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This Registration Document, which together with any related securities note and any related summary, constitutes a prospectus (the "**Prospectus**"), for the purposes of Article 3 of Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 (the "**Prospectus Regulation**") relating to Mainstay Medical International plc ("**Mainstay Medical**" or the "**Company**"), has been prepared in accordance with Chapter 1 of Part 23 of the Companies Act 2014, as amended, the European Union (Prospectus) Regulations 2019 of Ireland (the "**Irish Prospectus Regulations**"), Part 4 of the Central Bank (Investment Market Conduct) Rules 2019, Commission Delegated Regulation (EU) 2019/980 and Commission Delegated Regulation (EU) 2019/979 (the "**EU Prospectus Regulations**"). The Registration Document has been approved by the Central Bank of Ireland (the "**Central Bank**"), as competent authority under the Prospectus Regulation. The Central Bank only approves this Registration Document 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 that is the subject of this Registration Document.

Mainstay Medical International plc

(Incorporated and registered in Ireland under the Irish Companies Acts with registered number 539688 and LEI 635400IUPSOZ26H56Y03)

REGISTRATION DOCUMENT

Davy

Financial Adviser

This document does not constitute or form part of any offer or invitation to purchase, otherwise acquire, subscribe for, sell, otherwise dispose of or issue, or any solicitation of any offer to sell, otherwise dispose of, issue, purchase or otherwise acquire or subscribe for any security. You should read the whole of this document, together with any related securities note and any related summary and any documents incorporated herein by reference. In particular, your attention is drawn to the section entitled "Risk Factors" on pages 4 to 29 of this document, which contains a discussion of the risks that might affect the value of your shareholding in the Company. ONLY THE COMBINED SECURITIES NOTE, REGISTRATION DOCUMENT AND SUMMARY CONSTITUTE, AND CAN BE RELIED UPON AS, A PROSPECTUS.

The Directors, whose names appear on page 32 of this document, and the Company, accept responsibility for the information contained in this Registration Document. To the best of the knowledge of the Company and the Directors, such information is in accordance with the facts and this Registration Document does not omit anything likely to affect the import of such information.

Copies of the entire Prospectus in English and any related summary translated into French will be available on the Company's website at www.mainstay-medical.com from the date of publication of this document, and will continue to be available until at least the first anniversary of the publication of the Prospectus, of which this Registration Document forms part.

No action has been taken by the Company to permit a public offer of New Ordinary Shares under the applicable securities laws of any jurisdiction. Other than in Ireland and France, no action has been taken or will be taken to permit the possession or distribution of this document (or any other offering or publicity materials relating to the New Ordinary Shares) in any jurisdiction where action for that purpose may be required or where doing so is restricted by law. Accordingly, neither this document,

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OTHER IMPORTANT NOTICES AND DISCLAIMERS OF LIABILITY

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The contents of this document should not be construed as legal, financial or tax advice. This document is for your information only and nothing in this document is intended to endorse or recommend a particular course of action.

INTERPRETATION

Certain terms used in this document, including certain technical and other terms, are explained and defined in the *Glossary of Technical Terms* or *Definitions*, as the case may be, set out at the end of this document. References to the singular in this document shall include the plural and vice versa, where the context so requires. All references to time in this document are to Dublin time unless otherwise stated.

The language of this document is English. Certain legislative references or technical terms have been cited in their original language in order that the correct technical meaning may be ascribed to them under applicable law, or otherwise.

The date of this document is 25 October 2019.

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PART 1
RISK FACTORS

The following risks should be considered carefully by Shareholders and prospective investors.

This section addresses the existing and future material risks to Mainstay's business. However, the following does not set out an exhaustive list or explanation of all risks that Shareholders or prospective investors may face when making an investment in the Ordinary Shares and should be used as guidance only as further risks and uncertainties not currently known to the Board, or that the Board currently deems immaterial, may also have an adverse effect on the Company's or the Group's financial condition, business, prospects and/or results of operations. In such a case, the market price of Ordinary Shares could decline and investors may lose all or part of their investment.

The order in which risks are presented is not an indication of the likelihood of the risks actually materialising, of the potential significance of the risks or of the scope of any potential harm to the Company's or the Group's financial condition, business, prospects and results of operations.

This document contains forward-looking statements that involve risks and uncertainties. See "Forward Looking Statements" in Part 2 (Important Information) of this document. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by the Company and the Group described below and elsewhere in this document.

Shareholders and prospective investors should read this Part in conjunction with the entire Prospectus.

1.1 RISKS RELATING TO OUR FINANCIAL CONDITION AND CAPITAL REQUIREMENTS

(a) We have incurred significant operating losses and may not be able to achieve or subsequently maintain profitability

We have incurred significant net losses since we were founded. For the year ended 31 December 2018 and the half year ended 30 June 2019, we had a comprehensive loss of $31 million and $11.2 million respectively (and a comprehensive loss of $16.5 million for the half year ended 30 June 2018, $30 million for the year ended 31 December 2017 and $18.7 million for the year ended 31 December 2016). We fund our operations through equity capital and debt, and have raised more than $139 million of equity capital and we have drawn the full amount of the $15 million debt facility that we announced in August 2015 (the outstanding principal on this debt is $10.2 million as at 31 December 2018), as well as the full amount of a new tranche of $3.34 million that we announced on 29 July 2019. We have devoted substantially all of our resources to the research and development of ReActiv8, including completion of our feasibility study in October 2012, progress on our ReActiv8-A Clinical Trial (which commenced in 2014 and led to CE Marking in May 2016), progress of our U.S. Pivotal ReActiv8-B Clinical Trial (the purpose of which is to gather data in support of an application for Pre-Market Approval ("**PMA**") from the U.S. Food and Drug Administration ("**FDA**")), initial commercialisation, and expansion of our intellectual property portfolio.

To implement our business strategy and generate revenue and profit in the future, we need to, among other things, obtain regulatory approvals for ReActiv8 (which on the date of this document is our only product) in our target markets. We have obtained CE Marking of ReActiv8, which allows for commercialisation of ReActiv8 in the European Economic Area (the "**EEA**", which includes the EU, Iceland, Liechtenstein and Norway) and Switzerland. CE Marking also allows more rapid regulatory approval in certain other countries (e.g. Australia). In January 2017, we applied to the Australian Therapeutic Goods Administration ("**TGA**") for ReActiv8 to be admitted to the Australian Register of Therapeutic Goods ("**ARTG**") which would allow for commercialisation in Australia. In April 2018, the TGA requested additional clinical data with respect to ReActiv8 which we submitted in June 2019. To provide the most meaningful clinical data possible, we relied on the clinical data gathered as part of the U.S. Pivotal ReActiv8-B Clinical Trial. The U.S. Pivotal ReActiv8-B Clinical Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on two pre-specified alternative analyses of that endpoint and on multiple secondary endpoints. We cannot be certain whether the totality of the data from the U.S. Pivotal ReActiv8-B Clinical Trial will be

sufficient to demonstrate safety and efficacy to the satisfaction of the TGA to allow for the admission of ReActiv8 to the ARTG. There is no assurance that commercialisation in the EEA, Switzerland or Australia (if approval is obtained) will be successful or will generate sufficient revenue (and profits) to cover expenses or fund future growth.

We have not yet obtained regulatory approval for ReActiv8 in the U.S. We cannot be certain whether the totality of the data from the U.S. Pivotal ReActiv8-B Clinical Trial will be sufficient to demonstrate safety and efficacy to the satisfaction of the FDA to allow for the granting of a PMA. If U.S. regulatory approval is not obtained, then it will not be possible to commercialise ReActiv8 in the U.S. For more information on the U.S. regulatory approval process, see paragraph 4.5(a) of Part 4 (*Overview of the Market*) and paragraph 5.13 of Part 5 (*Information on the Group*) of this document.

If we are unable to obtain additional regulatory approvals for ReActiv8 in the U.S. and elsewhere, or if product development, manufacture, marketing, sales or commercialisation of ReActiv8 is delayed or abandoned, we may never generate significant revenue or become profitable. Even if we do become profitable in the short term, we may be unable to sustain or increase our profitability on a quarterly or annual basis over the medium to long term. In any case we will need to obtain additional capital to fund commercialisation (including expanding reimbursement), to fund continuing research and development, and to run additional Clinical Trials. We expect to incur losses for the foreseeable future as we continue to pursue these objectives.

(b) **We expect to require additional funds in the future in order to meet our capital and expenditure needs and further financing may not be available when required or, if available, could require us to agree to terms which are specifically favourable to new investors, or to restrictions significantly limiting our access to additional capital**

We expect to require additional funds in the future in order to meet our capital and expenditure needs, including funds to pay our financial obligations as they fall due, continue research and development, conduct Clinical Trials, continue our work to obtain regulatory approval and other activities necessary to bring ReActiv8 to target markets and to establish marketing and sales capabilities. However, we may not be able to obtain additional financing on terms favourable to us, if at all, when needed. If we are unable to obtain adequate financing or financing on terms satisfactory to us, when we require it, we may cease to have operations and may need to liquidate some or all of our assets, being, at this point, the Group's intellectual property. For more information on the Group's intellectual property, see paragraph 5.16 of Part 5 (*Information on the Group*).

In addition, if we raise additional funds through further issues of equity or debt or other forms of financing, existing shareholders could suffer significant adverse financial consequences including dilution. Any new equity securities could have rights, preferences and privileges superior to those of current shareholders. Any debt financing secured by us in the future could involve restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain any required additional capital.

(c) **Our future financial performance is entirely dependent on the commercial success of ReActiv8, our only product as of the date of this document, obtaining adequate reimbursement for ReActiv8, and rates of product adoption and market penetration**

Our only product as of the date of this document, ReActiv8, is designed to treat people suffering from Chronic Low Back Pain ("**CLBP**"), a serious and often debilitating medical condition. The success of ReActiv8 may be negatively impacted by many factors, including regulatory delays, adverse regulatory or legal actions, problems arising from manufacturing, research and development, rates of product adoption and market penetration and low sales in target markets. Because our business currently relies on the success of a single product, any factors that negatively impact the regulatory approval and commercialisation of ReActiv8 would adversely affect our financial condition, business, prospects and/or results of operations.

(d) **Failure to comply with debt covenants or failure to make repayments on our debt facility could have a material adverse effect**

On 24 August 2015, Mainstay Medical Limited entered into the Original IPF Facility Agreement for a debt facility of up to $15 million. As at 31 December 2018, the principal outstanding was $10.2 million. On 29 July 2019, we announced the drawdown of €3 million in additional debt from a new tranche of the existing debt facility. See paragraph 9.12(e) for further information on the new tranche.

The repayment schedule for the three existing tranches drawn under the debt facility was amended in April 2019 such that no principal or interest will be repaid until 2021, with the principal and accrued interest to be amortized over the period from 1 January 2021 through 30 September 2023. The repayment schedule for the new tranche is the same as the amended repayment schedule for the three existing tranches.

The interest rate for all tranches will be 8% per annum, with interest accruing but capitalized prior to January 1, 2021. All principal and accrued interest from all tranches will automatically convert into Ordinary Shares at a price per Ordinary Share of €8.00 upon the earlier of (a) FDA approval of the Company's PMA application for ReActiv8, (b) the date by which at least 900,000 Ordinary Shares are publicly sold on-market by non-affiliates of the Company since 18 April 2019 at a price per Ordinary Share of at least €8.00 or (c) IPF's election to undertake such conversion, in each case unless the Company elects to satisfy such obligation in whole or in part in cash.

The terms of the agreement include covenants, including a requirement that Mainstay Medical Limited hold cash at least equal to its projected cash expenditures for operations and debt repayment for each three-month period after 18 April 2019. In addition, on 18 April 2019 the Company issued to IPF warrants to purchase 1.5 million of its Ordinary Shares at a price per Ordinary Share of €6.00 at any time prior to the 6th anniversary of the amendment date (being 18 April 2019). The Company has issued further conditional warrants to IPF that will become exercisable only to the extent the Company elects to repay the debt in cash rather than issue Ordinary Shares when a conversion of the debt is triggered.

The facility is secured by way of fixed and floating charges over the assets and undertakings of Mainstay Medical Limited, and the IPF Debenture includes customary terms and conditions. In addition, the Company created a first fixed charge in favour of IPF over its present and future shares held in Mainstay Medical Limited.

If we fail to comply with the provisions included in the debt facility, and/or the debt covenants, and/or fail to make repayments of principal or interest, IPF might enforce their security, which might have a material adverse effect on our financial condition, business, prospects and/or results of operations.

1.2 RISKS RELATING TO OUR BUSINESS AND INDUSTRY

(a) **We operate in a highly regulated environment and regulatory approval is required before we can market or sell ReActiv8 in any market**

ReActiv8 is an active implantable medical device ("**AIMD**"), which requires regulatory approval before it can be marketed or sold by us. At the date of this document, the only regulatory approval we have received is the CE conformity assessment or CE Marking for ReActiv8, which allows commercialisation of ReActiv8 in the EEA and in Switzerland. In January 2017, we applied to the TGA for ReActiv8 to be admitted to the ARTG which would allow for commercialisation in Australia. In April 2018, the TGA requested additional clinical data with respect to ReActiv8 which we submitted in June 2019. To provide the most meaningful clinical data possible, we relied on the clinical data gathered as part of the U.S. Pivotal ReActiv8-B Clinical Trial. The U.S. Pivotal ReActiv8-B Clinical Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on two pre-specified alternative analyses of that endpoint and on multiple secondary endpoints. We cannot be certain whether the totality of the data from the U.S. Pivotal

ReActiv8-B Clinical Trial will be sufficient to demonstrate safety and efficacy to the satisfaction of the TGA to allow for the admission of ReActiv8 to the ARTG.

Regulatory approval in the U.S. is via a PMA issued by the FDA. Timing of a PMA is uncertain, as it depends on the progress and results of the U.S. Pivotal Reactiv8-B Clinical Trial to gather data for a Pre-Market Approval Application ("**PMAA**"). We cannot be certain whether the totality of the data from the U.S. Pivotal ReActiv8-B Clinical Trial will be sufficient to demonstrate safety and efficacy to the satisfaction of the FDA to allow for the granting of a PMA. The process typically takes significantly longer than CE Marking. Once granted, the PMA does not have an expiry date, however, regulatory approvals may be withdrawn if, for example, a new and unexpected risk emerges that would make continued marketing of our product no longer acceptable to the FDA. There is no guarantee that further regulatory approval will be obtained for ReActiv8 or any other product we develop, either now or in the future. Any such regulatory approval may also experience delays.

The regulatory approval process may delay or prevent the launch of our product in our target markets, which would negatively impact or prevent our ability to achieve our objectives. If we fail to obtain further approval of ReActiv8 in a timely manner, or at all, sales of ReActiv8 may be delayed or may not be achieved, thereby adversely affecting our ability to generate revenues or fund our on-going activities.

(b) **Seeking and obtaining regulatory approval for medical devices can be a long and uncertain process. Strict or changing regulatory regimes, government policies and legislation in any of our target markets may delay, prohibit or reduce potential sales**

We are primarily targeting commercialisation in markets in the EEA, Switzerland, Australia and the U.S. and we must comply with complex regulatory requirements in these markets before we can market or sell our product in each market. Once initial regulatory approval is gained for our product for a particular market, any subsequent products or product modifications may also require further regulatory approval before we can market the subsequent or modified products.

In the EU, regulatory approval is obtained via CE Marking according to the European Active Implantable Medical Devices Directive 90/385/EEC and subsequent amendments (the "**AIMD Directive**"), which provides approval for the EEA and is accepted by certain other non-EEA countries, including Switzerland. We received CE Marking in May 2016.

In May 2017, a package of European Union legislation entered into force, replacing the existing regulatory framework for medical devices in the EEA, including for AIMD (the "**New EU Medical Device Regulations**"). The New EU Medical Device Regulations will apply as of 2020, though require implementing action and strategic decisions as of now.

The New EU Medical Device Regulations mean a more centralised control of the European medical device market, and may increase the amount of work, time, or cost of obtaining regulatory approval for the marketing of medical devices in Europe. Under the new regulatory framework, it is likely that (i) the regulatory requirements for the design and manufacturing of AIMDs will be applied more stringently than in the past, (ii) there will be stricter requirements for clinical investigations and clinical evidence, (iii) the obligations for manufacturers to monitor the safety of their products, once placed on the market, will increase, and (iv) manufacturers will be subject to increased scrutiny. The New EU Medical Device Regulations will make the EU approval process for AIMDs more similar to the U.S. PMA process. The new legislation may also prevent or delay the EEA approval or clearance of any future products we may develop or impact our ability to modify currently EEA approved or cleared products on a timely basis. The specific impact of the New EU Medical Device Regulations on existing products is uncertain and could impact the approval of future products and/or could require additional resources to maintain compliance with the new regulations. A summary of the New EU Medical Device Regulations is included in paragraph 4.5(b) of Part 4 (Overview of the Market of this document).

In the U.S., regulatory approval is obtained via a PMA issued by the FDA. Regulatory approval can be a lengthy, expensive and uncertain process. Timing of a PMA is uncertain, as it depends on the

progress and results of the U.S. Pivotal Reactiv8-B Clinical Trial to gather data for a PMAA. The process typically takes significantly longer than obtaining CE Marking. Applications for regulatory approval require extensive pre-clinical, clinical and technical testing, all of which must be undertaken in accordance with the requirements of regulations and guidance for the FDA. For more information on the U.S. regulatory approval process, see paragraph 4.5(a) of Part 4 (*Overview of the Market*) and paragraph 5.13 of Part 5 (*Information on the Group*) of this document. During 2016, the Company commenced the U.S. Pivotal ReActiv8-B Clinical Trial which is intended to gather data in support of an application for PMA from the FDA. The U.S. Pivotal ReActiv8-B Clinical Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on two pre-specified alternative analyses of that endpoint and on multiple secondary endpoints. We cannot be certain whether the totality of the data from the U.S. Pivotal ReActiv8-B Clinical Trial will be sufficient to demonstrate safety and efficacy to the satisfaction of the FDA to allow for the granting of a PMA. For more information on the U.S. Pivotal ReActiv8-B Clinical Trial see paragraph 5.10 of Part 5 (*Information on the Group*) of this document.

The regulations to which we are subject are complex and have tended to become more stringent over time. We may be adversely affected by changes in government policy or legislation applying to regulation of AIMDs.

(c) **We are required to conduct Clinical Trials for regulatory approvals and other purposes. Clinical Trials carry substantial risks and are costly and time consuming, with uncertain results**

The outcomes of Clinical Trials are by their nature uncertain and dependent on a number of variables inherent to clinical research, such as the ability of the design of the Clinical Trial to produce the anticipated result, the suitability of the Clinical Trial patients for the therapy, the experience and the expertise of the referring and implanting medical professionals, the ability and willingness of the Clinical Trial patients to perform the activities required from their participation in the trial, and the quality of the clinical follow up.

Adverse events, both anticipated and unanticipated, and related or unrelated to the device, occur in Clinical Trials. Significant unanticipated adverse events associated with ReActiv8 could result in damage to our reputation, lawsuits, suspension or delay of Clinical Trials, and/or enrolment difficulties. Errors in associating adverse events with ReActiv8 could result in damage to our reputation, lawsuits, suspension or delay of Clinical Trials, and/or enrolment difficulties. Any delay or suspension of Clinical Trials may delay the filings of regulatory submissions and ultimately the ability to commercialise ReActiv8 and to generate revenues.

The U.S. Pivotal ReActiv8-B Clinical Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on two pre-specified alternative analyses of that endpoint and on multiple secondary endpoints. We cannot be certain whether the totality of the data from the U.S. Pivotal ReActiv8-B Clinical Trial will be sufficient to demonstrate safety and efficacy to the satisfaction of the FDA to allow for the granting of a PMA or to the satisfaction of other regulatory bodies. Failure to achieve FDA or other regulatory body approval may require product redesign, new or additional Clinical Trials, additional testing, and other measures which typically require significant additional cost and time.

We are required to fund Clinical Trials. This typically includes the payment of professional fees for physicians; hospital costs; fees for one or more contract research organisations ("**CROs**"); data collection; retention and management; fees for consultants to run committees; and Clinical Trial insurance premiums. Medical device companies are usually required to provide products and services at no charge during Clinical Trials leading to regulatory submissions, and therefore we will not generate revenue from product sales from the use of ReActiv8 in such Clinical Trials. We may be required to fund the cost of surgical procedures to replace or remove the device in clinical patients. The costs of the Clinical Trials may exceed the resources available to us, in the medium to long term, possibly resulting in delayed completion, cost overruns, or failure to complete.

Results of Clinical Trials are intended to be published after the trial concludes. Some physicians or other parties may prematurely publish clinical results prior to conclusion of the trial, which may adversely affect future trial enrolment, have adverse regulatory impact, prevent us from securing patent protection, result in diminished competitive position or damage our reputation.

(d) **We are required to conduct one or more post-approval studies which could be expensive and fail to produce the desired results**

Following CE Marking, a range of activities is required for Post Market Clinical Follow-Up ("**PMCF**") to gather additional data on long term performance and safety of Re-Activ8, including continuation of the ReActiv8-A Clinical Trial and implementation of a Registry. It is possible that the PMCF may uncover problems that did not emerge during the Clinical Trials of ReActiv8 which may result in product recall, suspension of sales, and/or restrictions on commercialisation. Such consequences could have a material adverse effect on our business and financial condition, business, prospects and/or results of operations.

As part of, or following, the FDA grant of a PMA for ReActiv8 in the U.S. (if granted), the FDA may require us to conduct one or more post-approval studies ("**PAS**"), which could be extensive, expensive and time consuming.

The PAS may uncover problems with ReActiv8 and may result in a need to redesign certain aspects of ReActiv8 and/or conduct additional studies and may include possible suspension from sale. Such consequences could have a material adverse effect on our financial condition, business, prospects and/or results of operations.

(e) **Attracting physicians and patients to perform Clinical Trials and meet Clinical Trial objectives is costly and uncertain**

Performing Clinical Trials requires the engagement of many hospitals, clinics, and clinicians. In particular, we must engage a physician at each Clinical Trial centre to maintain overall responsibility for the conduct of the Clinical Trial (the "**Investigator**"). Each Investigator may have additional physicians or other medical professionals working under his or her direction to conduct a trial (e.g. to recruit Clinical Trial patients or perform surgery or other procedures). We may not be able to attract a sufficient number of qualified Investigators to conduct Clinical Trials within an adequate time, and those Investigators may not be able to attract or enrol a sufficient number of patients to meet our Clinical Trial objectives.

Clinical Trial patients may be sourced from the Investigator's own practice clinic or hospital, or may be referred from another physician. Potential Clinical Trial patients must sign an informed consent before undergoing certain clinical tests to determine whether the patient meets the enrolment criteria for the Clinical Trial (inclusion and exclusion). Once a patient is enrolled in the Clinical Trial, the patient must comply with the trial requirements, including clinic visits, use of ReActiv8, and undergo certain tests. Some patients may not comply with the requirements of the trial, or could at any time withdraw from the trial, which could lead to poor or unusable data, which may compromise the results of the Clinical Trial.

Failure to attract a sufficient number of eligible Clinical Trial patients may lead to time and cost overruns, poor quality results, or inability to complete the Clinical Trial, all of which may materially adversely affect our ability to achieve regulatory approval, and thereby our ability to market our product and achieve revenues and profits.

(f) **There is no guarantee that the performance of ReActiv8 in commercialisation will match the performance of ReActiv8 in Clinical Trials**

While the Company will take steps including physician training and certification, and having company sales representatives or field clinical specialists attend some or all implant procedures, ReActiv8 clinical performance in commercialisation may be different from the clinical performance observed during the Clinical Trials for a number of reasons, including less control on the selection of

people suitable for use of the product, use by physicians with different experience and/or training, and failure to adhere to a follow up regimen in the absence of Clinical Trial oversight.

Furthermore, issues with product performance may subsequently be identified once a product is in the market. Regulatory authorities require medical device manufacturers to monitor and report certain types of adverse events as part of the medical device reporting ("**MDR**") regulations so that safety issues can be identified and addressed quickly. When such issues are identified, corrective actions may be required – such as modifying labelling or instructions for use, improving training, or removing the device from the market – to ensure proper use or patient safety. Any of these could result in significant time delays and/or expense and/or may harm our reputation. Such issues may result in the need for our product to be suspended from sale or withdrawn from the market. In these circumstances our product may require substantial redesign and/or re-engineering to address any identified issues. This may result in the need to undertake further Clinical Trials to re-establish the safety and efficacy of the revised product, which would be costly and time consuming and may exceed our resources.

Any of these circumstances may have a material adverse effect on the timing and extent of our future revenues and profitability.

(g) **We only recently began commercializing ReActiv8 in the EEA and have no history of commercializing ReActiv8 in the United States**

ReActiv8 has been CE Marked since 2016, enabling us to commercialize it throughout the EEA. We have not yet obtained approval from the FDA to commercially market in the United States. As a result, we have a limited history of commercializing ReActiv8 generally and no history of selling ReActiv8 in the United States. As an organization, we have never commercially launched a product in the United States, nor commenced a sales representative training program or conducted a launch of a similar expected size. A commercial launch and training program of this size is a significant undertaking that requires substantial financial and managerial resources. We may be unable to gain broader market acceptance in the countries in which we have already begun to commercialize ReActiv8 or successfully commercialize it in the United States for a number of reasons, including:

- established alternatives to ReActiv8 with strong relationships with customers, including physicians, hospitals and third-party suppliers;
- limitations in our ability to demonstrate differentiation and advantages of ReActiv8 compared to alternative methods for treating CLBP and the relative safety, efficacy and ease of use of ReActiv8;
- the limited size of our sales force and the learning curve required to gain experience selling ReActiv8;
- the inability to obtain sufficient supply of the components for the ReActiv8 system or secure second-source suppliers if our main suppliers are unable to fulfil our orders;
- insufficient financial or other resources to support our commercialization efforts necessary to reach profitability; and
- the introduction and market acceptance of new, more effective or less expensive competing products and technologies.

If we do not achieve significantly greater market acceptance of our product, do not gain momentum in our sales activities, or fail to significantly grow our market share, we will not be able to grow our revenue and our business and financial condition will be adversely affected.

(h) **There is no certainty that the market for ReActiv8 will develop as currently anticipated by the Directors or at all**

The Directors believe that the potential number of people with Chronic Low Back Pain who could benefit from ReActiv8 is large, based on our estimate of persons suffering with Chronic Low Back Pain in our key target markets. Further details of the Company's target markets are set out in paragraph 4.3 of Part 4 (*Overview of the Market*) of this document. However, development of the market depends on several factors including regulatory approvals, availability and level of reimbursement, acceptance of the treatment by the medical profession, product performance after approval, emergence of other current and future treatments for Chronic Low Back Pain, as well as the global trend to reduce healthcare costs. If, as a result of these factors, the market for our product does not develop as currently anticipated, our ability to generate revenue could be materially adversely affected.

(i) **If we fail to develop and retain an effective direct sales force in the United States or other major new markets, our business could suffer**

In order to commercialize ReActiv8 in the United States or other major new markets where we receive regulatory approval and plan to commercialize, we will likely be required to build a direct sales force. In any such case, we will initiate our commercial launch and increase our marketing efforts, which would require us to make significant investments to retain, develop and grow the number of direct sales personnel that we employ. There is significant competition for sales personnel experienced in relevant medical device sales. Once hired, the training process is lengthy because it requires significant education for new sales representatives to achieve the level of clinical competency with ReActiv8 expected by physicians. Upon completion of the training, our sales representatives typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of ReActiv8 often requires or benefits from direct support from us. If we are unable to attract, motivate, develop and retain a sufficient number of qualified sales personnel, and if our sales representatives do not achieve the productivity levels we expect them to reach, our revenue will not grow at the rate we expect, and our financial performance will suffer. Also, to the extent we hire personnel from other medical device companies, we may have to wait until applicable non-competition provisions have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories, and we may be subject to allegations that these new hires have been improperly solicited, or that they have divulged to us proprietary or other confidential information of their former employers. Any of these risks may adversely affect our business.

(j) **The success of ReActiv8 depends on its acceptance and adoption by medical professionals**

Our success will require acceptance and adoption by medical professionals of ReActiv8 as a new treatment for people with Chronic Low Back Pain. Such acceptance will depend on medical professionals being convinced of the clinical performance, benefits, safety and cost-effectiveness of ReActiv8 and being prepared to undertake special training in certain cases.

Acceptance of ReActiv8 depends on educating physicians as to the distinctive characteristics, perceived benefits, safety and ease of use of ReActiv8 as compared to alternative solutions and communicating to physicians the proper application of ReActiv8. The U.S. Pivotal ReActiv8-B Clinical Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on two pre-specified alternative analyses of that endpoint and on multiple secondary endpoints. We cannot be certain whether the totality of the data from the U.S. Pivotal ReActiv8-B Clinical Trial will be sufficient to demonstrate safety and efficacy to the satisfaction of physicians. If we are not successful in convincing physicians of the merits of ReActiv8 or educating them on the use of ReActiv8, they may not use ReActiv8 and we may be unable to increase our sales, sustain our growth or achieve profitability.

Even if the safety and efficacy of ReActiv8 is established, medical professionals may be hesitant to change their medical treatment practices or accept and adopt ReActiv8, including for the following reasons:

- general conservatism about adoption of new and innovative treatment practices;
- lack of awareness or acceptance of the role of inhibition of the multifidus muscle in causing CLBP and the suitability of neurostimulation therapy to address this inhibition;
- lack of experience with ReActiv8 and with neurostimulation as a treatment alternative;
- lack or perceived lack of long-term evidence, including that provided by the results of our U.S. Pivotal ReActiv8-B Clinical Trial, supporting additional patient benefits;
- perceived clinical risk of a new treatment;
- inability to convince key opinion leaders to provide recommendations regarding ReActiv8, or to convince patients, physicians, or payers that ReActiv8 is an attractive alternative to other products;
- perceived liability risks associated with the use of a new product and procedures;
- limited or lack of reimbursement and coverage within healthcare payment systems;
- cost associated with the purchase of new product and equipment;
- other procedures competing for physician time and attention; and
- the time commitment that may be required for special training.

Economic, psychological, ethical or related concerns may limit general acceptance and adoption of ReActiv8. Lack of acceptance and adoption of ReActiv8 by a significant number of medical professionals may limit our future revenues and profitability.

(k) **Active implantable medical devices such as ReActiv8 carry risks associated with the surgical procedure for implant, removal or use of the device, failure of the device, or associated with the therapy delivered by the device**

All medical devices have associated risks. Regulatory authorities regard AIMDs as the highest risk category of medical devices, and accordingly AIMDs are subject to the highest level of scrutiny when seeking regulatory approval. The risks include, among others, (i) risks associated with any surgical procedure, such as infection, allergic reaction, and consequences of anaesthesia and (ii) risks associated with any implantable medical device such as device movement, lead dislodgement, lead breaks or fracture, electromagnetic interference, device failure, tissue damage including nerve damage, pain and psychological effects. A comprehensive list of the risks associated with ReActiv8 is included in the documentation (labelling) provided with the device to both physicians and patients.

Adverse events associated with these risks may lead some patients to blame us, the physician 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 us. Any of those circumstances may have a material adverse effect on our ability to conduct our business, to sell ReActiv8, or to develop future products (if any).

(l) **Our business exposes us to an inherent risk of potential product liability claims relating to the manufacturing, Clinical Trials, marketing and sale, or recall of an active implantable medical device**

Our product is an AIMD with complex electronic circuits and software. It is not possible to design and build AIMDs which are 100% reliable as all such devices carry a risk of failure or malfunction.

Medical device manufacturers are exposed to the risk of potential product liability claims arising from device failures and malfunctions, product use and associated surgical procedures. A product liability claim may be raised as a result of factors outside our control, such as product failure, off-label use of our product, or failure of the medical practitioners or patients to follow the instructions for use. It is possible that a product liability lawsuit may be lost through no fault of ours, which could result in

reputational risk, increased insurance premiums, and depression of future sales, all of which may have an adverse effect on our financial condition, business, prospects and/or results of operations.

Device failures discovered during the Clinical Trials may lead to suspension or termination of the trial, which could have a material adverse effect on the Group.

Following regulatory approval and market release, device failures or malfunctions may result in a recall of the product, which may be restricted to a specific manufacturing lot or may impact all products in the field. Recalls may occur at any time during the life cycle of a device once regulatory approval has been obtained for the commercial distribution of the device. In most markets including the U.S. and the EU, authorities may request a manufacturer to carry out a recall, irrespective of whether the manufacturer itself deems this is required. Recalls can impact our business as they can be expensive, time consuming and can divert resources and management from normal operations. Replacement of products subject to recall can be free of charge under warranty and is therefore a potential expense for us. In some cases, the cost of a recall can include the cost of the surgical procedure to replace or remove a product. In addition, a recall may impact our future sales, or may lead to the loss of key suppliers or legal action against us by people affected by a recall and/or regulatory authorities whose role it is to supervise the distribution and sale of medical devices.

Consolidation of product liability claims into a class action lawsuit may require large dedication of resources for defence, which will be time consuming, costly, and a major distraction from the running of the business.

Following CE Marking of ReActiv8, we have purchased product liability insurance, at a level that the Directors believe to be appropriate for a company of our size and nature, to help cover the costs of defence of product liability lawsuits and for damages. For products used as part of a Clinical Trial, Clinical Trial insurance helps cover defence of lawsuits relating to the product, which is the subject of the Clinical Trial, and for damages, if awarded. We may not be able to maintain or increase product liability insurance on acceptable terms, and such insurance may not provide adequate coverage against potential liabilities. A successful claim brought against us in excess, or outside, of our insurance coverage could have a material adverse effect on our financial condition, business, prospects and/or results of operations. The Company regularly reviews the level and appropriateness of the product liability insurance in place.

(m) **ReActiv8 may cause or contribute to adverse medical events or be subject to failures o malfunctions that we are required to report to regulatory authorities, and if we fail to do so, we could be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with ReActiv8, or a recall of ReActiv8 either voluntarily or at the direction of a regulatory authority, could have a negative impact on us.**

If we obtain FDA approval, we will be subject to FDA's medical device reporting regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our 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 our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us 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 we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device approval, seizure of our products or delay in clearance or approval of future products.

The FDA and foreign regulatory bodies 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 the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labelling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, a regulatory authority may require, or we may decide, that we will need to obtain new approvals for the device before we may market or distribute the corrected device. Seeking such approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including 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 or other regulatory authorities. We may initiate voluntary withdrawals or corrections for ReActiv8 in the future that we determine do not require notification of a regulatory authority. If a regulatory authority disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

(n) **Competition in the medical device industry is intense and expected to increase**

Competition from medical device companies is intense and we expect it to further increase. We may not be able to compete successfully against our current and future competitors, including competitors with larger financial capabilities. Whilst the Directors are not currently aware of a direct competitor product on the market, potential competitors may develop new products or adapt existing products or their uses for the same patient group targeted by our product, which could present competition for ReActiv8, as further detailed in paragraph 4.4 of Part 4 (*Overview of the Market*).

Treatment for CLBP is potentially a very large market, and is attracting potential competitors. Any potential competitors' products currently in Clinical Trials, or in development, or developed in the future, could have superior clinical results, could be easier to implement clinically, could be more convenient for patients and/or less expensive than our product or could reach commercialisation before our product. Such occurrences could have a material adverse effect on our ability to generate sufficient revenues to sustain our business.

During a Clinical Trial for regulatory approval, products are generally provided at no charge. Entry by a competitive product into Clinical Trials, while our product is being commercialised, could have an adverse effect on our sales (for example, where our product is approved for use and released to the market and the competitor is still in clinical development), or may inhibit timely enrolment in our on-going Clinical Trials.

In addition, the commercial availability of any approved competing product could potentially inhibit recruitment and enrolment in our Clinical Trials. We may successfully conclude our Clinical Trials and obtain regulatory approval but may fail to compete against potential competitors or alternative treatments for Chronic Low Back Pain that may be available or developed. Any inability by us to compete effectively against other medical device companies or to effectively manage the risks related to competition may have a material adverse effect on our financial condition, business, prospects and/or results of operations.

(o) **New or competing treatments for Chronic Low Back Pain may emerge**

ReActiv8 is an AIMD designed as treatment for people with Chronic Low Back Pain. Alternative therapies for this patient group may include, among others, spine surgery, physical therapy (such as lumbar extensor strengthening exercises), watchful waiting (i.e. no therapy), traction therapy, the McKenzie Method of exercise therapy, massages, drugs (including analgesics, opioids, sleep aids, muscle relaxants and anti-depressants), acupuncture, steroid injections, back schools, various types of energy application including ultrasound, transcutaneous electrical nerve stimulation ("**TENS**"), osteopathic therapy, and thermotherapy, spinal cord stimulation ("**SCS**"), and lumbar stabilisation exercises. New treatment options, or modifications of existing treatments or their uses, may emerge which yield clinical results equal to, or better than, those achieved with ReActiv8, possibly at a lower cost. Patients might also prefer such new therapies to ReActiv8 therapy if such therapies do not require the patient to undergo a surgical procedure. Emergence of such new therapies may inhibit our ability to develop and grow the market for ReActiv8, which would have a material adverse effect on our financial condition, business, prospects and results of operations.

(p) **Our success will be heavily contingent on third party payment from government providers, healthcare insurance providers or other public or private sources**

The existence of coverage and adequate reimbursement for our product by government and private payers will be critical to market adoption for existing and future products. Medical professionals and hospitals will be unlikely to use ReActiv8, at all or to a great extent, if they do not receive adequate reimbursement for the procedures utilising our product, and potential patients may be unwilling to pay for the product themselves.

With the global pressure on healthcare costs, payers are attempting to contain costs by, for example, limiting coverage of, and the level of reimbursement for, new therapies. Any limitations on, decreases in or elimination of payments by third party payers may have an adverse effect on our financial condition, business, prospects and/or results of operations.

In many countries, a series of codes is used to classify diagnoses and clinical procedures performed, and there are separate coding systems for delivery of stationary (inpatient) and ambulatory (outpatient) care. Payment for ReActiv8 is dependent on classification of the procedure that utilises ReActiv8 within these coding systems. For more information on these coding systems, see paragraph 5.13(e) of Part 5 (*Information on the Group*) of this document.

If coding is not yet in place or coverage of available coding is insufficient in relevant markets, we will have to work with the relevant parties to establish appropriate coding and reimbursement levels. This can be a lengthy process (months to years) and there is no guarantee that coding can be obtained at satisfactory levels, or at all, or if obtained, that it will be adequate to enable us to build a profitable business selling ReActiv8.

There are existing reimbursement codes applicable to ReActiv8, which hospitals can use in Germany, Switzerland and Austria. For more details on the Group's strategy in respect of securing repayment for ReActiv8 through reimbursement codes, see paragraph 5.13(e) of Part 5 (*Information on the Group*) of this document.

Securing adequate or attractive reimbursement often depends on demonstrating the cost effectiveness of a product, for example with a medical economics study. There is also no assurance that we will be able to demonstrate cost effectiveness of ReActiv8 in a timely manner or at all.

Failure to obtain attractive reimbursement from payers may have a material adverse effect on our financial condition, business, prospects and results of operations.

(q) **Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions, which may affect our ability to sell ReActiv8 at prices necessary to support our current business strategies.**

Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators and third-party payers. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for pricing concessions in the future. Additionally, group purchasing organizations, independent delivery networks and large single accounts may continue to use their market power to consolidate purchasing decisions for hospitals. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our customers, which may exert further downward pressure on the prices of ReActiv8.

(r) **We are dependent on access to raw materials and products and manufacturing of our product is not guaranteed by the third parties with whom we contract**

Although we do not manufacture our product, our third party manufacturers are dependent on continuing supply of certain raw materials. In particular, some raw materials such as biocompatible polymers (plastics) may only be available from a sole supplier. If the supplier of the raw material encounters problems, goes out of business, refuses to supply certain materials, or dramatically increases the prices of certain materials, it may disrupt the ReActiv8 supply chain. Disruption in our supply chain via our third party manufacturers may result in interruption of supply of our product, which could have a material adverse impact on our ability to proceed with commercialisation, continuing Clinical Trials, and our financial condition, and could require product redesign and/or engagement with alternative manufacturers, which could be expensive and time consuming.

(s) **Manufacturing issues may arise that are detrimental to the Group**

We use external vendors to manufacture and supply ReActiv8. Vendors are required by applicable laws and regulations to have in place and implement appropriate quality management measures and are generally subject to inspections by regulatory authorities. A vendor may be unable to supply the quantity of products according to our requirements, or may suffer internal delays or problems which could impact the quality, delivery or compliance with the specifications of ReActiv8. This may have a material adverse effect on our financial condition, business, prospects and results of operations.

Any identified manufacturing or quality issue may require extensive rework of products or a complete scrapping of the inventory of affected products and could also require suspension of distribution of products, or products to be returned from the field for modification.

The design and development of an AIMD uses many disciplines including electrical, mechanical, software, biomaterials, and other types of engineering. Engineers employed by us undertaking research and development or manufacturing activities may make an incorrect decision or make a decision during the engineering phase without the benefit of long term experience, and the impact of such wrong decisions may not be apparent until well into a product's life cycle, which in either case may have a material adverse effect on our financial condition, business, prospects and/or results of operations.

In addition, ReActiv8 is subject to extensive testing to international standards such as for electrical safety and electromagnetic compatibility. Changes in standards may require re-testing of our product, and there is no assurance that compliance with an earlier standard will also mean compliance with a more recent version of a standard.

(t) **We depend on third party suppliers for the manufacture of ReActiv8. Disruption of the supply chain, or failure to achieve economies of scale could have a material adverse effect**

We depend on a limited number of third party suppliers for the manufacture of ReActiv8 and the loss of one or more of these third party suppliers or their inability or unwillingness to supply us with adequate quantities of products could harm our business in the future. Certain of our suppliers, including Oscor Inc. and CCC del Uruguay S.A, are sole suppliers. These sole suppliers and any of our other suppliers may be subject to circumstances which impact our ability to supply, including

enforcement action by regulatory authorities, natural disasters (e.g. hurricanes and earthquakes), industrial action (e.g. strikes), financial difficulties including insolvency, pressure or demands on manufacturing capacity (e.g. by products for other customers that compete for manufacturing capacity), among a variety of other internal or external factors.

If any of our existing suppliers are unable or unwilling to meet our demand for product or components, or fail to respect their contractual commitments to us, or if the components or finished products that they supply do not meet quality and other specifications, Clinical Trials or commercialisation of our product could be delayed. Alternatively, if we have to switch to a replacement manufacturer or replacement supplier for any of our product components, or commence our own manufacturing to satisfy market demand, we may face additional delays and other issues, and the manufacture and delivery of ReActiv8 could be interrupted for an extended period of time, which interruption could delay completion of our Clinical Trials or commercialisation. Alternative suppliers may be unavailable, may be unwilling to supply, may not have the necessary regulatory approvals, or may not have in place an adequate quality management system.

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 our operations and product delivery, may affect the performance specifications of ReActiv8 or could require that we modify its design. Even if we are able to find replacement suppliers, we will be required to verify that the new supplier maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. Any of these events could require that we obtain a new regulatory authority approval before we implement the change, which could result in further delay and which may not be obtained at all.

Our suppliers, in turn, depend on their own suppliers and supply chain. Any disruption of the supply chain could have a material adverse effect on our financial condition, business, prospects and/or results of operations.

Our suppliers may not be able to increase yields and/or decrease manufacturing costs over time, and the cost of goods sold may not decrease or may in fact increase, resulting in an adverse effect on our financial condition, business, prospects and/or results of operations.

In addition, our suppliers may discontinue supply of components or materials upon which we rely before the end of the product life of our product. The timing of the discontinuation may not allow us sufficient time to develop and obtain regulatory approval for replacement products or components before we exhaust our inventory. If suppliers discontinue supply of components or materials, we may have to pay premium prices to our suppliers to keep their production lines open. We may have to obtain alternative suppliers, buy substantial inventory to last until the scheduled end of life of our product or through such time as we have an alternative product developed and approved by the regulatory authorities. We may have to temporarily cease supplying our product once our inventory of the discontinued materials or component is exhausted.

Any of these interruptions to the supply of materials or components could result in substantial reduction in our available inventory and an increase in our production costs, which may have a material adverse effect on our financial condition, business, prospects and/or results of operations.

(u) **Compliance with regulations for quality systems for medical device companies is difficult, time consuming and costly. We may be found to be non-compliant, for example as a result of future changes in or interpretation of the regulations regarding quality systems in certain jurisdictions**

We have developed and maintained a Quality Management System ("**QMS**") to ensure quality of our product and activities. The QMS is designed to be in compliance with regulations in many different jurisdictions, including the Quality Systems Regulations ("**QSR**") mandated by the FDA, and the requirements of the AIMD Directive, including the international standard ISO 13485 required for obtaining CE Marking. In some circumstances, the requirements of regulations and standards may be different and may be mutually exclusive.

Compliance with regulations for quality systems for medical device companies is difficult, time consuming and costly, and it is possible that we may be found to be non-compliant at any time. In addition, we may be found to be non-compliant as a result of future changes in, or interpretation of, the regulations for quality systems. If we do not achieve compliance or subsequently become non-compliant, the regulatory authorities may (i) require that we take appropriate action to address non-conformance issues, (ii) withdraw marketing clearance, (iii) require product recall, or (iv) take other enforcement action.

Our external vendors must (in general) also comply with the QSR and ISO 13485. Any of our external vendors may become non-compliant with QSR or ISO 13485, which could result in enforcement action by regulatory authorities, including, by way of example, a warning letter from the FDA or a requirement to withdraw from the market or suspend distribution, export or use of products manufactured by one or more of our vendors. This may have a material adverse effect on our financial condition, business, prospects and results of operations.

Any change or modification to a device may require further approvals (depending on the jurisdiction) and must be made in compliance with appropriate regulations (QSR for the U.S. and the AIMD Directive for Europe), which compliance may cause interruption to or delays in the marketing and sale of our product. U.S. federal, state and other laws regarding the manufacture and sale of AIMDs are subject to future changes, as are administrative interpretation and policies of regulatory agencies. If we fail to comply with applicable laws where we would intend to market and sell our product, we could be subject to enforcement action including recall of our devices, withdrawal of approval or clearance and civil and criminal penalties. If any of these events occurs, there may be a material adverse effect on our financial condition, business, prospects and/or results of operations.

(v) **In some markets we may depend on distributors for the market and sale of ReActiv8 over which we have little or no control**

For some markets our intended distribution strategy may be to rely on third party distributors for ReActiv8. For further information on the Group's sales and distribution strategy, see paragraph 5.15 of Part 5 (*Information on the Group*).

In markets where we may depend on distributors, we would not directly control the performance of a distributor. Thus the level of sales we generate, and the profitability we achieve, in those markets may depend on the efforts of others. A distributor's failure to perform according to expectations and/or contractual obligations may have an adverse effect on our reputation, financial condition, business, prospects, and/or results of operations.

(w) **We may be unable to attract and retain management and other personnel we need to succeed**

We rely on the expertise and experience of our Directors, senior management and other key employees and contractors in management, research and development, clinical and regulatory matters, sales and marketing and other functions. The retention and performance of our Directors, senior management and other key employees are therefore significant factors in our ability to achieve our objectives. The departure of any of these individuals without timely and adequate replacement, or the loss of any of our senior management may have a material adverse effect on our financial condition, business, prospects and results of operations and there can be no guarantee that we would be able to find and attract other individuals with similar levels of expertise and experience or similar relationships with commercial partners and other market participants. In addition, our competitive position could be materially adversely affected if a member of senior management transferred to another company seeking to develop a rival product. Further, we conducted a reduction in workforce in early 2019, and working with fewer employees and losing the expertise of our departed employees may adversely affect our efficiency and ability to achieve key objectives.

Our future growth will require hiring a number of qualified clinical, scientific, commercial and administrative personnel. If we are unable to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development, commercialisation or growth.

Pursuant to rights afforded to Directors and officers of the Company under the Articles of Association, and as is customary for Irish incorporated listed public companies, we have entered into indemnification agreements with our Directors and senior management, including certain contractors. As a consequence of such indemnification agreements, we may have to use our resources to indemnify such persons, which could have an adverse effect on our future financial performance.

(x) **We rely on third parties for management services, manufacturing, marketing, regulatory advice and other services that are crucial to our business**

In order to carry out our business, we depend heavily on third party consultants, contractors, distributors, manufacturers, agents and numerous other partners for core and non-core services and functions, including management functions (e.g.: certain payroll services), clinical studies, applications for regulatory approval, commercial operations and other services and functions that may involve interactions with government and quasi-government authorities. As a result, if any of these parties fails to perform as promised or intended or contracted, our business plans for obtaining regulatory approval for ReActiv8 in targeted geographies and commercialising ReActiv8 may suffer, and our business may be materially adversely affected.

(y) **We may be at risk for non-compliance with applicable laws and regulations**

Doing business on a worldwide basis requires us to comply with the laws and regulations of various jurisdictions. In particular, our operations are subject to anticorruption laws and regulations, which may include the U.S. Foreign Corrupt Practices Act of 1977 (the "**FCPA**"), the UK Bribery Act of 2010, the Criminal Justice (Corruption Offences) Act 2018 and other Irish anti-bribery laws and regulations, and anti-bribery laws and regulations in other countries, including those having implemented the OECD Anti-Bribery Convention. Anticorruption laws prohibit corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to another person, including but not limited to a government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise improperly influence a person; the laws are broad and many apply to private as well as public bribery and also penalize the receipt as well as the giving of bribes. In the course of establishing and expanding our commercial operations and seeking regulatory approvals in the EU, the U.S., and internationally, we will need to establish and expand business relationships with various third parties and will interact more frequently with various officials, including regulatory authorities and physicians employed by state-run healthcare institutions who may be deemed to be "foreign officials" under the FCPA or similar laws, or who may otherwise be candidates for illicit payments in exchange for improper benefits. We have implemented policies and procedures designed to ensure compliance with the FCPA, UK Bribery Act of 2010, the Criminal Justice (Corruption Offences) Act 2018 and other Irish anti-bribery laws and other similar laws, however acts or omissions of any of the parties we rely on, including Directors, executive officers, employees, third party consultants, contractors, distributors, manufacturers, agents and numerous other partners, could potentially cause us to incur liability under applicable laws and regulations.

Our operations may also be subject to applicable laws and regulations on economic sanctions and export controls, including those administered by the U.S. and the EU, which are complex and may be violated inadvertently.

In case of a violation of any of the anti-bribery, economic sanctions or export control laws, we could be subject to fines, confiscation of profits or legal sanctions, such as termination of authorizations, licenses, concessions and financing agreements, suspension of our operations, or prohibitions on contracting with public authorities. Any such violation, even if prohibited by our policies, could have a material adverse effect on our financial condition, business, prospects and results of operations.

(z) **Information Technology ("IT") forms a key support requirement within our business. Any failure of our IT systems could present a substantial risk to our business continuity**

The efficient operation of our business depends on IT systems. We rely on our IT systems to help manage our administration, marketing, accounting and financial functions, clinical and regulatory functions, manufacturing processes, and our research and development functions.

The regulatory and legal environment of our industry requires us to maintain records for long periods of time, sometimes indefinitely. In most cases, those records are kept in electronic form and without paper copies.

We use third party suppliers to provide computing, communication, data storage and backup services, and failure of any of those third party suppliers may have an adverse effect on our ability to operate, which could have an adverse effect on our financial condition, business, prospects and results of operations. Although industry standard practices are in place for regular information backup, failure of our IT systems infrastructure may result in the inability to continue business until the records are recreated, and this may have an adverse effect on our financial performance or our financial condition, business, prospects and results of operations.

Our employees and contractors often work from home offices, in particular employees or contractors who need to be close to the customer base to enable rapid support (for example, field clinical specialists). This requires strong IT infrastructure support (telephone, email, internet access), which must be continuously maintained. Failure of our IT infrastructure, a security breach by a malicious third party, or loss of critical information may have an adverse effect on our financial condition, business, prospects and results of operations.

Our employees frequently utilise portable laptop or notebook computers. Loss, theft or damage to a portable computer could result in loss of key information (in some cases to a competitor), which could have a material adverse effect on our financial performance or our financial position.

(aa) **Rules relating to data privacy laws**

The Company is subject to regulation regarding the processing (including disclosure and use) of personal data. The Company therefore must comply with strict data protection and privacy laws and regulations, including Regulation 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (the "**GDPR**") which took effect from 25 May 2018 and is the primary legislation governing the use of personal data along with the Data Protection Act 2018. GDPR introduced substantial changes to data protection law, including an increased emphasis on businesses being able to demonstrate compliance with their data protection obligations, which required investment by the Company in its compliance strategies. In addition, relevant supervisory authorities are given the power to issue fines of up to 4 per cent. of an undertaking's annual global group turnover or €20 million (whichever is the greater) for failure to comply with certain provisions of the GDPR.

(bb) **U.S. "anti-inversion" tax laws could negatively affect our results**

Under rules contained in U.S. tax law (Section 7874 of the Internal Revenue Code), a non-U.S. company, such as Mainstay Medical, can be subject to tax as a U.S. corporation in the event it acquires substantially all of the assets of a U.S. corporation and the equity owners of that U.S. corporation own at least 80 per cent. of the non-U.S. company's stock by reason of their holding stock in the U.S. corporation.

In 2014 the Group undertook the 2014 Corporate Reorganisation during which the Company acquired the assets (being shares in MML) of Mainstay Medical Inc. ("**MMI**") (a U.S. corporation), and former shareholders of MMI became shareholders of the Company. The ownership of equity that former shareholders of MMI received in the 2014 Corporate Reorganisation is substantially below the 80 per cent. standard for application of the above U.S. rules. Accordingly, the Directors do not believe these rules should apply. There can, however, be no assurance that the IRS will not challenge the

determination that these rules are inapplicable. In addition to the 2014 Corporate Reorganisation, there was an earlier Group reorganisation transaction in 2012. The Directors do not believe integrated treatment of this transaction with the 2014 Corporate Reorganisation to be appropriate because there are independent business reasons for undertaking these transactions. In the event that the U.S. anti-inversion rules are held to apply to us, we would be subject to U.S. federal income tax on our worldwide income, which would negatively impact the cash available for distribution and the value of the Ordinary Shares.

(cc) **The anti-tax avoidance directive could negatively affect our results.**

The first Anti-Tax Avoidance Directive, or ATAD 1, was adopted as Council Directive (EU) 2016/1164 on July 12, 2016 and was required, for the most part, to be implemented by all EU member states by January 1, 2019. The ATAD 1 was required to be transposed into Irish law by January 1, 2019, with certain exceptions. The second Anti-Tax Avoidance Directive, which together with ATAD 1 is referred to as the ATADs, was adopted as Council Directive (EU) 2017/952 on May 29, 2017. ATAD 2 must be implemented by all EU member states by January 1, 2020, with certain exceptions. When implemented, it is possible that the ATADs may affect the tax treatment of our profits and therefore the value of our Ordinary Shares. However, the possible implications of the ATAD are unascertainable at this time.

(dd) **We are exposed to foreign exchange risk**

We are, and will in the future be increasingly, exposed to exchange rate fluctuations including, among others, the Euro, U.S. Dollar, Australian Dollar, Swiss Franc and Pound Sterling. Fluctuations of exchange rates outside a budgeted range may affect revenues, expenses, or our ability to raise future capital if it is needed, and may have an adverse impact on our financial condition, business, prospects and/or results of operations.

1.3 RISKS RELATING TO INTELLECTUAL PROPERTY

(a) **Any inability to fully protect and exploit our intellectual property may adversely impact our financial condition, business, prospects and results of operations**

Our success depends significantly on our ability to protect our proprietary rights, including the intellectual property related to and incorporated in ReActiv8. We rely on a combination of patent protection, trademarks and trade secrets, and we use confidentiality and other contractual agreements to protect our intellectual property. We generally seek patent protection where possible for those aspects of our technology and product that, the Directors believe, provide significant competitive advantages. As at the Latest Practicable Date, our patent portfolio includes 15 granted U.S. patents, 54 patents outside the U.S. and 34 U.S. and foreign patent applications in the patent families described in more detail in paragraph 5.16 of Part 5 (*Information on the Group*) of this document. However, we may be unable to adequately protect our intellectual property rights or may become subject to a claim of infringement or misappropriation, which we may be unable to settle on commercially acceptable terms. We cannot be certain that our pending or future patent applications will result in issued patents. In addition, we do not know whether any issued patents will be upheld as valid or will be proven to be enforceable against alleged infringers or that they will prevent the development of competitive patents or provide meaningful restriction against potential competitors or against potential competitive technologies.

The process of obtaining patent protection involves filing applications in multiple jurisdictions and patent offices, and may take many years. Success in one jurisdiction does not guarantee success in another jurisdiction, particularly as different jurisdictions may apply different legal principles. For example, it is possible to obtain a patent for a medical method in the U.S., but such patents cannot be applied for in Europe. Therefore, there may be circumstances where an invention is patented in one jurisdiction but a patent cannot be obtained in one or more other jurisdictions.

In responding to our patent application, a patent office may reject one or more (or sometimes all) claims. This may lead to an extensive dialogue between our patent attorneys and the patent office in

an effort to reach agreement and grant of a patent. There is no assurance that such efforts will be successful, and thus no assurance that all patent applications will result in an issued patent.

In addition to the requirements of each patent office setting forth the necessary characteristics of an invention in order to enable the issuance of a patent, patents are issuable only to the inventors of the invention covered or to their assignees. In some, but not all, jurisdictions the law provides that inventions made by employees during normal working hours and using employer resources belong to the employer. We require our employees to enter into proprietary information and inventions assignment agreements assigning to us ownership of their inventions made in the course of their employment. We also require consultants and vendors providing services to us that could result in the creation of inventions to enter into agreements with us to assign to us their inventions made as a result of their relationships with us. If we fail to obtain such an agreement from an employee in a jurisdiction where ownership of employee inventions does not automatically vest in the employer, or if we fail to obtain such an agreement from a consultant or vendor, inventions made by these employees, consultants or vendors might be owned by them and not by us. As a result, we might not be entitled to a patent on any such invention and we might not own such an invention. If such invention relates to any of our products in development or on sale, we might be required to cease such development or sale, and pay damages to the owners.

There is no assurance that our intellectual property rights will not be challenged, invalidated, circumvented or rendered unenforceable. Parties seeking to compete with us (directly or indirectly) or other third parties may successfully challenge and invalidate or render unenforceable our issued patents, including any patents that may be issued in the future or could develop competitor products to ReActiv8. This could prevent or limit our ability to stop potential competitors from marketing products that are identical or substantially equivalent to ours. In addition, such parties may be able to design around our patents, obtain competitive patents or other intellectual property rights regardless of prior art in our patents or patent applications, or develop products that provide outcomes that are comparable to our product but that are not covered by our patents.

Much of the Company's value is in our intellectual property, and any challenge to our intellectual property portfolio (whether successful or not) may impact the value of ReActiv8 and the Company.

(b) **We could become subject to intellectual property litigation or other disputes that could be costly, result in the diversion of management's time and efforts, require us to pay damages, prevent us from marketing ReActiv8 or other products and/or reduce the margins for ReActiv8**

Third party patents or other intellectual property may emerge which may have a materially adverse effect on our ability to commercialise ReActiv8 and there is no assurance that such third party patents or intellectual property will not emerge.

The medical device industry is characterized by rapidly changing products and technologies and there is intense competition to establish intellectual property and proprietary rights to use these new products and the related technologies. This vigorous protection and the pursuit of intellectual property rights and positions has resulted and will continue to result in extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, and the determination is often uncertain in advance. There may be existing or future patents that ReActiv8 may inadvertently infringe. Potential competitors may have or develop patents and other intellectual property that they assert our product infringes.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file one or more lawsuits and assert infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable or may refuse to enjoin the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly in differing jurisdictions or as new technologies develop. As a result, we cannot predict with certainty

how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Further, even if we prevail against an infringer in district court, there is always the risk that the infringer will file an appeal and the district court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted in a manner insufficient to achieve our business objectives.

Any infringement claim against us, even if without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources and/or divert the time and efforts of management from our core business. In addition, any potential intellectual property litigation could force us to do one or more of the following: stop selling/using our product or using technology that contains the allegedly infringing intellectual property; forfeit the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others; pay substantial damages to the party whose intellectual property rights we may be found to be infringing; redesign those products that contain or utilise the allegedly infringing intellectual property; or attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all. Any of these circumstances may have a material adverse effect on our financial condition, business, prospects and results of operations.

Requirements to obtain licenses to third party intellectual property rights may arise in the future. If we need to license any third party intellectual property, we could be required to pay lump sums or royalties on sales of our future products. In addition, there can be no assurances that, if we are required to obtain licenses to third party intellectual property, we will be able to obtain such licenses on commercially reasonable terms or at all. Our inability to obtain required third party intellectual property licenses on commercially reasonable terms or at all could have a material adverse impact on our business, results of operations, financial condition or prospects.

(c) **Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products**

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defence of our issued patents. On 16 September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switched the U.S. patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The U.S. Patent and Trademark Office (the "**USPTO**") developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on 16 March 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defence of our issued patents, all of which could have a material adverse effect on financial condition, business, prospects and results of operations.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defence of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the U.S. are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by the

U.S. or other countries. Those changes may affect our patents or patent applications and our ability to obtain additional patent protection in the future.

(d) **Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements**

The USPTO and various other non-U.S. government patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and other non-U.S. patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our product or procedures, we may not be able to stop a potential competitor from marketing products that are the same as, or similar, to our own, which could have a material adverse effect on our financial condition, business, prospects and results of operations.

(e) **We may not be able to adequately protect our intellectual property rights throughout the world**

Filing, prosecuting and defending patents on ReActiv8 in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some countries may not protect our intellectual property rights to the same extent as laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in some or all countries outside the U.S. Potential competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities.

We do not have patent rights in certain countries in which a market for ReActiv8 may exist. Moreover, in some jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful, collectible or enforceable. Thus, we may not be able to stop a competitor from marketing and selling in certain countries products that are the same as or similar to our products and our competitive position in those countries could be materially harmed.

(f) **We depend on confidentiality agreements with third parties to maintain confidential information**

We rely upon unpatented confidential and proprietary information, including technical information, and other trade secrets to develop and maintain our product and competitive position. While we generally enter into confidentiality and invention assignment agreements with our employees and other third parties to protect our intellectual property, there can be no assurance that they will provide meaningful protection for our trade secrets and proprietary information, that those employees or third parties will not breach such agreements or that adequate remedies will be available in the event of an unauthorised use or disclosure of such information. Unauthorised use or

disclosure of our confidential and proprietary information may have a material adverse effect on our financial condition, business, prospects and results of operations.

(g) **Intellectual property rights do not necessarily address all potential threats to our business**

Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, inter parties review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the challenged allowed or granted claims or may lose the allowed or granted claims altogether.

In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to develop and/or practice technology that is the same or similar to our technology or aspects of our technology, but that are not covered by the claims of the patents that we own or control, assuming such patents have issued or do issue, or otherwise infringe our other intellectual property rights;
- we or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operations.

(h) **If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected**

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks.

We may not be able to protect our rights in our trademarks and trade names, which we need in order to build name recognition with potential partners or customers in our target markets. In addition, third parties may have used trademarks similar and identical to our trademarks in foreign jurisdictions and have filed or may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market ReActiv8 in those countries. In any case, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected.

1.4 RISKS RELATING TO OUR SHARES

(a) Future issuances or exercise of Ordinary Shares, Share Options or Share Warrants may affect the market price of the Ordinary Shares and could dilute the interests of existing Shareholders

We have incurred significant net losses since we were founded. If we are unable to obtain regulatory approvals for ReActiv8 in the U.S. or elsewhere, or if product development, manufacture, marketing, sales or commercialisation of ReActiv8 is delayed or abandoned, we may never generate significant revenue or become profitable. Further, we expect to require additional funds in the future in order to meet our capital and expenditure needs. To date we have funded, and for the immediate future, we expect to continue to fund, our operations through equity capital (by way of issuance of new Ordinary Shares and/ or rights to subscribe for new Ordinary Shares) and debt.

Pursuant to the Shareholder resolutions described at paragraph 9.4(a)(i) and (ii) of Part 9 (*Additional Information*) of the Registration Document, the Shareholders have authorised the Board to allot securities of the Company, without having regard to statutory pre-emption rights, during the period ending on 20 September 2024 up to an aggregate nominal value amount of €17,000 (representing approximately 126.66% of the issued ordinary share capital of the Company as at the Latest Practicable Date), without seeking Shareholder approval. The issue price per new Ordinary Shares will be as determined by the Directors provided that no share be issued as a discount to its nominal value. If the Company issues additional Ordinary Shares it could cause dilution for the holders of Ordinary Shares and could have a negative impact on the price of Ordinary Shares.

Under the First Warrant Instrument, the Company has granted rights to subscribe for 1,500,000 Ordinary Shares at an exercise price of €6.00 per share. In addition, under the terms of the IPF Amendment and Restatement Agreement and the Second Warrant Instrument, the Company may be required to issue Ordinary Shares at a price of €8.00 per share on the basis described in paragraphs 9.12(c) and (e) of Part 9 (*Additional Information*) of the Registration Document. As at the Latest Practicable Date, assuming the triggers for conversion under the IPF Amendment and Restatement Agreement were met in the second half of 2020, this could result in the issuance of approximately 1.7 million new Ordinary Shares. If the existing subscription rights were to be exercised or triggered, or if further rights to subscribe for Ordinary Shares were to be granted or exercised, this could cause dilution for the holders of Ordinary Shares and could have a negative impact on the price of Ordinary Shares.

From time to time, the Company has issued Share Options to its employees, directors or consultants. Since the IPO, those Share Options have been granted with an exercise price equal to the market value of an Ordinary Share at the date of grant. As at the Latest Practicable date, the vast majority of those Share Options have an exercise price that is significantly in excess of the quoted price per Ordinary Share on Euronext Growth and Euronext Paris. The Employee Incentive Plan was amended in January 2019 to allow for the issue of RSUs, being rights to receive Ordinary Shares at no cost to the relevant employee, director or consultant. The Company has granted 390,000 RSUs as at the Latest Practicable Date. Vesting of existing Share Options or RSUs or the grant or vesting of Share Options or RSUs in the future could cause dilution for the holders of Ordinary Shares and could have a negative impact on the price of Ordinary Shares.

(b) **We may be a passive foreign investment company ("PFIC") for 2019 or subsequent years, which could result in adverse U.S. federal income tax consequences to U.S. investors**

For U.S. federal income tax purposes, a non-U.S. corporation will be considered a passive foreign investment company, or PFIC, for any taxable year if either (1) at least 75% of its gross income for such year is passive income or (2) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during such year) is attributable to assets that produce or are held for the production of passive income. If we are a PFIC for any taxable year during which a U.S. holder holds shares, the U.S. holder may be subject to adverse tax consequences, including (1) the treatment of any gain on disposition as ordinary income, rather than capital gain qualifying for preferential rates, (2) the application of an interest charge with respect to such gain and certain dividends and (3) compliance with certain reporting requirements. The Directors do not believe that the Company was a PFIC for its 2018 taxable year, although the U.S. Internal Revenue Service ("**IRS**") may disagree with this conclusion in the event it audits any U.S. shareholder's tax reporting. Based on the value and composition of our assets, we may, however, be a PFIC for 2019 and potentially for future taxable years. The determination of PFIC status is fact-specific, and a separate determination must be made for each taxable year (after the close of each such taxable year). Each U.S. shareholder is strongly urged to consult its tax advisors regarding these issues.

(c) **The market price and/or liquidity of our securities may fluctuate widely in response to various factors which may limit or prevent investors from selling their Ordinary Shares**

The market price and/or liquidity of Ordinary Shares could be subject to wide fluctuations in response to many risk factors listed in this section, beyond our control including (without limitation):

- actual or anticipated fluctuations in our financial condition and operating results;
- our failure to obtain regulatory approval for ReActiv8 beyond CE Marking;
- our failure to successfully commercialise ReActiv8;
- adverse results or delays in our Clinical Trials;
- actual or anticipated changes in our growth rate;
- competition from existing products or new products that may emerge;
- announcements by us, our collaborators or our potential competitors of significant acquisitions, strategic partnerships, joint ventures, strategic alliances, or capital commitments;
- adverse regulatory decisions;
- the inability to establish potential strategic alliances;
- unanticipated serious safety concerns related to the use of our product;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- price and volume fluctuations in trading of our Ordinary Shares on Euronext Growth of Euronext Dublin or Euronext Paris;
- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;

- our inability to obtain reimbursement by commercial third-party payers and government payers and any announcements relating to coverage policies or reimbursement levels;
- announcement or expectation of additional debt or equity financing efforts;
- issuances by the Company of Ordinary Shares or transfers or sales of Ordinary Shares by shareholders;
- issue or exercise of share warrants or share options; and
- general economic and market conditions.

The above and related market and industry factors may cause the market price, demand and/or liquidity of our Ordinary Shares to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their Ordinary Shares. In addition, the stock market in general, and development stage companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

(d) **Our Ordinary Share ownership is concentrated in the hands of our principal Shareholders, who may be able to exercise a direct or indirect controlling influence on us**

Our seven largest Shareholders together own approximately 78% of our Ordinary Shares in issue at the Latest Practicable Date. As a result, these Shareholders (or a combination of some of these Shareholders), if they were to act together, would have significant influence over all matters that require approval by our Ordinary Shareholders, including the election of directors and approval of significant corporate transactions. Subject to customary Shareholder protections on takeovers and related party transactions, corporate action might be taken even if other Ordinary shareholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our Company that other Ordinary Shareholders may view as beneficial.

(e) **If securities or industry analysts do not publish research or publish unfavourable research about our business, the price of our Ordinary Shares and trading volume could decline**

The trading market for our Ordinary Shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If few or no securities or industry analysts cover us, the trading price for our Ordinary Shares could be negatively impacted. If one or more of the analysts who covers us downgrades this recommendation on our Ordinary Shares, publishes unfavourable research about our business, ceases coverage of our Company or fails to publish reports on us regularly, demand for our Ordinary Shares could decrease, which could cause the price of our Ordinary Shares or trading volume to decline.

(f) **We do not currently intend to pay dividends, and, consequently, the ability to achieve a return on investment will depend on appreciation in the price of the Ordinary Shares**

We have never declared or paid any cash dividends on our Ordinary Shares and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your Ordinary Shares for the foreseeable future and the success of an investment in Ordinary Shares will depend upon any future appreciation in the value of the Company. Consequently, investors may need to sell all or part of their holdings of Ordinary Shares after price appreciation, which may never occur, as the only way to realize any future gains on their investment. Investors seeking cash dividends should not purchase our Ordinary Shares.

(g) **Irish law may afford fewer remedies in the event shareholders suffer losses compared to the U.S. or other jurisdictions**

As an Irish company, we are governed by the Irish Companies Act 2014 and Irish company law generally, which differ in some material respects from laws generally applicable to typical U.S.

corporations and other non-Irish corporations and their shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or other officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. You should also be aware that Irish law does not allow for any terms of legal proceedings directly equivalent to the class action available in U.S. courts. Accordingly, holders of our shares may have more difficulty protecting their interests than would holders of shares of a company organised in a jurisdiction of the U.S.

(h) **A takeover bid for the Company's securities would be subject to supervision by French and Irish regulatory authorities, which may add complexity to, and delay completion of, any takeover bid for the Company**

As a company with its registered office in Ireland and whose securities are admitted to trading on a regulated market (within the meaning of point (21) of Article 4(1) of Directive 2014/65/EU) in France only, the Company is, for the purposes of Directive 2004/25/EC of the European Parliament and the Council dated 21 April 2004 (the "**Takeover Directive**"), a shared jurisdiction company. This means that a takeover bid for its securities would be subject to the Irish Takeover Rules of the Irish Takeover Panel in some respects, but also subject to the general regulation (*règlement général*) (the "**French Takeover Rules**") of the *Autorité des marchés financiers* (the "**AMF**") in most other respects.

In the case of a takeover bid for a shared jurisdiction company, the Takeover Directive provides that matters relating to the consideration offered in the case of a bid, in particular the price, and matters relating to the bid procedure, in particular the information on the offeror's decision to make a bid, the contents of the offer document and the disclosure of the bid, shall be dealt with in accordance with the rules of the EU member state in which the securities of the company are admitted to trading on a regulated market, in this case France. Matters relating to the information to be provided to the employees of the offeree company and matters relating to company law, in particular the percentage of voting rights conferring "control" and any derogation from the obligation to launch a bid, as well as the conditions under which the board of the offeree company may undertake any action which might result in frustration of the bid, shall be determined by the rules of the EU member state in which the Company has its registered office, in this case, Ireland.

The Company is currently the only shared jurisdiction company (current or previous) for the purposes of the Takeover Directive where, in the case of a takeover bid, the relevant competent authorities would be those of France and Ireland. Accordingly, a takeover bid for the Company would be supervised by two competent authorities, who would need to agree amongst themselves the correct delineation, with respect to such takeover bid, between the application of their respective takeover rules, as well as between their respective responsibilities and powers. The Company believes that this could lead to additional complexity in planning, making and/or completing any such takeover bid, which in turn could result in an extension of the transaction timetable and increased transaction costs.

(i) **Future sales of Ordinary Shares by existing shareholders could depress the market price of the Ordinary Shares**

If our existing shareholders sell, or indicate an intent to sell, substantial amounts of Ordinary Shares in the public market, the trading price of the Ordinary Shares could decline significantly.

PART 2
IMPORTANT INFORMATION

2.1 Forward Looking Statements

This document includes statements that are, or may be deemed to be, forward looking statements. These forward looking statements can be identified by the use of forward looking terminology, including the terms "anticipates", "believes", "estimates", "expects", "intends", "may", "plans", "projects", "should" or "will", or "explore", or, in each case, their negative or other variations or comparable terminology, or by discussions of strategy, plans, objectives, goals, future events or intentions. These forward looking statements include all matters that are not historical facts. They appear throughout this document and include, but are not limited to, statements regarding the Company's intentions, beliefs or current expectations concerning, among other things, the Company's or the Group's results of operations, financial position, prospects, financing strategies, expectations for product design and development, regulatory applications and approvals, reimbursement arrangements, costs of sales and market penetration.

By their nature, forward looking statements involve risk and uncertainty because they relate to future events and circumstances. Forward looking statements are not guarantees of future performance and the actual results of the Company's or the Group's operations, and the development of ReActiv8, the markets and the industry in which the Company operates, may differ materially from those described in, or suggested by, the forward looking statements contained in this document. In addition, even if the Company's or the Group's results of operations, financial position and growth, and the development of ReActiv8 and the markets and the industry in which the Company operates, are consistent with the forward looking statements contained in this document, those results or developments may not be indicative of results or developments in subsequent periods. A number of factors could cause results and developments of the Company to differ materially from those expressed or implied by the forward looking statements including, without limitation, the successful launch and commercialisation of ReActiv8, the time and process required to obtain regulatory approvals, including any inability to timely obtain such approvals, the ability to raise additional capital to fund the Company's business and the cost of such capital, general economic and business conditions, the global medical device market conditions, industry trends, competition, changes in law or regulation, changes in taxation regimes, time required to commence and complete Clinical Trials, currency fluctuations, changes in its business strategy, political and economic uncertainty and other factors discussed in Part 1 (*Risk Factors*) of this document. The forward-looking statements herein speak only at the date of this document. Other than required by the Irish Prospectus Regulations, Prospectus Rules, the applicable market abuse law, the Transparency Regulations and Transparency Rules, the rules of Euronext Paris, the Euronext Growth Rules or by law, the Company undertakes no obligation to update these forward looking statements and will not publicly release any revisions it may make to these forward looking statements that may occur due to any change in the Company's expectations or to reflect events or circumstances after the date of this document. You should note that the contents of these paragraphs relating to forward looking statements are not intended to qualify the statements made as to sufficiency of working capital in this document.

2.2 Market, Economic and Industry Data

This document includes certain market, economic and industry data, which was obtained by the Company from scientific publications, industry publications, data and reports compiled by professional organisations and analysts, data from other external sources and internal surveys conducted by or on behalf of the Group. The market, economic and industry data sourced from third parties used to prepare the disclosures in this document have been accurately reproduced and, as far as the Company and the Directors are aware and are able to ascertain from the information provided to them by third parties, no facts have been omitted which would render the reproduced information inaccurate or misleading. Based on the market, economic and industry data, the Company has made a number of estimations regarding market size, the potential target market/population, and related markets and patient populations, using assumptions and judgments that the Company believes are reasonable. Although the Company believes that its assumptions and judgments are reasonable,

there is no guarantee that they will prove to be accurate, or that future events will conform to the assumptions and judgments believed to be reasonable at the time.

2.3 Currencies

Unless otherwise indicated, all references in this document to Euro and € are to the lawful single currency of member states of the EU that adopt or have adopted the Euro as their currency in accordance with the legislation of the EU relating to European Monetary Union, all references to Pounds Sterling, sterling, GBP, £ or p are to the lawful currency of the United Kingdom and all references to U.S. $, U.S. Dollars, USD, dollars or $ are to the lawful currency of the United States of America. The Company prepares its financial statements in United States Dollars ("**USD**").

2.4 Presentation of Financial Information

Except as otherwise indicated, financial data regarding the Group is extracted from the consolidated audited financial statements of the Group for the years ended 31 December 2016, 31 December 2017, 31 December 2018 and the Group's unaudited condensed consolidated financial statements for the half years ended 30 June 2019 and 2018. The consolidated audited financial statements of the Group for the years ended 31 December 2016, 31 December 2017 and 31 December 2018 and the Group's unaudited condensed consolidated financial statements for the half years ended 30 June 2019 and 2018 have been prepared in accordance with International Financial Reporting Standards ("**IFRS**") as adopted by the European Union.

All future financial information for the Company and the Group is intended to be prepared in accordance with IFRS as adopted by the European Union and, unless otherwise indicated, the financial information in this document has been prepared in accordance with IFRS as adopted by the European Union.

2.5 Rounding

Some financial information in this document has been rounded. As a result of this rounding, figures shown as totals in this document may vary slightly from the exact arithmetic aggregation of the figures that precede them. In addition, certain percentages presented in this document reflect calculations based upon the underlying information prior to rounding and, accordingly, may not conform exactly to the percentages that would be derived if the relevant calculations were based upon the rounded numbers.

2.6 No Incorporation of Website Information

This document will be made available to the public in France and Ireland at www.mainstay-medical.com. Save for information expressly stated to be incorporated by reference into this document as described in Part 10 (*Documentation Incorporated by Reference*), other materials on the Company's website are not incorporated into, and do not form part of, this document.

2.7 General Information

The contents of this document are not to be construed as advice relating to legal, financial, taxation, accounting or regulatory matters, investment decisions or any other matter. Shareholders and prospective investors must rely upon their own representatives, including their own legal advisors and accountants, as to legal, tax, accounting, regulatory, investment or any other related matters concerning the Company and an investment therein.

This document is for your information only and nothing in this document is intended to endorse or recommend a particular course of action. You should consult with an appropriate professional for specific advice rendered on the basis of your situation.

Certain information in relation to the Group is incorporated by reference into this document as set out in Part 10 (*Documentation Incorporated by Reference*) of this document.

PART 3
DIRECTORS, COMPANY SECRETARY, REGISTERED OFFICE AND ADVISERS

DIRECTORS	Oern Stuge MD (*Non-Executive Independent Chairman*) Jason Hannon (*Chief Executive Officer*) David Brabazon (*Non-Executive Independent Director*) Greg Garfield *(Non-Executive Director)* Antoine Papiernik (*Non-Executive Director*) James Reinstein (*Non-Executive Independent Director*) Dan Sachs MD (*Non-Executive Director*)
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AUDITORS AND REPORTING ACCOUNTANTS	KPMG 1 Stokes Place St. Stephen's Green Dublin 2 Ireland
FINANCIAL ADVISER	Davy Davy House 49 Dawson Street Dublin 2 Ireland

PART 4
OVERVIEW OF THE MARKET

Unless indicated otherwise, the information set out in this Part 4 constitutes the Directors' views of the potential market for the Group's product, ReActiv8, intended for people suffering from Chronic Low Back Pain. Unless indicated otherwise, all market and industry data set out in this Part 4 and reproduced elsewhere in this document that relate to the market for ReActiv8 are estimates and should be treated with caution. The Company has obtained market data from internal studies as well as information derived from third party publications, studies and surveys, market interviews, desktop, market and web-based research. Where information assimilated by third parties has been used in this Part 4 of this document, the source of such information has been identified. Third party reports, publications, studies and surveys generally state that the data contained therein have been obtained from sources believed to be reliable, but that there is no guarantee of the accuracy or completeness of such data.

The Company believes that the information provided by third parties has been accurately reproduced, and, so far as the Company is aware and has been able to ascertain, no facts have been omitted that would render the reproduced information inaccurate or misleading. Nonetheless, in light of the absence of publicly available information on the industry, the data on market sizes should be viewed with caution. In addition, certain of the market and industry data contained in this document come from the Company's own internal research, records, data and estimates based on the knowledge and experience of the Company's management in the market in which the Group operates (some of which may have been assimilated by third parties in their reports). While the Company believes that such research, records, data and estimates are reasonable and reliable, they, and their underlying methodology, have not been verified by any independent source for accuracy or completeness. Additional factors which should be considered in assessing the market and industry data are described elsewhere in this document, including those set out in Part 1 (Risk Factors). Accordingly, undue reliance should not be placed on any of the market and industry data contained in this Part 4.

4.1 Overview

We are focused on the development and commercialisation of our only product, ReActiv8, an active implantable medical device ("**AIMD**") designed to treat people with CLBP. Low Back Pain is the number one cause of years lived with disability worldwide[1] and is a leading cause of activity limitation and work absence throughout much of the world, imposing a high economic burden on individuals, families, communities, industry, and governments.

The term "Chronic Low Back Pain" embraces a constellation of conditions and a range of severity from mild to disabling. We estimate that approximately 1 - 6% of the population has disabling CLBP (for more information, see paragraph 4.3 of this Part 4 (*Overview of the Market*)). Of those, only approximately 15% have a form of CLBP that is suitable for surgical correction.[2] Most of the remainder of people who suffer from CLBP have attempted all or most therapeutic options without resolution of their CLBP – including physical therapy (such as lumbar extensor strengthening exercises), watchful waiting (i.e. no therapy), traction therapy, the McKenzie Method of exercise therapy, drugs (including analgesics, opioids, sleep aids, muscle relaxants and anti-depressants), massages, acupuncture, steroid injections, back schools, various types of energy application including ultrasound, TENS, osteopathic therapy, and thermotherapy, SCS, and lumbar stabilisation exercises.

For many of those people, the root cause of their CLBP is disruption in control of the key stabilising muscles of the low back, the most important of which are the lumbar multifidus muscles. The physiological mechanism whereby pain in a skeletal joint can disrupt control to the muscle that stabilises the joint is referred to as "arthrogenic inhibition".[3] In many cases of CLBP, the lumbar multifidus muscles show atrophy (i.e. shrinking) which is visible on Magnetic Resonance Imaging

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1 Global Burden of Disease Study 2013 Collaborators. "Global, Regional, and National Incidence, Prevalence, and Years Lived with Disability for 301 Acute and Chronic Diseases and Injuries in 188 Countries, 1990-2013: A Systematic Analysis for the Global Burden of Disease Study 2013." Lancet (London, England) 6736, no. 15 (June 2015): 1990–2013. doi:10.1016/S0140-6736(15)60692-4.

2 Deyo, R. A. & Weinstein, J. N. Low Back Pain. NEJM 344, 363–370 (2001).

3 Russo, M., Deckers, K., Eldabe, S., Kiesel, K., Gilligan, C., Vieceli, J. and Crosby, P. 2018. Muscle Control and Non-specific Chronic Low Back Pain. Neuromodulation 2018; 21:1-9.

("**MRI**"). Disruption of control of the lumbar multifidus muscle can result in overload of the back joints leading to a continuing cycle of pain and disability. Pain can be referred to as "nociceptive", meaning that the pain arises from pain receptors activated from damage to or inflammation of structures in and around the back joints. Nociceptive pain is to be contrasted with "neuropathic" pain, in which the perception of pain arises from compression or damage to the nerves in the back and which often leads to pain, tingling or numbness in the legs.

The therapy provided by our product, ReActiv8, is based on, the Directors believe, a solid foundation of research published in the scientific literature. Disruption of control of the key stabilising muscles of the lumbar spine is well understood, and indeed the front line physical therapy approach for CLBP is often to try to help people regain control of the muscles by attempting to teach them to voluntarily contract and exercise the lumbar multifidus muscles. However, this is difficult to do (most people do not have the ability to voluntarily contract the multifidus muscles), time consuming, and subject to compliance challenges (including challenges faced by patients in complying with physiotherapist advice and committing to the required medical routine/programme). Similarly, people with knee pain often suffer from arthrogenic inhibition of the quadriceps muscle (the big muscle at the front of the thigh)[4] and are often unable to perform the quadriceps strengthening exercises post knee surgery. Electrical stimulation through the skin to elicit contraction of the quadriceps has been shown to help restore control, allowing the quadriceps strengthening exercises to be performed.

The therapeutic concept behind ReActiv8 follows this model, by using electrical stimulation of the nerves that supply the lumbar multifidus muscle to elicit contraction of the muscle which, over time, can lead to restoration of control; once control of the stabilising muscles is restored, the continuing cycle of dysfunction in the muscle control system and spine instability is broken, allowing the back to recover from CLBP.

The Company estimates that there are approximately two million people in the EU and the U.S. who could be candidates for ReActiv8 today, representing a huge potential market. We plan to conduct work in the future to define as closely as possible specific sub-groupings of these potential candidates who may benefit most from treatment with ReActiv8. At present, we know of no other competing AIMD therapy on the market for treating this group of people with CLBP, as further detailed in paragraph 4.4 of Part 4 (*Overview of the Market*).

The therapeutic concept of ReActiv8 was tested in a European Feasibility Study commenced in 2011, and the results were published in a peer reviewed journal[5]. With experience from the European Feasibility Study, the design of ReActiv8 was completed.

The first Clinical Trial of ReActiv8, called ReActiv8-A, was designed to gather data in support of an application for CE Marking to allow commercialisation in the EU. The results were published in a peer reviewed journal[6] in January 2018.

CE Marking was obtained in May 2016. The first commercial sale and implant of ReActiv8 was announced on 1 February 2017. The implant was performed at the Catholic Hospital Koblenz-Montabaur in Koblenz, Germany. In May 2017, the Company announced the first commercial sale and implant of ReActiv8 in Ireland.

Our customers in Germany can use existing reimbursement codes for ReActiv8. Based on our review of the reimbursement climate (both internally and with external consultants), we believe hospitals in

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[4] Rice, D. A. & McNair, P. J. Quadriceps arthrogenic muscle inhibition: neural mechanisms and treatment perspectives. Semin. Arthritis Rheum. 40, 250–66 (2010).

[5] Deckers, Kristiaan, Kris De Smedt, Jean-Pierre van Buyten, Iris Smet, Sam Eldabe, Ashish Gulve, Ganesan Baranidharan, et al. "Chronic Low Back Pain: Restoration of Dynamic Stability." Neuromodulation: Journal of the International Neuromodulation Society 18, no. 6 (August 2015): 478–86. doi:10.1111/ner.12275.

[6] Deckers K., De Smedt K., Mitchell B., Vivian D., Russo M., Georgius P., Green M., Vieceli J., Eldabe S., Gulve A., van Buyten J.-P., Smet I., Mehta V., Ramaswamy S., Baranidharan G., Sullivan R., Gassin R., Rathmell J., Gilligan C.. "New Therapy for Refractory Chronic Mechanical Low Back Pain – Restorative Neurostimulation to Activate the Lumbar Multifidus: One Year Results of a Prospective Multicenter Clinical Trial" Neuromodulation: Technology at the Neural Interface 21: 48–55. doi:10.1111/ner.12741.

Switzerland and Austria can also use existing reimbursement codes for ReActiv8. For details on the reimbursement process, see paragraph 5.13(e) of Part 5 (*Information on the Group*) of this document.

The Company conducted the U.S. Pivotal ReActiv8-B Clinical Trial under an Investigational Device Exemption ("**IDE**") from the FDA with the purpose of gathering data in support of an application for Pre-Market Approval to the FDA, a key step towards the commercialisation of ReActiv8 in the U.S. See paragraph 5.10 of this Part 5 (*Information on the Group*) for further details on the U.S. Pivotal ReActiv8-B Clinical Trial.

4.2 Low Back Pain

Low Back Pain is usually defined as pain and discomfort, localized below the costal margin (i.e. the bottom of the ribs) and above the inferior gluteal fold (i.e. above the buttocks), with or without referred leg pain.[7,8] CLBP is usually defined as back pain lasting at least three months. The National Institutes of Health, or NIH, Task Force on Research Standards for Chronic Low Back Pain recommended[9] that Chronic Low Back Pain be defined as a back pain problem that has persisted for at least three months and has resulted in pain on at least half the days in the past six months.

Back pain is a major health problem, and the World Health Organisation reports that "Low back pain is the most prevalent of musculoskeletal conditions; it affects nearly everyone at some point in time and about 4–33% of the population at any given point"[10] and back pain is the number one cause of years lived with disability worldwide in 2013.[11]

The economic cost of Low Back Pain has been estimated to be 0.7% of Gross Domestic Product, or GDP, in Sweden, 0.9% of Gross National Product, or GNP, in Germany, 1.7% of GDP in the Netherlands[12] and 1% of GDP in the U.S..[13] The costs associated with Low Back Pain notably include the direct cost of medical care and the indirect costs of time lost from work, disability payments, and diminished productivity.

People with Acute Low Back Pain and associated disability usually improve rapidly within weeks, but pain and disability typically continue, and recurrences are common.[14] Although most episodes of acute back pain resolve within three months, "recovery after 12 weeks is slow and uncertain. Fewer than half of those individuals disabled for longer than 6 months return to work and, after 2 years of absence from work, the return-to-work rate is close to zero."[15]

Although there has been significant attention to, and investment in, surgical treatments for Low Back Pain, only approximately 15% of patients are suitable surgical candidates.[16] The remaining patients are sometimes referred to as having "non-specific low back pain" ("**NSLBP**") or "axial low back pain"

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7 Airaksinen, O. et al. Chapter 4. European guidelines for the management of chronic nonspecific low back pain. Eur. Spine J. 15 Suppl 2, S192–300 (2006).

8 Woolf, A. D. & Pfleger, B. Burden of major musculoskeletal conditions. Bull. World Health Organ. 81, 646–56 (2003).

9 Deyo, R. A., et al. Report of the NIH Task Force on Research Standards for Chronic Low Back Pain. Spine J. 14, 1375–91 (2014).

10 Woolf, A. D. & Pfleger, B. Burden of major musculoskeletal conditions. Bull. World Health Organ. 81, 646–56 (2003).

11 Global Burden of Disease Study 2013 Collaborators. "Global, Regional, and National Incidence, Prevalence, and Years Lived with Disability for 301 Acute and Chronic Diseases and Injuries in 188 Countries, 1990-2013: A Systematic Analysis for the Global Burden of Disease Study 2013." Lancet (London, England) 6736, no. 15 (June 2015): 1990–2013. doi:10.1016/S0140-6736(15)60692-4.

12 Wenig, Christina M, Carsten O Schmidt, Thomas Kohlmann, and Bernd Schweikert. "Costs of Back Pain in Germany." European Journal of Pain (London, England) 13, no. 3 (March 2009): 280–86. doi:10.1016/j.ejpain.2008.04.005

13 Luo X, Pietrobon R, Sun SX, Liu GG, Hey L. Estimates and patterns of direct health care expenditures among individuals with back pain in the United States. Spine 2004;29:79–86.

14 Pengel, L. H. M., Herbert, R. D., Maher, C. G. & Refshauge, K. M. Acute low back pain: systematic review of its prognosis. BMJ 327, 323 (2003).

15 Andersson, G. B. J. Epidemiological features of chronic low-back pain. Lancet 354, 581–585. (1999)

16 Deyo, R. A. & Weinstein, J. N. Low Back Pain. NEJM 344, 363–370 (2001).

("**ALBP**"). There are European clinical practice guidelines for chronic NSLBP and U.S. guidelines for ALBP and Chronic Low Back Pain are similar to the European guidelines.[17]

Many non-invasive conservative therapies have been tried with modest or no success, including physical therapy (such as lumbar extensor strengthening exercises), watchful waiting (i.e. no therapy), traction therapy, the McKenzie Method of exercise therapy, drugs (including analgesics, opioids, sleep aids, muscle relaxants and anti-depressants), massages, acupuncture, steroid injections, back schools, various types of energy application including ultrasound, TENS, osteopathic therapy, and thermotherapy, SCS, and lumbar stabilisation exercises.

Following failure of conservative therapy for CLBP, "usual care" or "conventional medical management" for CLBP usually consists of coping mechanisms for pain, and pain medications (often opioids).[18]

4.3 The Potential Market for ReActiv8

In approximately 7% of all cases of Low Back Pain the pain persists for more than three months[19], thus meeting the definition of chronic.

Of the people with CLBP, only a small percentage of cases result from an identified pathological condition (e.g., degenerative disc disease) or an anatomical defect (e.g., vertebral compression fracture or pars fracture) that may be correctable with spine surgery (e.g.: spinal fusion surgery, decompression and pain alleviation (such as nerve ablation)).[20]

Approximately 1 - 6% of the population has disabling Chronic Low Back Pain, of whom only about 15% are suitable for spine surgery.[21] The market for medical devices for spinal fusion surgery is estimated to be approximately $12.5 billion.[22]

A subset of people who have spine surgery have recurrence of their pain and disability, in what is called Failed Back Surgery Syndrome (FBSS).[23] Some of these people may become candidates for SCS.[24] The market for SCS for all indications is estimated to be approximately $1.4 billion.[25] ReActiv8 is intended for people without indications for spine surgery or SCS, and who have continuing pain despite medical management. We estimate that there are approximately two million people in the U.S. and the EU today who could be candidates for ReActiv8. We plan to conduct work in the future to define as closely as possible specific sub-groupings of these potential candidates who may benefit most from treatment with ReActiv8.

We use many published sources, detailed in this Part 4 (*Market Overview*) and Part 5 (*Information on the Group*) and listed in Annex A, on prevalence of Low Back Pain (i.e.: proportion of people with back pain in a defined population at a given time) to estimate the size of the potential target market for our product. We have factored in different definitions and measurements addressing different but similar population groups, timing differences, and country specific differences in defining the target market. Thus the data and calculations contained in this document and used to estimate the size of the potential market should be considered in light of these limitations.

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17 Chou, R. et al. Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society. Ann. Intern. Med. 147, 478–91 (2007).

18 Bogduk, Nikolai. Management of Chronic Lower Back Pain. Medical Journal of Australia (2004); 180 (2): 79-83.

19 Hall, Hamilton, and Greg McIntosh. "Low Back Pain (chronic)." Clinical Evidence 2008, no. May 2007 (January 2008): 1–28.

20 Cohen, S. P., Argoff, C. E. & Carragee, E. J. Management of low back pain. Bmj 337, a2718–a2718 (2008).

21 Deyo, R. A. & Weinstein, J. N. Low Back Pain. NEJM 344, 363–370 (2001).

22 Novation Ortho Watch 2015, Spine and Neuromodulation.

23 Bogduk, Nikolai. Management of Chronic Lower Back Pain. Medical Journal of Australia (2004); 180 (2): 79-83.

24 Bogduk, Nikolai. Management of Chronic Lower Back Pain. Medical Journal of Australia (2004); 180 (2): 79-83.

25 Novation Ortho Watch 2015, Spine and Neuromodulation.

In addition, back pain itself is the subject of differing definitions in published scientific literature. Manichikanti,[26] stated that "low back pain is a symptom that cannot be validated by an external standard. It is a disorder . . . occurring in many groups of the population, and with many definitions."

Back pain is measured with many instruments, including a Visual Analogue Scale ("**VAS**") or a Numerical Rating Scale ("**NRS**"). NRS asks the respondent to rate the pain on a scale from zero (no pain) to 10 (worst imaginable pain).[27] VAS asks the respondent to mark the pain on a 100 millimeter line with no pain at one end and very severe pain at the other end.[28]

In a systematic review of the global prevalence of Low Back Pain, Hoy[29] reviewed 165 studies from 54 countries published between 1980 and 2009. The review found that "Low back pain was shown to be a major problem throughout the world, with the highest prevalence among female individuals and those aged 40–80 years. After adjusting for methodologic variation, the . . . 1-month prevalence was estimated to be 23.2 ± 2.9%."

Breivik[30] reported in 2006 on a pan-European (plus Israel) pain survey of 46,394 randomly selected subjects. Of this sample, 19% reported having chronic pain (defined as pain lasting for at least 6 months) and with moderate to severe intensity (i.e.: an NRS pain score of 5 or higher) and for 18% of those, the location of pain was the lower back. Based on this study, 3.4% of the population (corresponding to 18% of 19%) suffer from moderate to severe CLBP.

Johannes[31] using similar methodology analysed data collected from 27,035 respondents in the U.S. and found that 21% of respondents reported moderate to severe chronic pain (for more than 6 months) and that 11% reported their primary pain was in the lower back. Thus to be consistent with the calculation used above based on the Breivik study, the prevalence of Chronic Low Back Pain in the U.S. based on the Johannes study is 2.3% (21% multiplied by 11%).

Schopflocher[32] published results of a similar epidemiologic study done in Canada and reported similar results. 18.9% of the respondents reported to be suffering from moderate to severe chronic pain (for more than 6 months). Of all respondents, 22.3% reported that their primary location of pain was the lower back. This means that 4.21% (18.9% x 22.3%) of the respondents were suffering from moderate to severe CLBP, based on this study. Meucci[33] surveyed 2,732 individuals in a city in Brazil and reported a Chronic Low Back Pain prevalence of 9.6%. This survey included all pain and defined chronic as "seven weeks or more in the last three months". Based on the distribution of severity in the studies above, prevalence of Chronic Low Back Pain with moderate to severe intensity would be approximately 6% (9.6% multiplied by 2/3).

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[26] Manchikanti, Laxmaiah, Salahadin Abdi, Sairam Atluri, Ramsin M Benyamin, Mark V Boswell, Ricardo M Buenaventura, David a Bryce, et al. "An Update of Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain. Part II: Guidance and Recommendations." Pain Physician 16, no. 2 Suppl (April 2013): S49–283. http://www.ncbi.nlm.nih.gov/pubmed/23615883.

[27] Dworkin, Robert H, Dennis C Turk, John T Farrar, Jennifer a Haythornthwaite, Mark P Jensen, Nathaniel P Katz, Robert D Kerns, et al. "Core Outcome Measures for Chronic Pain Clinical Trials: IMMPACT Recommendations." Pain 113, no. 1–2 (January 2005): 9–19. doi:10.1016/j.pain.2004.09.012.

[28] https://com-jax-emergency-pami.sites.medinfo.ufl.edu/files/2015/03/Visual-Analog-Scale-VAS-in-depth.pdf

[29] Hoy, Damian, Christopher Bain, Gail Williams, Lyn March, Peter Brooks, Fiona Blyth, Anthony D Woolf, Theo Vos, and Rachelle Buchbinder. "A Systematic Review of the Global Prevalence of Low Back Pain." Arthritis and Rheumatism 64, no. 6 (July 2012): 2028–37. doi:10.1002/art.34347.

[30] Breivik, Harald, Beverly Collett, Vittorio Ventafridda, Rob Cohen, and Derek Gallacher. "Survey of Chronic Pain in Europe: Prevalence, Impact on Daily Life, and Treatment." European Journal of Pain (London, England) 10, no. 4 (May 2006): 287–333. doi:10.1016/j.ejpain.2005.06.009.

[31] Johannes, Catherine B, T Kim Le, Xiaolei Zhou, Joseph a Johnston, and Robert H Dworkin. "The Prevalence of Chronic Pain in United States Adults: Results of an Internet-Based Survey." The Journal of Pain : Official Journal of the American Pain Society 11, no. 11 (November 2010): 1230–39. doi:10.1016/j.jpain.2010.07.002.

[32] Schopflocher, Donald, Paul Taenzer, and Roman Jovey. "The Prevalence of Chronic Pain in Canada." Pain Research & Management : The Journal of the Canadian Pain Society = Journal de La Société Canadienne Pour Le Traitement de La Douleur 16, no. 6 (2011): 445–50.

[33] Meucci, Rodrigo D, Anaclaudia G Fassa, Vera Mv Paniz, Marcelo C Silva, and David H Wegman. "Increase of Chronic Low Back Pain Prevalence in a Medium-Sized City of Southern Brazil." BMC Musculoskeletal Disorders 14 (January 2013): 155. doi:10.1186/1471-2474-14-155.

In summary, these studies indicate that prevalence of CLBP (moderate – severe) is fairly consistent across geographies, with Europe estimated at 3.4%, Canada 4.2%, the U.S. 2.3%, and Brazil 6%.[34] According to the same studies, approximately one third of these population groups suffer from severe, hence likely to be debilitating, CLBP.[35]

Less than 15% of people with CLBP have identifiable causes[36] and the remainder are sometimes referred to as having non-specific Low Back Pain.

On the basis of the research detailed above, we estimate that about 1% of the population in our key target markets in the EU and the U.S. have moderate to severe CLBP every day, of whom 80% are estimated to have abnormal multifidus function.[37] Based on input from our clinical advisors, we estimate that approximately 50% of these could be candidates for ReActiv8. Based on the latest population statistics available to the Company, of approximately 513 million people in the EU[38] and 330 million people in the U.S.,[39] we estimate that the number of people who could be candidates for ReActiv8 is approximately three million (i.e. (330 million + 513 million) x 1% x 80% x 50% = 3.37 million). The size of the target market is likely to be lower because the EU includes a variety of countries with different health care systems and ability to pay and obtaining acceptable levels of reimbursement may take time depending on the country. On that basis, we estimate the initial target market as approximately two million people (approximately 1.22 million in the EU and 0.78 million in the U.S.). We plan to conduct work in the future to define as closely as possible specific sub-groupings of these potential candidates who may benefit most from treatment with ReActiv8.

Although there are a number of factors which will affect our target population and our ability to develop the market (see Part 1 (*Risk Factors*) of this document), we do not consider the size of the potential market to be a limiting factor to our growth in the foreseeable future.

4.4 Competition for ReActiv8

SPR Therapeutics, LLC has received FDA clearance for the use of its SPRINT percutaneous peripheral nerve stimulation system for up to 60 days in the back and/or extremities for: (i) symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain; (ii) symptomatic relief of post-traumatic pain; and (iii) symptomatic relief of post-operative pain. There are several major companies serving the market for implantable neurostimulation devices such as Medtronic plc., Boston Scientific Corporation, Abbott Laboratories, Nevro Inc., Livanova plc., and Nuvectra Inc. Some of these, and some other companies such as Johnson & Johnson, Allergan plc., GlaxoSmithKline plc, and Pfizer Inc., have invested in early stage private neurostimulation companies. We are also aware of several early stage companies developing neurostimulation devices for many clinical conditions including back pain, obesity, hypertension, incontinence, drop-foot syndrome, headache, Parkinson's, swallowing disorders, epilepsy, and sleep apnoea.

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[34] Meucci, Rodrigo D, Anaclaudia G Fassa, Vera Mv Paniz, Marcelo C Silva, and David H Wegman. "Increase of Chronic Low Back Pain Prevalence in a Medium-Sized City of Southern Brazil." BMC Musculoskeletal Disorders 14 (January 2013): 155. doi:10.1186/1471-2474-14-155.

[35] Johannes, Catherine B, T Kim Le, Xiaolei Zhou, Joseph a Johnston, and Robert H Dworkin. "The Prevalence of Chronic Pain in United States Adults: Results of an Internet-Based Survey." The Journal of Pain : Official Journal of the American Pain Society 11, no. 11 (November 2010): 1230–39. doi:10.1016/j.jpain.2010.07.002.

[36] Hall, Hamilton, and Greg McIntosh. "Low Back Pain (chronic)." Clinical Evidence 2008, no. May 2007 (January 2008): 1–28.

[37] Freeman, Michael D, Mark A Woodham, and Andrew W Woodham. "The Role of the Lumbar Multifidus in Chronic Low Back Pain: A Review." PM & R : The Journal of Injury, Function, and Rehabilitation 2, no. 2 (2010): 142–46. doi:10.1016/j.pmrj.2009.11.006.

[38] http://epp.eurostat.ec.europa.eu/tgm/table.do?tab=table&language=en&pcode=tps00001&tableSelection=1&footnotes=yes&labeling=labels&plugin=1)

[39] http://www.census.gov/popclock/,

4.5 Government Regulation and Product Approval

We operate in the global medical device market, and therefore are subject to many factors common to all companies operating in this market. Some of those factors which may prove to be relevant are listed below.

Our product is subject to extensive regulation by the FDA and various other U.S. federal and state governmental entities as well as non-U.S. governmental authorities, such as the competent authorities of the countries of the EEA. Government regulation of medical devices is meant to assure their safety and effectiveness, and includes regulation of, among other things:

- design, development and manufacturing;
- testing, labelling, content and language of instructions for use and storage;
- Clinical Trials;
- product safety;
- marketing, sales and distribution;
- regulatory clearances and approvals, including premarket clearance and approval;
- conformity assessment procedures;
- product traceability and record keeping procedures;
- advertising and promotion;
- product complaints, complaint reporting, recalls and field safety 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;
- post-market studies; and
- product import and export.

To market and sell our product in any country, we must first seek and obtain regulatory approvals, certifications or registrations and comply with the laws and regulations of that country. These laws and regulations, including the requirements for approvals, certifications or registrations and the time required for regulatory review, vary from country to country. Obtaining and maintaining regulatory approvals, certifications and/or registrations are expensive, and we cannot be certain that we will receive regulatory approvals, certifications and/or registrations in any country or that we will be able to maintain any regulatory approvals, certifications or registrations that we currently possess. If we fail to obtain or maintain regulatory approvals, certifications or registrations in any country in which we currently market or plan to market our products or if we fail to comply with all applicable regulatory laws, rules and regulations, our ability to sell our products could be jeopardised and we could be subject to enforcement actions. See Part 1 (*Risks Factors*) of this document for a discussion of the risks and uncertainties that apply to ReActiv8 in connection with government regulation of our product. We may be found to be non-compliant, for example as a result of future changes in or interpretation of the regulations regarding quality systems in certain jurisdictions.

(a) Regulatory Requirements in the U.S.

Under the U.S. Federal Food, Drug and Cosmetic Act (the "**FDC Act**") manufacturers of medical devices must comply with extensive regulation relating to the issues described above, including regulations governing the design, testing, manufacturing, packaging, quality, servicing and marketing of medical products. Our immediate focus is upon the steps that we must take before our products can be marketed and sold in the U.S.

Pre-Market Approval (PMA)

Under the FDC Act, 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 extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. If a device is a Class III, or the highest risk, device (supports or sustains human life, is of substantial importance in preventing impairment of human health, or presents a potential, unreasonable risk of illness or injury) and cannot be cleared through the FDA's 510(k) process for low and moderate risk devices, then the device must have an approved PMA before being marketed in the U.S.. Some devices that cannot be cleared though the 510(k) process, because they are not substantially equivalent to a low or moderate risk device, may be eligible for the FDA's "*de novo*" process.

A PMA is the most stringent device marketing application required by the FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by the FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). As a result, the PMA application process is more costly and time consuming than the 510(k) process. Accordingly, a PMA application is typically supported by extensive data that may include, but is not limited to, technical information regarding device design and development, pre-clinical and Clinical Trials data, and labelling sufficient to support an FDA determination that the device is safe and effective for its intended use.

After a PMA application is complete, the FDA will accept and file the application and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the "accepted application," although, regulatory review time of the PMA application has varied historically. The latest data publicly available indicates that, in 2018 and 2017, the average time was 246 and 311 days respectively.[40] During this review period, the FDA may request additional information and/or clarification of information already provided. Also, during the review period, 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. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with its Quality System Regulations, or QSRs, which impose thorough design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process.

The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labelling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement actions, including the loss or withdrawal of the approval.

With certain limited exceptions, a PMA supplement is required by the FDA before a change may be made that may affect the safety or effectiveness of an already-approved device. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes that require a supplement include, for example, new indications for use of the device, labelling changes, and modifications to the manufacturing process that may affect safety and effectiveness. PMA supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes to the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

Our product cannot be marketed and sold in the U.S. without PMA approval. We anticipate that other products that we may develop in the future, as well as modifications to our existing product, will in all likelihood be subject to PMA approval rather than 510(k) clearance.

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[40] https://www.fda.gov/media/120474/download, https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-quarterly-performance-reports

IDE Applications

A Clinical Trial is almost always required to support a PMA application. Under FDA regulation, absent certain limited exceptions, Clinical Trials intended to support approval of a PMA require an approved IDE application. Some types of Clinical Trial deemed to present a "non-significant risk" are deemed to have an approved IDE once certain regulatory requirements are met and Institutional Review Board ("**IRB**") approval is obtained. If the device presents a "significant risk" to human health, safety or welfare of a patient, as defined by the FDA, the Clinical Trial sponsor also must submit the IDE application to the FDA, for FDA approval. A Clinical Trial conducted under an IDE may not begin until thirty days after the FDA receives the IDE application, unless the FDA notifies the sponsor that the investigation may not begin, or the FDA approves, by order, an IDE for the investigation. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to evaluate the device in humans and that the testing protocol is scientifically sound. For an IDE requiring FDA approval, such as ours, the IDE application must be approved in advance by the FDA for a specified number of human patients participating in the Clinical Trial.

Clinical Trials for a Class III device (like ReActiv8) may begin once the IDE application is approved by the FDA (or thirty days have passed without the FDA's objection to the IDE) and is approved by the responsible IRBs at the Clinical Trial sites. There can be no assurance that submission of an IDE will result in the ability to commence Clinical Trials. Additionally, after a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that there is reason to believe that the risks to the patients are not outweighed by the anticipated benefits to the patients and the importance of the knowledge to be gained, or informed consent is inadequate, or the investigation is scientifically unsound, or there is reason to believe that the device as used is ineffective.

During a study, sponsors are required to comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting and record-keeping and with prohibitions on promoting investigational devices or making safety or efficacy claims for them. The FDA may also conduct inspections at clinical sites and at sponsor's locations. Sponsors are also responsible for the appropriate labelling and distribution of investigational devices. Clinical Trials must be conducted in accordance with FDA regulations and federal and state regulations concerning human patient protection, including informed consent and healthcare privacy. The investigators must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices and comply with all reporting and record-keeping requirements, among other responsibilities.

In addition, the FDA's grant of permission to proceed with a Clinical Trial does not constitute a binding commitment that the FDA will consider a study design adequate to support PMA approval. In addition, there can be no assurance that the data generated during a Clinical Trial will meet chosen safety and effectiveness endpoints or otherwise produce results that will lead the FDA to grant marketing approval.

Our Product's U.S. Regulatory Process

After submitting an IDE application to the FDA in January 2015 to initiate a Clinical Trial of ReActiv8, multiple interactions with the FDA followed with the aim of designing a Clinical Trial that meets our needs, those of the FDA, and the population of people who could potentially benefit from ReActiv8.

In May 2015, we received approval from the FDA to begin a Clinical Trial of ReActiv8 under an IDE. This approval is to conduct a Clinical Trial at up to 40 Clinical Trial sites.

During 2016, the Company commenced the U.S. Pivotal ReActiv8-B Clinical Trial, an international, multi-centre, prospective randomised sham controlled triple blinded trial with one-way crossover, designed to evaluate the safety and efficacy of ReActiv8 for the treatment of adults with Chronic Low Back Pain and no prior back surgery.

The U.S. Pivotal ReActiv8-B Clinical Trial utilises an adaptive trial design, inclusive of an interim analysis of the primary efficacy end point for sample size re-estimation when primary outcome data are available for half the initial subjects to determine the definitive size of up to 232 patients in the pivotal cohort (the "**Interim Analysis**"). With this adaptive design, Mainstay commenced the U.S. Pivotal ReActiv8-B Clinical Trial with a sample size of 128 patients pending the Interim Analysis. During 2017, we continued to advance the U.S. Pivotal ReActiv8-B Clinical Trial and in December 2017, we announced the independent Data Monitoring Committee ("**DMC**") completed the Interim Analysis, which was based on data from the first 58 patients in the pivotal cohort to complete the primary endpoint. The DMC recommended continuation of the Clinical Trial with a definitive size of 168 evaluable patients. The ultimate number of patients in the Clinical Trial was 204 due to the nature of the enrolment process.[41] The DMC also reported that they observed no safety concerns in the Clinical Trial.

At the date of the Interim Analysis in December 2017, 133 patients had been implanted in the pivotal cohort, and the Clinical Trial was fully enrolled by the end of the second quarter of 2018, with a full data readout announced on 19 November 2018. The U.S. Pivotal ReActiv8-B Clinical Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on two pre-specified alternative analyses of that endpoint and on multiple secondary endpoints. We cannot be certain whether the totality of the data from the U.S. Pivotal ReActiv8-B Clinical Trial will be sufficient to demonstrate safety and efficacy to the satisfaction of the FDA to allow for the granting of a PMA. The Company held a pre-PMA meeting with the FDA on 25 June 2019 and submitted the final module of the PMA application to the FDA relating to ReActiv8 in August 2019. Regulatory review time of the PMAA has varied historically. The latest data publicly available indicates that, in 2018 and 2017, the average time was 246 and 311 days respectively.[42]

Pervasive and Continuing FDA Regulation

After a device is placed on the market, regardless of its classification or premarket pathway, numerous regulatory requirements apply. These include, but are not limited to:

- establishment registration and device listings with the FDA, which help facilitate FDA inspections and other regulatory action;
- QSRs, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, process control, documentation and other quality assurance procedures during all aspects of the development and manufacturing process;
- labelling control and advertising regulations, which prohibit the promotion of products for uncleared or unapproved, or off-label, uses or indications, and impose other restrictions on labelling;
- approval or clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use;
- medical device reporting regulations, which require that manufacturers monitor adverse events, maintain records, and report to the FDA on an expedited basis if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- corrections and removal 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 FDC Act that may present a risk to health.

[41] https://www.mainstay-medical.com/sites/default/files/2018-11/ReActiv8-B%2520Results%2520Presentation%2520PPT%2520v2.pdf

[42] https://www.fda.gov/media/120474/download, https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-quarterly-performance-reports

In addition, the FDA may order a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death; and

- post-approval restrictions or conditions, including requirements to conduct post-market surveillance studies to establish continued safety data.

The FDA has broad post-market and regulatory enforcement powers. Currently, our product is manufactured by third party manufacturers using their own facilities. If our product is approved, the third party's manufacturing facilities will be subject to FDA inspections and oversight, including for compliance with QSRs. These regulations require that they manufacture our products and maintain documents in a prescribed manner with respect to design, manufacturing, testing and quality control activities. As medical device manufacturers, they will also be required to comply with FDA requirements regarding the reporting of Adverse Events associated with the use of our medical devices, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. FDA regulations also govern product labelling and prohibit a manufacturer from marketing a medical device for unapproved intended uses. The FDA may conduct unannounced inspections to determine compliance with the QSR and other FDA regulations, and these inspections may include the manufacturing facilities of subcontractors.

Failure by us or our suppliers to comply with applicable regulatory requirements can result in enforcement actions by the FDA or other regulatory authorities, which may result in sanctions and related consequences including, but not limited to:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recall, detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusal of or delay in granting our requests for Pre-Market Approval or clearances of new products or modified products;
- withdrawal of Pre-Market Approvals or clearances previously granted;
- refusal to grant export approval for our products;
- criminal prosecution; and
- unanticipated expenditures to address or defend such actions.

The FDA Safety and Innovation Act

The FDA Safety and Innovation Act (the "**FDASIA**"), signed into law on 9 July 2012, expands the FDA's authorities and strengthens the agency's ability to safeguard and advance public health by giving it the authority to collect user fees from industry to fund reviews of innovator drugs, medical devices, generic drugs and biosimilar biological products; promote innovation to speed patient access to safe and effective products; increase stakeholder involvement in FDA processes; and enhance the safety of the drug supply chain. The long term impact of FDASIA is still evolving, and in particular the manner in which medical device companies interact with the FDA may change, possibly resulting in shorter or longer approval times.

The Medical Device Tax

The tax on the sale of certain medical devices by the manufacturer, producer, or importer of a medical device was introduced in the U.S. in January 2013 (part of the Patient Protection and Affordable Care Act (the "**PPACA**"), commonly referred to as the Affordable Care Act, that was signed into law on 23 March 2010) to cover the expansion of healthcare in the U.S.. The levy is set at 2.3% of the sale price of a medical device. Through a series of legislative amendments, the excise tax was subsequently

suspended by the U.S. Congress for medical device sales during calendar years 2016 through 2019. Absent further Congressional action, this excise tax will be reinstated for medical device sales beginning January 1, 2020.

Increased focus on Comparative Effectiveness Research

The Institute of Medicine ("**IOM**") defines Comparative Effectiveness Research ("**CER**") as "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care." The PPACA has created a quasi-governmental entity, the Patient-Centered Outcomes Research Institute ("**PCORI**"), to advance CER and its use by doctors, patients, and others.

Increased emphasis on CER, as well as other factors, may require more evidence of cost effectiveness than has previously been needed for reimbursement in the U.S. Such evidence may require us to expend additional time and cost to develop, and the evidence may not be adequately persuasive to obtain high levels of reimbursement in the U.S.

The "Sunshine Act"

Section 6002 of the PPACA, otherwise known as the "Physician Payment Sunshine Act," requires certain manufacturers of devices, biologicals, drugs, and medical supplies to report annually to the Centers for Medicare & Medicaid Services ("**CMS**") certain payments or transfers of value made to physicians holding licenses to practice in one or more U.S. states or to teaching hospitals (including direct payments, consulting fees, honoraria, Clinical Trial costs, travel reimbursement, meals, gifts and the like). Covered manufacturers also must report information on ownership and investment interests held by physicians and their immediate family members in the reporting company as well as direct and indirect payments made to such physician owners or investors. The Sunshine Act may have the impact of discouraging physicians and other health care providers from working with companies, which could adversely affect our ability to obtain advice and to have physicians present results and educational materials on our behalf.

Advertising and promotion

Advertising and promotion of medical devices, in addition to being regulated by the FDA, is also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Promotional activities for FDA-regulated products of other companies also have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fines or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

(b) **Regulatory Requirements Outside of the U.S.**

Sales of medical devices outside the U.S. are subject to non-U.S. regulatory requirements that vary widely from country to country. These laws and regulations range from simple product registration requirements in some countries to complex clearance and production controls in others. As a result, the processes and time periods required to obtain foreign marketing approval may be longer or shorter than those necessary to obtain FDA market approval. These differences may affect the efficiency and timeliness of market introduction of our products in the countries concerned.

Requirements in the EEA

In Europe, ReActiv8 is classified as an AIMD. Regulatory approval for an AIMD is obtained via the CE Marking process according to the AIMD Directive, which provides approval for the EEA (which includes the 28 Member states of the European Union, Iceland, Liechtenstein and Norway) and is accepted by certain other non-EEA countries, including Switzerland. AIMDs must meet the essential requirements set out in the AIMD Directive. To confirm that an AIMD meets the essential requirements, a certificate of conformity has to be obtained from a notified body. Once the certificate of conformity has been obtained, a declaration of conformity may be issued by the manufacturer, and a CE Mark may be affixed to the product. Once a CE Marking has been affixed to the medical device, it may then be placed on the market in any country within the EEA, Switzerland and elsewhere where accepted (subject to certain localized registration and language requirements).

In May 2017, a package of European Union legislation entered into force, replacing the existing regulatory framework for medical devices in the EEA, including for AIMD. The New EU Medical Device Regulations will apply as of 2020, though will require implementing action and strategic decisions to be made as of now.

The New EU Medical Device Regulations are designed to significantly tighten controls to ensure that only safe medical devices are placed on the EU medical device market, whilst continuing to foster innovation and contribute to maintaining the competitiveness of the medical device sector. The New EU Medical Device Regulations include wider and clearer scope of EU legislation to ensure that the safety and performance of products are correctly assessed before they are placed on the European market; stronger supervision of independent assessment bodies by national authorities; more powers and obligations for assessment bodies, to ensure thorough testing and regular checks on manufacturers, including unannounced factory inspections and sample testing; better traceability of devices throughout the supply chain, enabling a swift and effective response to safety concerns; stricter requirements for clinical evidence, to ensure patient and consumer safety; better coordination between national surveillance authorities, to ensure that only safe devices are available on the European market; and alignment to international guidelines, to facilitate international trade.

The New EU Medical Device Regulations mean a more centralised control of the European medical device market, and may increase the amount of work, time, or cost of obtaining regulatory approval for the marketing of medical devices in Europe. Under the new regulatory framework, it is likely that (i) the regulatory requirements for the design and manufacturing of AIMDs will be applied more stringently than in the past, (ii) there will be stricter requirements for clinical investigations and clinical evidence, (iii) the obligations for manufacturers to monitor the safety of their products, once placed on the market, will increase, and (iv) manufacturers will be subject to increased scrutiny. For further detail, see paragraph 1.2(b) of Part 1 (*Risk Factors*) of this document.

Our product's EEA regulatory process

One of the requirements of the existing AIMD Directive, (and also the new EU Medical Device Regulations) is the implementation of a Quality Management System ("**QMS**"). In December 2014, our quality management system was found to be in compliance with the international quality standards ISO 13485:2003 and EN ISO 13845:2012, which confirms that our medical device manufacturing QMS is compliant with globally recognized standards set forth by the International Organisation for Standardization. Our QMS is also designed to be in compliance with the FDA Quality System Regulations.

A new international quality standard, ISO 13485:2016 was released in 2016 to replace ISO 13485:2003 and EN ISO 13485:2012. During 2017 we completed the required transition activities to the new standard and we received confirmation of compliance from our Notified Body in November 2017. We are required to keep up-to-date and remain compliant with the most recently issued standards. For further detail on our QMS, see paragraph 5.12 of Part 5 (*Information on the Group*) of this document.

In November 2015, we announced we had summited an application for CE Marking for ReActiv8. The application included the results of the ReActiv8-A Clinical Trial and information on our QMS. In

addition extensive information about the design, testing and manufacturing of ReActiv8 was included.

Following multiple interactions, CE Marking for ReActiv8 was obtained in May 2016, allowing the start of commercialisation in the EU and in Switzerland. CE Marking can be used as the basis for regulatory approval in certain other countries.

Requirements outside of the EEA

In addition, we may try to obtain marketing authorization for our product in certain countries outside of the EEA. Commercialisation would become subject to the regulatory laws and regulations of any additional country in which we may apply for marketing approval and in order to maintain such approval. These regulatory laws are complex and vary from country to country.

PART 5
INFORMATION ON THE GROUP

5.1 Overview

With our business locations, we are well positioned to take advantage of infrastructure, an educated workforce, and a receptive environment for the medical device industry. The Company (the ultimate holding company of the Group) is incorporated in Ireland and headquartered in Dublin. We also have subsidiaries operating in Ireland, the U.S. (Minneapolis, MN), Australia, Germany and the Netherlands. Minneapolis is one of the leading global centres in the medical device industry, and Ireland is also a popular location for medical device companies, with just under three quarters of the world's top medical device companies having operations (or headquarters) in Ireland.

Our team (internal employees and external consultants) includes scientists, engineers, clinical experts, market development and sales personnel who are highly experienced in new medical devices addressing unmet clinical needs. The senior management team has multiple decades of experience in the AIMD industry and has been involved in design, Clinical Trials and world-wide commercialisation of many medical devices.

Our product, ReActiv8, uses a new approach to treat people with CLBP, based on, the Directors believe, a solid science foundation. We are growing our patent portfolio to provide broad protection for ReActiv8 and for other potential future products. See paragraph 5.16 of this Part 5 (*Information on the Group*) for further details on our patent portfolio.

As we grow our business, we may seek to enhance our product offering with new versions of ReActiv8 which may have expanded features, smaller form factor, lower cost, or other features which are targeted at improving our market penetration and competitive position.

We purchase all elements of our product (e.g. implantable pulse generator, leads, surgical tools) from a small number of reputable original equipment manufacturers who use well-proven technology platforms on which we designed our proprietary product. This has helped us to be time and capital efficient.

The ReActiv8-A Clinical Trial was conducted to gather data to support an application for CE Marking. The clinical results reported from the ReActiv8-A Clinical Trial show clinically important, statistically significant, and lasting improvement in pain, disability and quality of life, for a group of people who have attempted all or most treatment options and are not candidates for spine surgery or spinal cord stimulation. To the Company's knowledge, no other therapy for this patient group has demonstrated equivalent or better results. For further information on the ReActiv8-A Clinical Trial, see paragraph 5.7 of this Part 5 (*Information on the Group*).

During 2016 we commenced the U.S. Pivotal ReActiv8-B Clinical Trial under an IDE from the FDA. The U.S. Pivotal ReActiv8-B Clinical Trial is an international, multi-centre, prospective randomised sham controlled triple blinded trial with one-way crossover. Its purpose is to gather data in support of an application for Pre-Market Approval to the FDA, a key step towards the commercialisation of ReActiv8 in the U.S. The U.S. Pivotal ReActiv8-B Clinical Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on two pre-specified alternative analyses of that endpoint and on multiple secondary endpoints. We cannot be certain whether the totality of the data from the U.S. Pivotal ReActiv8-B Clinical Trial will be sufficient to demonstrate safety and efficacy to the satisfaction of the FDA to allow for the granting of a PMA.

People with CLBP seek help from a diversity of physicians.[43] Our target physician customers include interventional pain physicians, orthopaedic spine surgeons, neurosurgeons, and physical medicine and rehabilitation physicians. See paragraph 5.13(f) of this Part 5 (*Information on the Group*) for further details on target physicians. There is a growing trend of consolidation of these physician groups into

[43] National Institute of Neurological Disorders and Stroke (NINDS), Low Back Pain Factsheet, December 2014 - http://www.ninds.nih.gov/disorders/backpain/detail_backpain.htm

multi-disciplinary spine centres, where patients receive coordinated care across specialities for their back pain issues. This represents a concentrated customer base for us, providing the opportunity for us to commercialise ReActiv8 with a modestly sized sales force targeting a relatively small number of high value physician customers.

5.2 History and Development of the Group

The original idea for ReActiv8 was conceived by Dan Sachs, MD, an emergency medicine physician by training who became a medical device entrepreneur based in Minneapolis. In 2008, Dr. Dan Sachs filed a patent on the idea that led to ReActiv8, and formed Mainstay Medical, Inc. Dr. Dan Sachs is currently a Non-Executive Director of the Company.

2008	• Dan Sachs, MD filed a patent on the idea that led to ReActiv8
	• Mainstay Medical, Inc. ("**MMI**") founded in Minneapolis
2009	• Peter Crosby recruited as CEO in early 2009 to build the Group, its team and to develop ReActiv8 for commercialisation
2010	• $6.1 million capital raised in Series A Financing round in July 2010
	• Additional patents filed
2011	• First patient enrolled in the Feasibility Study
2012	• First pre-Investigational Device Exemption (pre-IDE) package submitted to the FDA
	• $20 million capital raised in Series B Financing round in September 2012
	• Mainstay Medical Limited ("**MML**") becomes the holding company of the Group
	• Group headquarters relocated to Dublin, Ireland
	• Last patient enrolled in the Feasibility Study in October
2013	• Appointment of Oern Stuge MD as independent Chairman of the Board
	• Core U.S. Patent 8,428,728 issued in April 2013 and U.S. Patent 8,606,358 B2 issued December 2013 as a continuation of U.S. Patent 8,428,728
	• Summary results of the Feasibility Study presented at the meeting of the International Neuromodulation Society ("**INS**") in Berlin in June 2013, and the Neuromodulation Society of the United Kingdom and Ireland, in Oxford in September 2013
	• Development of the key implanted elements of ReActiv8, proprietary implantable stimulation leads and an Implantable Pulse Generator ("**IPG**"), completed in 2013
2014	• First patients enrolled in ReActiv8-A Clinical Trial leading to an application for CE Mark
	• The Company was incorporated and registered in Ireland on 17 February 2014 as a plc and became the holding company of the Group on 3 April 2014 pursuant to the 2014 Corporate Reorganisation
	• Initial public offering, listing our Ordinary Shares on the ESM of the Irish Stock Exchange (now Euronext Growth of Euronext Dublin) and Euronext Paris (gross proceeds of $26 million received)
	• Our Quality Management System was certified to be in compliance with the international quality standards ISO 13485:2003 and EN ISO 13845:2012
2015	• FDA approval granted to start U.S. Pivotal ReActiv8-B Clinical Trial under an IDE
	• Multiple U.S. patents issued

- Non-dilutive debt facility secured for up to $15 million
- Application for CE Marking
- Announcement of positive results for the ReActiv8-A Clinical Trial

2016
- CE Marking obtained for ReActiv8
- Additional patent issued
- €30 million capital raised in the 2016 Placing in June 2016
- Commenced U.S. Pivotal ReActiv8-B Clinical Trial and first patient implanted in October 2016

2017
- First sale and implant of ReActiv8 in Germany announced in February 2017
- First sale and implant of ReActiv8 in Ireland announced in May 2017
- Jason Hannon appointed as Chief Executive Officer and joins Board of Directors in October 2017, resulting from succession planning associated with Peter Crosby's retirement
- Interim Analysis of U.S. Pivotal ReActiv8-B Clinical Trial performed and definite sample size determined

2018
- €30.1 million capital raised in the 2018 Placing announced in February 2018
- Headline results from U.S. Pivotal ReActiv8-B Clinical Trial announced in November 2018 (for further information see paragraph 5.10 of this Part 5 (*Information on the Group*))

2019
- Existing debt facility restructuring announced in April 2019
- €13.9 million capital raised in the 2019 Placing announced in July 2019
- €3.0 million capital draw down under restructured debt facility announced in July 2019
- Submission of final module of the PMA application to the FDA relating to ReActiv8 in August 2019

5.3 Corporate Structure

Mainstay Medical Inc. ("**MMI**") was founded in 2008 in Minnesota, U.S. After the Series B Financing in 2012, the parent company became Mainstay Medical Limited ("**MML**"), incorporated under the laws of Ireland, the headquarters of the business moved to Dublin and MMI ceased to be a member of the Group.

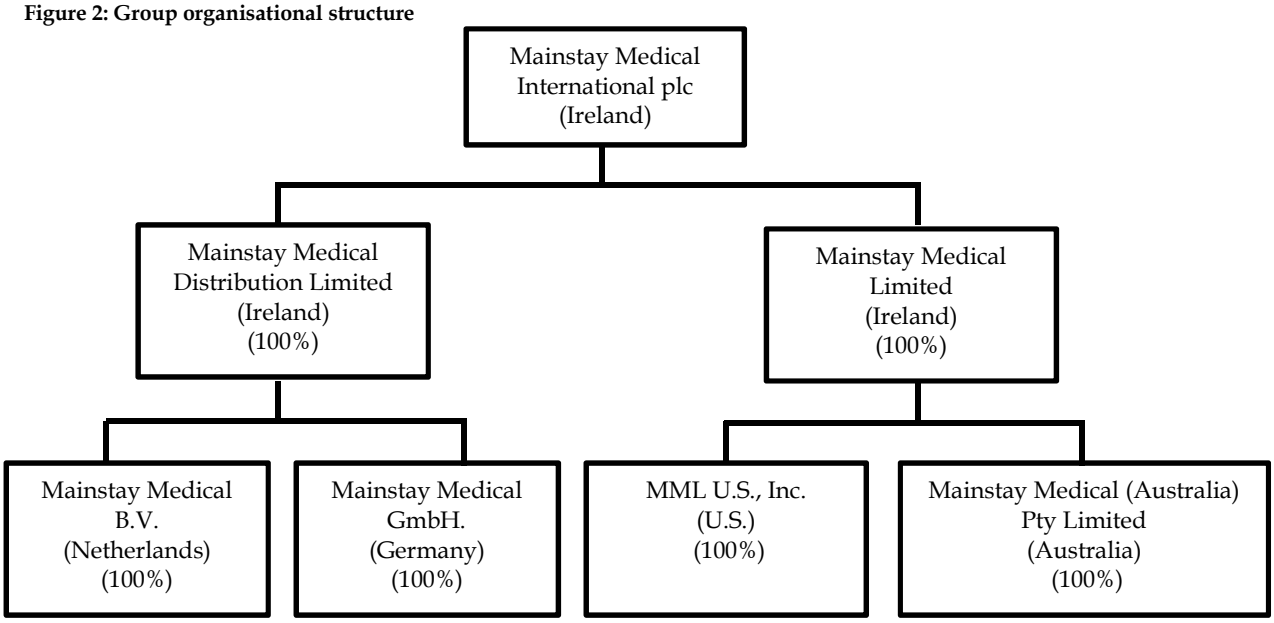
We undertook a corporate reorganisation in 2014 which resulted in the Company becoming the ultimate parent company of the Group. As a result of the 2014 Corporate Reorganisation, the previous parent, MML, became a wholly-owned operating subsidiary of the Company.

We are headquartered in Dublin, Ireland and have wholly owned subsidiaries operating in Ireland (MML and Mainstay Medical Distribution Limited ("**MMD**")), the U.S. (MML US, Inc. ("**MMLUS**")), Germany (Mainstay Medical GmbH ("**MMG**")), Australia (Mainstay Medical (Australia) Pty Limited ("**MMA**")) and the Netherlands (Mainstay Medical BV ("**MMBV**")).

MMLUS performs research and development services for us and manages our supply chain. In May 2013, MMA was established principally to provide support for human Clinical Trials in Australia.

In early 2016, we established two new wholly owned subsidiaries, MMG in Germany and MMD in Ireland. In 2017, we incorporated MMBV in the Netherlands. The focus of these companies is to support commercialisation in Europe.

Figure 2: Group organisational structure



5.4 Our strategy

We are focused on clinical development, regulatory approval and commercialisation of ReActiv8.

We have defined the pathway from ReActiv8 product development to revenue growth with four key elements as discussed below.

(a) **Obtain regulatory approvals in order to allow commercialisation**

CE Marking was obtained in May 2016 allowing the start of commercialisation in the EU. Our European commercial activities for ReActiv8 are initially focused on commercial validation in Germany and other select European markets by working with key physician partners who identify appropriate ReActiv8 patients in their centres in order to validate commercial adoption, refine patient selection strategies and follow ongoing patient progress.

In January 2017, we applied to the TGA for ReActiv8 to be admitted to the ARTG which would allow for commercialisation in Australia. In April 2018, the TGA requested additional clinical data with respect to ReActiv8 which we submitted in June 2019. To provide the most meaningful clinical data possible, we relied on the clinical data gathered as part of the U.S. Pivotal ReActiv8-B Clinical Trial. The U.S. Pivotal ReActiv8-B Clinical Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on two pre-specified alternative analyses of that endpoint and on multiple secondary endpoints. We cannot be certain whether the totality of the data from the U.S. Pivotal ReActiv8-B Clinical Trial will be sufficient to demonstrate safety and efficacy to the satisfaction of the TGA to allow for the admission of ReActiv8 to the ARTG. The TGA may request additional information during the review process. Review of an application for admission of a product to the ARTG has varied historically. The TGA is required to complete assessment of applications within approximately one year. Following admission of ReActiv8 to the ARTG, we will also apply for reimbursement approval in Australia.

Approval to enter the U.S. market is via a PMA issued by the FDA. We conducted the U.S. Pivotal ReActiv8-B Clinical Trial under an IDE from the FDA to gather information for the PMA application. See paragraph 5.10 of this Part 5 (*Information on the Group*) for further details on the U.S. Pivotal ReActiv8-B Clinical Trial.

(b) **Leverage existing reimbursement and expand coverage**

To our knowledge, hospitals in Germany are today using existing stationary (inpatient) reimbursement codes and associated tariffs for reimbursement payments related to ReActiv8. In addition, based on our review of the reimbursement climate (both internally and with external consultants), we believe hospitals in Switzerland and Austria can also use similar existing inpatient reimbursement codes for ReActiv8.

Where there is potential to do so, we may decide to seek specific reimbursement codes covering ReActiv8. We intend to gather data on cost effectiveness of ReActiv8 to support reimbursement in other target markets. For details on the reimbursement process, see paragraph 5.13(e) of this Part 5 (*Information on the Group*).

(c) **Drive adoption of ReActiv8 in routine clinical practice**

We continue to support the presentation of ReActiv8 and the results from past, present and future Clinical Trials of ReActiv8 by clinicians at scientific meetings. We also continue to support the publication of results of Clinical Trials of ReActiv8 in peer reviewed journals, and the growing body of evidence will help to drive adoption of ReActiv8 in routine clinical practice. In addition, we may support or sponsor regional or local meetings to drive awareness of ReActiv8 in the physician groups who see people with CLBP, with the objective or driving referrals to physicians who offer ReActiv8.

(d) **Drive broader awareness of ReActiv8**

We continue to seek and take advantage of opportunities to tell the ReActiv8 story in popular press, and other media (within the regulatory constraints of a medical device or an investigational device). Our objective is to drive awareness and education around the causes of CLBP, the role of the multifidus in spine stability, and the identification of patients who are likely to benefit from ReActiv8 amongst physicians and the broader healthcare community.

5.5 ReActiv8

ReActiv8 is an active implantable medical device, i.e., it is a medical device which is placed inside the body, in the general class of neurostimulation. It is active because it delivers electrical stimulation to nerves. ReActiv8 consists of two implantable leads (wires) each with four platinum-iridium electrodes, configured to deliver bilateral electrical stimulation to the medial branch of the dorsal ramus nerves (which supply the multifidus muscles) as they cross the transverse process at L3 vertebra (close to but outside the spinal column) to elicit contraction of the lumbar multifidus muscles. The leads are connected to a battery powered IPG, which is implanted just under the skin usually located above the buttocks.

The IPG is activated by an external remote control (the "**activator**" - part of the ReActiv8 system) and is programmed by or under the supervision of a clinician via a programmer, a computer which is used by the clinician to configure certain stimulation parameters of the ReActiv8 system and read information stored in the IPG. Several accessories are included as part of, or are used in the procedure to implant, ReActiv8. The implanted components of ReActiv8 are illustrated below.

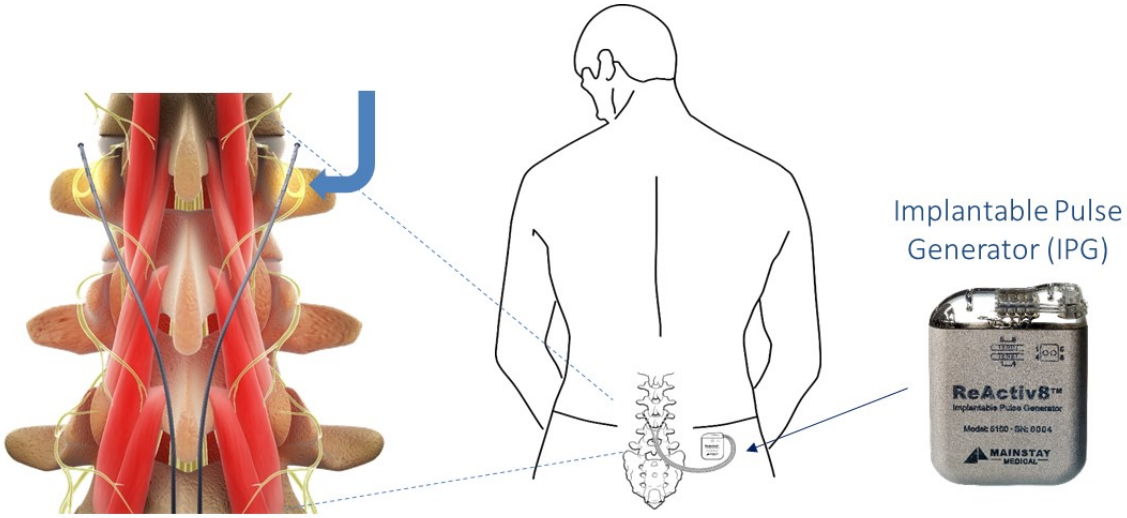


Figure 3: Implanted components of ReActiv8

Implanted components of ReActiv8

ReActiv8 is a new approach to the treatment of Chronic Low Back Pain. ReActiv8 is based on the hypothesis that electrical stimulation of the nerves that innervate the lumbar multifidus muscle causing muscle contraction can help reactivate the muscle control system, thereby leading to improved spine stability and improvement in Chronic Low Back Pain. The scientific rationale for ReActiv8 is supported by published research over many years.

- Many people with Chronic Low Back Pain have a dysfunction in the muscle control system of the muscles that stabilise the spine, in particular the lumbar multifidus muscle. Dysfunction appears to be cortically mediated (i.e. in the brain) and may be reversible.[44] This unstable spine is the root cause of Chronic Low Back Pain in many people.

- Several studies have shown that reactivation of the muscle control system with specialised exercises leads to improvement of Acute Low Back Pain and Chronic Low Back Pain.[45]

- Ultrasound image guided biofeedback can be used in some people to teach voluntary exercise of the multifidus muscle which helps reactivate the muscle control system.[46]

- The technique of ultrasound image guided biofeedback exercises has not become the standard of care due to the difficulty of achieving voluntary contraction of the lumbar multifidus as: (i) there are a small number of physical therapy practitioners with ultrasound imaging skills and access to equipment[47] and (ii) it is difficult for patients to perform and continue to do the exercises.

In a similar clinical situation relating to the knee, the muscle control system of the quadriceps (the large muscle at the front of the thigh which is the key stabilising muscle of the knee) is often disrupted after knee pain or knee surgery. It has been shown that electrical stimulation to cause

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[44] Tsao, Henry, Mary P Galea, and Paul W Hodges. "Driving Plasticity in the Motor Cortex in Recurrent Low Back Pain." European Journal of Pain (London, England) 14, no. 8 (February 2010): 832–39. doi:10.1016/j.ejpain.2010.01.001.

[45] Hides, Julie A, G A Jull, and Carolyn Anne Richardson. "Long-Term Effects of Specific Stabilizing Exercises for First-Episode Low Back Pain." Spine 26, no. 11 (June 2001): E243–48. http://www.ncbi.nlm.nih.gov/pubmed/11389408.

[46] Van, Khai, Julie A Hides, and Carolyn Anne Richardson. "The Use of Real-Time Ultrasound Imaging for Biofeedback of Lumbar Multifidus Muscle Contraction in Healthy Subjects." The Journal of Orthopaedic and Sports Physical Therapy 36, no. 12 (December 2006): 920–25. doi:10.2519/jospt.2006.2304.

[47] Jedrzejczak, A, and Lucy S Chipchase. "The Availability and Usage Frequency of Real Time Ultrasound by Physiotherapists in South Australia: An Observational Study." Physiotherapy Research International : The Journal for Researchers and Clinicians in Physical Therapy 13, no. 4 (December 2008): 231–40. doi:10.1002/pri.409.

contraction can reactivate the muscle control of the quadriceps.[48] Based in part upon this evidence, ReActiv8 is designed to electrically stimulate nerves to cause contraction of the key stabilising muscles in the back to help reactive the muscle control system for these key stabilising muscles of the lumbar spine, thereby reducing back pain.

The therapeutic concept of ReActiv8 was tested in the Feasibility Study from 2011, the results were published in a peer reviewed journal.[49] In 2015, we announced the results from our ReActiv8-A Clinical Trial, which was designed to gather data in support of an application for CE Marking. One year data results were announced in September 2016. The results from our ReActiv8-A Clinical Trial were published in a peer reviewed journal.[50] In 2018, we announced top line results from the U.S. Pivotal ReActiv8-B Clinical Trial. The U.S. Pivotal ReActiv8-B Clinical Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on two pre-specified alternative analyses of that endpoint and on multiple secondary endpoints.

ReActiv8 is implanted in a surgical procedure utilising a technique that is familiar to the majority of our physician customer base. During the implant procedure, the stimulation is tested and muscle contraction can be observed to confirm acceptable lead placement. No other "trial period" is required. After approximately two weeks the physician conducts further testing and programs the stimulation parameters into the IPG.

To use ReActiv8, the patient lies prone and places the antenna of the activator remote control over the IPG (the correct position is confirmed by the activator). Then the patient presses the green "start" button, and the stimulation cycle is initiated. Generally, stimulation is delivered for 10 seconds, followed by an off period of 20 seconds, and this cycle is repeated for 30 minutes, after which the stimulation stops automatically. Two stimulation sessions per day are recommended (morning and evening). There is no sensation of electrical shock, tingling or paraesthesia, and patients generally report the sensation as "soothing" or "comfortable." In other words, electrical stimulation elicits repetitive muscle contraction similar to a work out of any other muscle with exercise. The IPG has been validated to have a battery life of at least five years of one hour per day stimulation.

In Clinical Trials to date, most patients using the therapy have reported an improvement in CLBP by 90 or 120 days, and many continue to improve over longer times. Following improvement in or recovery from CLBP, there are several options for the disposition of ReActiv8 that the patient and physician can consider:

- ReActiv8 may be electively removed in a minor surgical procedure; or
- ReActiv8 can continue to be used on the same schedule (i.e. 30 minutes, twice a day), or a reduced schedule; or
- ReActiv8 can remain implanted but dormant in case there is a future episode of Low Back Pain which might benefit from ReActiv8 treatment.

ReActiv8 is a new implantable neurostimulator

There are several types of devices in the category of implanted neurostimulators, including deep brain stimulation (e.g. for movement disorders like Parkinson's), peripheral nerve stimulators (e.g. to treat phantom limb pain), and Spinal Cord Stimulation (SCS) (described in more detail below). All of

[48] Gondin, Julien, Marie Guette, Yves Ballay, and Alain Martin. "Electromyostimulation Training Effects on Neural Drive and Muscle Architecture." Medicine and Science in Sports and Exercise 37, no. 8 (August 2005): 1291–99. doi:10.1249/01.mss.0000175090.49048.41.

[49] Deckers, Kristiaan, Kris De Smedt, Jean-Pierre van Buyten, Iris Smet, Sam Eldabe, Ashish Gulve, Ganesan Baranidharan, et al. "Chronic Low Back Pain: Restoration of Dynamic Stability." Neuromodulation: Journal of the International Neuromodulation Society 18, no. 6 (August 2015): 478–86. doi:10.1111/ner.12275.

[50] Deckers K., De Smedt K., Mitchell B., Vivian D., Russo M., Georgius P., Green M., Vieceli J., Eldabe S., Gulve A., van Buyten J.-P., Smet I., Mehta V., Ramaswamy S., Baranidharan G., Sullivan R., Gassin R., Rathmell J., Gilligan C.. "New Therapy for Refractory Chronic Mechanical Low Back Pain – Restorative Neurostimulation to Activate the Lumbar Multifidus: One Year Results of a Prospective Multicenter Clinical Trial" Neuromodulation: Technology at the Neural Interface 21: 48–55. doi:10.1111/ner.12741.

these devices consist of an IPG and one or more leads that deliver electrical stimulation to neural structures. There is sometimes confusion about the differences between devices and how they work. Below we have explained the distinction between ReActiv8 and SCS.

Pain can be considered as two types – neuropathic and nociceptive. Neuropathic pain arises when nerves are damaged or compressed which can produce nerve signals which the brain interprets as pain in structures remote from the damage. Nociceptive pain arises from damage to structures which generates pain signals in nerves from those structures. As an example, when you bang your "funny bone" at the elbow, you may experience pain at the elbow itself (nociceptive pain), but it is common to also experience shooting pains and tingling down the arm as far as the fingers, which is neuropathic pain. Obviously, there is no damage to your fingers but the brain interprets the signals from the damaged nerve as pain in the arm and fingers.

ReActiv8 is designed and shown to treat nociceptive pain in the back, arising from overload or injury of the spine joints from dynamic instability of the spine. ReActiv8 is designed to treat the root cause of the back pain – disruption in the control of the key muscles that stabilise the spine – with episodic stimulation of nerves outside the spinal column, that supply the lumbar multifidus muscle.

SCS consists of a lead (wire) threaded inside the spinal canal and placed adjacent to the spinal cord, which delivers continuous electrical stimulation to the spinal cord to interfere with the brain's perception of pain. SCS is different from ReActiv8 in characteristics of pain treated, mechanism of action, mode of use, and surgical implant location. SCS has been shown to treat neuropathic pain of the legs and back arising from damage or compression to the spinal nerves in the back, for example, as a result of failed back surgery. SCS does not attempt to treat the root cause of pain, but rather provides analgesia.

5.6 Feasibility Study

Starting in 2011, we sponsored a Feasibility Study to investigate the electrical stimulation therapy to be delivered by ReActiv8. Five clinical investigation centres in the EU participated in the Feasibility Study, and 28 patients were enrolled at four of those centres. The first patient was enrolled in June 2011 and the last patient enrolled in October 2012. For this study, patients were implanted with commercially available IPGs and compatible leads selected by the investigational physician, and the IPGs were programmed to deliver electrical stimulation to elicit contraction of the lumbar multifidus muscle. Patients were asked to deliver twenty minutes of stimulation in each of the morning and afternoon, and the outcome measures of pain, disability and quality of life were assessed at baseline (i.e. before implant) and at three months after implant. The results were published in a peer reviewed journal.[51] In summary, the Feasibility Study demonstrated clinically important, statistically significant improvements in pain, disability and quality of life in the study patients.

The most important adverse events reported in the Feasibility Study were associated with lead migration (i.e. the lead moved from its intended position) of the commercially available leads. The ReActiv8 leads are designed to mitigate the risk of lead migration with a fixation mechanism at the distal end, adjacent to the electrodes. Other knowledge gained from the Feasibility Study was used to finalize the design of ReActiv8 prior to starting the ReActiv8-A Clinical Trial.

5.7 ReActiv8-A Clinical Trial

Following the Feasibility Study, we designed an international, multi-centre, prospective, single arm Clinical Trial of ReActiv8, for the purpose of gathering data to form part of the submission for CE Marking (the "**ReActiv8-A Clinical Trial**"). This trial was approved for up to 96 patients. The first patient was implanted in March 2014, and 47 patients were implanted during the period March 2014 to March 2015. We announced the results of the first 46 patients to reach the 90-day end point in August 2015, and additional data were announced in December 2015. One year data results were

[51] Deckers, Kristiaan, Kris De Smedt, Jean-Pierre van Buyten, Iris Smet, Sam Eldabe, Ashish Gulve, Ganesan Baranidharan, et al. "Chronic Low Back Pain: Restoration of Dynamic Stability." Neuromodulation : Journal of the International Neuromodulation Society 18, no. 6 (August 2015): 478–86. doi:10.1111/ner.12275.

announced in September 2016 which showed long term sustained performance. During September 2015 to November 2015, six additional patients were implanted in the ReActiv8-A Clinical Trial.

The ReActiv8-A Clinical Trial results show clinically important, statistically significant and lasting improvement in pain, disability and quality of life in a population of people with few treatment options. The results were published in a peer reviewed journal.[52]

Patients were enrolled in the ReActiv8-A Clinical Trial if they continued to experience disabling CLBP for at least 90 days despite medical management, which included at least physical therapy and drugs. Patients had attempted many other treatments including rhizotomies, spinal blocks, chiropractic, massage, and acupuncture. In addition, patients had no identifiable spine pathology that could be the clear cause of their CLBP, had no prior spine surgery, and were not candidates for spine surgery or spinal cord stimulation.

Key outcome measures were:

- **Back pain** – assessed using a Numerical Rating Scale ("**NRS**") in which patients were asked to grade their Low Back Pain from 0 (no pain) to 10 (worst imaginable pain).
- **Disability** – assessed using the Oswestry Disability Index ("**ODI**"), a disease specific validated questionnaire used to assess the disabling effects of back pain.
- **Quality of Life** – assessed using the EQ-5D Quality of Life Scale (**"EQ-5D")**.

Patients were instructed to not change their medications for Low Back Pain, and were instructed to not undertake any other treatment for back pain (e.g. physical therapy) until after data collection at the 90-day end point.

Patients were implanted with ReActiv8 in a surgical procedure. After approximately 14 days, patients began stimulation sessions with ReActiv8 for 30 minutes each morning and evening, and outcome data collection was at 90 days, 180 days and annually thereafter. Patients will continue to be followed by the Company for a period of up to 5 years post implant.

Baseline Characteristics

The key baseline characteristics for all 53 implanted patients are shown in Figure 4 below.

Characteristic	**Mean ± SD or n (%)**
Age (years)	44.1 ± 10.2
Gender (Male – Female)	23 (43%) - 30 (57%)
Duration of Back Pain (years)	14.3 ± 10.5
Average Back Pain NRS	6.8 ± 0.8
Disability on Oswestry Disability Index (ODI)	44.9 ± 10.1
Quality of Life on EQ-5D	0.4 ± 0.2
Back Pain Medications	
Opioids	38 (72%)

[52] Deckers K., De Smedt K., Mitchell B., Vivian D., Russo M., Georgius P., Green M., Vieceli J., Eldabe S., Gulve A., van Buyten J.-P., Smet I., Mehta V., Ramaswamy S., Baranidharan G., Sullivan R., Gassin R., Rathmell J., Gilligan C. 2018. New Therapy for Refractory Chronic Mechanical Low Back Pain – Restorative Neurostimulation to Activate the Lumbar Multifidus: One Year Results of a Prospective Multicenter Clinical Trial. Neuromodulation 2018; 21:48-55

Analgesics	31 (59%)
Non-Steroid Anti-Inflammatory Drugs (NSAIDS)	20 (38%)

Figure 4: Key baseline characteristics

In summary, the population was relatively young men and women who have suffered from disabling Low Back Pain for over a decade, have tried many other treatment options, and most of whom depended on strong medications for pain.

Results highlights

- Clinical performance of ReActiv8 at 90 days compared to baseline at the enrolment visit for all patients was:
    - 63% with clinically important improvement in back pain (defined as ≥2 point reduction on the 0-10 Numerical Rating Scale for Low Back Pain measured on the day).[53]
    - 58% responder rate: A responder is defined as a patient with a clinically important improvement in mean of prior 7 days average NRS with no clinically significant increase in medications taken for Low Back Pain.
    - 52% with a clinically important improvement[54] in disability on the Oswestry Disability Index.
    - 88% with a clinically important improvement[55] in quality of life on the EQ-5D scale.
- Clinical performance at 90 days is even better for the group of patients who do not receive financial compensation for being out of work due to their back pain. For those 32 patients the results were:
    - 72% with clinically important improvement in Low Back Pain NRS on the day.
    - 63% responder rate for pain.
    - 63% with clinically important improvement in ODI.
    - 69% with a clinically important improvement in EQ-5D.
- One year results showed sustained performance. Paired data for all patients at 90 days (n=52) and 1 year (n=47) days respectively were:
    - 63% and 57% with clinically important improvement in Low Back Pain NRS on the day.
    - 52% and 60% with clinically important improvement in ODI.
    - 88% and 81% with clinically important improvement in EQ-5D.
    - 60% and 65% reported >50% Pain Relief.

The results show that for a population of people with CLBP and limited treatment options, treatment with ReActiv8 delivers clinically important, statistically significant, and lasting improvement in pain, disability, and quality of life.

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[53] Dworkin, R. H., Turk, D. C., Wyrwich, K. W., Beaton, D., Cleeland, C. S., Farrar, J. T., … Zavisic, S. (2008). Interpreting the clinical importance of treatment outcomes in chronic pain Clinical Trials: IMMPACT recommendations. The journal of pain : official journal of the American Pain Society, 9(2), 105–21. doi:10.1016/j.jpain.2007.09.005

[54] Ostelo, R. W. J. G., Deyo, R. A., Stratford, P., Waddell, G., Croft, P., Von Korff, M., … de Vet, H. C. W. (2008). Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. Spine, 33(1), 90–4.

[55] Soer, R., Reneman, M. F., Speijer, B. L. G. N., Coppes, M. H., & Vroomen, P. C. A. J. (2012). Clinimetric properties of the EuroQol-5D in patients with Chronic Low Back Pain. Spine Journal, 12(11), 1035–1039.

As in a Clinical Trial of any new device, Adverse Events are expected and logged. Adverse Events were adjudicated by an independent Clinical Events Committee during the ReActiv8-A Clinical Trial and are reported and evaluated by the Clinical Trial site and reviewed by the Company following CE Marking and the continuation of the ReActiv8-A Clinical Trial as the ReActiv8-A PMCF Study (see paragraph 5.8 of this Part 5 (*Information on the Group*) of this document) to determine their severity, and relatedness to the device or procedure. As of the last date of report generation from the clinical database on 18 January 2018, there were 108 reported Adverse Events in 68 patients related to the device, therapy or procedure of which 92% were resolved, and none were reported as Serious Adverse Events.

The most common related Adverse Events were either associated with the surgical procedure (e.g. post-operative pain or discomfort), device over stimulation or loss of stimulation. There were 10 Serious Adverse Events ("SAEs") in seven patients none of which were related to the device, therapy or procedure. There were no unanticipated Adverse Events or unanticipated device-related Adverse Events. The Adverse Event incidence and type were comparable to Adverse Events in Clinical Trials reported for other neurostimulation devices.

As of 18 January 2018 (the last date of report generation from the clinical database), the ReActiv8 lead has shown one instance of lead migration (dislodgement) out of 192 implanted leads (including those implanted in revision procedures) for a lead migration incidence of less than 1%. These results demonstrate that the custom and proprietary ReActiv8 lead used in the ReActiv8-A Clinical Trial mitigates the risk of lead migration identified with commercially available neurostimulation leads in the earlier Feasibility Study.

As part of continuous testing, the ReActiv8 IPG can detect anomalies in a lead which, in some cases, can result in loss of stimulation. As of 18 January 2018 (the last date of report generation from the clinical database), lead anomalies led to elective revision/ explant surgery in 25 patients for a surgical revision incidence of 37%, which is comparable to published data for neurostimulation systems.

In many of the leads returned for analysis after elective revision surgery, a break in one or more wires inside the lead was found (lead conductor fracture). These conductor fractures were found not to result from the design or manufacture of the leads. In additional laboratory studies, in some cases a tight bend in the lead was observed as the lead traverses two layers of tissue that move in different directions relative to each other. A modification to the surgical approach with different lead routing, known as the "midline approach", was developed in conjunction with investigators to mitigate the risk of this lead bending.

The midline approach has been used in ReActiv8-A Clinical Trial and ReActiv8-A PMCF Study implants since 1 September 2015, and is recommended for all future implants. As of 18 January 2018 (the last date of report generation from the clinical database), there have been 41 subjects implanted with the midline approach, and the rate of revision surgery due to suspected lead conductor fracture is 10%.

The following tables and the comments that follow provide more detailed information on the ReActiv8-A Clinical Trial.

Outcomes – N=53 Subjects	**Day 90 (N=52)**	**Month 12 (N=47)**
Low back pain- prior 7 day average Numerical Rating Scale (0-10)		
Improvement from baseline – absolute mean ± SE	2.5±0.3 p<0.0001	Not recorded beyond 90 days per protocol
Improvement from baseline - %	36%	
Responder Rate (% of subjects)	58%	
Low back pain – on the day Numerical Rating Scale (0-10)		
Improvement from baseline – absolute mean ± SE	2.5±0.3 p<0.0001	2.4±0.4 p<0.0001

Improvement from baseline - %	35%	33%
Responder Rate (% of subjects)	63%	57%
Low back pain improvement – Percent Pain Relief (0-100%)		
Reported change (%) mean ± SE	47.1 ± 4.2	53.1 ± 4.7
% of subjects with ≥50% pain relief	60%	65%
Disability (Oswestry Disability Index) (0-100)		
Improvement from baseline	13.4 ± 2.2 p<0.0001	14.3 ± 2.3 p<0.0001
% of subjects with clinically important change	52%	60%
Quality of life (EQ-5D) (1=Maximum Value)		
Improvement from baseline	0.21 ± 0.03 p<0.0001	0.22 ± 0.03 p<0.0001
% of subjects with clinically important change	88%	81%

Figure 5: Information on the ReActiv8-A Clinical Trial.

Outcomes – Pain

The NRS is an 11-point scale from 0-10, where 0 is no pain and 10 is the worst imaginable pain. A "responder" is defined in accordance with the IMMPACT recommendations[56] as a patient with a reduction in NRS of 2 points or more from baseline, with the addition of no clinically significant increase in medications taken for Low Back Pain.

For the 90-day endpoint, the assessment was the mean of the prior seven days of patient-reported daily average Low Back Pain NRS recorded in a journal. The responder rate at 90 days was 58%.

For all assessments (including after 90 days), patients were asked to report their Low Back Pain NRS on the day. The responder rate was 63% at 90 days and 57% at 1 year.

Patients were also asked to rate their "Percent Pain Relief" compared to baseline. By this measure, 60% of patients reported 50% or better improvement at 90 days and 65% reported 50% or better improvement at 1 year.

Outcome – Disability (ODI)

The Oswestry Disability Index is a disease specific assessment of the disabling effects of back pain. The IMMPACT recommendations are that a reduction from baseline of 10 points or more constitutes an "important change".[57]

52% of patients had an important change in ODI at 90 days, and the mean improvement was 13 points. At 1 year, 60% had an important change in ODI, and the mean improvement was 14 points.

Outcome – Quality of Life (EQ-5D)

The European Quality of Life Assessment is commonly used as an outcome measure in studies on back pain.

[56] Dworkin, R. H., Turk, D. C., Wyrwich, K. W., Beaton, D., Cleeland, C. S., Farrar, J. T., Zavisic, S. (2008). Interpreting the clinical importance of treatment outcomes in chronic pain clinical Trials: IMMPACT recommendations. The Journal of Pain: Official Journal of the American Pain Society, 9(2), 105–21.

[57] Ostelo, R. W. J. G., Deyo, R. A., Stratford, P., Waddell, G., Croft, P., Von Korff, M., … de Vet, H. C. W. (2008). Interpreting change scores for pain and functional status in Low Back Pain: towards international consensus regarding minimal important change. Spine, 33(1), 90–4.

88% of patients had a clinically important improvement in EQ-5D at 90 days, and the mean improvement was 0.21 points. At 1 year, 81% had a clinically important improvement in EQ-5D, with a mean improvement of 0.22 points.

Other Outcomes

The Treatment Satisfaction Questionnaire is an assessment of the patient's satisfaction with the treatment. At 90 days (n=52) 89% of patients were satisfied, of whom 83% were very satisfied and at 1 year (n=48) 81% were satisfied of whom 74% were very satisfied.

The Clinical Global Impression is the physician's assessment of the patient compared to baseline, and at 90 days (n=52), 83% were rated as "better" and at 1 year (n=48), 79% of the subjects were rated as "better".

Effect of Financial Compensation

Analysis of the data showed significantly better outcomes in patients who were not receiving financial compensation for being out of work due to their back pain. There is consistent evidence in scientific literature that financial compensation for a change in work status due to back pain is a strong predictor for treatment failure in Clinical Trials of pain therapies. Therefore, it has become usual practice in Clinical Trials of therapies for pain (including recent spinal cord stimulation clinical trials) to exclude patients with financial compensation.[58]

In the ReActiv8-A Clinical Trial, there were 15 patients who were receiving financial compensation for being out of work due to their back pain. The 90 day mean improvement in NRS for this group was 1.4 points (21% improvement), and the responder rate was 29% (4/14). In contrast, the outcomes for those not receiving financial compensation (the "**Usual Cohort**") were superior (p=0.05 for the 90 day NRS outcome). The 90 day mean improvement in NRS for the Usual Cohort was 3.0 points (43% improvement, and the responder rate was 69% (22/32). Summary results for the Usual Cohort are presented in the table below.

Outcomes – N=32 – Usual Cohort	Day 90 (n=32)	Day 180 (n=31)
Low back pain – prior 7 day average Numerical Rating Scale (0 – 10)		
Improvement from baseline – absolute	3.0 ± 0.4 p<0.0001	Not recorded beyond 90 days per protocol
Improvement from baseline – %	43%	
Responder Rate (% of subjects)	69% (22/32)	
Low back pain – on the day Numerical Rating Scale (0 – 10)		
Improvement from baseline - absolute	2.8 ± 0.4 p<0.0001	2.4 ± 0.5 p<0.0001
Improvement from baseline – %	40%	35%
% of subjects with ≥2 point improvement	72% (23/32)	58% (18/31)
Low back pain improvement – Percent Pain Relief (0 – 100%)		
Reported change (%)	50% ± 5.4	55% ± 5.6
% of subjects with ≥50% pain relief	63% (20/32)	71% (22/31)
Disability (Oswestry Disability Index) (0 – 100)		
Improvement from baseline	16.5 ± 2.6 p<0.0001	12.0 ± 2.9 p=0.0002
% of subjects with clinically important change	63% (20/32)	58% (18/31)
Quality of life (EQ-5D) (1 = Maximum Value)		
Improvement from baseline	0.19 ± 0.03 p<0.0001	0.14 ± 0.05 p=0.0054
% of subjects with clinically important change	69% (22/32)	77% (24/31)

Figure 6: Summary results for the Usual Cohort

[58] See, for example, https://clinicalTrials.gov/show/NCT01609972 and https://clinicalTrials.gov/show/NCT01923285. See Dworkin, R. H., Turk, D. C., Peirce-Sandner, S., Baron, R., Bellamy, N., Burke, L. B., … Witter, J. (2010). Research design considerations for confirmatory chronic pain clinical Trials: IMMPACT recommendations. Pain, 149(2), 177–93.

5.8 ReActiv8-A Post Market Clinical Follow-Up ("PMCF") Study

The submission for CE Marking included the results of the ReActiv8-A Clinical Trial announced by the Company on 31 August 2015. Following CE Marking, a range of activities is required for Post Market Clinical Follow Up to gather additional data on the long term performance and safety of Re-Activ8.

The ReActiv8-A PMCF Study is a continuation of the ReActiv8-A Clinical Trial (but with CE Marked ReActiv8). It will gather additional data on performance and residual risk following CE Marking of ReActiv8 and all patients enrolled in the ReActiv8-A Clinical Trial in Belgium and the UK have been converted to the ReActiv8-A PMCF Study for long term follow up. Physicians commenced with these implants in late 2017.

5.9 ReActiv8-C Registry

In addition to the ReActiv8-A PMCF Study, the Company is conducting a Registry. The ReActiv8-C Registry is an international, multi-centre data collection registry. All centres that use the product commercially are invited to participate in the Registry program. All patients who are implanted with ReActiv8 at the centres participating in the Registry will be invited to enrol in the Registry until the target enrolment numbers have been reached. The purpose of the Registry is to gather additional summary data on long term performance of ReActiv8 in at least 50 patients.

5.10 U.S. Pivotal ReActiv8-B Clinical Trial

On 29 May 2015, we announced FDA approval to begin the U.S. Pivotal ReActiv8-B Clinical Trial under an IDE. We then worked with the FDA to refine the protocol, and during 2015 and 2016 we progressed Clinical Trial site selection and initiation, physician training, and submissions to Ethics Committees ("**EC**") (Institutional Review Boards (IRB) in the U.S.). The U.S. Pivotal ReActiv8-B Clinical Trial is designed to generate data to form part of the Pre-Market Approval Application of ReActiv8 to the FDA.

The U.S. Pivotal ReActiv8-B Clinical Trial is an international, multi-centre, prospective randomised sham controlled triple blinded trial with one-way crossover. In summary, this means that eligible patients have baseline data collected and then following verification that the enrolment criteria are met, ReActiv8 is implanted. At the 14-day post implant follow up visit, half the patients are randomised to receive appropriately programmed stimulation (the treatment arm), and half are randomised to receive sham stimulation/minimal stimulation (the control arm). The U.S. Pivotal ReActiv8-B Clinical Trial is a blinded trial, consequently, patients are not informed about their allocation to the treatment or control arm, and all patients are told that they may or may not feel something with stimulation, and all are encouraged to continue using ReActiv8 at least until the 120-day primary outcome assessment visit. Patients are instructed to not use any other therapies for CLBP from the time of enrolment until after data collection at the primary outcome assessment visit. Patients are also instructed to keep constant the use of medications prescribed and used for Low Back Pain until the primary outcome assessment visit. The primary efficacy endpoint of the U.S. Pivotal ReActiv8-B Clinical Trial is a comparison of responder rates between the treatment and control arms. A responder is defined as having at least 30% improvement in Low Back Pain reported on a 100mm Visual Analogue Scale (**"VAS"**) between baseline and the 120-day primary outcome assessment visit, with no increase in medications prescribed and taken for pain in the 14 days prior to the visit. Data for multiple secondary outcome measures was also gathered. After the primary outcome assessment visit, patients in the control arm are crossed over to receive appropriately programmed full strength stimulation, and all patients will continue to be followed.

The Clinical Trial utilizes an adaptive trial design, inclusive of an interim analysis, to determine the definitive size of up to 232 patients in the pivotal cohort. With this adaptive design, in September 2016, Mainstay commenced the Clinical Trial with a sample size of 128 patients pending the Interim Analysis.

In December 2017, the independent DMC completed the Interim Analysis, which was based on data from the first 58 patients in the pivotal cohort to complete the primary endpoint. The DMC recommended continuation of the Clinical Trial with a definitive size of 168 evaluable patients. The ultimate number of patients in the Clinical Trial was 204 due to the nature of the enrolment process. The DMC also reported that it observed no safety concerns in the Clinical Trial.

At the date of the Interim Analysis in December 2017, 133 patients had been implanted in the pivotal cohort, and the Clinical Trial was fully enrolled by the end of the second quarter of 2018, with a full top line data readout announced on 19 November 2018.

The subjects in the study had an average age of 47, and an average duration of chronic low back pain of 14 years. This patient population had tried many other treatment alternatives, including physical therapy and drugs, with limited success, and 79% of the subjects were on pain medication at baseline.

The following table shows the result on the primary efficacy endpoint:

Primary Efficacy Endpoint	**Treatment N=102**	**Control N=102**	**Difference p-value**
Responder (≥30% reduction in Low Back Pain VAS and no increase in pain medications)	57.1%	46.7%	10.4% p=0.1377

The same data as above, presented in a cumulative proportion of responders analysis that was pre-specified in the investigational plan, demonstrated a statistically significant difference ($p<0.05$) between the treatment and control groups, with the treatment group showing a higher proportion of responders across all threshold levels. This analysis, which is a comparison of ranks, inherently preserves information over a dichotomized endpoint, thereby improving statistical power.

In addition, the analysis of difference in mean low back pain VAS reduction between the treatment group and the control group was statistically significant ($p<0.05$) at the 120-day visit.

The investigational plan for the study includes a pre-specified analysis, assessing the impact of medication changes to treat acute, unrelated pain conditions on the primary endpoint.

The Company, in consultation with its statistical advisors, determined that a valid way to handle the subjects with pain medication increases for reasons unrelated to low back pain would be to analyze the endpoint with these subjects removed, as pain medication use for reasons unrelated to low back pain was an exclusion criterion in the study. By doing so, inference is limited to the population of subjects taking pain medication only for reasons related to low back pain, as intended by the patient selection criteria in the trial protocol.

Six subjects had increases in pain medications for reasons other than low back pain. The following table presents the results of the primary efficacy endpoint in the subjects not requiring an increase in pain medications for reasons other than for low back pain, showing a clinically-meaningful and statistically-significant difference:

Primary Efficacy Endpoint	**Treatment N=96**	**Control N=102**	**Difference p-value**
Responder (≥30% reduction in Low Back Pain VAS and no increase in pain medications)	60.6%	46.7%	14.0% p=0.048

Numerous secondary endpoints and supporting analyses were collected to assess improvements in the treatment group as compared to the control group at 120 days, including reduction from baseline in pain as measured by both mean reduction in VAS and percent pain relief (PPR), change from baseline in disability measured by the Oswestry Disability Index (ODI), change from baseline in quality of life measured by the European Quality of Life Score on Five Dimensions (EQ-5D), subject global impression of change (SGIC), clinician global impression of change (CGI), patient treatment satisfaction as measured by the treatment satisfaction questionnaire (TSQ) and pain resolution (VAS ≤2.5 cm). As shown in the following table, when evaluating the therapy across multiple dimensions of subject outcomes, the treatment effect is significant in seven of the eight secondary endpoints/supporting analyses: mean reduction in VAS, PPR, ODI, EQ-5D, SGIC, treatment satisfaction and CGI:

	Treatment N=102		**Control N=102**		**Difference p-value**
Endpoint	**N**	**Mean ± SD (Min, Max) or N (%)**	**N**	**Mean ± SD (Min, Max) or N (%)**	
Change in Low back pain VAS	100	-3.3 ± 2.7 (-8.5, 3.0)	101	-2.4 ± 2.9 (-8.8, 3.5)	0.9 p = 0.032
Percent Pain Relief	100	52 ± 32 (0, 100)	101	35 ± 36 (0, 100)	17 p ≤ 0.001
Change in ODI	100	-17.5 ± 15.1 (-58.0, 20.0)	101	-12.2 ± 14.6 (-48.0, 32.0)	5.4 p = 0.011
Change in EQ-5D	100	0.186 ± 0.199 (-0.365, 0.782)	100	0.115 ± 0.178 (-0.640, 0.665)	0.071 p = 0.009
Subject Global Impression of Change					
Much better	100	32 (32%)	101	18 (18%)	
Better	100	22 (22%)	101	16 (16%)	
A little better	100	25 (25%)	101	29 (29%)	NA p = 0.003
No change	100	10 (10%)	101	24 (24%)	
A little worse	100	6 (6%)	101	5 (5%)	
Worse	100	4 (4%)	101	6 (6%)	
Much worse	100	1 (1%)	101	3 (3%)	
Satisfied with Treatment					
Definitely Yes	100	61 (61%)	101	40 (40%)	NA p ≤ 0.001
Maybe	100	29 (29%)	101	37 (37%)	
Definitely Not	100	10 (10%)	101	24 (24%)	
Clinician Global Impression					NA p ≤ 0.001
Much Better	100	57 (57%)	100	22 (22%)	
Slightly Better	100	26 (26%)	100	29 (29%)	

	Treatment N=102		Control N=102		Difference p-value
Endpoint	**N**	**Mean ± SD (Min, Max) or N (%)**	**N**	**Mean ± SD (Min, Max) or N (%)**	
About the Same	100	16 (16%)	100	42 (42%)	
Slightly Worse	100	1 (1%)	100	5 (5%)	
Much Worse	100	0 (0%)	100	2 (2%)	
Remitters (VAS ≤ 2.5)	100	34 (34%)	101	28 (28%)	6.3% p = 0.335

At the 120-day visit, subjects in the control group were allowed to cross-over to receive stimulation at a therapeutic level. All control subjects elected to cross-over at this timepoint. At the time of filing of the PMA, 160 subjects had completed the 1-year assessment visit, consisting of 80 in each group. In this population, all efficacy outcomes for the treatment group and for the control group post crossover progressively improved through the 1-year assessment visit, consistent with the rehabilitative nature of the therapy (8 months of therapy for the crossover group). These results are subject to change as additional subjects complete the 1-year assessment visit.

Outcomes at 1 year (8 months of therapy for the crossover group):

- VAS Responders:
    - 69% in the treatment group
    - 63% in the crossover group
- Change in VAS:
    - -4.4 in the treatment group
    - -4.4 in the crossover group
- Average Percent Pain Relief:
    - 67% in the treatment group
    - 66% in the crossover group
- Average ODI Change:
    - 21-point reduction in the treatment group
    - 20-point reduction in the crossover group
- Average EQ-5D Change:
    - 0.218-point increase in the treatment group
    - 0.183-point increase in the crossover group
- Average SGIC:
    - 76% Better or Much Better in the treatment group

- 72% Better or Much Better in the crossover group

- Average Treatment Satisfaction:
  - 82% Definitely Satisfied in the treatment group
  - 76% Definitely Satisfied in the crossover group
- Average CGI:
  - 78% Much Better in the treatment group
  - 71% Much Better in the crossover group

Although the study was not designed to reduce medications after the 120-day visit, subjects were allowed to change medications after that time point. As the following table shows, of the 61 patients (treatment and crossover groups combined) who were on at least one opioid-containing medication at baseline and had a 1-year visit, 28% had discontinued use of opioids, and an additional 21% had decreased opioid use, for an overall rate of 49% of patients who decreased or discontinued opioids by the 1-year visit.

Medication Change Status	**Opioid** **% (n/N)**
Discontinued or Decreased	49% (30/61)
No Change	44% (27/61)
Increased or Added	7% (4/61)

Notably, patients who decreased or discontinued opioids had similar efficacy results as the overall population. In addition, 97% of those who were not on an opioid at baseline and had a 1-year visit remained off opioids.

The incidence and type of adverse events (AEs), including serious AEs, compares favourably to that of spinal cord stimulator devices, with no unanticipated AEs related to the device, procedure or stimulation.

In summary, the U.S. Pivotal ReActiv8-B Clinical Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on two pre-specified alternative analyses of that endpoint and on multiple secondary endpoints. We cannot be certain whether the totality of the data from the U.S. Pivotal ReActiv8-B Clinical Trial will be sufficient to demonstrate safety and efficacy to the satisfaction of the FDA to allow for the granting of a PMA. The Company held a pre-PMA meeting with the FDA on 25 June 2019 and submitted the final module of the PMA application to the FDA relating to ReActiv8 in August 2019. Regulatory review time of the PMAA has varied historically. The latest data publicly available indicates that, in 2018 and 2017, the average time was 246 and 311 days respectively.[59]

5.11 Manufacturing

The ReActiv8 components are manufactured by experienced manufacturers of AIMDs, supervised by our research and development ("**R&D**") and operations staff. The Directors believe that this is a capital efficient way of developing an AIMD product as it does not require large expenditure on capital equipment for product development.

[59] https://www.fda.gov/media/120474/download, https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-quarterly-performance-reports

We choose suppliers of the IPG and leads that are experienced and well-respected medical device manufacturers with multiple customers and that have existing quality control programs and registrations with the appropriate regulatory authorities. We verify key vendors' quality systems with periodic audits.

We have entered into long-term supply contracts with all of our key manufacturing vendors. Key vendors that supply products to us are subject to annual audits of their quality management system by ourselves. They are also generally subject to continuing audit by regulatory authorities (e.g. the FDA) and maintain compliance to international standards such as ISO 13485. Once a supplier meets our requirements, it is entered into an Approved Supplier List ("**ASL**") maintained by us.

We currently do not have manufacturing operations for ourselves, and rely solely on third party manufacturers, who rely on continuing supply of certain raw materials. We review manufacturing requirements on an ongoing basis and consider the appropriate manufacturing strategies as the Company progresses from a development stage into commercialisation.

We manage distribution of ReActiv8 from our manufacturing vendors.

Any device explanted (i.e. removed) from a patient is required to be decontaminated at the hospital where the explant is performed. Depending on the circumstances (e.g. which implantable component is explanted), returned devices are sent for further decontamination at a subcontractor, or returned to the supplying manufacturer or us for analysis.

Non-implanted returned devices (e.g. programmer, activator) may be returned directly to the manufacturer for analysis.

Following CE Marking of ReActiv8, we have purchased product liability insurance, at a level that the Directors believe to be appropriate for a company of our size and nature, to help cover the costs of defence of product liability lawsuits and for damages. For products used as part of a Clinical Trial, Clinical Trial insurance helps cover the cost of defence of lawsuits relating to the product, which is the subject of the Clinical Trial, and for damages, if awarded. The Company regularly reviews the level and appropriateness of the product liability insurance in place.

5.12 Quality Management System

We perform all our activities subject to a Quality Management System ("**QMS**"). In December 2014, our QMS was found to be in compliance with the international quality standards ISO 13485:2003 and EN ISO 13845:2012, which confirms that our medical device manufacturing QMS is compliant with globally recognized standards set forth by the International Organisation for Standardization. Our QMS is designed to be in compliance with the FDA Quality System Regulations ("**QSR**").

A new standard, ISO 13485:2016 was released in 2016 to replace ISO 13485:2003 and EN ISO 13485:2012. During 2017 we completed the required transition activities to the new standard and we received confirmation of compliance in November 2017.

These international standards provide an accepted international framework for meeting medical device quality standards and compliance certification is a requirement for CE Marking and the commercialisation of ReActiv8. This certification granted by our Notified Body covers the operational activities for developing and bringing to market implantable stimulation systems in the area of pain management.

Our QMS is implemented on a third party web-based document management platform, and contains back-up systems necessary to protect our integrity and security. We conduct periodic internal audits of our QMS and use external auditors from time to time.

In the U.S., compliance with QSR is required. Our QMS will also be audited by the FDA for compliance with the QSRs prior to any granting of a PMA to allow sale of ReActiv8 in the U.S.

We maintain a complaint system, which is designed to be in compliance with QSR and ISO 13485. The purpose of the complaint system is to receive, record, and respond to feedback from the field, including reports of suspected device failure, recommendations for device modifications or design changes, and reports of inadequate labelling or other documentation (collectively called "**complaints**"). All complaints are logged, and trends are tracked. A complaint may result in a corrective and preventive action. At least quarterly, we conduct a management review of our QMS during which the history of complaints is analysed and appropriate actions (if any) are initiated.

Complaints logged into our complaint system may result in a report to a regulatory authority. The U.S. Medical Device Reporting regulation contains mandatory requirements for manufacturers, importers and user facilities to report significant medical device adverse events to the FDA. The FDA uses this information to identify and respond to problems associated with medical devices. Similar to the FDA's system, the EU employs a vigilance reporting system. Other countries have generally similar obligations for reporting adverse events to the appropriate regulatory authority.

5.13 Commercialisation Strategy

We are pursuing three main activities necessary to commercialise ReActiv8:

- Obtaining regulatory approvals to allow commercialisation,
- Leveraging existing reimbursement and expanding coverage, for example through reimbursement by health care payers (e.g., insurance companies and government funded health care systems), and
- Execute our sales and marketing strategy (including building a sales organisation).

(a) Regulatory Approval for Commercialisation

In most countries targeted by the Company, approval by the country's regulator is necessary for the marketing and sale of any medical device. The regulatory approval pathway is different in each of our key target markets, but with many elements in common.

In general, regulatory approval of ReActiv8 requires submission of extensive engineering and technical data on the design, validation testing, pre-clinical (e.g. animal) testing (if necessary), manufacturing processes of ReActiv8, and details of our QMS.

A major part of the regulatory submission is the data generated from Clinical Trials. For example, the clinical data from the ReActiv8-A Clinical Trial was included in the submission for CE Marking which was approved in May 2016.

For approval to market ReActiv8 in the U.S., we conducted the U.S. Pivotal ReActiv8-B Clinical Trial under an Investigational Device Exemption (IDE), and data from that trial formed part of the submission for a PMA to the FDA.

We conduct our Clinical Trials with a combination of in-house resources and one or more external contract research organisations ("**CROs**"). All human Clinical Trials are conducted according to the international standard covering Clinical Trials, ISO 14155:2011 and FDA Regulations in the U.S.

Any Clinical Trial which generates data which we intend to submit to the FDA as part of an application for regulatory approval must also meet the FDA requirements, in particular traceability and audit of clinical data. At the time of application for regulatory approval in any jurisdiction (e.g. CE Marking for the EU or PMA for the U.S.), we are obliged to report all relevant clinical experience to the date of the submission. Registration of Clinical Trials on www.clinicaltrials.gov is mandated for any Clinical Trial (other than proof of concept or feasibility studies) for which the clinical results are to be presented or published.

(b) **CE Marking for the EEA**

In the EEA, regulatory approval is through CE Marking, which certifies compliance with the applicable standards and essential requirements. CE Marking is granted by a "Notified Body" designated by a competent authority. We have engaged BSI Group–Medical Devices as our Notified Body.

We submitted an application for the CE Marking for ReActiv8 in November 2015, representing the culmination of several years of work and a further key step towards commercialisation in Europe.

This application included the results of the ReActiv8-A Clinical Trial which showed clinically important, statistically significant, and lasting improvement in pain, disability, and quality of life for people with Chronic Low Back Pain and limited treatment options, further details of the results are set out in paragraph 5.7 of this Part 5 (*Information on the Group*). In addition to these clinical results, the application also included extensive information about the design, testing, manufacturing, and quality system for ReActiv8. We received CE Marking for ReActiv8 in May 2016.

(c) **PMA for the U.S. Market**

In the U.S., the FDA regulates the marketing and sale of medical devices. A PMA is usually required before a Class III medical device (like ReActiv8) can be marketed.

The key elements for a PMA submission include details of:

- Design and manufacturing (including validation testing);
- Quality Management System; and
- Results of an appropriate Clinical Trial.

The Clinical Trial leading to a PMA is conducted under an IDE granted by the FDA. The purpose of the IDE is to allow the importation or use of an investigational device solely for purposes of the Clinical Trial, and with appropriate safeguards.

We submitted, in January 2015, an application to the FDA for approval to start a Clinical Trial of ReActiv8 under an IDE. Multiple interactions with the FDA followed, to develop a Clinical Trial that meets our needs, those of the FDA, and the people who could potentially benefit from ReActiv8.

In May 2015, we received approval from the FDA to begin a Clinical Trial of ReActiv8 under an IDE. The FDA approved the U.S. Pivotal ReActiv8-B Clinical Trial, an international, multi-centre, prospective randomised sham controlled triple blinded trial with one-way crossover designed to evaluate the safety and efficacy of ReActiv8 for the treatment of adults with Chronic Low Back Pain and no prior back surgery.

The U.S. Pivotal ReActiv8-B Clinical Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on two pre-specified alternative analyses of that endpoint and on multiple secondary endpoints. We cannot be certain whether the totality of the data from the U.S. Pivotal ReActiv8-B Clinical Trial will be sufficient to demonstrate safety and efficacy to the satisfaction of the FDA to allow for the granting of a PMA. The Company held a pre-PMA meeting with the FDA on 25 June 2019 and submitted the final module of the PMA application to the FDA relating to ReActiv8 in August 2019.

(d) **Regulatory approval in other markets**

In addition, we may try to obtain marketing authorisation for our product in certain countries outside of the EEA. Commercialisation would become subject to the regulatory laws and regulations of any additional country in which we may apply for marketing approval and in order to maintain such approval. These regulatory laws are complex and vary from country to country.

In January 2017, we applied to the TGA for ReActiv8 to be admitted to the ARTG which would allow for commercialisation in Australia. In April 2018, the TGA requested additional clinical data with respect to ReActiv8 which we submitted in June 2019. To provide the most meaningful clinical data possible, we relied on the clinical data gathered as part of the U.S. Pivotal ReActiv8-B Clinical Trial. The U.S. Pivotal ReActiv8-B Clinical Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on two pre-specified alternative analyses of that endpoint and on multiple secondary endpoints. We cannot be certain whether the totality of the data from the U.S. Pivotal ReActiv8-B Clinical Trial will be sufficient to demonstrate safety and efficacy to the satisfaction of the TGA to allow for the admission of ReActiv8 to the ARTG. Review of an application for admission of a product to the ARTG has varied historically. The TGA is required to complete assessment of applications within approximately one year. Following admission of ReActiv8 to the ARTG, we will also apply for reimbursement approval in Australia.

(e) **Leveraging existing reimbursement and expanding coverage**

Once a medical device is approved for sale, arrangements must be made for payment. The term "payer" refers to the organisation which eventually provides the payment for a medical therapy. In some countries (e.g. the UK, Italy and Spain) this is a national health service, which provides healthcare for the population, mostly free of charge, at the point of use. Countries with a national health service often have a parallel private health insurance system that people can choose to subscribe and pay for in order to access products and services not available from the national health service, or more rapidly than available from the national health service. In other countries, the payer can be a social insurance program (e.g., Germany and France) or a private insurance company (e.g. the Netherlands). Countries with a social insurance system may also have a parallel private insurance sector to supplement reimbursement and to provide access to additional services. In the U.S., provision of healthcare is mainly paid for by private insurance. People have private insurance (often subsidised by an employer) or are covered by one of the government insurance schemes (e.g. Medicare and Medicaid) although there are many people who are uninsured.

In most countries, there are separate coding systems for delivery of stationary (inpatient) and ambulatory (outpatient) care. In either setting, a series of codes is used to classify diagnoses and clinical procedures performed. In stationary care, these are usually combined to describe an episode of care (e.g. DRG, which stands for Diagnosis Related Group) which forms the basis of the payment to the hospital for the patient's care relating to a procedure and associated hospital stay. Most of these systems aim to have a comprehensive code and associated tariffs to cover the total care package including any implants used. In some countries (e.g. Germany), there are some exceptions for implants including neurostimulators wherein some healthcare systems payments are made for the device implant on top of the payment made for the episode of care. The reimbursement amounts associated with each of the codes (episode of care and, where it is available, device) typically will be adjusted periodically based on actual procedure resource utilisation and product cost data. For each reimbursable device implant, the hospital will receive a total budget to cover the procedure and the device.

To our knowledge, hospitals in Germany are today using existing stationary (inpatient) reimbursement codes and associated tariffs for reimbursement related to ReActiv8. In addition, based on our review of the reimbursement climate (both internally and with external consultants), we believe hospitals in Switzerland and Austria can also use similar existing reimbursement codes for ReActiv8.

In some countries (e.g. the U.S.), purchase of medical supplies including medical devices is often done through a group purchasing organisation ("**GPO**") which negotiates on behalf of a group of customers with vendors to obtain best possible prices. We will engage with GPOs at the appropriate time to negotiate prices and payment for our products.

In some countries (e.g. Germany), prices are negotiated with individual hospitals, and may be subject to a time-limited contract. In other countries (e.g. France), prices for reimbursable implants are negotiated with the government. In some countries (e.g. Australia) purchase of medical supplies is

done via tender. We will apply for inclusion on lists of reimbursable implants and respond to tenders for our products wherever possible and appropriate. As our business develops, it is anticipated that we will expand our team of reimbursement specialists (consultants and/or employees) to help drive the reimbursement processes.

It is our objective to establish reimbursement and funding mechanisms to drive market access and adoption. Reimbursement is generally supported by data which demonstrates the value and cost effectiveness of a treatment. In addition to the ReActiv8-A Clinical Trial, which supported CE Marking of ReActiv8, relevant data is collected in the ReActiv8-A and ReActiv8-B Clinical Trials, and it is likely that we will initiate and support other clinical studies to gather additional data to support specific reimbursement applications and to provide input to health technology assessments ("**HTA**"). A HTA is generally conducted by an independent body such as the National Institute for Health and Care Excellence ("**NICE**") in the UK, which provides guidance on the use of new medical technologies. A positive HTA can help to obtain reimbursement and drive adoption of ReActiv8 into treatment guidelines. The Directors believe that the current lack of effective treatment alternatives and the high direct (medical) and indirect (societal) economic burden of Chronic Low Back Pain are strong motivators to find more effective ways to manage this problem.

We will use the available clinical and economic data to support efforts to include ReActiv8 in the clinical guidelines for treatment of Chronic Low Back Pain. Procedures, drugs and devices included in guidelines are generally adopted and reimbursed in most countries.

We expect that our strategy for the long-term maintenance of reimbursement levels will be supported by introducing product advances and generation of compelling clinical data.

In some countries, there may be a "private pay" market (i.e. private patients rather than hospitals), in which people may elect to pay for ReActiv8 from their own resources without the aid of insurance coverage. We will explore a private pay market, but do not presently believe that the private pay market would be a material contributor to the Group's long term revenues.

(f) **Market Development Strategy**

People with Chronic Low Back Pain seek treatment from many different medical practitioners, including general practitioners, rheumatologists, physical therapists, physical medicine and rehabilitation ("**PM&R**") specialists (sometimes known as physiatrists), interventional pain specialists, and spine surgeons (including orthopaedic spine surgeons and neurosurgeons). We are targeting medical practitioners who routinely see people with Chronic Low Back Pain as a large part of their clinical practice or who have a referral network of physicians who see these patients.

We categorise these physician customers into three groups, as illustrated below, based on their different approach to people with CLBP.

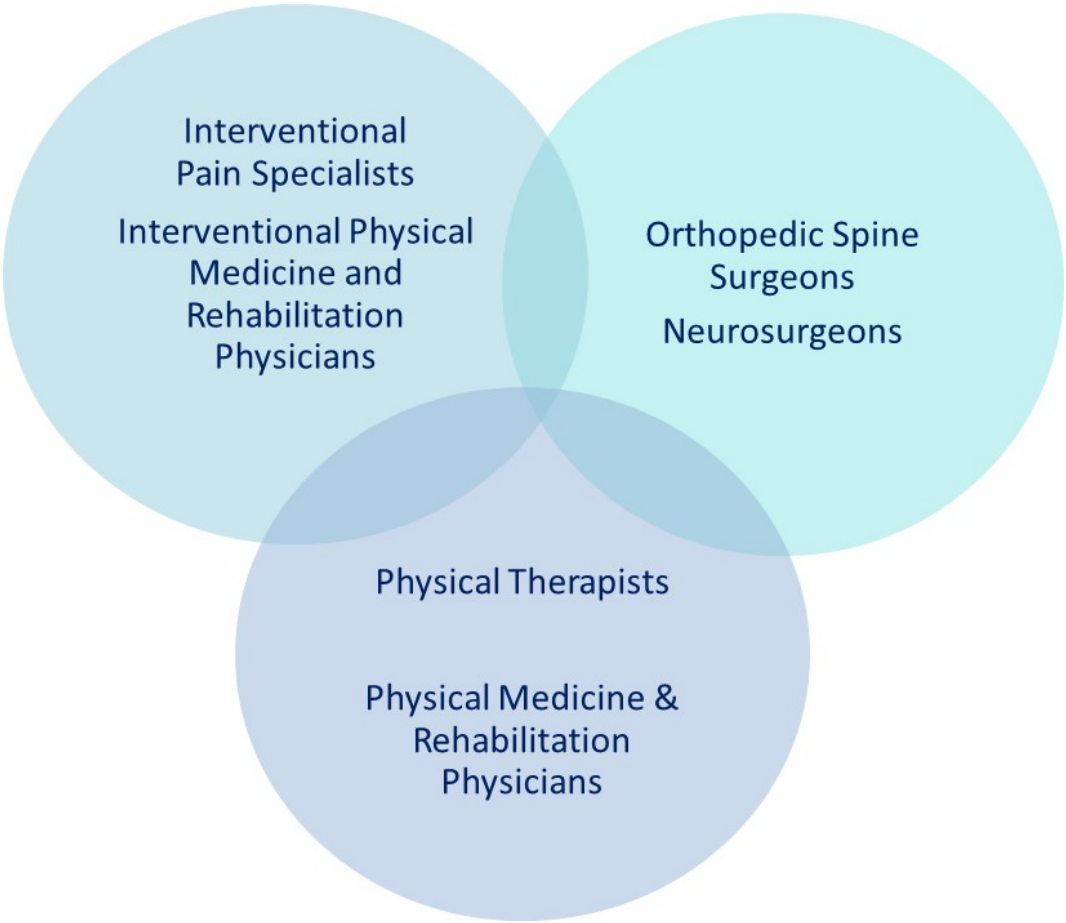
(i) ***Spine Surgeons (Orthopaedic Spine Surgeons and Neurosurgeons)*** have a diverse practice including trauma, cancers, deformities, and pain. The primary focus of the surgeon treating CLBP is to use surgical techniques and often a device to address a functional problem to help relieve pain. Neuropathic pain as a result of nerve root compression in the spine is commonly treated with surgery such as discectomy, and in some cases spinal fusion. Many people with Chronic Low Back Pain seek care from, or are referred to, spine surgeons, but in many cases these people are not candidates for spine surgery.

(ii) ***Physical Medicine and Rehabilitation (PM&R) Physicians (Physiatrists in the U.S., Physical and Rehabilitation Medicine in Europe)*** are physicians who are nerve, muscle, bone and brain experts who diagnose and treat injuries or illnesses that affect how people move, including Low Back Pain. The PM&R physician commonly works in close association with physical therapists. The goal of physical therapy and PM&R medicine is generally to help a patient perform exercises and movements to help address the root cause of a physical problem such as CLBP.

There are approximately 10,000 board certified physiatrists in the U.S. (Association of Academic Physiatrists, www.physiatry.org), of whom approximately 1,400 are also board certified as interventional pain specialists.[60] In the U.S., interventional PM&R physicians commonly perform nerve blocks and ablations, and may also implant SCSs, and therefore are likely to be easily trained to implant the ReActiv8.

(iii) ***Interventional Pain Physicians*** are usually a sub-specialty of anaesthesiology, neurology or PM&R. Most interventional pain specialists have dual board certification in their primary discipline and interventional pain. These pain physicians usually see those back pain patients who have exhausted all conventional treatment options or who have had failed back surgery, and the primary focus of a pain specialist is to help the patient cope with the pain, or provide pain treatments, without necessarily addressing the root cause of the problem.[61] An interventional pain physician will prescribe drugs including opioids, conduct nerve blocks, perform nerve ablation, and many will also implant SCSs, peripheral nerve stimulators, and intrathecal drug delivery systems.[62] The Company believes that the profile of European pain physicians is similar to that in the U.S.

The Company estimates that there are approximately 5,000 board certified interventional pain physicians in the U.S., who have a diverse practice, of which Chronic Low Back Pain is a major part. The Company believes that there are similar numbers of interventional pain physicians in Europe, although we are not aware of any consolidated database, as practice patterns differ between European countries.



[60] ABMS 2015-2016 Certification Statistics. Chicago. Retrieved from http://www.abmsdirectory.com/pdf/Resources_certification_statistics.pdf

[61] Manchikanti, L., et al. "The Evolution of Interventional Pain Management". Pain Physician. 2003; 6:485-494.

[62] Gupta, S., Gupta, M., Nath, S., & Hess, G. M. (2012). Survey of European pain medicine practice. Pain physician, 15(6), E983–94. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/23159983

Figure 7: Categorise Physician Customers

5.14 Target Medical Practitioner Customers for ReActiv8

There is a growing trend towards consolidation of these medical specialties into a multi-disciplinary spine centre ("**MDSC**") where patients receive coordinated care across specialities for their back pain issues.

We estimate that there are over approximately 700 MDSCs in the U.S., Europe and Australia. The MDSC approach is advantageous for the person with CLBP (many of whom self-refer), as it is more likely that referral will result in an encounter with the appropriate physician specialty for the clinical condition. The MDSC approach is also more advantageous for the physician members, as they are more likely to see patients who are appropriate for their clinical specialty. The MDSC approach is advantageous for us because MDSCs represent concentrated target customers, providing the opportunity for us to commercialise ReActiv8 with a modestly sized sales force targeting a relatively small number of high value physician customers. As mentioned, for any company commercialising a medical device for a new form of treatment, it is essential that medical practitioners are supportive of the approach, the product and the clinical use.

We have established relationships with key opinion leaders ("**KOLs**") in Europe, the U.S. and Australia, and have consulting contracts in place with many of these KOLs as clinical advisors. Our advisors are from many specialties including spine surgery, pain medicine, physical medicine and rehabilitation, physical therapy, and basic physiology.

In many cases, the implanting physician is not the primary contact for people suffering from Chronic Low Back Pain, and therefore it is important that our strategy also addresses engagement of referring clinicians. Referral pathways differ across markets, regions and sites but generally include physical medicine specialists (physiatrists), neurologists, rheumatologists, general practitioners and various non-physician clinicians such as physiotherapists, chiropractors and osteopaths. In some countries (e.g. the UK), patients with Chronic Low Back Pain are reviewed and referred by clinicians in specialised musculoskeletal clinics.

Good quality scientific data published by KOLs in peer-reviewed scientific journals and presented at national and international scientific congresses and symposia form the cornerstone of our strategy to drive adoption and referrals. We will encourage the publication of results from the various clinical and medical economic studies planned. In addition, further collaborative studies will be supported by us to add to the increasing body of evidence demonstrating the performance and value of ReActiv8.

We intend to provide or support local training programs (including those that can be certified to provide credits for continuing medical education ("**CME**")) and create tools for physicians and hospitals in support of patient selection, reimbursement and funding efforts and referral network development.

5.15 Sales and Distribution Channels

Medical devices are typically sold by a combination of direct sales force, typically for large sophisticated markets where the investment is justified on economic grounds, and third-party distributors, typically in smaller and financially, linguistically or politically more complicated markets.

We are using a direct sales force in the early stages of commercialisation in Germany because of the need to control and optimize clinical site selection, focus on referral networks, manage clinical outcomes and user experience, and retain learning inside the organisation. We intend to target markets we deem most important first, determined by market size and availability of reimbursement.

The timing of market entry to other markets will be determined primarily by the timing of regulatory approvals for those markets. We are focusing initially on key European markets such as Germany, Switzerland, and the UK. In some countries we may work with sales agents and/or distributors to gain market presence and penetration.

The U.S. is a key strategic market for us and the Company intends to prioritise resources to its U.S. entry strategy. Entry into the U.S. market will be subject to the granting of a PMA.

Pricing

The price of ReActiv8 is set by us. In practice, ReActiv8 pricing will be established in the context of reimbursement and/or funding mechanisms in each target market. We will endeavour to present compelling clinical efficacy and cost effectiveness data to individual hospitals or payers.

Once reimbursement is agreed and list prices are set, supply conditions will typically be negotiated between us and the purchasing institution (i.e. the hospital purchasing department) or a Hospital Buying Group (sometimes a Group Purchasing Organisation or GPO). This may in some cases be subject to a tender process.

Hospitals in many countries negotiate annual care contracts (procedure volumes and cost) with the payers. Our role will be to support the hospital in these negotiations, both of us benefiting from higher negotiated procedure volumes and reimbursements.

5.16 Our Intellectual Property

Patents, trademarks, and other intellectual property rights are important in the medical device industry in which we operate. We have implemented an intellectual property strategy with the objective of obtaining protection for key aspects of the technology embodied in ReActiv8 and certain methods of use. Our portfolio of patents, patent applications and other intellectual property related matters are managed in-house in collaboration with our U.S. and European patent counsel. We may, from time to time, file patent applications for inventions that may be of importance to our future business.

We may license or acquire rights to patents, patent applications or other intellectual property owned by third parties, academic partners or commercial companies which are of interest to us. Further, we may decide, from time to time, to license our intellectual property to other parties, for example, in exchange for cash, marketing collaboration, or other valuable consideration to us. As at the Latest Practicable Date, we have not in-licensed or out-licensed any of the patents or applications for inventions embodied in the ReActiv8 system.

We may pursue legal action to protect or defend our intellectual property rights including patent rights, trade secrets or know-how from infringement by others. Any such legal action could be costly and time consuming for us and we cannot be certain of the outcome. Invalidation of our key patents or proprietary rights or an unsuccessful outcome in such a lawsuit could have a material adverse effect on our financial condition, results of operations and/or impair our ability to prevent copying by potential competitors of inventions embodied in the ReActiv8 system.

Our policy is that our employees and contractors execute a propriety information and inventions assignment ("**PIIA"**) agreement, which protects proprietary information and assigns to us all inventions created by an employee during the term, and within the scope of, the employee's employment. Where possible and appropriate, agreements with third parties (e.g. consultants and vendors) contain language designed to protect our intellectual property and confidential information, and to provide for assignment to us of new inventions related to our business. There can be no assurance, however, that such agreements have been executed in all circumstances or that such agreements will not be breached or will provide meaningful protection for our trade secrets and proprietary information or that adequate remedies will be available in the event of an unauthorised use or disclosure of such information.

Patents

In general, we first file patent applications in the U.S., with corresponding applications filed later in other countries of interest to our business, e.g. Europe, Australia, Canada, and where deemed appropriate, China. The selection of countries in which to pursue such patent applications is based, in part, on our assessments of the importance of such future markets.

Securing a patent typically involves negotiations with the government authority that issues the patent, e.g., the U.S. Patent and Trademark Office ("**USPTO**") or the European Patent Office ("**EPO**"). In the course of such negotiation, the examining authority may initially reject the patent application claims, for example, based on its interpretation of prior art, and, from time to time, may issue a "final" ruling rejecting certain patent application claims. We, in conjunction with our patent attorneys in the pertinent jurisdiction, may modify or delete claims, or accept suggested claim amendments offered by the examining authority, to secure issuance of a patent. Alternatively, we may continue to pursue the same or similar patent application claims by way of a continuation application, a request for continued examination, or a divisional application, depending upon the applicable jurisdiction.

In general, patents describe an "apparatus" and/or a "method." European law prohibits the patenting of method of medical treatment claims, and, from time to time, we may seek to obtain method claims in a patent application in the U.S. without pursuing a corresponding patent application in Europe.

The term of a U.S. patent for an application filed on or after 7 June 1995 generally is 20 years from the earliest effective filing date claimed by the patent application, subject to patent term adjustment resulting from USPTO delay during examination, patent term extension as a result of regulatory delay in approval of a product embodying the patented invention, and payment of applicable maintenance fees. The actual protection afforded by a patent outside the U.S., which can vary from country to country, depends upon the type of patent, the scope of its coverage and the availability of legal remedies in the country. The maximum term for an Irish patent, in common with most jurisdictions in the EU, is 20 years.

Generally non-provisional patent applications are published about 18 months after the earliest claimed priority date. In some cases, the number of application claims filed in a patent application may include claims of various scope or directed to different inventions and, after interaction with the relevant patent examining authority, we may elect to file divisional applications, continuation applications, or other types of applications to pursue patents of varied scope.

On the Latest Practicable Date, our patent portfolio includes 13 patent "families". The U.S. patent number or application number is used for reference, and in certain cases, there are corresponding European patents or applications, as well as corresponding patents or applications in other jurisdictions. Our patent portfolio includes 15 granted U.S. patents, 54 patents outside the U.S. and 34 U.S. and foreign patent applications, including pending Patent Cooperation Treaty international applications.

Issued Patents

U.S. Patent No. 8,428,728

"Muscle Stimulator" – issued on 23 April 2013.

U.S. Patent No. 8,606,358

"Muscle Stimulator" (continuation) - issued on 10 December 2013

U.S. Patent No. 9,072,897

"Systems and Methods for Restoring Muscle Function to the Lumbar Spine" (continuation-in-part) – issued on 7 July 2015. A European regional patent – EP 2865412 B1 – has been granted in this patent family and validated in Belgium, Ireland, Italy, the Netherlands, France, Germany, Great Britain, Switzerland and Spain.

U.S. Patent No. 9,079,019

"Apparatus and Methods for Anchoring Electrode Leads for Use with Implantable Neuromuscular Electrical Stimulator" – issued on 14 July 2015. A Chinese patent – CN103889502 B – and an Australian patent – AU 2012290152 B2 - have been granted in this patent family. In addition, a

European regional patent – EP 2739344 B1 – has been granted in this patent family and validated in France, Germany and Great Britain.

U.S. Patent No. 9,108,053

"Apparatus and Methods for Rehabilitating a Muscle and Assessing Progress of Rehabilitation" – issued on 18 August 2015. A Chinese patent – CN 105263569 B – and an Australian patent – AU 2012355384 B2 – have been granted in this patent family. In addition, a European regional patent – EP 2794000 B1 – has been granted in this patent family and validated in Belgium, Ireland, Italy, the Netherlands, France, Germany, Great Britain and Switzerland.

U.S. Patent No. 9,186,501

"Systems and Methods for Implanting Electrode Leads for Use with Implantable Neuromuscular Electrical Stimulator" – issued on 17 November 2015. A Chinese patent – CN ZL201580029376.8 – has been granted in this patent family. In addition, a European regional patent – EP 3151911 B1 – has been granted in this patent family and validated in Belgium, Ireland, Italy, the Netherlands, France, Germany, Great Britain and Switzerland.

U.S. Patent No. 9,248,278

"Modular Stimulator for Treatment of Back Pain, Implantable RF Ablation System and Methods of Use" – issued on 2 February 2016. A Chinese patent – CN 103079633 B – a Canadian patent – CA 2792529 C – and an Australian patent – AU 2011224323 B2 – have been granted in this patent family. In addition, a European regional patent – EP 2544759 B1 – has been granted in this patent family and validated in Belgium, Ireland, Italy, the Netherlands, France, Germany, Great Britain and Switzerland.

U.S. Patent No. 9,474,906

"Systems and Methods for Restoring Muscle Function to the Lumbar Spine" (continuation) – issued on 25 October 2016.

U.S. Patent No. 9,861,811

"Electrical Stimulator for Treatment of Back Pain and Methods of Use" (continuation) - issued on 9 January 2018.

U.S. Patent No. 9,950,159

"Systems and Methods for Restoring Muscle Function to the Lumbar Spine and Kits for Implanting the Same" (continuation-in-part) – issued on 24 April 2018

U.S. Patent No. 9,981,122

"Systems and Methods for Implanting Electrode Leads for Use with Implantable Neuromuscular Electrical Stimulator" (divisional) – issued on 29 May 2018.

U.S. Patent No. 9,999,763

"Apparatus for Anchoring Electrode Leads Adjacent to Nervous Tissue" - issued on 19 June 2018. A Chinese patent – ZL201380031214.9 – and an Australian patent – AU 2013274422 B2 – have been granted in this patent family. In addition, a European regional patent – EP 2861295 B1 – has been granted in this patent family and validated in Belgium, Ireland, Italy, the Netherlands, France, Germany, Great Britain and Switzerland. A.

U.S. Patent No. 10,016,603

"Systems and Methods for Restoring Muscle Function to the Lumbar Spine" (continuation) – issued on 10 July 2018.

U.S. Patent No. 10,195,419

"Electrode Leads for Use with Implantable Neuromuscular Electrical Stimulator" (continuation-in-part) – issued on 5 February 2019.

U.S. Patent No. 10,327,810

"Systems and Methods for Enhanced Implantation of Electrode Leads Between Tissue Layers"– issued on 25 June 2019.

As we continue to innovate, new patent applications may be filed from time to time, to grow our intellectual property portfolio.

Trademarks

Trademarks have been registered for the company name (MAINSTAY) the design of the trademark for MAINSTAY MEDICAL, and the product name (REACTIV8) in the U.S. with the USPTO, in the EU as a Community Trade Mark (CTM), and in Australia. A third party filed an opposition to the ReActiv8 CTM application. We entered into a coexistence agreement with the third party for the Benelux territory whereby we agreed to limit distribution of goods under the ReActiv8 mark to the hospital sector.

Confidential Information and Trade Secrets

The success of our business depends, in part, on maintenance of confidential information and trade secrets, generally referred to as proprietary information. We have implemented procedures, where appropriate, to maintain the confidentiality of our proprietary information. Our policy is that employees and contractors enter into confidentiality agreements with us (PIIA mentioned above), and, where appropriate, that confidentiality agreements are executed before confidential information is revealed to any third party. Confidentiality provisions are also present in consulting agreements and supplier agreements in certain cases where the consultant or supplier may be exposed to confidential information.

Manufacturing IP

Manufacturing of our products is done by third party manufacturers using their own facilities; we have acquired no rights to any intellectual property of such third-party manufacturers.

5.17 Dividend Policy

The Company is at an early stage of its development and is concentrating all of its available capital resources on the commercialisation of the Group's only product ReActiv8. The Group has not paid dividends since it was established in 2008.

Under Irish company law, the Company may only make distributions to its Shareholders (including by way of dividend or, subject to some exceptions, by purchase or redemption of the Company's own shares) out of its profits available for that purpose. Such profits are, broadly, the Company's accumulated realised profits as far as not previously utilised by distribution or capitalisation less its accumulated realised losses. These requirements are independent of whether or not the Company has sufficient cash to pay a dividend or to fund such a redemption or repurchase. The Company may accrue an accumulated deficit on its profit and loss account. Until such time as that deficit is met by future profits or written off, the Company will be precluded from making any distributions.

In any event, the Company does not anticipate paying dividends for the foreseeable future. The Company intends to retain all available funds and future earnings for use in the development and commercialisation of its products and the expansion of its business.

5.18 Current Trading and Prospects

Since 31 December 2018, the date to which the last consolidated audited financial statements for the Group were prepared, the Group has continued to trade in line with the Board's expectations. Since 31 December 2018 the Group has seen significant progress with the announcement in April 2019 of a new tranche of €3.0 million (approximately $3.34 million) under the IPF Facility Agreement being made available to Mainstay, conditional upon Mainstay raising at least $10 million in gross proceeds from one or more offerings of equity prior to June 30, 2019. On 26 June 2019 we announced that the Company had entered into an amendment to its agreement with IPF to extend this deadline to July 31, 2019. On 29 July 2019 we completed the 2019 Placing, raising gross proceeds of €13.9 million and announced the drawdown of €3 million in additional debt from the new tranche of the existing debt facility. Furthermore, the Group has submitted a Pre-Market Approval Application to the U.S. Food and Drug Administration (FDA) and continues to progress commercial validation activities in Europe.

PART 6
DIRECTORS, SENIOR MANAGEMENT AND CORPORATE GOVERNANCE

6.1 DIRECTORS

The Directors and their principal functions within the Group, are set out below. The business address of each of the Directors (in such capacity) is Mainstay Medical International plc, 77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, Dublin 2, D02 VK60.

On the date of this document, the Board comprises the Chairman, one Executive Director and five additional Non-Executive Directors. The Chairman and two of the other Non-Executive Directors are considered by the Board to be independent Directors. Mr. Nael Kassar retired as a Director at the 2019 AGM.

The full names of the Directors, their nationalities, ages and positions are as follows:

Name	Age	Position
Oern Stuge MD (Norwegian)	64	*Non-Executive Independent Chairman*
Jason Hannon (American)	47	*Executive Director / Chief Executive Officer (the "**CEO**")*
David Brabazon (Irish)	49	*Non-Executive Independent Director*
Greg Garfield (American)	56	*Non-Executive Director*
Antoine Papiernik (French)	53	*Non-Executive Director*
James Reinstein (American)	55	*Non-Executive Independent Director*
Dan Sachs MD (American)	54	*Non-Executive Director*

Brief biographical details of each Director follow:

Oern Stuge MD

Dr. Oern R. Stuge is the independent non-executive Chairman of the Board. He is an international executive with 30 years of experience in the life science sector. Dr Stuge is the owner of ORSCO Life Sciences AG through which he holds several executive & non-executive board memberships & advisory roles.

During the last 8 years, Dr. Stuge has participated in Enterprise Development of different companies and successfully sold/listed 7 companies.

Prior to founding ORSCO, Dr. Stuge worked for 12 years for Medtronic, Inc. in different roles including Senior Vice President ("**SVP**") & President Europe & Central Asia, and SVP & President Cardiac Surgery. He was a member of the Medtronic Executive Committee & Operating Committee. Dr. Stuge led a successful transformation of Medtronic's Cardiac Surgery business. Under his leadership, Medtronic founded the Structural Heart Division and launched the first commercially available percutaneous heart valve in the world. Prior to this, he led business acceleration of Medtronic's neurological and cardiovascular business in Europe, Middle East & Africa.

Dr. Stuge earned an MD from University of Oslo, an MBA from IMD, Switzerland and an INSEAD Certificate of Corporate Governance.

Jason Hannon

Mr. Jason Hannon joined Mainstay Medical as Chief Executive Officer and as a Director in October 2017. Mr. Hannon has extensive experience in the medical devices industry, particularly in the areas most critical to the future success of Mainstay: commercialization of new products, penetration of new markets, product innovation, strategic and financial planning, raising capital, regulatory and

clinical management, and the building of a high-performance culture. Mr. Hannon previously served as President and Chief Operating Officer of NuVasive (NASDAQ:NUVA), a leading medical device company focused on transforming spine surgery with minimally disruptive, procedurally-integrated solutions. During his 12 years at the company, he helped grow NuVasive from a small U.S.-centric business with a handful of products into the third largest spine company in the world.

Mr. Hannon has a JD degree from Stanford University and a BA degree from the University of California, Berkeley.

David Brabazon

Mr. David Brabazon is a Non-Executive Director of Mainstay. He was a co-founder, Chief Financial Officer and board member of Adapt Pharma Limited from 2013 through to May 2019. Adapt Pharma Limited was a U.S. focused speciality pharmaceuticals business which was acquired by Emergent BioSolutions Inc. in October 2018. Mr. Brabazon previously was a co-founder and Chief Financial Officer of Azur Pharma plc, which merged with Jazz Pharmaceuticals plc in early 2012. Mr. Brabazon continued to serve in the merged business as Senior Vice President of Finance and Company Secretary until late 2012. Prior to Azur Pharma, Mr. Brabazon served as Vice President of Finance and Group Financial Controller of Elan Corporation plc.

Mr. Brabazon is a chartered accountant and holds a Masters of Accounting degree from University College Dublin, Ireland and a Master of Business Administration degree from INSEAD, France. David serves as a director of Headway (Ireland) Limited which provides support and services to people affected by brain injury.

Greg Garfield

Mr. Greg Garfield is a Non-Executive Director of the Company and is Head–Medical Technologies Division of KCK-U.S., Inc. Mr. Garfield serves as a director on the boards of numerous private and public companies in the healthcare industry. From 2006 to 2011, he had various roles at Acclarent, Inc., a medical technology company, including Chief Operating Officer and General Counsel. Acclarent, Inc. was acquired by Johnson and Johnson at a valuation of approximately $800 million cash in January 2010. From 1995 to 2006, Mr. Garfield had various roles at Guidant Corporation, a medical technology company, including Vice President of Business Development and General Counsel. Guidant was acquired by Boston Scientific Corporation in 2006 at a valuation of approximately $27 billion in cash and stock. Mr. Garfield has a Bachelor of Science degree from California Polytechnic State University and a JD degree from McGeorge School of Law, University of the Pacific.

Antoine Papiernik

Antoine Papiernik is a Managing Partner at Sofinnova Partners, which he joined in 1997.

Mr. Papiernik has been an initial investor and active board member in public companies like Actelion, ProQR, Shockwave Medical, NovusPharma (then sold to CTI), Movetis (then sold to Shire), Mainstay, Pixium Vision and Stentys, which went public respectively on the Zürich stock exchange, the NASDAQ, the Milan Nuovo Mercato, the Belgium Stock Exchange, and Euronext Paris, in Cotherix (initially NASDAQ listed, then sold to Actelion), CoreValve (sold to Medtronic), Fovea (sold to Sanofi Aventis), Ethical Oncology Science (EOS, sold to Clovis Oncology), and Recor Medical (sold to Otsuka). He has also invested in and is a board member of private companies Reflexion Medical, Tissium, SafeHeal, Mnemo Therapeutics, Ablacare and Rgenix. Antoine has an MBA from the Wharton School of Business, University of Pennsylvania. In 2012 and 2011 Antoine was selected by Forbes for its "Midas List" of the world's top venture capital investors. Antoine is one of the only Europeans on the list, and one of the few life science investors as well.

James Reinstein

James A. Reinstein is a Non-Executive Director of the Company with more than 25 years of medical device experience. Mr. Reinstein is a General Partner at Palo Alto Medtech Advisors (PAMTA), an

advisory firm assisting investment firms assess opportunities within the medical device space. PAMTA also advises medical device companies with strategic planning, funding and all other aspects to build and grow a business. He was the President, CEO and board member of Cutera, Inc. a NASDAQ listed global device company at the forefront of the medical aesthetics space until January 2019. Just prior to Cutera, he was the President and CEO of Drawbridge Health, a joint venture of GE Healthcare and GE Venture. Previous to Drawbridge, Mr. Reinstein was the President and CEO of Aptus Endosystems Inc., where he led the sale of the company to Medtronic for over $100 million. Prior to joining Aptus, Mr. Reinstein served as Executive Vice-President and Chief Commercial Officer at Cyberonics, a neuromodulation company focused on helping patients with epilepsy, depression and chronic heart failure. Mr. Reinstein spent 17 years at Boston Scientific in various roles and functions including business development, marketing and general management. Most of his career at Boston Scientific was spent working and living in Europe, Asia and Latin America.

Mr. Reinstein was employed by Procter and Gamble after graduating with a BA in Marketing from the Terry College of Business at the University of Georgia in Athens. He also completed post graduate studies in management at INSEAD Business School in Fontainebleau, France. Mr. Reinstein is a General Partner at Palo Alto Medtech Advisors, and also sits on the board of directors of Pixium Vision, a publicly traded company based in Paris, France, and Monteris Medical, a privately held company located in the United States.

Dan Sachs MD

Dr. Dan Sachs is a Non-Executive Director and a founder of Mainstay. Dr. Sachs is also the founder of KSpine Inc., Respicardia, Inc., and Amphora Medical, Inc., all venture-backed medical device companies. Dr. Sachs serves as Co-Director of the Innovation Fellows Program within the Institute for Engineering in Medicine at the University of Minnesota, and on the Oversight Committee of the Coulter Translational Research Program at the University of Michigan. Dr. Sachs was previously a venture capital investor with Investor Growth Capital and Spray Venture Partners, for which he served on the board of directors of Neuronetics (STIM), CoTherix (acquired), and CHF Solutions, (acquired).

Dr. Sachs previously served as Instructor in Medicine on the faculty of Harvard Medical School in the Division of Emergency Medicine. Dr. Sachs earned an MD from the University of Michigan, and an MBA from Harvard Business School.

6.2 SENIOR MANAGERS

In addition to the Chief Executive Officer, the current members of the senior executive management team with responsibility for day-to-day management of the Group's business are set out below. The business address of each of the Senior Managers (in such capacity) is Mainstay Medical International plc, 77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, Dublin 2, D02 VK60 although the physical address (including country of residence) may be different.

Jason Hannon (Chief Executive Officer) See paragraph 6.1 of this Part 6 (*Directors, Senior Management and Corporate Governance*).

Prashant Rawat (Chief Operating Officer) (Age 46) has worked more than 20 years in AIMDs (Guidant Corporation, Boston Scientific Corporation, CVRx Inc., CSF Therapeutics Inc.) and has a broad ranging experience in managing global engineering teams and achieving international regulatory product approval. Mr Rawat is responsible for all R&D activities, coordination of manufacturing and distribution, clinical operations and the quality management system.

Mr Rawat's responsibilities at the Group include:

- Leading the research and product development function (including the development of the therapy and medical system) and directing the preclinical research;
- Directing clinical operations (including clinical site preparation for clinical studies) and managing the internal team and contract clinical research organisations;

- Leading the quality department to create, maintain and ensure compliance with a suitable quality system;
- Development and expansion of the Group's intellectual property portfolio;
- Overseeing submissions for clinical studies and product commercialisation approval to regulatory authorities in various geographies; and
- Managing product manufacturing and distribution.

Mr Rawat has extensive international experience in the medical device industry including building internal R&D teams and relationships with foreign institutions and companies for joint research, product development and manufacturing. He also has broad experience in guiding new technology through the clinical and regulatory process in Europe, Asia and the U.S. Whilst acting in his capacity as a Technology Fellow and Manager of the Advanced Technology Group at Boston Scientific Corporation, he was responsible for the development of the world's first implantable long-range telemetry system. Since then, he has worked as an advisor to CVRx Inc., a private neurostimulation company developing an implantable device for the treatment of high blood pressure, and was Vice President of Research and Development at CSF Therapeutics, a venture capital-backed spinoff from the Cleveland Clinic, which was developing a novel invasive therapy to improve blood flow in stroke and traumatic brain injury victims.

Mr Rawat has a Bachelor of Engineering in Electronics Engineering and Telecommunications from the Maharaja Sayajirao University, Gujarat, India, and a Master of Science in Electrical Engineering and Applied Physics from Case Western Reserve University, Ohio, U.S. He is the inventor on over 25 patents and patent applications.

Matt Onaitis (Chief Financial Officer) (Age 48) has overall responsibility for the Group's financial performance, planning, reporting and analysis, as well as the strategic planning, business development, investor relations, legal, human resources and facilities functions, and he also serves as the Company Secretary. Mr. Onaitis has worked with dynamic healthcare businesses for 20 years, ranging from global multinationals including Biogen Idec and Elan Pharmaceuticals, to innovative specialty pharmaceutical companies such as Ignyta, Trius Therapeutics, and Somaxon Pharmaceuticals. He most recently served as Chief Financial Officer of Cidara Therapeutics (NASDAQ: CDTX), a biotechnology company developing novel anti-infectives including immunotherapies.

His experience includes building finance teams, leading numerous public and private financings, mergers and acquisitions and strategic collaborations, and the management of finance, accounting, business development, manufacturing, legal, and human resource functions.

Mr. Onaitis holds a J.D. from Stanford Law School and a B.S. in mechanical engineering from Carnegie Mellon University.

6.3 CONFLICTS OF INTEREST

Pursuant to the KCK Director Nomination Agreement, the Company agreed that KCK would have the right to nominate two additional Non-Executive Directors to the Board, immediately following completion of the 2016 Placing. Those Directors were Greg Garfield and Nael Karim Kassar. Except for the KCK Director Nomination Agreement, there are no company arrangements or understandings with major shareholders, members, suppliers or others pursuant to which any directors or executive officers were appointed.

There are no potential conflicts of interest between any of the Directors' or Senior Managers' duties to the Group and their respective private interests and any other duties. Senior Managers are entitled to and may provide consulting or other services to other companies and parties, subject to non-compete and other contractual arrangements as may apply to each individual. No Director or Senior Manager has a family relationship with any other Director or Senior Manager of the Company.

6.4 INTERESTS OF THE DIRECTORS AND SENIOR MANAGERS IN SHARE CAPITAL

(a) In addition to their interests in Ordinary Shares through their holdings of Share Options and/or RSUs (which holdings are detailed at sub-paragraph (c) below), the beneficial interests of the Directors (except for Antoine Papiernik, whose interests are disclosed at sub-paragraph (b) below) and the Senior Managers in the issued share capital of the Company as at the Latest Practicable Date are as follows:

Director/Senior Manager	**Number of Ordinary Shares**	**Percentage of issued ordinary share capital**
Oern Stuge MD	-	-
Jason Hannon	30,000	0.22%
Dan Sachs MD	515,000	3.84%
David Brabazon	212,828	1.59%
James Reinstein	-	-
Matt Onaitis	-	-
Greg Garfield	2,912	0.02%
Prashant Rawat	-	-

(b) The interests of Sofinnova Capital VI FCPR in the issued share capital of the Company as at the Latest Practicable Date are disclosed at paragraph 9.5 of Part 9 (*Additional Information*) of this document. Antoine Papiernik holds no interest in the issued share capital of the Company other than the interests that he is deemed to hold in the Company by virtue of the interests that he holds in Sofinnova Capital VI FCPR. The interests of Fountain Healthcare Partners Fund 1 L.P. and Fountain Healthcare Partners Fund 3 L.P. in the issued share capital of the Company are disclosed at paragraph 9.5 of Part 9 (*Additional Information*). The interests of KCK Limited in the issued share capital of the Company as at the Latest Practicable Date are disclosed at paragraph 9.5 of Part 9 (*Additional Information*) of this document.

(c) Details of Share Options and/or RSUs held by the Directors and Senior Managers are not included in the interests of the Directors and Senior Managers in the table at sub-paragraph (a) above. Certain of the Directors and Senior Managers also have options over Ordinary Shares and/or RSUs under the Employee Incentive Plan. As at the Latest Practicable Date, the Directors and Senior Managers held the following options over Ordinary Shares and/or RSUs:

Option Holder	*Deemed date of grant*	*No. of Ordinary Shares under option (Note 1)*	*Exercise price per ordinary share ($/€)*	*Expiry date*
Oern Stuge	23 January 2013	55,014	$1.00	10 years from vesting
Oern Stuge	13 December 2016	17,000	€15.50	10 years from vesting
Jason Hannon	13 August 2019	464,000	€3.76	10 years from vesting
Jason Hannon	23 March 2018	118,628	€16.90	10 years from vesting
Jason Hannon	6 September 2017	401,862	€14.85	10 years from vesting
David Brabazon	5 December 2013	18,427	$1.00	10 years from vesting
David Brabazon	13 December 2016	5,700	€15.50	10 years from vesting
James Reinstein	2 September 2015	20,000	€16.87	10 years from vesting

Option Holder	*Deemed date of grant*	*No. of Ordinary Shares under option (Note 1)*	*Exercise price per ordinary share ($/€)*	*Expiry date*
James Reinstein	13 December 2016	6,200	€15.50	10 years from vesting
Prashant Rawat	27 July 2010	22,500	$0.80	10 years from grant
Prashant Rawat	23 January 2013	27,500	$1.00	10 years from vesting
Prashant Rawat	4 February 2014	15,000	$1.00	10 years from vesting
Prashant Rawat	8 January 2015	10,000	€14.90	10 years from vesting
Prashant Rawat	17 December 2015	18,000	€17.95	10 years from vesting
Prashant Rawat	13 December 2016	25,000	€15.50	10 years from vesting
Prashant Rawat	23 March 2018	25,000	€16.90	10 years from vesting
Prashant Rawat	13 August 2019	110,000	€3.76	10 years from vesting
Matt Onaitis	21 August 2018	100,000	€15.00	10 years from vesting
Matt Onaitis	13 August 2019	90,000	€3.76	10 years from vesting

RSU Holder	*Deemed date of grant*	*No. of RSUs (Note 1)*	*Settlement date*
Jason Hannon	1 February 2019	120,000	1 January 2021
Prashant Rawat	1 February 2019	40,000	1 January 2021
Matt Onaitis	1 February 2019	40,000	1 January 2021

Note (1): As at the Latest Practicable Date, the total number of Ordinary Shares under option is 1,549,831 or in respect of which RSUs have been granted to Directors and Senior Managers is 200,000.

(d) Other than as set out in this paragraph 6.4 of this Part 6 (*Directors, Senior Management and Corporate Governance*), as at the Latest Practicable Date, no Director or Senior Manager (nor any person connected with a Director or Senior Manager, within the meaning of Section 220 of the Companies Act 2014) has any interest whether beneficial or non-beneficial in the issued share capital of the Company or any of its subsidiaries.

6.5 DIRECTORS' AND SENIOR MANAGERS REMUNERATION

Directors' Remuneration

The following table shows the amount of remuneration paid (including any contingent or deferred compensation) and benefits in kind granted to the Directors by the Group for services rendered in all capacities to the Group in respect of the year ended 31 December 2018:

2018:	**Directors' Fees**	**Salary**	**Annual Incentive**	**Benefits in Kind**	**Total**
Executive Directors					
Jason Hannon (Note 1 & 2)	$40,000	$473,474	-	$83,167	$596,641
Non-Executive Directors					
Oern Stuge MD	$106,292	-	-	-	$106,292
David Brabazon	$61,417	-	-	-	$61,417

Greg Garfield	-	-	-	-	-
Antoine Papiernik	-	-	-	-	-
James A. Reinstein	$61,417	-	-	-	$61,417
Manus Rogan PhD (Note 3)	-	-	-	-	-
Dan Sachs MD	-	-	-	-	-

Notes:

(1) Jason Hannon was appointed to the Board on 9 October 2017. The terms of Jason Hannon's appointment letter include an annual fee of $40,000 as a Director. For more information, see paragraph 6.7 of this Part 6 (*Directors, Senior Management and Corporate Governance*).
(2) Jason Hannon was granted 401,862 options over Ordinary Shares on 6 September 2017 and was granted 118,628 options over Ordinary Shares on 23 March 2018.
(3) Manus Rogan PhD retired as a Director on 24 September 2018.

The aggregate amount of remuneration paid (including any contingent or deferred compensation) and benefits in kind granted to Directors who held office during the year ended 31 December 2018 for services in all capacities to the Company and its subsidiaries was U.S. $825,767. Information on the Share Options and RSUs granted to Directors during 2018 are set out in paragraph 6.4(c) of this Part 6 (*Directors, Senior Management and Corporate Governance*).

Senior Managers' Remuneration

The aggregate amount of remuneration paid (including any contingent or deferred compensation) and benefits in kind granted to Senior Managers, excluding amounts disclosed above for Directors, who held office during the year ended 31 December 2018 for services in all capacities to the Company and its subsidiaries was U.S. $592,487. Information on the Share Options and RSUs granted to Senior Managers during 2018 are set out in paragraph 6.4(c) of this Part 6 *(Directors, Senior Management and Corporate Governance)*.

6.6 EMPLOYEE INCENTIVE PLAN

The Employee Incentive Plan was adopted by the Company on 1 April 2014 and amended on a number of occasions, most recently on 10 July 2019. The following is a summary of the key terms of the Employee Incentive Plan:

Eligibility for Participation

The Board may at its sole discretion and from time to time determine which employees and any other persons (including consultants and/or customers and/or directors of the Company or its subsidiaries) are to be offered Awards. The Employee Incentive Plan shall be administered by the Board such that all determinations and other decisions with respect to the Employee Incentive Plan shall be made at the sole discretion of the Board.

Grant of Awards

The Employee Incentive Plan shall be effective on the date on which it is adopted by the Board and Awards may be granted under the Employee Incentive Plan at any time until the termination of the Employee Incentive Plan.

Duration of Awards

Awards granted under the Employee Incentive Plan will be valid for a maximum term of ten years measured from the date of vesting, or such shorter term as may be determined by the Board on the date of the grant.

Exercise Price

The exercise price payable for each Ordinary Share subject to a Share Option shall be determined by the Board but shall not be less than the greater of (i) the market value of a share on the date of grant and (ii) the nominal value of a share. No consideration will be payable in connection with the grant or

settlement of an RSU, provided always that where any Ordinary Shares are issued pursuant to an RSU, the nominal value of each newly issued Ordinary Share shall be fully paid up.

Vesting of Awards

No Award will be exercisable (in the case of a Share Option) or settled (in the case of an RSU) until it has vested and the Board may specify the vesting conditions for each Award at the date of grant based on either the passage of time or the achievement of performance objectives. The Board may, at its sole discretion, permit a participant to exercise an Award which has not otherwise become exercisable or (as the case may be) permit an RSU to settle in circumstances where it has not otherwise become capable of settlement, in each case in accordance with the vesting conditions established for such Award.

Share Limits

Subject to variation due to changes in the capital structure, the number of Ordinary Shares in respect of which Awards may be granted shall not exceed 3,829,734 Ordinary Shares in accordance with the Employee Incentive Plan. At the Latest Practicable date, 5,562 Awards in respect of Ordinary Shares have been exercised and converted or settled (in the case of an RSU) into Ordinary Shares.

Leavers

Death

On the death of an Award holder, the Award holder's unvested Share Options or unsettled RSUs will lapse. However, the deceased Award holder's vested Share Options will remain exercisable by his legal personal representative for a period of 12 months following the Share Option holder's death (subject to any earlier expiration of the options). Each vested RSU held by the Award holder as at the date of his death shall be issued to the Award holder's legal personal representatives in that capacity.

Retirement

On the retirement of an Award holder his unvested Awards will lapse. However, if the holder's Share Options have vested by the time the Share Option holder retires, then, the vested Share Options will remain exercisable at any time for the following 12 months (subject to any earlier expiration of the options). Each vested RSU held by the Award holder as of his cessation date shall settle in the manner provided for in the Employee Incentive Plan.

Cessation of Employment

If an Award holder's employment is terminated for cause (termination of employment without notice) then his/her Awards shall lapse but the Board may, at its sole discretion, determine that any vested Award shall remain exercisable/capable of settlement after the date of cessation of the Award holder's employment in accordance with such conditions as the Board may specify.

In circumstances where an Award holder ceases to be an employee other than those mentioned above, the Award holder's unvested Awards will lapse. However, if the holder's Share Options have vested prior to the termination of the Award holder's employment then, the vested Share Options will remain exercisable at any time for the following 12 months (subject to any earlier expiration of the Share Options). Each vested RSU held by the Award holder as of his cessation date shall settle in the manner provided for in the Employee Incentive Plan.

Other provisions

On a change in control, corporate reorganisation or proposed initial public offering of shares of the Company, the Board may, at its sole discretion, determine what action the Board may take with respect to vested or unvested Awards. The Board may, for instance, determine that some or all of the unvested Awards are to vest immediately or at a later date and may, at its sole discretion, impose any conditions on any such vesting.

In the event of a reconstruction or amalgamation of the Company involving a material change in the nature of the shares comprised in any Award or, in the event of a winding-up of the Company, a Share Option holder may exercise any vested Share Option, subject to any conditions or limitations as the Board may, at its discretion, impose. Any vested RSUs shall be settled by the Company as soon as reasonably practicable thereafter.

If the Company varies its capital structure or distributes capital profits or capital reserves, the Board may decide to (i) adjust the maximum aggregate number of shares reserved for issuance under the Employee Incentive Plan, (ii) adjust the number of shares subject to any Award or to be allotted following exercise of any Share Option or the settlement of any RSU, and (iii) adjust the exercise price applicable to any Share Option.

As a condition precedent to the allotment of shares upon the exercise of a Share Option or settlement of an RSU, the Board shall be entitled to require the participant to become a party to any shareholder's agreement between the Company and its shareholders by executing a deed of adherence.

The Board shall have complete and exclusive authority to vary, amend or revoke any rules of the Employee Incentive Plan provided always that no such alteration, amendment or revocation shall increase the amount payable by any Award holder or otherwise impose more onerous obligations on any Award holder in respect of the exercise/settlement of an Award which has already been granted.

The Employee Incentive Plan shall terminate on the tenth anniversary of its adoption.

6.7 CHIEF EXECUTIVE OFFICER'S SERVICE AGREEMENT AND NON-EXECUTIVE DIRECTORS LETTERS OF APPOINTMENT

(a) Chief Executive Officer

The Chief Executive Officer of the Group, Jason Hannon, is employed under a service agreement with Mainstay Medical B.V. The Company announced Mr. Hannon's appointment as Chief Executive Officer on 5 September 2017, with effect from 9 October 2017. During the period from 9 October 2017 to 4 December 2017 (the effective date of the service agreement), Mr. Hannon was retained by the Company as Chief Executive Officer under interim arrangements, separate from the service agreement.

(i) Director Appointment Letter

Mr. Hannon was also appointed as an executive Director on 9 October 2017 under a letter of appointment with the Company. As an executive Director, Mr. Hannon is entitled to a fee of $40,000 per annum and is eligible for an annual bonus up to 50% of the annual fee based upon the achievement of goals and objectives determined by the Board in consultation with Mr. Hannon.

(ii) Benefits

Under the terms of his service agreement, Mr. Hannon is entitled to receive a base salary of $460,000 per annum and is eligible for an annual cash bonus up to 50% of his base salary, based upon the achievement of goals and objectives determined by the Board in consultation with Mr. Hannon.

Mr. Hannon is entitled to certain benefits including, inter alia, health insurance and the reimbursement of the cost of personal tax advice, immigration law advice and family education up to certain agreed amounts.

Mr. Hannon is entitled to participate in the Employee Incentive Plan.

For details of the number of Share Options granted to Mr. Hannon, see paragraph 6.4(c) of this Part 6.

(iii) Termination Provisions

MMBV may terminate Mr. Hannon's employment without cause (as that term is defined in the service agreement) at any time by providing written notice, which termination shall have immediate effect. In the event that MMBV terminates without cause, Mr. Hannon will be entitled to:

- base salary and benefits that would otherwise be payable to him under the service agreement through the date of his termination from employment;
- bonus for the fiscal year in which termination occurs, pro-rated for the portion of such year which has elapsed before such termination, based on and subject to achievement of (or degree of proportional progress toward achievement of) the applicable goals and objectives prior to termination in the relevant year, as reasonably determined by the Board; and
- continuation of his full base salary through the first anniversary of the date of termination, less standard deductions for all appropriate employment-related taxes and deductions. Provided, if during such continuation year, Mr. Hannon has actual full-time employment with another employer, the base salary amount payable shall be reduced by the gross cash compensation actually paid by such other employer to Mr. Hannon during such same standard pay period.

MMBV can immediately terminate with cause (as that term is defined in the service agreement), at any time (subject to applicable notice and/or cure requirements). In the event of a termination for cause, Mr. Hannon is entitled to base salary through the date of termination.

Mr. Hannon may terminate without good reason (as that term is defined in the service agreement) at any time by providing not less than 6 months' written notice (the "**Notice Period**"). In the event that he terminates without good reason, Mr. Hannon will be entitled to base salary and benefits that would otherwise be payable to him under the service agreement through the Notice Period.

Mr. Hannon may terminate his employment at any time by a written resignation for good reason (as that term is defined in the service agreement), subject to any applicable notice and /or cure requirements, which termination shall have immediate effect. In the event that he terminates for good reason, Mr. Hannon will be entitled to:

- base salary and benefits that would otherwise be payable to him under the service agreement through the date of his termination from employment;
- bonus for the fiscal year in which termination occurs, pro-rated for the portion of such year which has elapsed before such termination, based on and subject to achievement of (or degree of proportional progress toward achievement of) the applicable goals and objectives prior to termination in the relevant year, as reasonably determined by the Board; and
- continuation of his full base salary through the first anniversary of the date of termination, less standard deductions for all appropriate employment-related taxes and deductions. Provided, if during such continuation year, Mr. Hannon has actual full-time employment with another employer, the base salary amount payable shall be reduced by the gross cash compensation actually paid by such other employer to Mr. Hannon during such same standard pay period.

(iv) Restrictive Covenants

Mr. Hannon entered into an employee proprietary information and inventions agreement ("**PIIA**") with MMBV, effective upon commencement of employment. The PIIA sets out certain procedures and understandings in respect of intellectual property rights developed or created in the course of employment, as well as certain non-compete and non-solicit obligations of Mr. Hannon during the course of his employment and for a period of 12 consecutive months from the date of termination of employment for any reason (other than a voluntary termination without good reason (as that term is defined in the service agreement).

(v) Change in Control

MMBV shall ensure that, if all outstanding Share Options held by Mr. Hannon would terminate upon a Change-in-Control (as defined below), all then unvested Share Options held by him shall immediately vest immediately prior to a Change-in-Control. Also, MMBV shall ensure that, after a Change-in-Control where Share Options do not terminate upon a Change-in-Control, if (A) Mr. Hannon's employment is terminated by MMBV for reasons other than for cause (as that term is defined in the service agreement) or (B) Mr. Hannon terminates his employment for good reason (as that term is defined in the service agreement), or (C) Mr. Hannon continues to be employed at the six (6) month anniversary following such Change-in-Control, all then unvested Share Options held by Mr. Hannon shall immediately vest.

"Change of Control" means: (i) a merger, reorganisation, consolidation, business combination or similar transaction (any of the foregoing, a "**Merger**") as a result of which the persons who were the respective beneficial owners of the outstanding capital stock of the Company immediately before such Merger are not expected to beneficially own (in respect thereof), immediately after such Merger, directly or indirectly, more than 50% of the combined voting power of the then outstanding voting securities of the corporation or other entity resulting from such Merger, or the parent entity controlling such corporation or other entity, if applicable; provided, however, that customary venture capital or other such bona fide financing shall not result in a Change-in-Control; or (ii) the sale or other disposition of all or substantially all of the assets of the Company.

(b) **Non-Executive Directors**

Each of the Non-Executive Directors was appointed under a letter of appointment with the Company.

At the date of this document, there are six Non-Executive Directors. The terms of the Non-Executive Directors' letters of appointment can be summarised as follows:

Name	Title	Appointment date	Fee per annum	Initial term of appointment	Notice period
Oern Stuge MD (Note 1, 2 and 4)	Non-Executive Independent Chairman	3 April 2014	CHF103,500	12 Months	1 Month
Antoine Papiernik	Non-Executive Director	3 April 2014	NIL	12 Months	1 Month
Dan Sachs MD	Non-Executive Director	3 April 2014	NIL	12 Months	1 Month
David Brabazon (Note 3 and 4)	Non-Executive Independent Director	3 April 2014	€51,750	12 Months	1 Month
James Reinstein (Note 4)	Non-Executive Independent Director	22 June 2015	€51,750	12 Months	1 Month
Greg Garfield	Non-Executive Director	17 June 2016	NIL	Not applicable	Not applicable

Note:

(1) The Group made payments under a consultancy agreement to ORSCO Life Sciences AG (the "Consultancy Agreement"), a Swiss company which is controlled by Oern Stuge. Details of payment to ORSCO Life Sciences AG are included in the related party transaction notes to the financial statements for the financial year ended 31 December 2015 contained in the company's annual report for the financial year ended 31 December 2015 which are incorporated by reference into this document. Mainstay Medical Limited and ORSCO Life Sciences AG terminated the Consultancy Agreement with effect from 31 December 2015.

(2) On 1 January 2016, the Company entered into a new agreement with Oern Stuge with a fee per annum of CHF100,000.

(3) With effect from 21 October 2015, the Company revised the terms of David Brabazon's appointment letter and the fee per annum was revised to €40,000 Directors Fees per annum plus an additional €10,000 per annum for each Committee Chairman position held.

(4) With effect from 1 January 2017, the fees per annum paid to Oern Stuge, David Brabazon and James Reinstein were increased by 3.5%.

Termination provisions

The appointment of each Non-Executive Director will terminate without any entitlement to compensation if he is not elected or re-elected at an annual general meeting of the Company at which he retires and offers himself for election or re-election, he is required to vacate office for any reason pursuant to any of the provisions of the Articles, or he is removed as a Director or otherwise required to vacate office under any applicable law.

A Non-Executive Director's appointment may be terminated with immediate effect if he, amongst other things, commits a material breach of his obligations to the Company (whether contractual, statutory, fiduciary, or common law), or if he acts in a manner which is likely to bring him or the Company into disrepute or is materially adverse to the interests of the Company.

Share-based remuneration

For the year ended 31 December 2018, no Share Options were granted to the Non-Executive Directors. Information on the number of Share Options granted to the Non-Executive Directors for previous years is set out in paragraph 6.4(c) of this Part 6 (*Directors, Senior Management and Corporate Governance*).

Change in Control

The letter of appointment in respect of Dr. Oern Stuge's appointment as Director and Chairman of the Company, the letter of appointment in respect of David Brabazon's appointment as Director of the Company and the letter of appointment in respect of James Reinstein's appointment as Director of the Company (the "**Letters of Appointment**") each provide that if, after a 'Change in Control', the appointee is required to resign as a Director, of the Company, or continues to act as a Director for six months following a Change in Control, all of the unvested Share Options held by that person shall immediately vest.

A "**Change in Control**" is defined in the Letters of Appointment as: (i) a merger, reorganisation, consolidation, business combination or similar transaction (a "**Merger**") as a result of which the persons who were the respective beneficial owners of the outstanding capital stock of MML immediately before such Merger are not expected to beneficially own, immediately after such Merger, directly or indirectly, more than fifty per cent. (50%) of the combined voting power of the then outstanding voting securities of the corporation or other entity resulting from such Merger, or the parent entity controlling such corporation or other entity, if applicable, provided, however, that completion of the admission to trading of the Ordinary Shares to Euronext Growth and Euronext Paris as contemplated by this document, the 2018 Placing or that customary venture capital financing shall not result in a Change in Control; or (ii) the sale or other disposition of all or substantially all of the capital stock or assets of MML.

6.8 OTHER DIRECTORSHIPS AND PARTNERSHIPS

Other than as set out below, the Directors have not held any directorships of any company, other than the Company, or been a partner in a partnership, at any time in the 5 years prior to the date of this document. Notwithstanding other directorships, the Company is satisfied that all of the Directors will have sufficient time to discharge their responsibilities to the Company effectively.

Antoine Papiernik

Company	Where	Start Date	End Date
Sofinnova Partners SAS	France	5 May 2003	Current
Entourage Medical Technologies, Inc.	U.S.	13 January 2010	31 March 2016
MD Start I KG	Switzerland	26 August 2008	4 August 2016

Antoine Papiernik

Company	Where	Start Date	End Date
ReCor Medical, Inc.	U.S.	30 September 2009	16 July 2018
Stentys SA	France	29 September 2006	25 March 2015
Auris Medical AG	Switzerland	4 April 2013	21 September 2017
Shockwave Medical, Inc.	U.S.	3 July 2013	Current
Pixium Vision SA	France	13 November 2013	27 June 2017
Corwave SA	France	17 December 2013	21 October 2016
ProQR Therapeutics BV	Netherlands	1 January 2014	Current
Reflexion Medical Inc	U.S.	17 March 2014	Current
Impatients NV	Netherlands	13 November 2014	6 March 2018
Tissium (Gecko Biomedical)	France	9 March 2016	Current
Jump I, Inc	U.S.	8 January 2016	Current
Rgenix, Inc	U.S.	3 June 2016	Current
MD Start II	France	4 August 2016	Current
SafeHeal	France	14 October 2016	Current
Highlife	France	28 July 2017	Current
Medday Pharmaceuticals SA	France	4 September 2017	Current
AblaCare	France	4 June 2019	Current

Dan Sachs MD

Company	Where	Start Date	End Date
Kspine, Inc.	U.S.	27 June 2007	11 December 2014
Mainstay Medical Limited	Ireland	25 September 2012	3 April 2014
Amphora Medical, Inc.	U.S.	31 December 2011	18 July 2017
Mainstay Medical, Inc.	U.S.	13 July 2010	3 April 2014
Kenwood Medical Devices LLC	U.S.	31 December 2011	Current
Neuronetics, Inc.	U.S.	3 April 2003	10 May 2013

David Brabazon

Company	Where	Start Date	End Date
Mainstay Medical Limited	Ireland	5 December 2013	3 April 2014

David Brabazon

Company	Where	Start Date	End Date
Emergent Acquisition Limited	Ireland	15 October 2018	29 May 2019
Adapt Pharma Limited	Ireland	31 October 2013	May 2019
Adapt Pharma Operations Limited	Ireland	11 November 2013	May 2019
Adapt Pharma, Inc.	U.S.	8 November 2013	May 2019
Adapt Pharma Canada Limited	Canada	7 April 2016	May 2019
Headway (Ireland) Limited	Ireland	5 July 2012	Current
Drand Limited	Ireland	28 November 2011	Current
ALSHC Limited	Ireland	23 October 2017	Current

Oern Stuge MD

Company	Where	Start Date	End Date
ORSCO Life Sciences AG	Switzerland	2011	Current
Mainstay Medical Limited	Ireland	January 2013	Current
Phagenesis Ltd.	UK	February 2013	Current
Nobel Biocare AG	Switzerland	2010	December 2014
Aleva Neurotherapeutics SA	Switzerland	2011	September 2017
Acarix SA	Denmark	2011	May 2015
Bonesupport AB	Sweden	2010	December 2016
Pulmonix International SA	Switzerland	October 2013	Current
Advanced Cardiac Therapeutics, Inc	U.S.	2011	2013
Systagenix	UK	2011	2013
Mediq NV	Netherlands	2009	2013
Vision Ophthalmology Group GmbH	Germany	2015	June 2018
Balt SAS	France	November 2015	Current
GI Dynamics INC	U.S.	January 2016	Current
OrthoD Ltd	UK	April 2018	Current
Echosens SAS	France	April 2018	Current Board Observer

James Reinstein

Company	Where	Start Date	End Date
Aptus Endosystems Inc	U.S	February 2012	June 2015
Pixium Vision	France	June 2015	Current
Monteris Medical	U.S.	July 2015	Current
Drawbridge Health	U.S.	Nov. 2015	January 2017

James Reinstein

Company	Where	Start Date	End Date
Cutera Inc	U.S.	January 2017	January 2019
Previvo Genetics Inc.	U.S.	March 2019	Current

Greg Garfield

Company	Where	Start Date	End Date
Aerin Medical, Inc.	U.S.	December 2011	July 2019
Applaud Medical, Inc.	U.S.	August 2015	February 2019
BioInspire Technologies, Inc.	U.S.	January 2014	Current
C2 Therapeutics, Inc.	U.S.	December 2011	January 2017
Cogent Therapeutics, Inc.	U.S.	April 2013	Current
Reflexion Medical, Inc.	U.S.	April 2016	Current
ReVent Medical, Inc.	U.S.	July 2013	April 2017
Rodo Medical, Inc.	U.S.	January 2013	Current
Semler Scientific, Inc.	U.S.	October 2013	October 2016
Sonitus Medical, Inc. (Note 1)	U.S.	December 2011	January 2015
Sonitus Technologies, Inc.	U.S.	February 2016	Current
Intuity Medical Inc	U.S.	December 2016	July 2019
NeuroPace Inc	U.S.	September 2016	Current
Sonex Health	U.S.	August 2019	Current
Cerapedics	U.S.	June 2018	Current

Notes:

(1) Greg Garfield was a non-executive director of Sonitus Medical, Inc. until January 2015, when the company entered into a voluntary liquidation. The liquidation was completed in January 2016.

Jason Hannon

Company	Where	Start Date	End Date
Nemaris, Inc.	United States	September 2016	August 2017
NuVasive Austria GmbH	Austria	August 2015	November 2017
NuVasive Italia s.r.l.	Italy	September 2012	September 2017
NuVasive PR, Inc.	Puerto Rico	April 2008	August 2017
NuVasive Spain S.L.	Spain	May 2013	September 2017
MIS Spine Comercial	Mexico	February 2017	October 2017
NuVasive Southeast Asia Pte Lte	Singapore	December 2009	August 2017
NuVasive Ireland (Note 1)	Ireland	November 2013	February 2018
NuVasive International Technology	Ireland	November 2013	April 2015

Jason Hannon

Company	Where	Start Date	End Date
NuVasive AUST/NZ Pty. Ltd	Australia	December 2009	August 2017
NuVasive Germany GmbH	Germany	July 2006	September 2017
NuVasive Japan KK	Japan	May 2009	August 2017
NuVasive Malaysia Sdn Bhd (dissolved)	Malaysia	September 2010	January 2016
NuVasive Netherlands B.V.	Netherlands	July 2013	December 2016
NuVasive Netherlands Cooperatief	Netherlands	February 2015	December 2016
NT International C.V.	Netherlands	February 2015	July 2015
NuVasive Poland	Poland	January 2014	March 2015
NuVasive LLC	Russia	July 2014	September 2017
NuVasive UK Limited	United Kingdom	August 2005	August 2017
Cervitech, Inc. (dissolved)	United States	May 2009	August 2017
NuVasive Clinical Services Monitoring, Inc.	United States	September 2011	August 2017
NuVasive Clinical Services, Inc.	United States	October 2016	August 2017
NuVasive Specialized Orthopedics, Inc.	United States	October 2016	August 2017
NeuroMed, Inc.	United States	October 2016	August 2017
Mainstay Medical BV	Netherlands	September 2017	Current
Mainstay Medical Limited	Ireland	December 2017	Current
Mainstay Medical (Australia) PTY Limited	Australia	April 2018	Current
Mainstay Medical Distribution Limited	Ireland	July 2018	Current
Kuros Inc	Switzerland	June 2018	Current
Sequana Medical	Belgium	May 2019	Current

Notes:

(1) Jason Hannon was an executive director of NuVasive Ireland until February 2018. The company entered into liquidation in November 2016, which was completed in February 2018.

Other than as set out in this paragraph 6.8 of this Part 6 (*Directors, Senior Management and Corporate Governance*), within the period of 5 years preceding the date of this document, none of the Directors or Senior Managers have:

(a) any convictions in relation to fraudulent offences;

(b) been associated with any bankruptcy, receivership or liquidation while acting in the capacity of a director or senior manager (who is relevant to establishing that a company has the appropriate expertise and experience for the management of that company); or ever had any bankruptcy order made against them or entered into any individual voluntary arrangement with his creditors;

(c) ever been directors of a company which, while he was a director or within twelve (12) months after he ceased to be a director, has been placed into receivership, a creditors' voluntary

liquidation or administration or been subject to a company voluntary arrangement or any composition or arrangement with its creditors generally or with any class of its creditors;

(d) ever been partners of any partnership which, while he was a partner or within twelve (12) months after he ceased to be a partner, has been placed in compulsory liquidation or administration or been the subject of a partnership voluntary arrangement or has had a receiver appointed to any partnership asset;

(e) received any official public incrimination, any public criticism and/or sanction by any statutory or regulatory authorities (including designated professional bodies); and

(f) been disqualified by a court from acting as a director of a company or from acting in the management or conduct of the affairs of a company.

6.9 CORPORATE GOVERNANCE AND BOARD PRACTICES

(a) Corporate Governance for the Company

The Board recognises the importance of good governance in supporting growth in long term shareholder value and is accordingly committed to maintaining the highest standards of corporate governance commensurate with the size and stage of the development of the Group.

While, at the date of this document, there is no specific corporate governance regime mandated in Ireland for companies listed on Euronext Growth, nor is there any specific corporate governance regime mandated in France for companies who are listed on Euronext but not incorporated in France, the Company applies recognised corporate governance principles to the extent they are appropriate for a company of its size, stage of development and resources.

The Board will also take account of other institutional shareholder governance guidelines on disclosure and shareholder authorisations to the extent they are appropriate for a company of its size, stage of development and resources.

(b) The Board

The Board is responsible for the supervision and control of the Company and is accountable to the shareholders. The Board has reserved decision-making on a variety of matters, including determining strategy for the Group, reviewing and monitoring executive management performance and monitoring risks and controls.

The Board comprises seven Directors, including one Executive Director, six Non-Executive Directors and the Non-Executive Chairman. The roles of Chairman and Chief Executive Officer are not exercised by the same individual.

The Board meets regularly (no less than four times per year) to consider strategy, performance and the framework of internal controls. The Directors have also established an Audit, Risk and Compliance Committee, a Remuneration Committee, and a Nominations Committee with formally delegated rules and responsibilities. Each of the Committees currently comprises Non-Executive Directors only.

The Board comprises a mix of the necessary skills, knowledge and experience required to provide leadership, control and oversight of the management of the Company and to contribute to the development and implementation of the Company's strategy. In particular, the Board combines a group of Directors with diverse backgrounds within the medical device and related sectors, in both public and private companies.

Notwithstanding the fact that Dr. Oern Stuge was previously granted Share Options as disclosed in paragraph 6.4 of this Part 6 *(Directors, Senior Management and Corporate Governance)*, the Board considers him to be independent.

Notwithstanding the fact that David Brabazon was previously granted Share Options, as disclosed in paragraph 6.4 of this Part 6 *(Directors, Senior Management and Corporate Governance),* the Board considers him to be independent.

Notwithstanding the fact that James Reinstein was previously granted Share Options, as disclosed in paragraph 6.4 of this Part 6 *(Directors, Senior Management and Corporate Governance),* the Board considers him to be independent.

All the Directors bring independent judgment to bear on issues affecting the Group and all have full and timely access to information necessary to enable them to discharge their duties. The Articles require each Director retire at the annual general meeting held in the third calendar year following the year in which he was appointed or last re-appointed but unless he falls within the paragraph immediately below he shall be eligible for re-appointment.

A Director shall also retire at any annual general meeting if he has agreed to do so (whether in accordance with the terms of his appointment or otherwise) and, unless the Directors have agreed otherwise, he shall not be eligible for re-appointment.

(c) **Board Committees of the Company**

The Board has established a number of committees to deal with specific matters. Brief particulars are set out below:

Audit, Risk and Compliance Committee – Mr. David Brabazon (Independent Chairman), Mr. James Reinstein (Independent) and Dr. Oern Stuge (Independent);

Nominations Committee - Dr. Oern Stuge (Independent Chairman), Mr. David Brabazon (Independent), Mr. Antoine Papiernik and Mr. James Reinstein (Independent);

Remuneration Committee - Mr. James Reinstein (Independent Chairman), Mr. David Brabazon (Independent), Mr. Antoine Papiernik and Dr. Oern Stuge (Independent).

Audit, Risk and Compliance Committee

The Audit, Risk and Compliance Committee is chaired by Mr. David Brabazon (the Audit, Risk and Compliance Committee Financial Expert). The Chief Financial Officer and Chief Executive Officer may also be invited to attend meetings of the Committee. It meets at least three times a year and is responsible for ensuring that the financial performance of the Group is properly monitored and reported on. The Committee also meets with and reviews findings of the audit with the external auditor. It meets with the auditors at least once a year without any members of management being present and is also responsible for considering and making recommendations regarding the appointment and remuneration of such auditors.

Remuneration Committee

The Remuneration Committee is chaired by Mr. James Reinstein. It meets at least three times a year and considers and recommends to the Board the framework for the remuneration of the Chief Executive Officer, Chairman, Company Secretary, Chief Financial Officer, Executive Directors and such other officers as it is designated to consider and, within the terms of the agreed policy, considers and recommends to the Board the total individual remuneration package of each Executive Director including bonuses, incentive payments and share awards. It reviews the design of all incentive plans for approval by the Board and (if required) shareholders and, for each such plan, recommends whether awards are made and, if so, the overall amount of such awards, the individual awards to Executive Directors and the performance targets to be used. The Remuneration Committee has the power to grant share options under the Company's share options plans in force from time to time to persons eligible for participation thereunder. No Director is involved in decisions concerning his/her own remuneration.

Nominations Committee

The Nominations Committee is chaired by Dr. Oern Stuge. It meets at least two times a year and considers the selection and re-appointment of Directors. It identifies and nominates candidates for all Board vacancies and reviews regularly the structure, size and composition (including the skills, knowledge and experience) of the Board and makes recommendations to the Board with regard to any changes.

(d) **Internal controls**

The Board acknowledges that it is responsible for maintaining the Company's system of internal control and risk management processes required to safeguard the Group's assets and intellectual property. Such a system is designed to identify, manage and mitigate financial, operational and compliance risks inherent to the Company and the Group. The system is designed to manage rather than eliminate the risk of failure to achieve business objectives and can only provide reasonable, but not absolute assurance against material misstatement or loss.

The main features of internal control and risk management processes for preparing financial statements and financial reporting include:

- Board approval of the annual budget and strategy;
- Monitoring of performance against the annual budget through monthly Board reports detailing actual results versus budget, analysis of material variances, and re-forecasting where required;
- Finance function resourced to facilitate segregation of duties;
- Audit, Risk and Compliance Committee review of the integrity of the Company's annual report and half-yearly report;
- Board review and approval of the Company's annual report and half-yearly report; and
- Board approved authorization limits and investment policy.

(e) **Directors' share dealing**

The Company has adopted a share dealing code setting out the requirements and procedures for dealings in its Ordinary Shares by its Directors, other persons discharging managerial responsibilities ("**PDMRs**") (if any), and certain employees and other relevant persons. The share dealing code has been adopted by the Company in accordance with Rule 5.23 of the Euronext Growth Rules and is also intended to ensure compliance by Directors and other PDMRs (if any) with their obligations under Article 19 of the Market Abuse Regulation.

PART 7
OPERATING AND FINANCIAL REVIEW

The following operating and financial review should be read in conjunction with the Group's audited consolidated statement of profit or loss and other comprehensive income, consolidated statement of financial position, consolidated statement of cash flows and accompanying notes to this consolidated financial information, included in the Company's audited financial statements for the financial years ended 31 December 2018, 2017 and 2016 and the Group's unaudited condensed consolidated financial statements for the half years ended 30 June 2019 and 2018, all of which are incorporated into this document by reference and details of which are set out Part 10 (*Documentation Incorporated by Reference*) of this document.

The financial information contained in this Part 7 (*Operating and Financial Review*) has been extracted without material adjustment from the Group's consolidated audited financial statements for the financial years ended 31 December 2018, 2017 and 2016 and the Group's unaudited condensed consolidated financial statements for the half years ended 30 June 2019 and 2018 all of which are incorporated into this document by reference and details of which are set out Part 10 (*Documentation Incorporated by Reference*) of this document.

Certain statements in this Part are forward-looking and should be read in conjunction with Part 2 (*Important Information*) of this document.

The Group's consolidated audited and unaudited financial information has been prepared in accordance with IFRS as adopted by the EU. Accordingly, the figures used in this Part refer to the financial statements which have been prepared in accordance with IFRS as adopted by the EU.

7.1 Overview

We are a medical device group founded in 2008, focused on developing and bringing to market ReActiv8, an implantable restorative neurostimulation system to treat disabling Chronic Low Back Pain. The engineering development of ReActiv8 (including proprietary implantable stimulation leads and implantable pulse generator) was completed in December 2013. ReActiv8 was investigated in the ReActiv8-A Clinical Trial, an international, multi-centre, prospective, single arm trial to gather data for a submission for CE Marking. We announced results from this Clinical Trial in August 2015. These results show clinically important, statistically significant and lasting improvement in pain, disability and quality of life in a clinically challenging population of people with long term Low Back Pain who have attempted all or most other appropriate treatments.

From 2016 to the present we have conducted the U.S. Pivotal ReActiv8-B Clinical Trial under an IDE from the FDA. The U.S. Pivotal ReActiv8-B Clinical Trial is an international, multi-centre, prospective randomised sham controlled triple blinded trial with one-way crossover. Its purpose is to gather data in support of an application for PMA to the FDA, a key step towards the commercialisation of ReActiv8 in the U.S.

In May 2016, we received approval for CE Marking for ReActiv8. The first sale and implant of ReActiv8 in Germany was announced on 1 February 2017. The implant was performed at the Catholic Hospital Koblenz-Montabaur in Koblenz Germany. In May 2017, we announced that commercialisation had begun in Ireland.

In January 2017, we applied to the TGA for ReActiv8 to be admitted to the ARTG which would allow for commercialisation in Australia. In April 2018, the TGA requested additional clinical data with respect to ReActiv8 which we submitted in June 2019. To provide the most meaningful clinical data possible, we relied on the clinical data gathered as part of the U.S. Pivotal ReActiv8-B Clinical Trial. The U.S. Pivotal ReActiv8-B Clinical Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on two pre-specified alternative analyses of that endpoint and on multiple secondary endpoints. We cannot be certain whether the totality of the data from the U.S. Pivotal ReActiv8-B Clinical Trial will be sufficient to demonstrate safety and efficacy to

the satisfaction of the TGA to allow for the admission of ReActiv8 to the ARTG. The TGA may request additional information during the review process. Review of an application for admission of a product to the ARTG has varied historically. The TGA is required to complete assessment of applications within approximately one year. Following admission of ReActiv8 to the ARTG, we will also apply for reimbursement approval in Australia.

The majority of our expenditure is in U.S. Dollars and accordingly, for accounting purposes, we use U.S. Dollars as our functional currency.

To date, we have funded our operations primarily through the proceeds of equity funding of approximately $139.1 million as follows (proceeds received in euro are translated into USD at the rate prevailing on the date of receipt of proceeds):

- MMI closed the Series A Financing in July 2010 of $6.1 million from venture capital sources. The Series A Financing was received in tranches in 2010 and 2011.
- MML closed the Series B Financing in September 2012 of $20 million from venture capital and corporate sources. A further $0.2 million of Series B funding was received in July 2013.
- Funding of $0.1 million was contributed by shareholders on the incorporation of the Company, prior to an initial public offering.
- In May 2014, we raised gross proceeds of $26 million by way of the 2014 IPO.
- On 17 June 2016, we announced we had raised gross proceeds of €30 million (approximately $33.7 million) through the 2016 Placing.
- On 15 February 2018, we announced we had raised gross proceeds of €30.1 million (approximately $37.5 million) pursuant to the 2018 Placing.
- On 29 July 2019, we announced we had raised gross proceeds of €13.9 million (approximately $15.5 million) pursuant to the 2019 Placing.

In addition to equity funding, on 24 August 2015, we announced the closing of debt financing for up to $15 million. The facility which was provided by IPF was drawn in three tranches during 2015 and 2016. As at 31 December 2018 and 30 June 2019, the outstanding debt principal is $10.2 million and $9.45 million respectively. A new tranche of €3.0 million (approximately $3.34 million) was made available to Mainstay, conditional upon Mainstay raising at least $10 million in gross proceeds from one or more offerings of equity prior to June 30, 2019. This deadline was extended to July 31, 2019 by agreement with IPF. On 29 July 2019, we completed the 2019 Placing, raising gross proceeds of €13.9 million and announced the drawdown of €3 million in additional debt from the new tranche of the existing debt facility.

At 30 June 2019 and 31 December 2018, we held $5.8 million and $15.5 million in cash respectively.

For the three years ended 31 December 2018, we have incurred expenses on operating activities totalling $74.3 million. These expenses include approximately $11.2 million on research and development and quality (15%), $29.5 million on clinical and regulatory (39.7%), and $33.6 million on commercial, general and administrative expenses (45.2%).

As at the Latest Practicable Date, we did not own any plant or equipment which was material to the conduct of our business (other than typical office equipment such as computers, printers and copiers). All manufacturing was performed by third party contract manufacturers. Our strategy is to outsource manufacturing for our product development and early commercialisation activities and accordingly we have not invested in manufacturing facilities or equipment; similarly, we lease our facilities in Ireland and the United States, which were not capitalised as at 31 December 2018. From 1 January 2019, we have initially adopted IFRS 16 Leases which introduced a single on balance sheet accounting model. Further information on our lease commitments is available in note 2, page 17 of our 2019 half year report, note 23, page 89 of our 2018 annual report and in note 23, page 72 of our 2017 annual report, each of which is incorporated by reference in Part 8 (*Historical Financial Information*) of this

document. Consequently, the main asset included in the consolidated statement of financial position is cash.

7.2 Financial Operations Overview

(a) Revenue

The first sales of ReActiv8 were generated in the year ended 31 December 2017. Revenue is recognised when we transfer control over a product or service to a customer. This may arise on shipment, on delivery or in accordance with specific terms and conditions agreed with customers and provided there are no material remaining performance obligations required of the Group. The revenue is measured at the fair consideration received/receivable for the sale of goods to external customers net of value added tax and discounts.

Our customers to date are hospitals in Germany, the United Kingdom and Ireland and are served through our direct sales force.

The U.S. pathway to commercialisation requires obtaining a PMA from the FDA for ReActiv8.

(b) Cost of sales

We purchase all elements of our product (e.g. implantable pulse generator, leads, patient activators, surgical tools, and programmers) from third party manufacturers. Cost of sales consists primarily of acquisition costs of the elements of ReActiv8, and distribution-related expenses.

We expect the value of cost of sales to track changes in sales volumes. Cost of sales could vary as a percentage of revenue as a result of changes in third-party product costs, foreign exchange rates, freight charges, and scrap and inventory obsolescence associated with timing of product launches and enhancements.

(c) Operating expenses

Our operating expenses are detailed further below, line item by line item, from the statement of profit or loss and other comprehensive income.

(i) Research & development and quality assurance expenses

Research & development and quality assurance expenses reflect costs incurred for research, ongoing development and design related to ReActiv8 and its components. These expenses include the salaries of engineers, technicians, quality and regulatory specialists; the cost of outsourced development and manufacturing activities; biocompatibility and pre-clinical studies; and quality costs including the maintenance of our quality system.

We expense all research and development costs as they are incurred and have not capitalised any such expenses to date. Management determines at each reporting date whether the conditions for capitalising development costs are met, depending on the factors at that time.

(ii) Clinical and regulatory expenses

Clinical and regulatory expenses are related to our Clinical Trials and regulatory approvals. These include (without limitation) regulatory, clinical and legal consulting, the payroll costs of our direct employees and Clinical Trial costs. Clinical Trial costs can include direct hospital costs (for example operating theatre fees and costs related to the physicians and nurses time), training costs, clinical database fees, clinical monitoring fees, and the cost of the ReActiv8 device used in certain trials. All clinical and regulatory costs are expensed as incurred.

(iii) Selling, general and administrative expenses

Selling, general and administration expenses include costs relating to the executive, legal, finance and commercial functions. Executive, legal, and finance expenses include the salaries and other related costs for personnel, professional fees for accounting, audit and legal services, general and facilities

costs such as rent, insurances and IT costs. Selling costs include the salaries of our direct sales force, costs related to the development of the Group's commercial strategy, and costs related to obtaining and expanding reimbursement for the Group's product.

Selling expenses are expected to increase as we continue to develop our commercial strategy.

(d) Finance income

Finance income includes foreign exchange gains.

(e) Finance expense

Finance expense includes foreign exchange losses and interest expenses.

(f) Income Taxes

Income tax expense consists primarily of income tax expense on subsidiary profits earned in jurisdictions outside of Ireland.

Our unrecognised accumulated consolidated carry forward taxable losses to 31 December 2018 amount to approximately $107.7 million. These losses may be used to offset future taxable profits. In addition, capital allowances on intellectual property, which is recognised as an asset for tax purposes but is not capitalised under IFRS, of $15 million will be available should we generate relevant income.

No deferred tax assets have been recorded to date in relation to accumulated consolidated carry forward tax losses or capital allowances on intellectual property assets because we are in an early development stage and there is lack of certainty that we will generate taxable profits in the future against which these losses and allowances can be utilised.

(g) Other comprehensive income

The income statement and balance sheet of subsidiaries that have a functional currency different from the presentation currency of the Group are translated into the presentation currency as follows:

- assets and liabilities at each reporting date are translated at the closing rate at the reporting date of the balance sheet; and
- income and expenses in the income statement and statement of comprehensive income are translated at average exchange rates for the year. The average exchange rates are a reasonable approximation of the cumulative effect of the exchange rates on transaction dates.

All resulting exchange differences are recognised in other comprehensive income, and are taken to a separate currency reserve within equity, the foreign currency translation reserve.

7.3 Analysis of the consolidated statement of comprehensive income

The following table includes information relating to consolidated statement of profit or loss and other comprehensive income for the years ended 31 December 2018, 2017 and 2016 and for the half years ended 30 June 2019 and 30 June 2018.

($'000)	**Year ended 31 December 2018**	**Year ended 31 December 2017**	**Year ended 31 December 2016**	**Half year ended 30 June 2019**	**Half year ended 30 June 2018**
Revenue	663	348	-	552	358
Cost of sales	(359)	(190)	-	(316)	(170)
	304	158	-	236	188
Operating expenses	(29,589)	(27,877)	(16,828)	(9,559)	(15,849)
Operating loss	(29,285)	(27,719)	(16,828)	(9,323)	(15,661)
Finance income	-	46	-	-	-
Finance expense	(1,890)	(1,932)	(1,808)	(1,760)	(1,018)
Net finance expense	(1,890)	(1,886)	(1,808)	(1,760)	(1,018)
Loss before income taxes	**(31,175)**	**(29,605)**	**(18,636)**	**(11,083)**	**(16,679)**
Income taxes	98	(230)	(122)	(63)	156
Loss for the year	**(31,077)**	**(29,835)**	**(18,758)**	**(11,146)**	**(16,523)**
Other comprehensive income					
Items that may be reclassified subsequently to the statement of profit or loss:					
Foreign currency translation difference of foreign	33	(142)	35	(20)	56

operations

Total comprehensive loss for the year	**(31,044)**	**(29,977)**	**(18,723)**	**(11,166)**	**(16,467)**

(a) Revenues

Regulatory approvals for ReActiv8 are required before it can be sold commercially. The first such approval, CE Marking, was received in May 2016. Our first sale of ReActiv8 was in January 2017, and consequently, revenue was nil during the year ended 31 December 2016. Revenue was $0.3 million, $0.7 million and $0.6 million during the years ended 31 December 2017 and 2018 and the half year ended 30 June 2019 respectively and was generated principally from sales of ReActiv8 systems to hospitals in Germany, the United Kingdom and Ireland.

(b) Cost of sales

Cost of sales increased from nil during the year ended 31 December 2016 to $0.2 million during 2017, $0.4 million during 2018 and decreased to $0.3 million during the half year ended 30 June 2019 as a result of sales of ReActiv8 systems to customers in Germany, the United Kingdom and Ireland.

(c) Operating expenses

The following table provides analysis of our operating expenses and further detail on each of the headings in the table is provided in the commentary below:

($'000)	**Year ended 31 December 2018**	**Year ended 31 December 2017**	**Year ended 31 December 2016**	**Half year ended 30 June 2019**	**Half year ended 30 June 2018**
Research & development and quality assurance expenses	3,447	4,170	3,582	1,019	1,980
Clinical and regulatory expenses	11,047	12,850	5,599	2,879	7,197
Selling, general and administration expenses	15,095	10,857	7,647	5,661	6,672
Total operating expenses	**29,589**	**27,877**	**16,828**	**9,559**	**15,849**

(i) Research and development and quality assurance expenses

Research & development and quality assurance expenses were $1 million for the half year ended 30 June 2019, $2 million for the half year ended 30 June 2018, $3.5 million during the year ended 31 December 2018, $4.2 million in 2017 and $3.6 million in 2016.

A decrease of $1 million from 30 June 2018 to 30 June 2019 is primarily driven by reduced payroll related costs following a reduction in headcount in 2019.

A decrease of $0.7 million from 2017 to 2018 is primarily driven by a reclassification of 2018 IP legal costs to selling, general and administrative expenses.

The increase of $0.7 million from 2016 to 2017 is primarily driven by additional salary and share based compensation costs.

(ii) Clinical and regulatory expenses

Clinical and regulatory expenses were $2.9 million during the half year ended 30 June 2019, $7.2 million during the half year ended 30 June 2018, $11 million during the year ended 31 December 2018, $12.9 million in 2017, and $5.6 million in 2016.

A decrease of $4.3 million from 30 June 2018 to 30 June 2019 and $1.9 million from 2017 to 2018 is primarily driven by decreased direct trial costs relating to activities for the ReActiv8-B Clinical Trial, following the announcement in July 2018 of the completion of all implants.

Clinical and regulatory expenses increased by $7.3 million from 2016 to 2017. This is primarily driven by increased direct trial costs, consulting, training and travel costs relating to activities for the U.S. Pivotal ReActiv8-B Clinical Trial, which has sites in the U.S., Australia, and Europe.

(iii) Selling, general and administrative expenses

Our selling, general and administrative expenses were $5.6 million during the half year ended 30 June 2019, $6.6 million during the half year ended 30 June 2018, $15.1 million during the year ended 31 December 2018, $10.9 million during 2017, and $7.6 million in 2016.

A decrease of $1 million from 30 June 2018 to 30 June 2019 is primarily driven by the reduction in recruitment fees, travel and training costs, as well as certain marketing and market research costs. The increase of $4.2 million from 2017 to 2018 and $3.3 million from 2016 to 2018 is primarily driven by commercialization and the related increase in our direct sales force (impacting payroll, travel and training costs), as well as marketing costs. This increase is also impacted by a non-cash expense for share options granted.

(d) **Operating loss**

As a result of the foregoing, our consolidated operating loss before finance income and expense and taxes was $9.3 million for the half year ended 30 June 2019, $15.7 million for the half year ended 30 June 2018, $29.3 million in 2018, $27.7 million in 2017, and $16.8 million in 2016.

(e) **Finance income**

Finance income was nil for the half year ended 2019, nil for 2018, $0.05 million in 2017 and nil in 2016. The income in 2017 relates to foreign exchange gains.

(f) **Finance expense**

Finance expense was $1.7 million during the half year ended 30 June 2019, $1 million during the half year ended 30 June 2018, $1.9 million in 2018, $1.9 million in 2017 and $1.8 million in 2016.

(g) **Loss before income taxes**

Loss before income taxes, which includes operating losses and finance expense detailed above, was $11.1 million for the half year ended 30 June 2019, $16.7 million for the half year ended 30 June 2018, $31.2 million in 2018, $29.6 million in 2017 and $18.6 million in 2016.

(h) **Income taxes**

Income taxes expenses were $0.1 million for the half year ended 30 June 2019, ($0.2) million for the half year ended 30 June 2018, ($0.1) million in 2018, $0.2 million in 2017 and $0.1 million in 2016. To date, the Group's U.S., Australian and German subsidiaries provide services on a "cost plus" basis to

other Group companies, and consequently generate profits and revenues that are subject to corporation tax in the U.S., Australia and Germany. The taxes payable in Australia are offset by R&D tax credits that are receivable. Further information on income tax expenses is available in note 12, page 77 of the Company's 2018 annual report which is incorporated by reference in Part 8 (*Historical Financial Information*) of this document.

(i) **Loss**

Our consolidated losses were $11.1 million for the half year ended 30 June 2019, $16.5 million for the half year ended 30 June 2018, $31.1 million in 2018, $29.8 million in 2017 and $18.8 million in 2016.

(j) **Other comprehensive (expense)/ income**

Other comprehensive expense was $(0.02) million for the half year ended 30 June 2019, $0.06 million for the half year ended 30 June 2018, $0.03 million in 2018, expense of $(0.1) million in 2017 and income of $0.04 million in 2016. This expense or income reflects the foreign exchange gains arising on our Irish, Dutch and German subsidiaries which have a Euro functional currency, and our Australian subsidiary which has an Australian Dollar functional currency. This income and expense is impacted by fluctuations in exchange rates.

(k) **Total comprehensive loss**

Our total comprehensive loss was $11.1 million for the half year ended 30 June 2019, $16.5 million for the half year ended 30 June 2018, $31 million in 2018, $30 million in 2017 and $18.7 million in 2016.

7.4 Analysis of the consolidated statement of financial position

The table below sets forth our consolidated balance sheets as at 30 June 2019, 30 June 2018, 31 December 2018, 2017 and 2016.

($'000)	**31 December 2018**	**31 December 2017**	**31 December 2016**	**30 June 2019**	**30 June 2018**
Non-current assets					
Property, plant and equipment	235	201	255	191	177
Right of use asset	-	-	-	414	-
Total non-current assets	-	-	-	605	-

Current assets					
Trade and other receivables	813	571	889	871	875
Income tax receivable	213	205	103	212	345
Inventory	2,575	2,395	1,123	2,251	2,474
Cash and cash equivalents	15,545	9,975	36,670	5,806	29,711
Total current assets	19,146	13,146	38,785	9,140	33,405
Total assets	**19,381**	**13,347**	**39,040**	**9,745**	**33,582**
Equity					
Share capital	67	64	64	67	67
Share premium	143,897	106,414	106,360	143,898	143,897
Share based payment reserve	11,716	7,613	4,606	15,797	9,465
Other reserves	4,626	4,593	4,735	4,606	4,649
Retained loss	(157,022)	(124,505)	(94,707)	(168,219)	(142,468)
(Deficit)/ surplus on shareholders' equity	3,284	(5,821)	21,058	(3,851)	15,610
Non-current liabilities					
Loans and borrowings	8,791	11,177	13,276	9,684	9,991
Derivate financial instruments	-	-	-	1,098	-
Total non-current liabilities	8,791	11,177	13,276	10,782	9,991

Current liabilities					
Loans and borrowings	3,158	3,214	2,268	215	3,182
Income tax payable	18	124	58	64	12
Trade and other payables	4,130	4,653	2,380	2,473	4,787
Deferred Revenue	-	-	-	62	-
Total current liabilities	7,306	7,991	4,706	2,814	7,981
Total liabilities	**16,097**	**19,168**	**17,982**	**13,596**	**17,972**
Total equity and liabilities	**19,381**	**13,347**	**39,040**	**9,745**	**33,582**

(a) **Non-current assets**

Property, plant and equipment was $0.2 million as at 30 June 2019, $0.2 million as at 31 December 2018, $0.2 million as at 31 December 2017 and $0.3 million as at 31 December 2016. The Group's strategy is to outsource manufacturing for its product development and early commercialisation activities and accordingly the Group has not invested in manufacturing facilities or equipment. Similarly, the Group leases or licenses its facilities, and consequently, the movements in property, plant and equipment over the periods presented are minimal.

Right of use asset was $0.4 million as at 30 June 2019. The Group has initially adopted IFRS 16 from 1 January 2019. IFRS 16 introduced a single, on-balance sheet accounting model for lessees. As a result, the Group, as a lessee, has recognized right-of-use assets representing its rights to use the underlying assets and lease liabilities representing its obligation to make lease payments.

The Group has applied IFRS 16 using the modified retrospective approach, under which the cumulative effect of initial application is recognized in retained earnings at 1 January 2019. Accordingly, the comparative information presented has not been restated.

(b) **Trade and other receivables**

Trade and other receivables were $0.9 million as at 30 June 2019, $0.8 million as at 31 December 2018, $0.6 million as at 31 December 2017 and $0.9 million as at 31 December 2016.

The variances between the periods disclosed primarily relate to timing of payments received from customers and timing of prepayments.

(c) **Income Tax Receivable**

Income tax receivable was $0.2 million as at 30 June 2019, $0.2 million as at 31 December 2018, $0.2 million as at 31 December 2017 and was $0.1 million as at 31 December 2016. This income tax receivable relates to estimated R&D tax credits receivable from the Australian Tax Office on the cost of relevant R&D activities incurred by our Australian subsidiary. The increase in 2017 is due to

additional costs incurred on the U.S. Pivotal ReActiv8-B Clinical Trial which are eligible for the R&D credit.

(d) **Inventory**

Investment in inventory was $2.2 million as at 30 June 2019, $2.6 million as at 31 December 2018, $2.4 million as at 31 December 2017 and $1.1 million as at 31 December 2016. CE Marking was obtained in May 2016, and following this we commenced investment in inventory for commercialisation.

(e) **Cash and cash equivalents**

Cash and cash equivalents were $5.8 million as at 30 June 2019, $15.5 million as at 31 December 2018, $10.0 million as at 31 December 2017 and $36.7 million as at 31 December 2016. Movements in cash and cash equivalents can be seen in the consolidated cash flow statement at paragraph 7.5 of this Part 7 (*Operating and Financial Review*) and further details of such movements are discussed in that section.

(f) **Share capital**

Share capital was $0.07 million as at 30 June 2019, $0.07 million as at 31 December 2018 and $0.07 million as at 31 December 2017 and 2016. Share capital in 2018 was impacted by the issue of an additional 2,151,332 Ordinary Shares pursuant to the 2018 Placing. Share capital in 2016 was impacted by the issue of an additional 2,307,694 Ordinary Shares pursuant to the 2016 Placing.

During 2017 and 2016, share capital was also minimally impacted when warrants over Ordinary Shares were exercised by the holders and the Company issued new Ordinary Shares. A total of 13,000 warrants were exercised, with 6,945 exercised during 2017 and 6,055 exercised during 2016. For further details on the Company's share capital history, see paragraph 9.3(b) of Part 9 (Additional Information) of this document.

(g) **Share premium**

Share premium was $143.9 million as at 30 June 2019, $143.9 million as at 31 December 2018, $106.4 million as at 31 December 2017 and $106.4 million as at 31 December 2016.

Share premium increased by $33.8 million in 2016. The key items giving rise to the increase in share premium are:

(i) share premium increased by $33.7 million on the issue of Ordinary Shares by the Company as part of the 2016 Placing;

(ii) share premium also increased by $0.1 million in 2016 when 6,055 warrants were exercised by the holders and the Company issued 6,055 Ordinary Shares.

During 2017, share premium increased minimally when the Company issued 6,945 Ordinary Shares on the exercise of warrants over Ordinary Shares by the holders.

During 2018, share premium increased by $37.5 million on the issuance of Ordinary Shares by the Company as part of the 2018 Placing.

(h) **Share based payment reserve**

Share based payment reserve was $15.7 million as at 30 June 2019, $11.7 million as at 31 December 2018, $7.6 million as at 31 December 2017 and $4.6 million as at 31 December 2016. The increase of $4.1 million in 2018 and $3 million in 2017 reflect the non-cash share based compensation expense included in operating expenses in the respective years. The increase of $4 million in 2019 relates to a charge of $2.1 million for various Share Options and RSUs granted in the current and prior years, which are being recognized within the statement of profit or loss. The Company also recognized $1.9

million in the profit and loss related to the fair value of warrants granted to IPF. This amount has been recorded in finance expense as it related to the modification of the debt.

The Employee Incentive Plan was amended in January 2019 to allow for the issue of RSUs, being rights to receive Ordinary Shares at no cost to the relevant employee, director or consultant. The Company has granted 390,000 RSUs as at 30 June 2019.

The Group accounts for non-cash share based compensation in accordance with IFRS 2, whereby the grant date fair value of each option granted (which is calculated using the black scholes fair value model – a financial model commonly used for valuation of options) is recognised as an expense in the profit and loss account over the vesting period of the option, and a corresponding increase in the share based payment reserve is recorded over the same period. The vesting period of Company options has historically been about 4 years, however the Employee Incentive Plan allows for the Board to specify the vesting conditions for each option grant.

(i) **Other reserves**

Other reserves comprise of (i) the undenominated capital reserve, (ii) the reorganization reserve and (iii) the foreign currency translation reserve:

($'000)	31 December 2018	31 December 2017	31 December 2016	30 June 2019	30 June 2018
Undenominated capital reserve	49,273	49,273	49,273	49,273	49,273
Reorganization reserve	(44,573)	(44,573)	(44,573)	(44,573)	(44,573)
Foreign currency translation reserve	(74)	(107)	35	(94)	(51)
Total other reserves	**4,626**	**4,593**	**4,735**	**4,606**	**4,649**

i. Undenominated capital reserve

The undenominated capital reserve was $49.3 million at 30 June 2019, 31 December 2018, 2017 and 2016. The undenominated capital reserve represents the fair value uplift between the date of issue of preference shares on 3 April 2014 and the date they were converted into Ordinary Shares on 28 April 2014 immediately prior to the 2014 IPO. Further information on these transactions is available in our 2015 annual report which is available on the Company's website: https://www.mainstay-medical.com/en/investors/news.

ii. Reorganisation reserve

The reorganisation reserve was $(44.6) million as at 30 June 2019, 31 December 2018, 2017 and 2016. The reorganisation reserve arose as a result of the 2014 corporate reorganisation and 2012 corporate reorganisation (being the transactions or series of transactions completed by certain Group companies on or around 4 April 2014 and 21 September 2012 respectively). The reorganisation reserve represents a reserve related to requirements of the Irish Companies Acts. It comprises (i) fair value differences on ordinary shares arising as a result of Group restructurings in 2012 and 2014; and (ii) the pre-acquisition retained losses of subsidiaries at the date of the 2012 and 2014 restructurings. Further information on these transactions is available in the Company's 2015 annual report which is available on the Company's website: https://www.mainstay-medical.com/en/investors/news.

iii. Foreign currency translation reserve

This reserve reflects the foreign exchange gains and losses arising on our Irish, Netherlands and German subsidiaries which have a Euro functional currency, and our Australian subsidiary which has an Australian Dollar functional currency.

(j) **Retained losses**

Retained losses were $(168.2) million at 30 June 2019, $(157) million at 31 December 2018, $(124.5) million at 31 December 2017, and $(94.7) million at 31 December 2016. The increase in retained losses of $(11.2) million in the first half of 2019 reflects the loss for 2019. The increase in retained losses of $(32.5) million in 2018 reflects the loss for 2018, in addition to expenses arising on the 2018 Placing of $1.4 million which, in accordance with Irish company law, were changed directly to retained losses. The increase in retained losses of $(29.8) million in 2017 reflects the loss for 2017. The change in retained losses of $(19.9) million in 2016 reflected the loss for the year of $(18.8) million, in addition to expenses arising on the 2016 Placing of $1.2 million which, in accordance with Irish company law, were charged directly to retained losses.

(k) **Loans and borrowings (non-current liabilities and current liabilities)**

Loans and borrowings categorised as non-current liabilities and as current liabilities relate to loans advanced by IPF. The following table details both the non-current liabilities and current liabilities portions of loans and borrowings.

($'000)	**Year ended 31 December 2018**	**Year ended 31 December 2017**	**Year ended 31 December 2016**	**Half year ended 30 June 2019**	**Half year ended 30 June 2018**
Loans and borrowings – current					
Term Loan	3,000	3,000	2,025	-	3,000
Deferred finance cost	(90)	(90)	(91)	-	(90)
Accrued interest	248	304	334	-	272
Lease liabilities	-	-	-	215	-
Total current loans and borrowings	**3,158**	**3,214**	**2,268**	**215**	**3,182**
Loans and borrowings – non-current					
Term Loan	7,200	10,200	12,975	9,247	8,700
Deferred finance cost	(103)	(194)	(142)	-	(149)
Accrued interest	1,694	1,171	443	190	1,440
Lease liabilities	-	-	-	247	-

Total non-current loans and borrowings	**8,791**	**11,177**	**13,276**	**9,684**	**9,991**
Total loans and borrowings	**11,949**	**14,391**	**15,544**	**9,899**	**13,173**

On 24 August 2015, MML entered into the IPF Debt Facility for a facility of up to $15.0 million. The facility was drawn down in three tranches. As at 31 December 2018 and 30 June 2019, the principal outstanding was $10.2 million and $9.45 million respectively. In April 2019 a new tranche of €3.0 million (approximately $3.34 million) was made available to Mainstay, conditional upon Mainstay raising at least $10 million in gross proceeds from one or more offerings of equity prior to June 30, 2019. See paragraph 9.12(e) for further information on the new tranche. This deadline was extended to July 31, 2019 by agreement with IPF. On 29 July we completed the 2019 Placing, raising gross proceeds of €13.9 million and announced the drawdown of €3 million in additional debt from the new tranche of the existing debt facility.

The repayment schedule for the three existing tranches drawn under the debt facility was amended in April 2019 such that no principal or interest will be repaid until 2021, with the principal and accrued interest to be amortized over the period from 1 January 2021 through 30 September 2023. The repayment schedule for the new tranche will be the same as the amended repayment schedule for the three existing tranches. The interest rate for all tranches will be 8% per annum, with interest accruing but capitalized prior to January 1, 2021.

The initial tranche ("**Tranche A**") of $4.5 million was received on 9 September 2015.

A second tranche ("**Tranche B**") of $6.0 million was received on 3 December 2015.

A third tranche ("**Tranche C**") of $4.5 million was received on 28 July 2016.

A fourth tranche ("**Tranche D**") of approximately $3.34 was received on 29 July 2019.

During 2017 we commenced principal repayment, and repaid $1.8 million in 2017, $3 million in 2018 and $0.8 million in the first half of 2019. There were no principal repayments made during 2016 and 2015.

The Company considers the amendment to be a significant modification of the terms of the debt. Accordingly the previous loans and associated accruals were de-recognized and the new loan was recognized at fair value, resulting in a loss recognized in the period to 30 June 2019 of $1.1 million. The Company accounts for the conversion option as a derivative financial instrument carried at fair value through the statement of profit or loss.

The fair value of the conversion option is determined using a Black-Scholes model whose principal assumptions at 30 June 2019 were:

Stock price ($)	4.14
Exercise price (€)	8
Volatility	58.95%
Expected term (years)	4

In connection with the amendment to the debt facility, the Company also granted 1.5 million warrants over Ordinary Shares to IPF with an exercise price of €6 per warrant. The fair value of the warrants on

the grant date of $1.9 million, which was also calculated using a Black-Scholes model, was recognized in finance costs as part of the net cost of modification of the debt.

(l) **Income tax payable**

Our U.S. and German subsidiaries provide services on a "cost plus" basis to other Group companies, and consequently generate profits that are subject to corporation tax in the United States and Germany. Income tax payable was $0.1 million as at 30 June 2019, $0.02 million as at 31 December 2018, $0.1 million as at 31 December 2017, and $0.1 million as at 31 December 2016.

(m) **Trade and other payables**

Trade and other payables were $2.5 million as at 30 June 2019, $4.1 million as at 31 December 2018, $4.7 million as at 31 December 2017, and $2.4 million as at 31 December 2016. The decrease of $1.6million from 2018 to 30 June 2019 and $0.4 million from 2017 to 2018 is a result of timing of payments and a reduction in the U.S. Pivotal ReActiv8-B Clinical Trial accruals held due to the completion of all implants and less costs incurred from a reduction in patient visits.

The increase of $2.3 million from 2016 to 2017 included increases in accounts payable and accruals associated with increased levels of business activity principally driven by the U.S. Pivotal ReActiv8-B Clinical Trial and our expanded team supporting both the U.S. Pivotal ReActiv8-B Clinical Trial and also other activities such as commercialisation.

7.5 Cash Flows

The following table sets forth a summary of our consolidated cash flow statement for the years ended 31 December 2018, 31 December 2017 and 31 December 2016 and for the half years ended 30 June 2019 and 30 June 2018.

($'000)	**Year ended 31 December 2018**	**Year ended 31 December 2017**	**Year ended 31 December 2016**	**Half year ended 30 June 2019**	**Half year ended 30 June 2018**
Cash flow from operating activities					
Net loss attributable to equity holders	(31,077)	(29,835)	(18,758)	(11,146)	(16,523)
Add/(less) non-cash items					
Depreciation	89	107	120	174	50
Finance income	-	(46)	-	-	-
Finance expense	1,890	1,932	1,808	1,760	1,018
Share-based compensation	4,103	3,044	1,959	2,102	1,852
Income taxes	(98)	230	122	63	(156)
Add/(less) changes in working capital					

Trade and other receivables	(242)	318	(454)	(58)	(306)
Inventory	(180)	(1,272)	(929)	324	(80)
Trade and other payables	(517)	2,176	439	(1,793)	76
Taxes paid	(188)	(265)	(117)	(16)	(112)
Interest paid	(1,133)	(1,285)	(934)	(245)	(603)
Net cash used in operations	**(27,353)**	**(24,896)**	**(16,744)**	**(8,835)**	**(14,784)**
Cash flow from investing activities					
Acquisition of property and equipment	(123)	(53)	(195)	(6)	(26)
Net cash used in investing activities	**(123)**	**(53)**	**(195)**	**(6)**	**(26)**
Cash flow from financing activities					
Proceeds from issue of shares	37,486	54	33,775	-	37,486
Transaction costs on issue of shares	(1440)	-	(1,177)	-	(1,440)
Proceeds of borrowings	-	-	4,500	-	-
Repayment of borrowings	(3,000)	(1,800)	-	(750)	(1,500)
Transactions costs on borrowings	-	-	(113)	-	-
Payment of lease liabilities	-	-	-	(148)	-
Net cash from financing activities	**33,046**	**(1,746)**	**36,985**	**(898)**	**34,546**
Net increase/(decrease) in cash and cash equivalents	**5,570**	**(26,695)**	**20,046**	**(9,739)**	**19,736**

Cash and cash equivalents at beginning of period	9,975	36,670	16,624	15,545	9,975
Cash and cash equivalents at end of period	**15,545**	**9,975**	**36,670**	**5,806**	**29,711**

(a) **Non-cash items**

Non-cash items, which include (i) depreciation, (ii) finance income and expense, and (iii) share-based compensation are non-cash expenses which are included in the consolidated statement of comprehensive income and are adjusted as part of the calculation of net cash used in operations. The items with most significant movements are finance expense and share-based compensation.

Finance expense

Finance expense was ($1.8) million during the half year ended 30 June 2019. Finance expense was $1.9 million in 2018, $1.9 million in 2017, and $1.8 million in 2016. Finance expense primarily relates to interest paid on our interest-bearing loans and a small amount of foreign exchange losses.

Share-based compensation expenses

Share based compensation is a non-cash expense related to share options granted to employees and other consultants of the Group by members of the Group. Share based payment expense was $2.1 million for the half year ended 30 June 2019, $4.1 million in 2018, $3 million in 2017, and $2.0 million in 2016. The increase of $1.1 million in 2018 and $1.1 million in 2017 was primarily due to additional Ordinary Share options granted throughout these years to new and existing employees.

(b) **Changes in working capital**

Changes in working capital comprises trade and other receivables, inventory and trade and other payables.

Trade and other receivables

The changes in trade and other receivables, were $(0.1) million for the half year ended 30 June 2019, $(0.2) million in 2018, $0.3 million in 2017, and $(0.5) million in 2016. These adjustments primarily relate to timing of payments during the year from customers, insurance, rent and down-payments to inventory suppliers to secure inventory orders.

Inventory

Changes in inventory were $0.3 million from 2018 to 30 June 2019, $(0.2) million in 2018, $(1.3) million in 2017, and $(0.9) million in 2016. In May 2016 Mainstay received CE Marking for ReActiv8, and consequently we commenced build up of inventory in preparation for commercialisation during 2016 and 2017. After these build ups, Mainstay did not require significant additional inventory investment in 2018.

Trade and other payables

The changes in trade and other payables were $(1.8) million for the half year ended 30 June 2019, $(0.6) million in 2018, $2.4 million in 2017, and $0.6 million in 2016. The change in 2019 relates to an decrease in accruals and payables associated with business activities. The change in 2017 relates to an increase in accruals and payables associated with business activities (principally the U.S. Pivotal

ReActiv8-B Clinical Trial) and payroll and employee benefits accruals including the impact of increased employee numbers.

Taxes Paid

Taxes received or paid were $0.02 million paid in the half year ended 30 June 2019, $0.2 million paid in 2018, $0.3 million paid in 2017, and $0.1 million paid in 2016. Taxes paid during 2019, 2018 and 2017 primarily relate to corporation tax paid to the IRS on the profits generated in our U.S. subsidiary net of R&D tax credits received in other jurisdictions.

Interest Paid

Interest paid was $0.2 million for the half year ended 30 June 2019, $1.1 million in 2018, $1.3 million in 2017, and $0.9 million paid in 2016. The interest payments relate to interest payments on the IPF facility. We drew down tranches of the debt during 2015, 2016 and July 2019. Consequently the average principal outstanding on which interest is calculated was higher in 2017 than the average outstanding in previous years. Refer to paragraph 7.4(k) of this Part 7 (*Operating and Financial Review*) for information on principal outstanding on our interest-bearing liabilities as at 30 June 2019, 31 December 2018, 2017 and 2016, and timing of draw down dates of principal.

Net cash used in investing activities

Net cash used in investing activities represented a net cash outflow of $0.01 million for the half year ended 30 June 2019, $0.12 million in 2018, $0.05 million in 2017, and $0.2 million in 2016 and consisted primarily of expenditure on office fit out and computer equipment. Our strategy is to outsource manufacturing for our product development and early commercialisation activities and accordingly we have not invested in manufacturing facilities or equipment. Similarly, we lease or license our office facilities.

Proceeds from issue of shares

Net proceeds from issue of Ordinary Shares were a net cash inflow of nil for the half year ended 30 June 2019, $37.5 million in 2018, $0.1 million in 2017, and $33.8 million in 2016. These inflows relate to once off transactions, primarily (i) the 2018 Placing ($37.5 million received), (ii) proceeds received on the exercise of share options or warrants over Ordinary Shares in 2016 ($0.1 million received) and in 2017 ($0.1 million received), and (iii) the 2016 Placing ($33.7 million received).

Transaction costs on issue of shares

Transaction costs on issue of shares were $1.4 million in 2018 and related to the transaction fees on the 2018 Placing. Transaction costs on issue of shares were $1.2 million in 2016 and related to the transaction fees on the 2016 Placing.

Proceeds from borrowings

Proceeds from borrowings in 2016 relate to Tranche C of the IPF facility received in July 2016. Refer to the *loans and borrowings* section of paragraph *7.4(k)* of this Part 7 (*Operating and Financial Review*) for further information on the IPF facility.

Repayment of borrowings

In 2017 we commenced repayment of our IPF facility, and $1.8 million of principal repayments were made. We made a further $3 million in principal repayments in 2018 and $0.8 million in 2019. Refer to the *loans and borrowings* section of paragraph *7.4(k)* of this Part 7 (*Operating and Financial Review*) for further information on the IPF facility.

Transaction costs on borrowings

Transaction costs on borrowings in 2016 relate to structure fees paid to IPF due at the date of drawdown of our debt.

7.6 Impact of inflation

The result of the Group's operations for the periods discussed have not been materially affected by inflation.

7.7 Liquidity and capital resources

Since our inception to date, we have funded our operations through the issuance and sale of equity of approximately $139.1 million and as at 30 June 2019 we have outstanding debt principal of $9.45 million. From inception to 30 June 2019, we have generated a limited amount of revenue of $1.6 million.

On 29 July 2019, we announced the 2019 Placing pursuant to which we raised gross proceeds of $15.5 million and the drawdown of $3.3 million in additional debt from the Group's existing lender. The Company has used, and intends to continue to use over the course of the next 12 months, the net proceeds from the 2019 Placing:

- to further the application for pre-market approval from the FDA in the United States;
- to continue to advance the initial commercial validation of ReActiv8 in Germany and additional markets; and
- for general corporate purposes.

We expect to incur substantial operating expenditures in the foreseeable future in connection with commercialisation in Europe, ongoing research and development and the continuation of clinical trials and post market clinical follow-up activities. If ReActiv8 receives approval for commercial sale in the U.S., we expect that additional funding will be required to build the associated sales, marketing and distribution infrastructure necessary to roll-out ReActiv8.

We continue to explore funding strategies (e.g. equity, debt, collaboration) to support the Group's activities into the future. Additional equity, debt financing and/or corporate collaboration may not be available on acceptable terms, if at all. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the costs, timing and outcomes of clinical trials;
- the costs and timing of seeking and obtaining approvals from the FDA and other regulatory authorities, including the potential for the FDA and other regulatory authorities to require that we collect additional data, or perform additional clinical trials;
- the costs of maintaining regulatory approval;
- the costs, timing and outcomes of activities to obtain reimbursement for the ReActiv8 therapy;
- the costs of commercialisation activities including product sales, marketing, manufacturing and distribution;
- the degree and rate of market acceptance of ReActiv8;
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims;
- the extent to which competing technologies emerge or other adverse market developments;
- our need to implement additional infrastructure and internal systems; and
- our ability to hire additional personnel to support our ongoing operations.

7.8 Off-balance sheet arrangements

We have no off-balance sheet arrangements, and did not have any during the years presented.

Further information on our lease commitments is available in note 2, page 17 of our 2019 half year report, note 23, page 89 of our 2018 report, in note 23, page 72 of our 2017 annual report and in note 21, page 66 of our 2016 annual report, each of which is incorporated by reference in Part 8 (*Historical Financial Information*) of this document.

7.9 Quantitative and Qualitative Disclosures about Financial Risks

Our activities expose us to a variety of financial risks: credit risk, liquidity risk and market risk (comprising foreign currency risk and interest rate risk). Our principal financial instruments are cash and cash equivalents, which are used to finance our operations.

Credit risk

Credit risk is the risk of financial loss to the Group if a customer or counterparty to a financial instrument fails to meet contractual obligations, and arises principally from the Group's cash and cash equivalents and trade and other receivables. Credit risk is managed on a Group basis. The maximum exposure of each asset to credit risk is represented by their carrying value which, for cash and cash equivalents and trade and other receivables is a reasonable approximation of fair value. The Group's objective is to manage credit risk.

The Group maintained its cash balances with its principal financial institutions throughout the year, and the Group limits its exposure to any one financial institution by holding cash balances across several financial institutions. The Group's principal financial institutions have investment grade ratings at 30 June 2019. The credit rating status of the Group's principal financial institutions is reviewed by the Audit Committee or the Board at least annually. The cash balance is reported to the Board of Directors on a monthly basis, and a monthly review of all cash balances held at each institution is carried out by the CFO. The Group maintains most of its cash in USD denominated accounts.

The Group's credit risk management policy and process in relation to trade receivables involves carrying out credit checks where appropriate, and by active credit management. The utilisation of credit limits is regularly monitored. In addition, it involves periodically assessing the financial reliability of customers, taking into account their financial position, past experience and other factors.

As at 30 June 2019 and 31 December 2018 our trade receivables amounted to $0.2 million and $0.1 million respectively (2017: $0.1 and 2016: $nil), and we have not recognised any impairment losses in relation to these.

The below table provides an analysis of aging of receivables as at 30 June 2019:

($'000)	**Current**	**1 - 30 Days**	**31 - 60 Days**	**61 – 90 Days**	**>90 Days**
Trade and other receivables	47	14	15	-	100

The Group evaluates customer accounts with past-due outstanding balances, and analyses customer credit worthiness, payment patterns and trends. Based upon a review of these accounts and management's analysis and judgement, we estimate the future cash flows expected to be recovered from these receivables and we have not recorded any impairment losses.

Liquidity risk

Liquidity risk is the risk that we will not be able to meet our financial obligations as they fall due.

Since inception we have funded our operations primarily through (i) the issuance of equity securities and (ii) debt funding. We continue to explore funding strategies (e.g. equity, debt, collaboration) to support our activities into the future. Adequate additional financing may not be available to us on acceptable terms, or at all. Our inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy.

Foreign currency risk

Foreign currency risk refers to the risk that the fair value of a financial instrument will fluctuate due to changes in foreign currency rates. Our exposure to foreign currency risk arises because our reporting currency is the U.S. Dollar and some of our expenditures are incurred in Euros and Australian Dollars. Our Australian subsidiary has an Australian Dollar functional currency and three of the Group's subsidiaries located in Ireland, the Netherlands and Germany have a Euro functional currency. Exposures are generally managed through natural hedging via the currency denomination of cash balances and any impact currently is not material to us.

Any reasonable or likely movement between the U.S. Dollar and the Australian Dollar is considered not likely to have a material impact on the Group's statement of profit or loss and other comprehensive income.

Interest rate risk

Our cash balances are maintained in short term access accounts and carry a floating rate of interest. A 50 basis points change in the rate of interest applied to our cash balance would not have had a material impact on our results of operations.

At 30 June 2019 and 31 December 2018, the principal outstanding on our loan under the IPF facility was $9.5 million and $10.2 million respectively (2017: $13.2 million and 2016: $15 million). The loan originally carried a variable rate of 3-month Euribor plus a margin ranging from 10.5% to 12.5%. The terms of the debt agreement stipulated that if Euribor is less than zero, it is deemed to be zero. Any change in the Euribor rate above zero will directly affect the amount of interest repayable on this debt.

The repayment schedule for the three existing tranches drawn under the debt facility was amended under the IPF Amendment and Restatement Agreement such that no principal or interest will be repaid until 2021, with the principal and accrued interest to be amortized over the period from 1 January 2021 through 30 September 2023. The interest rate for all tranches will be 8% per annum, with interest accruing but capitalized prior to January 1, 2021.

7.10 Critical accounting policies and estimates

In the preparation of our financial statements, we are required to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities in our financial statements at the reporting date, as well as the disclosure of amounts of income and expenses for the reporting period. These estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Estimates are made in respect of fair values of financial instruments, impairment losses, income taxes and deferred income taxes, provisions for employee's vacation leave payments, advances repayable, share based payments, the useful life and residual values of equipment, and development costs.

Actual results could differ materially from these estimates, which could materially affect the results reported in these financial statements.

Our estimates and assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revisions affect only that period, or

in the period of the revisions and future periods if the revisions affect both the current and future periods.

PART 8
HISTORICAL FINANCIAL INFORMATION

8.1 Basis of the financial information

The financial statements of the Group included in the consolidated audited annual reports and accounts of the Group for each of the three years ended 31 December 2018, 31 December 2017 and 31 December 2016 (as identified in the cross reference list in paragraph 8.3 below), together with the audit reports thereon, are incorporated by reference into the Prospectus. The financial statements for the years ended 31 December 2018, 31 December 2017 and 31 December 2016 have been prepared in accordance with IFRS and IFRS interpretations as issued by the International Accounting Standards Board, as adopted by the European Union and with those parts of the Companies Act 2014 applicable to companies reporting under IFRS.

The condensed consolidated financial statements of the Group included in the 2019 half yearly financial results for the half year ended 30 June 2019 (as identified in the cross reference list in paragraph 8.3) are also incorporated by reference into the Prospectus. The condensed consolidated financial statements for the half year ended 30 June 2019 have been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the EU. The condensed consolidated financial statements for the half year ended 30 June 2019 have not been reviewed by the Company's auditors.

8.2 Selected historical key financial information

The summary historical financial information presented below as at and for the years ended 31 December 2018, 2017, 2016 and the half year ended 30 June 2019 has been extracted without material adjustment from the Group's Historical Financial Information, set out in the Group's summary financial information for the years ended 31 December 2018, 2017 and 2016 and has been audited by KPMG.

The summary historical financial information presented below as at and for the half year ended 30 June 2019 and 2018 has been extracted without material adjustment from the Group's unaudited 2019 half yearly financial results.

Information relating to the Group's consolidated statement of profit or loss and other comprehensive income:

($'000)	**Year ended 31 December 2018**	**Year ended 31 December 2017**	**Year ended 31 December 2016**	**Half year ended 30 June 2019**	**Half year ended 30 June 2018**
Revenue	663	348	-	552	358
Cost of sales	(359)	(190)	-	(316)	(170)
Gross profit	304	158	-	236	188
Operating expenses	(29,589)	(27,877)	(16,828)	(9,559)	(15,849)
Operating loss	(29,285)	(27,719)	(16,828)	(9,323)	(15,661)
Finance income	-	46	-	-	-
Finance expense	(1,890)	(1,932)	(1,808)	(1,760)	(1,018)
Net finance expense	(1,890)	(1,886)	(1,808)	(1,760)	(1,018)
Loss before income taxes	**(31,175)**	**(29,605)**	**(18,636)**	**(11,083)**	**(16,679)**
Income taxes	98	(230)	(122)	(63)	156
Loss for the year	**(31,077)**	**(29,835)**	**(18,758)**	**(11,146)**	**(16,523)**
Other comprehensive					

income					
Items that may be reclassified subsequently to the statement of profit or loss:					
Foreign currency translation difference of foreign operations	33	(142)	35	(20)	56
Total comprehensive loss for the year	**(31,044)**	**(29,977)**	**(18,723)**	**(11,166)**	**(16,467)**

Consolidated statement of financial position of the Group:

($'000)	**31 December 2018**	**31 December 2017**	**31 December 2016**	**Half year ended 30 June 2019**	**Half year ended 30 June 2018**
Non-current assets					
Property, plant and equipment	235	201	255	191	177
Right of use asset	-	-	-	414	-
Total non-current assets	235	201	255	605	177
Current assets					
Trade and other receivables	813	571	889	871	875
Income tax receivable	213	205	103	212	345
Inventory	2,575	2,395	1,123	2,251	2,474
Cash and cash equivalents	15,545	9,975	36,670	5,806	29,711
Total current assets	19,146	13,146	38,785	9,140	33,405
Total assets	**19,381**	**13,347**	**39,040**	**9,745**	**33,582**
Equity					
Share capital	67	64	64	67	67
Share premium	143,897	106,414	106,360	143,898	143,897
Share based payment reserve	11,716	7,613	4,606	15,797	9,465
Other reserves	4,626	4,593	4,735	4,606	4,649
Retained loss	(157,022)	(124,505)	(94,707)	(168,219)	(142,468)
(Deficit)/ surplus on shareholders' equity	3,284	(5,821)	21,058	(3,851)	15,610
Non-current liabilities					
Loans and borrowings	8,791	11,177	13,276	9,348	9,991
Derivate financial instruments	-	-	-	1,098	-
Total non-current liabilities	8,791	11,177	13,276	10,782	9,991

Current liabilities					
Loans and borrowings	3,158	3,214	2,268	215	3,182
Income tax payable	18	124	58	64	12
Trade and other payables	4,130	4,653	2,380	2,473	4,787
Deferred revenue	-	-	-	62	-
Total current liabilities	7,306	7,991	4,706	2,814	7,981
Total liabilities	**16,097**	**19,168**	**17,982**	**13,596**	**17,972**
Total equity and liabilities	**19,381**	**13,347**	**39,040**	**9,745**	**33,582**

Consolidated statement of cashflows of the Group:

($'000)	**Year ended 31 December 2018**	**Year ended 31 December 2017**	**Year ended 31 December 2016**	**Half year ended 30 June 2019**	**Half year ended 30 June 2018**
Cash flow from operating activities					
Net loss attributable to equity holders	(31,077)	(29,835)	(18,758)	(11,146)	(16,523)
Add/(less) non-cash items					
Depreciation	89	107	120	174	50
Finance income	-	(46)	-	-	-
Finance expense	1,890	1,932	1,808	1,760	1,018
Share-based compensation	4,103	3,044	1,959	2,102	1,852
Add/(less) changes in working capital					
Trade and other receivables	(242)	318	(454)	(58)	(306)
Inventory	(180)	(1,272)	(929)	324	(80)
Trade and other payables	(517)	2,406	561	(1,793)	76
Taxes paid	(188)	(265)	(117)	(16)	(112)
Interest paid	(1,133)	(1,285)	(934)	(245)	(603)
Net cash used in operations	**(27,353)**	**(24,896)**	**(16,744)**	**(8,835)**	**(14,784)**
Cash flow from investing activities					
Acquisition of property and equipment	(123)	(53)	(195)	(6)	(26)
Net cash used in investing activities	**(123)**	**(53)**	**(195)**	**(6)**	**(26)**
Cash flow from financing activities					
Proceeds from issue of shares	37,486	54	33,775	-	37,486
Transaction costs on issue of shares	(1,440)	-	(1,177)	-	(1,440)

Proceeds of borrowings	-	-	4,500	-	-
Repayment of borrowings	(3,000)	(1,800)	-	(750)	(1,500)
Transactions costs on borrowings	-	-	(113)	-	-
Payment of lease liabilities	-	-	-	(148)	-
Net cash from financing activities	**33,046**	**(1,746)**	**36,985**	**(898)**	**34,546**
Net increase/(decrease) in cash and cash equivalents	**5,570**	**(26,695)**	**20,046**	**(9,739)**	**19,736**
Cash and cash equivalents at beginning of period	9,975	36,670	16,624	15,545	9,975
Cash and cash equivalents at end of period	**15,545**	**9,975**	**36,670**	**5,806**	**29,711**

Certain significant changes impacted on the Group's financial position and results of operations during the financial years 2018, 2017 and 2016 and for the half year ended 30 June 2019. These included (i) a $15 million debt facility provided by IPF, of which $15 million was drawn and received at 31 December 2016, and during 2017 repayments of $1.8 million were made, and during 2018 repayments of $3 million were made, (ii) the 2016 Placing consisting of the issuance of 2,307,694 Ordinary Shares on 17 June 2016 for gross proceeds of approximately €30 million and (iii) the issuance of 2,151,332 Ordinary Shares pursuant to the 2018 Placing raising gross proceeds of approximately €30.1 million.

Save for the 2019 Placing as described in this Prospectus, there has been no significant change in the financial position or financial performance of the Group from 30 June 2019, being the end of the last financial period for which financial information of the Group has been published, being the 2019 half yearly financial results for the half year ended 30 June 2019 which are incorporated by reference herein.

8.3 Cross reference list

The following list is intended to enable investors to identity easily specific items of information which have been incorporated by reference into this document. Only the parts of the documents identified in the list below are incorporated into and form part of this document. The parts of the documents which are not incorporated by reference are either not relevant for prospective investors or are covered elsewhere in this document.

The financial statements for the year ended 31 December 2018 and the Independent Auditors' Report thereon are incorporated by reference to the Company's 2018 annual report. The 2018 annual report is available on the Company's website at

https://www.mainstay-medical.com/sites/default/files/2019-04/Mainstay%20-%20FY18%20Annual%20Report%20%20-%20with%20English%20press%20release_2.pdf

The page numbers below refer to the relevant pages of the 2018 annual report incorporated:

Section	**Page numbers in such document**

Section	Page numbers in such document
Directors' Responsibilities' Statement	57
Independent Auditors Report to the Members	59 - 63
Consolidated statement of profit or loss and other comprehensive income for the year	64
Consolidated statement of financial position	65
Consolidated statement of changes in shareholders' equity	66
Consolidated statement of cash flows	67
Notes to the consolidated financial statements	68 - 92
Parent Company financial statements	93 - 97

The financial statements for the year ended 31 December 2017 and the Independent Auditors' Report thereon are incorporated by reference to the Company's 2017 annual report. The 2017 annual report is available on the Company's website at

https://www.mainstay-medical.com/sites/default/files/2018-02/FY17-AR-15-Feb-2018-with-Press-Release-English-FINAL.PDF

The page numbers below refer to the relevant pages of the 2016 annual report incorporated:

Section	Page numbers in such document
Directors' Responsibilities' Statement	42
Independent Auditors Report to the Members	43-47
Consolidated statement of profit or loss and other comprehensive income for the year	48
Consolidated statement of financial position	49
Consolidated statement of changes in shareholders' equity	50
Consolidated statement of cash flows	51
Notes to the consolidated financial statements	52 - 73
Parent Company financial statements	74 - 78

The financial statements for the year ended 31 December 2016 and the Independent Auditor's Report thereon are incorporated by reference to the Company's 2016 annual report. The 2016 annual report is available on the Company's website at

https://www.mainstay-medical.com/sites/default/files/2017-03/MMIplc%20FY16%20AR%20Press%20Release%20English%20with%20Annual%20Report%20FINAL.pdf

The page numbers below refer to the relevant pages of the 2016 annual report incorporated:

Section	Page numbers in such document
Directors' Responsibilities' Statement	42
Independent Auditors Report to the Members	43 - 44
Consolidated statement of profit or loss and other comprehensive income for the year	45
Consolidated statement of financial position	46
Consolidated statement of changes in shareholders' equity	47
Consolidated statement of cash flows	48
Notes to the consolidated financial statements	49 - 67
Parent Company financial statements	68-72

The financial statements for the half year ended 30 June 2019 are incorporated by reference to the Company's 2019 half year financial results. The 2019 half year financial results are available on the Company's website at:

http://www.mainstay-medical.com/en/investors/results_and_presentations

The page numbers below refer to the relevant pages of the 2019 half year financial results incorporated:

Section	Page numbers in such document
Directors' Responsibilities' Statement	11
Condensed consolidated statement of profit or loss and other comprehensive income	12
Condensed consolidated statement of financial position	13
Condensed consolidated statement of changes in shareholders' equity	14
Condensed consolidated statement of cash flows	15
Notes to the condensed consolidated financial statements	16

PART 9
ADDITIONAL INFORMATION

9.1 RESPONSIBILITY

The Company and the Directors (whose names appear on page 32 of this document) accept responsibility for the information contained in this document. To the best of the knowledge of the Company and the Directors (who have taken all reasonable care to ensure that such is the case), the information contained in this document is in accordance with the facts and does not omit anything likely to affect the import of such information.

9.2 INFORMATION ON THE COMPANY

(a) The Company was incorporated and registered in Ireland on 17 February 2014 with registered number 539688 pursuant to the Irish Companies Acts as a public limited company under the name Mainstay Medical Holdings plc. It changed its name to Mainstay Medical plc on 10 March 2014 and to Mainstay Medical International plc on 25 March 2014.

(b) The principal legislation under which the Company operates, and under which the New Ordinary Shares were created, is the Companies Act 2014 and the regulations made thereunder.

(c) The Company is domiciled in Ireland. The registered office of the Company is at 77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, Dublin 2, D02 VK60.

(d) KPMG Chartered Accountants, whose address is 1 Stokes Place, St. Stephen's Green, Dublin 2, have been appointed as the auditors of the Company and have been the only auditors of the Company since its incorporation. Consolidated audited statutory financial statements comprising the results of the Group have been prepared for the years ended 31 December 2018, 2017 and 2016. The audited financial statements (together with other required information and documents) for the years ended 31 December 2018, 2017 and 2016 have been filed with the Companies Registration Office in Dublin.

9.3 SHARE CAPITAL OF THE COMPANY

Authorised and issued share capital

(a) As at the Latest Practicable Date, the authorised and issued share capital of the Company, all of which is fully paid up, is as follows:

Class of shares	Authorised Number	Issued and fully paid number
Ordinary Shares	20,000,000	13,421,504
Deferred Shares	40,000	40,000

As at 1 January 2018, there were in issue 6,618,897 Ordinary Shares and 40,000 Deferred Shares. As at 1 January 2019, there were in issue 8,770,229 Ordinary Shares and 40,000 Deferred Shares.

Share capital history

(b) The share capital history of the Company since 1 January 2016 is as follows:

(i) During 2016, 6,055 warrants over Ordinary Shares were exercised by the holders and the Company issued 6,055 Ordinary Shares.

(ii) On 17 June 2016, on completion of the 2016 Placing, the Company issued 2,307,694 Ordinary Shares. Those shares were admitted to trading on Euronext Paris and Euronext Growth on 16 August 2016.

(iii) During 2017, 6,945 warrants over Ordinary Shares were exercised by the holders and the Company issued 6,945 Ordinary Shares.

(iv) Pursuant to the 2018 Placing, the Company issued 2,151,332 new Ordinary Shares.

(v) Pursuant to the 2019 Placing, the Company issued 4,649,775 New Ordinary Shares

Conditional rights to subscribe for Ordinary Shares

(c) Pursuant to the First Warrant Instrument the Company has issued 1,500,000 warrants to subscribe for Ordinary Shares at an exercise price of €6.00 per Ordinary Share. See paragraph 9.12(b) of this Part 9 (*Additional Information*) for further information.

(d) Under the terms of the IPF Facility Agreement and the Second Warrant Instrument, the Company may be required to issue up to 1,851,515 Ordinary Shares at a price of €8.00 per Ordinary Share. See paragraphs 9.12(c) and 9.12(e) of this Part 9 (*Additional Information*) for further information.

Share Options and RSUs

(e) At the Latest Practicable date, 2,708,817 Share Options and 390,000 RSUs are in issue and outstanding. See paragraph 6.4(c) of Part 6 (*Directors, Senior Management and Corporate Governance*) for further information.

Other acquisition rights or obligations

(f) Save as disclosed in paragraph 9.3, there are no acquisition rights or obligations in relation to the issue of shares in the capital of the Company or an undertaking to increase the capital of the Company.

9.4 SHARE CAPITAL AUTHORISATIONS

(a) On 20 September 2019, at the Company's 2019 AGM, the Shareholders passed resolutions:

(i) authorising the Directors, pursuant to section 1021 of the Companies Act 2014, in substitution for all existing such authorities, to exercise all powers of the Company to allot relevant securities (within the meaning of section 1021 of the Companies Act 2014) up to an aggregate nominal amount of €17,000 during the period commencing on the date of the passing of the resolution and expiring on 20 September 2024 (being five years after the date of passing of the resolution), provided that the Company may before such expiry make an offer or agreement which would or might require relevant securities to be allotted after such expiry and the Directors may allot relevant securities in pursuance of such offer or agreement as if the authority hereby conferred had not expired.

(ii) empowering the Directors, pursuant to section 1023 of the Companies Act 2014, in substitution for all existing such authorities, to allot equity securities (within the meaning of section 1022 of the Companies Act 2014) for cash pursuant to the authority conferred by the resolution above as if sub-section (1) of section 1022 of the Companies Act 2014 did not apply to any such allotment, provided that this power shall be limited:

(A) to the allotment of equity securities in connection with a rights issue, open offer or other invitation to or in favour of the holders of ordinary shares in the Company where the equity securities respectively attributable to the interests of such holders are proportional (as nearly as may be) to the numbers of ordinary shares in the Company held by them (but subject to such exclusions or other arrangements as the Directors may deem necessary or expedient to deal with fractional entitlements that would otherwise arise or with legal or practical problems under the laws of, or the requirements of

any recognised regulatory body or any stock exchange in, any territory, or otherwise howsoever); and

(B) to the allotment (otherwise than pursuant to sub-paragraph (A) above) of equity securities up to an aggregate nominal amount of €17,000,

and shall expire on 20 September 2024 (being five years after the date of passing of the resolution), provided that the Company may before such expiry make an offer or agreement which would or might require equity securities to be allotted after such expiry and the Directors may allot equity securities in pursuance of such offer or agreement as if the power hereby conferred had not expired.

(b) The New Ordinary Shares issued under the 2019 Placing were authorised pursuant to resolutions passed at the Company's 2018 AGM similar to those describe above in paragraph 9.4(a).

9.5 INTERESTS OF MAJOR SHAREHOLDERS

In so far as is known to the Company, the following persons had an interest which represented three per cent. or more of the issued ordinary share capital of the Company, being an interest in the Company's capital or voting rights which is notifiable under the Transparency Rules:

	Immediately prior to the 2019 Placing		*As at the Latest Practicable Date*	
Name	*Number of issued Ordinary Shares*	*Percentage of issued ordinary share capital*	*Number of issued Ordinary Shares* (2)	*Percentage of issued ordinary share capital*
Sofinnova Capital VI FCPR	2,415,813	27.5%	2,949,146	22.0%
KCK Limited	1,582,418	18.0%	2,236,418	16.7%
Fountain Healthcare Partners (1)	935,220	10.7%	2,268,553	16.9%
ISIF	714,285	8.1%	714,285	5.3%
Dan Sachs, MD	515,000	5.9%	515,000	3.8%
Seamus Mulligan (3)	372,039	4.2%	772,039	5.8%
RICA Universal, S.A.	64,935	0.7%	1,064,935	7.9%

Notes:

(1) Fountain Healthcare Partners Fund 1, L.P holds 935,220 Ordinary Shares and Fountain Healthcare Partners Fund 3, L.P. holds 1,333,333 Ordinary Shares. Fountain Healthcare Partners Fund 1, L.P. also holds 40,000 Deferred Shares.

(2) Numbers include the following numbers of New Ordinary Shares subscribed for under the 2019 Placing: (i) Sofinnova Capital VI FCPR: 533,333 New Ordinary Shares (ii) KCK Limited: 654,000 New Ordinary Shares (iii) Fountain Healthcare Partners Fund 3, L.P: 1,333,333 New Ordinary Shares and (iv) Nerano Capital Limited (a company controlled by Seamus Mulligan): 400,000 New Ordinary Shares.

(3) Includes Ordinary Shares held by Barrymore Investments Limited and Nerano Capital Limited (both companies controlled by Seamus Mulligan).

As of the Latest Practicable Date the Company is not aware of any other person, who, directly or indirectly, jointly or severally, exercises or could exercise control over the Company nor is it aware of any arrangements the operation of which may at a subsequent date result in a change in control over the Company. All Ordinary Shares have the same voting rights. The Deferred Shares do not have any voting rights.

9.6 CONSTITUTION

The following is a summary of the Constitution, comprised of the Memorandum of Association and the Articles of Association, of the Company. Any Shareholder requiring further detail than that provided in the summary is advised to consult the copies of the Constitution of the Company, which are available at the Company's registered office in Ireland and on the Company's website.

(a) Memorandum of Association

The Memorandum of Association provides that the Company's objects are, among other things, to carry on the business of manufacturers, developers, designers or sellers of medical equipment, products, devices, processes, procedures, and all manners of like or related work or business; to carry out technical, engineering, theoretical, scientific, biological, chemical or pharmaceutical activities or any other form of related activities, procedures or businesses; to carry on the business of a holding company and to co-ordinate the administration, finances and activities of any subsidiary companies or associated companies; and to acquire the entire issued share capital of MML and its subsidiaries and subsidiary undertakings.

The objects of the Company are set out in full in clause 3 of the Memorandum of Association.

(b) Articles of Association

The Articles of Association of the Company contain (among others) provisions to the following effect:

Deferred Shares

The holders of Deferred Shares are not entitled to receive notice of, or to attend or vote at, any general meeting of the Company or to receive any dividend or distribution. On a return of assets on a winding up of the Company, the holders of the Deferred Shares shall only be entitled to repayment of the amounts paid up on those shares after the holders of the Ordinary Shares have received the sum of €1,000,000 for each Ordinary Share held by them and shall not be entitled to any further participation in the assets and profits of the Company. The Directors in their absolute discretion and without assigning any reason therefor may decline to register any transfer of a Deferred Share. The Company is authorised at any time to appoint any person to execute on behalf of the holder(s) of Deferred Shares a transfer thereof and/or an agreement to transfer the same, without making any payment to the holder(s) thereof and persons so entitled, to such person(s) as the Company may determine as holder(s) thereof and beneficially entitled thereto.

Disclosure of Interests

If in their absolute discretion the Directors consider it to be in the interests of the Company to do so, they may, at any time and from time to time, by notice require any holder of a share, or any other person appearing to be interested or to have been interested in such share, to disclose to the Company in writing within such period as may be specified in such notice (which shall not be less than 28 days from the date of issue of such notice) such information as the Directors shall require relating to the ownership of or any interest in such share and as lies within the knowledge of such holder or other person (supported if the Directors so require by a statutory declaration and/or by independent evidence) including (without prejudice to the generality of the foregoing) any information which the Company is entitled to seek pursuant to section 1062 of the Companies Act 2014.

Transfer of shares

Subject to such of the restrictions of the Articles and to such of the conditions of issue as may be applicable, the shares of any member may be transferred by instrument in writing in any usual or common form or any other form which the Directors may approve.

The instrument of transfer of any share shall be executed by or on behalf of the transferor and, in cases where the share is not fully paid, by or on behalf of the transferee. The transferor shall be

deemed to remain the holder of the share until the name of the transferee is entered in the register in respect thereof.

The instrument of transfer of any share may be executed for and on behalf of the transferor by the Secretary or such person(s) (whether an individual, body corporate, officeholder or firm) that the Secretary nominates for that purpose from time to time (whether in respect of specific transfers or pursuant to a general standing authorisation), and the Secretary or relevant nominee shall be deemed to have been irrevocably appointed agent for the transferor of such share or shares with full power to execute, complete and deliver in the name of and on behalf of the transferor of such share or shares all such transfers of shares held by the members in the share capital of the Company.

Any document which records the name of the transferor, the name of the transferee, the class and number of shares agreed to be transferred, the date of the agreement to transfer shares and the price per share, shall, once executed by the transferor or the Secretary or a relevant nominee as agent for the transferor (and separately by the Secretary or a relevant nominee on behalf of the Company where the transfer is to a Depositary), be deemed to be a proper instrument of transfer for the purposes of the Companies Act 2014.

The Company, at its absolute discretion and insofar as the Companies Act 2014 or any other applicable law permits, may, or may procure that a subsidiary of the Company shall, pay Irish stamp duty arising on a transfer of shares on behalf of the transferee of such shares of the Company. If stamp duty resulting from the transfer of shares in the Company which would otherwise be payable by the transferee is paid by the Company or any subsidiary of the Company on behalf of the transferee, then in those circumstances, the Company shall, on its behalf or on behalf of its subsidiary (as the case may be), be entitled to (i) seek reimbursement of the stamp duty from the transferee, (ii) set-off the stamp duty against any dividends payable to the transferee of those shares and (iii) insofar as permitted by the Companies Act 2014, to claim a first and permanent lien on the shares on which stamp duty has been paid by the Company or its subsidiary for the amount of stamp duty paid. The Company's lien shall extend to all dividends paid on those shares.

The Directors in their absolute discretion and without assigning any reason therefor may decline to register any transfer, or renunciation of a renounceable letter of allotment, of a share which is not fully paid provided that the Directors shall not refuse to register any transfer or renunciation of partly paid shares which are listed or dealt in on any Approved Market (as that term is defined in the Articles of Association) on the grounds that they are partly paid shares in circumstances where such refusal would prevent dealings in such shares from taking place on an open and proper basis.

The Directors may decline to recognise any instrument of transfer, or renunciation of a renounceable letter of allotment, of any shares unless:

- it is lodged at the registered office of the Company or at such other place as the Directors may appoint and is accompanied by the certificate of the shares to which it relates (except in the case of a renunciation) and such other evidence as the Directors may reasonably require to prove the title of the transferor or person renouncing and the due execution of the transfer or renunciation by him or, if the transfer or renunciation is executed by some other person on his behalf, the authority of that person to do so;
- it is in respect of one class of share only; and
- it is in favour of not more than four persons jointly.

Restriction of voting and other rights

(i) If at any time the Directors shall determine that a Specified Event (as defined in sub-paragraph (vii) below) shall have occurred in relation to any share or shares, they may in their absolute discretion serve a notice to such effect on the holder or holders thereof. Upon the expiry of 14 days from the service of any such notice (referred to as a "**Restriction Notice**") and for so long as such Restriction Notice shall remain in force:

(A) no holder or holders of the share or shares specified in such Restriction Notice (referred to as "**Specified Shares**") shall be entitled in respect of the Specified Shares to attend or vote either personally or by proxy at any general meeting of the Company or at any separate general meeting of the holders of the class of shares concerned or to exercise any other right conferred by membership in relation to any such meeting; and

(B) the Directors shall, where the Specified Shares represent not less than 0.25 per cent. of the class of shares concerned, be entitled:

(1) except in a winding up of the Company, to withhold payment of any sum (including shares issuable in lieu of dividends) payable, whether by way of dividend, capital or otherwise, in respect of the Specified Shares, and the Company shall not have any obligation to pay interest on any sum so withheld; and/or

(2) where the Specified Event concerned is the event described in sub-paragraph (vii) below, to refuse to register any transfer (other than an Approved Transfer as defined in sub-paragraph 9.6(b)(viii)(A) below) of the Specified Shares or any renunciation of any allotment of new shares or debentures made in respect of the Specified Shares.

(ii) A Restriction Notice shall be cancelled by the Directors as soon as reasonably practicable, but in any event not later than seven days, after the holder or holders concerned or any other relevant person shall have remedied the default by virtue of which the Specified Event shall have occurred. A Restriction Notice shall automatically cease to have effect in respect of any share comprised in an Approved Transfer upon registration thereof.

(iii) The Directors shall cause a notation to be made in the register against the name of any holder or holders in respect of whom a Restriction Notice shall have been served indicating the number of Specified Shares specified in such Restriction Notice and shall cause such notation to be deleted upon cancellation or cesser of such Restriction Notice.

(iv) Every determination of the Directors and every Restriction Notice served by them pursuant to the provisions of this paragraph shall be conclusive as against the holder or holders of any share and the validity of any notice served by the Directors in pursuance of this paragraph shall not be questioned by any person.

(v) If, while any Restriction Notice shall remain in force in respect of any Specified Shares, any further shares shall be issued in respect thereof pursuant to a capitalisation issue under the Articles, the Restriction Notice shall be deemed also to apply likewise to such holder or holders in respect of such further shares which shall as from the date of issue thereof form part of the Specified Shares for all purposes of this paragraph.

(vi) On the cancellation of any Restriction Notice, the Company shall pay to the holder (or, in the case of joint holders, the first named holder) on the register in respect of the Specified Shares as of the record date for any such sum all sums the payment of which shall have been withheld pursuant to the provisions of the Articles.

(vii) A "**Specified Event**" shall be deemed to have occurred in relation to a share if:

(A) the holder or any of the holders shall fail to pay any call or instalment of a call in respect of such share in the manner and at the time appointed for payment thereof;

(B) the holder or any of the holders or any other person shall fail to comply, to the satisfaction of the Directors and within the period prescribed by such notice, in relation to such share with the terms of any Disclosure Notice given to him under Article 11 of the Articles; or

(C) the holder or any of the holders or any other person shall fail to comply, to the satisfaction of the Directors and within the period prescribed by such notice, in relation to such share with the terms of any notice given to him pursuant to section 1062 of the Companies Act 2014.

(viii) For the purposes of the Articles:

(A) an "**Approved Transfer**" is a transfer of shares which:

(1) is made pursuant to acceptance of a general offer made by or on behalf of the offeror to all holders (or all such holders other than the offeror and nominees or subsidiaries of the offeror) of shares of any class; or

(2) the Directors are satisfied has been made pursuant to a bona fide sale of the whole of the beneficial interest in the shares comprised in the transfer to a person unconnected with the holder or with any other person appearing to be interested (within the meaning of Article 11 of the Articles) in such shares (and for this purpose it shall be assumed that no such sale has occurred where the relevant share transfer form presented for stamping has been stamped at a reduced rate of stamp duty by virtue of the transferor or transferee having claimed to be entitled to such reduced rate on the basis that no beneficial interest passes by the transfer); or

(3) is made pursuant to any bona fide sale on any stock exchange, unlisted securities market or over-the-counter market on which shares of that class are, for the time being, normally traded.

(B) reference to a person having failed to comply with the terms of a Disclosure Notice (as defined in the Articles) given to him under the Articles or a notice given to him pursuant to section 1062 of the Companies Act 2014 includes reference:

(1) to his having failed or refused to give all or any part of the information required by the notice; or

(2) to his having given information which he knows to be false in a material particular or having recklessly given information which is false in a material particular.

9.7 EMPLOYEES

Employees of the Group

Details of the number of the Group's permanent employees (including the Chief Executive Officer) during the years ended 31 December 2018, 31 December 2017 and 31 December 2016 are as follows:

Financial period ended	**Number of employees**
As at 31 December 2016	32
As at 31 December 2017	39
As at 31 December 2018	37
Latest Practicable Date	22

Latest Practicable Date

The table below sets out the number of employees of the Group for the Latest Practicable Date, as well as a breakdown of the persons employed by category:

Job Function	Ireland/ Europe	U.S.	Australia	Total
Research & Development and Quality	-	4	1	5
Clinical & Regulatory	-	1	1	2
Commercial General & Administration	12	3	-	15

As of the Latest Practicable Date, the Group's employees were based in Ireland, the Netherlands, Germany, and in U.S.

Consultants and temporary employees

The Group instructs a number of consultants who are integral to the business function.

As at the Latest Practicable Date, the Group employed the following consultants:

Job Function	Ireland/ Europe	U.S.	Australia	Total
Research & Development and Quality	-	2	-	2
Clinical & Regulatory	-	1	1	2
Commercial, General & Administration	2	-	-	2

31 December 2018

The table below sets out the number of employees of the Group for the financial period ended 31 December 2018, as well as a breakdown of the persons employed by category:

Job Function	Ireland/ Europe	U.S.	Australia	Total
Research & Development and Quality	3	9	-	12
Clinical & Regulatory	-	8	1	9
Commercial General & Administration	15	1	-	16

As of 31 December 2018, the Group's employees were based in Ireland, Germany, the Netherlands, Australia and in the U.S.

Consultants and temporary employees

The Group instructs a number of consultants who are integral to the business function.

As at 31 December 2018, the Group employed the following consultants:

Job Function	Ireland/ Europe	U.S.	Australia	Total
Research & Development and Quality	-	2	-	2
Clinical & Regulatory	3	1	3	7
Commercial, General & Administration	3	2	-	5

31 December 2017

The table below sets out the number of employees of the Group for the financial period ended 31 December 2017, as well as a breakdown of the persons employed by category:

Job Function	Ireland/ Europe	U.S.	Australia	Total
Research & Development and Quality	5	8	-	13
Clinical & Regulatory	-	9	1	10
Commercial General & Administration	15	1	-	16

As of 31 December 2017, the Group's employees were based in Ireland, Germany, the Netherlands, Australia and in the U.S.

Consultants and temporary employees

The Group instructs a number of consultants who are integral to the business function.

As at 31 December 2017, the Group employed the following consultants:

Job Function	Ireland/ Europe	U.S.	Australia	Total
Research & Development and Quality	-	2	-	2
Clinical & Regulatory	3	1	3	7
Commercial, General & Administration	3	2	-	5

31 December 2016

The table below sets out the number of employees of the Group for the financial period ended 31 December 2016, as well as a breakdown of the persons employed by category:

Job Function	Ireland/ Europe	U.S.	Australia	Total
Research & Development and Quality	5	7	-	12
Clinical & Regulatory	-	8	-	8
Commercial General & Administration	10	1	1	12

As of 31 December 2016, the Group's employees were based in Ireland, Germany, Australia and in the U.S.

Consultants and temporary employees

The Group instructs a number of consultants who are integral to the business function.

As at 31 December 2016, the Group employed the following consultants:

Job Function	Ireland/ Europe	U.S.	Australia	Total
Research & Development and Quality	-	2	-	2
Clinical & Regulatory	3	1	2	6
Commercial, General & Administration	2	1	-	3

9.8 WORKING CAPITAL

The Company having made due and careful enquiry is of the opinion that the Group has sufficient working capital for its present requirements that is, for at least the next 12 months from the date of the Prospectus.

9.9 NO SIGNIFICANT CHANGE

Save for the 2019 Placing as described in this Prospectus, there has been no significant change in the financial position or financial performance of the Group from 30 June 2019, being the end of the last financial period for which financial information of the Group has been published, being the 2019 half yearly financial results for the half year ended 30 June 2019 which are incorporated by reference herein.

9.10 RELATED PARTY TRANSACTIONS

(a) Related Party Transactions

With respect to the 2019 Placing, Sofinnova Partners, Fountain Healthcare Partners and KCK (who are considered substantial shareholders of the Company under the Euronext Growth Rules) subscribed for 533,333, 1,333,333 and 654,000 New Ordinary Shares respectively pursuant to the 2019 Placing. Their participation in the 2019 Placing constituted related party transactions under Rule 5.18 of the Euronext Growth Rules. The Directors (with the exception of Antoine Papiernik, Nael Karim Kassar and Greg Garfield), considered, having consulted with Davy, the Company's Euronext Growth Adviser, that the terms of their participation in the 2019 Placing were fair and reasonable insofar as the Company's shareholders were concerned.

David Brabazon, a Director, also participated in the 2019 Placing, subscribing for 155,000 New Ordinary Shares. As at the Latest Practicable Date, David Brabazon holds 212,828 Ordinary Shares, representing 1.59% of the issued ordinary share capital of the Company.

With respect to the 2018 Placing, Sofinnova Partners, Fountain Healthcare Partners and KCK (who are considered substantial shareholders of the Company under the Euronext Growth Rules) subscribed for 250,000, 138,280 and 428,572 new Ordinary Shares respectively pursuant to the 2018 Placing. Their participation in the 2018 Placing constituted related party transactions under Rule 5.18 of the Euronext Growth Rules. The Directors (with the exception of Antoine Papiernik, Dr. Manus Rogan, Nael Karim Kassar and Greg Garfield), considered, having consulted with Davy, the Company's Euronext Growth Adviser, that the terms of their participation in the 2018 Placing were fair and reasonable insofar as the Company's shareholders were concerned. Jason Hannon, David Brabazon and Greg Garfield, each a Director, also participated in the 2018 Placing, subscribing for 30,000, 30,000 and 2,912 new Ordinary Shares respectively.

Sofinnova Partners and Fountain Healthcare Partners (who are considered substantial shareholders of the Company under the Euronext Growth Rules) subscribed for 389,984 and 230,769 of the Ordinary Shares respectively pursuant to the 2016 Placing in June 2016. Their participation in the 2016 Placing constituted related party transactions under Rule 5.18 of the Euronext Growth Rules. The Directors appointed prior to the completion of 2016 Placing (with the exception of Antoine Papiernik and Dr. Manus Rogan), considered, having consulted with Davy, the Company's Euronext Growth Adviser, that the terms of their participation in the 2016 Placing were fair and reasonable insofar as the Company's shareholders were concerned. David Brabazon subscribed for 23,100 Ordinary Shares pursuant to the 2016 Placing.

Save as disclosed in this paragraph 9.10 of this Part 9 (*Additional Information*) and in the financial information set out in the related party transaction notes in the Company's financial statements for years ended 31 December 2016, 2017 and 2018 (which are incorporated into this document by reference) the Company did not enter into any material transactions with related parties during the financial years ended 31 December 2016, 2017 and 2018.

The Company did not enter into any other material transactions with related parties in the interim period up until the Latest Practicable Date.

See page 90, note 26 of the Company's 2018 annual report, page 72, note 26 of the Company's 2017 annual report, page 67 and note 24 of the Company's 2016 annual report "Related Party Transactions" contained in the consolidated financial information incorporated by reference in the Company's financial statements for financial years ended 31 December 2016, 2017 and 2018 in Part 8 (*Historical Financial Information*) of this document.

(b) Directors' shareholdings

Paragraph 6.4 of Part 6 (*Directors, Senior Management and Corporate Governance*) of this document sets out the interests of the Directors in the share capital of the Company as at the Latest Practicable Date.

9.11 GROUP SUBSIDIARIES

Name	*Location and Country of Incorporation*	*Shareholding %*
Subsidiaries		
Mainstay Medical Limited	Ireland	100
MML U.S., Inc.	United States	100
Mainstay Medical (Australia) Pty. Limited	Australia	100
Mainstay Medical Distribution Limited	Ireland	100
Mainstay Medical GmbH	Germany	100
Mainstay Medical B.V.	Netherlands	100

9.12 MATERIAL CONTRACTS

The following is a summary of all material contracts (not being contracts entered into in the ordinary course of business) which have been entered into by the Company or any member of the Group within the two years immediately preceding the date of this document and which are or may be material to the Group, and all other contracts (not being a contract entered into in the ordinary course of business), which contain any provision under which any member of the Group has any obligation or entitlement which is or may be material to the Group at the date of this document:

(a) Agreements with subscribers in connection with the 2019 Placing

In connection with the 2019 Placing, the Company, on 29 July 2019, entered into investor agreements with each of the investors (including certain of its existing long-term investors, namely Sofinnova Partners, Fountain Healthcare Partners and KCK) to subscribe for New Ordinary Shares in the 2019 Placing.

Pursuant to the agreements with each of the long-term investors respectively (i) KCK agreed to subscribe for 654,000 New Ordinary Shares (ii) Sofinnova Partners agreed to subscribe for 533,333 New Ordinary Shares; and (iii) Fountain Healthcare Partners Fund 3 agreed to subscribe for 1,333,333 New Ordinary Shares.

Pursuant to the agreements with each of the investors:

(i) the price payable per New Ordinary Share was €3.00;

(ii) the Company gave certain representations and warranties to the investor regarding the New Ordinary Shares and the business and operations of the Company. The aggregate liability of the Company in respect of all claims for breach of those warranties (other than those relating to matters such as authority and capacity) shall not in any event exceed the total amount paid by the investor for the New Ordinary Shares issued to it and any reasonably and properly incurred costs of the investor. A claim for breach of warranty must be made in writing and before the second anniversary of the date of the investor agreement; and

(iii) the Company agreed to take all actions and do all things necessary or appropriate to procure that the prospectus published by the Company in 2019 would be approved by the Central Bank and that admission of the New Ordinary Shares issued in connection with the 2019 Placing occurred by no later than 120 days after the date of the investor agreement, failing which the Company would have had to pay to the investor, as liquidated damages, a cash payment of 0.5% of the aggregate subscription price paid by the investor for each 30 day-period during which admission had not occurred (capped ultimately at 5% of the aggregate subscription price)

The investor agreements entered into in connection with the 2019 Placing are governed by Irish law and contain an Irish jurisdiction clause.

(b) First Warrant Instrument

On 18 April 2019, the Company entered into a warrant instrument with IPF (the "**First Warrant Instrument**"). Under the First Warrant Instrument the Company created rights to subscribe for up to 1,500,000 Ordinary Shares at any time up to 18 April 2025 on the basis that one warrant entitles the warrantholder to subscribe for one Ordinary Share at an exercise price of €6.00 per Ordinary Share.

Pursuant to the terms of the First Warrant Instrument, the Company agreed:

(i) subject to (ii) below, to use its reasonable endeavours to obtain the admission to trading on Euronext Growth and Euronext Dublin of any Ordinary Shares allotted

pursuant to the exercise of any warrants under the First Warrant Instrument not later than 5 business days after the date of allotment of the Ordinary Shares;

(ii) if admission of such Ordinary Shares requires the publication of a prospectus in accordance with EU prospectus law, to submit a draft prospectus to the Central Bank within 20 business days of the exercise of the warrants and to use its reasonable endeavours to publish such prospectus in order to obtain such admission as soon as reasonably possible after the date of allotment of the Ordinary Shares pursuant to the exercise of the warrants;

(iii) that the warrants are non-transferable except to affiliates of the warrantholder or to another reputable bank or financial institution to which IPF has lawfully assigned its rights and obligations under the IPF Facility Agreement provided that IPF many only transfer such warrants as is proportionate to the portion of the total debt in respect of which IPF has assigned its rights and obligations under the IPF Facility Agreement;

(iv) that while any warrants remain exercisable, after any allotment of Ordinary Shares by way of capitalisation of profits or reserves to existing holders of the Ordinary Shares or upon any sub-division or consolidation of the Ordinary Shares, the number and/or nominal value of Ordinary Shares to be subscribed on a subsequent exercise of each warrant will be increased or reduced proportionately on the basis that immediately after the allotment, sub-division or consolidation, the Ordinary Shares to be issued if the subscription rights attaching to the then outstanding warrants were exercised shall constitute the same percentage of the total number of issued Ordinary Shares as that which such Ordinary Shares would have constituted immediately before such allotment, sub-division or consolidation and the exercise price of the then outstanding warrants shall be adjusted accordingly;

(v) that while any warrants remain exercisable, if the Company pays a dividend which exceeds 10 per cent of the consolidated net asset value of the Company on the date of payment of the dividend, the exercise price shall be adjusted in such manner as the Company and the warrantholders agree (or which an independent competent financial advisor certifies as fair and reasonable) to take into account such dividend;

(vi) that if an offer is made to all holders of Ordinary Shares to acquire such Ordinary Shares and the Company becomes aware that as a result of such offer, the right to cast a majority of votes at a general meeting of the Company will become vested in the offeror or persons acting in concert with the offeror, then the Company shall give notice to the warrantholder of such actual or future vesting within 14 days of it becoming so aware. If the offeror makes an offer to warrantholders to acquire all outstanding warrants or proposes a scheme of arrangement with regard to the acquisition of such warrants, and the value of the consideration receivable by the warrrantholder pursuant to such offer or scheme represents no less than that which he would have received pursuant to the offer or scheme proposed to the holders of Ordinary Shares had his subscription rights been exercised on the date upon which such offer became wholly unconditional or the scheme became effective, then any warrants which are not the subject of an acceptance of the offer or are not transferred or cancelled pursuant to the scheme shall lapse upon the expiry of the offer or the date upon which the scheme is sanctioned by the court;

(vii) that subject to certain limited exceptions, a) if a fully pre-emptive offer is made by the Company to all holders of Ordinary Shares to subscribe for additional Ordinary Shares, then the Company shall procure that an offer is made to warrantholders as if their warrants had been exercised and b) if a non pre-emptive offer to subscribe for Ordinary Shares is made by the Company constituting over 5% of the Company's then issued Ordinary Share capital then the Company shall use reasonable

endeavours to ensure that the warrantholder is invited to participate in such non pre-emptive offer; and

(viii) if an order is made or resolution passed for winding up the Company and there would be a surplus available for distribution amongst the holders of Ordinary Shares which would exceed, in respect of each Ordinary Share, a sum equal to the exercise price of €6.00 then each warrantholder shall be treated as if his warrants had been exercised in full at the exercise price and such warrantholders shall accordingly be entitled to receive an amount equal to the sum to which he would have become entitled by virtue of such subscription after deducting a sum per Ordinary Share equal to the exercise price.

The First Warrant Instrument is governed by Irish law and contains and Irish jurisdiction clause.

(c) Second Warrant Instrument

On 18 April 2019, the Company entered into a second warrant instrument with IPF (the "**Second Warrant Instrument**"). The Second Warrant Instrument was entered into in connection with the IPF Amendment and Restatement Agreement. Under the Second Warrant Instrument the Company created conditional rights to subscribe for up to 1,851,515 Ordinary Shares on the basis that one warrant entitles the warrantholder to subscribe for one Ordinary Share at an exercise price of €8.00 per Ordinary Share. The warrants under the Second Warrant Instrument shall become exercisable only where (i) a conversion of the debt into Ordinary Shares is triggered under the terms of IPF Facility Agreement; and (ii) the Company elects to repay the debt in cash. In such circumstances the number of warrants that may be exercised will be equal to the amount of the debt not paid back through the issuance of Ordinary Shares divided by eight.

To the extent that the debt under the IPF Facility Agreement is satisfied in the event a conversion of the debt is triggered through the issuance by the Company of Ordinary Shares then any remaining warrants under the Second Warrant Instrument shall lapse and be immediately cancelled.

The Second Warrant Instrument contains provisions on the same basis as described at subparagraphs (i) to (viii) above except that any references to an exercise price shall be for an amount of €8.00, rather than €6.00. The Second Warrant Instrument is governed by Irish law and contains and Irish jurisdiction clause.

(d) ISIF Investor Agreement

On 15 February 2018, the Company and ISIF entered into the ISIF Investor Agreement. Pursuant to the ISIF Investor Agreement, the Company:

(i) agreed to issue ISIF 714,285 new Ordinary Shares for an amount of approximately €10 million (the "**ISIF Subscription Price**");

(ii) gave certain representations and warranties to ISIF regarding the new Ordinary Shares and the business and operations of the Company. The aggregate liability of the Company in respect of all claims for breach of those warranties (other than those relating to matters such as authority and capacity) shall not in any event exceed the total amount paid by ISIF for the new Ordinary Shares issued to it (approximately €10 million) and any reasonably and properly incurred costs of ISIF. A claim for breach of warranty must be made in writing and before the second anniversary of the date of the ISIF Investor Agreement, save for any claim relating to a tax warranty which must be made in writing and before the fourth anniversary of the date of the ISIF Investor Agreement;

(iii) agreed to pay the reasonable costs of ISIF up to €50,000 excluding VAT;

(iv) agreed to take all actions and do all things necessary or appropriate to procure that the prospectus published by the Company in 2018 would be approved by the Central

Bank and that admission of the new Ordinary Shares issued in connection with the 2018 Placing occurred by no later than 120 days after the date of the ISIF Investor Agreement, failing which the Company would have had to pay to ISIF, as liquidated damages, a cash payment of 0.5% of the ISIF Subscription Price for each 30 day-period during which admission had not occurred (capped ultimately at 5% of the ISIF Subscription Price); and

(v) confirmed with ISIF that the Company is implementing plans to bring additional elements of its operations to Ireland.

The ISIF Investor Agreement is governed by Irish law and contains an Irish jurisdiction clause.

(e) IPF Facility Agreement

Under a facility agreement dated 24 August 2015 (the "**Original IPF Facility Agreement**") between MML, the Company and IPF Fund I SCA SICAV-FIS ("**IPF**"), IPF agreed to provide MML with a debt facility of up to $15 million. The facility was to be drawn down in three tranches, with an initial tranche of $4.5 million made available on execution of the Original IPF Facility Agreement. The second and third tranches were drawn down following the achievement of certain milestones related to progress through the CE Marking process for ReActiv8. As at 31 December 2018, the principal outstanding was $10.2 million. On 18 April 2019, the Company, MML and IPF entered into an amendment and restatement agreement to the Original IPF Facility Agreement (the "**IPF Amendment and Restatement Agreement**"), pursuant to which a new tranche of €3.0 million (approximately $3.34 million) was made available to Mainstay, conditional upon Mainstay raising at least $10 million in gross proceeds from one or more offerings of equity prior to 30 June 2019 and the Original IPF Facility Agreement was amended to reflect this and other matters (the Original IPF Facility Agreement as amended by the IPF Amendment and Restatement Agreement being the "**IPF Facility Agreement**"). On 26 June 2019, the fundraising deadline in the IPF Amendment and Restatement Agreement was extended to 31 July 2019. On 29 July 2019, the fundraising condition was satisfied and the additional €3 million was drawn down.

The IPF Facility Agreement is subject to customary terms and conditions and includes voluntary prepayment provisions. The facility is guaranteed by the Company.

No principal or interest under the IPF Facility Agreement is repayable until 2021, with the principal and accrued interest to be amortized over the period from 1 January 2021 through 30 September 2023.

The interest rate for all tranches will be 8% per annum, with interest accruing but capitalized prior to January 1, 2021. All principal and accrued interest from all tranches will automatically convert into Ordinary Shares at a price per Ordinary Share of €8.00 upon the earlier of (a) FDA approval of the Company's PMA application for ReActiv8, (b) the date by which at least 900,000 Ordinary Shares are publicly sold on-market by non-affiliates of the Company since 18 April 2019 at a price per Ordinary Share of at least €8.00 or (c) IPF's election to undertake such conversion, in each case unless the Company elects to satisfy such obligation in whole or in part in cash.

The terms of the agreement include covenants, including a requirement that MML hold cash at least equal to its projected cash expenditures for operations and debt repayment for each three-month period after 18 April 2019.

Pursuant to the IPF Facility Agreement, the Company may issue convertible debt which is unsecured and convertible (in whole or in part) into shares in the Company, provided that no interest is payable thereon by the Company and such debt is not capable of being redeemed or repaid in whole or in part, in each case during the term of the facility. Under the terms of the agreement, no consent is required from IPF for the issuance of new shares in the Company. The IPF Facility Agreement does not include any preferential right to participate in a future financing of the Company. The IPF Facility Agreement contains subordination provisions pursuant to which the Company agrees that all claims it may have from time to time against MML are subordinate to claims IPF may have as against MML.

The IPF Facility Agreement is governed by Irish law and contains an Irish jurisdiction clause.

(f) IPF Debenture

In connection with the IPF Facility Agreement, on 24 August 2015, a mortgage debenture was entered into between MML and IPF (the "**IPF Debenture**") to secure the obligations of MML to IPF under the IPF Facility Agreement and the other finance documents referred to in the IPF Facility Agreement. Under the IPF Debenture, MML created, amongst other things, the following security in favour of IPF over the following assets:

- a first fixed charge and assignment over certain charged property, licences, agreements, book debts and goodwill;
- a first fixed charge and assignment over all of the shares held by MML in any of its subsidiaries from time to time;
- a first fixed charge and assignment over plant and machinery;
- a first fixed charge and assignment over certain bank accounts; and
- a floating charge over all other assets.

The IPF Debenture contains customary representations, covenants and enforcement provisions.

The IPF Debenture specifically excludes Excluded Assets from the security constituted by the IPF Debenture. "Excluded Assets" is defined to mean Intellectual Property and Core Intellectual Property, each of which are in turn defined in the IPF Facility Agreement to include all patents, trademarks, service marks, designs, business names, copyrights, design rights, inventions, confidential information, knowhow and other intellectual property rights and interests, whether registered or unregistered and the benefits of all rights to use such assets and including in particular all intellectual property scheduled to the IPF Facility Agreement and all present and future intellectual property derived therefrom or which otherwise relates to ReActiv8.

In connection with the IPF Amendment and Restatement Agreement and the additional €3.0 million tranche, MML and IPF entered into a supplemental debenture to the IPF Debenture dated 18 April 2019 (the "**IPF Supplemental Debenture**"). Under the IPF Supplemental Debenture, MML created further security of a nature consistent with that created under the IPF Debenture, in favour of IPF to secure the increased obligations of the Company and MML to IPF under the IPF Facility Agreement and the other related finance documents. The asset schedules in the IPF Supplemental Debenture were updated to provide current information with respect to certain secured assets such as insurance policies.

The IPF Debenture and the IPF Supplemental Debenture are governed by Irish law and contain an Irish jurisdiction clause.

(g) IPF Share Charge

In connection with the IPF Facility Agreement, on 24 August 2015, a charge over shares was entered into between the Company and IPF (the "**IPF Share Charge**") to secure the obligations of the Company to IPF under the finance documents referred to in the IPF Facility Agreement. This would include the obligations of the Company under the guarantee it has provided under the IPF Facility Agreement. Under the IPF Share Charge, the Company created a first fixed charge and security assignment over all of its interests present and future in the shares held by the Company in MML, to include all rights related to those shares. Pursuant to the terms of the IPF Share Charge, the Company was required to deliver customary share deliverables and provide customary representations and covenants. Prior to enforcement, the Company continues to be entitled to exercise voting rights and receive dividends albeit it is restricted from exercising voting rights in a manner that could be prejudicial to IPF.

The IPF Share Charge contains certain protective measures to ensure that, on enforcement, IPF is required to arrange for a valuation of the shares in MML to be conducted and for those shares to be actively marketed for a prescribed period before accepting an offer to purchase those shares for an amount less than the amount determined by the valuation.

In connection with the IPF Amendment and Restatement Agreement and the additional €3.0 million tranche, the Company and IPF entered into a supplemental share charge to the IPF Share Charge dated 18 April 2019 (the "**IPF Supplemental Share Charge**"). Under the IPF Supplemental Share Charge, the Company agreed to supplement the IPF Share Charge so as to provide security in favour of IPF of a nature consistent with that created under the IPF Share Charge, secure the increased obligations of the Company and MML to IPF under the IPF Facility Agreement and the other related finance documents.

The IPF Share Charge and IPF Supplemental Share Charge are governed by Irish law and contain an Irish jurisdiction clause.

(h) Euronext Growth Adviser and Broker Agreement

On 7 April 2014, the Company and Davy entered into a Euronext Growth Adviser and Broker Agreement pursuant to which Davy agreed to act as Euronext Growth adviser and broker to the Company for the purposes of the Euronext Growth Rules. Pursuant to the agreement, Davy receives a retainer fee of €50,000 per annum (exclusive of VAT). Either party may terminate the agreement forthwith in the event of a material breach by the other party of its obligations under the agreement. The Company shall be entitled to terminate the agreement in certain circumstances, including if Davy shall cease to be registered as a Euronext Growth adviser or broker.

The Euronext Growth Adviser and Broker Agreement is governed by and construed in accordance with the laws of Ireland.

(i) CCC Agreement

On 13 January 2017, the Company and CCC del Uruguay S.A. ("**CCC**") entered into a new supply agreement (the "**CCC Agreement**") which replaced the previous agreement between the parties which had been in place since 2010. Under the CCC Agreement, CCC agreed to manufacture, build and deliver the IPG and accompanying technology including software.

The material terms of the CCC Agreement include:

- CCC agreed to manufacture and deliver the products pursuant to purchase orders placed by MML and in consideration for receipt of the products, MML agreed to pay the relevant purchase price for each purchase order;
- MML is required to purchase certain minimum annual purchase quantities of products by the end of each calendar year of the CCC Agreement, or in the alternative, pay CCC a fixed fee to meet such obligation;
- the CCC Agreement shall continue in force for an initial two years from the date of the agreement and shall automatically be renewed for rolling additional one year term(s) unless either party notifies the other in writing at least six months prior to the expiry of the initial term or any additional one year term that it does not wish to renew the CCC Agreement;
- the CCC Agreement may be terminated by mutual agreement between the parties;
- either party may terminate the agreement, by written notice, where the other party materially breaches the CCC Agreement and fails to remedy the breach to the reasonable satisfaction of the non-breaching party after receiving written notice of the breach and the expiration of a cure period, or in the event of certain insolvency events;
- the parties are also subject to various other termination provisions;

- upon termination of the CCC Agreement, CCC shall provide reasonable cooperation and assistance to MML in the transition of the manufacturing of the products to a third party (if applicable); and
- the CCC Agreement is governed by the laws of the State of New York and each party submits exclusively to the courts of the State of New York.

(j) Oscor Agreement

Under a development agreement between Oscor Inc. ("**Oscor**") and MML entered into in October 2012 (the development agreement, as supplemented by related agreements, the "**Oscor Agreement**"), Oscor develops and exclusively manufactures the ReActiv8 lead (incorporating Oscor's proprietary lead body technology) and accessories in accordance with the design specifications set by the Group, and performs verification testing on the ReActiv8 lead and accessories to ensure compliance with design specifications. Oscor is certified to international quality standards including EN13485.

The material terms of the Oscor Agreement include:

- the Oscor Agreement will remain in force and shall continue until terminated;
- MML shall pay to Oscor compensation as set out under each project proposal provided by Oscor;
- either party may terminate the agreement by mutual agreement, and each may terminate if the other party materially defaults in the performance of any material obligation, after written notice and a cure period, or in the event of certain insolvency events;
- Oscor may terminate the agreement on provision of written notice of MML's failure to make payments, unless MML pays all overdue sums in full during a cure period;
- both parties are also subject to various other termination provisions;
- MML indemnifies Oscor against any claim arising from MML products not arising directly from Oscor's negligence or failure of OSCOR technology or workmanship;
- MML also indemnifies Oscor against any and all loss, damage, settlement or expense (including legal expenses) resulting from or arising out of any claims associated with alleged violation of a third party's intellectual property, government or regulatory action relating to the Group, and product liability claims alleged against the Group relating to products supplied by Oscor; and
- a party bringing an action under the Development Agreement must do so in the state which the defending party has its primary place of business.

9.13 GOVERNMENTAL, LEGAL OR ARBITRATION PROCEEDINGS

There have been no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which the Company is aware), during the previous 12 months from the date of this document which may have, or have had in the recent past (covering the 12 months preceding the date of this document) significant effects on Company's financial position or profitability.

9.14 INFORMATION ON HOLDINGS

The Company does not hold a proportion of capital in any undertakings likely to have a significant effect on the assessment of its own assets and liabilities, financial position or profits and losses.

9.15 PROPERTY, PLANT AND EQUIPMENT

The Company as at the date of this document does not own any plant or equipment which is material to the conduct of the Company's business. All manufacturing is performed by third party contract manufacturers, as discussed in Part 1 (*Risk Factors*) of this document and paragraph **Error! Reference source not found.** of Part 5 (*Information on the Group*) of this document. The Group has entered into leasing/licensing contracts for the purpose of renting premises (in the United States and Ireland) and office equipment (such as photocopiers).

9.16 GENERAL

Where information has been sourced from a third party this information has been accurately reproduced. So far as the Company and the Directors are aware and are able to ascertain from information provided by that third party, no facts have been omitted which would render the reproduced information inaccurate or misleading.

Paragraph 5.16 of Part 5 (*Information on the Group*) of this document and paragraph 9.12 of this Part 9 (*Additional Information*) set out summary information regarding the patents or licences, industrial, commercial or financial contracts or new manufacturing processes on which the Company is dependent and which are material to the Company's business or profitability.

Save as disclosed in Part 1 (*Risk Factors*) of this document, Part 4 (*Overview of the Market*) of this document, Part 5 (*Information on the Group*), paragraph 6.7 of Part 6 (*Directors, Senior Management and Corporate Governance*) of this document and paragraph 9.12 of this Part 9 (*Additional Information*) of this document, the Directors are not aware of any trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on the prospects of the Company for at least the current financial year.

9.17 DOCUMENTS ON DISPLAY

Copies of the documents referred to below will be available in electronic form on the Company's website www.mainstay-medical.com for the life of this document,

(a) the Memorandum and Articles of the Company;

(b) the Historical Financial Information of the Group and the Company;

(c) any related summary in English and translated into French;

(d) any related securities note; and

(e) this document.

This document is dated 25 October 2019.

PART 10: DOCUMENTATION INCORPORATED BY REFERENCE

The table below sets out the various sections of such documents which are incorporated by reference into this document so as to provide the information required under the Irish Prospectus Regulations and to ensure that Shareholders and others are aware of all information which, according to the particular nature of the Group, is necessary to enable Shareholders and others to make an informed assessment of the assets and liabilities, financial, position, profits and losses and prospects of the Group.

The following list is intended to enable investors to identity easily specific items of information which have been incorporated by reference into this document. Only the parts of the documents identified in the list below are incorporated into and form part of this document. The parts of the documents which are not incorporated by reference are either not relevant for prospective investors or are covered elsewhere in this document.

The financial statements for the year ended 31 December 2018 and the Independent Auditors' Report thereon are incorporated by reference to the Company's 2018 annual report. The 2018 annual report is available on the Company's website at:

https://www.mainstay-medical.com/sites/default/files/2019-04/Mainstay%20-%20FY18%20Annual%20Report%20%20-%20with%20English%20press%20release_2.pdf

The page numbers below refer to the relevant pages of the 2018 annual report incorporated:

Section	**Page numbers in such document**
Directors' Responsibilities' Statement	57
Independent Auditors Report to the Members	59-63
Consolidated statement of profit or loss and other comprehensive income for the year	64
Consolidated statement of financial position	65
Consolidated statement of changes in shareholders' equity	66
Consolidated statement of cash flows	67
Notes to the consolidated financial statements	68-92
Parent Company financial statements	93-97

The financial statements for the year ended 31 December 2017 and the Independent Auditors' Report thereon are incorporated by reference to the Company's 2017 annual report. The 2017 annual report is available on the Company's website at

http://www.mainstay-medical.com/sites/default/files/2018-02/FY17-AR-15-Feb-2018-with-Press-Release-English-FINAL.PDF

The page numbers below refer to the relevant pages of the 2017 annual report incorporated:

Section	Page numbers in such document
Directors' Responsibilities' Statement	42
Independent Auditors Report to the Members	43-47
Consolidated statement of profit or loss and other comprehensive income for the year	48
Consolidated statement of financial position	49
Consolidated statement of changes in shareholders' equity	50
Consolidated statement of cash flows	51
Notes to the consolidated financial statements	52-73
Parent Company financial statements	74-78

The financial statements for the year ended 31 December 2016 and the Independent Auditors' Report thereon are incorporated by reference to the Company's 2016 annual report. The 2016 annual report is available on the Company's website at http://www.mainstay-medical.com/sites/default/files/2017-03/MMIplc%20FY16%20AR%20Press%20Release%20English%20with%20Annual%20Report%20FINAL.pdf.

The page numbers below refer to the relevant pages of the 2016 annual report incorporated:

Section	Page numbers in such document
Directors' Responsibilities' Statement	42
Independent Auditors Report to the Members	43-44
Consolidated statement of profit or loss and other comprehensive income for the year	45
Consolidated statement of financial position	46
Consolidated statement of changes in shareholders' equity	47
Consolidated statement of cash flows	48
Notes to the consolidated financial statements	49-67
Parent Company financial statements	68-72

The financial statements for the half year ended 30 June 2019 are incorporated by reference to the Company's 2019 half year financial results. The 2019 half year financial results are available on the Company's website at:

http://www.mainstay-medical.com/en/investors/results_and_presentations

The page numbers below refer to the relevant pages of the 2019 half year financial results incorporated:

Section	Page numbers in such document
Directors' Responsibilities' Statement	11
Condensed consolidated statement of profit or loss and other comprehensive income	12
Condensed consolidated statement of financial position	13
Condensed consolidated statement of changes in shareholders' equity	14
Condensed consolidated statement of cash flows	15
Notes to the condensed consolidated financial statements	16

DEFINITIONS

The following definitions shall apply throughout this document unless the context requires otherwise:

"**€**" or "**EUR**" or "**Euro**"	the currency introduced at the start of the third stage of the European economic and monetary union pursuant to the Treaty establishing the European Community as amended;
"**£**" or "**Sterling**" or "**pounds**" or "**pence**"	the lawful currency of the United Kingdom;
"**$**" or "**U.S.$**" or "**U.S. dollars**" or "**cents**" or **"USD"**.	the lawful currency of the United States;
"2014 Corporate Reorganisation"	the reorganisation under which the Company became the ultimate holding company of the Group and MML became a wholly-owned subsidiary of the Company;
"2014 IPO"	the Company's initial public offering of Ordinary Shares in April and May 2014;
"2018 AGM"	the Company's annual general meeting held on 21 September 2018
"2019 AGM"	the Company's annual general meeting held on 20 September 2019;
"2016 Placing"	means the allotment and issue of the 2,307,694 new Ordinary Shares to certain new and existing institutional shareholders on 17 June 2016;
"**2018 Placing**"	means the allotment and issue of the 2,151,332 new Ordinary Shares to certain new and existing shareholders as announced on 15 February 2018;
"2019 Placing"	means the allotment and issue of 4,649,775 New Ordinary Shares to certain new and existing shareholders as announced on 29 July 2019;
"Admission"	means Euronext Admission and Euronext Growth Admission;
"AIMD Directive"	the European Active Implantable Medical Devices Directive 90/385/EEC and subsequent amendments, which sets out the approval requirements for an AIMD in the European Economic Area;
"AMF"	the French Financial Markets Authority (Autorité des marchés financiers);
"Approved Transfer"	has the meaning given to that term in paragraph 9.6(b)(viii)(A) of Part 9 (*Additional Information*) of this document;
"Articles" and "Articles of Association"	the articles of association of the Company, as amended from time to time;

"Audit, Risk and Compliance Committee"	the audit, risk and compliance committee of the Company as described in paragraph 6.9(c) of Part 6 (*Directors, Senior Management and Corporate Governance)* of this document;
"Award"	an award of a Share Option or an RSU granted under the Employee Incentive Plan;
"**business day**"	a day (excluding Saturday, Sunday and public holidays) on which banks generally are open for business in Ireland for the transaction of normal banking business;
"**CCC**"	has the meaning given to that term in paragraph 9.12(i) of Part 9 (*Additional Information*) of this document;
"CCC Agreement"	has the meaning given to that term in paragraph 9.12(i) of Part 9 (*Additional Information*) of this document;
"CE Mark" or "CE Marking"	means a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in EU harmonisation legislation providing for its affixing, including the related conformity assessment process;
"**Central Bank**"	the Central Bank of Ireland;
"**Companies Act 2014**"	the Companies Act 2014 of Ireland;
"**Company**"	Mainstay Medical International plc, a company incorporated under the laws of Ireland (registered under the number 539688), with its registered office at 77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, Dublin 2, D02 VK60;
"Constitution"	the constitution of the Company, from time to time;
"**CREST**"	the system of paperless settlement of trades in securities and the holding of uncertificated securities operated by Euroclear in accordance with the CREST Regulations;
"**CREST Regulations**"	the Companies Act 1990 (Uncertificated Securities) Regulations 1996 (S.1. 68 of 1996) of Ireland (as amended);
"**Davy**"	J&E Davy of Davy House, 49 Dawson Street, Dublin 2, trading as Davy or, as the context so requires, any affiliate thereof or company within its group;
"**Deferred Shares**"	fully paid up deferred shares of nominal value €1.00 in the capital of the Company;
"**Directors**" or "**Board**"	the directors of the Company, whose names as at the date of this document are set out in Part 3 (*Directors, Company Secretary, Registered Office and Advisors*) of this document;

"EEA"	means the European Economic Area which includes the EU, Iceland, Liechtenstein and Norway;
"**EU**"	the European Union;
"EU Prospectus Regulation"	Commission Regulation (EC) No. 809/2004;
"Employee Incentive Plan"	has the meaning given to that term in paragraph **Error! Reference source not found.** of Part 6 (*Directors, Senior Management and Corporate Governance*) of this document;
"**Euroclear**"	Euroclear UK & Ireland Limited, the operator of CREST;
"Euronext Admission"	listing and admission of the New Ordinary Shares to trading on Euronext Paris;
"**Euronext Dublin**"	the Irish Stock Exchange plc trading as Euronext Dublin;
"Euronext Growth"	the Euronext Growth Market, an authorised multilateral trading facility under the European Communities (Markets in Financial Instruments Directive) Regulations 2007, operated by Euronext Dublin and previously known as the Enterprise Securities Market or ESM;
"Euronext Growth Admission"	admission of the New Ordinary Shares to trading on Euronext Growth;
"**Euronext Growth Adviser**"	an adviser and broker to a company, whose shares are admitted to trading on Euronext Growth, for the purposes of the Euronext Growth Rules;
"Euronext Growth Adviser and Broker Agreement"	the Euronext Growth adviser and broker agreement entered into between the Company and Davy on 7 April 2014;
"Euronext Growth Rules" or "Euronext Growth Rules for Companies"	the Euronext Growth Markets Rule Book issued by Euronext;
"Euronext Paris"	the regulated market operated by Euronext Paris SA;
"**Executive Director**"	an executive Director;
"**Feasibility Study**"	a study designed and sponsored by the Group to investigate the scientific principles on which ReActiv8 is based;
"Financial Adviser"	means, with respect to Davy, financial adviser, prospectus adviser and Euronext Growth adviser;
"Fountain Healthcare Partners"	Fountain Healthcare Partners Fund, L.P. or Fountain Healthcare Partners Limited acting as General Partner of Fountain Healthcare Partners Fund, L.P.;
"French Takeover Rules"	means general regulation (*règlement général*) of the AMF;

"Group"	the Company and its subsidiaries and subsidiary undertakings;
"Historical Financial Information"	the historical financial information of the Group for each of the three years ended 31 December 2018, 31 December 2017 and 31 December 2016 set out in Part 8 (*Historical Financial Information*) of this document;
"**IFRS**"	International Financial Reporting Standards;
"**Interim Analysis**"	interim analysis of the U.S. Pivotal ReActiv8-B Clinical Trial;
"**IPF**"	has the meaning given to that term in paragraph 9.12(e) Part 9 (*Additional Information*) of this document;
"IPF Amendment and Restatement Agreement"	has the meaning given to that term in paragraph 9.12(e) Part 9 (*Additional Information*) of this document;
"IPF Debenture"	has the meaning given to that term in paragraph 9.12(f) Part 9 (*Additional Information*) of this document;
"**IPF Facility Agreement**"	has the meaning given to that term in paragraph 9.12(e) Part 9 (*Additional Information*) of this document;
"**IPF Share Charge**"	has the meaning given to that term in paragraph 9.12(g) Part 9 (*Additional Information*) of this document;
"IPF Supplemental Share Charge"	has the meaning given to that term in paragraph 9.12(g) Part 9 (*Additional Information*) of this document;
"IPF Supplemental Debenture"	has the meaning given to that term in paragraph 9.12(f) Part 9 (*Additional Information*) of this document;
"**Ireland**"	the island of Ireland excluding Northern Ireland, and the word "**Irish**" shall be construed accordingly;
"**Irish Companies Acts**"	the Irish Companies Acts 1963 to 2013 or, following the commencement of the relevant provisions of the Companies Act 2014 or otherwise, the Companies Act 2014 and every statutory modification, replacement and re-enactment thereof for the time being in force;
"**Irish Prospectus Regulations**"	European Union (Prospectus) Regulations 2019 of Ireland;
"**Irish Takeover Panel**"	the Irish Takeover Panel, established under the Irish Takeover Panel Act 1997;
"**Irish Takeover Rules**"	the Irish Takeover Panel Act 1997, Takeover Rules 2013, as amended;
"**ISIF**"	the National Treasury Management Agency, as controller and manager of the Ireland Strategic Investment Fund;
"**ISIF Investor Agreement**"	the investor agreement between the Company and ISIF dated 15 February 2018;

"**ISIF Subscription Price**"	has the meaning given to that term in paragraph 9.12(a) of Part 9 (*Additional Information*) of this document;
"**ISIN**"	International Security Identification Number;
"**KCK**"	KCK Limited, a private company limited by shares incorporated in British Virgin Islands (registered no. 1644955), whose registered office is at OMC Chambers, Wickhams Cay 1, Road Town, Tortola, British Virgin Islands;
"KCK Director Nomination Agreement"	the KCK Director Nomination Agreement between the Company and KCK dated 17 June 2016;
"**KCK Investor Agreement**"	the investor agreement between the Company and KCK dated 17 June 2016;
"KPMG"	KPMG Chartered Accountants, whose address is 1 Stokes Place, St. Stephen's Green, Dublin 2;
"**Latest Practicable Date**"	23 October 2019, being the latest practicable date prior to the publication of this document;
"Market Abuse Regulation"	the EU Market Abuse Regulation (596/2014);
"Memorandum" and "Memorandum of Association"	the memorandum of association of the Company, as amended from time to time;
"MMA"	Mainstay Medical (Australia) Pty Limited CAN 164 049 281, a proprietary company limited by shares registered in New South Wales, Australia;
"MMBV"	Mainstay Medical B.V., a company incorporated under the laws of the Netherlands;
"MMD"	Mainstay Medical Distribution Limited, a private company limited by share incorporated in Ireland with registered number 575701 having its registered office at 77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, Dublin 2, D02 VK60;
"MMG"	Mainstay Medical GmbH, a company incorporated under the laws of Germany;
"MMI"	Mainstay Medical, Inc., a company incorporated under the laws of the State of Delaware;
"MML"	Mainstay Medical Limited, a private company limited by share incorporated in Ireland with registered number 516089 having its registered office at 77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, Dublin 2, D02 VK60;
"MMLUS"	MML U.S., Inc., a company incorporated under the laws of the State of Delaware;
"**New EU Medical Device Regulations**"	has the meaning given to that term in paragraph 1.2(b) of Part 1 (*Risk Factors*) of this document;

"**New Ordinary Shares**"	the new Ordinary Shares issued pursuant to the 2019 Placing;
"**Nominations Committee**"	the nominations committee of the Company as described in paragraph 6.9(c) of Part 6 (*Directors, Senior Management and Corporate Governance*) of this document;
"**Non-Executive Director**"	a non-executive Director;
"**Ordinary Shareholders**"	a holder of Ordinary Shares from time to time;
"**Ordinary Shares**"	the ordinary shares of par value €0.001 each in the capital of the Company;
"ORSCO"	means ORSCO Life Sciences AG, a Swiss company controlled by Dr. Oern Stuge;
"Oscor"	has the meaning given to that term in paragraph 9.12(j) of Part 9 (*Additional Information*) of this document;
"**Oscor Agreement**"	has the meaning given to that term in paragraph 9.12(j) of Part 9 (*Additional Information*) of this document;
"PDMR"	a person discharging managerial responsibilities as defined in article 3(25) of the Market Abuse Regulation;
"**Prospectus**"	this Registration Document together with any related securities note and any related summary prepared, published and approved by the Central Bank of Ireland under the Prospectus Regulation;
"**Prospectus Regulation**"	Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017;
"Prospectus Rules"	the prospectus rules issued by the Central Bank from time to time;
"RSU"	a right to receive Award Shares granted under the Employee Incentive Plan , but excluding any such right which (i) has been cancelled by agreement between its holder and the Company or (ii) has lapsed or otherwise ceased to be capable of settlement under the Employee Incentive Plan for any reasons whatsoever (or in the case of any RSU which has only partially ceased to be capable of settlement, such part of it as shall have so ceased);
"ReActiv8"	means ReActiv8®;
"ReActiv8-A Clinical Trial"	is an international, multi-centre, prospective, single arm trial of ReActiv8 for the purpose of gathering data to form part of the submission for CE Marking;
"Register"	the register of members of the Company;
"Reporting Accountants"	KPMG;
"Registration Document"	means this registration document dated 25 October

	2019, which, together with any related securities note and any related summary constitute a prospectus;
"Restriction Notice"	has the meaning given to that term in paragraph 9.6(b)(i) of Part 9 (*Additional Information*) of this document;
"Senior Managers"	Prashant Rawat and Matt Onaitis;
"Series A Financing"	means the process by which the Group raised USD$6,100,000 by way of share capital investment in return for the issue of series A preferred stock in the capital of MMI to certain investors which was completed during July 2010;
"Series B Financing"	means the process by which the Group raised $20,000,000 by way of share capital investment in return for the issue of series B preferred stock in the capital of MMI and the issue of series B shares in the capital of MML to certain investors which was completed during September 2012;
"**Shareholder**"	a holder of shares in the Company from time to time;
"Share Options"	options over the Ordinary Shares;
"Sofinnova Partners"	means Sofinnova Capital VI FCPR or Sofinnova Partners acting on behalf of Sofinnova Capital VI FCPR;
"Specified Event"	has the meaning given to that term in paragraph 9.6(b)(vii) of Part 9 (*Additional Information*) of this document;
"Specified Shares"	has the meaning given to that term in paragraph 9.6(b)(i)(A) of Part 9 (*Additional Information*) of this document;
"**subsidiary**"	shall be construed in accordance with the Companies Act 2014;
"**subsidiary undertaking**"	shall be construed in accordance with the Companies Act 2014;
"takeover bid"	has the meaning given in the Takeover Directive
"Takeover Directive"	the Directive 2004/25/EC of the European Parliament and the Council dated 21 April 2004 on takeover bids;
"**Transparency Regulations**"	the Transparency (Directive 2004/109/EC) Regulations 2007 (SI No. 277 of 2007) , as amended;
"**Transparency Rules**"	the transparency rules issued by the Central Bank from time to time;
"**uncertificated**" or in "**uncertificated form**"	the Ordinary Shares recorded on the register of members of the Company as being held in uncertificated form in CREST and title to which, by virtue of the CREST Regulations, may be transferred by means of an instruction issued in accordance with

	the rules of CREST;
"**United Kingdom**" or "**UK**"	the United Kingdom of Great Britain and Northern Ireland;
"**United States**" or "**U.S.**"	the United States of America, its territories and possessions, any state of the United States and the District of Columbia;
"**U.S. Pivotal ReActiv8-B Clinical Trial**"	is an international, multi-centre, prospective randomised sham controlled triple blinded trial with one-way crossover trial of ReActiv8 for the purpose of gathering data to form part of the submission for FDA for Pre-Market Approval Application (PMAA); and
"USPTO"	the U.S. Patent and Trademark Office.

For the purpose of this document, references to one gender include the other gender.

Any references to any provision of any legislation or regulation shall include any amendment, modification, re-enactment or extension thereof for the time being and unless the context otherwise requires or specifies, shall be deemed to be legislation or regulations of Ireland.

GLOSSARY OF TECHNICAL TERMS

The following explanations are not intended as technical definitions, but rather are intended to assist the reader in understanding terms used in this document.

510(k)	A 510(K) is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to premarket approval.
Activator	An external remote control, part of the ReActiv8 system that activates the IPG.
Active implantable medical device (AIMD)	An implantable medical device that relies on a power source not provided by the body or gravity and is designed to be introduced into the body with the intention to remain there following the procedure. An AIMD for example is one that achieves its intended purpose by delivery of energy to the body (e.g.: electrical stimulation).
Acute Low Back Pain	Recent onset of an episode of Low Back Pain.
Adverse Event (AE)	A term used in Clinical Trials to describe any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in patients, users or other persons, whether or not related to the investigational medical device.
Arthrogenic muscle inhibition (AMI)	An impairment of muscle control caused by an on-going reflex inhibition of the musculature surrounding a joint as a result of pain in the joint.
Approved Supplier List (ASL)	List of suppliers which meet the Group's requirements following an audit of the supplier's quality management system.
Atrophy	Describes when a muscle shrinks, often as a result of disuse.
BSI Group – Medical Devices (BSI)	BSI Group – Medical Devices is the Group's Notified Body.
Chronic Low Back Pain	Low Back Pain of duration longer than 90 days.
Chronic Non-Specific Low Back Pain	Chronic Low Back Pain in which there is no definitive pathological cause (e.g.: no damage can be seen on X-Ray or MRI that could be the cause of the Low Back Pain).
Clinical Events Committee	The Clinical Events Committee is an adjudication group that evaluates clinical study Adverse Events, specifically by reviewing for appropriate classification, level of severity, relatedness to device and/or procedure and resolution, utilising a consistent and unbiased classification system. The CEC reviews and adjudicates all adverse events. The CEC membership is restricted to individuals free of apparent significant conflicts of interest.
Clinical Global Impression	The Clinical Global Impression is the physician's assessment of the patient compared to baseline.
Clinical Trial	A program of investigation that involves human patients to investigate a new therapy. Trials can be of multiple different designs,

	including; *Prospective randomised controlled trial* – the investigational therapy is compared to a control therapy (often a placebo) in which patients are prospectively (i.e.: in advance) allocated in a statistically random manner ("**randomised**") to either the investigational therapy or the control. Blinding (otherwise known as "**masking**") refers to keeping trial participants, investigators (usually health-care providers), or assessors (those collecting outcome data) unaware of an assigned intervention, so that they are not influenced by that knowledge. *Single arm trial* – a Clinical Trial design in which there is no control arm, and patients outcomes are compared to the characteristics prior to application of the investigational therapy. *Open label trial* – a Clinical Trial in which patients have knowledge of the investigational therapy (i.e.: they are not "**blinded**").
Contract Research Organisation (CRO)	Person or organisation contracted to perform one or more of the clinical investigation-related duties and functions.
Data Monitoring Committee (DMC)	The DMC, also known as a Data and Safety Monitoring Board, is a group of individuals with pertinent expertise (physicians and statisticians typically) that reviews on a regular basis accumulating data from one or more ongoing Clinical Trials. The DMC advises the Sponsor regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial. The DMC periodically reviews trial results, evaluates the treatments for excess adverse effects, determines whether the basic trial assumptions remain valid, judges whether the overall integrity and conduct of the Clinical Trial remain acceptable, and makes recommendations to the Sponsor, where applicable.
Electrode	A piece of metal (usually an alloy of platinum and iridium) placed adjacent to a tissue to be stimulated, for example a nerve. The electrode can deliver electrical stimulation pulses.
European Quality of Life Assessment (EQ-5D)	A clinical assessment instrument of a patient's quality of life by use of a questionnaire.
Ethics Committee (EC) (sometimes called Institutional Review Board or IRB in the U.S.)	An independent body whose responsibility is to review clinical investigations in order to protect the rights, safety and well-being of human patients participating in a clinical investigation. The term "ethics committee" is synonymous with "research ethics committee", "independent ethics committee" or "institutional review board". The regulatory requirements pertaining to Ethics Committees or similar institutions vary by country or region. The roles and responsibilities are spelled out in EN14155, and the Declaration of Helsinki.
Explant	A procedure to remove an implanted medical device, which is then described as explanted.
Failed Back Surgery Syndrome (FBSS)	A subset of patients who have new or persistent pain after spinal surgery for back or leg pain.
Food and Drug Administration (FDA)	A department of the U.S. Government's Health and Human Services administration which is responsible for controlling the approval and

	sale of medical devices, among other things.
Group Purchasing Organisation (GPO)	A Group Purchasing Organization is an entity which negotiates with vendors on behalf of a group of businesses to obtain the best possible prices for the group's members.
Health Technology Assessment (HTA)	A formal process of evaluating a new medical therapy to determine the cost effectiveness. The HTA is often used as an input to government policy regarding payment for new therapies.
Hospital Buying Group	An organisation that arranges for purchase of medical products (including medical devices, drugs, disposables) on behalf of one or more hospitals or clinics.
The Institute of Medicine (IOM)	A U.S. based independent, non-profit organisation that works outside of government to provide unbiased and authoritative advice to decision makers and the public. Established in 1970, the IOM is the health arm of the National Academy of Sciences.
International Neuromodulation Society (INS)	A non-profit group of clinicians, scientists and engineers dedicated to the scientific development and awareness of Neuromodulation.
Investigational Device Exemption (IDE)	An approved IDE permits a device to be shipped lawfully for the purposes of conducting investigations of the device without complying with other requirements of the Food, Drug, and Cosmetic Act (Act) that would apply to devices in commercial distribution.
Institutional Review Board or IRB in the U.S	An independent body whose responsibility is to review clinical investigations in order to protect the rights, safety and well-being of human patients participating in a clinical investigation. The term "ethics committee" is synonymous with "research ethics committee", "independent ethics committee" or "institutional review board". The regulatory requirements pertaining to Ethics Committees or similar institutions vary by country or region. The roles and responsibilities are spelled out in EN14155, and the Declaration of Helsinki.
IMMPACT	Initiative on Methods, Measurement, and Pain Assessment in Clinical;
Incidence	The number of new people who develop a condition over a period of time – usually calculated as the annual incidence.
Investigational Site	The location at which patients are seen and treated during a Clinical Trial. An Investigational Site may include one or more physical locations under a single management umbrella (e.g.: an outpatient clinic at which patients are seen and a separate operating room at which an implant is performed.)
Investigator	A physician responsible for overall conduct of a Clinical Trial at an investigational site, usually a hospital or clinic. There may be one or more Co-Investigators associated with a site. The term Principal Investigator is sometimes used to describe the Investigator with overall responsibility at a site, or who has overall responsibility for a trial.
Implantable Pulse Generator (IPG)	A hermetically sealed titanium can that contains a battery and electronics, and provides electrical stimulation pulses to leads via one or more connectors.

ISO 13485	An international standard governed by the International Organization for Standardization (an independent, non-governmental organisation, with a membership of 161 national standards bodies) which specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.
Low Back Pain (LBP)	Pain localized below the line of the twelfth rib and above the inferior gluteal folds (i.e.: the creases at the base of the buttocks), with or without leg pain.
Lead	The insulated wire that carries electrical signals between the IPG and the electrodes.
LM	Lumbar multifidus.
McKenzie Method	The McKenzie method is a classification system and a classification-based treatment for patients with Low Back Pain. An acronym for the McKenzie method is mechanical diagnosis and therapy (MTD).
National Institute for Health and Care Excellence (NICE) - http://www.nice.org.uk/	A UK government supported body (Non-Departmental Public Body or NDPB) which provides national guidance and advice to improve health and social care.
Neuromodulation	The International Neuromodulation Society defines therapeutic neuromodulation as "the alteration of nerve activity through the delivery of electrical stimulation or chemical agents to targeted sites of the body." A subset of neuromodulation is "neurostimulation" which is neuromodulation achieved through electrical stimulation.
Numerical Rating Scale (NRS)	A measurement instrument in which a patient is asked to select from a fixed set of numerical possibilities. A Back Pain NRS is usually presented as a range from 0 to 10 where 0 is defined as no pain, and 10 is defined as worst imaginable pain.
Non-Specific Low Back Pain (NSLBP)	LBP in which an anatomical or pathological cause is not identified.
Notified Body	A Notified Body, in the European Union, is an entity that has been accredited by a Member State to assess whether a product to be placed on the market meets certain preordained standards.
Non-Steroid Anti-Inflammatory Drugs (NSAIDs)	A class of drugs that reduces inflammation but is not a steroid – for example, aspirin.
Oswestry Disability Index (ODI)	A disease specific measure of the disabling effects of LBP.
Opioids	A class of drugs based on the active chemicals in opium, including morphine, codeine, heroin and their derivatives.
Paraesthesia (paresthesia)	A sensation of tingling, pricking or numbness, often caused by pressure on or damage to peripheral nerves, or as a result of local anaesthesia, or as a result of electrical stimulation. A common example is the "numbness" in the jaw felt after dental local

	anaesthesia
Patient Reported Outcome (PRO)	A measurement based on a report that comes directly from the patient about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. A PRO can be measured be self-report or by interview provided that the interviewer records only the patient's response.
Percent Pain Relief	Percent Pain Relief (PPR) is a question regarding that patient's perception of how much better the patient's back pain is compared to the time of baseline in the Registry, where 0% is no improvement, and 100% is no Low Back Pain.
Peripheral Nerve	The nervous system is divided into the central nervous system (CNS) which consists of the brain and spinal cord, and the Peripheral Nervous System which is all other nerves.
Peripheral Nerve Stimulation (PNS)	A form of neurostimulation in which electrodes are placed close to peripheral nerves (e.g.: just under the skin) and electrical stimulation applied to elicit paraesthesia
Placebo	A simulated treatment for a disease that is intended to deceive the recipient. In drug terms, this if often a "sugar pill." The "placebo effect" is the term used to describe the perceived or actual improvement in a clinical condition as a result of administration of a placebo.
Post Market Clinical Follow-Up (PMCF)	A study carried out following the CE Marking of a device and intended to answer specific questions relating to clinical safety or performance (ie: residual risks) of a device when used in accordance with its approved labelling.
Pre-Market Approval (PMA)	The action of the FDA which grants permission to sell a Class III medical device in the United States.
Pre-Market Approval Application (PMAA)	The application for Pre-Market Approval (PMA).
Prevalence	The number of people (in a specific population) with a condition, sometimes referred to as the "prevalence pool." The prevalence pool includes those who develop the condition (the incidence), plus those who previously developed the condition and remain with it, minus those who leave the prevalence pool for example because the condition is cured, the person dies, or leaves the population. Examples are the prevalence of breast cancer in women over the age of 40; the prevalence of learning disabilities in pre-school age children or the prevalence of disabling Chronic Low Back Pain in adults.
Principal Investigator (PI)	Qualified person responsible for conducting the clinical investigation at an investigation site. The term Principal Investigator is sometimes also used to describe the Investigator with overall responsibility for a multi-site trial.
Quality Management System (QMS)	A system of documentation, procedures and practices set up by a company to ensure compliance with laws and regulations governing the quality of medical devices, including design, validation, and manufacturing.

QOL	Quality of life.
Quality System Regulations (QSR)	A set of regulations promulgated and enforced by the U.S. FDA for manufacturers of medical devices.
Registry	The ReActiv8 Registry is an international, multi-centre, data collection registry. The purpose is to gather data on the long-term safety of ReActiv8 and identify any residual risks. A minimum of 50 patients will be implanted at up to 25 sites. patients will be followed for two years post-implant, at which time they will be exited from the Registry.
Serious Adverse Events (SAEs)	Adverse event that a) led to death, b) led to serious deterioration in the health of the patient, that either resulted in 1) a life-threatening illness or injury, or 2) a permanent impairment of a body structure or a body function, or 3) in-patient or prolonged hospitalisation, or 4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, c) led to foetal distress, foetal death or a congenital abnormality or birth defect. Planned hospitalisation for a pre-existing condition, or a procedure required by the CIP, without serious deterioration in health, is not considered a serious adverse event.
Spinal Cord Stimulator (SCS) or Spinal Cord Stimulation, as the context so requires	An implantable Neuromodulation device designed to deliver electrical stimulation pulses to the spinal cord (inside the spinal column) to interfere with the perception of pain.
Site	In the context of a Clinical Trial, a location (e.g.: hospital, clinic) where patients are recruited and procedures are performed (see also Investigational Site).
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a Clinical Trial.
Transcutaneous Electrical Nerve Stimulation (TENS)	The application of electrical stimulation pulses via electrodes applied directly to the skin.
Treatment Satisfaction Questionnaire	A questionnaire used to find out how satisfied the patient is with the treatment based on a yes/no question. Therefore, a higher percent indicates that more patients in the study are satisfied with the treatment. In addition, patients who indicate that they are satisfied with the treatment are asked if they are "satisfied" or "very satisfied".
Visual Analogue Scale (VAS)	A method of assessing an outcome. For example, to assess pain, a patient may be presented with a 100mm long line and asked to indicate with a mark on the line the current pain, where zero represent no pain, and 100 represents worst imaginable pain.

ANNEX A: SOURCE MATERIALS

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