-Therapeutics Participaties ("STAK"), an equity stake in ONWARD Medical B.V.. The Employee Investment Plan is set-up to align the Employee's interest with the interests of the Shareholders and to participate in the long term growth of the Company.

Eligible employees will be granted depository receipts (DR) via the STAK by means of a deed of issuance. At the time of the deed issuance, the eligible employee accepts the obligation to subscribe to (purchase) the DRs for a value of € 0,01 cent and payment is required within 10 days. The agreement does not provide the eligible employee with any options to be exercised at a future date.

From this point the owners obtain all rights and obligations from indirect share ownership. One depository receipt will at all times equal one ordinary non-voting E share in the capital of The Company. In the event of the distribution of proceeds, the ordinary shares (also from the DRs) will rank equal to all other shares after settlement with preferred A shares. At the time of the deed issuance the eligible employee purchases the DR for a value of € 0,01 cent. The DRs are not transferrable. The DRs have a one year cliff from grant date, after this one year cliff period 25% of the issue vests and the remaining 75% vests over the remaining 3 years. When employment ceases the non-vested part is forfeited except in the event of illness or death. The DRs issued to employees are considered to be shares in accordance with IFRS 2, that has been issued under an equity settled shared based compensation plan.

	30 June 2021	30 June 2020
Opening balance	3,671	971
Addition to the reserve	2,007	559
Closing balance	5,678	1,530

The following assumptions are applied in recognizing the share-based compensation expense in the profit and loss statement:

- The vesting start date is used as “Granting date”, regardless of when the certificates were issued.
- The vesting start date will be the valuation date, no revaluation takes place subsequent to the vesting start date.
- DR’s with a vesting start date from October 14, 2019 up and until April 2021 have a fair value of the DR’s for IFRS valuation purposes of € 1.20 which is equal to the price paid of the Pref A shares since October 14, 2019 up and until the execution of the CLA by the end of April 20, 2021 in which the price of € 1.20 is referenced.
- The graded vesting method (front loaded expense recognition method) is applied for the allocation of the vesting expenses.

11. Income taxes

Income tax expense is recognised 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 recognised 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 2021 was (0.1%) (six months ended 30 June 2020: (0.3%)). The change in effective tax rate was minimal.

12. Related party transactions

Note 1 provides the information about the Group’s structure including the details of the subsidiaries, the holding company, its shareholders and key management personnel. Outside the scope of the group, no other related parties are in place.

The convertible preference A shares debt, included in Note 8.1, is with related parties.

The Group considers the board and the leadership team to be key management as defined in IAS 24 ‘Related parties’.

Remuneration of the Leadership Team

	30 June 2021
Salary and bonuses (short-term employee benefits)	1,397
Pension premiums (post-employment benefits)	26
Share based payments	1,579
	<hr/> 3,002 <hr/>

13. Events after the reporting period

On July 21, 2021 ONWARD secured additional financing of € 3 million by means of a convertible loan agreement with several investors, resulting in the full value of € 30 million on the convertible loan.

On September 27, 2021 EPFL has notified ONWARD in writing about their wish to exercise both of its Options as referred to in Note 9.

No other events have taken place after the reporting period to date that need to be reported.

October 6, 2021

On behalf of the board of Directors:

Dave Marver (CEO)

Marko Jansen (CFO)

Independent auditor’s review report

Independent auditor's review report

To: the shareholders and board of directors of ONWARD Medical B.V.

Our conclusion

We have reviewed the condensed consolidated interim financial statements of ONWARD Medical B.V. based in Eindhoven for the period from 1 January 2021 to 30 June 2021.

Based on our review, nothing has come to our attention that causes us to believe that the condensed consolidated interim financial statements of ONWARD Medical B.V. for the period from 1 January 2021 to 30 June 2021, are not prepared, in all material respects, in accordance with IAS 34, "Interim Financial Reporting" as adopted by the European Union.

The condensed consolidated interim financial statements comprise:

- The condensed consolidated interim statement of financial position as at 30 June 2021
- The following condensed consolidated interim statements for the period from 1 January 2021 to 30 June 2021: the statements of profit or loss, comprehensive income, changes in equity and cash flows
- The notes comprising of a summary of the significant accounting policies and selected explanatory information

Basis for our conclusion

We conducted our review in accordance with Dutch law, including the Dutch Standard 2410, "Het beoordelen van tussentijdse financiële informatie door de accountant van de entiteit" (Review of interim financial information performed by the independent auditor of the entity). A review of interim financial information in accordance with the Dutch Standard 2410 is a limited assurance engagement. Our responsibilities under this standard are further described in the Our responsibilities for the review of the condensed consolidated interim financial statements section of our report.

We are independent of ONWARD Medical B.V. in accordance with 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 assurance evidence we have obtained is sufficient and appropriate to provide a basis for our conclusion.

Material uncertainty with respect to the going concern assumption

We draw attention to "Note 3 Continuity of the Group" in the condensed consolidated interim financial statements, which indicates that the Company's cash position would be negative as of 30 September 2022 based on the assumptions made by the board of directors regarding expected cash inflows and outflows over the next twelve months. These forecasts do not include financing alternatives currently under consideration by the board of directors. In this context, the board of directors is aware that the continuity of Company's operations depends on its ability to obtain these new sources of funding and that there are material uncertainties in this regard.

Please note that the Company's long-term success is contingent on achieving FDA approval and CE mark of its products. These conditions indicate the existence of a material uncertainty which may cast significant doubt on the company's ability to continue as a going concern. We draw attention to these disclosures.

Corresponding figures neither audited nor reviewed

We have not audited nor reviewed the condensed consolidated interim financial statements for the period from 1 January 2020 to 30 June 2020. Consequently, we have not audited nor reviewed the corresponding figures included in the condensed consolidated interim statements of profit or loss, comprehensive income, changes in equity and cash flows and the related notes.

Responsibilities of the board of directors for the condensed consolidated interim financial statements

The board of directors is responsible for the preparation and presentation of the condensed consolidated interim financial statements in accordance with IAS 34, "Interim Financial Reporting" as adopted by the European Union. Furthermore, the board of directors is responsible for such internal control as it determines is necessary to enable the preparation of the condensed consolidated interim financial statements that are free from material misstatement, whether due to fraud or error.

Our responsibilities for the review of the condensed consolidated interim financial statements

Our responsibility is to plan and perform the review in a manner that allows us to obtain sufficient and appropriate assurance evidence for our conclusion.

The level of assurance obtained in a review engagement is substantially less than the level of assurance obtained in an audit conducted in accordance with the Dutch Standards on Auditing. Accordingly, we do not express an audit opinion.

We have exercised professional judgement and have maintained professional skepticism throughout the review, in accordance with Dutch Standard 2410.

Our review included among others:

- Updating our understanding of ONWARD Medical B.V. and its environment, including its internal control, and the applicable financial reporting framework, in order to identify areas in the condensed consolidated interim financial statements where material misstatements are likely to arise due to fraud or error, designing and performing analytical and other review procedures to address those areas, and obtaining assurance evidence that is sufficient and appropriate to provide a basis for our conclusion
- Obtaining an understanding of internal control as it relates to the preparation of the condensed consolidated interim financial statements
- Making inquiries of the board of directors and others within the entity
- Applying analytical procedures with respect to information included in the condensed consolidated interim financial statements
- Obtaining assurance evidence that the condensed consolidated interim financial statements agree with, or reconcile to, ONWARD Medical B.V.'s underlying accounting records
- Evaluating the assurance evidence obtained
- Considering whether there have been any changes in accounting principles or in the methods of applying them and whether any new transactions have necessitated the application of a new accounting principle

- Considering whether the board of directors has identified all events that may require adjustment to or disclosure in the condensed consolidated interim financial statements
- Considering whether the condensed consolidated interim financial statements have been prepared in accordance with the applicable financial reporting framework and represent the underlying transactions free from material misstatement

The Hague, 6 October 2021

Ernst & Young Accountants LLP

signed by A.A. Kuijpers

Special purpose consolidated financial statements ONWARD Medical B.V.

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Consolidated statement of profit and loss

All amounts in EUR '000	Notes	For the period ended 31 December		
		2020	2019	2018
Grants	10	800	554	474
Total Revenues and Other Income		800	554	474
Science expenses	12, 18	(1,123)	(313)	(586)
Research and Development expenses	13, 18	(5,823)	(5,356)	(4,722)
Clinical & Regulatory expenses	14, 18	(2,770)	(1,239)	(654)
Marketing and Market Access expenses	15, 18	(394)	(261)	(98)
Patent and related expenses	16, 18	(1,186)	(525)	(455)
General and administrative expenses	17, 18	(5,016)	(3,632)	(2,364)
Total operating expenses		(16,312)	(11,326)	(8,879)
Operating loss for the period		(15,512)	(10,772)	(8,405)
Financial income		–	6	3
Financial expense	11	(4,482)	(2,678)	(1,492)
Net finance costs		(4,482)	(2,672)	(1,489)
Loss for the period before taxes		(19,994)	(13,444)	(9,894)
Income tax expense	19	(20)	(39)	(18)
Net loss for the period		(20,014)	(13,483)	(9,912)
Attributable to:				
Equity holders of the parent		(20,014)	(13,483)	(9,912)
Non-controlling interests		–	–	–
		(20,014)	(13,483)	(9,912)
Earnings per share (€):				
Basic earnings per share:		(2,22)	(1,77)	(1,47)
Diluted earnings per share:		(2,22)	(1,77)	(1,47)

Consolidated statement of comprehensive income

<i>All amounts in EUR '000</i>	Notes	For the period ended 31 December		
		2020	2019	2018
Net loss for the period		(20,014)	(13,483)	(9,912)
Remeasurement of post employment benefits	32	35	(165)	(48)
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods (net of tax)		35	(165)	(48)
Currency translation differences		(441)	(106)	15
Other comprehensive income that will be reclassified to profit or loss in subsequent periods (net of tax)		(441)	(106)	15
Total comprehensive result for the year, net of tax		(20,420)	(13,754)	(9,945)
Attributable to:				
Equity holders of the parent		(20,420)	(13,754)	(9,945)
Non-controlling interests		—	—	—
		(20,420)	(13,754)	(9,945)

Consolidated statement of financial position

<i>All amounts in EUR '000</i>	Notes	31 December 2020	31 December 2019	31 December 2018	1 January 2018
ASSETS					
Non-current assets					
Intangible fixed assets	9, 23	6,825	7,382	25	46
Property, plant and equipment	22	248	215	179	185
Right of use assets	6, 21	149	254	360	465
		<u>7,222</u>	<u>7,851</u>	<u>564</u>	<u>696</u>
Current assets					
Indirect tax receivables	26	93	131	190	98
Receivable from related parties		57	51	49	49
Other current assets	27	436	183	92	66
Cash and cash equivalents	28	6,382	15,129	8,665	7,274
		<u>6,968</u>	<u>15,494</u>	<u>8,996</u>	<u>7,487</u>
		<u>14,190</u>	<u>23,345</u>	<u>9,560</u>	<u>8,183</u>
EQUITY AND LIABILITIES					
Equity and reserves					
Shareholders' equity	29	–	–	–	–
Share premium	29	3,083	3,083	83	83
Other reserves	29, 31	18,465	15,217	9,117	5,549
Other Comprehensive income		(710)	(304)	(33)	–
Retained earnings	29	(52,933)	(32,919)	(19,436)	(9,524)
Total equity attributable to shareholders		<u>(32,095)</u>	<u>(14,923)</u>	<u>(10,269)</u>	<u>(3,892)</u>
Non-current liabilities					
Interest-bearing loans	24	41,817	33,479	17,144	10,195
Deferred tax liability	19	1,343	1,448	–	–
Lease liability	6, 21	61	198	324	419
Post-employment benefits	32	399	429	356	324
		<u>43,620</u>	<u>35,554</u>	<u>17,824</u>	<u>10,938</u>
Current liabilities					
Income tax liabilities		27	39	11	39
Lease liability	6, 21	137	126	95	49
Trade payables	33	911	1,306	852	348
Other payables	30	1,590	1,243	1,047	701
		<u>2,665</u>	<u>2,714</u>	<u>2,005</u>	<u>1,137</u>
		<u>14,190</u>	<u>23,345</u>	<u>9,560</u>	<u>8,183</u>

The above balance sheet should be read in conjunction with the accompanying notes.

Consolidated statement of changes in equity

<i>All amounts in EUR '000</i>	Notes	Issued Capital*	Share Premium	Other reserves	Currency translation differences	Retained Earnings	Total Equity
As at January 1, 2018	29	–	83	5,549	–	(9,524)	(3,892)
Loss for the year 2018		–	–	–	–	(9,912)	(9,912)
Other comprehensive income	32	–	–	(48)	15	–	(33)
Total comprehensive result		–	–	(48)	15	(9,912)	(9,945)
Share based payments	31	–	–	361	–	–	361
Issue of share capital		–	–	3,207	–	–	3,207
As at December 31, 2018	29	–	83	9,069	15	(19,436)	(10,269)
As at January 1, 2019	29	–	83	9,069	15	(19,436)	(10,269)
Loss for the year 2019		–	–	–	–	(13,483)	(13,483)
Other comprehensive income	32	–	–	(165)	(106)	–	(271)
Total comprehensive result		–	–	(165)	(106)	(13,483)	(13,754)
Share based payments	31	–	–	289	–	–	289
Issue of share capital		–	3,000	5,811	–	–	8,811
As at December 31, 2019	29	–	3,083	15,004	(91)	(32,919)	(14,923)
As at January 1, 2020	29	–	3,083	15,004	(91)	(32,919)	(14,923)
Loss for the year 2020		–	–	–	–	(20,014)	(20,014)
Other comprehensive income	32	–	–	35	(441)	–	(406)
Total comprehensive result		–	–	35	(441)	(20,014)	(20,420)
Share based payments	31	–	–	2,700	–	–	2,700
Issue of share capital		–	–	548	–	–	548
As at December 31, 2020	29	–	3,083	18,287	(532)	(52,933)	(32,095)

* share capital amounts to EUR 28,74 as at 31 December 2020 (2019: EUR 25,69; 2018: EUR 14,77)

Consolidated statement of cash flows

All amounts in EUR '000	Notes	For the period ended December 31,		
		2020	2019	2018
Cash flows from operating activities				
Loss for the period before taxes		(19,994)	(13,444)	(9,894)
Adjusted for:				
• Depreciation and impairment of property, plant and equipment and right-of-use assets	21-23	271	229	234
• Share based payment transaction expense	31	2,700	289	361
• Post-employment benefits		(5)	(105)	(4)
• Net finance costs		4,482	2,672	1,489
• Other non-cash items		(7)	–	–
Changes in working capital:				
Increase (-) Decrease (+) in Trade and other receivables		(221)	(24)	(118)
Increase (+) Decrease (-) in Trade and other payables		(48)	575	852
Interests received	11	–	1	–
Interests paid	11	(37)	(20)	(26)
Income tax paid		(31)	(11)	(45)
Bank Charges paid	11	(11)	(7)	(5)
Net cash generated /(used) from operating activities		(12,901)	(9,845)	(7,156)
Cash flows from investing activities				
Investments in fixed assets	21-22	(173)	(124)	(103)
Acquisition of a subsidiary, net of cash acquired	9	–	25	–
Net cash generated/(used) from investing activities		(173)	(99)	(103)
Cash flows from financing activities				
Proceeds from interest-bearing loans	24	3,946	11,743	5,489
Payment of principal portion of lease liabilities	21	(126)	(95)	(49)
Proceeds from issuance of shares	29	548	4,755	3,207
Net cash generated/(used) from financing activities		4,368	16,403	8,647
Movement in cash and cash equivalents				
Cash and cash equivalents at 1 January		15,129	8,665	7,274
Effect of exchange rates on cash and cash equivalents		(41)	5	3
Changes in cash and cash equivalents during the period		(8,706)	6,459	1,388
Cash and cash equivalents at 31 December		6,382	15,129	8,665

Notes to the special purpose consolidated financial statements

14. Corporate information

General

ONWARD Medical B.V. (“ONWARD”) is a limited liability company, incorporated on November 20, 2015. The registered office is located at High Tech Campus 32, Eindhoven, the Netherlands. ONWARD Medical B.V. was formerly known as GTX medical B.V.

ONWARD and its subsidiaries (the “Group”) are developing both an Implantable Neuro-stimulation System (INS) and a non-invasive system (since the merger with NRT) for electrical stimulation of specific areas of the spinal cord. Information on the Group’s structure is provided in Note 9. Information on other related party relationships of the Group is provided in Note 27.

Our vision and mission

Empowered by movement people with spinal cord injury will enjoy life in every way that matters to them.

At ONWARD Medical B.V. (“ONWARD”) we are working to enable people with spinal cord injury to move again, aided by ARC Therapy™ – targeted, programmed stimulation of the spinal cord.

In addition to restoring movement, we have observed other potential benefits from spinal cord stimulation that we may explore such as improved bladder control, sexual function, and blood pressure regulation.

The ONWARD code. We are:

- EMPOWERED
- COMMITTED
- PRAGMATIC
- INNOVATIVE
- OPEN
- TRUSTING
- COLLABORATIVE
- PASSIONATE

A bond between Lausanne and Eindhoven

ONWARD is based on two of the most productive sites for science and technology in Europe. In Lausanne, we are associated with the world-class research conducted at the Technical and Life Science Faculties of EPFL. In the Netherlands, we are based on the High Tech Campus Eindhoven, which is one of the Europe’s most attractive hubs for high-tech developments.

Combining the expertise of both sites results in a unique and dynamic fertilization that forms the basis for building world-class neuro-modulation devices.

Late 2019 ONWARD has acquired the activities of NeuroRecovery Technologies Inc. (“NRT”), a US based company. Herewith ONWARD adds a second product line to its portfolio focusing to restore the upper limb movement and hand function. As a result of this transaction, ONWARD is now also collaborating with universities in the US.

Directors

ONWARD Medical B.V. has a one-tier board which consists of the following statutory directors:

<i>Name</i>	<i>Function</i>
D.L. Marver	Executive Board
J.K. Øhrstrøm	Non-executive Board
J.P. de Koning	Non-executive Board
R. Hodits	Non-executive Board
P.F.J. van Beneden	Non-executive Board
G.R. Courtine	Non-executive Board
F.A. Colen	Non-executive Board
R. Bulthuis	Non-executive Board
I. Curtis	Non-executive Board

The leadership team of the Group consists of:

<i>Name</i>	<i>Function</i>
D.L. Marver	Chief Executive Officer
J. Murphy	Chief Technical Officer
M.F. Jansen	Chief Financial Officer
H.L. Lambert	Vice-president Clinical, Regulatory and Quality
V.C.P. Delattre	Vice-president Business Development
D. Harari	Managing Director US
R. Burkhanova	Global HR Director

Registered office

High Tech Campus 32
5656 AE Eindhoven
The Netherlands
Chamber of Commerce: 64598748

www.onwd.com

E-mail info@onwd.com

15. Basis of preparation

The special purpose consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted in the EU.

The special purpose consolidated financial statements have been prepared on a historical cost basis. The special purpose consolidated financial statements are presented in 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.

The special purpose consolidated financial statements provide comparative information in respect of the previous period. In addition, the Group presents an additional statement of financial position at the beginning of the earliest period presented when there is a retrospective application of an accounting policy, a retrospective restatement, or a reclassification of items in financial statements.

These special purpose consolidated financial statements were prepared for use in connection with a prospectus which the Company may issue in the foreseeable future. Separate statutory financial statements will be filed at the Chamber of Commerce.

16. Basis of consolidation

The special purpose consolidated financial statements comprise the financial statements of the Group and its subsidiaries as at 31 December 2020. 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 re-assesses 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. Assets, liabilities, income and expenses of a subsidiary acquired or disposed of during the year are included in the statement of comprehensive income from the date the Group gains control until the date the Group ceases to control 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 and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. 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 intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

17. Continuity of the Group

ONWARD Medical B.V. ("ONWARD") closed a Series A financing round of € 26 million in April 2016, with a group well-known European investors: LSP and Inkef Capital from Amsterdam, Wellington Partners from Munich and GIMV from Antwerp. In addition, the company secured an additional € 10 million Innovation loan from the Dutch ministry of economic affairs.

On October 14, 2019 ONWARD concluded a business combination with a US company named NeuroRecovery Technologies Inc. ("NRT"). The activities of NRT were brought in through an in-kind contribution of the NRT activities in exchange for shares in ONWARD Medical B.V. with a transaction value of € 6 million.

Prior to the NRT business combination, the Series A Funding was extended with an additional € 5 million to € 31 million. The open Funding Milestones of the initial Series A Funding were waived and the € 31 million was paid in full on October 14, 2019. After the NRT business combination the former NRT investors have also agreed to an additional investment of € 5 million into ONWARD that was fully paid as of November 2020.

On April 20, 2021 ONWARD closed an additional financing of € 27 million by means of a convertible loan agreement ("CLA") with several investors. The CLA allowed for a second close within 120 days to close an additional € 3 million that closed in July 2021.

The total new financing of € 30 million will be sufficient to fund the development and commercialization activities for the ARC Therapy thru at least September 2022.

Inherent uncertainties in these forecasts may have an impact on when the Company's cash position will actually become negative. To continue development and reach commercialization as planned after 30 September 2022, the Company has to attract additional funding. Please note that the Company's long-term success is contingent on achieving FDA approval and CE mark of its products.

The Company is actively involved in additional capital and financing discussions. The Board of Directors is aware that the continuity of Company's operations depends on its ability to find these new sources of funding and that there are material uncertainties in this regard. Considering the Company's history of successful attracting additional funding the Board of Directors have a reasonable expectation that ONWARD will be successful. As a result, the consolidated financial statements have been prepared on a going concern basis.

18. Summary of significant accounting policies

a) Business combinations and goodwill

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred, measured at acquisition date fair value and the amount of any non-controlling interest in the acquiree. For each business combination, the Group elects whether to measure the non-controlling interest in the acquiree at fair value or at the proportionate share of the acquirer's identifiable net assets. Acquisition-related costs are expensed as incurred and included in administrative expenses.

When the Group acquires a business, it assesses the financial assets and liabilities assumed for appropriate classification and designation in accordance with the contractual terms, economic circumstances and pertinent conditions as at the acquisition date. This includes the separation of embedded derivatives in host contracts by the acquiree.

If the business combination is achieved in stages, any previously held equity interest is re-measured at its acquisition date fair value and any resulting gain or loss is recognized in profit or loss. It is then considered in the determination of goodwill.

Any contingent consideration to be transferred by the acquirer will be recognized at fair value at the acquisition date. Contingent consideration classified as an asset or liability that is a financial instrument and within the scope of IFRS 9 *Financial Instruments*, is measured at fair value with changes in fair value recognized in the statement of profit or loss in accordance with IFRS 9. Other contingent consideration that is not within the scope of IFRS 9 is measured at fair value at each reporting date with changes in fair value recognized in profit and loss.

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 re-assesses 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 re-assessment 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.

b) 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.

c) Interest income

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, trade receivable, and other long term and current receivables.

d) Government subsidies

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. The governments subsidies are presented on a gross basis except for the WBSO ("Wet Bevordering Speur & Ontwikkeling") that is presented netted with the expensed amount for personnel expenses. Further details about the subsidies (including terms and conditions) are provided in Note 10.

e) Taxes

• 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 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.

f) 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.

g) Property, plant and equipment

Property, plant and equipment is stated at cost, net of accumulated depreciation and accumulated impairment losses, if any. Such cost 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

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 de-recognition 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.

h) Leases

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 recognises 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 impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognised, 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, as follows:

- Plant and machinery 3 to 15 years
- Motor vehicles and other equipment 3 to 5 years

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 (see Note 16).

- **Short-term leases and leases of low-value assets**

The Group applies the short-term lease recognition exemption to its short-term leases of machinery and equipment (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.

i) Borrowing costs

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.

j) Research and development costs

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

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. Further details about the in-process R&D are provided in Note 23.

k) 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.

Financial liabilities are classified as measured at amortized cost or at Fair Value through Profit or Loss (“FVPL”). 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, 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 (loans and borrowings)

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 (loans and borrowings)

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 derecognised 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 recognised 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.

1) Convertible preference shares

Convertible preference shares are separated into liability and equity components based on the terms of the contract.

On issuance of the convertible preference shares, the fair value of the liability component is determined using a market rate for an equivalent non-convertible instrument. This amount is classified as a financial liability measured at amortised cost (net of transaction costs) until it is extinguished on conversion or redemption. Upon conversion, the liability is reclassified to equity and no gain or loss is recognized in the statement of profit and loss.

The remainder of the proceeds is allocated to the conversion option that is recognised and included in equity. Transaction costs are deducted from equity, net of associated income tax. The carrying amount of the conversion option is not remeasured in subsequent years.

Transaction costs are apportioned between the liability and equity components of the convertible preference shares, based on the allocation of proceeds to the liability and equity components when the instruments are initially recognised.

m) Cash and short-term deposits

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.

n) Pensions and other employee 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 statement of income. 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 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 recognised in profit or loss on the earlier of:

- The date of the plan amendment or curtailment, and
- The date that the Group recognises related restructuring costs

Net interest is calculated by applying the discount rate to the net defined benefit liability or asset. The Group recognises 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.

o) Share based payments

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 had 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.

p) 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.

19. First-time adoption of IFRS

These financial statements, for the year ended 31 December 2020, are the first the Group has prepared in accordance with IFRS. For periods up to and including the year ended 31 December 2019, the Group prepared its financial statements in accordance with local generally accepted accounting principles (Local GAAP). In accordance with IFRS 1.23, the Group has prepared financial statements that comply with IFRS applicable as at 31 December 2020, together with the comparative period data for the years ended 31 December 2019 and 31 December 2018, as described in the summary of significant accounting policies. In preparing the financial statements, the Group's opening statement of financial position was prepared as at 1 January 2018, the Group's date of transition to IFRS. This note explains the principal adjustments made by the Group in restating its Local GAAP financial statements, including the statement of financial position as at 1 January 2018 and the financial statements as of, and for, the years ended 31 December 2019 and 31 December 2018.

Exemptions applied

IFRS 1 allows first-time adopters certain exemptions from the retrospective application of certain requirements under IFRS.

The Group has applied the following exemptions:

- IFRS 3 Business Combinations has not been applied to either acquisitions of subsidiaries that are considered businesses under IFRS, or acquisitions of interests in associates and joint ventures that occurred before 1 January 2018. Use of this exemption means that the Local GAAP carrying amounts of assets and liabilities, that are required to be recognised under IFRS, are their deemed cost at the date of the acquisition. After the date of the acquisition, measurement is in accordance with IFRS. Assets and liabilities that do not qualify for recognition under IFRS are excluded from the opening IFRS statement of financial position. The Group did not recognise any assets or liabilities that were not recognised under the Local GAAP or exclude any previously recognised amounts as a result of IFRS recognition requirements.
- The Group has not applied IAS 21 The Effects of Changes in Foreign Exchange Rates retrospectively to fair value adjustments and goodwill from business combinations that occurred before the date of transition to IFRS. Such fair value adjustments and goodwill are treated as assets and liabilities of the parent rather than as assets and liabilities of the acquiree. Therefore, those assets and liabilities are already expressed in the functional currency of the parent or are non-monetary foreign currency items and no further translation differences occur.
- Cumulative currency translation differences for all foreign operations are deemed to be zero as at 1 January 2018.

- IFRS 2 Share-based Payment has not been applied to equity instruments in share-based payment transactions that were granted on or before 7 November 2002, nor has it been applied to equity instruments granted after 7 November 2002 that vested before 1 January 2018. There were not cash-settled share-based payment transactions, therefore Group has not applied IFRS 2 to liabilities that were settled before 1 January 2018.
- The Group assessed all contracts existing at 1 January 2018 to determine whether a contract contains a lease based upon the conditions in place as at 1 January 2018.
- Lease liabilities were measured at the present value of the remaining lease payments, discounted using the lessee's incremental borrowing rate at 1 January 2018. Right-of-use assets were measured at the amount equal to the lease liabilities, adjusted by the amount of any prepaid or accrued lease payments relating to that lease recognised in the statement of financial position immediately before 1 January 2018. The lease payments associated with leases for which the lease term ends within 12 months of the date of transition to IFRS and leases for which the underlying asset is of low value have been recognised as an expense on either a straight-line basis over the lease term or another systematic basis.

Group reconciliation of equity as at 1 January 2018

	Notes	Previous GAAP	Consolidation adjustments	Remeasurements	IFRS as at 1 January 2018
<i>Amounts in EUR '000</i>					
ASSETS					
Non-current assets					
Financial fixed assets	A	307	(307)	–	–
Intangible fixed assets		–	46	–	46
Property, plant and equipment	A	176	9	–	185
Right of use assets	B	–	–	465	465
		483	(252)	465	696
Current assets					
Indirect tax receivables	A	83	15	–	98
Receivable from related parties	A	171	(122)	–	49
Other current assets	A	49	17	–	66
Cash and cash equivalents	A	6,641	633	–	7,274
		6,944	543	–	7,487
		7,427	291	465	8,183
EQUITY AND LIABILITIES					
Equity and reserves					
Shareholders' equity		–	–	–	–
Share premium		11,983	–	(11,900)	83
Other reserves	C, F	–	–	5,549	5,549
Other comprehensive income	A	–	–	–	–
Retained earnings	B, C	(8,114)	–	(1,410)	(9,524)
Total equity attributable to shareholders		3,869	–	(7,761)	(3,892)
Non-current liabilities					
Interest-bearing loans	F	2,761	–	7,434	10,195
Lease liability	B	–	–	419	419
Post-employment benefits	E	–	–	324	324
		2,761	–	8,177	10,938
Current liabilities					
Payable to related parties		–	–	–	–
Income tax liabilities		39	–	–	39
Lease liability	B	–	–	49	49
Trade payables	A	302	46	–	348
Other payables	A	456	245	–	701
		797	291	49	1,137
		7,427	291	465	8,183

Group reconciliation of equity as at 31 December 2018

	Notes	Previous GAAP	Consolidation entries	Remeasurements	IFRS as at 31 December 2018
<i>Amounts in EUR '000</i>					
ASSETS					
Non-current assets					
Financial fixed assets	A	406	(406)	–	–
Intangible fixed assets		–	25	–	25
Property, plant and equipment	A	171	8	–	179
Right of use assets	B	–	–	360	360
		577	(373)	360	564
Current assets					
Indirect tax receivable	A	151	39	–	190
Receivable from related parties	A	–	49	–	49
Other current assets	A	49	43	–	92
Cash and cash equivalents	A	8,490	175	–	8,665
		8,690	306	–	8,996
		9,267	(67)	360	9,560
EQUITY AND LIABILITIES					
Equity and reserves					
Shareholders' equity		–	–	–	–
Share premium		19,733	–	(19,650)	83
Other reserves	C, F	–	–	9,117	9,117
Other comprehensive income	A	–	–	(33)	(33)
Retained earnings	B, C	(16,534)	–	(2,902)	(19,436)
Total equity attributable to shareholders		3,199	–	(13,468)	(10,269)
Non-current liabilities					
Interest-bearing loans	F	3,986	–	13,158	17,144
Lease liability	B	–	–	324	324
Post-employment benefits		–	–	356	356
		3,986	–	13,838	17,824
Current liabilities					
Payable to related parties	A	349	(349)	–	–
Income tax liabilities		11	–	–	11
Lease liability	B	–	–	95	95
Trade payables	A	821	32	(1)	852
Other payables	A	901	250	(104)	1,047
		2,082	(67)	(10)	2,005
		9,267	(67)	360	9,560

Group reconciliation of equity as at 31 December 2019

	Notes	Previous GAAP	Consolidation adjustments	Remeasurements	IFRS as at 31 December 2019
<i>Amounts in EUR '000</i>					
ASSETS					
Non-current assets					
Financial fixed assets	A	6,315	(6,315)	–	–
Intangible fixed assets		–	7,479	(97)	7,382
Property, plant and equipment	A	176	39	–	215
Right of use assets	B	–	–	254	254
		6,491	1,106	254	7,851
Current assets					
Indirect tax receivables	A	110	21	–	131
Receivable from related parties	A	61	(10)	–	51
Other current assets	A	144	39	–	183
Cash and cash equivalents	A	14,775	354	–	15,129
		15,090	404	–	15,494
		21,581	1,607	157	23,345
EQUITY AND LIABILITIES					
Equity and reserves					
Shareholders' equity		–	–	–	–
Share premium		39,233	–	(36,150)	3,083
Other reserves	C, F	–	–	15,217	15,217
Other comprehensive income	A	–	–	(304)	(304)
Retained earnings	C	(27,643)	–	(5,276)	(32,919)
Total equity attributable to shareholders		11,590	–	(26,513)	(14,923)
Non-current liabilities					
Interest-bearing loans	F	7,561	–	25,918	33,479
Deferred tax liability		–	1,448	–	1,448
Lease liability	B	–	–	198	198
Post-employment benefits		–	–	429	429
		7,561	1,448	26,545	35,554
Current liabilities					
Payable to related parties	B	578	(578)	–	–
Income tax liabilities		39	–	–	39
Lease liability		–	–	126	126
Trade payables		1,202	107	(3)	1,306
Other payables		611	630	2	1,243
		2,430	159	125	2,714
		21,581	1,607	157	23,345

Group reconciliation of total comprehensive income for the year ended 31 December 2018

	Notes	Previous GAAP	Consolidation entries	Reclassifi- cations	Remeasure- ments	IFRS for the year ended 31 December 2018
<i>Amounts in EUR '000</i>						
Grants		474	–	–	–	474
Total Revenues and Other Income		474	–	–	–	474
Employee expenses	A, D	(3,634)	–	3,634	–	–
Science expenses	A, D	–	–	(545)	(41)	(586)
Research and Development expenses	A, D	(3,683)	–	(1,011)	(28)	(4,722)
Clinical and Regulatory expenses	A, D	–	–	(612)	(42)	(654)
Marketing and Market Access expenses	A, D	–	–	(98)	–	(98)
Patent and related expenses	A, D	–	–	(421)	(33)	(455)
Depreciation	A, D	(109)	(21)	234	(105)	–
General and administrative expenses	A, D	(1,151)	–	(1,179)	(34)	(2,364)
Total operating expenses		(8,577)	(20)	–	(283)	(8,879)
Operating loss		(8,103)	(20)	–	(283)	(8,405)
Financial income		–	3	–	–	3
Result from subsidiaries		–	–	–	–	–
Financial expenses	F	(280)	–	–	(1,212)	(1,492)
Net finance costs		(280)	3	–	(1,212)	(1,489)
Loss before tax		(8,383)	(17)	–	(1,494)	(9,894)
Income tax expenses		(18)	–	–	–	(18)
Net loss after taxation		(8,401)	(17)	–	(1,494)	(9,912)
Other comprehensive income						
Net other comprehensive loss that may be reclassified to profit or loss in subsequent periods		–	–	–	(48)	(48)
		–	–	–	(48)	(48)
Net other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods		–	–	–	15	15
		–	–	–	15	15
Other comprehensive income/(loss) for the year, net of tax		–	–	–	–	–
		–	–	–	(33)	(33)
Total comprehensive income for the year, net of tax		(8,401)	(17)	–	(1,527)	(9,945)

Group reconciliation of total comprehensive income for the year ended 31 December 2019

	Notes	Previous GAAP	Consolidation entries	Reclassifications	Remeasurements	IFRS for the year ended 31 December 2019
<i>Amounts in EUR '000</i>						
Grants	A	554	–	–	–	554
Total Revenues and Other Income		554	–	–	–	554
Employee expenses	A, D	(5,256)	–	5,256	–	–
Science expenses	A, D	–	–	(267)	(46)	(313)
Research and Development expenses	A, B, D	(3,581)	–	(1,630)	(145)	(5,356)
Clinical and Regulatory expenses	A, D	–	–	(1,233)	(6)	(1,239)
Marketing and Market Access expenses	A, D	–	–	(261)	–	(261)
Patent and related expenses	A, D	–	–	(504)	(21)	(525)
Depreciation	A, D	(123)	–	228	(105)	–
General and administrative expenses	A, B, D	(2,086)	–	(1,590)	44	(3,632)
Total operating expenses		(11,046)	–	–	(279)	(11,326)
Operating loss		(10,492)	–	–	(279)	(10,772)
Financial income		6	–	–	–	6
Result from subsidiaries		–	–	–	–	–
Financial expense	B, F	(585)	–	–	(2,093)	(2,678)
Net finance costs		(579)	–	–	(2,093)	(2,672)
Loss before tax		(11,071)	–	–	(2,372)	(13,444)
Income tax expenses		(30)	(9)	–	–	(39)
Net loss after taxation		(11,101)	(9)	–	(2,372)	(13,483)
Other comprehensive income						
Net other comprehensive loss that may be reclassified to profit or loss in subsequent periods		–	–	–	(106)	(106)
Net other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods		–	–	–	(165)	(165)
Other comprehensive income/(loss) for the year, net of tax		–	–	–	–	–
Total comprehensive income for the year, net of tax		(11,101)	(9)	–	(2,643)	(13,754)

Notes to the reconciliation of equity as at 1 January 2018, 31 December 2018 and 31 December 2019 and total comprehensive income for the years ended 31 December 2018 and 31 December 2019

General

From our evaluation we concluded that the company had limited reporting differences in valuation and measurement of assets and liabilities in the new reporting standard with exception of the items listed below.

A Consolidation entries

As ONWARD Medical B.V. was a small sized entity under Previous GAAP, the entity was not required to prepare consolidated financial statement under Previous GAAP. The Previous GAAP financial statements were prepared in accordance with Title 9, Book 2 of the Dutch Civil Code. As such, the effects of the first-time adoption of IFRSs from consolidated adjustments have been disclosed separately for 2018 and 2019. The consolidation adjustments relate to the consolidation of ONWARD Medical SA, Switzerland and ONWARD Medical Inc. as of November 2019.

B IFRS 16 Leases

The Group adopted IFRS 16 using the modified retrospective method of adoption with the date of initial application of January 1, 2018. Under this method, the standard is applied retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application. The weighted average incremental borrowing rate of 6% is used.

On February 1, 2019, the Group entered into a new lease contract for the current office building in Eindhoven. The old lease was terminated as the Group moved into a new and different location as of February 1, 2019.

The effect of adopting IFRS 16 is as follows:

	31 December 2020	31 December 2019	31 December 2018	1 January 2018
Assets				
Right of use assets	149	254	360	465
Total assets	149	254	360	465
Liabilities				
Lease liabilities	198	324	419	468
Total liabilities	198	324	419	468
Total adjustment on equity (retained earnings)	(49)	(70)	(59)	(3)
Impact on profit and loss	21	(10)	(56)	

The Group also elected to use the recognition exemptions for lease contracts that, at the commencement date, have a lease term of 12 months or less and do not contain a purchase option (short-term leases), and lease contracts for which the underlying asset is of low value (low-value assets).

C Share Based Compensation

Under local GAAP the company had no obligation to disclose the share-based compensation separately. This has been adjusted under IFRS. For details we refer to note 30.

D Reclassification operating expenses

Under local GAAP the profit and loss account had a categorial setup. For comparability management decided to break down other operating expenses in a functional setup. These expenses have been reclassified for 2018 and 2019.

E Post-employment benefits – Swiss pension plan

The company provides standard Swiss cash balance type pension benefits to its employees through the Collective Foundation BGV of Allianz Suisse. Under local GAAP the company accounts for the pension plan in Switzerland similar to a defined contribution plan. 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. Under IFRS this plan is considered a defined benefit plan. This has been adjusted under IFRS. For details refer to note 32.

F Convertible preference shares

The company raised capital through the issuance of Preference Shares, spread out over various Dates of Issuance. The Preference Shares carry interest at 6.0% per annum and can be converted to common shares of Onward, amongst others, at the discretion of the shareholder at a conversion ratio of 1:1 or when the net proceeds of an IPO are equal to or more than EUR 50 million. Based on the terms of the agreement, the convertible preference shares consist of a financial liability due to the unavoidable payments (dividends) and an equity portion for the conversion option that meets the fixed-for-fixed requirement. A valuation was performed to determine the allocation between debt and equity for each issuance at issue date. The debt is carried at amortized cost using the effective interest rate. Interest is included in Financial expense. Refer to Note 24 and 29 respectively for further details.

20. 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.

20.1 Judgments

In the process of applying the Group's accounting policies, management has made the following judgments which have the most significant effect on the amounts recognized in the consolidated financial statements.

20.1.1 Research/Development costs

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.

20.1.2 Taxes

The Group has losses before tax which arose in the Netherlands that are available for nine (9) years 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 2018. Considering the uncertainty and limited future profits, the Group

will, consistent with the treatment in the Dutch entity, not recognize any deferred tax assets for the Swiss entity.

All NOL's in the US entity prior to the business combination are not carried forward due to ownership change. Losses since the transaction can be carried forward for 20 years. These losses have not been recognized in the balance sheet to date.

20.1.3 Rights under the license agreements

The rights provided to Ecole Polytechnique Fédérale de Lausanne (EPFL) have been evaluated. The Group accounts for these options as equity settled transactions as per IFRS 2. Refer to Note 29 for further details.

20.2 Estimates and assumptions

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below. 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.

20.2.1 Share-based payments

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. The assumptions and models used for estimating fair value for share-based payment transactions are disclosed in Note 31.

20.2.2 Post-employment benefits

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. Further details about pension obligations are provided in Note 32.

21. 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 disclosed below. The Group intends to adopt these new and amended standards and interpretations, if applicable, when they become effective.

IFRS 17 Insurance Contracts

In May 2017, the IASB issued IFRS 17 Insurance Contracts (IFRS 17), a comprehensive new accounting standard for insurance contracts covering recognition and measurement, presentation and disclosure. Once effective, IFRS 17 will replace IFRS 4 Insurance Contracts (IFRS 4) that was issued in 2005. IFRS 17 applies to all types of insurance contracts (i.e., life, non-life, direct insurance and re-insurance), regardless of the type of entities that issue them, as well as to certain guarantees and financial instruments with discretionary participation features.

A few scope exceptions will apply. The overall objective of IFRS 17 is to provide an accounting model for insurance contracts that is more useful and consistent for insurers. In contrast to the requirements in IFRS 4, which are largely based on grandfathering previous local accounting policies, IFRS 17 provides a comprehensive model for insurance contracts, covering all relevant accounting aspects. The core of IFRS 17 is the general model, supplemented by:

- A specific adaptation for contracts with direct participation features (the variable fee approach)
- A simplified approach (the premium allocation approach) mainly for short-duration contracts

IFRS 17 is effective for reporting periods beginning on or after 1 January 2021, with comparative figures required. Early application is permitted, provided the entity also applies IFRS 9 and IFRS 15 on or before the date it first applies IFRS 17. This standard is not applicable to the Group.

Amendments to IAS 1: Classification of Liabilities as Current or Non-current

In January 2020, the IASB issued amendments to paragraphs 69 to 76 of IAS 1 to specify the requirements for classifying liabilities as current or non-current. The amendments clarify:

- What is meant by a right to defer settlement
- That a right to defer must exist at the end of the reporting period
- That classification is unaffected by the likelihood that an entity will exercise its deferral right
- That only if an embedded derivative in a convertible liability is itself an equity instrument would the terms of a liability not impact its classification. The amendments are effective for annual reporting periods beginning on or after 1 January 2023 and must be applied retrospectively. The Group is currently assessing the impact the amendments will have on current practice and whether existing loan agreements may require renegotiation.

Amendments to IFRS 3: *Definition of a Business*

In May 2020, the IASB issued Amendments to IFRS 3 Business Combinations - Reference to the Conceptual Framework. The amendments are intended to replace a reference to the Framework for the Preparation and Presentation of Financial Statements, issued in 1989, with a reference to the Conceptual Framework for Financial Reporting issued in March 2018 without significantly changing its requirements. The Board also added an exception to the recognition principle of IFRS 3 to avoid the issue of potential 'day 2' gains or losses arising for liabilities and contingent liabilities that would be within the scope of IAS 37 or IFRIC 21 Levies, if incurred separately. At the same time, the Board decided to clarify existing guidance in IFRS 3 for contingent assets that would not be affected by replacing the reference to the Framework for the Preparation and Presentation of Financial Statements. The amendments are effective for annual reporting periods beginning on or after 1 January 2022 and apply prospectively. The amendments are not expected to have a material impact on the Group.

Amendments to IAS 16: *Property, Plant and Equipment Proceeds before intended use*

In May 2020, the IASB issued Property, Plant and Equipment — Proceeds before Intended Use, which prohibits entities deducting from the cost of an item of property, plant and equipment, any proceeds from selling items produced while bringing that asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Instead, an entity recognises the proceeds from selling such items, and the costs of producing those items, in profit or loss. The amendment is effective for annual reporting periods beginning on or after 1 January 2022 and must be applied retrospectively to items of property, plant and equipment made available for use on or after the beginning of the earliest period presented when the entity first applies the amendment. The amendments are not expected to have a material impact on the Group.

Amendments to IAS 37: *Onerous Contracts – Costs of Fulfilling a Contract*

In May 2020, the IASB issued amendments to IAS 37 to specify which costs an entity needs to include when assessing whether a contract is onerous or loss-making. The amendments apply a "directly related cost approach". The costs that relate directly to a contract to provide goods or services include both incremental costs and an allocation of costs directly related to contract activities. General and administrative costs do not relate directly to a contract and are excluded unless they are explicitly chargeable to the counterparty under the contract. The amendments are effective for annual reporting periods beginning on or after 1 January 2022. The Group will apply these amendments to contracts for which it has not yet fulfilled all its

obligations at the beginning of the annual reporting period in which it first applies the amendments. The amendments are not expected to have a material impact on the Group.

Amendments to IFRS 1: First-time Adoption of International Financial Reporting Standards – Subsidiary as a first-time adopter

As part of its 2018-2020 annual improvements to IFRS standards process, the IASB issued an amendment to IFRS 1 First-time Adoption of International Financial Reporting Standards. The amendment permits a subsidiary that elects to apply paragraph D16(a) of IFRS 1 to measure cumulative translation differences using the amounts reported by the parent, based on the parent's date of transition to IFRS. This amendment is also applied to an associate or joint venture that elects to apply paragraph D16(a) of IFRS 1. The amendment is effective for annual reporting periods beginning on or after 1 January 2022 with earlier adoption permitted. The amendments are not expected to have a material impact on the Group.

IFRS 9 Financial Instruments – Fees in the '10 per cent' test for derecognition of financial liabilities

As part of its 2018-2020 annual improvements to IFRS standards process the IASB issued amendment to IFRS 9. The amendment clarifies the fees that an entity includes when assessing whether the terms of a new or modified financial liability are substantially different from the terms of the original financial liability. These fees include only those paid or received between the borrower and the lender, including fees paid or received by either the borrower or lender on the other's behalf. An entity applies the amendment to financial liabilities that are modified or exchanged on or after the beginning of the annual reporting period in which the entity first applies the amendment.

The amendment is effective for annual reporting periods beginning on or after 1 January 2022 with earlier adoption permitted. The Group will apply the amendments to financial liabilities that are modified or exchanged on or after the beginning of the annual reporting period in which the entity first applies the amendment. The amendments are not expected to have a material impact on the Group.

22. Group information

Information about subsidiaries

The consolidated financial statements of the Group include:

- ONWARD Medical SA, Switzerland; principal activities: the development and commercialization of an Implantable Neuro Stimulation System (INS) medical device solution to improve the lives of Spinal Cord Injured people. Holding 100%.
- Acquisition of NeuroRecovery Technologies, Inc ('NRT') in 2019 (subsequently renamed to ONWARD Medical Inc.); On October 14, 2019 the Group acquired 100% of the voting shares of NRT, a non-listed Delaware, USA based company, in exchange for the issuance of Company's shares. NRT is involved in the development and commercialization of a non-invasive medical device solution to improve the lives of Spinal Cord Injured people. For the assets acquired and liabilities assumed see next paragraph.

NRT Assets acquired and liabilities assumed

The fair values of the identifiable assets and liabilities of NRT as at the date of the acquisition were:

	<u>Note</u>	<u>Fair value recognised on acquisition</u>
Assets		
In-Process R&D	22	5,717
Office equipment	21	35
Prepayments		10
Cash and cash equivalents		<u>25</u>
		5,787
Liabilities		
Deferred tax liability		(1,472)
Short term loan		(69)
Accrued expenses		<u>(76)</u>
Total identifiable net assets at fair value		<u>4,240</u>
Goodwill arising on acquisition	22	1,760
Purchase consideration transferred		<u><u>6,000</u></u>

The acquisition was executed on a non-cash basis, based on a share for share deal where the NRT activities were valued at € 6 million. Shares were issued in exchange for 100% of the ownership in NRT. The opening equity value of NRT amounted to € -6k. The valuation for purchase price allocation purposes was performed by an external business valuator. The purchase consideration was settled through the issuance of 2,500 preference A shares and 2,500 ordinary O shares at the value of € 1.20 per share respectively. Transactions costs incurred relating to this acquisition amounted to € 427k.

In-Process R&D

The in-process R&D of € 5,717k comprises the value of the development of a transcutaneous Spinal Cord Stimulator ("tSCS"). tSCS is a portable stimulation system with gel- electrodes for transcutaneous treatments. The product/technology consists of a neuromodulator, electrode leads, battery charger and a patient programmer device with a custom software application.

The transcutaneous device is at a late stage development phase. It can be used at home, in the hospital or in rehabilitation (therapy) clinic.

Goodwill

The goodwill of € 1,760k comprises the value of expected synergies arising from the acquisition and market access, which is not separately identified. None of the goodwill recognised is expected to be deductible for income tax purposes.

If the acquisition had taken place on January 1, 2019, the net loss for the Group would have been € 14,3 million for the year ended December 31, 2019.

Shareholders

At December 31, 2020, the shareholders of ONWARD Medical B.V. are:

- LSP V Coöperatieve U.A., the Netherlands
- Stichting Depository INKEF Investment Fund, the Netherlands
- Wellington Partners Nominee Ltd., Jersey
- Gimv Investments H&C Netherlands 2016 B.V., the Netherlands
- G-Therapeutics Founders S.a.r.l., Switzerland
- Stichting G-Therapeutics Participaties, the Netherlands
- G-Therapeutics Participaties B.V., the Netherlands
- DHT Consultancy B.V., the Netherlands
- NRT Holdings LLC, USA
- GTX managers B.V., the Netherlands

None of these shareholders are considered an Ultimate Controlling party as none of the shareholders have more than 25% shares or voting rights in the company.

23. Revenues and other income

	2020	2019	2018
Government subsidies (EU)	800	554	474
Total revenues and other income	800	554	474

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.

	Total Grant *	2020	Recognized 2019	2018
Grants				
LEAP	376	–	–	113
RESTORE	370	37	100	133
DISPERSE	311	36	93	93
WALKAGAIN	500	185	180	135
CONFIRM	416	197	81	–
BESTABLE	99	25	59	–
SWISS LOCAL	79	24	41	–
PREP2GO	348	104	–	–
DARPA	1,152	192	–	–
Total		800	554	474

*) Please refer to the terms and conditions of the subsidies included below.

Terms & conditions

LEAP

This Eurostars funding agreement with the Swiss Innovation Agency Innosuisse for a total amount of EUR 376,154 started in April 2016 and ended in September 2018. The total grant has been received and has become unconditional. In this project, ONWARD collaborated with Motek Medical B.V, the Technical University of Delft, the Clinique Romande de Readaptation and EPFL to develop Rysen, an innovative body weight support system for neurorehabilitation. The system is now CE marked and commercialized by Motek.

RESTORE

This Eurostars funding agreement with the Netherlands enterprise agency RVO for a total amount of EUR 370,213 started in April 2017 and ended in September 2019, with follow up reporting resulting in the additional 10% granting of the allocated amount in 2020. The total grant amount has been received and has become unconditional. In this project, ONWARD collaborated with Zurich Medtech A.G., IT'IS Foundation, Universitair Medisch Centrum Utrecht and EPFL to develop a simulation framework supporting the pre-operative planning for ARC Therapy, using patient imagery data to generate patient personalized models of the spine to infer a priori optimal implant location and stimulation configurations.

DISPERSE

This Penta funding agreement with the Netherlands enterprise agency RVO for a total amount of EUR 310,867 started in March 2017 and ended in March 2020, with follow up reporting resulting in the additional 10% granting of the allocated amount. The total grant amount has been received and has become unconditional. In this project, ONWARD collaborated with Phillips and a large consortium of medical device development companies to investigate the influence of the coexistence of multiple implants on MRI safety.

Walkagain

This Eurostars funding agreement with the Netherlands enterprise agency RVO for a total amount of EUR 499,912 started in April 2018 and ended in September 2020, with follow up reporting resulting in the additional 10% granting of the allocated amount. The total grant amount has been received and has become unconditional. In this project, ONWARD collaborated with Gait-UP S.A. and EPFL to develop algorithms for closed-loop control of spinal cord stimulation based on motion sensor data.

CONFIRM

This Eurostars funding agreement with the Swiss Innovation Agency Innosuisse for a total amount of EUR 416,293 started in May 2019 and ends in October 2021, with follow up reporting resulting in the additional 25.75% granting of the allocated amount. At 31 December 2020, 74.25% of the total grant amount has been received and the remainder is expected in 2021 after submission of the final report which will trigger the payment of the last tranche. In this project, ONWARD is collaborating with Inomed A.G., Universitätsklinikum Heidelberg and EPFL to develop an intra-operative neuromonitoring system and algorithms facilitating the surgical implantation of ARC-IM.

BESTABLE

This Eurobench funding agreement with PKF ATTEST INNCOME S.L. and the Spanish National Research Council CSIC for a total amount of EUR 100,000 started in September 2019 and ends in December 2021. An amount equal to 85% of the grant is paid during the grant period in tranches in 2019, 2020 and 2021. The remaining 15% of the total grant amount will be paid after submission of the final report. In this project, ONWARD is collaborating with the Technical University of Delft and the University Rehabilitation Institute to develop a benchmarking system for assessment of balance performance.

PREP2GO

This Eurostars funding agreement with the Netherlands enterprise agency RVO for a total amount of EUR 347,802 started in April 2020 and ends 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 being paid after submission of the final report. In this project, ONWARD is collaborating 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

This US Department of Defense funding agreement for phase 1 for a total amount of EUR 1,152,000 (or USD 1,354,000) started in October 2020 and ends in March 2022. The grant amounts are being charged on a monthly basis over the 18 months period based on actual incurred costs. The agreement with the DOD provides for additional funding beyond March 2022. 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 correspond to a roadmap development of ARC-IM to be used in the hours following SCI.

24. Finance income and expenses

	2020	2019	2018
Interest on loans	(4,392)	(2,648)	(1,460)
Interest post employment benefits	(1)	(3)	(2)
Interest banks	(23)	–	–
Interest on lease liabilities	(14)	(20)	(25)
Exchange losses	(41)	–	–
Bank charges	(11)	(7)	(5)
Total Finance cost	(4,482)	(2,678)	(1,492)
Exchange gain	–	5	3
Interest income	–	1	–
Total Finance gain	–	6	3

25. Science expenses

	2020	2019	2018
Staff costs	779	160	166
Outsourced cost	344	153	420
	1,123	313	586

The Company's science expenses consist primarily of cost of sponsored research activities that are undertaken by universities with which it collaborates. Since its inception, the Company has had a close working relationship with two of the founders of the Company, Gregoire Courtine, Professor at EPFL and Jocelyne Bloch, Neurosurgeon at CHUV, Professor at Université de Lausanne.

The activities between the Company and EPFL are formalized in research agreements which govern the activities of Professor Courtine sponsored by the Company.

26. Research and development expenses

	2020	2019	2018
Staff costs	3,538	2,342	1,887
Outsourced cost	2,068	2,874	2,686
Depreciation and amortization expense	199	140	149
	5,823	5,356	4,722

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[™] systems as well as the employee related expenses for research and development, including salaries and benefits.

27. Clinical and regulatory expenses

	2020	2019	2018
Staff expenses	2,278	948	514
Outsourced expenses	482	288	140
Depreciation and amortization expense	11	3	–
	2,770	1,239	654

The Company's clinical and regulatory expenses consist of the employee related expenses including salaries and benefits for employees working on clinical trials, and as of 1 January 2020 also includes costs relating to the external Chief Risk Officer and study site of the Up-LIFT study.

28. Marketing and market access expenses

	2020	2019	2018
Staff expenses	209	209	50
Outsourced expenses	185	52	48
	394	261	98

The Company's marketing and market access expenses include rebranding activities relating to the introduction of the ONWARD brand as well as the investigating activities on the future therapy reimbursement performed by third party consultants.

29. IP and license agreement expenses

	2020	2019	2018
Staff expenses	277	194	200
Outsourced expenses	908	331	255
	1,185	525	455

The Company's patents 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 as well as related employee expenses, including salary and benefits in the area of business development.

30. General and administrative expenses

	2020	2019	2018
Staff costs	2,765	1,587	1,173
Outsourced cost	2,189	1,959	1,106
Depreciation and amortization expense	62	86	85
	5,016	3,632	2,364

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, quality assurance and supply chain.

31. Employee benefit expenses

	2020	2019	2018
Wages and salaries	6,037	4,427	3,239
Social security costs	615	446	305
Pension costs – defined benefit plan	51	(62)	26
Pension costs – other	154	170	148
Share based benefit expenses	2,700	289	361
Other labour costs	993	1,149	619
	10,550	6,419	4,698

As at 31 December 2020, the ONWARD Group employed 55.0 full-time equivalents, including white-collar employees and consultants. The following table presents a breakdown of the Company's full-time equivalents as at 31 December 2020, 2019 and 2018:

	2020	2019	2018
Science	0.2	0.2	0.2
Development	28.1	38.4	29.2
Clinical & Regulatory	14.0	8.0	4.0
Marketing and Market Access	1.0	1.0	1.0
IP and License agreements	1.0	1.0	1.0
General and administrative expenses	10.7	9.9	7.1
	55.0	58.5	42.5

As of 31 December 2020, the Company had 35.5 full-time equivalents located in The Netherlands (2019: 46.4, 2018: 34.4), 14.4 full-time equivalents located in Switzerland (2019: 10.1, 2018: 8.1) and 5.0 (2019: 2.0, 2018: 0) full-time equivalents located in the United States.

32. Income tax

	2020	2019	2018
Current income tax	(20)	(39)	(18)
Deferred income tax	–	–	–
Total corporate income tax in profit and loss	(20)	(39)	(18)
Current Income Tax charge at tax rate of 25%	4,999	3,361	2,474
Net operating tax losses not recognized	(5,051)	(3,406)	(2,508)
Effect of Tax rate difference Switzerland and US	32	6	16
	(20)	(39)	(18)

The unused Dutch operating tax losses for which no deferred tax asset is recognized expire after the year 2025 (€ 715k), 2026 (€ 1,434k), 2027 (€ 2,434k), 2028 (€ 3,181k) and 2029 (€ 4,093k).

The unused US operating tax losses for which no deferred tax asset is recognized expire after 2038 (€ 58k) and 2039 (€ 618k).

The deferred tax liability arose on the acquisition of NeuroRecovery Technologies, Inc ('NRT') in 2019 (subsequently renamed to ONWARD Medical Inc.).

	2020	2019
Opening balance as at January 1	(1,448)	–
Addition – acquisition of NRT	–	(1,472)
Foreign currency translation difference	(105)	(24)
Deferred tax liability as at December 31	(1,343)	(1,448)

33. Earnings per share (EPS)

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 therefore the effect of anti-dilutive potential ordinary shares is disregarded.

The following tables reflect the income and share data used in the EPS calculation:

Profit (loss) attributable to ordinary shareholders

	2020	2019	2018
Profit (loss) for the year, attributable to equity holders of the parent	(20,014)	(13,483)	(9,912)

Weighted-average number of ordinary shares

	2020 Thousands	2019 Thousands	2018 Thousands
Weighted average number of ordinary shares for basic EPS	8,732	7,543	6,694

34. Right of use assets and lease liabilities

Right-of-use assets

The Group leases the office building in Eindhoven, which is classified as a Right-of-use asset. Key movements relating to this lease are presented below:

	2020	2019	2018
Net book value at January 1	254	360	465
Additions	–	–	–
Depreciation for the year	(105)	(106)	(105)
Net book value at December 31	149	254	360

The office building is leased for office space. The lease includes an extension option exercisable up to one year before the end of the non-cancellable lease term. The option to renew the lease is for an additional period of the same duration after the end of the contract term and are at the option of the Group as lessee. The Group has elected not to exercise the option and no new lease agreement has been entered into as replacement yet.

Lease liabilities

The maturity of the lease liability in relation to the office building is as follows:

	2020	2019	2018
Less than one year	137	126	95
One to five years	61	198	324
More than five years	–	–	–
Total lease liability	198	324	419

Movement of the lease liability:

	2020	2019	2018
Balance as at January 1	324	419	468
Repayments	(139)	(115)	(74)
<i>Of which relates to interest</i>	13	20	25
Total lease liability	198	324	419

The incremental borrowing rate applied is 6%.

Additionally, the group leases an office building in Lausanne and a car with contract terms of one to three years. These leases are short-term and/or leases of low-value items. The expense recognised in profit and loss for the year is € 70k (2019: € 52k / 2018: € 35k). The Group has elected not to recognise right-of-use assets and lease liabilities for these leases.

35. Office equipment

	2020	2019	2018
Cost	538	379	276
Accumulated depreciation	(323)	(200)	(91)
Net book value at January 1	215	179	185
Investments	173	124	103
Assets acquired from business combination	—	35	—
Depreciation for the year	(140)	(123)	(109)
Net change	33	36	(6)
Cost	711	538	379
Accumulated depreciation	(463)	(323)	(200)
Net book value at December 31	248	215	179

36. Intangible assets

	2020	2019	2018
Goodwill	1,607	1,732	—
In-Process R&D	5,218	5,650	25
Net book value at December 31	6,825	7,382	25

Goodwill

	2020	2019	2018
Cost	1,732	—	—
Accumulated amortization	—	—	—
Net book value at January 1	1,732	—	—
Additions	—	1,760	—
Foreign currency translation difference	(125)	(28)	—
Depreciation for the year	—	—	—
Impairments	—	—	—
Net change	(125)	1,732	—
Cost	1,607	1,732	—
Accumulated amortization	—	—	—
Net book value at December 31	1,607	1,732	—

In-Process R&D

	2020	2019	2018
Cost	5,777	152	152
Accumulated changes	(127)	(127)	(106)
Net book value at January 1	5,650	25	46
Acquisition of In-process R&D NRT	–	5,717	–
Foreign currency translation difference	(407)	(92)	–
Additions	–	–	–
Depreciation for the year	(25)	–	(21)
Impairments	–	–	–
Net change	(432)	(5,625)	(21)
Cost	5,370	5,777	152
Accumulated changes	(152)	(127)	(127)
Net book value at December 31	5,218	5,650	25

The In-process R&D was acquired through the acquisition of GTX medical SA and the business combination with NRT Inc., for which reference is made to note 9. The value of the In-process R&D is contingent on the success of the FDA approval of the NRT product.

The Group performed its annual impairment test at year end (2020) based on the most recent budgets and forecast calculations. These budgets and forecast calculations cover a period of five years. A long-term growth rate is calculated and applied to project future cash flows after the fifth year.

Key assumptions used in the impairment test was the growth rate, EBITDA and the rate for discounting the projected cash flows. The cash flow projections were determined using management's internal forecasts that cover an initial period from 2021 to 2025, after which a terminal value was calculated. The values assigned to the key assumptions represent management's assessment of future expectations and were based on historical data from both external and internal sources. A reasonable change in either the discount rate or terminal growth rate of 2% would not cause the carrying amount to exceed its recoverable amount.

	2020	2019
Discount rate	14.45%	14.45%
Terminal value growth rate	1.75%	1.75%

37. Financial liabilities

Innovation loan

At February 5, 2016, the Group was granted a loan from RVO NL (Dutch Government) of € 10 million payable according a set payment scheme.

	2020	2019	2018
Loan as per January 1	7,561	3,986	2,761
Loan amount received	1,994	2,998	946
Interest accrued during the year	855	577	279
Net book value at December 31	10,410	7,561	3,986

The loan carries interest at 10%.

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 2020.

Convertible preference A shares

On 31 December 2020, there were 37,666,666 convertible preference A shares in issue (2019: 35,583,332; 2018: 20,000,001). The preference shares carry a dividend of 6% per annum. The dividend rights are cumulative. The preference shares rank ahead of the ordinary shares in the event of a liquidation. The preference A shares can be converted into Ordinary Shares of the company under different scenarios, where the rights and number of Ordinary Shares received differs as summarized below:

Conversion Option	Option Holder/ Lender/ Mandatory	Fixed or Variable Number of Shares
Voluntary conversion	Option holder	Fixed, 1:1 conversion rate subject to adjustments for any changes in the share capitalization of the Company
Conversion upon IPO	Mandatory	
Conversion upon other Financing	Option holder	
SSA Defaulting Party of Issuer	Mandatory	Fixed, 10:1 conversion ratio

For the purpose of the valuation management assumed mandatory conversion upon IPO as the most likely scenario at a conversion rate of one ordinary share for one preference share. The presentation of the equity portion of these shares and the valuation assumptions are explained in Note 29.

	2020	2019	2018
Balance as at January 1	25,918	13,158	7,434
Preference shares issued	1,952	10,689	4,543
Cumulative preference dividend (accrued)	3,537	2,071	1,181
Balance as at December 31	31,407	25,918	13,158

38. Financial risk management objectives and policies

The Group's principal financial liabilities comprise of loans and borrowings, trade and other payables, and financial guarantee contracts. 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 exposed to various risks. The Board of Directors reviews and agrees policies for managing each of these risks which are summarised below.

Liquidity risk

The Company 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 CE mark, which is related to future financing rounds.

The following table details the undiscounted remaining contractual maturity for the Company's financial liabilities with agreed repayment periods, including both interest and principal cash flows as of 31 December 2020:.

	Less than 1 year	1-3 years	3-5 years	More than 5 years	Total
Innovation loan	–	–	–	19,298	19,298
Convertible preference A shares	–	–	–	60,541	60,541
Lease liability	137	61	–	–	198
Trade & other payables	2,501	–	–	–	2,501
Total	2,638	61	–	79,839	82,538

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 Company's activities may expose it to changes in foreign currency exchange rates and interest rates. The Company 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 Company only works with international reputable commercial banks and financial institutions.

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.

39. Indirect tax receivables

The tax receivables consist of refundable VAT and are collectable within 12 months.

40. Other current assets

At December 31, 2020, the Group had other current assets mainly related to prepayments for the Stimo feasibility study at the CHUV in Lausanne and prepaid pension and insurance premiums. The Group has pledged € 20k (2019: € 14k) of its cash at banks to fulfil collateral requirements relating to the EPFL rental agreement.

41. Cash and cash equivalents

	2020	2019	2018
Cash at bank	6,382	15,129	8,665
	6,382	15,129	8,665

Short-term deposits comprise a liquidity management account that is used, depending on the immediate cash requirements of the Group, and earns interest at the respective short-term deposit interest rates.

At December 31, 2020, the Group had no bank overdrafts. All cash is freely at the disposal of the company.

42. Issued capital and reserves

The authorized share capital is equal to the issued and paid capital

Share Capital

Issued and fully paid shares (Number of shares)	Ordinary € 1	Ordinary E € 0.000003	Ordinary O € 0.000003	Ordinary R € 0.0000001	Total
Opening balance as at 20 November 2015	82,584	-	-	-	82,584
Series A Financing (april '16)	-82,584	977,778	2,306,221	2,500,001	5,701,416
As at December 31, 2016	-	977,778	2,306,221	2,500,001	5,784,000
Series A Financing (dec '17)	-	694,444	-	-	694,444
As at December 31, 2017	-	1,672,222	2,306,221	2,500,001	6,478,444
Series A Financing (sept '18)	-	861,111	-	-	861,111
As at December 31, 2018	-	2,533,333	2,306,221	2,500,001	7,339,555
Series A Financing - NRT (oct '19)	-	1,222,222	2,500,000	-2,500,001	1,222,221
As at December 31, 2019	-	3,755,555	4,806,221	-	8,561,776
Series A Financing - NRT (oct '19)	-	1,018,519	-	-	1,018,519
As at December 31, 2020	-	4,774,074	4,806,221	-	9,580,295
Share Capital value	€ -	€ 14.32	€ 14.42	€ -	€ 28.74

The Ecole Polytechnique Fédérale de Lausanne (EPFL) has the right to acquire 493,778 Ordinary shares at nominal value set forth in the terms of the license agreement in respect of the use of EPFL's intellectual property rights (the "**EPFL Option 1**"). The EPFL Option 1 can be exercised by EPFL until an initial public offering ("IPO") or an exit transaction ("Exit"). An "Exit" shall mean: (i) the sale of all or substantially all of the Company's assets, or (ii) the sale of more than fifty per cent (50%) of the Company's issued and outstanding capital stock, to any company, entity or person, or (iii) the liquidation, dissolution or winding up of the Company including, without limitation, any merger or consolidation where the Company is not the surviving company.

In addition EPFL has the right to acquire 0.3% of the total Ordinary shares of the Company at zero consideration at the time of an IPO as set forth in the terms of the license agreement in respect of the use of EPFL's intellectual property rights (the "**EPFL Option 2**").

Under this agreement EPFL also has a right to receive the cash value equivalent to the number of shares representing 0.3% of the total capital stock of the Company existing, on a fully diluted basis, at the time of an Exit not being an IPO. An Exit, not being an IPO, is not considered to be the most probable outcome. The rights are non-cumulative and shall only apply once according to the earliest event. Cash settlement is therefore not probable.

These rights are accounted for under IFRS 2 as equity settled share based payments. The fair value of the goods and services received on the respective grant dates were considered negligible mainly due to the lack of regulatory approvals.

Share Premium Reserve

	2020	2019	2018
Balance at January 1	3,083	83	83
Issuance of shares, net of closing costs – in cash	–	–	–
Issuance of shares, net of closing costs – in kind (business combinations)	–	3,000	–
Balance at December 31	3,083	3,083	83

Other Reserve

	Conversion option preference shares	Share-based payments	Total
Balance at January 1, 2018	5,228	321	5,549
Series A Financing (sept'18)	3,207	–	3,207
Share based payment expense for the year	–	361	361
Balance at December 31, 2018	8,435	682	9,117
Series A Financing - NRT (oct'19)	5,811	–	5,811
Share based payment expense for the year	–	289	289
Balance at December 31, 2019	14,246	971	15,217
Series A Financing (jul'20)	337	–	337
Series A Financing (oct'20)	53	–	53
Series A Financing (nov'20)	158	–	158
Share based payment expense for the year	–	2,700	2,700
Balance at December 31, 2020	14,794	3,671	18,465

Share-based payments

The share-based payments reserve is used to recognise the value of equity-settled share-based payments provided to employees, including key management personnel, as part of their remuneration. Refer to Note 31 for further details of these plans.

Convertible preference shares

Onward also raised capital through the issuance of Preference Shares, spread out over the Dates of Issuance. On 31 December 2020, there were 37,666,666 convertible preference A shares in issue (2019: 35,583,332; 2018: 20,000,001). The preference shares carry a dividend of 6% per annum. The dividend rights are cumulative. The preference shares rank ahead of the ordinary shares in the event of a liquidation. The preference A shares can be converted into Ordinary Shares of the company under different scenarios, where the rights and number of Ordinary Shares received differs as summarized below:

Conversion Option	Option Holder/ Lender/ Mandatory	Fixed or Variable Number of Shares
Voluntary conversion	Option holder	Fixed, 1:1 conversion rate subject to adjustments for any changes in the share capitalization of the Company
Conversion upon IPO	Mandatory	
Conversion upon other Financing	Option holder	
SSA Defaulting Party of Issuer	Mandatory	Fixed, 10:1 conversion ratio

For the purpose of the valuation management assumed mandatory conversion upon IPO as the most likely scenario at a conversion rate of one ordinary share for one preference share. The liability component is included in Interest-bearing loans and borrowings (see Note 24).

The equity component of the issued convertible preference A shares was determined at each issue date. The preference shares were valued by discounting the future dividend payments to their present value. The value of the embedded conversion options is equal to the remaining difference between the transaction value of the Preference Shares and the fair value of the debt portion.

For the discounting of the expected future interest and principal payments, an appropriate discount rate is determined using the (historic) debt spreads as determined by Aswath Damodaran, a renowned valuation practitioner. The applied debt spreads are based on the issue dates of the Preference Shares, as well as an indicative credit rating to incorporate the implied credit risk of Onward as at the valuation date.

Moody's rating methodology for pharmaceutical companies was used to estimate an indicative credit rating for Onward. This methodology not only considers financial metrics but also qualitative factors and the potential of Onward and its pipeline. Notching adjustments are included to incorporate the risk profile of the subordinate ranking of the preference shares. An assumed maturity period of 10 years from the first issuance date in 2016 was chosen. This is considered a best estimate for a normal go-to-market period for similar types of devices. This was kept consistent for all subsequent issues.

Based on the result of the valuation management used the mid-range of the outcome for the recognition of the embedded conversion option.

The table below includes a sensitivity analysis if the discount rate would increase or decrease with 1% or 2% respectively:

Issue April 2016					
Discount rate	13,03%	14,03%	15,03%	16,03%	17,03%
<i>(sensitivity on discount rate)</i>	(2,0)%	(1,0)%	-	1,0%	2,0%
Value debt portion	3.159	2.893	2.651	2.431	2.231
Implied option value	2.841	3.107	3.349	3.569	3.769
Total preference shares value	6.000	6.000	6.000	6.000	6.000
Issue December 2017					
Discount rate	9,13%	10,13%	11,13%	12,13%	13,13%
<i>(sensitivity on discount rate)</i>	(2,0)%	(1,0)%	-	1,0%	2,0%
Value debt portion	4.907	4.547	4.217	3.914	3.635
Implied option value	1.343	1.703	2.033	2.336	2.615
Total preference shares value	6.250	6.250	6.250	6.250	6.250
Issue September 2018					
Discount rate	11,74%	12,74%	13,74%	14,74%	15,74%
<i>(sensitivity on discount rate)</i>	(2,0)%	(1,0)%	-	1,0%	2,0%
Value debt portion	5.197	4.858	4.543	4.251	3.981
Implied option value	2.553	2.892	3.207	3.499	3.769
Total preference shares value	7.750	7.750	7.750	7.750	7.750

Issue October 11, 2019					
Discount rate	11,33%	12,33%	13,33%	14,33%	15,33%
<i>(sensitivity on discount rate)</i>	(2,0)%	(1,0)%	-	1,0%	2,0%
Value debt portion	4.363	4.117	3.886	3.670	3.468
Implied option value	1.637	1.883	2.114	2.330	2.532
Total preference shares value	6.000	6.000	6.000	6.000	6.000
Issue October 11, 2019					
Discount rate	11,33%	12,33%	13,33%	14,33%	15,33%
<i>(sensitivity on discount rate)</i>	(2,0)%	(1,0)%	-	1,0%	2,0%
Value debt portion	3.636	3.430	3.238	3.059	2.890
Implied option value	1.364	1.570	1.762	1.941	2.110
Total preference shares value	5.000	5.000	5.000	5.000	5.000
Issue October 14, 2019					
Discount rate	11,32%	12,32%	13,32%	14,32%	15,32%
<i>(sensitivity on discount rate)</i>	(2,0)%	(1,0)%	-	1,0%	2,0%
Value debt portion	2.183	2.059	1.944	1.836	1.735
Implied option value	817	941	1.056	1.164	1.265
Total preference shares value	3.000	3.000	3.000	3.000	3.000
Issue October 14, 2019					
Discount rate	11,32%	12,32%	13,32%	14,32%	15,32%
<i>(sensitivity on discount rate)</i>	(2,0)%	(1,0)%	-	1,0%	2,0%
Value debt portion	1.819	1.716	1.620	1.530	1.446
Implied option value	681	784	880	970	1.054
Total preference shares value	2.500	2.500	2.500	2.500	2.500
Issue July 2020					
Discount rate	8,81%	9,81%	10,81%	11,81%	12,81%
<i>(sensitivity on discount rate)</i>	(2,0)%	(1,0)%	-	1,0%	2,0%
Value debt portion	1.291	1.225	1.163	1.104	1.049
Implied option value	209	275	337	396	451
Total preference shares value	1.500	1.500	1.500	1.500	1.500
Issue October 2020					
Discount rate	8,69%	9,69%	10,69%	11,69%	12,69%
<i>(sensitivity on discount rate)</i>	(2,0)%	(1,0)%	-	1,0%	2,0%
Value debt portion	218	207	197	188	179
Implied option value	32	43	53	62	71
Total preference shares value	250	250	250	250	250
Issue November 2020					
Discount rate	8,68%	9,68%	10,68%	11,68%	12,68%
<i>(sensitivity on discount rate)</i>	(2,0)%	(1,0)%	-	1,0%	2,0%
Value debt portion	654	622	592	563	536
Implied option value	96	128	158	187	214
Total preference shares value	750	750	750	750	750

43. Other payables

The other payables can be broken down as follows:

	2020	2019	2018
Wage tax and social security	367	2	100
Government grants	101	223	(5)
Bonus	843	678	461
Invoices to be received	102	146	340
Other	177	194	151
	1,590	1,243	1,047

The current liability regarding government grants consist of an amount received in advance from Eurostars in relation to the Confirm project.

	2020	2019	2018
Balance at January 1	223	(5)	35
Received in advance during the year	158	304	–
Recognized as Income	(280)	(76)	(40)
Balance as at December 31	101	223	(5)

44. Share-based payment reserve

Employee Investment Plan

Under the Employee Investment Plan, eligible employees have the opportunity to subscribe for, indirectly via Stichting G-Therapeutics Participaties (“STAK”), an equity stake in ONWARD Medical B.V.. The Employee Investment Plan is set-up to align the Employee's interest with the interests of the Shareholders and to participate in the long term growth of the Company.

Eligible employees will be granted depository receipts (DR) via the STAK by means of a deed of issuance. At the time of the deed issuance, the eligible employee accepts the obligation to subscribe to (purchase) the DRs for a value of € 0,01 cent and payment is required within 10 days. The agreement does not provide the eligible employee with any options to be exercised at a future date. From this point the owners obtain all rights and obligations from indirect share ownership. One depository receipt will at all times equal one ordinary non-voting E share in the capital of The Company. In the event of the distribution of proceeds, the ordinary shares (also from the DRs) will rank equal to all other shares after settlement with preferred A shares. The DRs are not transferrable. The DRs have a one year cliff from grant date, after this one year cliff period 25% of the issue vests and the remaining 75% vests over the remaining 3 years. When employment ceases the non-vested part is forfeited except in the event of illness or death. The DRs issued to employees are considered to be shares in accordance with IFRS 2, that have been issued under an equity settled shared based compensation plan.

	2020	2019	2018
Balance at January 1	971	682	321
Addition to the reserve	2,700	289	361
Balance as at December 31	3,671	971	682

The following assumptions are applied in recognizing the share-based compensation expense in the profit and loss statement:

- The vesting start date is used as “Granting date”, regardless of when the certificates were issued.
- The vesting start date will be the valuation date, no revaluation takes place subsequent to the vesting start date.
- Up and until October 13, 2019 the fair valuation of DR's for IFRS valuation purposes is € 1,00 which is equal to the price paid by the Series A investors for the Pref A shares through that date.
- DR's with a vesting start date from October 14, 2019 up and until April 2021 have a fair value of the DR's for IFRS valuation purposes of € 1.20 which is equal to the price paid of the Pref A shares since October 14, 2019 up and until the execution of the CLA by the end of April 20, 2021 in which the price of € 1.20 is referenced.
- The graded vesting method (front loaded expense recognition method) is applied for the allocation of the vesting expenses.

45. Post-employment benefits: defined benefit obligation

	2020	2019	2018
Plan assets	879	927	852
Obligation	(1,278)	(1,356)	(1,208)
Net liability	399	429	356

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 62 (female) and 63 (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

	2020	2019	2018
Balance as at January 1	429	355	324
Service costs	41	28	21
Admin costs	10	7	5
Past service costs	-	(97)	-
Employee benefit expenses	51	(62)	26
Net interest costs / (income)	1	3	2
Included in statement of profit and loss	52	(59)	28
Actuarial gains / (losses)			
- Financial assumptions	35	147	(47)
- Demographic assumptions	(72)	-	-
- Experience adjustment	(8)	4	83
- Return on assets excluding interest income	10	14	12
	(35)	165	48
Exchange rate differences	6	9	(15)
Included in statement of comprehensive income	(29)	174	33
Contributions by employer	(53)	(41)	(30)
Balance as at December 31	399	429	355

The principal assumptions used in determining post-employment (pension) benefit obligations for the plan are shown below:

	2020	2019	2018
Discount rate	0,15%	0,30%	0,90%
Salary increase	2,50%	2,50%	2,50%
Interest credit rate	0,60%	0,60%	0,60%
Mortality base table	BVG2020	BVG2015	BVG2015
Longevity improvement	CMI2018; 1,25%	CMI2016; 1,25%	CMI2016; 1,25%

A quantitative sensitivity analysis for significant assumptions as at 31 December is shown below:

	2020	2019	2018
Discount rate			
+ 25bps	(57)	(65)	(55)
- 25bps	62	70	59
Salary increase			
+ 25bps	4	4	7
- 25bps	(4)	(4)	(7)
Interest credit rate			
+ 25bps	24	28	23
- 25bps	(19)	(27)	(22)
Mortality base table			
Life expectancy + 1 year	26	27	15
Life expectancy - 1 year	(26)	(27)	(15)

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:

	2020	2019	2018
Within the next 12 months	51	51	50
Between 2 and 5 years	205	185	178
Beyond 5 years	472	220	205
Total expected payments	727	456	433

The average duration of the defined benefit plan obligation at the end of the reporting period is 19 years (2019: 20 years; 2018: 19 years).

Plan assets allocation

The asset allocation in the Swiss pension plan at December 31 was as follows:

	2020	2019	2018
Bonds	519	547	528
Equities	70	74	60
Loans	44	46	9
Mortgages	106	120	128
Real Estate	141	139	128
	879	927	852

Plan assets in 2020 do not include property occupied by or financial instruments issued by ONWARD.

46. Trade and other payables

Trade payables and accrued expenses are non-interest bearing and are normally settled on 30-90 day terms.

47. Commitments and contingencies

Legal claim contingencies

As at December 31, 2020, the Group had no legal claim contingencies.

Guarantees

The Group has provided a guarantee to High Tech Campus for € 41k and to EPFL for € 20k as collateral for the lease of the office space.

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.

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. In addition the company will be required to pay a change of control/IPO fee of the higher of USD 1 million and the value of 2% of phantom stock (based on ordinary shares in existence prior to the merger of NRT with the Company).

48. Related party transactions

Note 9 provides the information about the Group's structure including the details of the subsidiaries, the holding company, its shareholders and key management personnel. Outside the scope of the group, no other related parties are in place.

The convertible preference A shares debt, included in Note 24, is with related parties.

The Group considers the board and the leadership team to be key management as defined in IAS 24 'Related parties'.

Remuneration of the key management

	2020	2019	2018
Salary and bonuses (short-term employee benefits)	2,054	1,682	1,348
Pension premiums (post-employment benefits)	38	34	35
Share based payments	2,205	229	233
	4,297	1,945	1,616

49. Fair value and fair value hierarchy of the financial statements

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
2020		
Financial liabilities		
Innovation credit loan (Level 2)	10,410	11,393
Convertible preference A shares (Level 3)	31,407	35,549
Total financial liabilities	41,817	46,942
2019		
Financial liabilities		
Innovation credit loan (Level 2)	7,561	8,341
Convertible preference A shares (Level 3)	25,918	26,110
Total financial liabilities	33,479	34,451
2018		
Financial liabilities		
Innovation credit loan (Level 2)	3,986	4,399
Convertible preference A shares (Level 3)	13,158	17,121
Total financial liabilities	17,144	21,520

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.

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.

The fair value of the convertible preference A shares has been calculated by discounting the expected future cash flows using a discount rate that is based on comparable market information, where necessary adjustments have been made to incorporate the specific risk profile. For details on the valuation of the convertible preference A shares, refer to Note 29.

All assets and liabilities for which fair value is measured or disclosed in the financial statements are categorised 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.

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.

50. Events after the reporting period

On April 20, 2021 and subsequently on May 6, 2021 and July 21, 2021 ONWARD secured an additional financing of € 30 million by means of a convertible loan agreement with several investors.

On June 2, 2021 the Company issued 3,727,098 additional Ordinary E-shares in support of grants under the Employee Investment plan.

On September 27, 2021 EPFL has notified ONWARD in writing about their wish to exercise both of its Options as referred to in Note 29.

No other events have taken place after the reporting period to date that need to be reported.

October 6, 2021

On behalf of the board of Directors:

Dave Marver (CEO)

Marko Jansen (CFO)

Independent auditor's report

Independent auditor's report

To: the shareholders and the board of directors of ONWARD Medical B.V.

Our opinion

We have audited the special purpose consolidated financial statements of ONWARD Medical B.V., based in Eindhoven.

In our opinion the accompanying special purpose consolidated financial statements give a true and fair view of the financial position of ONWARD Medical B.V. as at 31 December 2020, 31 December 2019 and 31 December 2018, and of its results and its cash flows for the years ended 31 December 2020, 31 December 2019 and 31 December 2018 in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRS).

The special purpose consolidated financial statements comprise:

- The consolidated statement of financial position as at 31 December 2020, 31 December 2019, 31 December 2018 and 1 January 2018
- The following statements for the years ended 31 December 2020, 31 December 2019 and 31 December 2018: the consolidated statement of profit and loss, the consolidated statements of comprehensive income, changes in equity and cash flows
- The notes comprising a summary of the significant 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 special purpose consolidated financial statements section of our report.

We are independent of ONWARD Medical B.V. (hereinafter: the company) in accordance with 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.

Emphasis on the special purpose and restriction on use

We draw attention to note 2, which describes the special purpose of the special purpose consolidated financial statements. The special purpose consolidated financial statements do not represent ONWARD Medical B.V.'s financial statements in accordance with Section 2:361 of the Dutch Civil Code and its articles of association and are prepared for the purpose of including in the prospectus in order for ONWARD Medical B.V. to comply with the requirements for historical financial information by, or pursuant to, Regulation (EU) 2017/1129).

As a result, the special purpose consolidated financial statements may not be suitable for another purpose. Our independent auditor's report is required by the Commission Delegated Regulation (EU) 2019/980 and is issued for the purpose of complying with that Delegated Regulation. Therefore, our auditor's report should not be used for another purpose.

Material uncertainty with respect to the going concern assumption

We draw attention to note 4 Continuity of the Group in the special purpose consolidated financial statements, which indicates that the Company's cash position would be negative as of 30 September 2022 based on the assumptions made by the board of directors regarding expected cash inflows and outflows over the next twelve months. These forecasts do not include financing alternatives currently under consideration by the board of directors. In this context, the board of directors is aware that the continuity of company's operations depends on its ability to obtain these new sources of funding and that there are material uncertainties in this regard. Please note that the Company's long-term success is contingent on achieving FDA approval and CE mark of its products. These conditions indicate the existence of a material uncertainty which may cast significant doubt on the company's ability to continue as a going concern. We draw attention to these disclosures.

Our opinion is not modified in respect of these matters.

Responsibilities of the board of directors for the special purpose consolidated financial statements

The board of directors is responsible for the preparation and fair presentation of the special purpose consolidated financial statements in accordance with EU-IFRS. Furthermore, the board of directors is responsible for such internal control as the board of directors determines is necessary to enable the preparation of the special purpose consolidated financial statements that are free from material misstatement, whether due to fraud or error.

As part of the preparation of the special purpose consolidated 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 special purpose consolidated 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 special purpose consolidated financial statements.

Our responsibilities for the audit of the special purpose consolidated 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 special purpose consolidated 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. Our audit included among others:

- Identifying and assessing the risks of material misstatement of the special purpose consolidated financial statements, whether due to fraud or error, designing and performing audit procedures responsive to those risks, and obtaining audit evidence that is sufficient and appropriate to provide a basis for our opinion. 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
- 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
- Concluding on the appropriateness of the board of directors' use of the going concern basis of accounting, and based on the audit evidence obtained, whether a material uncertainty exists related to 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 special purpose consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. 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
- Evaluating the overall presentation, structure and content of the special purpose consolidated financial statements, including the disclosures
- Evaluating whether the special purpose consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation

We communicate with those charged with governance 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.

The Hague, 6 October 2021

Ernst & Young Accountants LLP

signed by A.A. Kuijpers

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