THIS PROSPECTUS IS IMPORTANT AND REQUIRES YOUR IMMEDIATE ATTENTION. If you are in any doubt about the contents of this Prospectus, or as to what action you should take, you are recommended to immediately consult if you are resident in Ireland, an organisation or firm authorised or exempted pursuant to the European Communities (Markets in Financial Instruments) Regulations 2007 (Nos. 1 to 3) or the Investment Intermediaries Act 1995 (as amended), or another appropriately authorised professional advisor if you are in a territory outside Ireland.

This document constitutes a prospectus for the purposes of Article 3 of the European Parliament and Council Directive 2003/71/EC of 4 November 2003 (the "**Prospectus Directive**") relating to Mainstay Medical International plc ("**Mainstay Medical**" or the "**Company**") (the "**Prospectus**") and has been prepared in accordance with Part 5 of the Prospectus (Directive 2003/71 EC) Regulations 2005 of Ireland, as amended (the "**Prospectus Regulations**") and the Commission Regulation (EC) No. 809/2004, as amended (the "**EU Prospectus Regulations**"). This Prospectus has been approved by the Central Bank of Ireland (the "**Central Bank**"), as competent authority under the Prospectus Directive. The Central Bank only approves this Prospectus as meeting the requirements imposed under Irish and EU law pursuant to the Prospectus Directive. Such approval relates only to the ordinary shares of the Company (the "**Ordinary Shares**") which are to be admitted to trading on the regulated market of Euronext Paris ("**Euronext Paris**") for the purposes of the Directive 2004/39/EC and/or which are to be offered to the public in any member state of the European Economic Area ("**EEA**"). The Company has requested that the Central Bank provide a certificate of approval and a copy of the Prospectus, together with a translation of the summary (the "**Summary**") of the Prospectus into the French language, to the French Financial Markets Authority (Autorité des marchés financiers) (the "**AMF**") in France for passporting in connection with the Company's application for the listing and admission to trading on Euronext Paris of all the Ordinary Shares and a public offering of new Ordinary Shares in France pursuant to an *offre à prix ouvert* (Open Price Offering). This document also comprises an admission document in relation to the Enterprise Securities Market, an authorised multilateral trading facility under the European Communities (Markets in Financial Instruments Directive) Regulations 2007, operated by the Irish Stock Exchange (the "**ESM**"). The admission document has been drawn up to comply with the ESM Rules for Companies published by the Irish Stock Exchange (the "**ESM Rules**") and has been issued in connection with the proposed admission to trading of the Ordinary Shares to the ESM. **The ESM is a market designed primarily for emerging or smaller companies to which a higher investment risk tends to be attached than to larger or more established companies. ESM securities are not admitted to the Official List of the Irish Stock Exchange. A prospective investor should be aware of the risks of investing in such companies and should make the decision to invest only after careful consideration and, if appropriate, consultation with an independent financial advisor. Each ESM company is required pursuant to the ESM Rules for Companies to have an ESM Adviser. The ESM Adviser is required to make a declaration to the Irish Stock Exchange on ESM Admission in the form set out in Schedule Two to the Rules for Enterprise Securities Market Advisers. The Irish Stock Exchange has not itself examined or approved the contents of this document.**

Mainstay Medical International plc

(Incorporated and registered in Ireland under the Irish Companies Acts with registered number 539688

Offer of up to 1,125,678[1] Ordinary Shares of nominal value €0.001 each at an Offer Price expected to be between €20.00 and €27.00 per Ordinary Share

and

Admission to Euronext Paris and the ESM of the Irish Stock Exchange

Kempen & Co
Joint Bookrunner

Société Générale Corporate & Investment Banking
Joint Bookrunner

Davy
Prospectus Adviser, ESM Adviser
Co-lead Manager

(1) Represents the maximum number of new Ordinary Shares which may be issued under the Offer, including any new Ordinary Shares issued pursuant to exercise of the Extension Clause and any new Ordinary Shares issued pursuant to exercise of the Over-allotment Option.

The Directors, whose names appear on page 46 of this Prospectus, and the Company, accept responsibility for the information contained in this Prospectus. To the best of the knowledge and belief of the Company and the Directors (who have taken all reasonable care to ensure that such is the case), such information is in accordance with the facts and this Prospectus does not omit anything likely to affect the import of such information.

Prospective investors should read this entire Prospectus and, in particular, Part 2 (*Risk Factors*) for a discussion of certain factors that should be considered in connection with an investment in the Ordinary Shares. Prospective investors should be aware that an investment in the Company involves a degree of risk and that, if certain of the risks described in this Prospectus occur, investors may find their investment materially adversely affected. Accordingly, an investment in the Ordinary Shares is only suitable for investors who are particularly knowledgeable in investment matters and who are able to bear the loss of the whole or part of their investment.

Application will be made for the listing and admission to trading of all of the Ordinary Shares on Euronext Paris and on the ESM. Conditional dealings in the Ordinary Shares are expected to commence on Euronext Paris and the ESM at 8.00 a.m. GMT (9.00 a.m. CET) on 29 April 2014. When admitted to trading the Ordinary Shares will be registered with International Securities Identification Number ("**ISIN**") IE00BJYS1G50, SEDOL number BJYS1G5 and will trade under the symbol MSTY. Conditional dealings before Settlement and ESM Admission will only be settled if Settlement and ESM Admission take place. All dealings in Ordinary Shares prior to the commencement of unconditional dealings will be on a "as-if-and-when-issued-or-delivered" basis and of no effect if Settlement and ESM Admission does not take place and will be at the sole risk of the parties concerned. It is expected that Settlement and ESM Admission will become effective and that unconditional dealings will commence in the Ordinary Shares on the ESM and on Euronext Paris at 8.00 a.m. GMT (9.00 a.m. CET) on 2 May 2014 and 5 May 2014, respectively. No application has been, or is currently intended to be, made for the Ordinary Shares to be admitted to listing or trading on any other stock exchange.

Copies of the entire Prospectus in English and the Summary translated into French will be available on the Company's website at www.mainstay-medical.com from the date of publication of this Prospectus.

The Price Range is indicative only, it may change during the course of the Offer and the Offer Price may be set within, above or below the Price Range. The amount to be raised and the number of new Ordinary Shares to be issued by the Company may be increased or decreased during the course of the Offer. A number of factors will be considered in determining the Offer Price, the amount to be raised pursuant to the Offer and the basis of allocation to investors, including the level and nature of the demand for the new Ordinary Shares during the bookbuilding process, prevailing market conditions and the objective of establishing an orderly after-market in the Ordinary Shares. Unless required to do so by law or regulation, the Company does not envisage publishing any supplementary prospectus triggering the right to withdraw applications for new Ordinary Shares, as the case may be, on determination of the Offer Price. If the Offer Price is set within the Price Range a pricing statement containing the Offer Price, confirming the number of new Ordinary Shares which are the subject of the Offer (the "**Pricing Statement**") and related disclosures, together with a notice by Euronext Paris expected to be published by the Company on or about 28 April 2014 together with a press release via a Regulatory Information Service, and both will be available on the Company's website at www.mainstay-medical.com. If the Offer Price is (i) set above the Price Range or the Price Range is revised higher; and/or if (ii) the number of new Ordinary Shares to be issued in the Offer is set above the Offer Size Range, then the Company will make an announcement via a Regulatory Information Service, Euronext Paris will issue a notice, and prospective investors will have a statutory right to withdraw their application for new Ordinary Shares within two Business Days of the date on which a supplementary prospectus is published. In such circumstances, the Pricing Statement would not be published until the period of exercising such withdrawal rights has ended. Therefore the expected date of publication of the Pricing Statement would be extended by a minimum period of two Business Days. The arrangements for withdrawing offers to subscribe for Ordinary Shares, as the case may be, would be made clear in the announcement. Further details of how the Offer Price is to be determined are contained in Part 14 (*The Offer*) of this Prospectus.

OVER-ALLOTMENT AND STABILISATION

In connection with the Offer, the Joint Bookrunners, or any of their agents, may (but will be under no obligation to), to the extent permitted by applicable law and for stabilisation purposes, over-allot Ordinary Shares up to a total of 15 per cent. of the total number of new Ordinary Shares comprised in the Offer. Pursuant to applicable laws and regulations, in particular the EU Directive 2003/06 and EU Regulation 2273/2003, Société Générale (as Stabilising Manager), in agreement with Kempen & Co, on behalf and for the account of the Joint Bookrunners and the Co-lead Manager, may effect other transactions with a view to supporting the market price of the Ordinary Shares at a higher level than that which might otherwise prevail in the open market. The Stabilising Manager is not required to enter into such transactions and such transactions may be effected on any securities market, over-the-counter market, stock exchange or otherwise and may be undertaken at any time during the period commencing on the date of the conditional dealings of the Ordinary Shares on Euronext Paris and on the ESM and ending no later than 30 calendar days thereafter. However, there will be no obligation on the Stabilising Manager or any of its agents to effect stabilisation transactions and there is no assurance that stabilisation transactions will be undertaken. Such stabilisation, if commenced, may be discontinued at any time without prior notice. In no event will measures be taken to stabilise the market price of the Ordinary Shares above the Offer Price. Except as required by law or regulation, neither the Stabilising Manager nor any of its agents intends to disclose the extent of any over-allotments made and/or stabilisation transactions conducted in relation to the Offer.

To allow the Stabilising Manager to cover short positions resulting from any such over-allotment and/or from sales of Ordinary Shares effected by it during the stabilising period, it will enter into the Over-allotment Option with the Company pursuant to which it may subscribe (or nominate subscribers for) additional new Ordinary Shares representing up to 15 per cent. of the total number of new Ordinary Shares comprised in the Offer (before utilisation of the Over-allotment Option) (the "**Over-allotment Shares**", together with the new Ordinary Shares pursuant to the Base Offer and the Extension Clause being the "**Offered Shares**") at the Offer Price. The Over-allotment Option may be exercised in whole or in part upon notice by the Stabilising Manager at any time on or before the 30th calendar day after the commencement of conditional dealings of the Ordinary Shares on Euronext Paris and the ESM. Any Over-allotment Shares made available pursuant to the Over-allotment Option will be sold on the same terms and conditions as the new Ordinary Shares being offered pursuant to the Offer and will rank *pari passu* in all respects with, and form a single class with, the other Ordinary Shares (including for all dividends and other distributions declared, made or paid on the Ordinary Shares).

NOTICE TO INVESTORS OUTSIDE FRANCE AND IRELAND

The distribution of this Prospectus and offer of new Ordinary Shares in certain jurisdictions other than France and Ireland may be restricted by law. No action has been taken by the Company to permit a public offer of Ordinary Shares or possession or distribution of this Prospectus (or any other Offer or publicity materials relating to Ordinary Shares) in any other jurisdiction where action for that purpose may be required or doing so is restricted by law. Accordingly, neither this Prospectus nor any advertisement may be distributed or published in any other jurisdiction except under circumstances that will result in compliance with any applicable laws and regulations. Persons into whose possession this Prospectus comes are required by the Company, the Joint Bookrunners and the Co-lead Manager to inform themselves about and observe any such restrictions. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdiction.

This Prospectus does not constitute or form part of an offer to sell, or the solicitation of an offer to buy or subscribe for, Ordinary Shares to any person in any jurisdiction to whom or in which such offer or solicitation is unlawful. Further information on the restrictions to which the distribution of this Prospectus is subject is set out in Part 14 (*The Offer*).

The Ordinary Shares have not been and will not be registered under the applicable securities laws of Australia, Canada, Japan, Switzerland or the Republic of South Africa. Accordingly, subject to certain exceptions (noted below), the Ordinary Shares may not be offered or sold in Australia, Canada, Japan or Switzerland or to, or for the account or benefit of, any resident of Australia, Canada, Japan or Switzerland.

NOTICE TO PROSPECTIVE INVESTORS IN THE U.S.

The Ordinary Shares have not been, and will not be, registered under the U.S. Securities Act of 1933, as amended (the "**U.S. Securities Act**"), or under the securities laws of any state or other jurisdiction of the United States and may not be offered or sold, directly or indirectly, within the United States, except pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the U.S. Securities Act and applicable state or local securities laws.

The offer and sale of the Ordinary Shares is being made (i) in the United States only to persons reasonably believed to be qualified institutional buyers (each a "**QIB**") as defined in Rule 144A under the U.S. Securities Act ("**Rule 144A**"), or institutional accredited investors (each an "**IAI**") as defined in Rule 501 under the U.S. Securities Act, in reliance on and in accordance with an exemption from, or in transactions not subject to, the registration requirements of the U.S. Securities Act and applicable state or local securities laws, which may include Rule 144A in the case of QIBs; and (ii) outside of the United States only in offshore transactions in reliance on and in accordance with Regulation S. Prospective purchasers are hereby notified that sellers of the Ordinary Shares may be relying on the exemption from the provisions of section 5 of the U.S. Securities Act provided by Rule 144A. For a description of these and certain further restrictions on offers, sales and transfers of the Ordinary Shares and the distribution of this Prospectus, see paragraph 14.2 of Part 14 (*The Offer*).

None of the U.S. Securities and Exchange Commission, any other U.S. federal or state securities commission or any U.S. regulatory authority has approved or disapproved of the Ordinary Shares offered by this Prospectus nor have such authorities reviewed or passed upon the accuracy or adequacy of this Prospectus. Any representation to the contrary is a criminal offence in the United States.

The Ordinary Shares are subject to selling and transfer restrictions in certain jurisdictions. Prospective purchasers should read the restrictions described in paragraph 14.2 of Part 14 (*The Offer*). Each purchaser of the Ordinary Shares will be deemed to have made the relevant representations described therein and in Part 14 (*The Offer*) at the time of purchase.

NOTICE TO NEW HAMPSHIRE RESIDENTS ONLY

NEITHER THE FACT THAT A REGISTRATION STATEMENT OR AN APPLICATION FOR A LICENCE HAS BEEN FILED UNDER CHAPTER 421-B OF THE NEW HAMPSHIRE REVISED STATUTES ANNOTATED, 1955, AS AMENDED ("RSA"), WITH THE STATE OF NEW HAMPSHIRE NOR THE FACT THAT A SECURITY IS EFFECTIVELY REGISTERED OR A PERSON IS LICENSED IN THE STATE OF NEW HAMPSHIRE CONSTITUTES A FINDING BY THE SECRETARY OF STATE OF THE STATE OF NEW HAMPSHIRE THAT ANY DOCUMENT FILED UNDER RSA 421-B IS TRUE, COMPLETE AND NOT MISLEADING. NEITHER ANY SUCH FACT NOR THE FACT THAT AN EXEMPTION OR EXCEPTION IS AVAILABLE FOR A SECURITY OR A TRANSACTION MEANS THAT THE SECRETARY OF STATE OF THE STATE OF NEW HAMPSHIRE HAS PASSED IN ANY WAY UPON THE MERITS OR QUALIFICATIONS OF, OR RECOMMENDED OR GIVEN APPROVAL TO, ANY PERSON, SECURITY OR TRANSACTION. IT IS UNLAWFUL TO MAKE OR CAUSE TO BE MADE, TO ANY PROSPECTIVE PURCHASER, CUSTOMER OR CLIENT ANY REPRESENTATION INCONSISTENT WITH THE PROVISIONS OF THIS PARAGRAPH.

NOTICE TO PROSPECTIVE INVESTORS IN AUSTRALIA

This Prospectus has been prepared under the laws and operating rules of foreign markets, namely Ireland and France. This Prospectus does not constitute a disclosure document under Part 6D.2 of the Corporations Act 2001 of the Commonwealth of Australia (the "**Australian Corporations Act (Cth)**") and has not been, and will not be, lodged with the Australian Securities and Investments Commission. Accordingly, this Prospectus does not necessarily contain all of the information a prospective investor would expect to be contained in a disclosure document in Australia or which he/she may require to make an investment decision. The Company is not, and will not be, subject to the continuous disclosure requirements of the Australian Corporations Act.

The offer of Ordinary Shares under this Prospectus to investors in Australia will only be made to the extent that such offers do not need disclosure to investors under Part 6D.2 of the Australian Corporations Act. In particular, any person who receives an offer of Ordinary Shares under this Prospectus in Australia represents and warrants to the Company, the Joint Bookrunners and the Co-lead Manager that they are a person who falls within an exemption from disclosure to investors provided by section 708 of the Australian Corporations Act, including a "sophisticated investor" within the meaning of section 708(8) of the Corporations Act, or a "professional investor" within the meaning of section 708(11) of the Australian Corporations Act. Any offer of Ordinary Shares received in Australia is void to the extent that it needs disclosure to investors under the Australian Corporations Act.

Any person to whom Ordinary Shares are issued or sold pursuant to an exemption provided by section 708 of the Australian Corporations Act must not, within 12 months after the Offer, offer those Ordinary Shares for sale in Australia unless that offer is itself made pursuant to a disclosure document under Part 6D.2 of the Australian Corporations Act or is made in reliance on an exemption from the disclosure requirements provided by section 708 of the Australian Corporations Act.

NOTICE TO INVESTORS IN ITALY

The offering of the Ordinary Shares has not been registered pursuant to Italian securities legislation and, accordingly, no Ordinary Shares may be offered, sold or delivered, nor may copies of this Prospectus or of any other document relating to the Ordinary Shares be distributed in the Republic of Italy, except:

(i) to qualified investors (investitori qualificati), as defined in Article 26, first paragraph, letter d), of Commissione Nazionale per le Società e la Borsa ("**CONSOB**") Regulation No. 16190, pursuant to Article 34-ter, first paragraph, letter b) of CONSOB Regulation No. 11971 of May 14, 1999, as amended from time to time ("**Issuers' Regulation**"), implementing Article 100 of Legislative Decree No. 58 of February 24, 1998, as amended (the "**Financial Services Act**"); or

(ii) in other circumstances which are exempted from the rules on public offerings pursuant to Article 100 of the Financial Services Act and its implementing CONSOB regulations, including the Issuers' Regulation.

Any offer, sale or delivery of the Ordinary Shares or distribution of copies of this Prospectus or any other document relating to the Ordinary Shares in Italy under (i) or (ii) above must be:

(a) made by investment firms, banks or financial intermediaries permitted to conduct such activities in the Republic of Italy in accordance with the relevant provisions of the Legislative Decree No. 385 of September 1, 1993, as amended (the "**Banking Act**"), the Financial Services Act and the Issuers' Regulation (as amended from time to time) and any other applicable law and regulations; and

(b) in accordance with any Italian securities, tax, exchange control and any other applicable laws, including any requirements or limitations which may be imposed by CONSOB, the Bank of Italy or by any other Italian authority from time to time.

Any investor purchasing the Ordinary Shares is solely responsible for ensuring that any offer, sale, delivery or resale of the Ordinary Shares by such investor occurs in compliance with applicable Italian laws and regulations.

NOTICE TO INVESTORS IN THE UNITED KINGDOM

This document is only being distributed to and is only directed at (i) persons who are outside the United Kingdom, (ii) to investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "**Order**") or (iii) high net worth entities falling within Article 49(2)(a) to (d) of the Order, and other persons to whom it may be lawfully communicated (all such persons together being referred to as "relevant persons"). The Company's shares are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such Ordinary Shares will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this Prospectus or any of its contents.

NOTICE TO INVESTORS IN SWITZERLAND

The distribution of the Ordinary Shares in or from Switzerland will be exclusively made to, and directed at, regulated qualified investors (the "**Regulated Qualified Investors**"), as defined in Article 10(3)(a) and (b) of the Swiss Collective Investment Schemes Act of 23 June 2006, as amended ("**CISA**"). Accordingly, the Company has not been and will not be registered with the Swiss Financial Market Supervisory Authority ("**FINMA**") and no Swiss representative or paying agent have been or will be appointed in Switzerland. This Prospectus and/or any other Offer materials relating to the Ordinary Shares may be made available in Switzerland solely to Regulated Qualified Investors.

NOTICE TO INVESTORS IN CANADA

The Ordinary Shares have not been nor will they be qualified for sale to the public under applicable Canadian securities laws and, accordingly, any offer and sale of the Ordinary Shares in Canada will be made on a basis which is exempt from the prospectus requirements of Canadian securities laws.

Any resale of the Ordinary Shares must be made in accordance with, or pursuant to an exemption from, or in a transaction not subject to, the prospectus requirements of those laws. In addition, in order to comply with the dealer registration requirements of Canadian securities laws, any resale of the Ordinary Shares must be made either by a person not required to register as a dealer under applicable Canadian securities laws, or through an appropriately registered dealer or in accordance with an exemption from the dealer registration requirements.

These Canadian resale restrictions may in some circumstances apply to resales made outside of Canada. Purchasers of Ordinary Shares are advised to seek Canadian legal advice prior to any resale of Ordinary Shares.

NOTICE TO INVESTORS IN JAPAN

No registration pursuant to Article 4, paragraph 1 of the financial instruments and exchange law of Japan (the "**FIEL**") has been made or will be made with respect to the Ordinary Shares offered in the Offer on the ground that Article 2, paragraph 3, item 2-(i) of the FIEL is applied to such solicitation. As described in this Prospectus, the offering of the Ordinary Shares is limited to and made only to the qualified institutional investors ("**QIIS**") as defined in Article 2, paragraph 3, item 1 of the FIEL and article 10 of the cabinet order regarding the definitions under Article 2 of the FIEL. No transfer of the Ordinary Shares may be made to persons other than QIIS, as described in this Prospectus.

OTHER IMPORTANT NOTICES AND DISCLAIMERS OF LIABILITY

Kempen & Co., which is authorised and regulated by the Netherlands Authority For the Financial Markets, is acting exclusively for the Group and no one else in connection with the Offer and admission of the Ordinary Shares to listing on Euronext Paris and ESM Admission and will not be responsible to anyone other than the Group for providing the protections afforded to its clients, for the contents of this Prospectus or for providing any advice in relation to this Prospectus, the Offer or Admission. Kempen & Co, or any person affiliated with it, does not accept any responsibility whatsoever and makes no representation or warranty, express or implied, in respect of the contents of this Prospectus, or its issue, including its accuracy or completeness or for any other statement made or purported to be made by any of them, or on behalf of them, in connection with the Group, the Ordinary Shares, the Offer and admission of the Ordinary Shares to listing on Euronext Paris and ESM Admission, and nothing in this Prospectus is or shall be relied upon as a promise or representation in this respect, whether as to the past or future. In addition, Kempen & Co does not accept responsibility for, nor authorise the contents of, this Prospectus or its issue, including without limitation, under section 41 of the 2005 Act or Regulation 31 of the Prospectus Regulations. Kempen & Co accordingly disclaims all and any liability whatsoever, whether arising in tort, contract or otherwise which it might otherwise have to any person, other than the Group, in respect of this Prospectus.

Société Générale, which is authorised in France by the Autorité de contrôle prudentiel et de résolution (the French Prudential Control and Resolution Authority) ("**ACPR**") and is regulated in France by the AMF and the ACPR, is acting exclusively for the Group and no one else in connection with the Offer and admission of the Ordinary Shares to listing on Euronext Paris and ESM Admission and will not be responsible to anyone other than the Group for providing the protections afforded to clients, for the contents of this Prospectus or for providing any advice in relation to this Prospectus, the Offer or admission of the Ordinary Shares to listing on Euronext Paris and ESM Admission. Société Générale, or any person affiliated with it, does not accept any responsibility whatsoever and makes no representation or warranty, express or implied, in respect of the contents of this Prospectus, or its issue, including its accuracy or completeness or for any other statement made or purported to be made by any of them, or on behalf of them, in connection with the Group, the Ordinary Shares, the Offer and admission of the Ordinary Shares to listing on Euronext Paris and ESM Admission, and nothing in this Prospectus is or shall be relied upon as a promise or representation in this respect, whether as to the past or future. In addition, Société Générale does not accept responsibility for, nor authorise the contents of, this Prospectus or its issue, including without limitation, under section 41 of the 2005 Act or Regulation 31 of the Prospectus Regulations. Société Générale accordingly disclaims all and any liability whatsoever, whether arising in tort, contract or otherwise which it might otherwise have to any person, other than the Group, in respect of this Prospectus.

Davy, which is authorised and regulated in Ireland by the Central Bank of Ireland, has been appointed as ESM adviser (pursuant to the ESM Rules) and broker to the Group. Davy is also acting as Prospectus Advisor and Co-lead Manager to the Group. Davy is acting exclusively for the Group and no one else in connection with the Offer and admission of the Ordinary Shares to listing on Euronext Paris and ESM Admission and will not be responsible to anyone other than the Group for providing the protections afforded to its clients, for the contents of this Prospectus or for providing any advice in relation to this Prospectus, the Offer or admission of the Ordinary Shares to listing on Euronext Paris and ESM Admission. Apart from the responsibilities and liabilities, if any, which may be imposed by the Central Bank or the Irish Stock Exchange, Davy, or any person affiliated with it, does not accept any responsibility whatsoever and makes no representation or warranty, express or implied, in respect of the contents of this Prospectus, or its issue, including its accuracy or completeness or for any other statement made or purported to be made by any of them, or on behalf of them, in connection with the Group, the Ordinary Shares, the Offer and admission of the Ordinary Shares to listing on Euronext Paris and ESM Admission, and nothing in this Prospectus is or shall be relied upon as a promise or representation in this respect, whether as to the past or future. In addition, Davy does not accept responsibility for, nor authorise the contents of, this Prospectus or its issue, including without limitation,

under section 41 of the 2005 Act or Regulation 31 of the Prospectus Regulations. Davy accordingly disclaims all and any liability whatsoever, whether arising in tort, contract or otherwise (save as referred to above) which it might otherwise have to any person, other than the Group or the Irish Stock Exchange, as set out below, in respect of this Prospectus.

In accordance with the ESM Rules, Davy has confirmed to the Irish Stock Exchange that it has satisfied itself that the Directors have received advice and guidance as to the nature of their responsibilities and obligations to ensure compliance by the Company with the ESM Rules. The responsibilities of Davy as ESM adviser and broker under the ESM Rules and Rules for Enterprise Securities Markets Advisers are owed solely to the Irish Stock Exchange, and are not owed to the Company nor any Director of the Company nor to any other person in respect of their decision to acquire Ordinary Shares in the Company in reliance on any part of this Prospectus. No representation or warranty, express or implied, is made by Davy as to the contents of this document, or for the omission of any material from this Prospectus.

No person has been authorised to give any information or make any representations other than those contained in this Prospectus and, if given or made, such information or representations must not be relied upon as having been authorised by the Company. Neither the publication of this Prospectus nor any subscription or sale made hereunder shall, under any circumstances, create any implication that there has been no change in the affairs of the Group since the date of this Prospectus or that the information in this Prospectus is correct as at any time subsequent to its date. The contents of this Prospectus should not be construed as legal, financial or tax advice. Each prospective investor should consult his, her or its own legal, financial or tax advisor for advice.

IRISH STAMP DUTY

Transfers or sales of ordinary shares of Irish companies are subject to ad valorem stamp duty, irrespective as to whether the shareholder is resident in Ireland, France or elsewhere. This is payable by the purchaser. The Irish rate of stamp duty on shares is currently 1 per cent. of the higher of the consideration paid or the market value of the shares. See paragraph 13.2 of Part 13 (*Taxation*) under the heading "*Stamp Duty*" for further information.

INTERPRETATION

Certain terms used in this Prospectus, 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 Prospectus. References to the singular in this Prospectus shall include the plural and vice versa, where the context so requires. References to sections or Parts are to sections or Parts of this Prospectus. The terms "subsidiary", "subsidiary undertaking" and "undertaking" have the meanings given to them by the Irish Companies Acts. All references to time in this Prospectus are to Dublin time unless otherwise stated.

The language of the Prospectus 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 Prospectus is 9 April 2014.

TABLE OF CONTENTS

PART 1

SUMMARY

Summaries are made up of key disclosure requirements known as 'Elements'. These elements are numbered in Sections A – E (A.1 – E.7).

This summary contains all the mandatory Elements required to be included in a summary for this type of securities and issuer. Because some Elements are not required to be addressed, there may be gaps in the numbering sequence of the Elements.

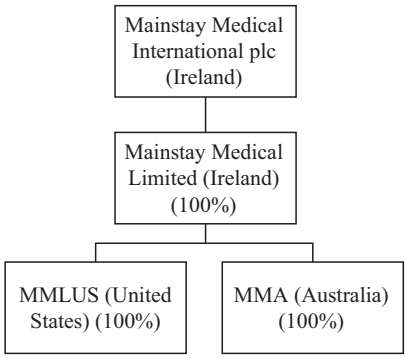
Even though an Element may be required to be inserted in the summary because of the type of securities and issuer, it is possible that no relevant information can be given regarding the Element. In this case a short description of the Element is included in the summary with the mention of 'not applicable'.

Section A – Introduction and warnings		
A.1	**Introduction and warning to prospective investors:**	**THIS SUMMARY SHOULD BE READ AS AN INTRODUCTION TO THIS PROSPECTUS. ANY DECISION TO INVEST IN THE ORDINARY SHARES SHOULD BE BASED ON CONSIDERATION OF THE PROSPECTUS AS A WHOLE BY THE INVESTOR, INCLUDING IN PARTICULAR THE RISK FACTORS.** **Where a claim relating to the information contained in this Prospectus is brought before a court, the plaintiff investor might, under the national legislation of the member states of the European Union, have to bear the costs of translating this Prospectus before the legal proceedings are initiated.** Civil liability attaches only to those persons who have tabled the summary including any translation thereof, but only if the summary is misleading, inaccurate or inconsistent when read together with the other parts of the Prospectus or it does not provide, when read together with other parts of the Prospectus, key information in order to aid investors when considering whether to invest in such securities.
A.2	**Consent of the issuer to the use of the prospectus for subsequent resale of securities or final placement of securities through financial intermediaries:**	Not applicable. The Company is not engaging any financial intermediaries for any resale of securities or final placement of securities requiring a prospectus after publication of this document.

Section B – Issuer		
B.1	**The legal and commercial name of the issuer:**	Mainstay Medical International plc.
B.2	**Domicile/legal form/legislation/country of incorporation:**	The Company is incorporated in Ireland with registered number 539688 as a public limited company under the Irish Companies Acts and is domiciled in Ireland. The Company's registered headquarters are located at Clonmel House, Forster Way, Swords, Co. Dublin.

B.3	**Current operations, products and principal markets:**	The Company was incorporated and registered in Ireland on 17 February 2014 as a public limited company and became the ultimate holding company of the Group on 3 April 2014 pursuant to the 2014 Corporate Reorganisation. The Company, together with Mainstay Medical Limited ("**MML**"), its U.S. subsidiary MML US Inc. ("**MMLUS**") and the Australian subsidiary Mainstay Medical (Australia) Pty. Limited ("**MMA**") form the "**Group**". The first holding company of the Group, Mainstay Medical, Inc. ("**MMI**"), was founded in 2008, to develop innovative neurostimulation therapies for the population of people with debilitating Chronic Low Back Pain, which remains the Group's objective. MMI ceased to be a member of the Group, and MML became the holding Company of the Group, in September 2012. Since then the Group has been headquartered in Dublin, Ireland, with subsidiaries operating in the United States and Australia. The Group's team includes scientists, engineers, clinical experts and external scientists and clinicians who are experienced in developing and commercialising technologies addressing unmet clinical needs. The Group is focussed on the development of ReActiv8, an active implantable medical device (AIMD) designed to treat people with Chronic Low Back Pain. Chronic Low Back Pain is generally defined as Low Back Pain where the pain persists for more than three months. Low Back Pain is a leading cause of activity limitation and work absence throughout much of the developed world, imposing a high economic burden on individuals, families, communities, industry, and governments. Based on published research (Hall et al, 2008) the Company estimates that in approximately 7 per cent. of all cases of Low Back Pain, the pain persists for more than three months. The people who fall into that category thus include the Company's target market of people with Chronic Low Back Pain. The Group has completed the design of ReActiv8 and is now focussed on clinical development, regulatory approval and commercialisation. The Group has defined the expected pathway from ReActiv8 product development to revenues and profits with four key elements as follows: 1. Obtain regulatory approval in order to gain market access; 2. Leverage existing reimbursement and expand coverage; 3. Drive adoption of ReActiv8 in routine clinical practice; and 4. Drive market awareness in the general population. Once a medical device has received regulatory approval for marketing, it is allowed to be placed on the market and sold.

		The price for a medical device is determined by the company selling the product, however in practice arrangements must be made for payment by the payer. The term "payer" refers to the organisation which eventually provides the payment for a medical therapy. Depending on the country, a "payer" can be a national health service, a social insurance company, a private insurance company or an individual. In most countries, a series of codes are used to classify diagnoses and clinical procedures and a reimbursement amount is associated with each of the codes. The reimbursement amount is intended to define the amount paid to the hospital or health care provider by the payer for a clinical procedure and includes all costs associated with the procedure (e.g. physician costs, consumables, operating room cost if appropriate, and the costs of a device if involved with the procedure). The Company believes that existing reimbursement codes in some target markets can be used to allow hospitals and clinics to be reimbursed in full or in part for procedures using ReActiv8 immediately following CE Mark approval (assuming it is obtained). In countries where coding is not yet in place or coverage of available coding is insufficient to reach levels of reimbursement deemed acceptable, the Group will work with the relevant parties (e.g. health care providers and physicians) to help establish appropriate coding and reimbursement levels. Higher reimbursement rates allow for higher negotiated selling prices. It should be noted that obtaining proper reimbursement codes may take months or years depending on the country. The Company plans to use a direct sales force in the early stages of commercialisation because of the need to control and optimise clinical site selection, focus on referral networks, manage clinical outcomes and user experience, and retain learning inside the organisation. The Company intends to target certain specific markets that it has determined to be the most important ones first. The Company determines the importance of a market based on potential market size or population and the availability of reimbursement within healthcare payment systems from government and other payers such as insurance companies. The timing of market entry will be determined primarily by the timing of regulatory approvals for those markets. Subject to and following CE Mark approval, the Company intends to focus initially on key European markets that it deems to be the most important, such as Germany, UK, France, Austria, Switzerland and the Benelux (Belgium, Netherlands, Luxembourg) countries. This will be followed by market entry into strategically important non-EU countries such as Australia.

		The U.S. is a key strategic market for the Group. Entry into the U.S. market is subject to the granting of a PMA, and is expected to follow the key EU and strategically important non-EU markets, although entry into the U.S. market could take significantly more time (i.e. counted in years) than entry into other markets. The Group has raised more than $26 million in venture capital to date to finance the development of ReActiv8 and to conduct clinical trials. The Group has not yet generated revenues.
B.4a	**Recent trends:**	Since 31 December 2013, the date to which the last audited accounts for the Group were prepared, the Group has continued to trade in line with the Board's expectations. The period since 31 December 2013 has also seen significant progress as the Group has continued to advance its activities, and in March 2014 recruitment started in the clinical trial of ReActiv8 for the purpose of obtaining the CE Mark. Based on the performance achieved in the financial year to date, the Board remains confident of the outlook for the full financial year ending 31 December 2014.
B.5	**Group Structure:**	The Group undertook a corporate reorganisation (the "**2014 Corporate Reorganisation**"), which resulted in Mainstay Medical International plc being incorporated on 17 February to become the ultimate parent company of the Group, effective 3 April 2014. As a result of the 2014 Corporate Reorganisation, MML became a wholly-owned operating subsidiary of the Company. The Group is headquartered in Dublin, Ireland and has subsidiaries operating in the United States (MMLUS) and Australia (MMA). MMLUS performs research and development services for the Group and manages the Group's supply chain. In May 2013, MMA was established principally to oversee the management of clinical trials of ReActiv8 in Australia. **Group Organisational Structure (at the date of this Prospectus):** 

B.6	**Major shareholders:**	As of the Latest Practicable Date, in so far as is known to the Company, the following persons have an interest which represents three per cent. or more of the issued share capital of the Company:

	As of the Latest Practicable Date		*After the Base Offer and before exercise of the Extension Clause and the Over-allotment Option[2][3]*	
Name	*Number of shares[1]*	*Percentage of Existing Issued Share Capital*	*Number of Ordinary Shares*	*Percentage of Enlarged Issued Share Capital*
Sofinnova Capital VI FCPR	1,556,999	45.7%	1,753,946	41.2%
Fountain Healthcare Partners Fund 1, L.P.	496,403	14.6%	559,194	13.1%
Dan Sachs MD	515,000	15.1%	515,000	12.1%
Capricorn Health-Tech Fund NV	227,358	6.7%	256,117	6.0%
Medtronic, Inc.	200,931	5.9%	231,782	5.4%
Seventure Partners Managed Funds	170,915	5.0%	191,991	4.5%

	After the Base Offer and exercise in full of the Extension Clause and before exercise of the Over-allotment Option[2][3]		*After the Base Offer and exercise in full of the Extension Clause and the Over-allotment Option[2][3]*	
Name	*Number of Ordinary shares*	*Percentage of Enlarged Issued Share Capital*	*Number of Ordinary Shares*	*Percentage of Enlarged Issued Share Capital*
Sofinnova Capital VI FCPR	1,753,946	40.0%	1,753,946	38.7%
Fountain Healthcare Partners Fund 1, L.P.	559,194	12.8%	559,194	12.3%
Dan Sachs	515,000	11.7%	515,000	11.4%
Capricorn Health-Tech Fund NV	256,117	5.8%	256,117	5.7%
Medtronic, Inc.	231,782	5.3%	231,782	5.1%
Seventure Partners Managed Funds	191,991	4.4%	191,991	4.2%

Notes:

(1) As at the Latest Practicable Date, the Shareholders listed above hold various classes of shares. All issued shares in the Company will convert to Ordinary Shares on a one for one basis shortly before admission to listing on Euronext Paris and prior to ESM Admission.

(2) Assuming the issue of 851,175 new Ordinary Shares, being the maximum number under the Base Offer.

(3) Assuming the aggregate subscription (where applicable) of these Shareholders under their respective Subscription and Lock-Up Deeds of an amount of €8m, corresponding to 340,424 new Ordinary Shares based on the mid-point of the Price Range.

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.

B.7	**Selected historical key financial information:**	The tables below, which have been extracted without material adjustment from Part 12 ("*Historical Financial Information*"), set out the Group's summary financial

information for the years ended 31 December 2013, 2012 and 2011.

Information relating to the Group's consolidated statement of profit or loss and other comprehensive income

	For the year ended 31 December		
($'000)	*2013*	*2012*	*2011*
Revenue	–	–	–
Operating expenses	(8,396)	(5,295)	(2,911)
Operating loss	(8,396)	(5,295)	(2,911)
Finance income	821	319	9
Finance expense	(2,711)	(937)	(339)
Net finance expense	(1,890)	(618)	(330)
Loss before income taxes	(10,286)	(5,913)	(3,241)
Income taxes	(32)	30	–
Loss for the year and comprehensive loss for the year	(10,318)	(5,883)	(3,241)

Consolidated Balance Sheet of the Group

	As at 31 December		
($'000)	*2013*	*2012*	*2011*
Non-current assets			
Property, plant and equipment	68	66	32
Current assets			
Prepayments and other receivables	385	187	41
Cash and cash equivalents	9,590	17,370	4,364
Total current assets	9,975	17,557	4,405
Total assets	10,043	17,623	4,437
Equity			
Share capital	1	1	2
Share premium	250	250	–
Share based payment reserve	534	104	96
Reorganisation reserve	(9,609)	(9,609)	–
Retained losses	(13,146)	(2,828)	(5,901)
Deficit on shareholders' equity	(21,970)	(12,082)	(5,803)

			As at 31 December		
		($'000)	*2013*	*2012*	*2011*
		Non-current liabilities			
		Preference shares	24,965	22,235	5,136
		Derivative financial instruments	4,622	5,393	2,730
		Deferred tax	96	–	–
		Loans and borrowings	–	800	1,579
		Total non-current liabilities	29,683	28,428	9,445
		Current liabilities			
		Loans and borrowings	785	768	367
		Trade and other payables	1,545	509	428
		Total current liabilities	2,330	1,277	795
		Total liabilities	32,013	29,705	10,240
		Total equity and liabilities	10,043	17,623	4,437

Group's consolidated cash flow statement

		For the year ended 31 December		
	($'000)	*2013*	*2012*	*2011*
	Cash flows from operating activities			
	Net loss attributable to equity holders	(10,318)	(5,883)	(3,241)
	Non-cash adjustments			
	Depreciation	23	9	4
	Net finance expense	1,890	618	330
	Share-based compensation	430	8	20
	Gain on sale of property, plant and equipment	–	–	2
	Changes in working capital			
	Prepayments and other receivables	(198)	(146)	(24)
	Trade and other payables	1,148	18	320
	Interest paid	(83)	(213)	(5)
	Net cash used in operations	(7,108)	(5,589)	(2,594)
	Cash flow from investing activities			
	Proceeds on sale of equipment	–	–	5
	Acquisition of property, plant and equipment	(25)	(43)	(31)
	Net cash used in investing activities	(25)	(43)	(26)

($'000)	*For the year ended 31 December 2013*	*2012*	*2011*
Cash flows from financing activities			
Proceeds from issue of preferred shares (net)	153	19,038	2,428
Repayment of borrowings	(800)	(400)	–
Proceeds from new borrowings	–	–	2,000
Net cash (used in)/from financing	(647)	18,638	4,428
Net (decrease)/increase in cash and cash equivalents	(7,780)	13,006	1,808
Cash and cash equivalents at beginning of year	17,370	4,364	2,556
Cash and cash equivalents at end of year	9,590	17,370	4,364

Certain significant changes impacted on the Group's financial position and results of operations during the financial years 2011, 2012 and 2013. These include the Group's funding rounds in order to develop and expand its operations, most significantly the Series B Financing of $20 million from venture capital and corporate sources in September 2012.

The Group has applied the funding raised to increase its operating expenditure by $2.4 million, or 83 per. cent, from $2.9 million in 2011 to $5.3 million in 2012, and further by $3.1 million, or 58 per. cent, to $8.4 million in 2013. These increases are primarily driven by growth in research and development expenses as well as additional headcount and operating expenses across the Group's other functions during the period to 31 December 2013.

There has been no significant change in the financial or trading position of the Group since 31 December 2013 the date to which the last audited consolidated financial information of the Group was prepared.

B.8	**Selected key pro forma financial information:**	Not applicable. This Prospectus does not contain pro forma financial information.
B.9	**Profit forecasts:**	Not applicable. No profit forecasts or estimates have been made.
B.10	**Report on the historical financial information – qualifications:**	Not applicable. KPMG's report in respect of the Historical Financial Information was unqualified.

B.11	**Working capital – qualifications:**	Not applicable; the Company having made due and careful enquiry is of the opinion that, taking into account the Minimum Net Proceeds to be received by the Company from the Offer, 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.

Section C – Securities		
C.1	**Description of type and class of securities being offered and/or admitted to trading:**	The Offer comprises an offer of new Ordinary Shares in the Company. When admitted to trading, the Ordinary Shares will be registered with ISIN number IE00BJYS1G50, SEDOL number BJYS1G5 and will trade under the symbol MSTY. The Ordinary Shares will, on Settlement and ESM Admission, comprise the entire issued and to be issued ordinary share capital of the Company. The product name on Euronext Paris will be Mainstay Medical. The company will belong to ICB Classification 4535 Medical Equipment. The Ordinary Shares should be eligible to be placed in tax-advantaged savings accounts in France (*PEAs* and "*PME-ETI*" *PEAs*).
C.2	**Currency of the securities issue:**	The Ordinary Shares are denominated in Euro.
C.3	**Number of Ordinary Shares issued and par value:**	The Company is proposing to issue up to 851,175 new Ordinary Shares pursuant to the Base Offer, which may be increased by a maximum number of up to 127,676 new Ordinary Shares if the Extension Clause is fully exercised, and up to 146,827 new Ordinary Shares if the Over-allotment Option is fully exercised. The Ordinary Shares have a nominal value of €0.001 each, all of which will be issued fully paid.
C.4	**Rights attaching to Ordinary Shares:**	The new Ordinary Shares will be issued credited as fully paid and will rank *pari passu* in all respects with each other and will rank equally for all dividends and other distributions thereafter declared, made or paid in respect of existing Ordinary Shares. Subject to the provisions of the Irish Companies Acts, any equity securities issued by the Company for cash must first be offered to Shareholders in proportion to their holdings of Ordinary Shares. The Irish Companies Acts allow for the disapplication of pre-emption rights, which may be waived by a special resolution of the Shareholders. The Ordinary Shares are not redeemable. However, the Company may purchase or contract to purchase any of the Ordinary Shares on or off market, subject to the Irish Companies Acts and the requirements of Euronext Paris and the ESM.

		On a show of hands, each Shareholder will have one vote and on a poll each Shareholder will have one vote per Ordinary Share held. As part of the Offer the Company is authorised to, depending on the level of the demand expressed by investors, increase the number of new Ordinary Shares offered under the Base Offer by up to 15 per cent. pursuant to the Extension Clause. The Company will separately grant the Joint Bookrunners an Over-allotment Option entitling them to subscribe for a number of Over-allotment Shares equal to a maximum of 15 per cent. of the number of new Ordinary Shares issued pursuant to the Offer (including where the Extension Clause is exercised in full) including for the purpose of carrying out stabilisation activities.
C.5	**Restrictions on transfer:**	Not Applicable; following Settlement and ESM Admission and subject to the Lock-up Agreements that apply to certain persons mentioned in E.5 below, the Ordinary Shares will be freely transferable and there will be no restrictions on transfer in France or Ireland.
C.6	**Admission to trading:**	Application will be made for the listing and admission to trading of the Ordinary Shares on Euronext Paris and on the ESM. Conditional dealings in the Ordinary Shares are expected to commence on Euronext Paris and the ESM at 8.00 a.m. GMT (9.00 a.m. CET) on 29 April 2014. All dealings in Ordinary Shares prior to the commencement of unconditional dealings will be on a "as-if-and-when-issued-or-delivered" basis and of no effect if Settlement and ESM Admission does not take place and will be at the sole risk of the parties concerned. It is expected that Settlement and ESM Admission will become effective and that unconditional dealings will commence in the Ordinary Shares on the ESM and on Euronext Paris at 8.00 a.m. GMT (9.00 a.m. CET) on 2 May 2014 and 5 May 2014, respectively. No application has been, or is currently intended to be, made for the Ordinary Shares to be admitted to listing or trading on any other stock exchange.
C.7	**Dividend policy:**	The Company has never declared or paid dividends and 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.

Section D – Risks		
D.1	**Key information on the key risks specific to Mainstay Medical International plc and its industries:**	Prior to investing in the Ordinary Shares, prospective investors should consider the risks associated therewith.

		The risks relating to the Company and/or its industry include the following: • The Group has incurred significant operating losses and may not be able to achieve or subsequently maintain profitability. • The Group will likely require additional funds in the future in order to meet its capital and expenditure needs and further financing may not be available when required or could significantly limit the Group's access to additional capital. • The Group's future financial performance is entirely dependent on the commercial success of Reactiv8, its only product as at the date of this Prospectus. • The Group operates in a highly regulated environment and regulatory approval (which the Group currently does not have) is required before the Group can market or sell Reactiv8. • 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 the Group's target markets may delay, prohibit or reduce potential sales. • The Group is 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.
D.3	**Key information on the key risks relating to the Ordinary Shares and the Offer:**	The risks relating to the Ordinary Shares and the Offer include the following: • A liquid market for the Ordinary Shares may fail to develop, which may cause the shares to trade at a discount to the Offer Price and make it difficult to sell the shares. • The market price of the Ordinary Shares may fluctuate widely in response to various factors and investors may not be able to sell their Ordinary Shares at or above the Offer Price. • The market price of the Ordinary Shares could be negatively impacted by sales of substantial number of Ordinary Shares in the public markets. • Future issuances of Ordinary Shares, options, warrants or other convertible securities may affect the market price of the Ordinary Shares and could dilute the interests of existing Shareholders. • Certain significant Shareholders of the Company may have different interests from the Company after

		the Offer and may be able to influence the Company, including the outcome of Shareholder votes. • The Company does not intend to pay dividends for the foreseeable future.

Section E – Offer		
E.1	**Net proceeds/expenses:**	Assuming a full issuance of up to 851,175 new Ordinary Shares (the "**Base Offer**") at an Offer Price at the mid-point of the Price Range, i.e. €23.50 per Ordinary Share, the gross proceeds of the Offer will be €20,002,612.50 and the net proceeds of the Offer, after deduction of fees and expenses relating to the Offer are expected to be €16,500,596.83. On this basis, the fees and expenses relating to the Offer are expected to be approximately €3.5 million. Should the Offer fail to yield the Minimum Net Proceeds, the Offer will be cancelled and no Ordinary Shares will be issued pursuant to the Offer.
E.2a	**Reasons for the Offer/use of proceeds:**	The estimated net proceeds are as set out in E.1 above. The minimum net proceeds of the Offer is set at an aggregate amount of €12 million (net of fees and expenses) (the "**Minimum Net Proceeds**"). The Minimum Net Proceeds together with existing cash resources will be used to conduct Clinical Trials, initially in Australia and then additionally in Europe, to submit an application for CE Mark approval and for general working capital purposes for at least the next twelve months. The Company intends that remaining net proceeds of the Offer will be used for the following clinical, regulatory and related commercialisation activities through 2014 and 2015: • to submit an application for IDE approval to start a clinical trial in the US; • following and subject to CE Mark approval, to commence commercialisation, and in particular to start to build a European sales force and support organisation; • to grow and strengthen the Group's intellectual property portfolio; and • to commence development of the next generation of the Group's products. Additional capital may also be required to complete the matters set forth above, depending on circumstances and events. At the relevant time, the Company will explore options for sourcing additional capital, which may include strategic partners, private placement, and a public offering.

		In addition, the Board believes that becoming a public company will benefit the Company as it will: • give the Group access to a wider range of capital-raising options which may be of use in the future; and • assist in recruiting, retaining and incentivising key management and employees.
E.3	**Terms and conditions of the Offer:**	The Offer will be made by the release on the market of up to 1,125,678 new Ordinary Shares. Depending on the scale of the demand expressed for the Base Offer, the initial number of new Ordinary Shares may be increased by 15 per cent. in the case of full exercise of the Extension Clause. The Company will also grant the Joint Bookrunners an Over-allotment Option entitling them to subscribe for a number of Over-allotment Shares equal to a maximum of 15 per cent. of the number of new Ordinary Shares issued in the Offer (i.e. including where the Extension Clause is exercised in full). The Offer will comprise two elements: a public offering in France pursuant to an *offre à prix ouvert* (open price offer); and an institutional private placement to certain institutional investors in France and elsewhere. The allocation of the new Ordinary Shares between the Retail Offer and the Institutional Placement will be effected depending on the nature and amount of demand. If the level of demand expressed in the context of the Retail Offer is sufficient, the number of new Ordinary Shares allocated in response to the orders issued as part of the Retail Offer will be at least equal to 10 per cent. of the number of new Ordinary Shares offered. The allocation of new Ordinary Shares between the investors will be made by the Joint Bookrunners following consultation with the Company. The price of the new Ordinary Shares in the Retail Offer will be equal to the price of the new Ordinary Shares in the Institutional Placement. The Offer Price will be determined by the Board following consultation with Joint Bookrunners. The Offer Price, together with details of the final number of Ordinary Shares to be issued under the Offer, will be set out in a press release by the Company and the Pricing Statement and this information will be disseminated publicly on or around 28 April 2014 via a Regulatory Information Service. The press release and the Pricing Statement will, subject to certain access restrictions for parties in certain foreign jurisdictions, also be published in electronic form and be available on the Company's website at www.mainstay-medical.com.

		It is currently expected that the Offer Price will be within the Price Range, but this range is indicative only and the Offer Price may be set within, above or below it. A number of factors will be considered in determining the Offer Price, including the level and the nature of the demand for new Ordinary Shares, the prevailing market conditions and the objective of establishing an orderly and liquid after-market in the Ordinary Shares. The Offer Price will be established at a level determined in accordance with these factors, taking into account indications of interest received (whether before or after the times and/or dates stated) from market-makers, fund managers and other persons. The Company and the Joint Bookrunners reserve the right to increase or decrease the aggregate number of new Ordinary Shares offered pursuant to the Offer. If the Offer Price is set above the Price Range or the Price Range is revised higher prior to the announcement of the final Offer Price, the revised Price Range will be announced and advertised as soon as possible by the Company and in a Euronext notice and the Company will publish a supplementary prospectus. It is expected that the Offer Price will be set on 28 April 2014, it being specified that this date may be postponed if the market conditions and results of the order bookbuilding do not allow for the Offer Price to be set under satisfactory conditions. Under the terms and conditions of the Offer, each investor makes certain representations, warranties and acknowledgements to the Company customary for an offer of this type, including but not limited to: (i) in relation to certain characteristics of the investor; (ii) the investor's compliance with restrictions contained in the Offer and with specified laws and regulations; (iii) reliance, responsibility and liability in respect of this Prospectus, the Offer and information outside of this Prospectus; (iv) compliance with laws; (v) jurisdiction; and (vi) liability for duties or taxes. Each investor placing an order agrees with the Company to the terms and conditions of the Retail Offer and/or the Institutional Placement set out in this Prospectus. The Company, the Directors, the Joint Bookrunners and the Co-lead Manager will be subject to the Placing Agreement under which the Joint Bookrunners and the Co-lead Manager will severally agree, subject to certain conditions that are typical for an agreement of this nature (the last condition being ESM Admission) to procure subscribers for the new Ordinary Shares offered under the Offer at the Offer Price and failing which, to subscribe and pay for those new Ordinary Shares themselves. The Placing Agreement will be executed on the day on which the Offer Price is set, which according to the indicative timetable is expected to take place on 28 April 2014.

		Completion of the Offer will be subject, inter alia, to the determination of the Offer Price and the Board's decision to proceed with the Offer. It will also be subject to the satisfaction of conditions contained in the Placing Agreement, including Settlement and ESM Admission occurring and to the Placing Agreement not having been terminated in accordance with its provisions. The Offer cannot be terminated once unconditional dealings in the Ordinary Shares have commenced.
E.4	**A description of any interest that is material to the Offer including conflicting interests:**	The Company considers that each of Fountain Healthcare Partners Fund 1, L.P. and Sofinnova Capital VI FCPR has interests that are material to the Offer by virtue of the size of their existing shareholdings in the Company. The Company does not consider that these are conflicting interests, or that there are other interests, including conflicts of interest, that are material to the Offer.
E.5	**Selling Shareholder(s)/lock-up agreements:**	(A) ***Selling Shareholder(s)*** Not applicable. Save for the Company, there are no entities or persons selling Ordinary Shares in the Offer. (B) ***Lock-up Agreements*** The Company has agreed that it will not issue any new Ordinary Shares for a period of 360 days from the date of ESM Admission, except as requested to comply with the terms of existing or permitted grants of Share Options or Share Warrants. Each of the Shareholders as at the date of this Prospectus, the Directors holding Ordinary Shares or Share Options as at the date of this Prospectus and the Senior Managers have agreed that, subject to certain customary exceptions, they will not dispose of any Ordinary Shares (other than Ordinary Shares subscribed for by these parties under the Offer, as described in the following paragraph) for a period of 365 days from the date of ESM Admission. Sofinnova Partners, Fountain Healthcare Partners, Medtronic, Inc., Capricorn Health Tech Fund NV and Seventure Partners Managed Funds, have irrevocably undertaken to subscribe under the Offer (in the proportions described at paragraph 14.2.2 of Part 14 (*The Offer*)) for the issue of new Ordinary Shares with an aggregate subscription price of €8 million, provided that this amount may be reduced based on actual market demand and pursuant to usual allocation practice.
E.6	**Dilution:**	Between 851,175 new Ordinary Shares (assuming no exercise of the Extension Clause or the Over-allotment Option) and 1,125,678 new Ordinary Shares (assuming full exercise of the Extension Clause and the Over-allotment Option) will be issued pursuant to the Offer. The number of such new Ordinary Shares as a percentage of the Enlarged Issued Share Capital of the Company immediately

		following Settlement and ESM Admission will be equal to between 20.0 and 24.8 per cent.
E.7	**Estimated expenses charged to investors:**	Not applicable. No expenses will be charged to any investor by the Company in respect of the Offer.

PART 2

RISK FACTORS

Any investment in the Ordinary Shares is subject to a number of risks. Accordingly, prior to making any investment decision, prospective investors should carefully consider all the information contained in this Prospectus and, in particular, the risk factors described below.

This Prospectus also contains forward-looking statements that involve risks and uncertainties. See "Forward Looking Statements" in Part 3 (Important Information) of this Prospectus. 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 Prospectus.

Prospective investors should note that the risks relating to the Company, the Group, its industry and the Ordinary Shares outlined in the section of this Prospectus headed Part 1 (Summary) are the risks that the Directors believe to be the most essential to an assessment by a prospective investor of whether to consider an investment in the Ordinary Shares. However, as the risks which the Company and the Group faces relate to events and depend on circumstances that may or may not occur in the future, prospective investors should consider not only the information on the key risks summarised in the section of this Prospectus headed Part 1 (Summary) but also, among other things, the risks and uncertainties described below.

The Board considers the following risks to be material for prospective investors in the Company. However, the following is not an exhaustive list or explanation of all risks that prospective investors may face when making an investment in the Ordinary Shares and should be used as guidance only. In addition to the material risks listed below, 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. Investors should consider carefully whether an investment in the Ordinary Shares is suitable for them in light of the information in this Prospectus and their personal circumstances. If investors are in any doubt about any action they should take, they should consult a competent independent professional advisor who specialises in advising on the acquisition of listed securities. 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.

Prospective investors should read this Part in conjunction with this entire Prospectus.

2.1 RISKS RELATING TO THE GROUP'S BUSINESS AND INDUSTRY

2.1.1 ***The Group has incurred significant operating losses and may not be able to achieve or subsequently maintain profitability***

The Group has incurred significant net losses since it was established. As of 31 December 2013, the Group had a comprehensive loss for the year of U.S.$10.3 million, compared to losses of $5.9 million and $3.2 million as of 31 December 2012 and 2011, respectively. The Group raised more than $26 million in the Series A Financing and the Series B Financing in 2010 and 2012 respectively and to date the Group has devoted substantially all of its resources to the research and development of Reactiv8, including completion of recruitment in a feasibility study in October 2012 (the "**Feasibility Study**") using commercially available devices, development work on the ReActiv8 implantable pulse generator ("**IPG**") and leads, and expansion of the Group's intellectual property portfolio.

The Group has not yet obtained regulatory approval for Reactiv8, which as at the date of this Prospectus is its only product. To implement its business strategy, the Group needs to, among other things, obtain regulatory approval for Reactiv8, work to help organisations secure reimbursement by payers, fund continued research and development, continue to establish its manufacturing, marketing

and sales networks and commercialise its product. The Group expects to incur losses for the foreseeable future as it continues to pursue these objectives.

If the Group is unable to obtain regulatory approval for Reactiv8, or if product development, manufacture, marketing, sales or commercialisation of Reactiv8 is delayed or abandoned, the Group may never generate significant revenue or become profitable. Even if the Group does become profitable in the short term, the Group may be unable to sustain or increase its profitability on a quarterly or annual basis over the medium to long term.

2.1.2 ***The Group will likely require additional funds in the future in order to meet its capital and expenditure needs and further financing may not be available when required or could significantly limit the Group's access to additional capital***

The Group will likely require additional funds in the future in order to meet its capital and expenditure needs, including in order to continue research and development and conduct regulatory approval activities necessary to bring ReActiv8 to market and to establish effective marketing and sales capabilities. However, the Group may not be able to obtain additional financing on terms favourable to it, if at all, when needed. If the Group is unable to obtain adequate financing or financing on terms satisfactory to it, when the Group requires it, the Group may cease to have operations and may need to liquidate some or all of its assets.

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

2.1.3 ***The Group's future financial performance is entirely dependent on the commercial success of Reactiv8, its only product as at the date of this Prospectus***

The Group's only product as at the date of this Prospectus, ReActiv8, is designed to treat people suffering from Chronic Low Back Pain, a serious and often debilitating medical condition. The Group's business strategy is entirely dependent on the success of Reactiv8 and the Group is not currently pursuing the commercialisation of any other product. The success of Reactiv8 may be negatively impacted by many factors, including regulatory delays, adverse regulatory or legal actions, problems arising from manufacture, research and development and low sales in target markets. Because the Group's business currently relies on the success of a single product, any factors that negatively impact the development and commercialisation of Reactiv8 could adversely affect the Group's business, financial condition and prospects.

2.1.4 ***The Group operates in a highly regulated environment and regulatory approval is required before the Group can market or sell Reactiv8***

ReActiv8 is an active implantable medical device (AIMD), which requires regulatory approval before it can be marketed or sold by the Group. Currently, the Group has not received approval from any regulatory authority for its products and there is no guarantee that regulatory approvals will be obtained for ReActiv8 or any other product developed by the Group, either now or in the future. Although the Company believes that CE Mark regulatory approval for ReActiv8 will be achieved by the end of 2015, there is no guarantee this date or any other date will be achieved.

Timing for regulatory approval via a Pre-Market Approval (PMA) by the U.S. Food and Drug Administration (FDA) is uncertain, as it depends on the details of the clinical trial to be agreed between the Group and including parameters such as number of subjects and duration of follow up. The process is expected to take significantly longer than obtaining CE Mark approval. 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 which would make continued marketing of the Group's products no longer acceptable.

The regulatory approval process may delay or prevent the launch of the Group's products in its target markets, which would negatively impact or prevent the Group's ability to achieve its milestones. If the Group fails to obtain approval of its products in a timely manner, or at all, the marketing and sale of the Group's products may be delayed or may not be achieved, thereby adversely affecting the Group's ability to generate revenues and/or causing it to cease operations.

2.1.5 ***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 the Group's target markets may delay, prohibit or reduce potential sales***

The Group currently does not have regulatory approval to market Reactiv8 in any country. The Group is primarily targeting sales in markets in Europe and North America, including the U.S., and is obliged to comply with regulatory requirements that include obtaining regulatory approval pursuant to the applicable laws and regulations before it can market or sell its products in each market. Once initial regulatory approval is gained for a particular market, any subsequent products or product modifications may also require further regulatory approval before the Group can market the subsequent or modified products.

In Europe, regulatory approval is obtained via the CE Mark process according to the European Active Implantable Medical Devices Directive 90/385/EEC and subsequent amendments (the "**AIMD Directive**"), which provides approval for the European Economic Area (the "**EEA**", which includes the EU, Iceland, Liechtenstein and Norway) and is accepted by certain other non-EEA countries, including Switzerland. In the U.S., regulatory approval is obtained via pre-market approval ("**PMA**") from the U.S. Food and Drug Administration (the "**FDA**"). Regulatory approval can be a lengthy, expensive and uncertain process. 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 established by the relevant regulatory agencies. The regulations to which the Group is subject are complex and have tended to become more stringent over time. The Group may be adversely affected by changes in government policy or legislation applying to AIMDs.

Following a recent scandal where a number of executives who had worked at a French breast implant company, Poly Implant Prothèse (PIP), were sentenced for their roles in concealing a substandard product (the silicone used in the PIP products never obtained regulatory approval for medical use and was found to be the cause of ruptured implants), the European Commission has proposed changes to the CE Mark Process, including the process for AIMDs. ReActiv8 is an AIMD. A proposal for changes has been published at the EU level, which if adopted would likely make the approval process for Reactiv8 more difficult and time consuming. EU member states have not yet agreed to the changes, and several amendments have been proposed. It is not known if, when and to what extent the regulations for AIMDs will change, or when any such changes will become effective, and what the impact of those changes, if any, may be on the Group. It is unlikely that the changes, if any, will be implemented prior to the Groups' submission for CE Mark for ReActiv8. However, the impact of proposed changes could delay or prevent approval or add substantial cost to the approval process for all products subject to the new regulations. It is, however, likely that (i) the regulatory requirements for the design and manufacturing of AIMDs will be tightened, (ii) the obligations for manufacturers to monitor the safety of their products, once placed on the market, will increase, and (iii) manufacturers will be subject to increased scrutiny. The EU proposals, if implemented, may make the EU approval process for AIMDs more similar to the US PMA process. The Group has implemented a quality management system intended to comply with the requirements of the PMA process.

Review of the Group's regulatory submissions by regulatory agencies may result in requests to perform additional or repeat testing, to redesign one or more aspects of the Group's products, or to change materials. Any of these events may cause significant delays and additional costs.

The Group may at some time request that the indications for use of the Group's products be expanded, and that expansion of indications is likely to also require regulatory approval. Subsequent regulatory approvals for modified products or expanded indications are usually less arduous than an initial

application for regulatory approval. For example, in the U.S., subsequent regulatory approval is based on the process referred to as a PMA Supplement to an existing approved PMA.

There is no certainty that the regulatory approval process will not delay or prevent the launch of Reactiv8 in target markets. If the Group fails to obtain approval of Reactiv8, or if the timely approval of Reactiv8 is not achieved, the marketing and sale of the Group's products may not be achieved or may be delayed, thereby adversely affecting the Group's ability to generate significant revenues and continue operations.

2.1.6 ***The Group is 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 Group has limited clinical trial experience to date with ReActiv8. While the results of the Feasibility Study on the therapy to be delivered by ReActiv8 were encouraging, that study was a small single arm (non-randomised) study, using commercially available devices, rather than the current ReActiv8, with limitations customary for a feasibility stage study. The results of the Feasibility Study will need to be confirmed with future clinical trials with ReActiv8 and are likely to include prospective randomised clinical trials. These trials may not produce the anticipated clinical efficacy outcomes, or may uncover previously unknown safety issues or risks. The first human clinical trials of ReActiv8, which will be partly funded by the proceeds of the Offer, commenced in March 2014, and those trials may uncover product design issues not yet discovered by bench and pre-clinical (animal) testing, which could lead to delays or suspension of the clinical trials while unexpected issues are resolved.

Even if the Group obtains approval to market ReActiv8, future studies or clinical trials may suggest that ReActiv8 does not significantly improve clinical outcomes. Such results would slow or possibly stop the adoption of ReActiv8, would substantially reduce the Group's ability to achieve sales estimates and could prevent the Group from achieving or maintaining profitability.

In particular, the safety and performance of ReActiv8 may not be demonstrated to the satisfaction of regulatory bodies to allow regulatory approval. For approval to market an AIMD in the U.S., the FDA generally requires a prospective randomised clinical trial with results that meet pre-specified endpoints for safety and efficacy. The Group and FDA may not agree on a clinical trial design or, if a clinical trial design is accepted, one or more clinical trial endpoints may not be achieved, and that may undermine support for PMA approval. Failure to meet the endpoints may require product redesign, new or additional clinical trials, additional testing, and other measures which typically require significant additional cost and time.

The outcomes of clinical trials are by their nature uncertain and dependent on a number of variables inherent to clinical research, such as the suitability of the clinical trial subjects for the therapy, the experience and the expertise of the referring and implanting medical professionals, the ability and willingness of the clinical trial subjects 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, occur in clinical trials. Adverse events may be associated with ReActiv8, or may be incorrectly ascribed to the Group's products. Any adverse events in the clinical trials ascribed to ReActiv8 could result in damage to the Group's reputation, lawsuits, suspension of clinical trials, and/or enrolment difficulties. Whilst adverse events resulting from the failure of a physician to follow the instructions for use are out of the Group's control, the Group mitigates this risk with training, instructions for use (labelling), and oversight by the Group's personnel. Any delay or termination of clinical trials may delay the filings of regulatory submissions and ultimately the ability to commercialise products and to generate revenues.

The Group is required to fund clinical trials. This includes the payment of professional fees for physicians; fees for one or more Contract Research Organizations; data collection, retention and management; fees for consultants to run committees; and clinical trial insurance premiums. Medical device groups are usually required to provide products and services at no charge during planned

clinical trials, and therefore the Group will attract no revenue from product sales during such clinical trials. The costs of the clinical trials are high and may exceed the resources available to the Group, 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, may have adverse regulatory impact, may prevent the Group from securing patent protection and may result in diminished competitive position, or damage the reputation of the Group.

2.1.7 ***Attracting physicians and subjects 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, the Group must engage a physician at each clinical trial centre to maintain overall responsibility for conduct of the clinical trial (the "**Investigator**"). Each Investigator may have additional physicians working under his or her direction to conduct a trial. The Group may not be able to attract sufficient qualified Investigators to conduct clinical trials within an adequate time, and those Investigators may not be able to attract or enrol sufficient subjects to meet the Group's clinical trial objectives.

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

Failure to attract a sufficient number of eligible clinical trial subjects may lead to time and cost overruns, poor quality results, or inability to complete the clinical trial, all of which may materially adversely affect the Group's ability to achieve regulatory approval, and thereby the Group's ability to market its products and achieve revenues and profits.

2.1.8 ***Even if the Group has obtained regulatory approval for its products, there is no guarantee that the products will perform as intended***

Even if the Group has obtained regulatory approval for its products following completion of clinical trials, the product performance in the market may be different from the performance observed during the clinical trial for a number of reasons, including less control on the selection of people suitable for use of the products, use by physicians with different experience and/or training and failure to adhere to a follow up regimen in the absence of clinical trial enrolment and oversight.

Furthermore, issues with product performance may subsequently be identified once a product is in the market. The FDA requires medical device manufacturers to monitor and report 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, the FDA may require corrective actions – 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 and expense to correct and may harm the reputation of the Group. Such issues may result in the need for the Group's products to be suspended from sale or withdrawn from the market. In these circumstances the Group's products may require substantial redesign and/or re-engineering to address any identified issues. This may result in the Group needing to undertake further clinical trials to re-establish the safety and efficacy of the revised products, which would be costly and time consuming and may exceed the resources of the Group.

Similar reporting requirements exist for CE Marked devices in Europe and for devices approved within the regulatory frameworks of other countries. The regulatory authorities in the different countries may require actions similar to those described above in relation to the FDA.

Additionally, as part of or following the FDA grant of a PMA for the Group's products in the U.S., the FDA may require the Group to conduct one or more post-approval studies ("**PAS**"), which could be extensive, expensive and take additional time, effort and capital to complete. The requirement for corrective actions in response to MDRs, as well as a PAS may delay or inhibit the Group's ability to market its products.

The Group's products are subject to extensive testing to international standards such as for electrical safety and electromagnetic compatibility. Testing at the end of the product development phase may uncover problems or non-compliance with standards that may require a substantial product redesign, resulting in extensive delays and additional costs. Changes in standards may require re-testing of the Group's products, and there is no assurance that compliance with an earlier standard will also mean compliance with a more recent version of a standard. 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 includes possible suspension from sale. Such consequences could have a material adverse effect on the Group's business and financial performance.

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

2.1.9 ***There is no certainty that the market for ReActiv8 to address people with Chronic Low Back Pain will develop as currently anticipated by the Group or at all***

Although the potential number of people which the Group believes could benefit from the Group's products is large, based on the Company's estimate of persons suffering with Chronic Low Back Pain in its key target markets, development of the market depends on several factors including regulatory approvals, reimbursement by healthcare payers and the level of such reimbursement, acceptance of the treatment by qualified physicians, product performance after approval, emergence of other current or future treatments for Chronic Low Back Pain, as well as the global trend to reduce healthcare costs. If as a result of these or other factors the market for the Group's product does not develop as currently anticipated, the Group's ability to generate revenue could be materially adversely affected.

2.1.10 ***The success of ReActiv8 depends on its acceptance and adoption by medical professionals***

The success of ReActiv8 will require acceptance and adoption by medical professionals of this new treatment for Chronic Low Back Pain. Such acceptance will depend on medical professionals being convinced of the distinctive characteristic, clinical performance, benefits, safety and cost-effectiveness of ReActiv8 and being prepared to undertake special training in certain cases. Furthermore, the Company believes that medical professionals will not widely adopt ReActiv8 unless they determine, based on experience, clinical data, and published peer-reviewed journal articles, that ReActiv8 is an attractive option to treat Chronic Low Back Pain.

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, perceived higher risk treatment practices;
- lack or perceived lack of long-term evidence supporting additional patient benefits;
- perceived liability risks associated with the use of new products and procedures;
- limited or lack of reimbursement and coverage within healthcare payment systems,
- cost associated with the purchase of new products and equipment;

- other procedures competing for physician time and attention; and
- the time commitment that may be required for special training.

Economic, psychological, ethical and other concerns may also limit general acceptance and adoption of ReActiv8. Lack of acceptance and adoption of ReActiv8 as an effective treatment for Chronic Low Back Pain by a sufficient number of relevant medical professionals may limit future revenues and profitability.

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

The Group's products are AIMDs with complex electronic circuits and software. It is not possible to design and build AIMDs which are 100 per cent. reliable as all electronic devices carry a risk of failure. Furthermore, all surgical procedures carry risks and the effectiveness of any medical therapy varies between patients. The consequences of failure of the Group's products, complications arising through product use and associated surgical procedures can range from minor to life-threatening effects and even death.

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, 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 the Group, 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 the Group. Any of those circumstances may have a material adverse effect on the Group's ability to conduct its business, to continue selling approved products, or to develop future products.

2.1.12 ***The Group's business exposes the Group to an inherent risk of potential product liability claims relating to the manufacturing, clinical trials, marketing and sale, and recall of an active implantable medical device***

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 the control of the manufacturer, such as off-label use of the Group's 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 the Group, which could result in reputation risk, increased insurance premiums, and depression of future sales, all of which may have an adverse effect on the financial performance and/or financial position of the Company or the Group.

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

In addition, device failures and malfunctions may result in a recall of the product, which may relate 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 as required. Recalls can impact the business operations of the Group as they can be expensive, time

consuming and can divert resources and management from normal operations. Replacement of product subject to recall is generally free of charge under warranty and is therefore a potential expense for the Group. In addition the recall may impact on future sales by the Group, or may lead to the loss of key suppliers or legal action against the Group 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.

Prior to first sale of any of the Group's products, the Group will purchase product liability insurance to help pay for the defence of product liability lawsuits. Until that time, clinical trial insurance helps cover defence of lawsuits relating to products which are the subject of clinical trials. Product liability insurance may not be able to be maintained or increased on acceptable terms, and such insurance may not provide adequate coverage against potential liabilities. A successful claim brought against the Group in excess, or outside, of its insurance coverage could have an adverse effect on the financial performance and/or financial position of the Company or the Group.

2.1.13 ***Competition in the medical device industry is intense and expected to increase***

Competition from medical device companies and medical device subsidiaries of large healthcare and pharmaceutical companies is intense and expected by the Company to increase. There can be no assurance that the Group will be able to compete successfully against its current and future competitors, including competitors with larger financial capabilities. Although the Company is not aware at the date of this Prospectus of any AIMD which represents direct potential competition to the Group's ReActiv8, competitors may develop new products or adapt existing products for the same patient group targeted by the Group's products.

Any 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 the Group's products or could reach commercialisation before the Group's products. Such occurrences could adversely affect the Group's ability to generate sufficient revenues to sustain its business.

During clinical trials, products are generally provided at no charge. Entry by a competitive product into clinical trials while the Group's products are being commercialised, could have an adverse effect on the Group's sales (for example where the Group's products are approved for use and released to the market and the competitor is still in clinical development), or may inhibit timely enrolment in the Group's ongoing clinical trials.

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

2.1.14 ***Other treatments for Chronic Low Back Pain may emerge***

The Group's ReActiv8 is an AIMD designed as treatment for people with Chronic Low Back Pain. Alternative therapies for this patient group include exercise, drugs (including analgesics, opioids, sleep aids, muscle relaxants and anti-depressants), steroid injections, surgery, Transcutaneous Electrical Nerve Stimulation (TENS), continuing or repeat physical therapy, acupuncture, lumbar supports or manual therapy, including massage, among others. New treatment options, or modifications of existing treatments, may emerge which yield clinical results equal to or better than those achieved with ReActiv8, possibly at a lower cost. Emergence of such new therapies may inhibit

the Group's ability to develop and grow the market for ReActiv8, which will have a material adverse effect on the Group's financial condition, business, prospects and results of operations.

2.1.15 ***Any inability to fully protect and exploit the Group's intellectual property may adversely impact the Group's financial performance and prospects***

The Group's success depends significantly on its ability to protect its proprietary rights, including the intellectual property related to and incorporated in ReActiv8. The Group relies on a combination of patent protection, trademarks and trade secrets, and the Group uses non-disclosure, confidentiality and other contractual agreements to protect its proprietary technology. The Group generally seeks patent protection where possible for those aspects of its technology and products that it believes provide significant competitive advantages. At the date of this Prospectus, the Group's patent portfolio includes two granted US patents, one patent outside the US and 15 pending US and foreign patent applications in the seven patent families described in more detail in paragraph 8.12 of Part 8 (*Information on the Company*). However, the Group may be unable to adequately protect its intellectual property rights or may become subject to a claim of infringement or misappropriation, which it is unable to settle on commercially acceptable terms. The Group cannot be certain that patents will be issued with respect to the Group's pending or future patent applications. In addition, the Group does not know whether any issued patents will be upheld as valid or proven enforceable against alleged infringers or that they will prevent the development of competitive patents or provide meaningful restriction against competitors or against 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 have 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 a patent application by the Group, a patent office may reject one or more (or sometimes all) claims. This may lead to an extensive dialogue between the Group's 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.

There is no assurance that the Group's intellectual property rights will not be challenged, invalidated, circumvented or rendered unenforceable. The Group's competitors or other third parties may successfully challenge and invalidate or render unenforceable the Group's issued patents, including any patents that may be issued in the future. This could prevent or limit the Group's ability to stop competitors from marketing products that are identical or substantially equivalent to the Group's. In addition, competitors may be able to design around the Group's patents or develop products that provide outcomes that are comparable to the Group's products but that are not covered by the Group's patents.

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

The Group decides on a case by case basis the countries in which to seek patent protection. It is not economically feasible or practical to seek patent protection in every country, and it is possible that one or more third parties may develop and market devices similar to ReActiv8 in countries in which the Group has not obtained patent protection. The Group may not be able to prevent such third party action, which may limit the Group's ability to pursue those markets.

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

While the Company is not aware of third party patents or other intellectual property which may adversely impact the Group's ability to commercialise its products, there is no assurance that such third party patents or intellectual property do not exist.

The medical device industry is characterised 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 patents of which the Company or the Group is unaware that ReActiv8 or other future products under development may inadvertently infringe. Competitors may have or develop patents and other intellectual property that they assert the Group's products infringe.

Any infringement claim against the Group, even if without merit, may cause the Group to incur substantial costs, and could place a significant strain on the Group's financial resources and/or divert the time and efforts of management from the Group's core business. In addition, any potential intellectual property litigation could force the Group to do one or more of the following: stop selling products or using technology that contains the allegedly infringing intellectual property; forfeit the opportunity to license the Group's technology to others or to collect royalty payments based upon successful protection and assertion of its intellectual property against others; pay substantial damages to the party whose intellectual property rights the Group 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 the Company's or the Group's financial condition, business, prospects and results of operations.

The Group is not aware of any requirement to obtain licenses to third party intellectual property, but such requirements may arise in the future. If the Group needs to license any third party intellectual property, it could be required to pay lump sums or royalties on its products. In addition, there can be no assurances that, if the Group is required to obtain licenses to third party intellectual property, it will be able to obtain such licenses on commercially reasonable terms or at all. The Group's inability to obtain required third party intellectual property licenses on commercially reasonable terms or at all could have a material adverse impact on its business, results of operations, financial condition or prospects.

2.1.17 ***The Group depends on confidentiality agreements with third parties to maintain confidential information***

The Group relies upon unpatented confidential and proprietary information, including technical information, and other trade secrets to develop and maintain the Group's product and competitive position. While the Group generally enters into confidentiality and invention assignment agreements with its employees and other third parties to protect its intellectual property, there can be no assurance that such agreements will not be breached, that they will provide meaningful protection for the Group's trade secrets and proprietary information or that adequate remedies will be available in the event of an unauthorised use or disclosure of such information. Unauthorised use or disclosure of the Group's confidential and proprietary information may have a material adverse effect on the Group's business, operations and profitability.

2.1.18 ***The Group's success is partly contingent on third party payment from government providers, healthcare insurance providers or other public or private sources***

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.

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

Any limitations on, decreases in or elimination of payments by third party providers may have an adverse effect on the financial performance and/or financial position of the Company or the Group.

In many countries, payment for the Group's products will be dependent on obtaining a "reimbursement code" for the procedure and product. Obtaining a reimbursement code can be a lengthy process (months to years) and there is no guarantee that such a code can be obtained at satisfactory levels, or at all.

Following granting of a "reimbursement code" payers (e.g. national health care systems or health insurance companies) have to agree to provide coverage for the procedure(s) that use the Group's products. There is no guarantee that such coverage can be obtained, or that if obtained it will be adequate to enable the Group to build a profitable business selling its products.

Securing adequate or attractive reimbursement often depends on successful outcome of a medical economics study, which is a clinical trial designed to demonstrate the cost effectiveness of a product. There is also no assurance that the Group 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 the Group's financial condition, business, prospects and results of operations.

2.1.19 ***Manufacturing issues may arise that are detrimental to the Group***

The Group uses 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 the Group's 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 the Company's or the Group's 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 product and could also require suspension of distribution of products or product to be returned from the field for modification.

The Group designs AIMDs, which use many disciplines including electrical, mechanical, software, biomaterials, and other types of engineering. Engineers employed by the Group 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 felt until well into a product's life cycle, which may have an adverse effect on the financial performance and/or financial position of the Company or the Group. The Group mitigates such risks with its Quality Management System which incorporates reviews, checks and balances.

2.1.20 ***The Group depends 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 on the Group***

The Group depends 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 to supply the Group with adequate quantities of products could harm the Group's business in the future. A third party supplier may be subject to circumstances which impact its 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, among a variety of other internal or external factors.

If any of the Group's existing suppliers are unable or unwilling to meet its demand for product or components, or if the components or finished products that they supply do not meet quality and other specifications, clinical trials or commercialisation of the Group's products could be delayed. Alternatively, if the Group has to switch to a replacement manufacturer or replacement supplier for any of its product components, or commence its own manufacturing to satisfy market demand, it may face additional delays, and the manufacture and delivery of Reactiv8 could be interrupted for an extended period of time, which could delay completion of its 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.

The Group's suppliers, in turn, depend on their own suppliers and supply chain. Any disruption of the supply chain could adversely affect the Group.

The Group's current business expectation is that the cost of goods sold will decline over time as its vendors gain experience in manufacturing the Group's products and the cumulative volume manufactured grows. However, there is no guarantee that the Group's suppliers will be able to increase yields and/or decrease manufacturing costs with time, and in fact costs may increase, resulting in adverse financial performance of the Company or the Group.

In addition, the Group's suppliers may discontinue supply of components upon which the Group relies before the end of the product life of its products. The timing of the discontinuation may not allow the Group sufficient time to develop and obtain regulatory approval for replacement products or components before the Group exhausts its inventory. If suppliers discontinue supply of components or materials, the Group may have to pay premium prices to its suppliers to keep their production lines open or to obtain alternative suppliers, buy substantial inventory to last until the scheduled end of life of its products or through such time as the Group has an alternative product developed and approved by the regulatory authorities or temporarily cease supplying its products once its 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 the Group's available inventory and an increase in its production costs, which may have an adverse effect on the financial performance and/or financial position of the Group.

2.1.21 ***Compliance with regulations for quality systems for medical device companies is difficult, time consuming and costly. The Group 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***

The Group has developed and maintains a Quality Management System (QMS) to ensure quality of the Group's products 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 ISO13485 required for obtaining a CE Mark. In some circumstances, the requirements of regulations and standards may be different.

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

The Group's external vendors must (in general) also comply with the QSR and ISO13485. Any of its external vendors may become non-compliant with QSR or ISO13485, 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, or export or use of products manufactured by one or more of the Group's vendors. This may have a material adverse effect on the Company's or the Group's 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 U.S. and the AIMD Directive for Europe), which compliance may cause interruption to or delays in the marketing and sale of the Group's products. 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 the Group fails to comply with such U.S. federal, state or other laws, or the laws of other jurisdictions where the Group would intend to market the product, the Group could be subject to enforcement action including recall of its devices, withdrawal of approval or clearance and civil and criminal penalties. If any of these events occur it may have an adverse effect on the financial performance and/or financial position of the Company or the Group.

2.1.22 ***The Group may be unable to attract and retain management and other personnel it needs to succeed***

The Group relies on the expertise and experience of the 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 the Directors and senior management are therefore significant factors in the Group's ability to achieve its objectives. The departure of any of these individuals (in particular the CEO and COO) from the Group without timely and adequate replacement or the loss of any of the Group's senior management may have a material adverse effect on the Company's or the Group's financial condition, business, prospects and results of operations and there can be no guarantee that the Group 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, the Group's competitive position could be materially adversely affected if a member of senior management transferred to a competitor.

If the Group receives regulatory approval for Reactiv8, the Group currently expects to expand its operations and grow its research and development, product development and administrative operations. The Group's growth will require hiring a number of qualified clinical, scientific, commercial and administrative personnel. If the Group is unable to identify, attract, retain and motivate these highly skilled personnel, it may be unable to continue its development, commercialisation or growth.

The Group has entered into indemnification agreements with its Directors, key employees and senior management, including certain contractors. As a consequence of such indemnification agreements, the Group may have to use its resources to indemnify such persons which could have an adverse effect on future financial performance.

2.1.23 ***In some markets the Group will depend on distributors over which the Group has little or no control***

For some markets the Group's intended distribution strategy is to rely on third party distributors for ReActiv8 and other future products.

In such markets where the Group will depend on distributors, the Group does not directly control the performance of a distributor. Thus the Group's success in these 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 the reputation, financial performance or financial position of the Company or the Group.

2.1.24 ***The Group relies on third parties for management services, manufacturing, marketing, regulatory advice and other services that are crucial to its business***

In order to carry out its business, the Group depends heavily on third party consultants, contractors, distributors, manufacturers, agents and numerous other partners for core and non-core services and functions, including management functions, clinical studies, applications for regulatory approval 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, the Group's business plans for obtaining regulatory approval for Reactiv8 and moving its product to market may suffer, and its business may be materially adversely affected. In addition, acts or omissions of any of the parties the Group relies on could potentially cause the Group to incur liability under applicable laws and regulations, such as the U.S. Foreign Corrupt Practices Act (FCPA), the UK Bribery Act, the OECD Anti-Bribery Convention and other anti-bribery laws and regulations, export and import control laws in the EU, U.S. and other jurisdictions, and sanctions programs, including those administered by the U.S. Office of Foreign Asset Controls (OFAC) and the European Commission. Any failure to comply directly or indirectly with applicable law, including as a result of a business partners' breach, could lead to substantial liabilities and repercussions on the Group's reputation, potentially slowing or precluding the commercialisation of its products.

2.1.25 ***Information Technology (IT) forms a key support requirement within the Group's business. Any failure of the Group's IT systems could present a substantial risk to its business continuity***

The efficient operation of the Group's business depends on information technology systems. The Group relies on its information technology systems to effectively manage its marketing, accounting and financial functions; manufacturing processes; and its research and development functions.

The regulatory and legal environment of the Group's industry requires the Group to maintain records for long periods of time, sometimes forever. In most cases, those records are kept in electronic form, and without paper copies.

The Group uses 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 the Group's ability to operate, which could have an adverse effect on the financial performance or financial position of the Company or the Group.

Although industry standard practices are in place for regular information backup, failure of the Group's IT systems infrastructure may result in the inability to continue business until the records are recreated, and this may have an adverse effect on the financial performance or financial position of the Company or the Group.

The Group's 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 the Group's IT infrastructure, a security breach by a malicious third party, or loss of critical information may have an adverse effect on the financial performance or financial position of the Company or the Group.

The Group's 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 the financial performance or financial position of the Company or the Group.

2.1.26 ***U.S. "anti-inversion" tax laws could negatively affect the Group's results***

Under rules contained in U.S. tax law (Section 7874 of the Internal Revenue Code), a non-U.S. company, such as the Company, 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 the 2014 Corporate Reorganisation, the Company acquired the assets (being shares in MML) of MMI (a U.S. corporation), and former shareholders of MMI became shareholders of the Company. However, the ownership of Company 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 Company does 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. For example, there are earlier transactions that, if viewed as integrated with the 2014 Corporate Reorganisation, could lead the U.S. tax authorities to assert that the above 80 per cent. test was met. The Company does not believe such integrated treatment to be appropriate because there are independent business reasons for undertaking these earlier transactions, whether or not the Offer occurred. In the event that the U.S. anti-inversion rules are held to apply to the Company, it would be subject to the U.S. federal income tax on its worldwide income, which would negatively impact the cash available for distribution and the value of the Ordinary Shares.

2.1.27 ***Foreign Exchange Risk***

The Group is and will in the future be exposed to exchange rate fluctuations including among others, the Euro, U.S. Dollar, Australian Dollar, and Pound Sterling. Fluctuations of exchange rates outside a budgeted range may affect revenues, expenses, or the ability to raise future capital if it is needed, and may have an adverse impact on the financial performance and/or financial position of the Company or the Group.

2.2 RISKS RELATING TO THE COMPANY'S SHARES AND THE OFFER

2.2.1 ***A liquid market for the Ordinary Shares may fail to develop, which may cause the shares to trade at a discount to the Offer Price and make it difficult to sell the shares***

Following admission a liquid market for the Ordinary Shares may not develop. The Company cannot predict the extent to which investors' interest in the Company will lead to the development of an active liquid market. Prior to the admission to trading on Euronext Paris and the ESM, there has been no public market for the Ordinary Shares and there is no guarantee that an active trading market will develop or be sustained after the admission to trading on Euronext Paris and the ESM. If an active trading market is not developed or maintained, the liquidity and trading price of the Ordinary Shares may be adversely affected. Even if an active trading market develops, the market price of the Ordinary Shares may not reflect the Company's underlying value or financial performance.

As set out in paragraph 15.13.5 of Part 15 (*Additional Information*), the number of Ordinary Shares that are available for sale in the public market following the admission to trading on Euronext Paris and the ESM will be limited by several lock-up arrangements further described in the aforementioned paragraph of this Prospectus. Pending such arrangements, the liquidity of the shares trading on the regulated market of Euronext Paris and the ESM of the Irish Stock Exchange may be limited and this may negatively impact the Company's share price.

2.2.2 ***The market price of the Ordinary Shares may fluctuate widely in response to various factors and investors may not be able to sell their Ordinary Shares at or above the Offer Price***

Potential investors should consider an investment in the Ordinary Shares as risky and invest only if they can afford a significant or total loss or tolerate wide fluctuations in the market value of their investment. A number of factors may significantly affect the market price of the Ordinary Shares including changes in the operating results of the Company or the Group and its competitors, divergence in financial results from stock market expectations, changes in analyst's estimates, changes in the general conditions in the medical device industry and general economic, financial market and business conditions in the countries in which the Company or the Group operates.

Other factors which could cause the price of Ordinary Shares to fluctuate or could influence the reputation of the Company or the Group include, amongst other things:

- announcements of technological innovations or new commercial products or collaborations by the Group's competitors or the Group itself;
- disputes and other developments concerning intellectual property rights, including patents;
- public information regarding actual or potential results relating to products and product candidates under development by the Group's competitors or the Group itself;
- third party reimbursement developments in Europe, the U.S. and other jurisdictions;
- the Group's ability to obtain regulatory clearances or approvals;
- changes in governmental regulation with regards to the regulatory approvals, and clearances;
- product liability claims or other litigation involving the Company or the Group;
- changes in accounting principles; or
- any publicity (whether true or false) derived from any business affairs, contingencies, litigation or other proceedings, the Company's or the Group's assets (including the imposition of any lien), its management, or its significant shareholders or collaborative partners.

In addition, stock markets from time to time experience extreme price and volume volatility which, in addition to general economic, financial and political conditions, could affect the market price of the Ordinary Shares regardless of the operating results or financial condition of the Group.

2.2.3 ***The market price of the Ordinary Shares could be negatively impacted by sales of substantial number of Ordinary Shares in the public markets***

Sales by the Company or its Shareholders of a substantial number of Ordinary Shares in the public markets following the Offer, or the perception that such sales might occur, could cause the market price of the Ordinary Shares to decline. Furthermore, there is no commitment on the part of any of the existing Shareholders to remain a Shareholder or to retain a minimum interest in the Company after the expiry of the respective lock-up periods provided for in the Lock-up Agreements. Upon termination or expiry of such arrangements, sales of Ordinary Shares that were previously subject to transfer restrictions could cause a decrease in the Company's share price. Any large, unorganised sale of Ordinary Shares could have an adverse effect on the Company's share price. For more information regarding the Lock-up Agreements, see paragraph 15.13.5 of Part 15 (*Additional Information*). As a result, no investment decision should be made on the basis that any of the existing Shareholders will retain any interest in the Company following the expiration of the Lock-up Agreements.

2.2.4 ***Future issuances 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***

Any dilution resulting from the exercise of outstanding Share Warrants or Share Options or the issue and exercise of further Share Warrants or Share Options could adversely affect the price of the Ordinary Shares. Additionally, the Company may decide to raise capital in the future through the issue of Ordinary Shares or convertible securities, or rights to acquire these securities. Pursuant to the Shareholder resolution described at paragraph 15.3.5(d) of Part 15 (*Additional Information*), in addition to the Ordinary Shares authorised to be issued under the Offer, the Shareholders have authorised the Board to allot securities of the Company during the period ending on 1 April 2019 up to an aggregate nominal value amount of €5,000, which will be equal to approximately 117 per cent. of the expected nominal value of the Enlarged Issued Share Capital following ESM Admission (assuming that 851,175 new Ordinary Shares are issued under the Base Offer and no exercise of the Extension Clause or the Over-allotment Option), without seeking Shareholder approval. Furthermore, pursuant to the Shareholder resolution described at paragraph 15.3.5(e) of Part 15 (*Additional*

Information), the Shareholders have authorised the Board to disapply, until the Company's annual general meeting in 2015, the statutory pre-emption provisions applying to the issue of Ordinary Shares for cash up to an aggregate nominal value amount of €2,500, which will be equal to approximately 59 per cent. of the expected nominal value of the Enlarged Issued Share Capital following ESM Admission (assuming that 851,175 new Ordinary Shares are issued under the Base Offer and no exercise of the Extension Clause or the Over-allotment Option), without seeking Shareholder approval. If the Company raises capital by these or other means, it could cause dilution for the holders of Ordinary Shares and could have a negative impact on the price of Ordinary Shares.

2.2.5 ***Risk related to conditional trading in Ordinary Shares prior to Settlement and ESM Admission***

Conditional trading of Ordinary Shares on Euronext Paris and on the ESM of the Irish Stock Exchange on an "as-if-and-when-issued-or-delivered" basis may occur in accordance with Rules 6.8 and 6904 of the Euronext Rule Book – Book I: Harmonized Rules and ISE market practice. Pursuant to the Euronext Rules, Euronext Paris will publish the dates of the When-Issued Period beforehand. During the When-Issued Period or conditional trading period, Euronext Paris will flag the Ordinary Shares under the product name MAINSTAY AIW. In the event that the Ordinary Shares admitted on an "as-if-and-when-issued-or-delivered" basis on Euronext Paris are not delivered on the first trading day following the end of the When-Issued Period or conditional trading period, all transactions made in such shares will be cancelled. Euronext Paris will make public any such cancellation immediately in a notice. All dealings in Ordinary Shares on Euronext Paris during the When-Issued Period or on the ESM during the conditional trading period are at the sole risk of the parties concerned. The Joint Bookrunners, the Co-lead Manager, the Company, the Group, Euronext Paris and the ISE do not accept any responsibility or liability with respect to any person as a result of the cancellation of any transaction of Ordinary Shares during the When-Issued Period or conditional trading period.

2.2.6 ***Certain significant Shareholders of the Company may have different interests from the Company after the Offer and may be able to influence the Company, including the outcome of shareholder votes***

Following completion of the Offer, Settlement and ESM Admission, the Company will have a small number of significant Shareholders. For an overview of the Company's current significant Shareholders and their expected shareholdings before and after the Offer, refer to paragraph 15.5 of Part 15 (*Additional Information*).

Currently, the Company is not aware that any of its current Shareholders has entered or intends to enter into a shareholders' agreement with respect to the exercise of their voting rights in the Company after completion of the Offer. Nevertheless, they could, alone or together, have the ability to elect or dismiss Directors, and, depending on how broadly the Company's other Ordinary Shares are held, take certain other Shareholders' decisions that require, or require more than, 50 per cent. of the votes of the Shareholders that are present or represented at Shareholders' meetings where such items are submitted to Shareholders for approval. Alternatively, to the extent that these Shareholders have insufficient votes to impose certain Shareholders' resolutions, they could have the ability to block proposed Shareholders' resolutions that require, or require more than, 50 per cent. of the votes of the Shareholders that are present or represented at Shareholders' meetings where such items are submitted to Shareholders for approval, such as change in control transactions. Any such voting by these Shareholders may not be in accordance with the interests of the Company or the other Shareholders of the Company.

2.2.7 ***The Company does not intend to pay dividends for the foreseeable future***

The Company has never declared or paid dividends and 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.

In any event, the Company will not be able to pay dividends until such time as it has profits available for that purpose, as determined in accordance with Irish company law. The generation of profits

available for distribution will depend on a number of factors including successful development of the Company's products, as well as the capital expenditure and financing requirements resulting from the strategy implemented by the Board. Any dividends and other distributions paid by the Company in the future will be made at the discretion of the Board.

Accordingly, investors may have to sell some or all of their new Ordinary Shares in order to generate cash flow from their investment. Investors may never receive a gain on their investment when they sell shares and may lose the entire amount of their investment.

2.2.8 ***The requirements of being a public company will increase the Company's costs and may strain its resources and distract its management***

The Group has historically operated its business under a private company regime. As a public company, the Company will face increased legal, accounting, administrative and other costs and expenses than those costs and expenses which the Group incurred as a private company. As a public company, the Company will be required to:

- prepare and distribute periodic public reports and other Shareholder communications in compliance with the Transparency Regulations, Irish and French market abuse law, the ESM Rules and the rules of Euronext Paris;
- expand the roles and duties of the Board and committees and controls;
- institute more comprehensive financial reporting and disclosure compliance functions;
- establish new internal policies, including those relating to trading in its securities and disclosure controls and procedures;
- involve and retain to a greater degree outside legal counsel and accountants; and
- enhance its investor relations functions.

The rules and regulations applicable are expected to increase the legal and financial compliance costs and to make some activities more time-consuming and costly than they are currently.

2.2.9 ***Any sale, purchase or exchange of the Ordinary Shares may become subject to the Financial Transaction Tax***

On 14 February 2013, the EU Commission adopted a proposal for a Council Directive (the "**Draft Directive**") on a common financial transaction tax (the "**FTT**"). According to the Draft Directive, the FTT must be implemented and enter into effect in 11 EU Member States (Austria, Belgium, Estonia, France, Germany, Greece, Italy, Portugal, Spain, Slovakia and Slovenia, each a "**Participating Member State**") toward the middle of 2014.

Pursuant to the Draft Directive, the FTT will be payable on financial transactions provided at least one party to the financial transaction is established or deemed established in a Participating Member State and there is a financial institution established or deemed established in a Participating Member State which is a party to the financial transaction, or is acting in the name of a party to the transaction. The FTT shall, however, not apply to (inter alia) primary market transactions referred to in Article 5(c) of Regulation (EC) No 1287/2006, including the activity of underwriting and subsequent allocation of financial instruments in the framework of their issue.

The rates of the FTT shall be fixed by each Participating Member State but for transactions involving financial instruments other than derivatives shall amount to at least 0.1 per cent. of the taxable amount. The taxable amount for such transactions shall in general be determined by reference to the consideration paid or owed in return for the transfer. The FTT shall be payable by each financial institution established or deemed established in a Participating Member State which is either a party to the financial transaction, or acting in the name of a party to the transaction or where the transaction has been carried out on its account. Where the FTT due has not been paid within the applicable time

limits, each party to a financial transaction, including persons other than financial institutions, shall become jointly and severally liable for the payment of the FTT due.

Investors should therefore note, in particular, that any sale, purchase or exchange of Ordinary Shares will be subject to the FTT at a minimum rate of 0.1 per cent. provided the abovementioned prerequisites are met. The investor may be liable to pay this charge or reimburse a financial institution for the charge, and/or the charge may affect the value of the Ordinary Shares. Under the terms of the current Draft Directive, the issuance of new Ordinary Shares should not be subject to the FTT.

The Draft Directive is still subject to negotiation between the Participating Member States and therefore may be changed at any time. Moreover, once the Draft Directive has been adopted (the "**FTT Directive**"), it will need to be implemented into the respective domestic laws of the Participating Member States and the domestic provisions implementing the FTT Directive might deviate from the FTT Directive itself. Investors should consult their own advisers in relation to the consequences of the FTT associated with subscribing for, purchasing, holding and disposing of Ordinary Shares.

2.2.10 ***Overseas shareholders may have only limited ability to bring actions or enforce judgments against the Company or the Directors***

The ability of an overseas shareholder to bring an action against the Company may be limited under law. The Company is a public limited company incorporated in Ireland. The rights of holders of Ordinary Shares are governed by Irish law and by the Articles of Association. These rights differ from the rights of Shareholders in typical U.S. corporations and other non-Irish corporations. In particular, the circumstances under which Shareholders may bring derivative actions under Irish law is subject to significant limitations; and, in general terms, only a company may be the claimant in proceedings in respect of wrongful acts committed against it. In addition, it may be difficult for an overseas shareholder to effect service of process outside Ireland or to prevail in a claim against the Company under, or to enforce liabilities predicated upon, non-Irish securities laws, including U.S. appraisal rights afforded to dissenting Shareholders, U.S. disclosure liability laws and other U.S. federal securities laws.

2.2.11 ***Overseas shareholders may not be able to exercise future pre-emptive rights and their ownership interests may therefore be diluted***

In order to raise funding in the future, further share capital increases and issues of Ordinary Shares by the Company may be proposed in the future. Shareholders are entitled to pre-emptive rights in respect of new issues of Ordinary Shares for cash unless those rights are waived by a Shareholders' resolution.

Overseas shareholders in certain jurisdictions may not be able to exercise their pre-emptive rights with respect to any future issue of Ordinary Shares for cash (even if pre-emption rights were not waived), unless the Company decides to comply with applicable securities requirements in such jurisdiction or an exemption from such requirements is available. This is because securities laws of certain jurisdictions may restrict the Company's ability to allow participation by certain Shareholders in any future issue of Ordinary Shares. In particular, Shareholders who are located in the United States may not be able to exercise their rights on a future issue of Ordinary Shares, unless a registration statement under the U.S. Securities Act is effective with respect to such rights or an exemption from such registration requirements is available.

The Ordinary Shares will not be registered under the U.S. Securities Act, or under the securities laws of any state or other jurisdiction of the United States and the Company may not file any such registration statements for future issues of Ordinary Shares, and an exemption to the registration requirements of the U.S. Securities Act may not be available in any case. In such an event, Shareholders with a registered address, or who are located, in the United States would be unable to participate in such an issue and, as a result, the percentage ownership interests in the Company of such Shareholders would be reduced.

PART 3

IMPORTANT INFORMATION

3.1 Forward Looking Statements

This Prospectus 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, 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 Prospectus 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 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 the markets and the industry in which the Company or the Group operates, may differ materially from those described in, or suggested by, the forward looking statements contained in this Prospectus. In addition, even if the Company's or the Group's results of operations, financial position and growth, and the development of the markets and the industry in which the Company or the Group operates, are consistent with the forward looking statements contained in this Prospectus, 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 or the Group to differ materially from those expressed or implied by the forward looking statements including, without limitation, general economic and business conditions, the global medical device market conditions, industry trends, competition, changes in law or regulation, changes in taxation regimes, the availability and cost of capital, currency fluctuations, changes in its business strategy, political and economic uncertainty and other factors discussed in Part 2 (*Risk Factors*). The forward-looking statements therein speak only at the date of this Prospectus. Save as required by the Prospectus Regulations, Prospectus Rules, the Market Abuse Rules, the Transparency Regulations and Transparency Rules, the rules of Euronext Paris, the ESM Rules and the Irish Stock Exchange 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 Prospectus. Investors 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 Prospectus.

3.2 Market, Economic and Industry Data

This Prospectus includes certain market, economic and industry data, which were 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 Prospectus 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.

3.3 Currencies

Unless otherwise indicated, all references in this Prospectus 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 intends to prepare its financial statements in United States Dollars (USD).

3.4 Presentation of Financial Information

This Prospectus includes the consolidated audited financial statements of the Group for the years ended 31 December 2011, 31 December 2012 and 31 December 2013 prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union presented in paragraph 12.1.B of Part 12 (*Historical Financial Information*).

Furthermore, the audited financial information of the Company as at 28 February 2014 prepared in accordance with IFRS as adopted by the European Union is presented in paragraph 12.2.B of Part 12 (*Historical Financial Information*). The Company was recently incorporated and became the parent company of the Group on 3 April 2014 pursuant to the terms of the 2014 Corporate Reorganisation.

All future financial information for the Company and the Group is intended to be prepared in accordance with IFRS as adopted by the EU and, unless otherwise indicated, the financial information in this Prospectus has been prepared in accordance with IFRS as adopted by the EU. In making an investment decision, prospective investors must rely on their own examination of the Company from time to time, the terms of the Offer and the financial information in this Prospectus.

3.5 Rounding

Some financial information in this Prospectus has been rounded. As a result of this rounding, figures shown as totals in this Prospectus may vary slightly from the exact arithmetic aggregation of the figures that precede them. In addition, certain percentages presented in this Prospectus 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.

3.6 No Incorporation of Website Information

This Prospectus will be made available to the public in France and Ireland at www.mainstay-medical.com. Notwithstanding the foregoing, the contents of the Company's website, the contents of any website accessible from hyperlinks on the Company's website, or any other website referred to in this Prospectus are not incorporated in and do not form part of this Prospectus.

3.7 Investment considerations

An investment in the Company is suitable only for investors who are capable of evaluating the risks and merits of such investment, who understand the potential risk of capital loss and that there may be limited liquidity in the Ordinary Shares, for whom an investment in the Ordinary Shares constitutes part of a diversified investment portfolio, who fully understand and are willing to assume the risks involved in investing in the Company and who have sufficient resources to bear any loss (which may be equal to the whole amount invested) which might result from such investment. Investors may wish to consult their stockbroker, bank manager, solicitor, accountant or other independent financial advisor before making an investment in the Company.

The Ordinary Shares are intended to be held over the long term and may not be suitable as short-term investments. There is no guarantee that any appreciation in the value of the Company will occur and investors may not get back the full value of their investment. Any objectives of the Company or the Group are targets only and should not be treated as assurances or guarantees of performance.

A prospective investor should be aware that the value of an investment in the Company is subject to normal market fluctuations and other risks inherent in investing in securities. There is no assurance that any appreciation in the value of the Ordinary Shares will occur or that the objectives of the Company will be achieved. Investors may not recoup the original amount invested in the Company.

The contents of this Prospectus are not to be construed as advice relating to legal, financial, taxation, accounting or regulatory matters, investment decisions or any other matter. 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 Prospectus should be read in its entirety before making any investment in the Ordinary Shares. All Shareholders are entitled to the benefit of, are bound by, and are deemed to have notice of, the provisions of the Memorandum of Association and the Articles of Association which prospective investors should review. A summary of the Memorandum of Association and the Articles of Association is contained in paragraph 15.7 of Part 15 (*Additional Information*) of this Prospectus.

PART 4

DIRECTORS, COMPANY SECRETARY, REGISTERED OFFICE AND ADVISORS

DIRECTORS	Oern Stuge MD (*Non-Executive Independent Chairman*) Antoine Papiernik (*Non-Executive Director*) Manus Rogan PhD (*Non-Executive Director*) Dan Sachs MD (*Non-Executive Director*) David Brabazon (*Non-Executive Independent Director*) Peter Crosby (*Chief Executive Officer*)
COMPANY SECRETARY	Hugh Kavanagh
COMPANY REGISTERED OFFICE	Clonmel House Forster Way Swords County Dublin Ireland
Company Telephone Number:	+353 (1) 8970270
JOINT BOOKRUNNERS	Kempen & Co Beethovenstraat 300 1077 WZ Amsterdam Postbus 75666 1070 AR Amsterdam The Netherlands Société Générale 29 boulevard Haussmann 75009 Paris France
PROSPECTUS ADVISER, ESM ADVISER AND CO-LEAD MANAGER	Davy Davy House 49 Dawson Street Dublin 2 Ireland
LEGAL ADVISERS TO THE COMPANY	(as to Irish law) McCann FitzGerald Riverside One Sir John Rogerson's Quay Dublin 2 Ireland (as to French and U.S. Law) Jones Day 2, Rue Saint-Florentin, 75001 Paris France

LEGAL ADVISERS TO BANKING SYNDICATE	(as to Irish law) Matheson 70 Sir John Rogerson's Quay Dublin 2 Ireland (as to French Law) Paul Hastings 96 boulevard Haussmann 75008 Paris France (as to U.S. Law) Paul Hastings Park Avenue Tower 75 East 55th Street NY 10022 United States
AUDITORS AND REPORTING ACCOUNTANTS	KPMG 1 Stokes Place St. Stephen's Green Dublin 2 Ireland
REGISTRAR	Computershare Investor Services (Ireland) Limited Heron House Corrig Road Sandyford Industrial Estate Dublin 18 Ireland
PAYING AGENT (in FRANCE)	Société Générale Securities Services 32 rue du Champ de Tir CS 30812 44308 Nantes Cedex 3 France

PART 5

EXPECTED TIMETABLE OF PRINCIPAL EVENTS

	Time and Date[2][3]
Publication of the Prospectus	9 April 2014
Publication of the Prospectus Summary translated into French	9 April 2014
Public offer in France (*offre à prix ouvert*), principally to retail investors (the "**Retail Offer**"), and private placement principally to institutional investors (the "**Institutional Placement**" or "**Placing**") open	10 April 2014
Latest time and date for receipt of completed application forms by intermediaries in respect of the Retail Offer	5.00 p.m. and 8.00 p.m. (CET) for internet orders on 25 April 2014
Latest time and date for receipt of indications of interest from institutional investors in respect of the Institutional Placement	12.00 p.m. (CET) on 28 April 2014
Announcement of the Offer Price and the number of new Ordinary Shares (the "**Offer Size**") through a Regulatory Information Service, publication of the pricing statement (the "**Pricing Statement**"), and notification of allocations of new Ordinary Shares (including publication by Euronext Paris of the results of the Retail Offer)[1]	28 April 2014
Commencement of conditional dealings in Ordinary Shares on Euronext Paris and the ESM	9.00 a.m. (CET) on 29 April 2014
Settlement and delivery of new Ordinary Shares: CREST and Euroclear France accounts credited in respect of Ordinary Shares in uncertificated form	9.00 a.m. (CET) on 2 May 2014
Commencement of unconditional dealings in Ordinary Shares on the ESM and Euronext Paris	9.00 a.m. (CET) on 2 May and 5 May 2014, respectively

(1) The Offer Price and details of the Offer Size will be announced by Euronext Paris in a notice and by way of a press release of the Company via a Regulatory Information Service and set out in the Pricing Statement. The press release and the Pricing Statement will not automatically be sent to persons who receive this Prospectus, but will be available free of charge at the registered office of the Company at Clonmel House, Forster Way, Swords, Co. Dublin, Ireland. In addition, the press release and the Pricing Statement will, subject to certain access restrictions for parties in certain foreign jurisdictions, be published in electronic form and be available on the Company's website at www.mainstay-medical.com. If the Offer Price is set above the Price Range or the Price Range is revised higher the Company will make an announcement via a Regulatory Information Service, Euronext Paris will publish a notice and prospective investors will have a statutory right to withdraw their application for new Ordinary Shares within two Business Days of the date on which a supplementary prospectus is published. In such circumstances, the Pricing Statement would not be published until the period for exercising such withdrawal rights has ended. Therefore, the expected date of publication of the Pricing Statement would be extended by a minimum period of two Business Days. The arrangements for withdrawing offers to subscribe for Ordinary Shares would be made clear in the announcements.

(2) Times and dates set out in the timetable above and mentioned throughout this Prospectus that fall after the date of publication of this Prospectus are indicative only and may be subject to change without further notice.

(3) All references to time in this timetable are to Dublin, Ireland time save as specifically disclosed.

It should be noted that, if Settlement and ESM Admission do not occur, all conditional dealings will be of no effect and any such dealings will be at the sole risk of the parties concerned.

PART 6

OFFER STATISTICS

Price Range (per new Ordinary Share)[1]	€20.00 to €27.00
Number of Ordinary Shares that will be in issue immediately prior to the commencement of conditional trading	3,404,702
Expected number of Ordinary Shares that may be issued in the Base Offer[2]	851,175
Expected number of Ordinary Shares that may be issued assuming exercise in full of the Extension Clause	127,676
Expected number of Ordinary Shares that may be issued under the Over-allotment Option (assuming full issue under the Extension Clause)	146,827
Estimated gross proceeds of the Offer receivable by the Company[3]	€20,002,612.50
Estimated net proceeds of the Offer receivable by the Company[3][4]	€16,500,596.83
Indicative market capitalisation of the Company at the mid-point of the Price Range[3]	€100,013,109.50

Notes:

(1) It is currently expected that the Offer Price will be within the Price Range; however, this range is indicative only and may change during the course of the Offer. If the Price Range does change, the Company would not envisage making an announcement until determination of the Offer Price, unless required to do so by law or regulation. To the fullest extent permitted by law, final applications received under the Institutional Placement and the Retail Offer are irrevocable and are based on the amount the applicant wishes to invest and not the number of new Ordinary Shares or the Offer Price. The Company expects to publish the press release and the Pricing Statement containing the Offer Price and the Offer Size, the extent of which will also be contained in a Euronext Paris notice on or around 28 April 2014. Further details of the Offer are contained in Part 14 (*The Offer*) of this Prospectus. A number of factors will be considered in determining the Offer Price, including the level and the nature of the demand for Ordinary Shares, the prevailing market conditions and the objective of establishing an orderly and liquid after-market in the Ordinary Shares.

(2) Calculated on the assumption that there is no exercise of the Extension Clause or the Over-allotment Option. The maximum number of Ordinary Shares under the Base Offer is indicative only; it may change during the course of the Offer and the actual number of Ordinary Shares under the Base Offer may exceed this number. Unless required to do so by law or regulation, the Company does not envisage making any announcement or publishing any supplementary prospectus in respect of the actual number of Ordinary Shares issued under the Base Offer. A Pricing Statement containing the Offer Price will also state the number of Ordinary Shares that are the subject of the Offer and is expected to be published on or around 28 April 2014.

(3) Assumes full issuance of the Base Offer at the mid-point of the Price Range i.e. €23.50 per Ordinary Share and no exercise of the Extension Clause or the Over-allotment Option.

(4) After deduction of commissions and expenses of €3,502,015.67.

PART 7

MARKET OPPORTUNITY AND OVERVIEW

Unless indicated otherwise, the information set out in this Part 7 constitutes the Directors' views of the potential market for the Group's ReActiv8 for people suffering from Chronic Low Back Pain. Unless indicated otherwise, all market and industry data set out in this Part 7 and elsewhere in this Prospectus 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 7, 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 Prospectus 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 Company 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 Prospectus, including those set out in Part 2 (Risk Factors). Accordingly, undue reliance should not be placed on any of the market and industry data contained in this Prospectus.

The Group's only product is ReActiv8, which is an active implantable medical device (AIMD) designed to treat people with Chronic Low Back Pain.

7.1 BACKGROUND

Low Back Pain is a major health and socioeconomic issue

Low Back Pain is recognised by multiple academic and governmental bodies as a major health and socioeconomic problem in developed countries. Low Back Pain is subject to a variety of clinical and other descriptions and definitions. In the Bulletin of the World Health Organisation, Wollf & Pfleger (2003) offer the following definition for Low Back Pain: *"It usually is defined as pain localized below the line of the twelfth rib and above the inferior gluteal folds, with or without leg pain; and it can be classified as "specific" (suspected pathological cause) or "non-specific" (about 90 per cent. of cases). Back pain is usually defined as acute if it lasts less than six weeks; subacute if between six weeks and three months; and chronic when it lasts more than three months. Frequent episodes are described as recurrent back pain."*

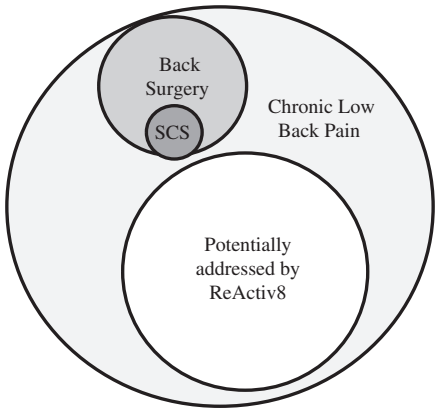
Low Back Pain, which is a subset of all back and neck pain, is characterised by the Company through the following complex and multifaceted features:

- Most episodes of Low Back Pain resolve rapidly with few long term sequelae or consequences.
- Based on published research (Hall et al, 2008) the Company estimates that in approximately 7 per cent. of all cases of Low Back Pain, the pain persists for more than 3 months, and thus are in the Company's target market of people with Chronic Low Back Pain.
- Of the people with Chronic Low Back Pain, only a small percentage of cases result from an identified pathological condition (e.g.: degenerative disc disease) or an anatomical defect that may be correctable with spinal surgery (e.g.: vertebral compression fracture or pars fracture).

- The root cause of Chronic Low Back Pain is not identified in most cases.
- The majority of people suffering from Chronic Low Back Pain can choose from many treatments (physical therapy, drugs, acupuncture, chiropractic, massage among others), which may relieve symptoms but for which there is little evidence of solving the root cause.
- There is also limited evidence that spinal surgery for Chronic Low Back Pain in the absence of identified anatomical defects is effective in the long term.

An approximate guide to the Chronic Low Back Pain target population is shown in figure 1. There is a large number of people with Chronic Low Back Pain, of whom a relatively small proportion are eligible for spinal surgery. A subset of people who have spine surgery develop Failed Back Surgery Syndrome (FBSS) and suffer from continuous leg and back pain from a variety of sources such as pressure on nerves. Some of these people may become candidates for Spinal Cord Stimulation (SCS) therapy. A subset of people with Chronic Low Back Pain who are not candidates for and have never had spinal surgery could potentially benefit from ReActiv8. See paragraph 7.5 of Part 7 (*Market Opportunity and Overview*) for a more detailed analysis of the Group's target population.

Figure 1: Approximate guide to the target population of people with Chronic Low Back Pain



Source: Company's Estimates

Based on published literature detailed in this Part 7 and listed in Annex A, Low Back Pain is one of the most common causes of activity limitation in the working population, one of the most frequent reasons for visits to the physician, one of the most common causes of admission to hospital, and one of the most common causes of surgical procedures. Ehrlich (2003) states that *"Low back pain is a leading cause of disability. It occurs in similar proportions in all cultures, interferes with quality of life and work performance, and is the most common reason for medical consultations. Few cases of back pain are due to specific causes; most cases are non-specific."*

Research shows that most patients with Low Back Pain recover quickly and without residual functional loss, with approximately 60–70 per cent. of patients estimated to recover within 6 weeks and approximately 80–90 per cent. estimated to recover within 3 months. Recovery after 12 weeks is slow and uncertain. For individuals categorised as disabled by their Low Back Pain for longer than 6 months, fewer than half return to work. Following 2 years of absence from work, the return-to-work rate is close to zero.

A study (Wenig, C. et al, 2009) has estimated the economic cost of Low Back Pain at 0.7 per cent. of GDP (Sweden), 0.9 per cent. of GNP (Germany) and 1.7 per cent. of GDP (Netherlands). 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. According to Vos, T. et al (2012), Low Back Pain is "*the leading cause of years lived with disability in all developed countries*".

7.1.1 *The cause of Low Back Pain is unknown in most cases*

There are multiple sets of data available on the cause of Low Back Pain measuring different phenomenon among different population groups. According to research published in the British

Medical Journal, the cause of mechanical Low Back Pain is unknown in approximately 65-70 per cent. of cases and is usually attributed to muscle strain or ligamentous injury. Guidelines from the American Pain Society and the American College of Physicians state that, of the patients who present to primary care for low back pain, more than 85 per cent. of cases cannot reliably be attributed to a specific disease or spinal abnormality.

7.1.2 ***Disruption of the muscle control system is associated with Chronic Non-Specific Low Back Pain***

One of the recognised root causes of Chronic Non-Specific Low Back Pain is a disruption of the control system (brain, spinal cord and nerves) of the back muscles, and in particular the strongest stabilising muscle of the lower back, the lumbar multifidus. This is referred to as "*motor control impairment*" (O'Sullivan, 2005) or disrupted muscle control. When the control system of the multifidus muscle is not functioning properly, the spine joints can move outside their pain-free zones, leading to continuous, recurrent or Chronic Low Back Pain. Even after recovery from an individual episode of Low Back Pain, the disruption of the multifidus muscle can continue, leading to a higher risk of future episodes (Hides, J. A. et al, 1996).

People with Chronic Low Back Pain as a result of motor control impairment, are the population that the Group has identified and is targeting for ReActiv8.

7.2 CURRENT TREATMENTS FOR CHRONIC LOW BACK PAIN

Many treatments have been tried and are available for people with Chronic Low Back Pain. Physicians can refer to many published clinical guidelines for the management of Low Back Pain including when it is diagnosed as chronic (Airaksinen, O. et al, 2006).

The current general approach to the treatment of Low Back Pain is set out in clinical guidelines. When patients first present with Low Back Pain in a primary care setting (general practice or family practice) in accordance with clinical guidelines, medical practitioners are advised to reassure patients that they do not have a serious disease, that they should stay as active as possible and that they should progressively increase their activity levels (Koes, B. W. et al, 2010).

A multidisciplinary clinical approach using physical therapists, physiatrists, neurologists, psychologists and other clinical disciplines is often used for Chronic Low Back Pain and a combination of therapies may be tried. The treatments available include, among others:

drugs	analgesics to dull the pain and/or anti-inflammatories to reduce the joint inflammation that causes pain. Some people are prescribed anti-depressants and/or sleep aids;
steroid injections	to reduce inflammation;
back schools	classes to teach people how to use their back appropriately in lifting and moving;
exercise therapy	to strengthen muscles, improve proprioception and address muscle control issues;
acupuncture	fine needles inserted at certain points in the body;
lumbar supports	specialised belts or garments purportedly to support the back;
massage and manual therapy	procedures in which the therapist's hands directly contact the body to apply pressure or movement to treat the joints and/or soft tissues;
TENS	Transcutaneous Electrical Nerve Stimulation (TENS), being the application of electrical current to electrodes applied to the skin to interfere with the perception of pain; and
surgery	several types including nerve root decompression, disc ablation, discectomy, total disc replacement with an artificial disc or spinal fusion.

Notwithstanding the number of therapies available, as described in published guidelines, there is little high quality scientific evidence or research to support the effectiveness of most of these treatments in people with Chronic Low Back Pain (Hall, H. et al, 2008). Many of the scientific publications on performance of the variety of therapies for Chronic Low Back Pain are inconsistent.

According to a systematic review of published trials by Artus, et al. (2010), symptoms of Non-Specific Low Back Pain show a similar pattern of improvement following a wide range of treatments in a primary care setting and consequently the research suggests that it is difficult to assess whether these improvements are due to the particular therapy administered. The Company believes that this general recovery trajectory leads to the perception that the root cause has been resolved, and that this is one reason for the lack of focus on therapies to address the root cause of Low Back Pain. Studies of recurrence rates of Low Back Pain, however, reveal that motor control impairment may persist even after symptoms have resolved (Hides, 1996 and Hides et al, 2001), providing support for the Company's hypothesis that motor control impairment is one of the root causes contributing to persistence of Chronic Low Back Pain.

ReActiv8 is targeted at people who:

- have Chronic (>90 days) Low Back Pain;
- have Chronic Low Back Pain rated as moderate to severe (i.e., at least 5 on a 0 to 10 point Numerical Rating Scale of back pain);
- are not otherwise candidates for back surgery with no anatomical or pathological defect identifiable on imaging (X-Ray, CT or MRI), that is, they have Non-Specific Low Back Pain;
- have abnormal functioning of the muscle control system of key stabilising muscles in the back; and
- have continuing pain despite conventional therapies including physical therapy and drugs.

These people have very limited options for therapy, most of which are addressed at relieving symptoms, including:

- drugs, including analgesics, opioids, sleep aids, muscle relaxants and anti-depressants;
- steroid injections;
- continuing or repeat physical therapy;
- acupuncture;
- lumbar supports;
- manual therapy, including massage; and
- TENS.

To the Group's knowledge, there are no implantable medical device therapies available today that are indicated for this patient group. It is possible that other therapies could be developed in the future, and the Group will continue to monitor ongoing developments.

7.3 THE GROUP'S APPROACH TO TREATMENT FOR CHRONIC LOW BACK PAIN

7.3.1 *Breaking the cycle of Chronic Low Back Pain*

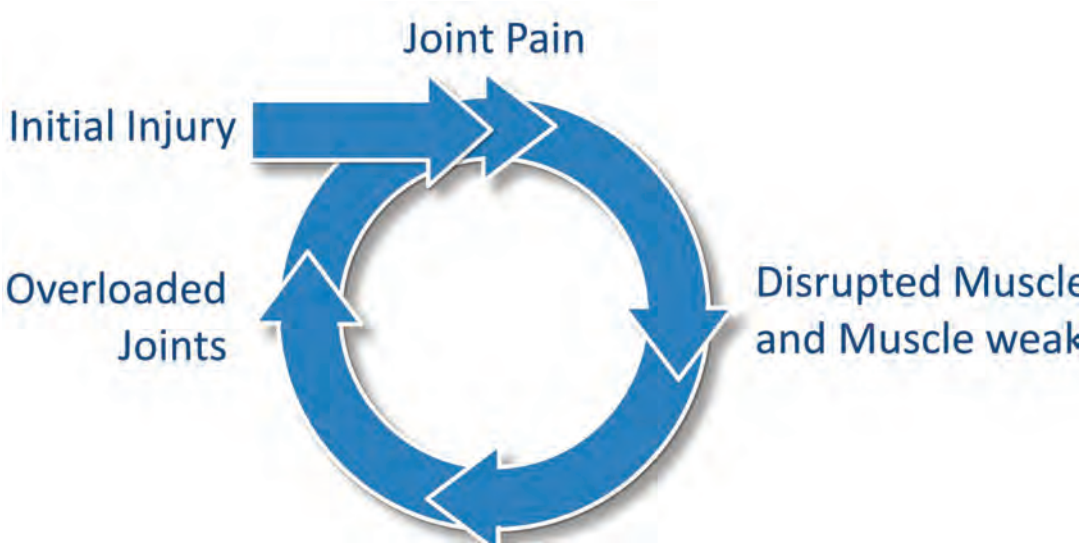


Figure 2: Cycle of Chronic Low Back Pain

The Group's approach to the treatment of Chronic Low Back Pain is based on review of scientific literature that suggests the root cause in many cases is not addressed, leading to a cycle of Chronic Low Back Pain as illustrated in figure 2. After an initial episode of Low Back Pain, some people are susceptible to continuing low back pain superimposed with occasional flare ups in a repetitive cycle of Chronic Low Back Pain. The initial injury leads to joint pain. That joint pain leads to disrupted muscle control and muscle weakening. The disrupted muscle control may lead to an unstable spine. An unstable spine may result in spine joints and muscles being overloaded, which can lead to more pain.

Research has shown that specific exercises to restore control to key spine stabilising muscles, including the lumbar multifidus, can result in improvement in the severity of symptoms of Chronic Low Back Pain, and a reduction in recurrence (Hides, J.A. et al, 2001). As demonstrated by several researchers, reactivation of muscle control is an important step to break the cycle of Chronic Low Back Pain (Hebert, J.J. et al, 2010 and, Costa, L. O. P., 2009). Specific exercise programs can help restoration of control of the spine stabilising muscles (Hauggaard, A. et al, 2007) in people with Chronic Low Back Pain.

Physical therapists and physicians sometimes use ultrasound imaging for biofeedback to help teach a person to contract the lumbar multifidus muscle to help reactivate the muscle control system (Ghamkhar, L. et al, 2011). However, physicians report to the Group that many people find it difficult to voluntarily contract their multifidus muscle, even with ultrasound imaging biofeedback.

Effective treatment of Low Back Pain by specific exercises depends on a patient's dedication to a demanding, technically challenging, regular exercise program, and compliance can be a problem. Even with exercises to improve muscle control, results can be disappointing, and physicians who deal with Chronic Low Back Pain are concluding that a new approach is needed (Deckers, K., et al, 2013).

7.3.2 *Electrical stimulation helps reactivate muscle control after knee injury*

In a similar clinical situation, pain in the knee has been found to lead to disruption of the muscle control system to the key stabilising muscle of the knee, the quadriceps, in a physiological process called arthrogenic muscle inhibition (AMI) (Rice, D. A. et al, 2010). AMI has been shown to be a limiting factor in rehabilitation (Hopkins, J. et al, 2000) and research has demonstrated that it is an important underlying factor in persistent quadriceps muscle weakness after knee injury or surgery (Hart, J. M., et al, 2010). One of the treatments for AMI in the knee is neuromuscular electrical

stimulation (NMES), whereby electrical stimulation is delivered from electrodes applied to the surface of the skin to cause the quadriceps to contract, thereby facilitating restoration of neural drive to the muscle and an increase in strength (Gondin, J. et al, 2005).

The core hypothesis of the Group is that episodic electrical stimulation of the nerve that innervates the multifidus to elicit muscle contractions will achieve comparable results to a program of exercise therapy to reactivate the muscle control system of the lumbar spine, thereby leading to improved stability and a reduction in the effects of back pain. Electrical stimulation to elicit muscle contraction overcomes the technical difficulty of achieving voluntary contraction of the multifidus and the compliance difficulty of a demanding, technically challenging, regular exercise program. The results of the Feasibility Study presented in 2013 have strengthened the Company's belief in this core hypothesis.

7.3.3 ***Electrical stimulation to help reactivate muscle control in Chronic Lower Back Pain***

Based on its understanding of the cycle of Chronic Low Back Pain and the effects of specific exercises and electrical stimulation, the Group developed ReActiv8, representing a new approach to the treatment of Chronic Low Back Pain. ReActiv8 applies electrical stimulation to nerves that supply one of the key stabilising muscles in the back, the lumbar multifidus muscle. ReActiv8 is designed to provide electrical stimulation to the nerve that innervates the lumbar multifidus muscle to cause episodic contraction of the muscle which the Company believes can help reactivate the muscle control system, leading to improved spine stability and improvement in symptoms of Chronic Low Back Pain.

7.3.4 ***Reactiv8 is not Spinal Cord Stimulation, and addresses a different pathology than Spinal Cord Stimulation***

Spinal cord stimulation ("**SCS**") is the use of an implantable medical device to deliver electrical stimulation to activate sensory nerve fibres in the spinal cord via electrodes on a lead placed inside the spinal canal to create a tingling sensation (paraesthesia). SCS is usually applied continuously, 24 hours a day and while stimulation is delivered, SCS interferes with the perception of pain. SCS can be helpful for the management of drug-refractory pain in a number of chronic conditions where drugs are not effective (Lanner, G., 2007) including pain of neuropathic origin (i.e. nerve damage or disease) such as Failed Back Surgery Syndrome (FBSS) that results in chronic, intractable pain of the trunk and/or limbs. This may occur as a result of spine surgery that results in continuing pain, Chronic Regional Pain Syndrome (CRPS), and chronic refractory Angina Pectoris.

ReActiv8 represents a different approach in that it delivers electrical stimulation to peripheral nerves (i.e.: not the spinal cord) to elicit muscle contraction to help restore the muscle control system of the spine stabilising muscles. The target patient group are those with Chronic Low Back Pain who have not had back surgery and are not otherwise candidates for back surgery, and therefore excludes those with FBSS. Furthermore, ReActiv8 is not intended to ameliorate pain of neuropathic origin and therefore targets a different patient group (Chronic Non-Specific Low Back Pain) than that targeted by SCS. Unlike ReActiv8, SCS is not intended to address the root cause of pain but provides palliative pain management to help people cope by numbing their pain.

7.4 THE NEUROMODULATION MARKET

The Group's first product ReActiv8 fits into the general medical device category of Neuromodulation defined by the International Neuromodulation Society (INS) as "*the alteration of nerve activity through the delivery of electrical stimulation or chemical agents to targeted sites of the body.*"

Neuromodulation via electrical stimulation is typically referred to as neurostimulation. Neurostimulation is commonly delivered by AIMDs for many applications including:

- Spinal Cord Stimulation (SCS) to alleviate pain of neuropathic origin;
- Peripheral Nerve Stimulation (PNS) to alleviate pain in several conditions;
- Occipital Nerve Stimulation (ONS) for headache;
- Deep Brain Stimulation (DBS), e.g.: for treatment of Parkinson's and epilepsy;
- Vagal Nerve Stimulation (VNS) to treat epilepsy;

- Sacral Nerve Stimulation (SNS) for incontinence control; and
- Developing indications including hypoglossal nerve stimulation (apnoea), vagal nerve stimulation for several applications, obesity, hypertension, sensory prostheses.

Markets for implantable neurostimulation devices can be large and grow rapidly. Industry research shows that the US neurostimulation market in 2012 generated sales of almost $1.9 billion (Medtech Insight, 2013) and that there has been consistent market growth over recent years.

7.4.1 ***Competition in the market for implantable neurostimulation devices***

The major public companies serving the market for implantable neurostimulation devices are large, established medical device companies such as Medtronic, Inc., Boston Scientific Corporation and St Jude Medical, Inc. Other companies such as Johnson and Johnson, Allergan Inc, Covidien plc, Abbott Laboratories, GlaxoSmithKline plc, and Pfizer, Inc. have invested in early stage private neurostimulation companies. The Group is aware of other private development stage companies (e.g.: Nevro Corp; Spinal Modulation, Inc.) or subsidiaries of other large companies (e.g.: QiG Group – a subsidiary of Greatbatch, Inc.) who are also active with a focus on SCS or variants of it. The Group is also aware of several early stage companies developing neurostimulation devices for many clinical conditions including obesity, hypertension, incontinence, drop-foot syndrome, headache, Parkinson's, swallowing disorders, epilepsy, and sleep apnoea.

The Group is not aware that these companies or any other companies are developing neurostimulation products for Chronic Low Back Pain with a therapeutic approach similar to that of ReActiv8. The Group is also not aware that any of these companies has publicly announced an intention to target this application.

7.5. ESTIMATED SIZE OF THE TARGET MARKET

The Company uses many published sources to estimate the size of the potential target market for the Group's products. The Group has factored in different definitions and measurements addressing different but similar population groups, contradictory information, timing differences, and country specific differences in defining the target market. Thus the prevalence numbers and calculations contained in this document should be considered in light of these limitations and as for information purposes only.

In addition, back pain itself is the subject of differing definitions in published scientific literature. Manichikanti, (Manichikanti et al, 2013) stated that "*low back pain is a symptom that cannot be validated by an external standard. It is a disorder with many possible aetiologies, occurring in many groups of the population, and with many definitions.*"

In a systematic review of the global prevalence of Low Back Pain, Hoy (Hoy et al, 2012) 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 mean ±SEM point prevalence was estimated to be 11.9±2.0 per cent., and the 1-month prevalence was estimated to be 23.2±2.9 per cent.*"

Breivik et al reported in 2006 on a pan-European (plus Israel) pain survey of 46,394 randomly selected subjects. Of this sample, 19 per cent. reported having chronic pain (defined as pain lasting for at least 6 months) and an NRS pain score of 5 or higher (which is moderate to severe intensity). For 18 per cent. of the respondents the location of pain was the lower back. Thus 18 per cent. of 19 per cent. gives a prevalence estimate of 3.4 per cent. of the population who suffer from CLBP with NRS≥5, based on this study.

Johannes et al (2010) using similar methodology analysed data collected from 27,035 respondents in the U.S. and they found that 21 per cent. of respondents reported chronic pain (>6 months) with NRS≥5 and that 11 per cent. 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 USA based on the Johannes study is 2.3 per cent. (21 per cent. multiplied by 11 per cent.).

Schopflocher et al (2011) published results of a similar epidemiologic study done in Canada and reported similar results. 18.9 per cent. of the respondents reported to be suffering from chronic pain (>6 months) and NRS≥5. Of all respondents 22.3 per cent. reported that their primary location of pain was the lower back. This means that 4.21 per cent. (18.9 per cent. x 22.3 per cent.) of the respondents were suffering from CLBP with an NRS≥5, based on this study. Meucci et al 2013 surveyed 2,732 individuals in a city in Brazil and reported a Chronic Low Back Pain prevalence of 9.6 per cent. 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 other studies above, prevalence of Chronic Low Back Pain with moderate to severe intensity would be approximately 6 per cent. (9.6 per cent. multiplied by 2/3). The higher level of this number can be explained by the difference in definitions of "chronic" as well as the relatively high proportion of heavy manual labour in that geography.

In summary, these studies indicate that prevalence of CLBP (moderate – severe) is fairly consistent across geographies. Europe: 3.4 per cent., Canada, 4.2 per cent., U.S. 2.3 per cent., and Brazil: 6 per cent. According to the same studies, approximately one third of these population groups suffer from severe, hence likely to be debilitating CLBP (Johannes et al 2010).

Less than 15 per cent. of people with CLBP have identifiable causes (Hall & McIntosh 2008) and the remainder have Non-Specific Low Back Pain.

On the basis of the research detailed above, the Company estimates that about 1 per cent. of the population in its key target markets in the EU and the US have moderate to severe Chronic Low Back Pain every day of whom 80 per cent. are estimated to have abnormal multifidus function (Freeman et al 2010). Based on input from the Group's clinical advisors, the Group estimates that approximately 50 per cent. of these could be candidates for and could be willing to try the ReActiv8 therapy. Based on population statistics of approximately 500 million people in the EU and 315 million people in the US, the Company estimates the number of people who could be candidates for ReActiv8 is approximately three million (i.e. (315 million + 500 million) x 1 per cent. x 80 per cent. x 50 per cent. = 3.26 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 as detailed in paragraph 8.10.2 below, obtaining proper reimbursement may take time depending on the country. On that basis, the Company estimates the initial target market as approximately two million people (approximately 1.23 million in the EU and 0.77 million in the US).

Although there are a number of factors which will affect the Group's target population and the development of a market (see Part 2 (*Risk Factors*)) the Group does not consider the size of the potential market to be a limiting factor to its growth in the foreseeable future.

7.6. THE CURRENT GLOBAL MEDICAL DEVICE MARKET

The Group operates in the Neuromodulation sub-segment of the global medical device market, and therefore is subject to many factors common to all companies operating in the global medical device market. Some of those factors which may prove to be relevant are listed below:

7.6.1 ***The Medical Device Tax in the U.S.*** (part of the Patient Protection and Affordable Care Act 2010, otherwise known as "Obamacare"). 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 to cover the expansion of healthcare in the U.S. The levy is set at 2.3 per cent. of the sale price of a medical device.

A taxable medical device is a device that is listed as a device with the Food and Drug Administration (FDA) under section 510(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 807, pursuant to FDA requirements. The Group would be subject to this levy when its products are sold in the United States.

7.6.2 ***Proposed changes to the EU regulation of medical devices*** were published on 26 September 2012[1] by the European Commission. The proposed changes also respond to the scandal involving fraudulent sale of breast implants in the EU. The proposals are designed to significantly tighten controls to

1. http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm

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 proposals 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 proposed changes would result in 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. The Company understands, from public reports and European Commission publications and pronouncements, that the final rules are unlikely to be ratified until the end of 2014, and those rules are unlikely to come into effect until 2017.

7.6.3 ***Increased focus on Comparative Effectiveness Research (CER), particularly in the U.S.*** The Institute of Medicine (IOM) defines 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 Patient Protection and Affordable Care Act (PPACA) has created a quasi-governmental entity, the Patient-Centred Outcomes Research Institute (PCORI), to advance CER and its use by doctors, patients, and others.

Increased emphasis on CER may require more evidence of cost effectiveness than has hitherto been needed for reimbursement in the U.S. Such evidence may require the Group 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.

7.6.4 ***The Food and Drug Administration Safety and Innovation Act (FDASIA).*** The FDASIA, signed into law on July 9, 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.

7.6.5 ***The "Sunshine Act".*** In the U.S., Section 6002 of the Patient Protection and Affordable Care Act (PPACA) – otherwise known as "the "Physician Payment Sunshine Act" (42CFR Part 403) requires all manufacturers of medical devices (and other health-care companies) to publicly report (e.g.: via the manufacturer's website) all payments greater than $10 made to U.S. physicians, medical institutions (e.g.: hospitals and clinics) and other health care professionals (including direct payments, consulting fees, honoraria, clinical trial costs, travel reimbursement, meals, gifts and the like). The Sunshine Act may have the impact of discouraging physicians and other health care providers from working with companies, which could adversely affect the Group's ability to obtain advice and to have physician's present results and educational materials on the Group's behalf.

7.6.6 ***The "French Sunshine Act".*** In France, the French Ministry of Health in 2013 published decree no. 2013-414 (hereinafter referred to as the French Sunshine Act) imposing transparency obligations on companies manufacturing medical devices, similar to those of the US Sunshine Act. Like its US equivalent, the French Sunshine Act may influence the availability of physicians and other health care providers for collaboration with companies.

PART 8

INFORMATION ON THE GROUP

8.1 OVERVIEW

The Group was founded in 2008, to develop innovative neurostimulation therapies for the population of people with debilitating Chronic Low Back Pain. The Group is headquartered in Dublin, Ireland and has subsidiaries operating in the United States and Australia.

The Group's team includes scientists, engineers, clinical experts and external scientists and clinicians who are highly experienced in developing and commercialising technologies addressing unmet clinical needs.

The Group is focussed on the development of ReActiv8, an active implantable medical device (AIMD) designed to treat people with Chronic Low Back Pain. As set out in Part 7 (*Market Opportunity and Overview*) above, Low Back Pain is a leading cause of activity limitation and work absence throughout much of the developed world, imposing a high economic burden on individuals, families, communities, industry, and governments.

The Company has an experienced Board of Directors consisting of the founder, the CEO, an independent Chairman, representatives from two substantial and experienced industry venture capital investors and one independent Non-Executive Director.

The Group has raised more than $26 million in venture capital to date to finance the development of ReActiv8 and to conduct clinical trials. In mid-2010, Sofinnova Partners led a Series A Financing of the Group in excess of $6 million. Other investors in the Series A Financing included Twin Cities Angels and a private individual. The proceeds of the Series A Financing were used principally to finance the Feasibility Study, which commenced in 2011, start development work on the ReActiv8 and expand the Group's intellectual property portfolio.

In September 2012, Fountain Healthcare Partners led a Series B Financing of $20 million. Other experienced venture capital firms Seventure Partners, on behalf of the Seventure Partners Managed Funds, and Capricorn Venture Partners, and medical device company Medtronic, Inc. also participated in the Series B Financing along with existing shareholders.

The Group has not yet generated revenues and has incurred operating losses of $2.9 million in 2011, $5.3 million in 2012, and $8.4 million in 2013.

The Group is seeking to raise new capital, and to list the Company on Euronext Paris and on the ESM of the Irish Stock Exchange, primarily to finance the clinical trials required for regulatory approvals in the EU and an application for IDE approval to start a clinical trial in the US, and the subsequent commercialisation of ReActiv8. In addition, the Board believes that becoming a public company will benefit the Company as it will give the Group access to a wider range of capital-raising options which may be of use in the future; and assist in recruiting, retaining and incentivising key management and employees.

8.2 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 Sachs filed a patent on the idea that led to ReActiv8, and formed MMI. Dr Sachs is currently a Non-Executive Director of the Company.

The CEO of the Group, Mr Peter Crosby, was recruited to MMI in early 2009 to build the company and its team. Mr Crosby was instrumental in the development of ReActiv8, and the design and conduct of the Feasibility Study. Until the Series A Financing in mid-2010, Mr Crosby worked without any cash compensation (but did receive restricted stock in the company). After the Series A Financing Mr Crosby relocated to Minneapolis, where the Group headquarters were located at that time. After the Series B

Financing, Mr Crosby relocated to Dublin, Ireland, where the Group headquarters are currently located. Mr Crosby is also an inventor on several of the patents filed by the Group since its inception.

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 develop ReActiv8 for commercialisation

2010
- $6.1 million capital raised in Series A Financing round in July 2010
- Additional patent applications filed

2011
- First patient enrolled in the Feasibility Study, a study designed and sponsored by the Group to investigate the therapeutic approach on which ReActiv8 is based

2012
- First pre-Investigational Device Exemption (pre-IDE) package submitted to the FDA as a first step towards receiving Pre-Market Approval (PMA) in the U.S. for ReActiv8
- Mainstay Medical Limited (MML) becomes the holding company of the Group
- $20 million capital raised in Series B Financing round in September 2012
- Group HQ relocated to Dublin, Ireland
- MML US, Inc. created as a subsidiary of MML
- 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, with claims directed to a neuromuscular electrical stimulation system for improving stability of a patient's lumbar spine
- Summary results of the Feasibility Study presented at the meeting of the International Neuromodulation Society (INS) in Berlin in June 2013
- Summary results of the Feasibility Study presented at the Neuromodulation Society of the United Kingdom and Ireland, in Oxford in September 2013
- Awarded "Gold Electrode Award for Most Promising Startup" by Neurotech Reports (October 2013)
- U.S. Patent 8,606,358 B2 issued December 2013 as a continuation of U.S. Patent 8,428,728
- Development of the key implanted elements of ReActiv8, proprietary Implantable Stimulation Leads and an Implantable Pulse Generator, completed in 2013
- Submission to ethics committee to start international multi-centre clinical trial of ReActiv8
- Mainstay Medical (Australia) Pty. Limited created as a subsidiary of Mainstay Medical Limited
- Appointment of David Brabazon as new independent director based in Ireland

2014
- 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 in accordance with the 2014 Corporate Reorganisation
- Approval received from ethics committee to begin the international multi-centre clinical trial of ReActiv8 at first sites in Australia and commencement of patient recruitment
- First subjects enrolled in international multi-centre clinical trial of ReActiv8 leading to an application for CE Mark

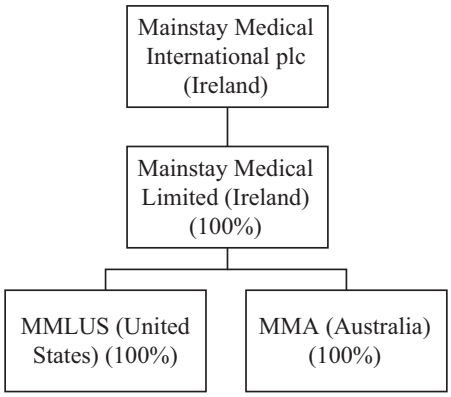
8.3 CORPORATE STRUCTURE

The Group agreed to undertake the 2014 Corporate Reorganisation which resulted in Mainstay Medical International plc becoming the ultimate parent company of the Group. As a result of the 2014 Corporate Reorganisation, Mainstay Medical Limited (MML) became a wholly-owned operating subsidiary of the Company.

The Group is headquartered in Dublin, Ireland and has subsidiaries operating in the United States (MMLUS) and Australia (MMA). Mainstay Medical, Inc. was founded in 2008 in Minnesota, United States, and the headquarters of the business moved to Dublin in 2012 which offers an environment conducive to the growth and development of medical technology businesses and companies, in the presence of many of the large global medical device companies which have Irish operations.

MMLUS performs research and development services for the Group and manages the Group's supply chain. In May 2013, MMA was established principally to oversee the management of human clinical trials in Australia.

Figure 3: Group Organisational Structure (at the date of this Prospectus)



8.4 DESCRIPTION OF ReActiv8

ReActiv8 represents a new approach to the treatment of Chronic Low Back Pain. ReActiv8 applies electrical stimulation to nerves that supply key stabilising muscles in the back, including the lumbar multifidus muscle. The hypothesis on which ReActiv8 is based is that electrical stimulation of the nerve that innervates the lumbar multifidus muscle to cause contraction of the muscle 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 as set out in Part 7 (*Market Opportunity and Overview*) above.

- 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. 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 and Chronic Low Back Pain (Hides, J.A. et al, 2001 and Kasai R., 2006).
- 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 (Van, K. et al, 2006).
- 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, the small number of physical therapy practitioners with ultrasound imaging skills and access to equipment (for example Jedrzejczak A., 2008), and the difficulty for patients to perform and continue to do the exercises.

In a similar clinical situation relating to the knee, the key stabilising muscle of the knee is the quadriceps, and the muscle control system of the quadriceps is often disrupted after knee pain or knee surgery. It has been shown that electrical stimulation to cause contraction can reactivate the muscle control of the quadriceps (Gondin et al, 2005). Therefore the Company believes that similar electrical stimulation of the key stabilising muscles in the back will help reactive the muscle control system for the key stabilising muscles of the lumbar spine, thereby reducing back pain.

8.5 FEASIBILITY STUDY

The Group designed and sponsored a Feasibility Study to investigate the stimulation treatment on which ReActiv8 is based. The purpose of the study was to investigate electrical stimulation (using commercially available neurostimulators) to elicit contraction of the multifidus muscle and measure the resulting effect on Chronic Low Back Pain. Five Investigators (i.e.: physicians responsible for conduct of the study) in Europe participated in the Feasibility Study, and 28 patients were enrolled at four European hospitals. The first patient was enrolled in June 2011 and the last patient enrolled in October 2012. Summary results of the Feasibility Study were presented at the meeting of the International Neuromodulation Society (INS) in Berlin in June 2013 (Deckers, K., et al, 2013), and a more detailed publication is in preparation, for submission to a scientific journal in 2014. A summary of the key aspects of the Feasibility Study follows.

8.5.1 *Feasibility Study key outcome measures and headline results*

The Feasibility Study was designed as a single arm, open label trial, with subjects serving as their own controls (comparison of outcome measures in each patient before and after treatment). The key outcome measures were:

Pain — as measured on a Visual Analogue Scale (VAS) – where the patient was asked to mark a point on a 100mm long line where 0 is no pain and 100 is the worst imaginable pain.

Disability — the disabling effects of back pain were assessed with the Oswestry Disability Index (ODI) – a disease specific, 10 category assessment of the disabling effects of back pain.

Quality of life — assessed with the 5 category European Quality of Life measure (EQ-5D).

Other data collected included changes in drug use, work status, and perceptions of the stimulation. Outcome measures were assessed at the three month endpoint (3M) after activation of stimulation and compared to baseline (BL – prior to implant). Endpoints were assessed in two ways – difference in population means between BL and 3M, and assessment of number of "responders" for VAS and ODI where a "responder" is a patient who showed a clinically important improvement in VAS or ODI between BL and 3M.

Key inclusion criteria were:

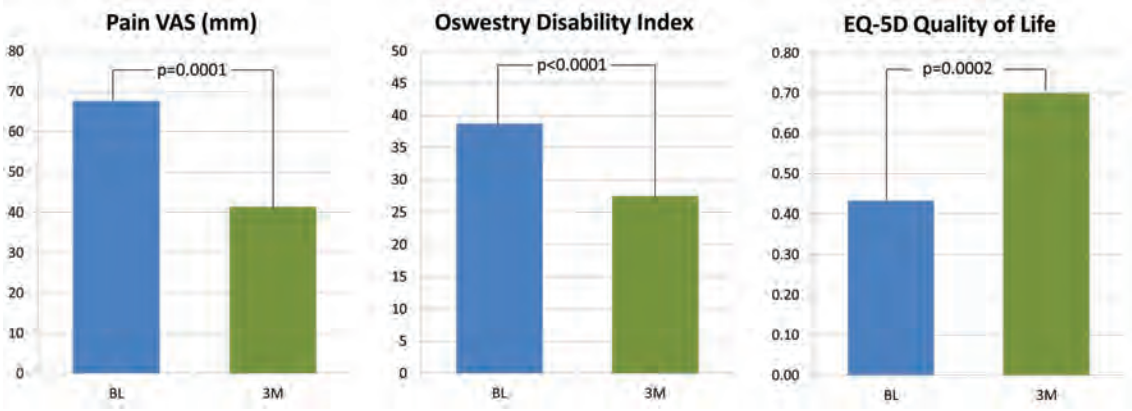
- Chronic Non-Specific Low Back Pain (>90 days at time of enrolment) with continuing back pain despite physical therapy and medical management;
- Oswestry Disability Index >25 per cent. (on 100 point scale);
- Not a candidate for spine/back surgery;
- No prior back surgery;
- Age greater than 18 years and less than 60 years; and
- Body Mass Index of less than or equal to 35.

Twenty eight patients were enrolled and of those twenty six were implanted with commercially available neurostimulators (Implantable Pulse Generator (IPG) and leads) selected by the Investigators. After recovery from the surgical procedure, the patients were supplied with an external

device to initiate and terminate electrical stimulation sessions. Patients were instructed to deliver stimulation for two sessions per day of 20 minutes each. After three months of patient initiated stimulation, the 3M outcome measures were collected, and then one month later the stimulation was interrupted for one month to assess sustainability of the effect, and additional data were collected at five months. Of the 26 patients implanted, 19 patients reached the 3M endpoint. For reasons described below, seven patients did not reach the endpoint.

The differences in population means for the three key outcome measures between BL and 3M are shown below. Note that the "P value" is an indication of statistical significance (lower is better). The term "statistically significant" means that the results are unlikely to be a result of chance. In clinical trials a "P value" of 0.05 is commonly considered statistically significant, and anything lower is highly significant.

Figure 4: Feasibility Study Headline Results



Source: Company Data

In clinical trials of medical devices, it is important that results are not only statistically significant but also clinically important – in other words, the results represent a clinically important change. For clinical trials in pain, there is a published expert consensus agreement on the Minimally Important Change (MIC) that must be achieved for the effect to be considered clinically important (Dworkin, R. H. et al, 2008).

Based on this approach:

- 74 per cent. of patients showed a MIC in VAS (≥15mm)
- 63 per cent. of patients showed a MIC in ODI (≥10 per cent.)

Other key outcomes from the Feasibility Study are below:

- 85 per cent. reported an increase in EQ-5D and none reported a decrease;
- 5/11 (45 per cent.) patients who were on disability leave at BL had returned to work at 3M;
- There was a reduction in the use of opioids and Non-Steroid Anti-Inflammatory Drugs (NSAIDs), but the numbers were too small to calculate statistical significance;
- At 3M, 15 patients described the stimulation sensation as "comfortable" and the other 4 described it as "tolerable"; and
- At the five month assessment (which concluded one month of interruption of stimulation), half the subjects reported at least 50 per cent. reduction in pain as measured by VAS.

8.5.2 ***Feasibility Study – safety and risk assessment***

One important objective of any clinical trial is to assess safety and risk. The common methodology is to record adverse events, and to classify the adverse events by seriousness and relatedness to the investigational device or therapy. An adverse event could be as simple as a face rash (non-serious, unlikely related to the therapy), or be more serious, ranging from infection through to death.

There were a total of 60 adverse events related to the device and/or procedure, most of which were not serious or device related. The most frequent device related adverse events included dislodgement of the commercially available leads (i.e.: the lead moved in the body such that the electrodes were no longer in the original position) leading to surgical intervention or inadequate stimulation (21 events), pain (8 events) and overstimulation of tissue (5 events). A total of 13 patients experienced the 21 events related to lead dislodgements, resulting in 12 surgical procedures. Eleven of those procedures were to restore stimulation by repositioning or replacing the lead(s) while one procedure was a permanent explant of the device. Two device and/or procedure-related serious adverse events were reported (one nausea and vomiting due to surgical anaesthesia, and one infection leading to the above mentioned device explant).

The most important adverse events recorded in the Feasibility Study were associated with lead dislodgement. When a lead dislodged, the stimulation could no longer be delivered to the target location, and effectively was discontinued. Seven patients did not reach 3M and are not included in the 3M data. Of those seven patients, five were due to lead dislodgement, one was a result of device removal secondary to infection, and one patient suspended treatment during recovery from unrelated elective surgery.

8.5.3 ***Experience gained from Feasibility Study***

The unexpected number of lead dislodgements led to the Group's conclusion that the commercially available neurostimulation leads are unlikely to be suitable for this application. As a result, the Group has designed a custom and proprietary lead which is part of Reactiv8. Experience gained in the Feasibility Study also led to a custom IPG design, which incorporates specific features not included in commercially available devices.

Based on the Feasibility Study the Group concluded:

- The therapeutic approach that was the subject of the study showed statistically significant improvement in all outcome measures including back pain, disability and quality of life, and clinically important improvements in back pain and the disabling effects of back pain.
- The therapeutic approach that was the subject of the study demonstrated a favourable safety profile with the exception of the higher than expected number of lead dislodgements.
- A stimulation lead with a design specific to this stimulation site is required.
- The Feasibility Study provided valuable experience to guide future clinical trial design:
  - Refinement of subject enrolment criteria.
  - Refinement of endpoint assessment tools and methods.
  - Understanding of drivers of patient recruitment.
- The design of ReActiv8 is based on the experience gained with commercially available devices used in the Feasibility Study.
- The Feasibility Study experience guides the methodology used for validation testing.

8.6 REACTIV8

With experience from the Feasibility Study available, the Group finalised the development of ReActiv8 and all its components.

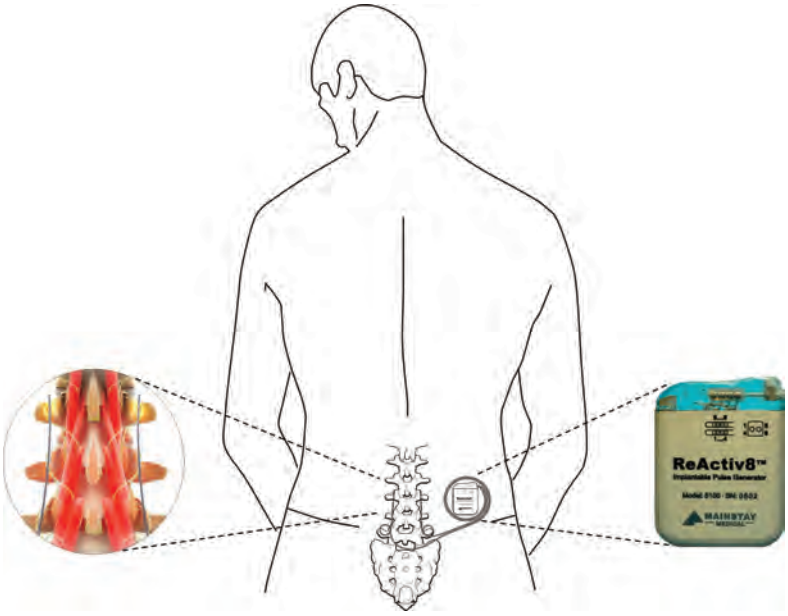
ReActiv8 was designed by the Group's research and development team, which is located primarily in Minneapolis, U.S. and which operates through the Group's wholly owned subsidiary, MML US, Inc. The team consists of highly trained and experienced engineers, quality specialists, and clinical experts with a long history of development of AIMDs. In addition, the Group draws on a wide network of advisors and consultants, including physicians, regulatory specialists, and statisticians. The Group uses external contract organisations to provide facilities and services, which would be impractical or uneconomical for the Group to perform itself, including amongst others, animal studies, biocompatibility testing, electromagnetic interference testing, electrical safety standards compliance testing, and mechanical endurance testing.

As illustrated in figure 5 (below) ReActiv8 consists of two implantable stimulation leads with four electrodes each, configured to deliver electrical stimulation to the nerves that supply the lumbar multifidus muscle to elicit muscle contraction. The leads are coupled to an implantable battery powered pulse generator, which is wirelessly activated by an external activator and is wirelessly programmed via a physician programmer.

The key implanted elements of ReActiv8 as shown in the illustration below (figure 5) are:

- Implantable Stimulation Leads; and
- The Implantable Pulse Generator ("IPG").

Figure 5: Key Implanted Elements of ReActive8



Each ReActiv8 lead has four platinum-iridium electrodes at the distal end where it lies adjacent to the nerve, and four stainless steel rings which connect with the IPG when inserted into the connector aperture on the IPG. The ReActiv8 lead incorporates a unique distal fixation mechanism and a coiled conductor lead body. The distal fixation mechanism is designed to reduce the risk of lead dislodgement, and the coiled conductor lead body is designed to reduce the risk of conductor fracture. The Group has conducted extensive pre-clinical testing (bench testing and animal studies) with the proprietary ReActiv8 lead, and based on the studies the Group believes that the identified risk of lead dislodgement has been reduced to acceptable levels.

The ReActiv8 IPG comprises a small hermetically sealed titanium can with a header (containing the connector) made of biocompatible polymer. Inside the titanium can are custom electronics and a lithium based battery. The IPG incorporates features not found in many existing commercially available neurostimulators, including internal logging of data - time of start and stop – of every stimulation session, which, it is anticipated, will be useful in follow up and assessing compliance with treatment.

In addition to the implanted elements of ReActiv8, specialised surgical tools are used to assist the physician with the implant procedure and to facilitate positioning the stimulation electrodes in the correct place. The

ReActiv8 IPG is configured using a programmer based on a commercially available laptop computer and a custom-designed programming wand which communicates with the IPG wirelessly through the skin.

Once ReActiv8 is implanted, stimulation sessions can be started and stopped by an external activator – which is a hand-held device placed over the site of the IPG which communicates wirelessly to send commands to the IPG. A small magnet can also be used to stop delivery of stimulation if so desired.

ReActiv8 has been subjected to bench-testing by the Group to assure compliance with relevant standards for AIMDs, and to ensure that the engineering claims made (such as battery life) are met or exceeded. In addition, the Group is working with its suppliers to secure scalable and reproducible manufacturing processes, and that the products to be delivered will consistently meet the specifications determined by the Group. The Group has conducted a risk assessment in compliance with the international standard ISO14971 Medical Device Risk Management to identify risks associated with use of ReActiv8, and to ensure risks are mitigated to what the Company believes to be acceptable levels, where possible.

In addition, extensive pre-clinical (animal) work has been conducted by the Group to meet the requirements of biocompatibility and safety testing (including safety of electrical stimulation of nerves).

The Company believes that ReActiv8 is now ready for performing clinical trials for CE Mark and for performing a clinical trial under an IDE, if granted by the U.S. FDA.

8.6.1 ***Implant Procedure***

The implant procedure for ReActiv8 was developed by the Group together with physician advisors. In particular, implant of prototype devices was tested in animals and human cadavers under controlled conditions.

ReActiv8 is implanted using a surgical procedure that is modelled on other commonly used surgical procedures (medial branch radio frequency ablation or rhizotomy, and implantation of a SCS IPG) so that implanting physicians will find the procedure familiar. Typical procedure time is expected to be approximately one hour.

- the patient is placed under anaesthetic (local or general can be used);
- the leads are placed in the correct location under fluoroscopic (X-Ray) guidance;
- the stimulation thresholds are measured and adjustments are made if necessary;
- the leads are tunnelled under the skin to a subcutaneous pocket in which the IPG is placed;
- the leads are connected to the IPG;
- the ReActiv8 is tested to ensure proper functioning; and
- the surgical incisions are closed and dressed.

Once implanted in the body, the leads and pulse generator remain under the skin, and are often invisible. Three small surgical scars remain, which will generally heal within a few weeks. The operation to implant the device is reversible and ReActiv8 can be removed.

After adequate time for post-surgical recovery, the IPG is programmed by the physician and the patient is instructed in how to use it.

8.6.2 ***How Reactiv8 is used***

Stimulation is delivered under patient control for up to one hour a day, typically twice a day in two sessions of 30 minutes each. In the Feasibility Study (when ReActiv8 was still in the development phase), patients used the commercially available devices to deliver stimulation in 20 minute sessions twice per day, and after reviewing the results of the Feasibility Study, the Group's clinician advisors recommended the daily stimulation should be increased to two 30 minute sessions per day. During each session, the patient lies comfortably prone (on the stomach) or on the side, and uses the activator

to initiate the stimulation to cause multifidus muscle contraction. During the session, stimulation is delivered cyclically for 10 seconds, followed by a 20 second pause. This cycle is designed to minimise the risk of muscle fatigue. A stimulation session can be stopped at any time by the patient by using the activator or a supplied magnet – for example, if the phone rings or a child needs attention.

The IPG has internal memory that is used to store data on electrode and battery characteristics, and for logging time of start and stop of each stimulation session.

Based on bench testing, the anticipated battery life of the IPG is five years, and may be longer depending on actual usage. Once the battery in the IPG is depleted, the IPG can be replaced with a new IPG which is connected to the existing leads in a simple surgical procedure, similar to replacement of IPGs for other applications (e.g.: cardiac pacemakers, spinal cord stimulators).

8.7 MANUFACTURING AND OPERATIONS

The ReActiv8 components are manufactured by a group of experienced manufacturers of AIMDs, supervised by the Group's research and development ("**R&D**") and operations staff. The Company believes that this is a capital efficient way of developing an AIMD company as it does not require large expenditure on capital equipment for manufacturing, nor in-house development of specialised manufacturing processes.

In the Company's opinion, the suppliers of the IPG and leads are experienced and well-respected medical device manufacturers with multiple customers including the Group and have existing quality control programs and registrations with the appropriate regulatory authorities. The Group verifies key vendors' quality systems with periodic audits.

The Group has entered into long-term supply contracts with all of its key manufacturing vendors. Key vendors that supply products to the Group are subject to annual audit of their quality management system by the Group. Once a supplier meets the Group's requirements (see paragraph 8.8 of Part 8 (*Information on the Company) below*), it is entered into an Approved Supplier List ("**ASL**") maintained by the Group.

The Company currently does not plan to establish manufacturing operations for the Group.

Distribution of the Group's products is managed by the Group's manufacturing vendors, in combination with its own staff and facilities. The Group has established a distribution facility in Australia to handle product shipment and return, and is in the process of establishing a distribution facility at its offices in Ireland.

Any devices explanted (i.e. removed) from a patient are 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 directly to the supplying manufacturer for analysis.

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

8.8 QUALITY MANAGEMENT SYSTEM

The Group performs all its activities subject to a Quality Management System ("**QMS**"). The Group's QMS is designed to be in compliance with international standards (particularly ISO13485 required for Europe and for obtaining a CE Mark) and the U.S. FDA Quality System Regulations ("**QSR**"). ISO13485 and QSR requirements are similar but not identical. The QMS is subject to audit and enforcement by regulatory authorities such as the U.S. FDA and the Notified Body that grants the CE Mark.

The Group's QMS is implemented on a computer based document management platform. It is completely paperless and the Company believes that it has put in place back-up systems necessary to protect its integrity and security. The Group conducts periodic internal audits of its QMS and uses external auditors from time to time.

Sale of medical devices without certification of compliance with ISO13485 is illegal in most countries outside the United States. In the United States compliance with FDA QSR is required. Compliance to

ISO13485 is assessed by a Notified Body and the Group has engaged BSI Group – Medical Devices ("**BSI**") as its Notified Body to conduct audit of compliance with ISO13485 and provide certification. The Group's QMS will also be audited by the U.S. FDA for the compliance with the QSRs prior to any granting of a PMA to allow sale of ReActiv8 in the U.S.

The Group maintains a complaint system, which is designed to be in compliance with QSR and ISO13485. The purpose of the complaint system is to receive, record, and disposition 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 ("**CAPA**"). At least quarterly, the Group conducts a management review of its QMS during which the history of Complaints is analysed and appropriate actions (if any) are initiated.

Complaints logged into the Group's complaint system may result in a report to a regulatory authority. The U.S. Medical Device Reporting ("**MDR**") regulation (21 CFR 803) 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 MDR system, the European Union employs a vigilance reporting system as described in MEDDEV 2.12-1, Rev 8 (Guidelines on a Medical Devices Vigilance System). Other countries have generally similar obligations for reporting adverse events to the appropriate regulatory authority.

8.9 PHYSICIAN CUSTOMERS

People with Chronic Low Back Pain seek treatment from many different physician specialties, including general practitioners, rheumatologists, physical medicine and rehabilitation ("**PM&R**") specialists (sometimes known as physiatrists), interventional pain specialists, and spine surgeons (including orthopaedic spine surgeons and neurosurgeons). The Group is targeting physician customers who routinely see Chronic Low Back Pain as a large part of their clinical practice.

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. The Group has established relationships with Key Opinion Leaders ("**KOLs**") in Europe, the U.S. and Australia, and has consulting contracts in place with many of these KOLs as clinical advisors to the Group. The Group's advisors are from many specialties including spine surgery, pain medicine, physical medicine and rehabilitation, physical therapy, and basic physiology. The Group meets with its clinical advisors from time to time, for example at scientific meetings and conferences. Note that the payments to physician advisors are subject to the Sunshine Act regulations as mentioned in paragraph 7.6.5 of Part 7 (*Market Opportunity and Overview*) above.

The key target physician customers for the Group are those who see significant numbers of people with Chronic Low Back Pain. Many physicians who see significant number of patients with Chronic Low Back Pain also have the skills and experience to implant the ReActiv8, whereas others may refer the patient to a different person to perform the implant. There are three key physician groups that meet these criteria:

8.9.1 ***Physical Medicine and Rehabilitation (PM&R) Physicians (Physiatrists in 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.

There are approximately 10,000 board certified physiatrists in the United States (Association of Academic Physiatrists, www.physiatry.org), of whom approximately 1,400 are also board certified as interventional pain specialists (ABMS, 2012 Certification Statistics. Chicago). 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 able to implant the ReActiv8. There are over 11,000 PM&R physician specialists in Europe (Ward, A. B. 2006).

8.9.2 ***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. 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 (Gupta, S. et al, 2012). 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 the Company is not aware of any consolidated database, as practice patterns differ between European countries.

8.9.3 ***Spine Surgeons (Orthopaedic Spine Surgeons and Neurosurgeons)*** have a diverse practice including trauma, cancers, deformities, and pain. Neuropathic pain as a result of nerve 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.

8.10 COMMERCIALISATION

The Group has completed the design of ReActiv8 and is now focussed on clinical development, regulatory approval and commercialisation.

The Group has defined the pathway from ReActiv8 product development to revenues and profits with four key elements as follows:

1. Obtain regulatory approval in order to gain market access;
2. Leverage existing reimbursement and expand coverage;
3. Drive adoption of ReActiv8 in routine clinical practice; and
4. Drive awareness of ReActiv8 in the general population.

8.10.1 ***Obtain Market Access***

Regulatory approval is necessary for the marketing and sale of any medical device. The regulatory approval pathway is different in each of the Group's key target markets, but with many elements in common.

In general, regulatory approval of AIMDs requires submission of data generated from clinical trials. The Group plans to conduct several clinical trials for both regulatory approval and to drive reimbursement and market adoption. The Company expects to conduct these clinical trials with a combination of in-house resources and one or more external Contract Research Organisations ("**CROs**"). All human clinical trials are to be conducted according to the international standard covering clinical trials, ISO14155:2011.

Any clinical trial which generates data which the Group intends to submit to the U.S. FDA as part of an application for regulatory approval also must meet the U.S. 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 Europe or PMA for U.S.), the Group is 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.

8.10.1.1 *CE Mark for Europe*

In Europe (EU and EEA), regulatory approval is granted by the awarding of the CE Mark (*Conformité Européenne*), which certifies compliance with the applicable standards and essential requirements. The CE Mark is granted by a Notified Body with authority designated by a Competent Authority. The Group has engaged BSI Group – Medical Devices ("BSI") as its Notified Body, and has had several meetings since 2010 with BSI.

The key elements to obtaining CE Mark are:

- Submission of a CER;
- Submission of a technical dossier with extensive details;
- Certification of the quality system to the international standard ISO13485; and
- Agreement to a programme of Post Market Clinical Follow Up ("**PMCF**"), which usually includes Post Market Surveillance ("**PMS**") with the purpose of monitoring long term performance of an approved device in a larger population, and to gather data on residual risks.

The Group has submitted the CER to BSI and has received initial responses. In the coming months, the Group is expecting to review with BSI the additional clinical work that may be necessary to be eligible for granting of the CE Mark.

Submission of the technical dossier requires completion of some long-term device testing and manufacturing process validation, which is on-going.

The Company anticipates that it will be ready for inspection and certification to ISO13485 by the third quarter of 2014.

As part of the PMCF (and possibly as part of the CE Mark submission), the Group is planning to conduct a prospective single arm clinical trial with approximately 96 subjects at up to 8 sites in Australia and Europe. The Group will review with BSI the exact clinical work needed and currently expects that data on 40 subjects could be sufficient to apply for a CE Mark. Australia has been selected for the first sites for this clinical trial because the regulatory approval pathway to commence a clinical trial with an investigational device is usually shorter in Australia than in the EU or the U.S. This clinical trial has been registered and has been granted the identifier NCT01985230, and information about clinical trials has been published on www.clinicaltrials.gov and will be updated from time to time.

Ethics Committee approval has been obtained for the first three clinical sites in Australia, and enrolment has commenced.

Although sale of medical devices in the EEA is regulated under the European Active Implantable Medical Devices Directive, there is no EU-wide framework for conduct of clinical trials, and clinical trials are subject to approval on a country by country basis. The Group will have to obtain Competent Authority approval and ethics committee approval in any EEA country where it intends to carry out clinical trials of an investigational device. The Group expects to file submissions to appropriate competent authorities in Europe to expand the trial to European centres.

8.10.1.2 *Premarket Approval (PMA) for the U.S. Market*

In the United States, 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 Investigational Device Exemption (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.

The final design of the clinical trial to be conducted under an IDE intended to lead to a PMA is subject to agreement with the FDA. As part of its consideration and approval of a clinical trial design, the FDA encourages a process (called a pre-IDE submission) of dialogue between companies and the FDA, to obtain feedback and suggestions prior to committing to a formal IDE submission. The Group has submitted one pre-IDE submission and received comments and suggestions from the FDA. The Group is in the process of preparing a second pre-IDE submission. The Group anticipates making a formal IDE submission to start clinical trials in the U.S. in the third quarter of 2014. Once the IDE is granted, the clinical trial will be registered on www.clinicaltrials.gov, as required with details of the trial. Enrolment in the US clinical trial can commence after IDE approval, subject to approval by each investigational site's Institutional Review Board (IRB), negotiation and finalisation of contracts with each investigational site and investigator, physician training, and other practical requirements. The time for IDE approval is unknown and cannot be predicted with accuracy but is counted in years and not months.

The Group currently intends to submit an IDE application to conduct a prospective randomized clinical trial. An adaptive design will be used which allows the Group to fine tune the exact number of patients based on certain attributes of the data at an interim look (e.g.: the amount of variability). Subject enrolment criteria and endpoint data collection will likely be substantially the same as the clinical trial started in Australia in March 2014. The choice of the control arm for the IDE trial is the subject of continuing discussion and anticipated negotiation with the FDA.

8.10.2 ***Leverage Existing Reimbursement and Expand 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.: 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 citizens can choose to pay for to access products and services not available from the national health service. In other countries, the payer can be a social insurance company (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 top up reimbursement and to provide access to additional services. In the U.S. provision of healthcare is mainly by private institutions. 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 patients who are uninsured.

In most countries, a series of codes is used to classify diagnoses and clinical procedures. These are usually combined to describe an episode of care which forms the basis of the payment to the hospital for the patient stay. Most of these systems aim to have a single code and associated tariff to cover the total care package including any implants used. There are some exceptions for implants including neurostimulators where in some healthcare systems, payments are made for the 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 utilization and product cost data. For each reimbursable device implant the hospital will receive a total budget to cover the procedure and the device.

The Company believes that existing reimbursement codes in some target markets can be used to obtain payment for devices immediately following CE Mark approval. In countries where coding is not yet in place or coverage of available coding insufficient, the Group will work with the relevant parties to establish appropriate coding and reimbursement levels.

In some countries (e.g.: U.S.), purchase of medical supplies including medical devices is done through a group purchasing organization (GPO) which negotiates on behalf of a group of customers with vendors to obtain best possible prices. The Group will engage with GPOs at the appropriate time to negotiate prices and payment for its 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. The Group will apply for inclusion on lists of reimbursable implants and respond to tenders for its products wherever possible and appropriate.

As the Group's business develops, it is anticipated that the Group will expand its team of reimbursement specialists (consultants and/or employees) to help drive the reimbursement processes.

It is the Group's objective to establish the highest possible reimbursement to maximise revenues. Higher reimbursement is generally supported by data which demonstrates the value and relative cost effectiveness of treatment. Following and subject to CE Mark approval, the Group plans to undertake a medical economics study in the key European markets in which cost-effectiveness of ReActiv8 will be compared to usual care for people with Chronic Low Back Pain.

The medical economics study will be used both to support specific reimbursement applications and to provide input to health technology assessments ("**HTA**"). An 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 stronger reimbursement and to drive inclusion of ReActiv8 in treatment guidelines. The current high cost burden of Chronic Low Back Pain (for drugs, physical therapy or other treatments, and the societal cost of lost working days and disability payments) is a strong motivator to find more cost effective ways to manage this problem.

Once persuasive clinical and economic data are available, the Group will 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.

The Company expects that its strategy for the long-term maintenance of high reimbursement will be supported with a programme of continuous product improvement and clinical data generation.

8.10.3 ***Drive adoption of ReActiv8 in routine clinical practice***

One of the Group's objectives is to get ReActiv8 adopted into routine clinical practice for people suffering from Chronic Low Back Pain. As one part of the strategy to achieve this objective, the Group expects to target clinicians who manage, triage or refer people with Chronic Low Back Pain, in addition to physicians who will perform the implant of ReActiv8. In some cases, this may be the same clinical specialty.

In most cases, the implanting physician is not the primary contact for people suffering from Chronic Low Back Pain, and therefore it is important that the Group's strategy also addresses engagement of referring clinicians. Referral pathways vary 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, osteopaths. In some countries (e.g. UK), patients with Chronic Low Back Pain are reviewed and referred by clinicians in specialized musculoskeletal clinics.

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

The Group will 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.

8.10.4 ***Drive market awareness in the general population***

Many people with Low Back Pain do not seek medical care (Mannion et al, 2013). Thus, the Company believes there is a large group of people with Chronic Low Back Pain who could benefit from ReActiv8 but have little interaction with the medical community. As part of its overall strategy, the Group plans to inform the public that ReActiv8 is a new option for people dealing with Chronic Low Back Pain. Activities include the implementation awareness campaigns on Chronic Low Back Pain in the popular press, and with television and radio advertisement where appropriate and permissible under local laws. In many jurisdictions (e.g.: UK and U.S.) direct to patient advertising requires prior regulatory approval.

8.11 SALES AND MARKETING

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.

The Company believes that in its key target markets, the market for ReActiv8 is concentrated, with a relatively small number of physicians who see a relatively large number of people who might benefit from ReActiv8 and that it can be best served by a direct sales force.

The Company plans to use a direct sales force for the Group in the early stages of commercialisation because of the need to control and optimise clinical site selection, focus on referral networks, manage clinical outcomes and user experience, and retain learning inside the organisation. The Company intends to target markets it deems most important first, determined by market size and availability of reimbursement.

The timing of market entry shall be determined primarily by the timing of regulatory approvals for those markets. Following CE Mark approval, the Company intends to focus initially on key European markets such as Germany, UK, France, Austria, Switzerland and the Benelux (Belgium, Netherlands, Luxembourg) countries. This will be followed by market entry into strategically important non-EU countries such as Australia.

The U.S. is a key strategic market for the Group. Entry into the U.S. market will follow subject to the granting of a PMA, and is expected to follow the key EU and strategically important non-EU markets.

8.11.1 ***Clinical Support***

The Company intends to adopt a strategy of maintaining a dual purpose sales force for the Group. Under this approach each direct sales representative shall perform the selling function and also provide clinical implant and follow-up support. As the business grows, the Group expects to deploy field clinical representatives ("**FCRs**") alongside sales representatives, where the primary task of the FCR is to provide technical and clinical support for the Group's products.

8.11.2 ***Pricing***

The price of ReActiv8 will be set by the Group. In practice the Group's pricing determinations will be influenced by local reimbursement and/or funding mechanisms in each market. The Group 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, a supply contract will typically be negotiated between the Group and the purchasing institution or a Hospital Buying Group. 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. The role of the Group will be to support the hospital in these negotiations, both the Group and the hospital benefiting from higher negotiated procedure volumes and reimbursements.

Based on its market research and comparison with other neurostimulation devices, the Company currently anticipates that the price of ReActiv8 will be set at around €15,000 in key European markets.

8.12 INTELLECTUAL PROPERTY

Patents, trademarks, and other intellectual property rights are important in the medical device industry in which the Group operates. The Group has implemented an intellectual property protection policy with the objective of obtaining protection for key aspects of the technology embodied in the ReActiv8 system and certain methods of use. The Group's portfolio of patents, patent applications and other intellectual property related matters are managed in-house in collaboration with its US and European patent counsel. The Group may, from time to time, file patent applications for inventions that may be of importance to its future business.

The Group 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 the Group. Further, the Group may decide, from time to time, to license its intellectual property to other parties, for example, in exchange for cash, marketing collaboration, or other valuable consideration to the Group. As of the date of this Prospectus, the Group has not in-licensed or out-licensed any of the patents or applications for inventions embodied in the ReActiv8 system.

The Group may pursue legal action to protect or defend its 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 the Group and the Group cannot be certain of the outcome. Invalidation of key patents or proprietary rights of the Group or an unsuccessful outcome in such a lawsuit could have a material adverse effect on the Group's financial condition, results of operations and/or impair the Group's ability to prevent copying by competitors of inventions embodied in the ReActiv8 system.

The Group policy is that employees and contractors of the Group execute a propriety information and inventions assignment (PIIA) agreement, which protects proprietary information and assigns to the Group all inventions created by an employee during the term of employment. Where possible and appropriate, agreements with third parties (e.g., consultants and vendors) contain language designed to protect the Group's intellectual property and confidential information, and to provide for assignment to the Group of new inventions related to the Group's 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 the Group's trade secrets and proprietary information or that adequate remedies will be available in the event of an unauthorized use or disclosure of such information.

8.12.1 *Patents*

In general, the Group first files patent applications in the United States, with corresponding applications filed later in other countries of interest to the Group's 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 the Group's assessments of the importance of such future markets.

Securing a patent typically involves negotiation between the Group and the governmental authority that issues the patent, e.g., the United States 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. The Group, in conjunction with its 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, the Group 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, the Group may seek to obtain method claims in a patent application in the US without pursuing a corresponding patent application in Europe.

The term of a US patent for an application filed on or after June 7, 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 US, 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.

Patent applications may be kept secret until published by the USPTO. 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, the Group may elect to file divisional applications, continuation applications, or other types of applications to pursue patents of varied scope.

On the date of this Prospectus, the Group's patent portfolio includes seven patent "families" as described below. The US patent number or application number is used for reference, and in certain cases, there are corresponding European applications, as well as corresponding applications in other jurisdictions. The Group currently owns 2 U.S. patents, and 18 pending U.S. and foreign patent applications, including pending PCT International Applications.

U.S. Patent No. 8,428,728 "Muscle Stimulator"
U.S. Patent No. 8,606,358 "Muscle Stimulator" (continuation)
The first US patent (US 8,428,728) issued on 23 April 2013. US patent 8,606,358 issued on 10 December 2013. Rejection of all claims of the European counterpart application currently is on appeal to the EPO Board of Appeal. A divisional application also has been filed in Europe. The Group has also been granted a utility model patent in Germany.

U.S. Patent Publication No. 2011/0224682
"Methods of Implanting Electrode Leads for Use with Implantable Neuromuscular Electrical Stimulator."

U.S. Patent Publication No. 2011/0224665
"Modular Stimulator for Treatment of Back Pain, Implantable RF Ablation System and Methods of Use." Corresponding National Stage applications have been filed in Europe, Canada, Australia, and China.

U.S. Patent Publication No. 2013/0131766
"Apparatus and Methods for Anchoring Electrode Leads for use with Implantable Neuromuscular Electrical Stimulator." Corresponding National Stage applications have been filed in Europe, Canada, and Australia, and Chinese counsel has been instructed to file a National Stage application in China.

U.S. Patent App. No. 13/718,806
"Apparatus and Methods for Rehabilitating a Muscle and Assessing Progress of Rehabilitation." A corresponding PCT International Application also is pending.

U.S. Patent Publication No. 2013/0338730
"Apparatus and Methods for Anchoring Electrode Leads Adjacent to Nervous Tissue." A corresponding PCT International Application also is pending.

U.S. Patent Publication No. 2014/0046398
"Systems and Methods for Restoring Muscle Function to the Lumbar Spine." This US application is a continuation-in-part of the "Muscle Stimulator" application described above.

The Company can give no assurance that any of the Group's patent rights, whether issued or pending, will not be circumvented or invalidated by others. Furthermore, there are many existing patents and pending patent applications directed to numerous aspects of medical products. There can be no assurance that the Group's existing or planned products do not or will not infringe such rights or that others will not claim infringement of their patents. No assurance can be given that the Group will be

able to prevent competitors from challenging the Group's patents or entering markets the Group intends to serve with competing products.

As the Group continues to innovate, new patent applications may be filed from time to time, and it is anticipated that the Group's intellectual property portfolio will grow. The Group does not intend to make announcements as new patent applications are filed for commercial and competitive reasons.

8.12.2 ***Trademarks***

The Group has applied for trademark registration of the company name (MAINSTAY) the design of the trademark for MAINSTAY MEDICAL, and the product name (REACTIV8) in the US with the USPTO, in the European Union as a Community Trade Mark (CTM), and in Australia. Trademarks have been registered in Australia and Europe, and it is anticipated that more approvals will be received in the future. A third party filed an opposition to the ReActiv8 CTM application. A member of the Group and the third party entered into a coexistence agreement for the Benelux territory whereby the member of the Group agreed to limit distribution of goods under the ReActiv8 mark to the hospital sector.

8.12.3 ***Confidential Information and Trade Secrets***

The success of the Group's business depends, in part, on maintenance of confidential information and trade secrets, generally referred to as proprietary information. The Group has implemented procedures, where appropriate, to maintain the confidentiality of its proprietary information. The Group's policy is that employees and contractors enter into confidentiality agreements with the Group (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.

8.12.4 ***Manufacturing IP***

Manufacturing of the Group's products is done by third party manufacturers using their own facilities; the Group has acquired no rights to any intellectual property of such third party manufacturers.

8.13 USE OF PROCEEDS AND FINANCING STRATEGY

Assuming a full issuance of the Base Offer at an Offer Price at the mid-point of the Price Range, i.e. €23.50 per Ordinary Share, the gross proceeds of the Offer will be €20,002,612.50 and the net proceeds of the Offer, after deduction of fees and expenses relating to the Offer are expected to be €16,500,596.83. On this basis, the fees and expenses relating to the Offer are expected to be approximately €3.5 million. Should the Offer fail to yield the Minimum Net Proceeds, the Offer will be cancelled and no Ordinary Shares will be issued pursuant to the Offer.

The Minimum Net Proceeds together with existing cash resources will be used to conduct Clinical Trials, initially in Australia and then additionally in Europe, to submit an application for CE Mark approval and for general working capital purposes, for at least the next twelve months.

The Company intends that remaining net proceeds of the Offer will be used for the following clinical, regulatory and related commercialisation activities through 2014 and 2015:

- to submit an application for IDE approval to start a clinical trial in the US;
- following and subject to CE Mark approval, to commence commercialisation, and in particular to start to build a European sales force and support organisation;
- to grow and strengthen the Company's intellectual property portfolio; and
- to continue development of the next generations of the Group's products.

Additional capital may also be required to complete the steps set forth above, depending on circumstances and events. The Company anticipates that additional capital will be required to complete the U.S. clinical trial and achieve PMA approval, and to expand commercialisation in Europe and other markets. In the future, the Company will explore options for sourcing additional capital, which may include strategic partners, private placement, and public offering.

8.13.1 ***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 has no plans to distribute dividend payments at any time in the foreseeable future.

8.14 CURRENT TRADING AND PROSPECTS

Since 31 December 2013, the date to which the last audited accounts for the Group were prepared, the Group has continued to trade in line with the Board's expectations. The period since 31 December 2013 has also seen significant progress as the Group has continued to advance ReActiv8, for example its recruitment in the clinical trial for the purpose of obtaining the CE Mark, which started in March 2014.

As explained in Part 7 (*Market Opportunity and Overview*) above, the Company believes that there is a large addressable market for the treatment of people with Chronic Low Back Pain in the EU and that, subject to such regulatory approval being granted, and the product being made available for sale in the EU and reimbursement being in place, ReActiv8 could generate significant revenues from this market.

PART 9

DIRECTORS, SENIOR MANAGEMENT AND CORPORATE GOVERNANCE

9.1 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, Clonmel House, Forster Way, Swords, Co. Dublin, Ireland.

On the date of this Prospectus, the Board comprises the Chairman, one executive Director (CEO), and four Non-Executive Directors. The Chairman, and one of the Non-Executive Directors are considered by the Board to be independent Directors.

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

Name	*Age*	*Position*
Oern Stuge MD (Norwegian)	59	*Non-Executive Independent Chairman*
Antoine Papiernik (French)	47	*Non-Executive Director*
Manus Rogan PhD (Irish)	46	*Non-Executive Director*
Dan Sachs MD (U.S.)	49	*Non-Executive Director*
David Brabazon (Irish)	44	*Non-Executive Independent Director*
Peter Crosby (Australian and U.S.)	61	*Executive Director*

Brief biographical details of each Director follow:

Oern Stuge MD

Dr. Oern R. Stuge is the independent Chairman of the Board. He is an international executive with over 25 years of experience in the life science sector. Dr Stuge controls ORSCO Life Sciences AG, through which he holds several executive and non-executive board memberships and advisory roles.

Prior to founding ORSCO Life Sciences AG, Dr Stuge worked for 12 years for Medtronic, Inc. in different roles including Senior Vice President (SVP), President of Europe and Central Asia, and SVP and President of Cardiac Surgery. He was a member of the Medtronic Executive Committee and Operating Committee. Under the leadership of Dr. Stuge, Medtronic Cardiac Surgery, entered the field of structural heart disease, and introduced the first ever regulatory approved (CE-Marked) percutaneous heart valve (known as "melody valve").

Dr Stuge earned an MD (summa cum laude) from the University of Oslo, and an MBA from IMD, Switzerland.

Antoine Papiernik

Antoine Papiernik is a Non-Executive Director of the Company and is the Managing Partner at Sofinnova Partners SAS, which he joined in 1997. He was previously with CDC-Innovation, the venture arm of the Caisse des Dépôts group.

Since joining Sofinnova Partners SAS, Mr. Papiernik has been an initial investor and an active board member in public companies like Actelion Ltd., Addex Pharmaceuticals SA, Orexo AB, Novuspharma S.p.A. (sold to Cell Therapeutics, Inc.), Movetis NV (sold to Shire plc) and Stentys SA, which went public respectively on the Zürich stock exchange, the Stockholm stock exchange, the Milan Nuovo Mercato, the Belgium Stock Exchange and Euronext Paris, and in Cotherix, Inc. (initially NASDAQ listed, then sold to Actelion Ltd.), CoreValve, Inc. (sold to Medtronic, Inc.), Fovea Pharmaceuticals SA (sold to the Sanofi group) and E.O.S spa. (sold to Clovis Oncology). He has also invested in and is a board member of the following private

companies: Auris Medical AG, Shockwave Medical, Inc., ReCor Medical, Inc., ProQR Therapeutics BV, Reflexion Medical and Pixium Vision SA. Antoine has an MBA from the Wharton School of Business, University of Pennsylvania.

Manus Rogan PhD

Dr Manus Rogan is a Managing Partner and co-founder of Fountain Healthcare Partners. He has over 23 years of investment and operating experience in the life science sector in both the US and Europe.

Dr Rogan began his career in product development at GlaxoSmithKline in the UK and in 1996 joined Elan Corporation's business development group. For four years he was responsible for licensing products and drug delivery technologies in Europe and Japan. In 2001, Dr Rogan joined Elan's Corporate Venture Capital group in New York where he invested in private and public biotechnology companies. Investments included Sirna (acquired by Merck, 2006) and Beyond Genomics (IPO, 2011). In his seven years at Elan, Manus concluded over 25 investment and technology licensing transactions involving companies in the US, Europe and Japan. Manus currently serves on the board of Opsona Therapeutics and Mainstay Medical. He recently stepped down as Chairman of the Irish Venture Capital Association ('IVCA') and previously represented Fountain Healthcare Partners on the board of Amarin Corporation.

Dr Rogan earned a PhD in chemistry from the University of York (sponsored by GlaxoSmithKline) and an MBA from Trinity College Dublin.

Dan Sachs MD

Dr. Dan Sachs is a founder of Respicardia, Inc., Kspine, Inc., MMI, and Amphora Medical, Inc., all venture-backed medical device companies. He was previously a venture capital investor with Investor Growth Capital and Spray Venture Partners, and 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.

David Brabazon

Mr. David Brabazon is an independent Non-Executive Director, a co-founder of Adapt Pharma Limited and serves as Chief Financial Officer and a board member. Adapt Pharma Limited. is a U.S. focused speciality pharmaceuticals business with its corporate headquarters in Ireland. 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 plc, Mr Brabazon served as Vice President of Finance and Group Financial Controller of Elan Corporation plc. Mr Brabazon currently serves as a Director of Headway (Ireland) Limited, which provides support and services to people affected by brain injury.

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.

Peter Crosby

Peter Crosby is the CEO of the Company and has been a member of the Board of MMI since he was appointed CEO of MMI in mid-2009. Mr Crosby was instrumental in founding the Group and raising the Series A Financing and the Series B Financing. He is an internationally experienced medical device executive who has been CEO or chairman of 7 medical device companies (public and private) in four countries.

Mr Crosby has contributed to the development and introduction to the global markets of dozens of medical devices over a career spanning more than 30 years. After working for five years in a hospital environment, Mr Crosby entered industry as one of the first three employees of Cochlear Ltd., and continued his career with executive roles in many more companies. He has direct experience in active implantable medical devices (AIMDs) (cardiac pacemakers and defibrillators (Telectronics Pacing Systems), cochlear implants (Cochlear Ltd), left ventricular assist devices (Ventracor Limited), Neuromodulation (Mainstay Medical

Limited), ultrasound (Ausonics, Ltd., NeoVision, Inc.), software (Cardicomm Solutions Inc.), and in-vitro diagnostics (First Medical, Inc. and Ischemia Technologies, Inc.)). Mr Crosby has raised capital for many medical device companies, and has been directly involved in the sale of several companies.

Mr Crosby graduated with a Bachelor of Engineering (Electrical) and a Masters in Engineering Science (Biomedical Engineering) from the University of Melbourne, Australia. He is a named inventor on over 25 patents and applications, primarily in the field of biomedical engineering.

9.2 SENIOR MANAGERS

In addition to the executive Director, 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, Clonmel House, Forster Way, Swords, Co. Dublin, Ireland, although the physical address (including country of residence) may be different.

Peter Crosby (*Chief Executive Officer*) See paragraph 9.1 of Part 9 (*Directors, Senior Management and Corporate Governance*) above.

Prashant Rawat (*Chief Operating Officer*) (Age 40) has worked more than 17 years in AIMDs (Guidant 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 organizations ("**CROs**");
- 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 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.

Jan Pieter Heemels (*VP Commercial Operations*) (Age 51) has over 25 years of experience in medical devices (Cordis Corporation, Guidant Corporation, Boston Scientific Corporation, Spinal Modulation, Inc.), including five years in Neuromodulation.

Mr Heemels' current responsibilities at the Group include:

- Market and key account development;
- Securing reimbursement in major global markets;
- Marketing and communications;
- Alignment of the clinical trial strategy with the Company's commercial objectives; and
- Development and expansion of the Group's intellectual property portfolio.

Previously Mr Heemels managed new product definition, clinical trials, sales and market development for Cardiac Rhythm Management products (implantable cardiac pacemakers and defibrillators) at Guidant Corporation and Boston Scientific Corporation. Subsequently he was a consultant to privately held start-up companies in Neuromodulation (Spinal Modulation, Inc.) and medical imaging for urology (Advanced Medical Diagnostics s.a). Since joining the Group in early 2011, he has been instrumental in completing the Feasibility Study and preparing the Group for the commercialisation of ReActiv8.

Mr Heemels earned a Master of Science degree in physics from the VU University in Amsterdam and a Master of Business Administration degree from the University of Minnesota. He is named inventor on 9 key patents in the field of cardiac rhythm management and Neuromodulation and is the author on several scientific publications.

Kristen Jaax MD PhD (*Chief Medical Officer*) (Age 41) has over 10 years of experience in Neuromodulation devices (Advanced Bionics Corporation, Boston Scientific Corporation).

Dr Jaax's current responsibilities at the Group include medical and scientific contributions to:

- Clinical trial strategy and design;
- Risk management and safety, including contribution to post-market surveillance systems;
- Regulatory submissions;
- Clinical experience reports;
- Due diligence; and
- Development and expansion of the Group's intellectual property portfolio.

Dr Jaax was the first Medical Director for the Boston Scientific Neuromodulation Division, where she created the Medical Sciences organization to support both commercial and development activities for a broad range of Neuromodulation devices. Responsibilities included medical aspects of clinical research, risk management, new product development, intellectual property and new business development. Prior to that, Dr Jaax was with Advanced Bionics Corporation, a start-up later acquired by Boston Scientific Corporation, where she worked on creating new Neuromodulation therapies using the Bion and spinal cord stimulator platforms. Her work there included scientific and management roles within the Emerging Indications group. Dr Jaax received her Medical Degree in 2003 and Doctor of Philosophy in Bioengineering in 2001 through the NIH-funded Medical Scientist Training Program at the University of Washington. She received her Bachelor of Science in Mechanical Engineering from Stanford University in 1994. Dr Jaax is a named inventor on 49 patents in the field of Neuromodulation. Dr. Jaax works for the Group on a contract basis. For additional details relating to Dr Jaax's consultancy agreement, refer to paragraph 15.13.22 of Part 15 (*Additional Information*).

Hugh Kavanagh (*Chief Financial Officer*) (Age 52) is a Chartered Accountant with over 20 years of financial management experience in both early stage and large established multinational companies (Tyco (now Covidien), Boston Scientific Corporation, Abbott Vascular).

Mr Kavanagh's current responsibilities at the Group include:

- Company Secretary:

- Management and operation of the Group's finance and administration functions; and
- Human resources (HR).

Mr. Kavanagh is a Chartered Accountant with extensive senior management experience in a number of large U.S. multinational and start-up companies in the medical device and information technology industries. Previous roles include acting as financial controller in the start-up of Irish and international operations, with Oracle Europe Manufacturing Limited and acting as Managing Director responsible for the set-up of activities for RSA Security's international operations and shared service centre. He has also held positions as financial controller or finance director with Abbott Vascular, Tyco (now Covidien), and Transitions Optical Ltd., as CFO of Irish medical device start-up company Crospon Ltd. and more recently he worked with Boston Scientific Corporation. Some of these roles also included functional responsibility for supply chain, HR and information systems (IS). Throughout his careers, Mr Kavanagh has gained a broad business experience and has a particular expertise in financial management.

Mr Kavanagh qualified as a Chartered Accountant whilst working with PriceWaterhouse (now PwC) and he holds a Bachelor of Commerce Degree and a Post Graduate Diploma in Professional Accounting from University College Dublin.

9.3 CONFLICTS OF INTEREST

Other than the appointments of Antoine Papiernik, Dan Sachs and Manus Rogan PhD to the Board under the Amendment and Restatement Agreement (which will terminate shortly before Settlement and ESM Admission), there are no arrangements or understandings with major shareholders, members, suppliers or others pursuant to which any Directors or Senior Managers were appointed.

Other than the details of payment to ORSCO Life Sciences AG as disclosed in paragraph 15.11 of Part 15 (*Additional Information*), 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.

9.4 INTERESTS OF THE DIRECTORS AND SENIOR MANAGERS IN SHARE CAPITAL

(a) As at close of business on the Latest Practicable Date, the interests (all of which are beneficial unless otherwise stated) of the Directors (except Antoine Papiernik and Manus Rogan, which are disclosed at sub-paragraph (b) below) and Senior Managers in the Existing Issued Share Capital which have been notified by each Director (except Antoine Papiernik and Manus Rogan, which are disclosed at sub-paragraph (b) below) and Senior Manager to the Company pursuant to sections 53 or 64 of the 1990 Act or which are required pursuant to section 59 of the 1990 Act to be entered into the register referred to therein are as follows:

Director	*Number of shares*[(1)]	*Percentage of Existing Issued Share Capital*	*Number of Ordinary Shares following the Offer*[(2)]	*Percentage of Enlarged Issued Share capital*[(2)]
Oern Stuge MD	–	–	–	–
Peter Crosby	81,400	2.4%	81,400	1.91%
Dan Sachs MD	515,000	15.1%	515,000	12.10%
David Brabazon	–	–	–	–

Notes:

(1) As at the Latest Practicable Date, the Shareholders listed above hold various classes of shares. All issued shares in the Company will convert to Ordinary Shares on a one for one basis shortly before ESM Admission

(2) Assumes that up to 851,175 new Ordinary Shares are issued, based on the maximum number of shares under the Base Offer only.

(b) The interests of Sofinnova Capital VI FCPR in the issued share capital of the Company are disclosed at paragraph 15.5 of Part 15 (*Additional Information*). 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. in the issued share capital of the Company are disclosed at paragraph 15.5 of Part 15 (*Additional Information*). Manus Rogan 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 interests that he holds in Fountain Healthcare Partners Fund 1 L.P..

(c) As at the close of business on the Latest Practicable Date, the Directors had no interests in Share Options in the Company, save as disclosed in sub-paragraph (e) below.

(d) As at close of business on the Latest Practicable Date, the Senior Managers had no interests in Ordinary Shares in the Company, save as disclosed in sub-paragraph (e) below.

(e) Details of options over Ordinary Shares 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 under the 2014 Share Option Plan. As at the Latest Practicable Date, the Directors and Senior Managers held the following options over Ordinary Shares:

Option Holder	*Deemed date of grant*	*No. of Ordinary Shares under option*	*Exercise price per Ordinary Share ($)*	*Expiry date*
Peter Crosby	23 January 2013	75,000	1.00	10 years from vesting
Oern Stuge	23 January 2013	55,014	1.00	10 years from vesting
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	27 July 2010	22,500	0.80	10 years from vesting
Jan Pieter Heemels	23 January 2013	17,500	1.00	10 years from vesting
Jan Pieter Heemels	11 January 2011	360	0.80	10 years from vesting
Jan Pieter Heemels	13 July 2011	1,600	0.80	10 years from vesting
Jan Pieter Heemels	4 December 2011	12,500	0.80	10 years from vesting
Hugh Kavanagh	23 January 2013	2,000	1.00	10 years from vesting
Hugh Kavanagh	3 October 2013	13,000	1.00	10 years from vesting
Dr Kristen Jaax	13 November 2013	15,000	1.00	10 years from vesting
David Brabazon	5 December 2013	18,427	1.00	10 years from vesting

(f) Save as set out in this paragraph 9.4 of Part 9 (Directors, Senior Management and Corporate Governance), no Director or Senior Manager (nor any connected Persons) has any interest whether beneficial or non-beneficial in the Existing Issued Share Capital of the Company or any of its subsidiaries.

9.5 LOCK-UP ARRANGEMENTS

Each of the Shareholders at the date of this Prospectus, the Directors holding Ordinary Shares or Share Options as at the date of this Prospectus and the Senior Managers has agreed that, subject to certain customary exceptions, they will not dispose of any Ordinary Shares (other than Ordinary Shares subscribed for by these parties under the Offer) for a period of 365 days from the date of ESM Admission. Further details of these arrangements are described in paragraph 15.13.5 of Part 15 (*Additional Information*).

9.6 DIRECTORS' AND SENIOR MANAGERS REMUNERATION

The following table shows the amount of remuneration paid 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 2013:

Directors	*Fees*	*Salary*	*Other Payments*	*Benefits in Kind*	*Pension*	*Total*
Oern Stuge MD (Note 1 and 2)	$51,258	–	–	–	–	$51,258
Antoine Papiernik	–	–	–	–	–	NIL
Peter Crosby	–	$400,207	–	$27,601	–	$427,808
Manus Rogan PhD	–	–	–	–	–	NIL
Dan Sachs MD	–	$12,000	–	$21,259	–	$33,259
David Brabazon (Note 3)	–	–	–	–	–	NIL

Notes:

1. The Group makes payments under a consultancy agreement to ORSCO Life Sciences AG, a Swiss company which is controlled by Oern Stuge. Details of payment to ORSCO Life Sciences AG are included in paragraph 15.11 of Part 15 (*Additional Information*).
2. Oern Stuge was granted 55,014 options over Ordinary Shares in the Company to be held subject to the rules of the 2014 Share Option Plan.
3. David Brabazon was granted 18,427 options over Ordinary Shares in the Company to be held subject to the rules of the 2014 Share Option Plan.

The aggregate amount of remuneration paid (including any contingent or deferred compensation) and benefits in kind granted to Senior Managers (including payments to companies controlled by them) who held office during the year ended 31 December 2013 for services in all capacities to the Company was $1,064,318.

9.7 2014 SHARE OPTION PLAN

Upon completion of the 2014 Corporate Reorganisation, the 2014 Share Option Plan (the "**2014 Share Option Plan**") was adopted by the Company on substantially the same terms as the 2012 share option plan of MML. Furthermore, under the terms of the Re-organisation Agreement, the Company issued options to subscribe for Ordinary Shares (on a 1 for 20 basis) to each of the persons who had previously held options over common stock in MMI and/or ordinary shares in MML in substitution for and in replacement of the options previously held by them.

The following is a summary of the key terms of the 2014 Share Option 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 options over the Ordinary Shares. The 2014 Share Option Plan shall be administered by the Board such that all determinations and other decisions with respect to the 2014 Share Option Plan shall be made at the sole discretion of the Board.

Grant of Options

The 2014 Share Option Plan shall be effective on the date on which it is adopted by the Board and options over Ordinary Shares may be granted under the 2014 Share Option Plan at any time until the termination of the 2014 Share Option Plan.

Duration of Options

Options over Ordinary Shares granted under the 2014 Share Option 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 an 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.

Vesting of Options

No option will be exercisable until it has vested and the Board may specify the vesting conditions for each option 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 option which has not otherwise become exercisable in accordance with the vesting conditions established for such option.

Share Limits

Subject to variation due to changes in the capital structure, the number of Ordinary Shares in respect of which options may be granted shall not exceed 794,734 Ordinary Shares.

Leavers

Death

On the death of an option holder, the option holder's unvested options will lapse. However, the deceased option holder's vested options will remain exercisable by his legal personal representative for a period of 12 months following the option holder's death (subject to any earlier expiration of the options).

Retirement

On the retirement of an option holder, his unvested options will lapse. However, if the option holder's options have vested by the time the option holder retires, then, the vested options will remain exercisable at any time for the following 12 months (subject to any earlier expiration of the options).

Cessation of Employment

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

In circumstances where an option holder ceases to be an employee other than those mentioned above, the option holder's unvested options will lapse. However, if the option holder's options have vested prior to the termination of the option holder's employment then, the vested options will remain exercisable at any time for the following 12 months (subject to any earlier expiration of the options).

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 options. The Board may, for instance, determine that some or all of the unvested options 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 option or, in the event of a winding-up of the Company, an option holder may exercise any vested option, subject to any conditions or limitations as the Board may, at its discretion, impose.

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 2014 Share Option Plan, (ii) adjust the number of shares subject to any option or to be allotted following exercise of any option, and (iii) adjust the exercise price applicable to any option.

As a condition precedent to the allotment of options, the Board shall be entitled to require the participant to become a party to any shareholders 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 2014 Share Option Plan provided always that no such alteration, amendment or revocation shall increase the amount payable by any option holder or otherwise impose more onerous obligations on any option holder in respect of the exercise of an option which has already been granted.

The 2014 Share Option Plan shall terminate on the tenth anniversary of its adoption.

9.8 CHIEF EXECUTIVE OFFICER'S SERVICE AGREEMENTS AND NON-EXECUTIVE DIRECTORS LETTERS OF APPOINTMENT

9.8.1 ***Chief Executive Officer***

The Chief Executive Officer of the Group, Peter Crosby (the "**CEO**"), is employed under two service agreements with two companies in the Group, MMLUS and the Company.

The terms of the CEO's employment are as set out below (split by reference to the relevant company in the Group):

Employing Entity	*Contract Date*	*Basic Salary*	*Notice Period*
Mainstay Medical International plc	7 April 2014 **Note:** The Chief Executive Officer has continuity of service with both companies since 1 February 2013	€198,000 With target bonus equal to 35% of base salary	6 months (save in cases of breach/misconduct etc.)
MML US, Inc.	2 April 2014 **Note:** The Chief Executive Officer has continuity of service with both companies since 1 February 2013	$182,000 With target bonus equal to 35% of base salary	Simultaneous with the contract with the Company

(a) *Benefits*

Under the terms of the service agreements, the CEO has an annual performance target bonus of 35 per cent. of base salary under each service agreement, subject to the achievement of agreed milestones. This benefit is expressed to be discretionary and subject to amendment or withdrawal at the instance of the Board at any time.

Under the terms of the service agreements, the CEO is entitled to join any occupational pension scheme (in the case of the Company) or 401(k) plan (in the case of MMLUS), which the employing company may establish. There is no contractually provided employer pension contribution and the Company has established no such scheme.

Under the terms of the service agreements, the CEO is entitled to certain benefits including health insurance, life assurance, income continuance cover, share options, payment of professional subscriptions up to an agreed amount and reimbursement of cost of personal tax advice up to an agreed amount. The CEO is also entitled to reimbursement of "out-of-pocket" relocation expenses to the US arising within six months of the termination of his service agreement with the Company.

The Chief Executive Officer is entitled to participate in the 2014 Share Option Plan and holds 75,000 options under this contract with the Company.

(b) *Termination Provisions*

The service agreement that the CEO has entered into with the Company provides for a mutual notice period of twelve months, payment in lieu of notice and gardening leave, (the period of time where an employee is salaried but does not come to work) and for retirement at the age of 65. The services agreement that the CEO has entered into with MMLUS provides that should his employment with the Company terminate for any reason, then his employment with MMLUS shall also terminate. On such a termination, the conditions of such termination shall be governed by his service agreement with the Company.

(c) *Restrictive Covenants*

Each of the CEO's service agreements with the Company and MMLUS incorporate restrictive covenants for non-competition, non-solicitation of certain customers, non-solicitation of certain employees and non-interference with certain suppliers, each applying for 12 months post-termination plus up to six months of any period of garden leave.

(d) *Change in Control*

Under the terms of the service agreements with the Company, following a "**Change in Control**" (defined below) of the Company, all outstanding share options that the CEO may have shall immediately vest if: (i) the CEO's employment is terminated for any reason other than breach/misconduct etc.; (ii) the CEO resigns for "good reason" (including material changes to duties, cumulative reduction in base salary of greater than 10 per cent., refusal to move office more than 30 miles from MML's then offices or a material breach by the Company of the contract); or (iii) if the CEO remains an employee six months following the change in control of the Company.

Under the service agreement between the CEO and the Company, "**Change in 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, immediately after such Merger, directly or indirectly, more than 50 per cent. 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 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 the Company.

9.8.2 ***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 five Non-Executive Directors. The terms of the Non-Executive Directors' letters of appointment can be summarised as follows:

Name	*Title*	*Appointment date*[1]	*Fee per annum*	*Initial term of appointment*	*Notice period*
Oern Stuge MD	Non-Executive Independent Chairman	3 April 2014	CHF 40,000	12 Months	1 Month
Antoine Papiernik	Non-Executive Director	3 April 2014	NIL	12 Months	1 Month
Manus Rogan PhD	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	Non-Executive Independent Director	3 April 2014	U.S.$20,000	12 Months	1 Month

Note:

(1) Each of the Non-Executive Directors were appointed to the board of directors of MML on the following dates: Oern Stuge MD was appointed on 23 January 2013, Antoine Papiernik was appointed on 2 August 2012, Manus Rogan PhD was appointed on 25 September 2012, Dan Sachs MD was appointed on 25 September 2012 and David Brabazon was

appointed on 5 December 2013. Each of these Non-Executive Directors resigned from the board of directors of MML on 3 April 2014.

(2) The Group makes payments under a consultancy agreement to ORSCO Life Sciences AG, a Swiss company which is controlled by Oern Stuge. Details of payment to ORSCO Life Sciences AG are included in paragraph 15.11 of Part 15 (*Additional Information*).

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

By resolution of the board of directors of MML on 23 January 2013, Oern Stuge MD was granted, subject to the rules of the 2012 share option plan of MML, options over 1,100,293 ordinary shares in MML. As part of the 2014 Corporate Reorganisation, these options were replaced by 55,014 options over Ordinary Shares in the Company to be held subject to the rules of the 2014 Share Option Plan as described in paragraph 9.6 of this Part 9 (*Directors, Senior Management and Corporate Governance*).

Under his letter of appointment dated 5 December 2013, David Brabazon was granted, subject to the rules of the 2012 share option plan of MML, options over 368,551 ordinary shares in MML. As part of the 2014 Corporate Reorganisation, these options were replaced by 18,427 options over Ordinary Shares in the Company to be held subject to the rules of the 2014 Share Option Plan as described in paragraph 9.6 of this Part 9 (*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) and the letter of appointment (in respect of David Brabazon's appointment as Director of the Company) ("**Letters of Appointment**") 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 options 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 50 per cent. 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 the ESM and Euronext Paris as contemplated by this Prospectus, the Offer or 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.

9.9 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 Prospectus. 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	05 May 03	Current
CoAxia, Inc.	U.S.	19 June 09	Current
Entourage Medical Technologies, Inc.	U.S.	13 January 10	Current
Mainstay Medical, Inc.	U.S.	13 July 10	Current
Mainstay Medical Limited	Ireland	25 September 2012	3 April 2014
MD Start I KG	Switzerland	26 August 08	Current
ReCor Medical, Inc.	U.S.	30 September 09	Current
Stentys SA	France	29 September 06	Current
Auris Medical AG	Switzerland	04 April 13	Current
Shockwave Medical, Inc.	U.S.	03 July 13	Current
Pixium Vision SA	France	13 November 13	Current
Corwave SA	France	17 December 13	Current
CoreValve, Inc.	U.S.	11 September 06	31 March 09
Lectus Therapeutics Limited	UK	20 December 05	30 December 11
Movetis NV	Belgium	15 December 06	12 October 10
Pro-Med AG	Austria	06 March 02	30 September 11
Diatos SA	France	27 September 99	18 May 09
Fovea Pharmaceuticals SA	France	28 October 05	30 October 09
Addex Pharmaceuticals SA	Switzerland	10 June 03	19 March 13
E.O.S spa	Italy	09 June 06	20 November 13

Dan Sachs MD

Company	*Where*	*Start Date*	*End Date*
Kspine, Inc.	U.S.	27 June 2007	Current
Mainstay Medical, Inc.	U.S.	8 July 2008	Current
Mainstay Medical Limited	Ireland	25 September 2012	3 April 2014
Amphora Medical, Inc.	U.S.	31 December 2011	Current
Kenwood Medical Devices LLC	U.S.	31 December 2011	Current
Neuronetics, Inc.	U.S.	3 April 2003	29 April 2013
Respicardia, Inc.	U.S.	4 April 2006	1 Oct 2008

Manus Rogan PhD

Company	*Where*	*Start Date*	*End Date*
Mainstay Medical, Inc.	U.S.	25 September 2012	3 April 2014
Mainstay Medical Limited	Ireland	25 September 2012	Current
Amarin Corp	Ireland	October 2009	December 2011
Amarin Pharmaceuticals Ltd	Ireland	October 2009	December 2011
Opsona Therapeutics Ltd	Ireland	December 2008	Current
Opsona Research Ltd	Ireland	December 2008	Current
Irish Venture Capital Association Ltd	Ireland	June 2009	Current
Fountain Healthcare Partners Ltd	Ireland	March 2005	Current

David Brabazon

Company	*Where*	*Start Date*	*End Date*
Mainstay Medical Limited	Ireland	5 December 2013	3 April 2014
Headway (Ireland) Limited	Ireland	5 July 2012	Current
Drand Limited	Ireland	28 November 2011	Current
Adapt Pharma Limited	Ireland	31 October 2013	Current
Adapt Pharma Operations Limited	Ireland	11 November 2013	Current
Adapt Pharma, Inc.	U.S.	8 November 2013	Current
Jaguar Merger Sub, Inc.	U.S.	13 September 2011	18 January 2012
Azur Pharma, Inc.	U.S.	7 February 2006	18 January 2012
Jazz Pharmaceuticals Ireland Limited	Ireland	16 November 2006	30 September 2012
Jazz Pharmaceuticals International Limited	Bermuda	11 January 2006	28 September 2012
Jazz Pharmaceuticals International II Limited	Bermuda	27 November 2006	28 September 2012
Jazz Pharmaceuticals International III Limited	Bermuda	17 May 2007	28 September 2012

Oern Stuge MD

Company	*Where*	*Start Date*	*End Date*
ORSCO Life Sciences AG	Switzerland	2011	Current
Mainstay Medical Limited	Ireland	January 2013	3 April 2014
Phagenesis Ltd.	UK	February 2013	Current
Nobel Biocare AG	Switzerland	2010	Current
Aleva Neurotherapeutics SA	Switzerland	2011	Current
Acarix SA	Denmark	2011	Current
Bonesupport AB	Sweden	2010	Current
Pulmonix International SA	Switzerland	Oct 2013	Current
Qforma, Inc.	U.S.	February 2013	October 2013
Dacadoo AG	Switzerland	2010	20 March 2014
Advanced Cardiac Therapeutics, Inc	U.S.	2011	2013
Systagenix	UK	2011	2013
Mediq NV	Netherlands	2009	2013
Impulse Dynamics NV	Netherlands Antilles	2011	2012
Eucomed	Belgium	2007	2009

Peter Crosby

Company	*Where*	*Start Date*	*End Date*
Mainstay Medical Limited	Ireland	25 September 2012	Current
Mainstay Medical, Inc.	U.S.	14 July 2010	Current
MML US, Inc.	U.S.	October 2012	Current
Mainstay Medical (Australia) Pty. Limited	Australia	31 May 2013	Current
Ventracor Limited (and subsidiaries)	Australia	July 2006	April 2009

Peter Crosby was associated with receivership of Ventracor Limited in Australia in 2009. Mr Crosby was CEO and Managing Director of Ventracor Limited, an Australian public company (and its subsidiaries in Europe and the U.S.) developing and commercialising a Left Ventricular Assist Device (LVAD). Ventracor Limited was placed into administration in early 2009 following its inability to raise capital to fund continued operations as a consequence of the global financial crisis in 2008.

Other than as set out in this paragraph 9.9 of Part 9 (*Directors, Senior Management and Corporate Governance*), within the period of 5 years preceding the date of this Prospectus, none of the Directors or Senior Managers have:

(a) any unspent convictions in relation to indictable 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 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 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) or have 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; 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.

9.10 CORPORATE GOVERNANCE AND BOARD PRACTICES

9.10.1 ***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 Prospectus, there is no specific corporate governance regime mandated in Ireland for companies listed on ESM (whether or not such companies are listed on a regulated market in another country), the Company supports the corporate governance principles of the QCA Corporate Governance Code for Small and Mid-Size Quoted Companies and will seek to apply these 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.

9.10.2 ***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.

On ESM Admission, the Board will comprise six Directors, including one executive Director, four Non-Executive Directors and the Chairman. The roles of chairman and chief executive are not exercised by the same individual. The Company intends to appoint an additional independent Non-Executive Director within 12 months of ESM Admission.

Notwithstanding Dr. Oern Stuge's relationship with the Company, and the fact that he was previously granted Share Options as disclosed in paragraph 9.8.2 of this Part 9 (*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 9.8.2 of this Part 9 (*Directors, Senior Management and Corporate Governance*), the Board considers him to be independent.

The Board meets regularly to consider strategy, performance and the framework of internal controls and, following ESM Admission, will meet no less than four times per year. 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 of Directors 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.

All the Directors bring independent judgement to bear on issues affecting the Group and all have full and timely access to information necessary to enable them to discharge their duties. Non-Executive Directors are appointed for a term of three years. Accordingly, every Director will be subject to re-election at least every three years.

9.10.3 ***Board Committees of the Company***

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

Audit, Risk and Compliance Committee – Mr. David Brabazon (*Chairman*), Dr. Manus Rogan, Mr Antoine Papiernik and Dr. Oern Stuge

Nominations Committee – Dr. Oern Stuge (*Chairman*), Dr. Manus Rogan, Mr. David Brabazon and Mr Antoine Papiernik

Remuneration Committee – Mr. David Brabazon (*Chairman*), Mr. Antoine Papiernik, Dr. Manus Rogan and Dr. Oern Stuge

Audit, Risk and Compliance Committee

The Audit, Risk and Compliance Committee will be chaired by Mr. David Brabazon. The chief financial officer may also be invited to attend meetings of the committee. It will meet at least three times a year and will be responsible for ensuring that the financial performance of the Group is properly monitored and reported on. The committee will also meet with and review findings of the audit with the external auditor. It will meet with the auditors at least once a year without any members of the management being present and will also be responsible for considering and making recommendations regarding the identity and remuneration of such auditors.

Remuneration Committee

The Remuneration Committee will be chaired by Mr. David Brabazon. It will meet at least three times a year and will consider and recommend 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 will, consider and recommend to the Board the total individual remuneration package of each executive Director including bonuses, incentive payments and share awards. It will review the design of all incentive plans for approval by the Board and (if required) Shareholders and, for each such plan, recommend 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. No Director will be involved in decisions concerning his/her own remuneration.

Nominations Committee

The Nominations Committee will be chaired by Dr. Oern Stuge. It will meet at least two times a year and will consider the selection and re-appointment of Directors. It will identify and nominate candidates for all Board vacancies and review regularly the structure, size and composition (including the skills, knowledge and experience) of the Board and make recommendations to the Board with regard to any changes.

9.10.4 ***Internal controls***

The Board acknowledges that it is responsible for maintaining the Company's system of internal control and risk management process 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.

9.10.5 ***Directors' share dealing***

The Directors intend to comply with Rule 21 of the ESM Rules relating to share dealings by Directors, and will take all reasonable steps to ensure compliance with ESM Rule 21 by the Group's Applicable Employees. The Company has adopted a share dealing code for the Directors, officers and employees of the Group to facilitate compliance with Rule 21 and any applicable securities legislation with effect from ESM Admission.

PART 10

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 Part 12 (*Historical Financial Information*) of this Prospectus. Certain statements in this Part are forward-looking and should be read in conjunction with Part 3 (*Important Information*). The Group's consolidated 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.

10.1 Overview

The Group is a medical device group founded in 2008, which is developing innovative neurostimulation therapies for the population of people with debilitating Chronic Low Back Pain. It is focused on the development and commercialisation of an active implantable medical device (AIMD) designed to treat people with Chronic Low Back Pain. The Group is committed to fully exploiting its proprietary technology, to develop, obtain regulatory approval and bring to market its ReActiv8 product. The Group has completed engineering development of ReActiv8, which is ready for use in human clinical trials that are starting in Australia. To date the Group has not generated revenue from its operations.

The Group originally commenced its business and trade in the United States through a U.S. registered corporation, Mainstay Medical, Inc. ("**MMI**"). MMI was formed in 2008 in Minneapolis, Minnesota, United States. In 2012, Mainstay Medical Limited ("**MML**"), an Irish registered company based in Dublin was formed and in September 2012, MML took over operation and control of MMI's business by issuing shares to MMI in return for the contribution of substantially all of its business at that time. MML continues to have a presence in Minneapolis through its US subsidiary MML US, Inc. ("**MMLUS**"). After the formation of MMLUS in 2012, the employees of MMI transferred to MMLUS. MMLUS provides research and development services to MML. In May 2013, MML established a wholly owned Australian subsidiary, Mainstay Medical (Australia) Pty Limited ("**MMA**"). The initial focus for MMA is the management of human clinical trials taking place in Australia. The Company became the ultimate holding company of the Group following the 2014 Corporate Reorganisation on 3 April 2014. Mainstay Medical International plc has no trading history as a newly incorporated entity. The Company, MML, MMLUS and MMA now form the Group.

The introduction of MML as a new holding company for the Group in September 2012 has been accounted for as a continuation of the business previously carried out by MMI. Consequently, even though MML was only formed during 2012 and was not a Group company prior to this, the disclosures in the financial information for periods prior to August 2012 are those relating to the operations of MMI. Further details are outlined in Note 3 to the consolidated financial information (see paragraph 12.1.B of Part 12 (*Historical Financial Information*).

The majority of the Group's expenditure is in U.S Dollar and accordingly, for accounting purposes, the Group uses U.S Dollars as its functional currency.

Through to 31 December 2013, the Group has funded its operations through the proceeds of two funding rounds amounting in aggregate to $26.3 million:

- MMI raised the Series A Financing of $6.1 million, which closed in July 2010. The Series A Financing was received in tranches through 2010 and 2011; and
- MML raised the Series B Financing of $20 million from venture capital and corporate sources which closed in September 2012. A further $0.2 million of Series B funding was received in July 2013.

For the three years ended 31 December 2013, the Group had a total spend on operating activities of $16.1 million (this excludes the non-cash accounting charge of $0.5 million for share based compensation, which is included in "Operating Expenses" and includes spend of approximately $7.8 million on research and development and quality (48 per cent.), $3.3 million on clinical and regulatory (21 per cent.), and $5.0 million on general and administrative expenses including commercial activities (31 per cent.). At 31 December 2013, the Group held $9.6 million in cash.

The Group's strategy is to outsource manufacturing of its products and accordingly the Group has not invested in manufacturing facilities or equipment; similarly the Group leases or licenses its office facilities using operating leases that have not been capitalised. Consequently the main asset on the Group's statement of financial position is cash.

10.2 Factors affecting the results of operations

10.2.1 *Revenue*

The success in obtaining regulatory approvals for the commercialisation of Reactiv8, the Group's first product, is uncertain and the Group expects to continue to incur operating losses in the foreseeable future as it continues its research and development work and undertakes clinical trial activities with a view to obtaining regulatory approvals for its product. At the date of this Prospectus, the Group cannot precisely estimate the timing and costs of the efforts that will be necessary to continue development, to undertake human clinical trials and to obtain regulatory approval of Reactiv8. It is also unable to predict when material cash inflows will commence from sales of Reactiv8. Set forth below is a discussion of the main factors that the Company believes will materially impact the Group's results in future periods.

10.2.2 *Operating expenses*

The Group's operating expenses are detailed further below, line item by line item, from its statement of profit or loss and other comprehensive income.

10.2.1.1 *Research and development expenses*

The Group's research and development expenses reflect costs incurred for research and development and design of the Group's first product ReActiv8, including the salaries of engineers, technicians, quality and regulatory specialists; the cost of outsourced development and manufacturing activities relating to the various components of ReActiv8, including the implantable pulse generator (IPG), the leads and the external programmer and activator; biocompatibility and pre-clinical studies; and quality costs including the set-up and maintenance of the Group's quality system. Research and development expenses also include the costs of prosecuting and maintaining the Group's intellectual property portfolio, including legal costs and associated filing and maintenance fees (for a presentation of the Group's existing intellectual property portfolio, see paragraph 8.12 of Part 8 (*Information on the Company*)).

The Group expenses all research and development costs as they are incurred and has consequently not capitalised any such expenses to date. Management determines at each reporting date whether the conditions for recognising development costs are met, depending on the factors at that time. The Group plans to continue to fund its research and development at a level broadly consistent with its 2013 expenses to complete work on the manufacturing validation of ReActiv8 and to fund research and development on future products and product development.

10.2.1.2 *Clinical and regulatory expenses*

The Group's clinical and regulatory expenses are related to clinical trials and regulatory approvals, and include consulting costs for these activities. These include the cost of a Feasibility Study initiated in 2011 and continued into 2012; clinical consulting; regulatory consulting; and, more recently, salary costs for clinical specialists as the Group begins human

clinical trials with its ReActiv8. All clinical and regulatory costs are expensed as incurred. To date, the Group has not capitalised any of such costs. The Group may review this practice in the future depending on the outcome of future clinical trials and may if appropriate capitalise some or all of these costs in the future where they meet the specific accounting criteria for capitalisation.

The Group expects clinical and regulatory expenses to increase significantly as the Group prepares for and initiates human clinical trials with ReActiv8.

10.2.1.3 *General and administrative expenses*

The Group's general and administration expenses consist of salaries and other related costs for personnel in executive, finance and commercial functions. It also includes the professional fees for accounting, audit and legal services; general and facilities costs such as rent, insurances and IT costs; and commercial costs which consist primarily of consulting and related costs. Commercial activities are focused on the development of the Group's commercial strategy and on planning and managing the process to obtain reimbursement for the Group's products after regulatory approvals have been obtained and the products are available to be sold commercially. General and administrative expenses are expected to increase with the expansion of the Group's resources to include new personnel responsible for accounting and administration, as well as an increase in other professional fees associated with meeting the responsibilities related to being a public company. Commercial operations expenses will increase in preparation for a commercial launch of ReActiv8.

10.2.1.4 *Share-based compensation expenses*

At the date of this Prospectus, the Group operates the 2014 Share Option Plan, which allows the Group to grant share options to employees of Group companies, Directors and consultants. Share based compensation is a non-cash expense as all share options are to be settled through the physical delivery of shares. There will be an ongoing requirement to account for share based compensation in accordance with IFRS 2.

10.2.1.5 *Finance income*

Preference shares issued by the members of the Group have conversion and other rights that give rise to a requirement under IFRS to account for these shares either in part or in full as derivatives. Under IFRS derivatives are accounted for at fair value on a continuous basis. The main components of finance income are the fair value gains on these derivative financial instruments. These fair value entries have no cash impact. Shortly before ESM Admission, existing preference shares in the Company will convert into Ordinary Shares and these derivative instruments will cease to exist and the related fair value adjustments giving rise to this financial income will be eliminated. The other components of financial income are exchange gains and interest income.

10.2.1.6 *Finance expense*

Finance expense includes interest charges on a $2 million loan advanced in 2011 from Silicon Valley Bank, and accrued dividends on convertible redeemable preference shares of the Company that are classified as debt in accordance with IFRS. The balance of the Silicon Valley Bank loan was repaid on 7 March 2014 and consequently the related interest charges ceased from that date. Shortly before ESM Admission, existing preference shares in the Company will convert into Ordinary Shares and this will eliminate the requirement to accrue for future preference share dividends.

10.2.1.7 *Income Taxes*

Since its establishment in 2012, MML has not made profits and has not paid corporate taxes. MMLUS provides services to MML on a "cost plus basis" and consequently generates profits

that are subject to corporation tax in the US. The estimated amount of this tax cost is provided for in the financial statements.

The accumulated consolidated taxable losses in MML to 31 December 2013 amount to $14 million. These losses can be used to offset future profits. However, no deferred tax assets have been recorded to date in relation to accumulated consolidated tax losses because of the development stage of the Group and the lack of certainty that the Group will generate taxable profits in the future.

10.3 Analysis of the consolidated statement of comprehensive income

The Group has not yet generated revenue. The following table includes information relating to the Group's consolidated statement of profit or loss and other comprehensive income for the years ended 31 December 2013, 2012 and 2011.

	For the year ended 31 December		
($'000)	*2013*	*2012*	*2011*
Revenue	–	–	–
Operating expenses	(8,396)	(5,295)	(2,911)
Operating loss	(8,396)	(5,295)	(2,911)
Finance income	821	319	9
Finance expense	(2,711)	(937)	(339)
Net finance expense	(1,890)	(618)	(330)
Loss before income taxes	(10,286)	(5,913)	(3,241)
Income taxes	(32)	30	–
Loss for the year and comprehensive loss for the year	(10,318)	(5,883)	(3,241)

10.3.1 ***Operating expenses***

The following table provides analysis of the Group's operating expenses and further detail on each of the heading in the table is provided in the commentary below:

	For the year ended 31 December		
($'000)	*2013*	*2012*	*2011*
Research and development expenses	3,980	2,432	1,389
Clinical and regulatory expenses	945	1,574	754
General and administration expenses	3,041	1,281	679
Share-based compensation expenses	430	8	89
Total operating expenses	8,396	5,295	2,911

10.3.1.1 *Research and Development expenses*

The Group's research and development expenses reflect costs incurred for research and development and design of the Group's first product ReActiv8. ReActiv8 is comprised of a number of components including the implantable pulse generator, leads and the external programmer and activator. The Group expenses all research and development costs as they are incurred and has consequently not capitalised any such expenses to date.

The Group's research and development expenses increased from $1.4 million in 2011 to $2.4 million in 2012 and $4.0 million in 2013. Following the closing of the Series B Financing in September 2012, the Group accelerated development of ReActiv8. The increase of $1.0 million in expenses in 2012 reflected this increase in activity in the latter part of 2012

associated with the ramp-up of design activity on ReActiv8 based on experience gained in the European Feasibility Study. In 2013 the higher level of research and development activity associated with the development work on ReActiv8 continued throughout the year and gave rise to the increase in 2013 research and development expenses of $1.5 million i.e. the increase reflected the cost of a full year's expenses at the higher run-rate as compared to 2012, when the ramp up in activity was only for the latter part of the year. In 2011, the number of employees and contractors dedicated to research and development and quality was 3, by the end of 2012 this number was 7, and 8 at the end of 2013.

10.3.1.2 *Clinical and Regulatory expenses*

In 2013, clinical and regulatory expenses for the Group were $0.9 million, a decrease of $0.7 million from $1.6 million in 2012, and 2012 clinical and regulatory expenses increased by $0.8 million from $0.8 million in 2011. In 2011 the Group commenced a Feasibility Study, that continued into 2012. The increase in 2012 related mainly to the cost of this Feasibility Study, for which much of the cost was incurred in 2012. The decrease of $0.7 million in 2013 reflected the lower level of clinical activity following the conclusion of the Feasibility Study.

Clinical and regulatory expenses are anticipated to increase significantly in future years as the Group plans to carry out further clinical trials with its ReActiv8.

10.3.1.3 *General and Administrative expenses*

General and administrative expenses for the Group (including commercial costs) increased from $0.7 million in 2011 to $1.3 million in 2012 and to $3 million in 2013. The increase in general and administrative expenses of $0.6 million in 2012 is explained by fees associated with the Group restructuring and relocation to Ireland and financing efforts in 2012. The increase of $1.7 million in 2013 related to a number of factors including the addition of resources in the executive and finance functions in MML and in the new Australian subsidiary, increased facilities costs, additional professional and board related costs, and commercial operations expenses. 2013 was the first year in which there was significant expenditure on commercial operations ($0.6 million). These expenses consisted mainly of consulting and related costs and were associated with the development, commercial and reimbursement strategies of the Group.

10.3.1.4 *Share-based compensation expenses*

Share based compensation, which is accounted for in accordance with IFRS2, is a non-cash expense related to share options and warrants granted by members of the Group. This expense reduced marginally from $0.09 million in 2011 to $0.008 million in 2012 and increased by $0.4 million to $0.4 million in 2013. The increase in this non-cash expense in 2013 relates to share options granted under the 2012 share option plan of MML.

10.3.2 ***Operating loss***

As a result of the foregoing, the consolidated operating loss of the Group before finance income and expense and taxes was $8.4 million in 2013, $5.3 million in 2012, and $2.9 million in 2011.

10.3.3 ***Finance income***

Preference shares issued by the members of the Group have conversion and other rights that give rise to a requirement under IFRS to account for these shares either in part or in full as derivatives. Under IFRS derivatives are accounted for at fair value on a continuous basis. The main components of finance income are the fair value gains on these derivative financial instruments. These fair value entries have no cash impact. Finance income was $0.8 million in 2013, an increase of $0.5 million from $0.3 million in 2012, which in turn was $0.3 million higher than the 2011 amount of $0.01 million. The increases in both 2012 and 2013 mainly reflected the fair value gain on derivative

financial instruments, i.e. that portion of the Group's various share issuances that are accounted for as derivative financial instruments.

10.3.4 ***Finance expense***

Finance expense was $2.7 million in 2013, $0.9 million in 2012 and $0.3 million in 2011. The increase of $1.8 million in 2013 is driven by the non-cash finance expense related to preference shares and the increase of $0.6 million in 2012 is driven both by the non-cash finance expense related to preference shares and interest paid on a $2 million loan advanced by Silicon Valley Bank in 2011.

10.3.5 ***Net finance expense***

The net finance expense is a sub-total which includes the previous headings finance income and finance expense.

10.3.6 ***Loss before income taxes***

Loss before income taxes comprises (i) operating expenses, which is discussed in detail at paragraph 10.3.1, (ii) finance income, which is discussed in detail at paragraph 10.3.3, and (iii) finance expense, which is discussed in detail at paragraph 10.3.4. The Group's loss before income taxes was $10.3 million in 2013, $5.9 million in 2012, and $3.2 million in 2011.

10.3.7 ***Income taxes***

Income taxes were $(0.03) million in 2013 a decrease of $0.06 million related to research and development tax credits of $0.03 million in 2012 and with a charge of $nil recorded in 2011.

10.3.8 ***Loss for the year and comprehensive loss for the year***

As a result of the foregoing, the Group's consolidated losses were $10.3 million in 2013, $5.9 million in 2012, and $3.2 million in 2011.

10.4 Analysis of the consolidated statement of financial position

The table below sets forth the consolidated balance sheet of the Group as at 31 December 2013, 2012 and 2011.

	As at 31 December		
($'000)	*2013*	*2012*	*2011*
Non-current assets			
Property, plant and equipment	68	66	32
Current assets			
Prepayments and other receivables	385	187	41
Cash and cash equivalents	9,590	17,370	4,364
Total current assets	9,975	17,557	4,405
Total assets	10,043	17,623	4,437
Equity			
Share capital	1	1	2
Share premium	250	250	–
Share based payment reserve	534	104	96
Reorganisation reserve	(9,609)	(9,609)	–
Retained loss	(13,146)	(2,828)	(5,901)
Deficit on shareholders' equity	(21,970)	(12,082)	(5,803)
Non-current liabilities			
Preference shares	24,965	22,235	5,136
Derivative financial instruments	4,622	5,393	2,730
Deferred tax	96	–	–
Loans and borrowings	–	800	1,579
Total non-current liabilities	29,683	28,428	9,445
Current liabilities			
Loans and borrowings	785	768	367
Trade and other payables	1,545	509	428
Total current liabilities	2,330	1,277	795
Total liabilities	32,013	29,705	10,240
Total equity and liabilities	10,043	17,623	4,437

10.4.1 ***Property, plant and equipment***

Property, plant and equipment was $0.07 million as at 31 December 2013, $0.07 million as at 31 December 2012 and $0.03 million as at 31 December 2011. The Group's strategy is to outsource manufacturing of its products and accordingly the Group has not invested in manufacturing facilities or equipment. Similarly, as the Group leases or licenses its office facilities, these are operating leases and have not been capitalised. Consequently the increases in property, plant and equipment over the period are minimal.

10.4.2 ***Prepayments and other receivables***

Prepayments and other receivables were $0.4 million as at 31 December 2013, $0.2 million as at 31 December 2012 and $0.04 million as at 31 December 2011. The increase of $0.2 million in 2013 related mainly to an increase in income tax receivables associated with research and development tax credits and the associated increase in 2012 from 2011 was $0.15 million.

10.4.3 ***Cash and cash equivalents***

Cash and cash equivalents were $9.6 million as at 31 December 2013, $17.4 million as at 31 December 2012 and $4.4 million as at 31 December 2011. Movements in cash and cash equivalents can be seen in the consolidated cash flow statement at paragraph 10.5 of this Part 10 (*Operating and Financial Review*) below and further details of such movements are discussed in that section.

10.4.4 ***Share capital***

Most investments in the Group are in the form of preference shares, which will be converted into Ordinary Shares shortly before ESM Admission. The various classes of preference shares have conversion and other rights, which give rise to a requirement under IFRS to account for these shares as debt, with embedded derivatives treated separately for accounting purposes. Preference shares, accounted for as a non-current liability and derivative financial instruments are discussed in paragraphs 10.4.9 and 10.4.10 of this Part 10 (*Operating and Financial Review*).

10.4.5 ***Share premium***

Share premium was $0.25 million as at 31 December 2013, $0.25 million as at 31 December 2012 and nil as at 31 December 2011. Share premium was recognised as a result of the 2012 Corporate Reorganisation which occurred in September 2012, in which new MML shares were issued. The amount of share premium was unchanged between 31 December 2012 and 31 December 2013.

10.4.6 ***Share based payment reserve***

Share based payment reserve was $0.5 million as at 31 December 2013, $0.1 million as at 31 December 2012 and $0.1 million as at 31 December 2011. The increase of $0.4 million in 2013 and the minimal increase in 2012 reflected the non-cash share based compensation expense included in operating expenses in the respective years.

10.4.7 ***Reorganisation reserve***

The reorganisation reserve was ($9.6) million as at 31 December 2012, and 31 December 2013, and was nil as at 31 December 2011. The reorganisation reserve arose as a result of the 2012 Corporate Reorganisation, which took place in September 2012, and is broadly equivalent to the accumulated losses that had been incurred prior to the 2012 Corporate Reorganisation.

10.4.8 ***Retained losses***

Retained losses were ($13.1) million as at 31 December 2013, ($2.8) million as at 31 December 2012 and ($5.9) million as at 31 December 2011. The increase in retained losses of ($10.3) million in 2013 is detailed in the Group's consolidated statement of profit or loss and other comprehensive income at paragraph 10.3 of this Part 10 (*Operating and Financial Review*), and the decrease of $3.1 million from 31 December 2011 to 31 December 2012 reflected the net impact of the changes detailed in the Group's consolidated statement of profit or loss and other comprehensive income for 2012 and the accumulated losses incurred prior to the 2012 Corporate Reorganisation, which are now reflected in the reorganisation reserve.

10.4.9 ***Preference shares (Non-current liabilities)***

Preference shares have conversion and other rights which under IFRS require that they be accounted for in part as liabilities and in part as derivative financial instruments. The preference share amounts reflected as non-current liabilities as at 31 December 2013, 31 December 2012, and 31 December 2011 were $25.0 million, $22.2 million, and $5.1 million respectively. The main driver of the increases in preference shares of $17.1 million in 2012 was additional funding received from investors. Preference shares will convert to Ordinary Shares shortly before ESM Admission and this is expected to extinguish the preference share liabilities and associated derivatives in full.

10.4.10 ***Derivative financial instruments***

As previously noted preference shares have conversion and other rights which under IFRS require that they are accounted for in part as liabilities and in part as derivative financial instruments. The derivative financial instruments, associated with preference shares, were $4.6 million as at 31 December 2013, $5.4 million as at 31 December 2012, and $2.7 million as at 31 December 2011. As noted above, all issued preference shares in the Company will convert to Ordinary Shares shortly before ESM Admission.

10.4.11 ***Loans and borrowings***

Loans and borrowings categorised as non-current liabilities and as current liabilities both related to a loan advanced to the Group by Silicon Valley Bank. The following table details both the non-current liabilities and current liabilities portions of loans and borrowings.

	As at 31 December		
($'000)	*2013*	*2012*	*2011*
Loans and borrowings			
Non-current liabilities	–	800	1,579
Current liabilities	785	768	367
Total Loans and borrowings	785	1,568	1,946

A loan of $2.0 million was advanced by Silicon Valley Bank in 2011. The decrease of $0.4 million in 2012 and $0.8 million in 2013 related to repayments of this loan. On or around 7 March 2014, all outstanding amounts due and owing under the loan were repaid by MML to Silicon Valley Bank.

10.4.12 ***Trade and other payables***

Trade and other payables were $1.5 million as at 31 December 2013, $0.5 million as at 31 December 2012 and $0.4 million as at 31 December 2011. The increase of $1.0 million in 2013 and $0.1 million in 2012 included increases in accounts payable and accruals associated with increased levels of business activity.

10.5 Analysis of Cash flows

The following table sets forth the Group's consolidated cash flow statement for the years ended 31 December 2013, 2012 and 2011.

	For the year ended 31 December		
($'000)	*2013*	*2012*	*2011*
Cash flows from operating activities			
Net loss attributable to equity holders	(10,318)	(5,883)	(3,241)
Non-cash adjustments			
Depreciation	23	9	4
Net finance expense	1,890	618	330
Share-based compensation	430	8	20
Gain on sale of property, plant and equipment	–	–	2
Changes in working capital			
Prepayments and other receivables	(198)	(146)	(24)
Trade and other payables	1,148	18	320
Interest paid	(83)	(213)	(5)
Net cash used in operations	(7,108)	(5,589)	(2,594)

($'000)	For the year ended 31 December 2013	2012	2011
Cash flow from investing activities			
Proceeds on sale of equipment	–	–	5
Acquisition of property, plant and equipment	(25)	(43)	(31)
Net cash used in investing activities	(25)	(43)	(26)
Cash flows from financing activities			
Proceeds from issue of preferred shares (net)	153	19,038	2,428
Repayment of borrowings	(800)	(400)	–
Proceeds from new borrowings	–	–	2,000
Net cash (used in)/from financing	(647)	18,638	4,428
Net (decrease)/increase in cash and cash equivalents	(7,780)	13,006	1,808
Cash and cash equivalents at beginning of year	17,370	4,364	2,556
Cash and cash equivalents at end of year	9,590	17,370	4,364

10.5.1 ***Non-cash adjustments***

Non-cash adjustments, which include (i) depreciation (ii) net finance expense (iii) share-based compensation and (iv) gain on sale of property, plant and equipment, 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 net finance expense which is comprised of Finance Income and Finance Expense and Share-based compensation.

($'000)	For the year ended 31 December 2013	2012	2011
Finance income	(821)	(319)	(9)
Finance expense	2,711	937	339
Net finance expense	1,890	618	330

10.5.1.1 *Finance income*

Preference shares issued by the members of the Group have conversion and other rights that give rise to a requirement under IFRS to account for these shares either in part or in full as derivatives. Under IFRS derivatives are accounted for at fair value on a continuous basis. The main components of finance income are the fair value gains on these derivative financial instruments. These fair value entries have no cash impact. Finance income was $0.8 million in 2013, an increase of $0.5 million from $0.3 million in 2012, which in turn was $0.3 million higher than the 2011 amount of $0.01 million. The increases in both 2012 and 2013 mainly reflected the fair value gain on derivative financial instruments, i.e. that portion of the Group's various share issuances that are accounted for as derivative financial instruments.

10.5.1.2 *Finance expense*

Finance expense was $2.7 million in 2013, $0.9 million in 2012 and $0.3 million in 2011. The increase of $1.8 million in 2013, and the increase of $0.6 million in 2012 relate to non-cash finance expense in respect of preference shares.

10.5.1.3 *Share-based compensation expenses*

Share based compensation is a non-cash expense related to share options and warrants granted by members of the Group. This reduced marginally from $0.09 million in 2011 to

$0.008 million in 2012 and increased by $0.4 million to $0.4 million in 2013. The increase in this non-cash item in 2013 relates to share options granted under the 2012 Share Option Plan.

10.5.2 ***Changes in working capital***

Changes in working capital comprises of prepayments and other receivables, and trade and other payables.

10.5.2.1 *Prepayments and other receivables*

The changes in prepayments and other receivables, which show as uses of cash, were ($0.02) million in 2011, ($0.15) million in 2012, and ($0.2) million in 2013. The use of cash of ($0.15) million in 2012 related to an increase in prepayments, and VAT recoverable. The use of cash of ($0.2) million in 2013 related to an increase in prepayments, and income taxes receivable.

10.5.2.2 *Trade and other payables*

The changes in trade and other payables, which show as source of cash, were $0.3 million in 2011, $0.02 million in 2012, and $1.1 million in 2013. The change in 2013 relates to an increase in accruals and payables associated with trading activity and corporation tax accruals.

10.5.2.3 *Interest Paid*

Interest paid was $0.1 million in 2013, $0.2 million in 2012 and $0.015 million in 2011. This relates to loan advanced by Silicon Valley Bank in late 2011, the increase of $0.2 million in 2012 reflects interest charges for a full year and the reduction of $0.1 million in 2013 reflects the reducing interest charge on a declining loan balance as the principal was repaid.

10.5.3 ***Net cash used in operations***

Net cash used in operations represented a net cash outflow of $7.1 million in 2013, $5.6 million in 2012 and $2.6 million in 2011. This net cash outflow reflected the cost of the research and development activities carried out in preparation for a feasibility clinical study, the cost of carrying out the Feasibility Study and the costs to date of developing and designing ReActiv8.

10.5.4 ***Proceeds from issue of preferred shares (net)***

Cash flow from preferred shares financing activities represented a net cash inflow of $0.2 million and $19 million in 2013 and 2012, respectively. These inflows related to the Series B Financing. In 2011, preferred shares financing cash inflows of $2.4 million represented the second tranche of the Series A Financing.

10.5.5 ***Repayment of borrowings and Proceeds from new borrowings***

The Group received $2 million in debt funding from Silicon Valley Bank in 2011, and has made debt repayments of $0.4 million and $0.8 million in 2012 and 2013, respectively. On or around 7 March 2014 all outstanding amounts due and owing in connection with the debt funding were repaid by MML to Silicon Valley Bank.

10.6 Impact of inflation

The results of the Group's operations for the periods discussed have not been materially affected by inflation.

10.7 Liquidity and capital resources

General

The Group's liquidity requirements primarily relate to the funding of clinical and regulatory activities including human clinical trials using ReActiv8, which are required as part of the regulatory approval process;

ongoing research and development activities; preparation for commercial launch of ReActiv8; general and administrative expenses; and working capital requirements.

As of end of December 2013, the Group had been funded by financing rounds conducted respectively in July 2010, September 2012, and in June 2013 for a total of $26.3 million.

10.8 Off-balance sheet liabilities

The Group has no off-balance sheet liabilities.

10.9 Disclosures about interest rates, credit and currency risk

The Group has limited interest rate risk as its debt financing is at fixed interest rate. As the Group is still pre-revenue it is not currently exposed to credit risk on accounts receivable. The majority of the Group's expenditure is in U.S Dollars, and accordingly, for accounting purposes, the Group uses the U.S Dollar as its functional currency. However the Group also has expenditure in Euro and the cost of clinical trials being carried out in Australia will give rise to an Australian dollar exposure. The Group has not entered and does not currently envisage entering into any currency hedging arrangements in the near future in order to cover its currency exposure. However, the Group does maintain a Euro currency balance to reduce its economic exposure to the Euro and it currently envisages following a similar strategy in relation to the Australian dollar exposure.

10.10 Critical accounting policies and estimates

The preparation of the Group's financial statements required management to make reasonable estimates and assumptions that affected the reported amounts of assets and liabilities as reflected in its financial statements at the reporting date, as well as the disclosure of amounts of income and expenses for the period being reported on. These estimates were made in respect of fair values of financial instruments, impairment losses, deferred income taxes, provisions for employee's vacation leave payments, advance repayable, share based payments as well as the useful life and residual values of equipment, and development costs.

Therefore, these estimates are subject to measurement uncertainty. Future results could differ from and affect the results reported in these financial statements. The Group has not identified at a reporting date any sources of estimation uncertainty, which involve a significant risk of material adjustment to the financial statements in the following year.

The notes to the consolidated financial information of the Group, particularly note 3 "Significant accounting policies" provide further disclosures, which may aid the understanding of the Group's financial statements. Refer to paragraph 12.1B of Part 12 (*Historic Financial Information*) for more information.

PART 11

CAPITALISATION AND INDEBTEDNESS

The following tables set forth the Group's actual capitalisation and net indebtedness as at 31 January 2014. The Group's capitalisation will change significantly as a result of the 2014 Corporate Reorganisation and the Offer. For information on the proceeds of the Offer, please see Part 14 of this Prospectus.

This information should be read in conjunction with the Historical Financial Information and related notes thereto presented in Part 12 of this Prospectus.

Capitalisation (in $'000)	*As at 31 January 2014*
Total Current financial debt	723
Secured	723
Unsecured	–
Total Non-Current debt	29,587
Secured	–
Unsecured	29,587
Shareholder's Equity (deficit)	(22,948)
Share capital	1
Share premium	250
Share based payment reserve	534
Reorganisation reserve	(9,609)
Retained loss	(14,124)
Total Capitalisation	7,362

Net indebtedness (in $'000)	*As at 31 January 2014*
Cash and cash equivalent	(8,546)
Current financial debt	723
Net Current Financial Indebtedness (Cash)	(7,823)
Non-Current financial indebtedness	29,587
Net Financial Indebtedness (Cash)	21,764

At 31 January 2014, the Group reported secured borrowings amounting to $0.7 million under the Loan and Security Agreement with Silicon Valley Bank dated 2 December 2011. The Group repaid the outstanding balance due to the Silicon Valley Bank in full on 7 March 2014.

The Group received the Series A Financing and Series B Financing in the form of convertible redeemable preference shares which under IFRS are accounted for as debt (not as equity). At 31 January 2014, the Group's non-current debt of $29.6 million related to these preference shares and associated accrued dividends as well as derivative financial instruments. Under the terms of the articles of association of the Company at the date of this Prospectus the Company's Series A Shares, Series B Shares and Series Z Shares will convert to Ordinary Shares shortly before ESM Admission. Consequently, the Company's non-current debt will be eliminated at that time.

PART 12

HISTORICAL FINANCIAL INFORMATION

SECTION 12.1A: ACCOUNTANT'S REPORT ON THE CONSOLIDATED FINANCIAL INFORMATION OF MAINSTAY MEDICAL LIMITED AS AT 31 DECEMBER 2013, 2012 AND 2011, AND FOR EACH OF THE THREE YEARS ENDED 31 DECEMBER 2013

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The Directors
Mainstay Medical International plc
Clonmel House
Forster Way
Swords
County Dublin
Ireland

9 April 2014

Dear Sirs

Mainstay Medical Limited and its subsidiary undertakings (together the "Group")

We report on the consolidated financial information of Mainstay Medical Limited ("consolidated financial information") set out in paragraph 12.1B of Part 12 (*Historical Financial Information*) for each of the years ended 31 December 2011, 31 December 2012 and 31 December 2013. The consolidated financial information has been prepared for inclusion in the prospectus dated 9 April 2014 of Mainstay Medical International plc (the "Company") on the basis of the accounting policies set out in Notes 2 and 3 to the consolidated financial information. The consolidated financial information includes the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of financial position, the consolidated statement of changes in shareholders' equity, the consolidated statement of cash flows and the related notes. This report is required by paragraph 20.1 of Annex I of Commission Regulation (EC) No. 809/2004 (the "Prospectus Directive Regulation") and is given for the purpose of complying with that paragraph and for no other purpose.

Responsibilities

The Directors of the Company are responsible for preparing the consolidated financial information on the basis of preparation set out in Notes 2 and 3 to the consolidated financial information.

It is our responsibility to form an opinion on the consolidated financial information and to report our opinion to you.

Save for any responsibility arising under paragraph 2(2)(f) of Schedule 1 to the Prospectus (Directive 2003/71/EC) Regulations 2005 (S.I. No. 324 of 2005), as amended (the "Prospectus Regulations") to any person as and to the extent there provided, to the fullest extent permitted by law we do not assume any responsibility and will not accept any liability to any other person for any loss suffered by any such other person as a result of, arising out of, or in connection with this report or our statement, required by and given solely for the purposes of complying with paragraph 23.1 of Annex I of the Prospectus Directive Regulation, consenting to its inclusion in the Prospectus.

Basis of opinion

We conducted our work in accordance with Standards for Investment Reporting issued by the Auditing Practices Board of the United Kingdom and Ireland. Our work included an assessment of evidence relevant to the amounts and disclosures in the consolidated financial information. It also included an assessment of the significant estimates and judgments made by those responsible for the preparation of the consolidated financial information and whether the accounting policies are appropriate to the entity's circumstances, consistently applied and adequately disclosed.

We planned and performed our work so as to obtain all the information and explanations which we considered necessary in order to provide us with sufficient evidence to give reasonable assurance that the consolidated financial information is free from material misstatement whether caused by fraud or other irregularity or error.

Opinion

In our opinion, the consolidated financial information gives, for the purposes of the Prospectus, a true and fair view, of the state of affairs of the Group as at 31 December 2013, 31 December 2012 and 31 December 2011 and of its losses, cash flows and changes in equity for each of the periods then ended in accordance with the basis of preparation set out in Notes 2 and 3 to the consolidated financial information.

Declaration

For the purposes of paragraph 2(2)(f) of Schedule 1 to the Prospectus Regulations we are responsible for this report as part of the Prospectus and declare that we have taken all reasonable care to ensure that the information contained in this report is, to the best of our knowledge, in accordance with the facts and contains no omission likely to affect its import. This declaration is included in the prospectus in compliance with paragraph 1.2 of Annex I of the Prospectus Directive Regulation.

Yours faithfully

KPMG
Chartered Accountants
Dublin, Ireland

SECTION 12.1B: CONSOLIDATED FINANCIAL INFORMATION AS AT 31 DECEMBER 2013, 2012 AND 2011, AND FOR EACH OF THE THREE YEARS THEN ENDED

Consolidated statement of profit or loss and other comprehensive income
for the years ended 31 December 2011, 2012 and 2013

($'000)	*Notes*	*2013*	*2012*	*2011*
Revenue		–	–	–
Operating expenses	5	(8,396)	(5,295)	(2,911)
Operating loss		(8,396)	(5,295)	(2,911)
Finance income	6	821	319	9
Finance expense	6	(2,711)	(937)	(339)
Net finance expense		(1,890)	(618)	(330)
Loss before income taxes		(10,286)	(5,913)	(3,241)
Income taxes	8	(32)	30	–
Loss for the year and comprehensive loss for the year		(10,318)	(5,883)	(3,241)
Net loss attributable to equity holders		(10,318)	(5,883)	(3,241)
Basic and diluted loss per share (in $)	7	(6.34)	(5.79)	(7.76)

As further described in Note 3, due to the 2012 Corporate Reorganisation of the Group whereby the operations of MMI were transferred to MML, the financial information above relates to MMI from 1 January 2011 to 21 September 2012 and to MML from 21 September 2012 to 31 December 2013.

Consolidated statement of financial position
at 31 December 2011, 2012 and 2013

($'000)	*Notes*	*2013*	*2012*	*2011*	*1 January 2011*
Non-current assets					
Property, plant and equipment	9	68	66	32	8
Current assets					
Prepayments and other receivables	10	385	187	41	17
Cash and cash equivalents	11	9,590	17,370	4,364	2,556
Total current assets		9,975	17,557	4,405	2,573
Total assets		10,043	17,623	4,437	2,581
Equity					
Share capital	14	1	1	2	2
Share premium	14	250	250	–	–
Share based payment reserve	19	534	104	96	7
Reorganisation reserve	3	(9,609)	(9,609)	–	–
Retained loss		(13,146)	(2,828)	(5,901)	(2,660)
Deficit on shareholders' equity		(21,970)	(12,082)	(5,803)	(2,651)
Non-current liabilities					
Preference shares	12	24,965	22,235	5,136	2,806
Derivative financial instruments	15	4,622	5,393	2,730	2,307
Deferred tax	8	96	–	–	–
Loans and borrowings	12	–	800	1,579	–
Total non-current liabilities		29,683	28,428	9,445	5,113
Current liabilities					
Loans and borrowings	12	785	768	367	–
Trade and other payables	13	1,545	509	428	119
Total current liabilities		2,330	1,277	795	119
Total liabilities		32,013	29,705	10,240	5,232
Total equity and liabilities		10,043	17,623	4,437	2,581

As further described in Note 3, due to the 2012 Corporate Reorganisation of the Group whereby the operations of MMI were transferred to MML, the financial information above relates to MMI at 1 January 2011 and 31 December 2011 and to MML at 31 December 2012 and 31 December 2013.

Consolidated statement of changes in shareholders' equity
for the years ended 31 December 2011, 2012 and 2013

($'000)	*Share capital*	*Share premium*	*Reorganisation reserve*	*Share based payment reserve*	*Retained loss*	*Total equity*
Balance at 1 January 2011	2	–	–	7	(2,660)	(2,651)
Share-based payments	–	–	–	20	–	20
Warrant on issue of debt	–	–	–	69	–	69
Loss for the year	–	–	–	–	(3,241)	(3,241)
Balance at 31 December 2011	2	–	–	96	(5,901)	(5,803)
Share-based payments	–	–	–	8	–	8
Loss for the year	–	–	–	–	(5,883)	(5,883)
Transaction with shareholders[(i)]	–	–	–	–	(85)	(85)
Effect of reorganisation:						
Notional reclassification of historic MMI legal equity properly classified as debt	26	7,290	–	–	–	7,316
Cancellation of historic legal equity of MMI	(28)	(7,290)	(1,619)	(104)	9,041	–
Issue of legal shares in MML	27	7,859	(7,990)	104	–	–
Recognition of certain MML legal shares as debt	(26)	(7,609)	–	–	–	(7,635)
Balance at 31 December 2012	1	250	(9,609)	104	(2,828)	(12,082)
Share-based payments	–	–	–	430	–	430
Loss for the year	–	–	–	–	(10,318)	(10,318)
Balance at 31 December 2013	1	250	(9,609)	534	(13,146)	(21,970)

Note:

(i) Effective distribution of assets to MMI that were not transferred to MML.

Consolidated statement of cash flows
for the years ended 31 December 2011, 2012 and 2013

($'000)	*Notes*	*For the year ended 31 December 2013*	*2012*	*2011*
Cash flows from operating activities				
Net loss attributable to equity holders		(10,318)	(5,883)	(3,241)
Non-cash adjustments				
Depreciation	9	23	9	4
Net finance expense	6	1,890	618	330
Share-based compensation	19	430	8	20
Gain on sale of property, plant and equipment		–	–	2
Changes in working capital				
Prepayments and other receivables		(198)	(146)	(24)
Trade and other payables		1,148	18	320
Interest paid		(83)	(213)	(5)
Net cash used in operations		(7,108)	(5,589)	(2,594)
Cash flow from investing activities				
Proceeds on sale of equipment	9	–	–	5
Acquisition of property, plant and equipment	9	(25)	(43)	(31)
Net cash used in investing activities		(25)	(43)	(26)
Cash flows from financing activities				
Proceeds from issue of preferred shares (net)		153	19,038	2,428
Repayment of borrowings		(800)	(400)	–
Proceeds from new borrowings		–	–	2,000
Net cash (used in)/from financing		(647)	18,638	4,428
Net (decrease)/increase in cash and cash equivalents		(7,780)	13,006	1,808
Cash and cash equivalents at beginning of year	11	17,370	4,364	2,556
Cash and cash equivalents at end of year	11	9,590	17,370	4,364

Notes to the consolidated financial information

1. Reporting entity

Mainstay Medical Limited (MML) is domiciled in Ireland with its registered office at Clonmel House, Forster Way, Swords, County Dublin (company registration number 516089). The consolidated financial information of MML as set out for the year ended 31 December 2013 comprises MML and its subsidiary undertakings (together the "Group"). During 2012, MML was incorporated and took over the previous business and operations of Mainstay Medical Inc ("MMI"), a US entity, in a group re-organisation which resulted in the contribution of substantially all of MMI's business to MML in return for the issuance of shares to MMI. This has been accounted for as a continuation of the original MMI business via the new MML entity. Consequently, the financial information presented for periods prior to 2013 represents that of Mainstay Medical, Inc. (MMI) for the year ended 31 December 2011, and a combination of MMI and MML's trade and operations for the year ended 31 December 2012 as has been further detailed in Note 3.

MML was the parent company of the Group as of 31 December 2013, the date as of which this financial information has been prepared. On 3 April 2014, Mainstay Medical International plc became the new holding company of the Group.

The Group is focused on developing an active implantable medical device (AIMD) designed to treat Chronic Low Back Pain (ReActiv8®).

2. Basis of preparation

Statement of compliance

The consolidated financial information has been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and as endorsed by the European Union (EU) and in accordance with the Prospectus Regulations. The consolidated financial information was approved by the Board of Directors on 9 April 2014.

In this consolidated financial information, the Group has prepared its financial information in accordance with IFRSs as adopted by the EU for the first time, effective from 1 January 2011. Details of the transition to IFRS are provided in Note 22. As a result of the first time adoption of IFRS, this consolidated financial information includes the Group's opening IFRS Statement of Financial Position as at 1 January 2011.

The IFRSs adopted by the EU applied by the Group in the preparation of this financial information are those that were effective for accounting periods beginning on or after 1 January 2013.

These are not the statutory financial statements of MML as required to be laid before the Company's members at the AGM. Those financial statements will be separately prepared by the Directors and filed with the Companies Registration Office in Ireland. This financial information is prepared for this Prospectus document and for no other purpose.

Going concern

MML has incurred losses of $13.1 million to date and recorded a shareholders' deficit of $21.97 million as at 31 December 2013. The Group is at a pre-revenue stage for ReActiv8 and expects to incur further losses in the medium term. To fund development of ReActiv8, the Group has raised debt and equity and is in the process of the initial public offering (the "Offer") for which this Prospectus has been prepared. The funding from this Offer is expected to assist the Group through clinical trials and commercialisation of ReActive8. The Company expects to successfully conclude the Offer and consequently expect that the Group will have sufficient funds to ensure that it is able to meet its liabilities as they fall due for a period of at least 12 months from the date of preparation of this financial information. Accordingly this financial information is prepared on a going concern basis.

Basis of measurement

The consolidated financial information is prepared on the historic cost method, except for:

- Share based payments, which are initially measured at grant date fair value; and

- Derivative financial instruments, which are measured at fair value through profit or loss and other comprehensive income; and
- The issue of shares in MML as part of the 2012 Corporate Reorganisation as defined and dealt with in Note 3 below, which were accounted for at fair value at the date of the 2012 Corporate Reorganisation as required by the Irish Companies Acts 1963 to 2013.

Currency

The functional and presentational currency of MML is the U.S. dollar. The consolidated financial information is presented in U.S. dollars and all values are presented in thousands ($000), except where otherwise indicated.

Use of estimates and judgements

The preparation of the financial information in conformity with IFRS requires management to make judgements, estimates and assumptions. Estimates are reviewed on an ongoing basis.

The areas where judgement has the most significant effect on amounts recognised in this financial information are:

- Fair value determination of preference shares issued by MML for the purposes of calculating the reorganisation reserve following the 2012 Corporate Reorganisation (Note 3 and Note 15);
- Determination of the carryover basis of accounting for the 2012 Corporate Reorganisation (Note 3);
- Measurement of derivative financial instruments held at fair value (Note 15);
- Measurement of potential deferred tax liabilities and assets (Note 8);
- Initial fair value measurement of equity-settled share based payments (Note 19);
- Measurement of contingencies (Note 21).

Details of the inputs into the fair values of each of the above are provided in the relevant notes as listed above. Fair value disclosures for financial instruments as required by IFRS 13 are provided in Note 15.

3. Significant accounting policies

Basis of consolidation

The Group financial information consolidates the financial statements of MML and all of its subsidiary undertakings made up to 31 December 2013.

Business combinations, other than the 2012 Corporate Reorganisation, which is defined and dealt with below, are accounted for using the acquisition method as at the acquisition date, which is the date on which control transfers to the Group. Control is the power to govern the financial and operating policies of an entity.

The Group measures goodwill at the acquisition date as:

- the fair value of consideration transferred; plus
- the recognised amount of any non-controlling interest in the acquiree; plus
- if the business combination is achieved in stages, the fair value of any pre-existing interest; less
- the fair value of the assets and liabilities acquired/assumed.

When the excess is negative, the gain is recognised immediately in profit or loss. Transaction costs are expensed as incurred. Contingent consideration is measured at fair value on the acquisition date and any subsequent remeasurement is dealt with through profit or loss in the consolidated statement of profit or loss and other comprehensive income.

2012 Corporate Reorganisation

In September 2012, MMI transferred substantially all of its trade, assets and liabilities to MML in exchange for (i) a promissory note convertible into preference shares of MML, and (ii) an option to purchase ordinary shares of MML, in each case pursuant to a Contribution and Assumption Agreement dated 21 September 2012 between MMI and MML. The existing liabilities of MMI under the Loan and Security Agreement with Silicon Valley Bank were novated to MML through a Consent Assumption and Amendment to the Loan and Security Agreement between Silicon Valley Bank, as lender, MMI and MML.

As part of the 2012 Corporate Reorganisation MML issued 1,626,000 ordinary shares with a par value of $0.001 per share, 10,000,000 series Z shares with a par value of $0.001 per share and 15,868,520 series A shares with a par value of $0.001 per share on the conversion of the promissory note above. In accordance with the Companies Act 1963, these shares and the associated share premium were recorded in the Statement of Financial Position at the fair value of the consideration received on the date of their issue. Details of inputs into the fair value calculations related to shares are provided in Note 15.

The difference between the carrying amount of shares classified as debt and other equity items, including retained losses previously held by MMI and the fair value of the shares, including instruments classified as debt issued by MML on the date of the 2012 Corporate Reorganisation is reflected in the Statement of Changes in Equity for the year ended 31 December 2012 where it is recorded in the reorganisation reserve.

The impact of the above on the reorganisation reserve was a transfer of $9,041,000 from retained losses, representing the accumulated losses of MMI, a fair value increase in ordinary shares in issue of $249,000 and a fair value increase in series A shares in issue, which are classified as debt, of $319,000, resulting in a total reorganisation reserve of $9,609,000.

Additionally, in September 2012, new series B shares, which are classified as debt, were issued by MML directly to a combination of the existing shareholders of MMI and to new shareholders (the "2012 external fundraising"). Prior to and post both the 2012 Corporate Reorganisation and the 2012 external fundraising, no individual shareholder or party was considered to have outright control of the Group.

Owing to the nature of the 2012 Corporate Reorganisation, a business combination was not deemed to have occurred. The introduction of MML as a new holding company for the Group has been accounted for as a continuation of the business previously carried out by MMI. Consequently, even though MML was only incorporated on 2 August 2012 and was not a group company as at 1 January 2011, 31 December 2011 or for the period from 1 January 2012 to the date of the 2012 Corporate Reorganisation, the disclosures in the consolidated financial information for those periods are those of MMI. The financial information has been presented as if the previous business and trade of MMI continued as before through each of the accounting periods presented, albeit that the principal trading and parent entity became MML with effect from 21 September 2012.

Subsidiaries

Subsidiaries are entities controlled by the Group. The financial statements of subsidiaries are included in the financial information from the date that control commences until the date that control ceases.

Pension costs

The Group provides pensions to its employees under a defined contribution scheme. Obligations for contributions to the defined contribution schemes are expensed as the related service is provided.

Property, plant and equipment

Property, plant and equipment is stated at cost less accumulated depreciation. Depreciation is calculated to write off the cost of each asset over its estimated future life, as follows:

Computer and office equipment: 3 – 5 years

Leases

Operating leases related to the Group's offices are charged to profit or loss on a straight line basis over the lease term. An operating lease is one where the majority of risks and rewards of the asset are not transferred to the Group over the lease term. The Group has no finance leases.

Taxation

Tax expense comprises current and deferred tax. Current and deferred taxes are recognised in the consolidated statement of profit or loss and other comprehensive income except to the extent that they relate to a business combination, or items recognised directly in equity.

Current tax is the expected tax payable or receivable on the taxable result for the year and any adjustments in relation to tax payable or receivable in respect of the previous years.

Deferred tax is recognised in respect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Deferred tax is not recognised for:

- temporary differences on the initial recognition of assets and liabilities in a transaction that is not a business combination and that affects neither accounting nor taxable profit; and
- temporary differences related to subsidiaries to the extent that it is probable that they will not reverse in the foreseeable future.

Deferred tax is measured at the tax rates at which the temporary differences are expected to reverse, using tax rates enacted or substantively enacted at the reporting date. Deferred tax assets and liabilities are offset where the entity has a legally enforceable right to set off current tax assets against current tax liabilities and the deferred tax assets and liabilities related to the same taxation authority. Deferred tax assets are recognised to the extent that it is probable that there will be taxable profits in the foreseeable future against which they can be utilised.

Foreign currency transactions and balances

Transactions in foreign currencies are recorded at the rate ruling at the date of the transactions. Any resulting monetary assets and liabilities are translated at the exchange rate at the reporting date and all exchange differences thereon are dealt with in profit or loss.

Financial instruments

(i) *Non-derivative financial assets*

Financial assets are initially recognised on the date they are originated and when the Group obtains contractual rights to receive cash flows. The Group derecognises financial assets when the contractual rights to cash flows expire or it transfers the right to receive cash flows in a transaction which transfers substantially all the risks and rewards of ownership of the asset.

The Group holds the following categories of financial assets:

Receivables
Such assets are initially recognised at fair value and subsequently measured at amortised cost less accumulated impairment losses.

Cash and cash equivalents
Cash and cash equivalents comprise cash balances and call deposits with maturities of three months or less.

(ii) *Non-derivative financial liabilities*

The Group's non-derivative financial liabilities comprise the following categories:

Loans and borrowings
These are initially recorded at fair value less applicable transaction costs and are subsequently measured at amortised cost using the effective interest method over the contractual term of the associated liability.

Preference share liabilities
Preference shares classified as liabilities are initially recognised at fair value and subsequently measured at amortised cost using the effective interest rate method over the expected life of the associated liability.

Preference shares are classified as financial liabilities if they are redeemable on a specific date or at the option of the shareholders, if dividend payments are not discretionary, or if the conversion rights attaching to the shares require a variable number of ordinary shares be delivered by the Company in the event of conversion. Such preference shares include MML series A, series B and series Z shares. The conversion option is treated as an embedded derivative and separately recognised.

Trade and other payables
Trade and other payables are measured initially at fair value and subsequently at amortised cost.

(iii) *Derivative financial instruments*

Series A, series B and series Z shares include conversion rights which are settleable in a variable number of ordinary shares. These conversion rights are classified as derivative financial instruments in accordance with IAS 39 and are carried at fair value through profit or loss and other comprehensive income. Details of the significant inputs and assumptions into the fair values of these instruments are provided in Note 15.

Equity

Ordinary share capital is recognised directly in equity at fair value on issue and is not subsequently remeasured.

Impairment

Financial assets

Financial assets are assessed at each reporting date to determine if there is objective evidence of impairment. The Group considers the need for impairment of financial assets at both an individual and collective level. Impairment losses are recognised in profit or loss in the consolidated statement of profit or loss and other comprehensive income.

Non-financial assets

All non-financial assets, other than deferred taxes are reviewed at the reporting date to determine whether there is evidence of impairment. If such indicators exist, then the asset's recoverable value is determined. An impairment loss is recognised if the carrying value exceeds the recoverable amount. Recoverable amount is the greater of an asset's value in use and its fair value. In assessing value in use, the estimated future cashflows associated with the asset are discounted to their present value using a pre-tax discount rate that reflects current market conditions.

Provisions

A provision is recognised if, as a result of a past event, the Group has a present obligation that it is probable, will result in an outflow of resources and this can be estimated reliably.

Finance income and expense

Finance income comprises foreign exchange gains on financial items, fair value gains on derivative financial instruments and deposit interest. Interest income is recognised as it accrues. Finance costs comprise interest on borrowings, dividends on series A and series B shares recognised on an effective interest rate basis and fair value losses on derivative financial instruments.

Share based payments

The grant date fair value of equity-settled share based awards made to employees and non-employees is recognised as an expense, with a corresponding adjustment to equity, over the vesting period of the award. The amount recognised as an expense is adjusted to reflect the number of awards for which the achievement of service and non-market conditions are expected to be met, such that the amount ultimately recognised represents only vested awards.

As at 31 December 2013, the Group has granted share awards in the form of share options and restricted stock units. The grant-date fair value of share options granted to employees is determined using a Black-Scholes model, details of which are provided in note 19. The grant-date fair value of share options granted to non-employees is determined based on the fair value of services received in return for the award, or where such a value is not available, based on the same model as used for employee options. The fair value of restricted stock units is calculated as the fair value of the underlying shares on the grant date since the only restrictions are as regards voting powers and delayed vesting. Awards can only be settled by way of share issues.

The transfer of share options and restricted share units from MMI to MML had no material impact.

Warrants

Embedded warrants issued alongside debt instruments are initially recognised at fair value with a corresponding reduction in the debt instrument liability whereon this cost is amortised to the income statement on an effective interest rate basis.

All warrants issued by the Group can only be settled in a fixed number of equity instruments and accordingly are classified as an equity instrument. Equity instruments are not re-measured over the life of the instrument.

Forthcoming requirements

A number of new standards, amendments to standards and interpretations are effective for annual periods beginning on or after 1 January 2014, and have not been applied in preparing this financial information. The Group does not plan to adopt these standards early; instead it will apply them from their effective dates as determined by their dates of EU endorsement. The expected impacts of these upcoming requirements on the Group are noted below.

IFRS 10 Consolidated Financial Statements, IFRS 11 Joint Arrangements, IFRS 12 Disclosure of Interests in Other Entities.

IFRS 10 establishes a new control-based model for consolidation that replaces the existing requirements of both IAS 27 and SIC-12. IFRS 11 classifies joint arrangements as either joint operations or joint ventures and focuses on the nature of the rights and obligations of each arrangement. IFRS 12 sets out more comprehensive disclosures relating to the nature, risks and financial effects of interests in subsidiaries, associates, joint arrangements and unconsolidated structured entities.

The Group does not expect that the adoption of the above standards will have a material impact on the Group's results.

Amendment to IAS 32 Offsetting Financial Assets and Financial Liabilities

This amendment clarifies the circumstances in which companies may offset financial instruments on the statement of financial position. The Group does not expect that this amendment will have a material impact on the Group's statement of financial position.

4. Segmental reporting

Due to the nature of the Group's current activities, the Company considers there to be one operating segment, active implantable medical devices (AIMDs). The results of the Group are reported on a consolidated basis to the Chief Operating Decision Maker of the Group, the Chief Executive. There are no reconciling items between the Group's reported consolidated statement of profit or loss and other comprehensive income and statement of financial position and the results of the AIMDs segment.

The Group has operations in Europe, the U.S. and Australia. The non-current assets in these jurisdictions are detailed below:

	At 31 December			*1 January*
($'000)	*2013*	*2012*	*2011*	*2011*
Ireland	19	17	–	–
United States	49	49	32	8
Total non-current assets	68	66	32	8

The Group as yet has no income.

5. Operating expenses

	For the year ended 31 December		
($'000)	*2013*	*2012*	*2011*
Research and development expenses	3,980	2,432	1,389
Clinical and regulatory expenses	945	1,574	754
General and administration expenses	3,041	1,281	679
Share-based compensation expenses	430	8	89
Total operating expenses	8,396	5,295	2,911

6. Net finance expense

	For the year ended 31 December		
($'000)	*2013*	*2012*	*2011*
Finance income			
Foreign exchange gain	50	–	–
Fair value gain on derivative financial instruments	771	319	–
Interest income	–	–	9
Total finance income	821	319	9
Finance expense			
Interest expense on borrowings	134	213	15
Finance expense related to preference shares	2,577	724	324
Total finance expense	2,711	937	339
Net finance expense	1,890	618	330

Further information on the Group's loans and borrowings are provided in note 12.

7. Earnings per share

Earnings per share are calculated by dividing net loss attributable to equity holders of the period by the weighted average number of ordinary shares outstanding during the period. As the Group is incurring operating losses, there is no difference between the basic and the diluted earnings per share.

The weighted average number of ordinary shares (denominator) amounted to 1,628,000 in 2013 (*2012: 1,015,500, 2011: 417,583*). There are no adjustments between reported comprehensive income from continuing operations and earnings used for the purposes of earnings per share.

The loss per share for the year ended 31 December 2013 was $6.34 (*2012: $5.79; 2011: $7.76*).

8. Taxes

Current income tax

Current income tax assets and liabilities for the current and prior periods are measured at the amount expected to be recovered from or paid to the relevant taxation authorities. The tax rates and tax laws used to compute the amount are those used in Ireland, the United States and Australia.

	For the year ended 31 December		
($'000)	*2013*	*2012*	*2011*
Irish tax	(136)	(30)	–
Income tax in other jurisdictions	72	–	–
Deferred tax	96	–	–
Total income tax charge/(credit)	32	(30)	–

Reconciliation of effective tax rate

	For the year ended 31 December		
($'000)	*2013*	*2012*	*2011*
Loss before tax	(10,286)	(5,913)	(3,241)
Taxed at tax rate in Republic of Ireland of 12.5% (U.S. rate of 40% used for activities prior to the 2012 Corporate Reorganisation)	(1,286)	(1,959)	(1,296)
Non-deductible expenses	58	1	20
Fair value movements	(96)	–	–
Tax credits	(164)	(30)	–
Foreign rate differential	69	–	–
Unrecognised tax losses	1,451	1,958	1,276
Total income tax	32	(30)	–

Deferred tax liability

Deferred tax is attributable to the following:

		At 31 December		*1 January*
($'000)	*2013*	*2012*	*2011*	*2011*
Derivative financial instruments	96	–	–	–
Deferred tax liability	96	–	–	–

Reconciliation of opening and closing deferred tax liabilities

($'000)	*Derivative financial instruments*	*Total*
At 1 January 2011	–	–
Recognised in income	–	–
At 31 December 2011	–	–
Recognised in income	–	–
At 31 December 2012	–	–
Recognised in income	96	96
At 31 December 2013	96	96

Unrecognised deferred tax assets

The Group has unrecognised potential deferred tax assets arising as follows. These potential assets are not recognised as the timing of any potential taxable profits against which these assets may be offset by the Group is uncertain.

	At 31 December		
($'000)	*2013*	*2012*	*2011*
Losses carried forward	1,938	487	1,280
Share based payments	99	53	–
Derivative financial instruments	–	472	600
Total unrecognised deferred tax assets	2,037	1,012	1,880

Tax losses to 21 September 2012 available to MMI are no longer available to the Group.

9. Property, plant & equipment

	At 31 December		
($'000)	*2013*	*2012*	*2011*
Cost			
At beginning of year	82	39	11
Additions	25	43	31
Disposals	–	–	(3)
At end of year	107	82	39
Depreciation			
At beginning of year	16	7	3
Charge for year	23	9	4
At end of year	39	16	7
Net book value	68	66	32

10. Prepayments and other receivables

	At 31 December			At 1 January
($'000)	*2013*	*2012*	*2011*	*2011*
Prepayments	101	52	18	17
Income taxes receivable	193	30	–	–
VAT recoverable	52	90	–	–
Other receivable	39	15	23	–
Total prepayments and other receivables	385	187	41	17

11. Cash and cash equivalents

	At 31 December			At 1 January
($'000)	*2013*	*2012*	*2011*	*2011*
Cash in bank accounts – U.S. dollar	8,148	14,178	4,364	2,556
Cash in bank accounts – Euro	1,409	3,192	–	–
Cash in bank accounts – AUD	33	–	–	–
Total cash and cash equivalents	9,590	17,370	4,364	2,556

12. Loans and borrowings and shares classified as debt

On 2 December 2011, Silicon Valley Bank provided the Group with a loan of $2,000,000 with a fixed annual interest rate of 10 per cent. to be serviced by interest-only payments until 1 July 2012, followed by monthly principal and interest payments until 1 December 2014. Borrowings under the Loan and Security Agreement dated 2 December 2011 are collateralised by substantially all of the Group's assets except for intellectual property. This agreement contains reporting covenants including monthly and annual financial reporting requirements. The Group is not in breach of any such covenants at 31 December 2013 and has not been in breach at any reporting date.

In connection with these borrowings, MML issued immediately exercisable warrants to purchase up to 260,000 shares at $0.385 per share with an expiration date of 2 December 2021. The fair value of these warrants on the date of issue was $69,000.

	At 31 December			At 1 January
($'000)	*2013*	*2012*	*2011*	*2011*
Loans and borrowings – current				
Term loan	800	800	400	–
Unamortised discount	(21)	(46)	(46)	–
Accrued interest	6	14	13	–
Total current loans and borrowings	785	768	367	–
Loans and borrowings – non-current				
Term loan	–	800	1,600	–
Unamortised discount	–	–	(21)	–
Total non-current loans and borrowings	–	800	1,579	–
Total loans and borrowings	785	1,568	1,946	–
Shares classified as non-current debt				
– Series A preference shares	5,032	5,032	4,713	2,707
– Series B preference shares	17,171	17,018	–	–
Unamortised discount on series B shares	(722)	(914)	–	–
Accrued dividends	3,484	1,099	423	99
Total non-current preference shares	24,965	22,235	5,136	2,806

Expenses associated with the issuance of series B shares have been capitalised against the related liability and are being amortised to profit or loss on an effective interest basis over the earliest contractual redemption term of the shares. See Note 15 for further detail.

13. Trade and other payables

	At 31 December			1 January
($'000)	*2013*	*2012*	*2011*	*2011*
Trade and other payables	1,083	424	428	119
Accrued expenses	462	85	–	–
Total trade and other payables	1,545	509	428	119

14. Called up share capital

Shares in issue – ($'000 except share numbers)

	Ordinary $0.001 shares			
Share capital classified as equity	*Number of shares*	*Share capital*	*Share premium*	*Total*
At 1 January 2011	228,000	2	–	2
Issued of restricted stock units	350,000	–	–	–
At 31 December 2011	578,000	2	–	2
Issue of restricted stock units	350,000	–	–	–
Cancellation of historic equity of Mainstay Medical, Inc.	(928,000)	(2)	–	(2)
Issue of shares in MML	2,000	–	–	–
Issue of shares in MML as part of 2012 Corporate Reorganisation	1,626,000	1	250	251
At 31 December 2012	1,628,000	1	250	251
At 31 December 2013	1,628,000	1	250	251

	Series A $0.001 preferred shares			Series B $0.001 preferred shares			Series Z $0.001 shares			
Share capital classified as debt	*Number of shares*	*Share capital*	*Share premium*	*Number of shares*	*Share capital*	*Share premium*	*Number of shares*	*Share capital*	*Share premium*	*Total*
At 1 January 2011	9,521,111	10	3,505	–	–	–	10,000,000	10	–	3,525
Issue of Series A shares	6,347,409	6	2,422	–	–	–	–	–	–	2,428
At 31 December 2011	15,868,520	16	5,927	–	–	–	10,000,000	10	–	5,953
Cancellation of historic shares in Mainstay Medical, Inc.	(15,868,520)	(16)	(5,927)	–	–	–	(10,000,000)	(10)	–	(5,953)
Issue of shares in MML	15,868,520	16	5,927	38,986,354	39	18,999	10,000,000	10	1,490	26,481
At 31 December 2012	15,868,520	16	5,927	38,986,354	39	18,999	10,000,000	10	1,490	26,481
Issue of Series B shares	–	–	–	357,286	–	153	–	–	–	153
At 31 December 2013	15,868,520	16	5,927	39,343,640	39	19,152	10,000,000	10	1,490	26,634

Share issuances

Mainstay Medical, Inc.

Series A Preferred Stock

On 9 December 2010, MMI received gross proceeds of $3,665,627 in a private placement to various investors for issuance of 9,521,111 shares of its series A shares at $0.385 per share.

On 16 November 2011 and 7 December 2011, MMI received gross proceeds of $2,443,753 in a private placement to various investors for issuance of 6,347,409 shares of its series A shares at $0.385 per share.

Costs of US$168,000 were set off against the above issue proceeds.

Series Z Preferred Stock
On 8 July 2010, MMI issued 10,000,000 shares of its series Z shares at $0.001 per share.

Mainstay Medical Limited

Ordinary shares
On incorporation MML issued 2,000 ordinary shares at $0.001 each.

2012 Corporate Reorganisation – ordinary shares, series A shares and series Z shares
As part of the 2012 Corporate Reorganisation further detailed in Note 3, MML issued 1,626,000 ordinary shares, 15,868,520 series A shares and 10,000,000 series Z shares to MMI.

Series B shares
In September 2012, MML raised approximately $20,000,000 by way of subscriptions for 38,986,354 series B shares at $0.513 per share. Costs of $962,000 were set off against the above issue proceeds.

On 27 June 2013, MML raised gross proceeds of $183,288 by way of subscriptions for 357,286 series B shares.

Rights attaching to MML shares as of 31 December 2013

As at 31 December 2013, the rights of each class of shares is set forth below.

As at 31 December 2013, all classes of shares rank *pari passu* except for as follows:

Dividend rights

The series B shares grant the holder a right to a fixed, cumulative dividend of 8 per cent. per annum out of the profits of MML available for distribution in preference to all other classes of share. The series A shares grant the holder a fixed cumulative dividend of 8 per cent. per annum out of the profits available for distribution in preference to all other class of share save for the series B shares. The series A shareholders are also entitled to a one time dividend at the rate of $0.0340 per series A share in preference to all other class of share save for the series B shares. This dividend has been accrued in these financial statements over the period to 21 September 2012. These dividends become mandatorily payable under certain conditions, including liquidation or redemption.

Conversion at the option of the holder

Any holder of series B shares, series A shares or series Z shares may require conversion of some or all of the relevant class of preferred shares held by them at any time into ordinary shares. The conversion ratios for each class of share are governed by MML's Articles of Association, initially on a one-for-one basis based on the subscription price per share and include anti-dilution provisions related to certain events such as down rounds, stock splits, sub-divisions or consolidations.

Mandatory conversion

All of the preferred shares in MML shall mandatorily convert to ordinary shares upon the completion of a stock market listing of MML's ordinary shares with an offering price per ordinary share of not less than five times the original purchase price of the series B shares and gross proceeds of not less than $50,000,000. All series B shares and series A shares shall mandatorily convert to ordinary shares upon the receipt by MML of a request for conversion by the holders of at least 75 per cent. of the number of each respective class of share then in issue. All series Z shares shall mandatorily convert to ordinary shares upon receipt by MML of a request for conversion by the holders of more than 50 per cent. of series Z shares then in issue.

Liquidation preference

On a return of assets on liquidation, or certain other transactions involving MML's share capital, the series B shareholders shall have first preference over the liquidation proceeds, followed by the series A shareholders, the series Z shareholders and finally the ordinary shareholders.

Liquidation preference payment amounts and the order of payment are based on defined ratios and other terms set out in the MML's Articles of Association.

Redemption rights

At any time after 21 September 2017 and at the election of greater than 66.7 per cent. of the holders of the series B shares, MML shall redeem (out of profits available for distribution) all or a portion of the series B shares that remain unconverted into ordinary shares. The amount payable on redemption shall be the higher of the fair market value of the shares at the date of redemption or the original purchase price of such shares, plus any unpaid but accrued dividends arising from issue to the date of redemption and any declared and unpaid dividends.

At any time after 21 September 2017 provided that all series B shares have either been redeemed or converted into ordinary shares, and at the election of a majority of the holders of the series A shares, MML shall redeem (out of profits available for distribution) the series A shares that have at the redemption date not been converted into ordinary shares. The amount payable on redemption shall be the original purchase price of such shares plus any unpaid but accrued dividends arising from issue to the date of redemption and any declared and unpaid dividends.

Voting

Each holder of series B, series A or series Z shares shall be entitled to one vote per share on an as-converted basis at all general meetings of MML. Each holder of ordinary shares shall be entitled to one vote per share at all general meetings of MML.

Nomination of directors

The holders of a majority of series Z shares shall, as long as the series Z shares, represent greater than 10 per cent. of the total preferred shares in issue, be entitled to nominate one person for appointment as director. Furthermore, the shareholders Sofinnova Partners and Fountain Healthcare Partners have additional director nomination rights.

Authorised share capital

As at 31 December 2013 the authorised share capital of MML was 100,000,000 Ordinary Shares, 10,000,000 Series Z Shares, 16,128,520 Series A Shares and 45,000,000 Series B Shares.

Issued shares with no currently exercisable voting rights

At 31 December 2013, 350,000 ordinary shares, which had been issued by the Group as restricted share units to employees carried no voting or other rights as the vesting period for these shares had not completed (*2012: 750,000, 2011: nil*).

Fair value of shares issued in the 2012 Corporate Reorganisation

The fair value of shares issued by MML as part of the 2012 Corporate Reorganisation was calculated using the same methodology as detailed for the fair value disclosures of preference shares provided in Note 15. Details of the split of these fair values between liabilities held at amortised cost and derivatives are provided in Note 15.

15. Financial instruments

Financial risk management

In terms of financial risks, the Group has exposure to credit risk, liquidity risk and market risk comprising foreign currency risk and interest rate risk. This note presents information about the Group's exposure to each of the above risks together with the Group's objectives, policies and processes for measuring and managing those risks.

Risk management framework

MML's Board of Directors has overall responsibility for the establishment and oversight of the Group's risk management framework. The Group's risk management policies are established to identify and analyse the risks faced by the Group, to set appropriate risk limits and controls and to monitor risks and adherence to the limits. Risk management systems and policies will be reviewed regularly as the Group expands its activities and resource base to take account of changing conditions.

Due to the current pre-revenue nature of the Group's activities, there are no significant concentrations of risk other than concentration of cash and there has been no significant change during the financial year, or since the end of the year to the types or quantum of financial risks faced by the Group or the Group's approach to the management of those risks.

Credit risk

The Group's only exposure to significant credit risk relates to cash on deposit. The Group maintained its cash balances with its principal lender throughout the periods covered by this financial information. The Group's principal lender carried investment grade ratings throughout the period.

Liquidity risk

The following is an analysis of the maturity of the contractual outflows associated with the Group's financial liabilities:

($'000)	*Carrying value*	*Cashflow (total)*	*Less than 1 year*	*Between 1-2 years*	*Between 2-5 years*	*More than 5 years*
31 December 2013						
Trade and other payables	1,545	1,545	1,545	–	–	–
Term loans	785	811	811	–	–	–
Derivative financial instruments	4,622	–	–	–	–	–
Series A and series B shares classified as liabilities*	24,965	36,000	–	–	36,000	–
At 31 December 2013	31,917	38,356	2,356	–	36,000	–
31 December 2012						
Trade and other payables	509	509	509	–	–	–
Term loans	1,568	1,745	934	811	–	–
Derivative financial instruments	5,393	–	–	–	–	–
Series A and series B shares classified as liabilities*	22,235	36,000	–	–	–	36,000
At 31 December 2012	29,705	38,254	1,443	811	–	36,000

($'000)	Carrying value	Cashflow (total)	Less than 1 year	Between 1-2 years	Between 2-5 years	More than 5 years
31 December 2011						
Trade and other payables	428	428	428	–	–	–
Term loans	1,946	2,358	613	934	811	–
Derivative financial instruments	2,730	–	–	–	–	–
Series A shares classified as liabilities*	5,136	7,802	–	–	–	7,802
At 31 December 2011	10,240	10,588	1,041	934	811	7,802

* As at 31 December 2013 MML's series A and series B shares were redeemable at a majority of the holders' request from 30 September 2017 subject to the availability of profits for distribution. The redemption price of the series A shares was fixed at the initial subscription price of the shares plus any accrued and unpaid dividends as of the date of redemption. The redemption price of the series B shares was the higher of the shares' fair value and their initial subscription price plus any accrued and unpaid dividends as of the date of redemption. The tables above assume payment of the principal plus the accumulated unpaid dividends on that date as it represented the earliest date at which the Group could have been compelled to make payment. The conversion rights inherent in series A, series B and series Z shares are classified as derivative financial instruments as they required the Group to deliver a variable number of shares but carried no contractual cash flows.

Details of the Group's term loans are provided in Note 12 and details of the preference shares are provided in Note 14.

Foreign currency risk

The Group's reporting currency is the U.S. dollar. The U.S. dollar is also the functional currency of all significant entities in the Group. The Group's foreign currency risk arises through expenditure incurred in Euro and Australian dollars. The Group's Australian subsidiary has an AU$ functional currency.

The Group did not have material asset or liability amounts in foreign currencies at year end other than cash in current bank accounts denominated in Euro as detailed in Note 11.

A strengthening (or weakening) of the U.S. Dollar against the Euro of 5 per cent. would have (decreased)/increased the loss for the year ended 31 December 2013 by $43,000 (*2012: $98,000, 2011: $nil*). Any reasonable or likely movements between the U.S. dollar and the Australian dollar are considered not likely to have a material impact on the Group's income statement.

Interest rate risk

The Group's primary liabilities, comprising its borrowings and preference shares, carry legal fixed rates of interest as detailed in the table below:

	As at 31 December		
	2013	*2012*	*2011*
Fixed rate			
Term loans	10.0%	10.0%	10.0%
Series A shares	8.0%	8.0%	8.0%
Series B shares	8.0%	8.0%	–

The Group does not account for any fixed rate financial liabilities at fair value through profit or loss and therefore a change in interest rates at the end of the reporting period would have no impact on profit or loss.

The Group's cash balances are maintained in short term access accounts and carry a floating rate of interest. A 1 per cent. change in the rate of interest would not have had a material impact on the Group's income statement in any financial period.

Fair values

The Group's derivative financial instruments, comprising the conversion rights embedded in the series A, B and Z shares are all level III financial instruments carried at fair value through profit and loss. There were no transfers into or out of any classification of financial instruments in any period. A reconciliation of the fair values of derivative financial instruments at each reporting date is provided below:

	At 31 December		
($'000)	*2013*	*2012*	*2011*
At beginning of year	5,393	2,730	2,307
Arising on series A share issue	–	–	423
Arising on series B share issue	–	2,982	–
Fair value movement recognised in profit or loss	(771)	(319)	–
At end of year	4,622	5,393	2,730

Details of the key unobservable inputs and methodologies used by the Group in determining the fair values of derivative financial instruments and the fair value disclosures for other financial instruments held at amortised cost are provided below. Fair values of derivative financial instruments and the liability components of series A, B and Z shares classified as liabilities at amortised cost are classified as Level III as they contain unobservable inputs. Loans and borrowings are Level II.

Type	*Valuation approach*	*Key unobservable inputs*	*Interaction between key unobservable inputs and fair value*
Gross value of series A, B and Z shares on issue and at 31 December 2013	Option model based on probability assessment of liquidation preferences derived from the series A and series B funding rounds.	• Risk free rate (1.6 per cent.) • Volatility (60 per cent.) • Term (5 years) • No dividend yield	The fair value would increase with a decrease in the risk free rate, an increase in volatility or a lengthening of the expected term.
Value on issue of component of series A and B shares classified as liabilities held at amortised cost	Discounted cashflows based on contractual cashflows at a market rate of interest.	• Term (5 years) • Interest rate (10 per cent.)	An increase in the interest rate would reduce the fair value of the liability component and increase the value of the derivative component below.
Valuation of conversion rights in series A, B and Z shares classified as derivative financial instruments	The fair value of the derivative was determined as the residual difference between the gross value of the instruments and the fair value of the component classified as liability held as amortised cost above.	• Inputs as above	As above.

Type	*Valuation approach*	*Key unobservable inputs*	*Interaction between key unobservable inputs and fair value*
Loans and borrowings (excluding shares classified as liabilities)	Discounted cashflows based on contractual cashflows at a market rate of interest.	• Interest rate (10 per cent.)	An increase in the interest rate would reduce the fair value of the liability.

Sensitivity analysis for items carried at fair value through profit or loss

A 2 per cent. change from 10 per cent. to 12 per cent. in the interest rates used to calculate the present value of contractual cashflows used to determine the fair value of liabilities held at amortised cost and the resulting residual calculation of the fair value of derivative financial instruments would have resulted in an additional interest charge of $244,000 in 2013 ($50,000 in 2012 and $nil in 2011).

A 10 per cent. increase in the option model valuation in 2013 would have resulted in a fair value loss on derivative financial instruments in 2013 of $180,000.

Fair values and carrying amounts for all financial instruments

($'000)	*Designated at fair value*	*Held to maturity*	*Loans and receivables*	*Financial liabilities at amortised cost*	*Total carrying value*	*Fair value*
31 December 2013						
Assets:						
Cash and cash equivalents	–	–	9,590	–	9,590	N/A
Liabilities:						
Trade and other payables	–	–	–	(1,545)	(1,545)	N/A
Term loans	–	–	–	(785)	(785)	(811)
Derivative financial instruments	(4,622)	–	–	–	(4,622)	(4,622)
Series A shares and series B shares	–	–	–	(24,965)	(24,965)	(24,965)
At 31 December 2013	(4,622)	–	9,590	(27,295)	(22,327)	N/A

Cash and trade payables are settleable within 30 days and accordingly fair value is equal to carrying value in accordance with IFRS 13.

($'000)	*Designated at fair value*	*Held to maturity*	*Loans and receivables*	*Financial liabilities at amortised cost*	*Total carrying value*	*Fair value*
31 December 2012						
Assets:						
Cash and cash equivalents	–	–	17,370	–	17,370	N/A
Liabilities:						
Trade and other payables	–	–	–	(509)	(509)	N/A
Derivative financial instruments	(5,393)	–	–	–	(5,393)	(5,393)
Term loans	–	–	–	(1,568)	(1,568)	(1,614)
Series A shares and series B shares	–	–	–	(22,235)	(22,235)	(22,235)
At 31 December 2012	(5,393)	–	17,370	(24,312)	(12,335)	N/A

($'000)	*Designated at fair value*	*Held to maturity*	*Loans and receivables*	*Financial liabilities at amortised cost*	*Total carrying value*	*Fair value*
31 December 2011						
Assets:						
Cash and cash equivalents	–	–	4,364	–	4,364	N/A
Liabilities:						
Trade and other payables	–	–	–	(428)	(428)	N/A
Term loans	–	–	–	(1,946)	(1,946)	(1,946)
Derivative financial instruments	(2,730)	–	–	–	(2,730)	(2,730)
Series A shares	–	–	–	(5,136)	(5,136)	(5,136)
At 31 December 2011	(2,730)	–	4,364	(7,510)	(5,876)	(9,812)

16. Commitments

The Group had no capital commitments authorised and not contracted for at any reporting date.

Operating lease commitments

The Group has entered into various leasing contracts for the purpose of renting buildings and equipment. There are no restrictions or liens placed upon the Group by entering into these leases.

Operating lease expenses amounted to $170,401 in 2013, $22,935 in 2012 and $4,666 in 2011.

The future aggregate minimum lease payments under non-cancellable operating leases are payable as follows:

	2013	*2012*	*2011*
Within one year	152	113	–
After one year but no more than five years	192	225	–
More than five years	–	–	–
Total operating leases	344	338	–

17. Pension schemes

Defined contribution schemes

The Group operates defined contribution pension schemes for certain employees. The assets of the schemes are held separately from those of the Group in independently administered funds. The advice of a professionally qualified pension consultant was taken in the setting up and maintenance of the schemes.

Total pension costs of the defined contribution schemes for the period ended 31 December 2013 amounted to $8,000 (year ended 31 December 2012: $ nil; year ended 31 December 2011 $ nil). There were no accruals or prepayments in respect of the pension costs at any year-end date.

18. Subsidiary undertakings

At 31 December 2013, the Group had the following subsidiaries and owns 100 per cent. of the called up ordinary share capital of each such subsidiary:

- MML US Inc. The principal activity of MML US Inc. is the provision of research, development and support services to other group companies. MML US Inc. is registered in the United States of America.

- Mainstay Medical (Australia) Pty. Limited. The principal activity of Mainstay Medical (Australia) Pty. Limited is the provision of support services to other group companies. Mainstay Medical (Australia) Pty. Limited is registered in Australia.

19. Share based payments

Stock Incentive Plan

The Group operates a Stock Incentive Plan (the "Plan"). As at 31 December 2013, the Plan allows for the Group to grant various classes of share awards to employees of the Group companies, consultants and other contractors. As at 31 December 2013, share options over ordinary shares and restricted share units have been granted under the Plan.

The Plan allows for flexibility in the grant conditions of each individual award, including variations on the amount of awards granted, the vesting requirements for each award and the expiration terms of the awards. All awards are to be settled through the physical delivery of shares in MML.

Share options

Details of share options granted as at 31 December 2013 are as follows:

Grant date/entitled employees	*Number of instruments in thousands*	*Contractual life of options*
Options granted in 2010	823	10 Years
Options granted in 2011	334	10 Years
Options granted in 2012	65	10 Years
Options granted in 2013	5,386	10 Years
Total share options in issue	6,608	

No share options have expired unexercised or have been exercised in the three years ended 31 December 2013. The above options all include non-market vesting conditions related to employee and non-employee service and vest over periods ranging from one to four years.

Options granted prior to 2013 have an exercise price of $0.04. Options granted in 2013 have an exercise price of $0.05. 903,412 options were currently exercisable at 31 December 2013 (2012: 586,972, 2011: 291,695).

The value of services received in return for the share options granted to employees and non-employees was based on the fair value of the options granted, measured using a Black-Scholes model with the following inputs:

	2013	*2012*	*2011*
Weighted average share price	0.18	0.04	0.04
Weighted average exercise price	0.05	0.04	0.04
Weighted average expected share volatility	60%	60%	60%
Expected term (years)	7	7	7
Expected dividends	–	–	–
Risk free rate	1.6%	0.85%	0.85%
Fair value of option	0.15	0.02	0.02

Restricted share units

As of 31 December 2013, the Group has granted 1,628,000 rights to restricted share units in 2010 which vest over a 4 year period. The fair value of each restricted share unit granted was $0.04, which represented the fair value of the underlying shares on the date of grant.

Share based payment charge

The charge to the income statement in 2013 in relation to share based payments was $430,000 (*2012: $8,000; 2011: $89,000*).

20. Related party transactions

The Group has availed of the exemption available in IAS 24, "Related Party Disclosures", from the requirement to disclose details of transactions with related party undertakings where those parties are 100 per cent. members of the Group.

During 2013 the Group purchased services of $64,085 (*2012 $ nil and 2011 $ nil*) from ORSCO Life Sciences AG, a company controlled by Oern Stuge.

During 2013 the Group paid $nil in fees to MMI, a shareholder and former operating company in the Group, for clinical services provided to the Group (*2012: $231,000, 2011 $nil*).

Key management compensation

The Group defines key management as its executive directors and senior management. Details of remuneration for key management personnel are provided below:

	For the year ended 31 December		
($'000)	*2013*	*2012*	*2011*
Salary	715	681	533
Other remuneration	773	316	222
Pension	3	–	–
Share based payments	234	5	4
Total remuneration	1,725	1,002	759

21. Contingencies

The Directors and management are not aware of any contingencies that may have a significant impact on the financial position of the Group.

22. Impact of the adoption of International Financial Reporting Standards

In this consolidated financial information, the Group has prepared its financial information in accordance with IFRS as adopted by the EU for the first time, effective from 1 January 2011. In accordance with IFRS 1 this financial information includes the Group's opening IFRS Statement of Financial Position as at 1 January 2011.

The Group had previously kept its books and records for MMI in accordance with U.S. GAAP. The Group has not previously published financial statements.

Due to the nature of the Group's activities prior to 1 January 2011 the only adjustment was to record the conversion option in series Z and series A shares at fair value. The impact of this change was to reduce equity by $1,474,000 and increase finance costs in 2010 by the same amount.

23. Events subsequent to 31 December 2013

On 3 April 2014, in connection with the 2014 Corporate Reorganisation, Mainstay Medical International plc issued 793,425 Series A Shares, 1,967,177 Series B Shares, 500,000 Series Z Shares and 81,400 Ordinary Shares to former shareholders in MML, in each case on the basis of one share in the Company in place of each 20 shares in MML of the same class that had been transferred to Mainstay Medical International plc under the terms of the 2014 Corporate Reorganisation.

On the same date all outstanding share options and restricted share units in MML were surrendered by the holders in return for share options in Mainstay Medical International plc on substantially the same terms.

Section 12.2A: ACCOUNTANT'S REPORT ON MAINSTAY MEDICAL INTERNATIONAL PLC

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The Directors
Mainstay Medical International plc
Clonmel House
Forster Way
Swords
County Dublin
Ireland

9 April 2014

Dear Sirs

Mainstay Medical International plc (the 'Company')

We report on the financial information of Mainstay Medical International plc set out in paragraph 12.2.B of Part 12 (*Historical Financial Information*) for the period from incorporation (being 17 February 2014) to 28 February 2014. This financial information has been prepared for inclusion in the prospectus dated 9 April 2014 (the 'Prospectus') on the basis of the accounting policies set out Note 1 to the financial information. The financial information includes the statement of profit or loss and other comprehensive income, the statement of financial position, the statement of cashflows, the statement of changes in shareholders' equity and the related notes. This report is required by paragraph 20.1 of Annex I of Commission Regulation (EC) No. 809/2004 (the 'Prospectus Directive Regulation') and is given for the purpose of complying with that paragraph and for no other purpose.

Responsibilities

The Directors of the Company are responsible for preparing the financial information on the basis of preparation set out in Note 1 to the financial information.

It is our responsibility to form an opinion on the financial information and to report our opinion to you.

Save for any responsibility arising under paragraph 2(2)(f) of Schedule 1 to the Prospectus (Directive 2003/71/EC) Regulations 2005 (S.I. No. 324 of 2005), as amended (the 'Prospectus Regulations') to any person as and to the extent there provided, to the fullest extent permitted by law we do not assume any responsibility and will not accept any liability to any other person for any loss suffered by any such other person as a result of, arising out of, or in connection with this report or our statement, required by and given solely for the purposes of complying with paragraph 23.1 of Annex I of the Prospectus Directive Regulation, consenting to its inclusion in the Prospectus.

Basis of opinion

We conducted our work in accordance with Standards for Investment Reporting issued by the Auditing Practices Board of the United Kingdom and Ireland. Our work included an assessment of evidence relevant to the amounts and disclosures in the financial information. It also included an assessment of the significant estimates and judgments made by those responsible for the preparation of the financial information and whether the accounting policies are appropriate to the entity's circumstances, consistently applied and adequately disclosed.

We planned and performed our work so as to obtain all the information and explanations which we considered necessary in order to provide us with sufficient evidence to give reasonable assurance that the financial information is free from material misstatement whether caused by fraud or other irregularity or error.

Opinion on financial information

In our opinion, the financial information gives, for the purposes of the Prospectus, a true and fair view of the state of affairs of the Company as at 28 February 2014 and of its profits, cash flows and changes in equity for the period then ended in accordance with the basis of preparation set out in Note 1 to the financial information.

Declaration

For the purposes of paragraph 2(2)(f) of the Prospectus Regulations we are responsible for this report as part of the Prospectus and declare that we have taken all reasonable care to ensure that the information contained in this report is, to the best of our knowledge, in accordance with the facts and contains no omission likely to affect its import. This declaration is included in the Prospectus in compliance with paragraph 1.2 of Annex I of the Prospectus Directive Regulation.

Yours faithfully

KPMG
Chartered Accountants
Dublin, Ireland

Section 12.2B: HISTORICAL FINANCIAL INFORMATION OF THE COMPANY

The financial information set out below in respect of the Company for the period from incorporation (being 17 February 2014) to 28 February 2014 has been prepared by the Directors on the basis set out in Note 1.

Statement of profit or loss and other comprehensive income and statement of cash flows

The Company did not trade during the period from incorporation to 28 February 2014 and received no income and incurred no expenditure. Consequently, during this period the Company made neither a profit nor loss.

The Company has no other recognised gains or losses, nor any cash flows during this period and accordingly no statement of cash flows is presented.

Statement of financial position

As at 28 February 2014	*Note*	*2014* €
Current assets		
Other receivables		38,500
		38,500
Total assets		38,500
Equity		
Called up share capital	2	38,500
Retained earnings		–
Total equity		38,500
Total equity and liabilities		38,500

Statement of changes in equity

During the period the Company issued 38,500 "A" ordinary shares in return for a deed of undertaking (the "**Deed of Undertaking**"). There were no other movements in shareholders' equity.

1. Summary of Accounting Policies

Reporting entity

The Company is a company domiciled in Ireland. The Company's registered office address is Clonmel House, Forster Way, Swords, County Dublin, Ireland.

The Company was incorporated on 17 February 2014 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.

Statement of compliance

The financial information has been prepared in accordance with IFRS and their interpretations issued by the IASB as adopted by the EU. The IFRSs adopted by the EU as applied by the Company in the preparation of these financial statements are those that were effective for accounting periods ending on or before 28 February 2014.

Basis of preparation

The financial information presents the financial records of the Company for the period from incorporation (being 17 February 2014) to 28 February 2014.

The financial information is presented in Euro (€), being the functional currency of the Company's operations.

The preparation of financial information in conformity with IFRSs as adopted by the EU requires management to make judgments, estimates and assumptions that affect the application of policies and reported amounts of assets and liabilities, income and expenses. The estimates and associated assumptions are based on historical experience and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis of making the judgements about the carrying values of assets and liabilities that are not readily available from other sources. Actual results may differ materially from these estimates.

The estimates and underlying assumptions are reviewed on an on-going basis. Revisions in accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period or in the period of revision and future periods if the revision affects both current and future periods. Due to the nature of the company there are no judgments in the financial information presented.

As a company seeking admission, the Company is required by paragraph 20.1 of Annex I to the Prospectus Regulation to prepare and present in this Prospectus the last three years (or such shorter period that the issuer has been in operation) of audited historical financial information in a form consistent with the accounting policies to be adopted by the Company's next published annual financial statements. Accordingly, the Directors have prepared financial information for the Company for the period ended 28 February 2014 on the basis expected to be applicable, in so far as this is currently known, for the first set of consolidated financial statements of the Company expected to be prepared for the period ended 31 December 2014, except where otherwise required or permitted by IRFS 1 (First time adoption of International Financial Reporting Standards).

These are not the statutory financial statements of the Company required to be laid before the members at the AGM. Those financial statements will be separately prepared and filed with the Companies Registration Office in Ireland.

Forthcoming requirements

There are no standards issued but not yet effective that would have a material impact on the statement of financial position.

Share capital

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares options are shown in equity as a deduction, net of taxation, from the proceeds.

Other classes of share capital are classified as equity where the instruments are non-redeemable, or redeemable only at the Company's option, and any dividends are discretionary. Discretionary dividends thereon are recognised as distributions within equity upon approval by the Company's shareholders.

2. Share capital

	2014
Authorised	
40,000 "A" ordinary shares of €1.00 each	40,000
Allotted, called up and paid equity	
38,500 "A" ordinary shares of €1.00 each	38,500
	38,500

On incorporation the issued share capital of the Company was €38,500 divided into 38,500 "A" ordinary shares of €1.00 each.

On 17 February 2014 the Company entered into a Deed of Undertaking with the subscribers for the 38,500 "A" ordinary shares representing the subscription shares.

3. Indebtedness

As at the date of this financial information, the Company has no guaranteed, secured, unguaranteed or unsecured debt and no indirect or contingent indebtedness.

4. Related Party Transactions

As at the date of this Prospectus, the Company has not entered into any related party transactions.

5. Subsequent Events

By written resolution of the shareholders of the Company dated 28 March 2014, it was resolved to increase the authorised share capital of the Company by the creation of new classes of shares in the Company, comprising Series A Shares, Series B Shares, Series Z Shares and Ordinary Shares, in addition to the class of A Ordinary Shares already in existence.

By written resolution of the shareholders of the Company dated 2 April 2014 it was resolved to approve the conversion, on completion of the 2014 Corporate Reorganisation, of the A Ordinary Shares to redeemable shares ("**Redeemable Shares**") and by resolutions dated 28 March 2014, the directors of the Company resolved that, immediately upon completion of the 2014 Corporate Reorganisation, subject to the Irish Companies Acts, the Redeemable Shares be redeemed by the Company at par. The Company and MML have together incurred costs of €0.8 million in connection with the 2014 Corporate Reorganisation. The Company expects to write off part of these costs against the premium arising in relation to the 2014 Corporate Reorganisation prior to the projected issuance of new Ordinary Shares in the Offer.

Upon the adoption of new articles of association by the Company on 28 March 2014 ("**Pre-IPO Articles**"), the Company had an authorised share capital of €50,000 divided into 40,000 A Ordinary Shares of €1.00 each, 5,000,000 ordinary shares of €0.001 each, 1,000,000 Series A Shares of €0.001 each, 3,000,000 Series B Shares of €0.001 each and 1,000,000 Series Z Shares of €0.001 each.

On 2 April 2014:

(i) Sofinnova Partners subscribed for 28,469 Series B Shares for an aggregate subscription price of €26,305.36;

(ii) Fountain Healthcare Partners subscribed for 9,074 Series B Shares for an aggregate subscription price of €8,384.38;

(iii) Capricorn Venture Partners subscribed for 4,157 Series B Shares for an aggregate subscription price of €3,841.07;

(iv) Dan Sachs subscribed for 15,000 Ordinary Shares at nominal value, giving an aggregate subscription price of €15.00; and

(v) Medtronic, Inc. subscribed for 6,000 Ordinary Shares at nominal value, giving an aggregate subscription price of €6.00,

giving aggregate subscription proceeds of €38,551.80, which proceeds were used to fund the redemption of the 38,500 Redeemable Shares on 3 April 2014.

On 3 April 2014, in connection with the 2014 Corporate Reorganisation the Company issued 793,425 Series A Shares, 1,967,177 Series B Shares, 500,000 Series Z Shares and 81,400 Ordinary Shares to former shareholders in MML, in each case on the basis of one share in the Company in place of each 20 shares in MML of the same class that had been transferred to the Company under the terms of the 2014 Corporate Reorganisation.

The authorised, issued and fully paid up share capital of the Company as at the date of this report is as follows:

Class	*Authorised Number*	*Nominal Value*	*Issued and fully paid up number*	*Nominal value aggregate*
Ordinary Shares	5,000,000	€0.001	102,400	€102.40
Series A Shares	1,000,000	€0.001	793,425	€793.43
Series B Shares	3,000,000	€0.001	2,008,877	€2,008.88
Series Z Shares	1,000,000	€0.001	500,000	€500.00

On 3 April 2014, in connection with the 2014 Corporate Reorganisation, the 2014 Share Option Plan was adopted by the Company on substantially the same terms as the 2012 share option plan of MML.

PART 13

TAXATION

13.1 OVERVIEW

The following generally summarizes the material Irish, French and U.S. federal income tax consequences of purchasing, owning and disposing of Ordinary Shares. This discussion is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of our ordinary shares. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

This summary does not constitute a legal opinion or tax advice. Shareholders are urged to consult their own tax advisers regarding the tax consequences of the purchase, ownership and disposition of Ordinary Shares in light of their particular circumstances.

This discussion is intended only as a general summary and does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership or disposition of the Ordinary Shares to any particular investor. Shareholders are advised to consult their own tax advisers with regard to the application of Irish and French tax law and U.S. federal income tax law to their particular situations, as well as any tax consequences arising under the laws of any state, local or other foreign jurisdiction.

13.2 IRISH TAXATION

The following paragraphs are meant as a general guide only and constitute a high-level summary of the Company's understanding of current Irish law in respect of the holding and transfer of shares in an Irish company (which is subject to change). This summary is based on the key aspects of Irish tax law and the practice of the Irish Revenue in effect at the date of this Prospectus as they apply to the Company.

The statements of Irish tax laws set out below are based on existing Irish tax laws, including relevant regulations, administrative rulings and practices in effect on the date of this Prospectus and which may apply to investors who are the beneficial owners of shares in an Irish company. Legislative, administrative or judicial changes may modify the tax consequences described below.

The statements do not constitute tax advice and are intended only as a general summary.

Prospective purchasers should consult their own tax advisors as to the tax consequences in Ireland or other relevant jurisdictions of the purchase, ownership and disposition of the Ordinary Shares (being shares in an Irish company).

This summary sets out the Irish tax treatment of Shareholders who hold their Ordinary Shares directly as an investment and who are the absolute beneficial owners of both the Ordinary Shares in and dividends from an Irish company.

Prospective investors who are in doubt about their tax position, or who are subject to tax in a jurisdiction other than Ireland, should consult their own appropriate independent professional advisor without delay whether they are entitled to claim any repayment of tax, and, if so, the procedure for doing so.

Irish taxation of shareholders who are Irish resident and/or ordinarily resident individuals

Irish resident and/or ordinarily resident individual Shareholders will be liable to Irish income tax on dividends from the Company at their marginal rate, plus social security and the universal social charge, depending on their circumstances, on the aggregate of the net dividend received and the withholding tax deducted.

Subject to certain exceptions, the Company is required to apply dividend withholding tax at source at the standard rate (currently 20 per cent.) on dividends paid to Irish resident and/or ordinarily resident individual

Shareholders. The Company should provide the Shareholder with a certificate setting out the gross amount of the dividend, the amount of tax withheld, and the net amount of the dividend.

Where tax has been withheld at source the Shareholder may, depending on their circumstances (i) be liable to further tax on their dividend at their applicable marginal rate, (ii) incur no further liability on their dividend, or (iii) be entitled to claim repayment of some or all of the tax withheld on their dividend. The withholding tax deducted will be available as a credit against the individual's income tax liability. An individual may claim to have the withholding tax refunded to him to the extent that it exceeds his/her income tax liability.

Irish resident and/or ordinarily resident individual Shareholders may be liable to capital gains tax (currently 33 per cent.) on gains realised on the disposal of Ordinary Shares.

Irish taxation of Shareholders who are Irish resident companies

A Shareholder who is an Irish resident company will not be subject to Irish corporation tax on dividends received from the Company.

Tax will not be withheld at source by the Company on dividends paid to an Irish resident company Shareholder provided the appropriate declaration is validly made. If dividend withholding tax is withheld at source, the Irish resident company Shareholder can set the tax withheld against any liability to corporation tax in the accounting period in which the distribution is received.

Irish resident company Shareholders which are close companies, as defined under Irish legislation, may be subject to a corporation tax surcharge on dividend income to the extent that it is not re-distributed within the appropriate time frame.

Capital gains tax (currently 33 per cent.) may apply on gains realised on the disposal of shares in the Company by an Irish company shareholder. Substantial shareholding exemptions may apply to Shareholders who own more than 5 per cent. in the shares of the Company.

Irish taxation of certain other Irish resident Shareholders

Tax will not be withheld at source by the Company on dividends to certain other Irish resident Shareholders including certain pension schemes, collective investment undertakings and charities provided the appropriate declaration is validly made. If dividend withholding tax is withheld at source, the Shareholder can set the tax withheld against their liability to income or corporation tax in the accounting period in which the distribution is received.

Capital gains tax (currently 33 per cent.) may apply on gains realised on the disposal of shares in the Company by such other Irish resident Shareholders depending on their specific tax status.

Irish taxation of Shareholders who are not resident for tax purposes in Ireland

The Company is obliged to apply dividend withholding tax at the standard rate (currently 20 per cent.) on dividends made to non-resident Shareholders.

However, dividends made to certain non-residents may be exempt from dividend withholding tax on the basis that the distribution is made to:

(a) a resident of a foreign country with which Ireland has a tax treaty;

(b) a resident of an EU Member State (other than Ireland);

(c) a company not resident in Ireland which is ultimately controlled by a resident of a tax treaty country or an EU Member State (other than Ireland); or

(d) a company if its principal class of share is substantially and regularly traded on a recognised stock exchange in a tax treaty country or Member State.

In each case, an appropriate declaration must be made and evidence of entitlement to exemption provided.

Non-Irish residents will not be liable to capital gains tax in Ireland as the Company is a public listed company, unless such persons are either ordinarily resident in Ireland or hold the shares in connection with a branch or agency carried on in the state.

Irish Capital Acquisitions Tax

Capital acquisitions tax ("CAT") covers both gift tax and inheritance tax. Irish CAT may be chargeable on an inheritance or a gift of Ordinary Shares as such shares would be considered Irish property, notwithstanding that the gift or inheritance is between two non-Irish resident and non-ordinarily Irish resident individuals. The current rate of CAT is 33 per cent. Shareholders should consult their tax advisors with respect to the CAT implications of any proposed gift or inheritance of Ordinary Shares.

Stamp Duty

Transfers or sales of ordinary shares of Irish companies may be subject to ad valorem stamp duty. The Irish rate of stamp duty on shares is currently 1 per cent. of the higher of the consideration paid or the market value of the shares.

No stamp duty is payable on the issue of Ordinary Shares as part of the Offer.

Transfers of Ordinary Shares within the CREST system or where Ordinary Shares are held in certificated form

Legislation (Finance Act (No. 2) 2013) was enacted in December 2013 to provide an exemption from stamp duty on the transfer of certain listed shares (including those admitted to trading on ESM). However, this provision does not become effective until such time as it is commenced by Ministerial Order. The Ministerial Order is outstanding pending EU approval of the proposed stamp duty exemption and therefore it is uncertain whether (and, if so, when) the Ministerial Order will be made.

Pending the making of the Ministerial Order on such terms as to exempt transfers of Ordinary Shares admitted to trading on ESM from a charge to stamp duty, transfers of Ordinary Shares (i) within the CREST system or (ii) that are held in certificated form (i.e. where the Shareholder holds a share certificate and effects the transfer by way of written instrument) may, in each case, be subject to stamp duty.

Stamp duty is normally payable by the purchaser or transferee (although where such purchase is effected through a stockbroker or other financial intermediary, that person should normally account for the liability to stamp duty and should indicate this has been done in any contract note issued to a buyer). Paperless transfers of the Ordinary Shares within the CREST system may be liable to stamp duty and the duty on such transactions is generally settled within the CREST system.

Transfers of Ordinary Shares clearing through the Euroclear France system

The Irish Revenue Commissioners have confirmed that they will not seek to collect stamp duty in relation to electronic transfers of Ordinary Shares that are settled via the Euroclear France settlement system.

13.3 FRENCH TAXES

The following is a summary of certain tax considerations which may be relevant for holders of the Ordinary Shares that are resident of France for tax purposes (the "**French Resident Shareholders**") and are either (i) individuals holding the Ordinary Shares as part of their personal portfolio (the "**Individual French Resident Shareholders**") or (ii) French legal entities subject to corporation tax in France (the "**French Resident Corporate Shareholders**").

This summary is provided for general information purposes only, and it does not purport to be a comprehensive description of all the tax considerations which may be relevant for specific French Resident Shareholders in light of their particular circumstances.

French Resident Shareholders which do not fall within any of these two categories should contact their own tax advisor to determine the tax consequences in connection with their acquisition or holding of the Ordinary Shares.

This summary is based on the tax laws and regulations currently in force in France, including the double tax treaty entered into between Ireland and France on 21 March 1968 (the "**Ireland/France Tax Treaty**"), as currently in effect and applied by the French tax authorities, all of which being subject to change or different interpretation.

This summary is not intended to be, nor should it be construed as being legal or tax advice.

Individual French Resident Shareholders

Dividends

Dividends distributed by the Company to Individual French Resident Shareholders should not be subject to a dividend withholding tax in Ireland (please see paragraph 13.2 of Part 13 (*Taxation*) above). Should any Irish domestic dividend withholding tax be imposed, the rate of such withholding tax would not be reduced under the current provisions of the Ireland/France Tax Treaty, but it could give rise to a tax credit in France (please see below).

Individual French Resident Shareholders are subject to personal income tax in France at progressive rates up to 45 per cent. on the gross amount of the dividends received. As the Company is subject in Ireland to a tax equivalent to the French corporation tax (i.e. Irish corporation tax), has its head office located in Ireland, and assuming that the relevant dividends distribution is made in accordance with Irish company law, dividends received by Individual French Resident Shareholders should be eligible to an allowance equal to 40 per cent. of the gross amount of the dividends received, as provided for by Article 158, 3°-2 of the French tax code. In addition, a so-called exceptional contribution on high income should be due by Individual French Resident Shareholders on the gross amount of the dividends received if the total taxable income of their household exceeds certain thresholds. Such exceptional contribution is levied (i) at the rate of 3 per cent. on the portion of the taxable income comprised between €250,000 and €500,000 for single taxpayers and between €500,000 and €1,000,000 for joint taxpayers, and (ii) at the rate of 4 per cent. on the portion of the taxable income exceeding €500,000 for single taxpayers and €1,000,000 for joint taxpayers.

Pursuant to Article 117 *quater* of the French tax code, in advance of payment of the personal income tax liability of any relevant year, Individual French Resident Shareholders are subject (except where their annual taxable income does not exceed certain specific thresholds) to a mandatory withholding tax at the rate of 21 per cent. on the gross amount of the dividends received, to be paid to the French tax authorities by the paying agent established in France (or by the paying agent established within the EEA and duly authorized by the taxpayer to pay such withholding tax on his behalf) or by the Individual French Resident Shareholders if the paying agent is established outside France, within 15 days of the first day of the month following the month of payment of the dividends. This mandatory withholding tax is creditable against the personal income tax liability eventually due.

Should any dividend withholding tax be levied in Ireland, a tax credit would be deductible, under certain conditions, from the personal income tax due in France, in accordance with Article 21 of the Ireland/France Tax Treaty.

Dividends received from the Company by Individual French Resident Shareholders will also be subject to social contributions at the aggregate rate of 15.5 per cent. (including (i) the *contribution sociale généralisée* at the rate of 8.2 per cent., 5.1 per cent. of which being deductible for personal income tax purposes, (ii) the *contribution pour le remboursement de la dette sociale* at the rate of 0.5 per cent., (iii) the *prélèvement social* at the rate of 4.5 per cent., (iv) the *contribution additionnelle* at the rate of 0.3 per cent., and (v) the *prélèvement de solidarité* at the rate of 2 per cent.).

Capital gains

Pursuant to Article 7-1° of the Ireland/France Tax Treaty, capital gains realized by Individual French Resident Shareholders upon the sale or disposal of Ordinary Shares should be exclusively taxable in France.

Under current French tax law, capital gains realized upon the sale or disposal of Ordinary Shares are subject to (i) personal income tax at progressive rates up to 45 per cent., (ii) the so-called exceptional contribution

on high income at the rate of 3 per cent. and 4 per cent., and (iii) the 15.5 per cent. social contributions, in each case under the conditions described above.

In accordance with Article 150-0 D of the French tax code, capital gains realized by Individual French Resident Shareholders upon the sale or disposal of Ordinary Shares may however benefit, for personal income tax purposes only, from an allowance equal (i) 50 per cent. of the amount of the capital gains in case of a holding period comprised between two and eight years, or (ii) 65 per cent. of the amount of the capital gains in case of a holding period exceeding eight years. Such allowance may be increased, under certain conditions, to (i) 50 per cent. of the amount of the capital gains in case of a holding period comprised between one and four years, (ii) 65 per cent. of the amount of the capital gains in case of a holding period comprise between four and eight years, and (iii) 85 per cent. of the amount of the capital gains in case of a holding period exceeding eight years.

In accordance with Article 150-0 D of the French tax code, capital losses realized upon the sale or disposal of Ordinary Shares should be deductible from capital gains realized upon the sale or disposal of securities of the same nature in the same year or during the ten years following the relevant sale or disposal.

Special tax regime for stock-savings plans (plan d'épargne en actions or "PEA")

For shareholders domiciled in France, the Ordinary Shares should be eligible assets for PEA purposes. The PEA investment ceiling amount is €150,000 (€300,000 for a couple).

Under certain conditions, the PEA gives entitlement:

- for the duration of the PEA, to exemption from income tax and social security contributions on the net capital gains generated by the investments made as part of the PEA, on condition that those capital gains are retained in the PEA, and
- when the PEA is closed (if closure occurs more than five years after the opening date of the PEA) or upon a partial withdrawal (if more than eight years after the opening date of the PEA), to exemption from income tax on the net gain realised as from when the plan was opened. However, these gains remain subject to social security contributions including any additional contributions thereon, to the "CSG" contribution (*Contribution Social Généralisée*) and to the "CRDS" contribution (*Contribution pour la Réduction de la Dette Sociale*) at the overall tax rate of 15.5 per cent.

Losses realised on the shares held in a PEA are, in principle, not tax deductible but can be set off against any gains realised under the same plan (special rules apply, however, in certain circumstances, when closing a PEA). Investors are advised to consult their own tax advisers on this issue.

Subject to the aforementioned exemptions, capital gains realised on the sale of investments made as part of a PEA are taxable (i) when the sale occurs within two years from its opening, at the rate of 22.5 per cent. (Article 200 A of the French General Tax Code) and (ii) when the sale occurs between two and five years from the opening of the PEA, at a rate of 19 per cent., plus the social security amounts described above, if any, at the overall rate of 15.5 per cent.

The 2014 French Finance Act (*Loi de finances pour 2014)* also created a new category of PEA called a "PME-ETI" exclusively for investment in small and medium sized businesses, which provides for the same tax benefits as the PEA. Eligible securities must, in particular, have been issued by a company that employs less than 5,000 people and has annual revenues not exceeding €1.5 billion or a balance sheet total not exceeding €2 billion. An implementing decree (No. 2014-283) specifying these conditions was published on March 5, 2014.

Provided that the Company qualifies as an "autonomous enterprise" within the meaning of Article 3 of Annex I of Regulation (EC) No. 800/2008 of August 6, 2008, the Ordinary Shares should be eligible for a "PME-ETI" PEA. The "PME-ETI" PEA investment ceiling amount is €75,000 (€150,000 for a couple).

The "PME-ETI" PEA may be combined with an ordinary PEA, and each taxpayer may hold only one "PME-ETI" PEA (for married persons and civil union partners each person or partner may hold a "PME-ETI" PEA).

Wealth tax

Ordinary Shares held by Individual French Resident Shareholders should be within the scope of the French wealth tax (*impôt de solidarité sur la fortune*). Individual French Resident Shareholders should contact their own tax advisor to determine whether any allowance or exemption could be available depending on their personal situation.

French Resident Corporate Shareholders

Dividends

Dividends distributed by the Company to French Resident Corporate Shareholders should not be subject to a dividend withholding tax in Ireland (please see paragraph 13.2 of Part 13 (*Taxation*) above). Should any Irish domestic dividend withholding be imposed, the rate of such withholding tax would not be reduced under the current provisions of the Ireland/France Tax Treaty, but it could give rise to a tax credit in France (please see below).

Dividends received by French Resident Corporate Shareholders will be subject to French corporation tax at the standard rate of 33⅓ per cent. increased by (i) the 3.3 per cent. social contribution assessed on the amount of the corporation tax liability in excess of €763,000 in a relevant year, and (ii) the 10.7 per cent. exceptional contribution assessed on the amount of corporation tax due by companies realising an annual turnover exceeding €250,000,000. A reduced corporation tax rate of 15 per cent. up to €38,120 of the taxable income realized in the relevant fiscal year may also be available, subject to certain conditions.

In accordance with Articles 145 and 216 of the French tax code, French Resident Corporate Shareholders holding at least 5 per cent. of the capital of the Company are eligible, under certain conditions, to the French parent-subsidiary regime under which dividends are exempt from corporation tax subject to an add-back to the taxable income of an lump sum amounting to 5 per cent. of the dividends received (so-called *quote-part de frais et charges*), which is subject to French corporation tax at the standard rate of 33⅓ per cent. increased by (i) the 3.3 per cent. social contribution assessed on the amount of the corporation tax liability in excess of €763,000 in a relevant year, and (ii) the 10.7 per cent. exceptional contribution assessed on the amount of corporation tax due by companies realising an annual turnover exceeding €250,000,000.

Should any dividend withholding tax be levied in Ireland, a tax credit would be deductible, under certain conditions, from the corporation tax due in France, in accordance with Article 21 of the Ireland/France Tax Treaty (except where the above-mentioned French parent-subsidiary regime is applicable, in which case no tax credit would be available).

Capital gains

Pursuant to Article 7-1° of the Ireland/France Tax Treaty, capital gains realized by French Resident Corporate Shareholders upon the sale or disposal of Ordinary Shares should be exclusively taxable in France, unless the relevant Ordinary Shares are held through a permanent established of the relevant French Resident Corporate Shareholder in Ireland.

Capital gains and losses realized upon the sale or disposal of Ordinary Shares by French Resident Corporate Shareholders are in principle included in the taxable income realized in the relevant fiscal year by the French Resident Corporate Shareholder, and thus subject to corporation tax at the standard rate of 33⅓ per cent. (increased, as the case may be, by (i) the 3.3 per cent. social contribution assessed on the amount of the corporation tax liability in excess of €763,000 in a relevant year, and (ii) the 10.7 per cent. exceptional contribution assessed on the amount of corporation tax due by companies realising an annual turnover exceeding €250,000,000). A reduced corporation tax rate of 15 per cent. up to €38,120 of the taxable income realized in the relevant fiscal year may also be available, subject to certain conditions.

French Resident Corporate Shareholders may however be eligible to a specific corporation tax treatment under the French participation-exemption regime to the extent that the Ordinary Shares held (i) qualify as a so-called qualifying interest (*titres de participation*) within the meaning of Article 219-1 a *quinquies* of the French tax code, and (ii) were held for a period of at least two years as at the date of the sale or disposal. In accordance with Article 219-1 a *quinquies* of the French tax code, only 12 per cent. of the gross amount of

the capital gains realized upon the sale or disposal of such controlling interest held for at least two years as at the date of the sale or disposal is subject to corporation tax at the standard rate of 33,1/3 per cent. (increased, as the case may be, by (i) the 3.3 per cent. social contribution assessed on the amount of the corporation tax liability in excess of €763,000 in a relevant year, and (ii) the 10.7 per cent. exceptional contribution assessed on the amount of corporation tax due by companies realising an annual turnover exceeding €250,000,000).

Other taxes and duties

French financial transactions tax

In accordance with Article 235 *ter* ZD of the French tax code, acquisitions of certain equity securities or similar instruments issued by a company having its head office in France and having a market capitalization in excess of €1,000,000,000 are subject to the French financial transaction tax at the rate of 0.2 per cent. Such tax may also apply to acquisitions of certain securities issued by an issuer whose head office is not in France where such securities represent certain equity securities or similar instruments issued by a company having its head office in France and having a market capitalization in excess of €1,000,000,000.

In accordance with Article 235 ter ZD of the French tax code and with official administrative guidelines BOI-TCA-FIN-10-10-20140115 issued by the French tax authorities, when the issuer does not have its head office in France, its securities do not fall within the scope of the French financial transactions tax, even if they are (i) admitted to trading on a French trading platform or (ii) their issue account is held by a central depositary in France.

As long as the head office of the Company is not in France, acquisitions of Ordinary Shares on Euronext Paris should thus not be subject to the French financial transactions tax.

Registration duties

Pursuant to Articles 726 and 718 of the French tax code, registration duties are payable in France upon a sale of shares in a listed company whose head office is abroad only where the aforementioned sale is recorded in any written agreement formed in France formalising the sale of such shares. Where applicable, such registration duties apply at the proportional rate of 0.1 per cent. levied on the higher of the sale price of the shares or their fair market value.

Other situations

French Resident Shareholders which are subject to taxation regimes other than those described above should contact their own tax advisor to determine their personal situation.

Irish Stamp Duty

Transfers or sales of ordinary shares of Irish companies are subject to ad valorem stamp duty, irrespective as to whether the shareholder is resident in Ireland, France or elsewhere. See paragraph 13.2 of this Part 13 (*Taxation*) under the heading "*Stamp Duty*" for further information.

13.4 U.S. TAXES

U.S. Taxes

Internal Revenue Service Circular 230 Notice: **To ensure compliance with Internal Revenue Service Circular 230, prospective investors are hereby notified that: (a) any discussion of United States federal tax issues contained or referred to in this Prospectus is not intended or written to be used, and cannot be used, by prospective investors for the purpose of avoiding penalties that may be imposed on them under the Internal Revenue Code; (b) such discussion is written in connection with the promotion or marketing of the transaction or matters addressed herein; and (c) prospective investors should seek advice based on their particular circumstances from an independent tax adviser.**

The following generally summarizes the material U.S. federal income tax consequences to U.S. holders (as defined below) of purchasing, owning and disposing of Ordinary Shares. For the purposes of this discussion,

a U.S. holder is a beneficial owner of Ordinary Shares that is (i) an individual who is a U.S. citizen or resident for U.S. federal income tax purposes, (ii) a U.S. domestic corporation or certain other entities created or organized in or under the laws of the United States or any state thereof, including the District of Colombia, (iii) an estate, the income of which is subject to U.S. federal income taxation regardless of its source, (iv) a trust that (1) is subject to the primary supervision of a court within the United States and the control of one or more U.S. persons for all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person, or (v) otherwise subject to U.S. federal income taxation on a net income basis in respect of Ordinary Shares.

If a partnership holds Ordinary Shares, the tax treatment of a partner generally will depend upon the status of the partner and the activities of the partnership. *If a U.S. holder is a partner in a partnership that holds Ordinary Shares, the holder is urged to consult its own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Ordinary Shares*.

The discussion applies only to investors that hold Ordinary Shares as capital assets that have the U.S. dollar as their functional currency. Certain holders (including, but not limited to, U.S. expatriates, partnerships or other entities classified as partnerships for U.S. federal income tax purposes, banks, insurance companies, regulated investment companies, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax, persons who acquired the Ordinary Shares pursuant to the exercise of employee stock options or otherwise as compensation, persons that own (directly, indirectly or by attribution) 10 per cent. or more of our voting stock, dealers in securities or currencies, persons that elect to mark their securities to market generally for U.S. federal income tax purposes and persons holding Ordinary Shares as a position in a synthetic security, straddle or conversion transaction) may be subject to special rules not discussed below. *U.S. holders of Ordinary Shares are advised to consult their own tax advisers with regard to the application of U.S. federal income tax law to their particular situations, particularly with regard to the application of the Passive Foreign Investment Company ("**PFIC**") rules below*.

Taxation of Dividends

Subject to the PFIC and other rules discussed below, for U.S. federal income tax purposes, the gross amount of any distribution paid to U.S. holders (that is, the net distribution received plus any tax withheld therefrom) will be treated as ordinary dividend income to the extent paid or deemed paid out of the current or accumulated earnings and profits of the Company (as determined under U.S. federal income tax principles). Dividends paid by the Company will not be eligible for the dividends received deduction generally allowed to corporate U.S. holders.

Subject to the PFIC rules below (and certain exceptions for short-term and hedged positions), the U.S. dollar amount of dividends received by a non-corporate U.S. Holder, including an individual U.S. holder with respect to Ordinary Shares is currently subject to taxation at a maximum rate of 20 per cent. provided that the dividends are "qualified dividends". Dividends are qualified dividends if (i) the Company is eligible for the benefits of a comprehensive income tax treaty with the United States that the Internal Revenue Service has approved for the purposes of the qualified dividend rules (ii) the Company was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the dividend is paid, a PFIC and (iii) certain holding periods are met. The income tax treaty between the United States and Ireland has been approved for these purposes and the Company expects to be eligible for the benefits of the treaty. Nevertheless, because the Company may be a PFIC for 2014 and subsequent taxable years (see "*Passive Foreign Investment Company and Similar Rules*", below), dividends on the Ordinary Shares will not be treated as qualified dividends until the year after the Company ceases to be a PFIC, which may not ever occur. U.S. holders of Ordinary Shares should consult their own tax advisers regarding the availability of the reduced dividend tax rate in light of the PFIC rules and their own particular circumstances.

If you are a U.S. holder, dividend income received by you with respect to Ordinary Shares generally will be treated as foreign source income for foreign tax credit purposes. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. Distributions out of earnings and profits with respect to the Ordinary Shares generally will be treated as "passive category" income (or, in the case of certain U.S. holders, "general category" income).

Dividends paid on the Ordinary Shares to a U.S. holder should not be subject to a dividend withholding tax in Ireland (see "Irish taxation of shareholders who are not resident for tax purposes in Ireland" in paragraph 13.2 of Part 13 (*Taxation*) above). Should any Irish withholding or other non-U.S. withholding tax be imposed, on the dividends, subject to the above and other limitations, any such tax withheld could be claimed as a credit against the U.S. federal income tax liability of a U.S. holder if such U.S. holder elects for that year to credit all foreign income taxes. Alternatively, such non-U.S. withholding tax could be taken as a deduction against taxable income. Foreign tax credits will not be allowed for withholding taxes imposed in respect of certain short-term or hedged positions in Ordinary Shares and may not be allowed in respect of certain arrangements in which a U.S. holder's expected economic profit is insubstantial. *The U.S. federal income tax rules governing the availability and computation of foreign tax credits are complex. U.S. holders should consult their own tax advisers concerning the implications of these rules in light of their particular circumstances*.

To the extent that an amount received by a U.S. holder exceeds the allocable share of the Company's current and accumulated earnings and profits, such excess will be applied first to reduce such U.S. holder's tax basis in its Ordinary Shares and then, to the extent it exceeds the U.S. holder's tax basis, it will constitute capital gain from a deemed sale or exchange of such Ordinary Shares (see "*Gain or Loss upon Sale (or Other Disposition*" in paragraph 13.4 of Part 13 (*Taxation*), below).

The amount of any distribution paid in Euro will be equal to the U.S. dollar value of the Euro amount distributed, calculated by reference to the exchange rate in effect on the date the dividend is received by a U.S. holder of Ordinary Shares regardless of whether the payment is in fact converted into U.S. dollars on such date. *U.S. holders should consult their own tax advisers regarding the treatment of foreign currency gain or loss, if any, on any Euro received by a U.S. holder that are converted into U.S. dollars on a date subsequent to receipt.*

Passive Foreign Investment Company and Similar Rules

The Company may meet the definition of a PFIC for its 2014 taxable year and subsequent taxable years. As a result, any U.S. holder of Ordinary Shares that receives an "excess distribution" on its Ordinary Shares (which includes gain realized on a sale or other disposition of its Ordinary Shares, as discussed below) will be subject to an increased tax amount with respect to each prior year it held the Ordinary Shares, based on an assumption that such excess was economically earned over all such prior years. All such amounts will be treated as ordinary income, rather than capital gain or qualified dividends. These consequences can be mitigated if the U.S. holder makes the Qualified Electing Fund ("QEF") election described below. The application of the PFIC rules can be detrimental in terms of timing and character of income from an investment in the Ordinary Shares, as well as quite complex. Potentially affected U.S. holders of Ordinary Shares are encouraged to consult their own tax advisors with regard to the PFIC rules and the QEF and other elections discussed below that might be used to mitigate their detrimental effects.

PFIC Definition

A non-U.S. corporation is deemed to be a PFIC if in any year in which either (1) 75 percent or more of its "gross income" is passive-type income (the "**Income Test**"), or (2) 50 percent or more of its assets (based on quarterly average values) are assets that produce passive-type income (the "**Asset Test**"). The Company is expected to meet the Income Test in 2014 and may also meet the Income Test in subsequent taxable years. The Company may also meet the Asset Test for 2014 and subsequent years due to the large proportion of its assets that are cash and cash equivalents (which are treated as producing passive-type income for purposes of the Asset Test). It is possible that the Company will not, however, meet the Asset Test in these years. For example, even in 2014, it is possible that the trading value of the Company's stock will be sufficiently high for all quarters that the annual average value of the Company's goodwill (which should be such total trading value minus the aggregate value of other assets) will be sufficiently large that the Asset Test is not met. It is also possible that the proportion of the Company's assets represented by cash and cash equivalents will be sufficiently reduced that the Asset Test will not be met.

PFIC Taxation

Absent the elections discussed below, if the Company is a PFIC during any taxable year in a U.S. holder's holding period, all "excess distributions" made to the shareholder (including gain on a sale or disposition of the Ordinary Shares, as described below), in that year and in all subsequent years are subject to a special tax regime that requires ordinary income treatment and applies an increased tax amount based on an assumption that such excess was economically earned over all prior years of the U.S. holder's holding period. The total excess distribution for any taxable year is the excess of (a) the total distributions received by the taxpayer during the year over (b) 125 percent of the average amount received by the taxpayer during the three preceding years (or, if shorter, the taxpayer's holding period). In addition, all gain on the disposition of the Ordinary Shares will be treated as an excess distribution. The increased tax amount for the excess distribution is equal to the sum of (a) the aggregate increases in taxes (computed at the maximum marginal rate) for each year in the taxpayer's holding period before the current year that would result from allocating the excess distributions rateably over the taxpayer's holding period and (b) an interest charge on those increases. Amounts allocated to the taxable year in which the sale or excess distribution occurs and to any year before the Company became a PFIC would be taxed as ordinary income in the taxable year in which the sale or excess distribution occurs. If applicable to a U.S. holder of Ordinary Shares, the rules pertaining to a "controlled foreign corporation" (discussed below) effectively override the PFIC rules in most circumstances.

In order to avoid the application of the above PFIC rules, U.S. holders of Ordinary Shares may wish to consider making the QEF election. If a U.S. holder makes a valid QEF election, instead of being subject to the "excess distribution" rules discussed above, such U.S. holder will generally be required to include as ordinary income its pro rata share of the Company's ordinary earnings for each taxable year and to include in gross income as capital gains its pro rata share of the Company's net capital gains for the taxable year (even if the amount of such income exceeds the cash received by the U.S. holder for the taxable year). Subsequent dividends received by the U.S. holder will not be taxable to the extent of amounts previously included in gross income by the U.S. holder under these rules. Any losses of the Company in a taxable year will not be available to such U.S. holder and may not be carried back or forward in computing the Company's ordinary earnings and net capital gain in other taxable years. The Company intends to provide U.S. holders of Ordinary Shares (or arrange for them to be provided) with an annual information statement to allow them to determine their pro rata share of the Company's ordinary earnings and net capital gains for purposes of the QEF election rules.

A U.S. holder making the QEF election may have amounts of so-called "phantom income" — i.e., income for U.S. federal income tax purposes that exceeds the amounts distributed on the Ordinary Share. Such phantom income may, under some circumstances, make the QEF election undesirable (as compared to reporting under the "excess distribution" rules for PFICs described above).

U.S. holders of Ordinary Shares that make the QEF election may also elect to defer payment of some or all of their taxes on the Company's income, subject to an interest charge on the deferred amount. A special election is also available for U.S. holders who have not made the QEF election for all relevant years to "purge" PFIC status (and thus cease the application of the "excess distribution" rules) in exchange for a one-time income inclusion.

Provided that the Ordinary Shares are treated as "marketable stock" for purposes of the PFIC rules, a U.S. holder may also be able to avoid application of the "excess distribution" rules by making a mark-to-market election with respect to its Ordinary Shares. A U.S. holder that makes an effective mark-to-market election will include as ordinary income each year the excess of the fair market value of its Ordinary Shares at the end of the year over its adjusted tax basis in its Ordinary Shares. Similarly, any gain realized on the sale, exchange or other disposition of the Ordinary Shares will be treated as ordinary income. A U.S. holder that makes a mark-to-market election will be entitled to deduct as an ordinary loss each year the excess of its adjusted tax basis in its Ordinary Shares over their fair market value at the end of the year, but only to the extent of the net amount previously included in income as a result of the mark-to-market election. A U.S. holder that makes a mark-to-market election will increase its adjusted tax basis in its Ordinary Shares by the amount of any income inclusions and decrease its adjusted tax basis in its Ordinary Shares by the amount of any deductions under the mark-to-market rules. If a U.S. holder makes a mark-to-market election, it will be effective for the taxable year for which the election is made and all subsequent taxable years unless we the

Company is no longer treated as a PFIC, the Ordinary Shares are no longer regularly traded on a qualified exchange or the Internal Revenue Service consents to the revocation of the election.

All U.S. holders of Ordinary Shares are urged to consult with their own tax advisors with regard to the consequences and desirability of making the QEF and these other elections.

If the Company were a PFIC, certain subsidiaries and other entities in which the Company has a direct or indirect interest may also be PFICs ("**Lower-tier PFICs**"). Under attribution rules, U.S. holders would be deemed to own their proportionate shares of Lower-tier PFICs and would be subject to U.S. federal income tax according to the rules described above on (i) certain distributions by a Lower-tier PFIC and (ii) a disposition of shares of a Lower-tier PFIC, in each case as if the U.S. holder held such shares directly, even though such U.S. holder had not received the proceeds of those distributions or dispositions. A U.S. holder may not make a mark-to-market election with respect to the shares of any Lower-Tier PFIC. Thus, the mark-to-market election is not available to mitigate the adverse tax consequences attributable to any Lower-Tier PFIC.

Controlled Foreign Corporation Rules

If U.S. holders of Ordinary Shares or U.S. holders treated as constructively owning Ordinary Shares, each owning 10 per cent. of the equity of the Company by vote ("**10-per cent. Shareholders**") own in total more than 50 per cent. of the Company by vote or equity value, the Company will be treated as a controlled foreign corporation ("**CFC**"). If the Company were treated as a CFC, a U.S. holder of Ordinary Shares would be treated, subject to certain exceptions, as receiving a deemed dividend at the end of the taxable year of the Company in an amount equal to its pro rata share of the "subpart F income" of the Company. Among other items, and subject to certain exceptions, "subpart F income" includes interest and gains from the sale or exchange of certain assets. Thus, it is likely that, if the Company were to constitute a CFC, some of its income would be subpart F income. If the Company were treated as a CFC and a U.S. holder were treated as a 10-per cent. Shareholder therein, the Company would not be treated as a PFIC with respect to such U.S. holder for the period during which the Company remained a CFC and such U.S. holder remained a 10 per cent. Shareholder therein. The application of the rules governing CFCs can be quite complex, and potentially affected U.S. holders of Ordinary Shares are encouraged to consult their own tax advisors.

Gain or Loss upon Sale (or Other Disposition)

Subject to the special PFIC and CFC rules below, in general, a U.S. holder that sells, exchanges or otherwise disposes of its Ordinary Shares (including by redemption) will recognize capital gain or loss in an amount equal to the U.S. dollar value of the difference between the amount realized for the Ordinary Shares and the U.S. holder's adjusted tax basis (determined as below in U.S. dollars) in the Ordinary Shares. Such gain or loss generally will be U.S. source gain or loss, and will be treated as long-term capital gain or loss if the U.S. holder's holding period in the ordinary shares exceeds one year at the time of disposition. For non-corporate U.S. holders, including individuals, any capital gain generally will be subject to U.S. federal income tax at preferential rates (currently a maximum of 20 per cent.) if specified minimum holding periods are met. The deductibility of capital losses is subject to significant limitations.

Initially, a U.S. holder's tax basis for an Ordinary Share will equal the cost of such share to the U.S. holder. Such basis will be increased by amounts taxable to such U.S. holder by virtue of a QEF election, or by virtue of the CFC rules, and decreased by actual distributions from the Company that are deemed to consist of such previously taxed amounts or are treated as a non-taxable reduction to the U.S. holder's tax basis for the Ordinary Shares (as discussed above). If the Company is a PFIC for 2013 or any subsequent year of the U.S. holder's holding period, and the U.S. holder does not make a timely QEF election for all such years (or one of the other elections discussed above), any gain realized on the sale, exchange, redemption, retirement or other taxable disposition of the U.S. holder's Ordinary Shares will be taxed as ordinary income and subject to the additional tax reflecting the deemed interest discussed above (see "PFIC Taxation" above). If the Company were treated as a CFC and a U.S. holder were treated as a 10-percent Shareholder therein, then any gain realized by such U.S. holder upon the disposition of Ordinary Shares would be treated as ordinary income to the extent of the U.S. holder's share of the current or accumulated earnings and profits of the

Company. In this regard, earnings and profits would not include any amounts previously taxed pursuant to a QEF election or pursuant to the CFC rules.

Medicare Tax

Certain U.S. holders who are individuals, estates or trusts are now required to pay a Medicare tax of 3.8 per cent. (in addition to taxes they would otherwise be subject to) on their "net investment income" which would include, among other things, dividends and capital gains from the Ordinary Shares.

Information Reporting and Backup Withholding Tax

Distributions made to holders and proceeds paid from the sale, exchange, redemption or disposal of Ordinary Shares may be subject to information reporting to the Internal Revenue Service. Such payments may be subject to backup withholding taxes unless the holder (i) is a corporation or other exempt recipient or (ii) provides a taxpayer identification number and certifies that no loss of exemption from backup withholding has occurred. Holders that are not U.S. persons generally are not subject to information reporting or backup withholding. However, such a holder may be required to provide a certification of its non-U.S. status in connection with payments received within the United States or through a U.S. related financial intermediary to establish that it is an exempt recipient. Backup withholding is not an additional tax. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a holder's U.S. federal income tax liability. A holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service and furnishing any required information.

Foreign Asset Reporting

In addition, a U.S. holder that is an individual (and, to the extent provided in future regulations, an entity), may be subject to recently enacted reporting obligations with respect to Ordinary Shares if the aggregate value of these and certain other "specified foreign financial assets" exceeds $50,000. If required, this disclosure is made by filing Form 8938 with the U.S. Internal Revenue Service. Significant penalties can apply if holders are required to make this disclosure and fail to do so. In addition, a U.S. holder should consider the possible obligation to file a Form TD F 90-22.1 — Foreign Bank and Financial Accounts Report as a result of holding Ordinary Shares. Holders are thus encouraged to consult their U.S. tax advisors with respect to these and other reporting requirements that may apply to their acquisition of Ordinary Shares.

State and Local Taxes

In addition to U.S. federal income tax, U.S. holders of Ordinary Shares may be subject to U.S. state and local taxes with respect to such Ordinary Shares. *Holders of Ordinary Shares are advised to consult their own tax advisers with regard to the application of U.S. state and local income tax law to their particular situation*.

Irish Stamp Duty

Transfers or sales of ordinary shares of Irish companies are subject to ad valorem stamp duty, irrespective as to whether the shareholder is resident in Ireland, France or elsewhere. See paragraph 13.2 of this Part 13 (*Taxation*) under the heading "*Stamp Duty*" for further information.

PART 14

THE OFFER

14.1 OFFER TERMS AND CONDITIONS AND SUBSCRIPTION TERMS AND CONDITIONS

14.1.1 ***Terms and conditions of the Offer***

The Offer will be made by issue of up to 851,175 new Ordinary Shares (the "**Base Offer**"). The Offer can be increased by up to 127,676 new Ordinary Shares in the case of full exercise of the Extension Clause (as defined below) and up to 146,827 new Ordinary Shares in the case of full exercise of the Extension Clause and full exercise of the Over-allotment Option (as defined below).

The Offer will comprise two elements:

- a public offering in France conducted by means of an open price offering (*offre à prix ouvert*), mainly intended for individuals or retail investors (the "**Retail Offer**") the main characteristics of which are set out in paragraph 14.1.3.1 of this Part 14 (*The Offer*); and
- an institutional private placement principally intended for institutional investors (the "**Institutional Placement**"), the main characteristics of which are set out in paragraph 14.1.3.2 of this Part 14 (*The Offer*):

  (i) to certain institutional investors in France and elsewhere outside the United States in reliance on Regulation S under the U.S. Securities Act and/or an exemption under the Prospectus Directive as implemented in the relevant EEA Member State; and

  (ii) in the United States only to persons reasonably believed to be "qualified institutional buyers" as defined by Rule 144A under the U.S. Securities Act, or institutional accredited investors (each an "**IAI**") as defined in Rule 501 under the U.S. Securities Act, in reliance on and in accordance with an exemption from, or in transactions not subject to, the registration requirements of the U.S. Securities Act, which may include Rule 144A in the case of QIBs.

There will be no offering to the public of Ordinary Shares in Ireland.

The new Ordinary Shares will be distributed to the public in France in accordance with the provisions of sections P 1.2.1 et seq. of Book II of the Euronext Market Rules relating to the special rules applicable to French regulated markets. The allocation of the new Ordinary Shares between the Retail Offer and the Institutional Placement will be effected depending on the nature and amount of demand in compliance with the principles set out by Article 315–35 of the AMF's General Regulations. If the level of demand expressed in the context of the Retail Offer is sufficient, the number of new Ordinary Shares allocated in response to the orders issued as part of the Retail Offer will be at least equal to 10 per cent. of the number of new Ordinary Shares offered as part of the Offer before any exercise of the Extension Clause and of the Over-allotment Option as defined in paragraphs 14.2.4 and 14.2.5, respectively, of this Part 14 (*The Offer*). If the demand expressed for the Retail Offer is lower than 10 per cent. of the number of new Ordinary Shares offered in the Offer, the remaining balance of unallotted new Ordinary Shares offered will be reallocated to participants in the Institutional Placement.

Extension Clause

Depending on the level of the demand expressed for the Base Offer, the initial number of new Ordinary Shares may be increased by up to 15 per cent., i.e. a maximum of 127,676 new Ordinary Shares (the "**Extension Clause**"). The possible exercise of the Extension Clause will be decided by the Board on the day when the Offer's final terms and conditions are set.

Over-allotment Option

The Company will grant the Joint Bookrunners an Over-allotment Option (as defined in paragraph 14.2.5 of this Part 14 (*The Offer*)) entitling them to subscribe for a number of Over-allotment Shares (as defined in paragraph 14.2.5 of this Part 14 (*The Offer*)) equal to a maximum of 15 per cent. of the number of new Ordinary Shares, i.e. a maximum of 146,827 Ordinary Shares in case of exercise in full of the Extension Clause and a maximum number of 127,676 Ordinary Shares if no such option is exercised.

14.1.2 ***Proceeds from the Offer***

Assuming a full issuance of the Base Offer at an Offer Price at the mid-point of the Price Range, i.e. €23.50 per new Ordinary Share, the gross proceeds of the Offer will be €20,002,612.50 and the net proceeds of the Offers will amount to approximately €16,500,596.83 after deduction of estimated commissions and expenses payable by the Company in relation to the Offer of approximately €3,502,015.67.

14.1.3 ***Procedure and period of the Offer***

14.1.3.1 *Main characteristics of the Retail Offer*

Subscription period of the Retail Offer

The Retail Offer in France will start on 10 April 2014, following publication of this Prospectus and will end on 25 April 2014 at 5.00 p.m. (CET) for subscriptions at counters and 8.00 p.m. (CET) for Internet subscriptions. The closing date of the Retail Offer may be changed (see paragraph 14.3.2 of this Part 14 (*The Offer*) below for further information).

Number of New Ordinary Shares offered as part of the Retail Offer

If the level of demand expressed in the context of the Retail Offer is sufficient, the number of new Ordinary Shares allocated in response to participants in the Retail Offer will be at least equal to 10 per cent. of the number of new Ordinary Shares offered as part of the Offer before possible exercise of the Extension Clause and of the Over-allotment Option.

The number of new Ordinary Shares offered in the Retail Offer may be increased or decreased in accordance with the terms and conditions specified in paragraph 14.3.2 of this Part 14 (*The Offer*) below.

Authorised persons, receipt and transmission of orders

The persons authorised to issue orders as part of the Retail Offer are individuals of French nationality or residents of France or nationals of one of the States that ratified the agreement and protocol of the European Economic Area (European Union Member States, Iceland, Norway and Liechtenstein, hereinafter the "**EEA Member States**"), French *fonds communs de placement* (mutual funds) or legal entities that are French or nationals of one of the EEA Member States which are not, within the meaning of Article L. 233-3 of the French Commercial Code, under the control of entities or persons that are neither incorporated in, nor nationals of, non-EEA Member States, as well as investment associations and clubs domiciled in France or in the EEA Member States and whose members are nationals of France or of one of the EEA Member States, subject to the provisions appearing in paragraph 14.2.1 of this Part 14 (*The Offer*). Other persons must inform themselves regarding local investment restrictions as indicated in paragraph 14.2.1 of this Part 14 (*The Offer*) below.

Individuals, legal entities and mutual funds (*fonds communs de placement*) who/that do not have accounts in France allowing for the subscription of Ordinary Shares in the context of the Retail Offer must open such an account for this purpose with an authorised intermediary to submit their orders.

The subscription order must be signed by the instructing party responsible for submitting the order or his or her legal representative or, in the case of an account managed under mandate (i.e., in which investment authority has been delegated to an account manager), by the account manager acting as the investor's agent. In the case of an account manager, the manager must either:

- have a mandate agreement which includes a specific undertaking by the client to refrain from placing orders directly in any situation in which only one order is permitted (such as the Offer for the new Ordinary Shares), without having first obtained written confirmation from the manager that he or she has not submitted an order on behalf of the client as part of the managed account services; or
- implement any other reasonable measure seeking to prevent multiple orders (for example, the manager must inform the client that he or she has submitted an order on his or her behalf and that, accordingly, the client cannot directly submit an order of the same nature directly without first taking steps to allow the manager to cancel the corresponding order).

Order categories liable to be issued in response to the Retail Offer
Persons wishing to participate in the Retail Offer must place their orders with a financial intermediary authorised in France, at the latest by 5.00 p.m. (CET) on 25 April 2014 for subscriptions at counter or by 8.00 p.m. (CET) for Internet subscriptions.

A Orders
Pursuant to section P 1.2.16 of Book II of the Euronext rulebook relating to the special rules applicable to French regulated markets, the orders (known as A orders) will be broken down depending on the number of new Ordinary Shares requested:

- Al orders: from 10 new Ordinary Shares up to and including 130 new Ordinary Shares; and
- A2 orders: in excess of 130 new Ordinary Shares.

A1 orders will enjoy preferred treatment if not all A orders can be fully served.

All orders placed in the Retail Offer are A orders that are ultimately split between A1 and A2 orders, in order to ensure a preferred treatment to smaller orders (A1) in case A orders are to be reduced as a result of strong demand.

Furthermore, it is specified that:

- each A order must relate to a minimum number of 10 new Ordinary Shares;
- each party responsible for submitting a given A order can only place a single A order; this A order may not be divided between several financial intermediaries and must be sent to a single financial intermediary only;
- each member of a tax household may place one A order only. Orders from minors must be placed by their legal guardians; each of these A orders will enjoy the same benefits that are normally attached to them; in the event of a reduction in the number of new Ordinary Shares allotted to each A order, the reduction will be applied separately to the orders of each of said members of the tax household;
- orders may be subject to a reduction in accordance with the terms and conditions set forth below;
- no A order may relate to a number of new Ordinary Shares accounting for more than 20.00 per cent. of the number of new Ordinary Shares offered as part of the Retail Offer;

- if the application of the reduction rate(s) does not lead to the allocation of a whole number of new Ordinary Shares, this number will be rounded down to the nearest whole number;
- A orders will be expressed in numbers of new Ordinary Shares with no indication of price and will be deemed stipulated at the Offer Price; and
- even in the case of a reduction, the A orders will be irrevocable, subject to the indications referred to in paragraph 14.3.2 of this Part 14 (*The Offer*).
- each party placing an order agrees with the Company to the terms and conditions of the Retail Offer set out in this Prospectus.

Financial intermediaries authorised in France will send the A orders to Euronext Paris, according to the timetable and terms and conditions specified in the opening notice of the Retail Offer that will be published by Euronext Paris.

Potential investors are reminded that orders will be void if the press release from the Company and the Pricing Statement indicating the final terms and conditions of the Institutional Placement and of the Retail Offer is not published by the Company.

Reduction of orders
A1 orders have priority in relation to A2 orders. A reduction rate ranging up to 100 per cent. may be applied to A2 orders to serve the A1 orders.

Reductions will be made proportionally within each order category. In cases where the application of the reduction terms leads to a non-whole number of new Ordinary Shares, this number will be rounded down to the nearest whole number.

Revocation of orders
Subscription orders received in the context of the Retail Offer are irrevocable even in the case of a reduction of the orders, subject to the provisions applicable in case a new indicative price range is set or in case the price is set outside of the indicative price range referred to below or in case the number of Offered Shares is changed (see paragraph 14.3.2 of this Part 14 (*The Offer*) below).

Result of the Retail Offer
The result of the Retail Offer will be published by the Company, together with details of the Institutional Offer by way of a Company press release and the Pricing Statement and by a notice issued by Euronext Paris the release of which is planned for 28 April 2014, unless the Offer is closed earlier in which case the press release and the Pricing Statement and Euronext notice would be published the day after the day the Offer period closes.

This notice will specify any reduction rate applied to the orders.

14.1.3.2 *Main characteristics of the Institutional Placement*

Subscription period of the Institutional Placement
The Institutional Placement will start at 9am (CET) on 10 April 2014 and will end at 12.00 p.m. (CET) on 28 April 2014. In case the closing date of the Retail Offer is extended (see paragraph 14.3.2 of this Part 14 (*The Offer*) below), the closing date of the Institutional Placement may also be extended accordingly.

The Institutional Placement may be closed early without notice (see paragraph 14.3.2 of this Part 14 (*The Offer*) below).

Persons authorised to issue orders in the context of the Institutional Placement
The Institutional Placement will be made principally with institutional investors in France and elsewhere, subject to the selling and transfer restrictions applicable to the Offer as described in paragraph 14.2.1.2 of this Part 14 (*The Offer*).

Orders liable to be issued in the context of the Institutional Placement
Orders will be expressed in numbers of new Ordinary Shares or in amount requested. They may include conditions relating to the price.

Receipt and transmission of orders liable to be issued in the context of the Institutional Placement
In order to be taken into account, orders issued in the context of the Institutional Placement must be received by one of the Joint Bookrunners at the latest by 12.00 p.m. (CET), on 28 April 2014, unless closed early.

Only orders at a price expressed in Euro, higher than or equal to the Offer Price, which will be set in the context of the Institutional Placement under the conditions indicated in paragraph 14.3.1 of this Part 14 (*The Offer*), will be taken into consideration in the allocation procedure.

Reduction of orders
The orders issued in the context of the Institutional Placement may be the subject of a total or partial reduction.

Revocation of orders
Any order issued in the context of the Institutional Placement may be revoked directly with the Joint Bookrunner who received the order, until 12.00 p.m. (CET) on 28 April 2014 (except if the Offer is closed earlier or extended as described in paragraph 14.3.2.4).

Result of the Institutional Placement
The result of the Institutional Placement will be published by the Company together with details of the Retail Offer by way of a press release and the Pricing Statement and by a notice issued by Euronext Paris the release of which is planned for 28 April 2014, unless the Offer is closed earlier (see paragraph 14.3.2.4) in which case the press release and the Pricing Statement and Euronext notice would be published the day after the day the Offer period closes.

14.1.4 ***Revocation or suspension of the Offer***

The Offer will be carried out provided that the Placing Agreement referred to in paragraph 14.4.3 of this Part 14 (*The Offer*) is signed and is not terminated at the latest on the Settlement date of the Offer.

Accordingly, if the Placing Agreement is not signed or is terminated, the subscription orders and the Offer will be retroactively cancelled. All trading in the Ordinary Shares that has taken place up to (and including) the Settlement date will be cancelled and will therefore be the responsibility of the investor. More precisely:

- the Retail Offer and the Institutional Placement, as well as all the orders placed in this context, will be cancelled; and
- all conditional trading in the Ordinary Shares that has taken place up to (and including) the Settlement date will be cancelled and will have to be unwound, with each investor assuming any losses resulting from such a cancellation as his or her personal responsibility.

In the case of failure to sign or of termination of the Placing Agreement, this information will be the subject of a press release published by the Company and a notice published by Euronext Paris. In such case, the Ordinary Shares will not be admitted to trading on Euronext Paris or on ESM.

14.1.5 ***Reduction of orders***

Details as regards the reduction of orders issued in the context of the Offer are dealt with, for the Retail Offer, in paragraph 14.1.3.1 of this Part 14 (*The Offer*) above, and for the Institutional Placement, in paragraph 14.1.3.2 of this Part 14 (*The Offer*) above.

14.1.6 ***Minimum or maximum number of Ordinary Shares to which an order may relate***

See paragraph 14.1.3.1 of this Part 14 (*The Offer*) above for detailed information on the minimum or maximum number of new Ordinary Shares to which orders issued in the context of the Retail Offer may relate.

There is no minimum or maximum number of orders which can be submitted in the context of the Institutional Placement.

14.1.7 ***Revocation of orders***

See respectively paragraphs 14.1.3.1 and 14.1.3.2 of this Part 14 (*The Offer*) above for a description of the revocation of orders issued in the context of the Retail Offer and of the Institutional Placement.

14.1.8 ***Payments of funds and terms and conditions of delivery of the Offered Shares***

The Offer Price (see paragraph 14.3.1.of this Part 14 (*The Offer*) below) must be paid in cash by the instructing parties at the latest on the Settlement date of the Offer, i.e., according to the indicative timetable, on 2 May 2014.

The new Ordinary Shares will be registered in the accounts of the instructing parties as soon as possible from publication of the results of the Offer by Euronext Paris, i.e., expected to be 28 April 2014 and at the latest on the Settlement date i.e., expected to be on 2 May 2014.

Settlement of the funds to the Company corresponding to the issuance of the Over-allotment Shares as part of the Over-allotment Option is planned at the latest for the third Business Day following the exercise date of the Over-allotment Option.

14.1.9 ***Publication of the results of the Offer***

The result and the final terms and conditions of the Offer will be published by the Company in a press release and the Pricing Statement and in a notice by Euronext Paris, the publication of which is planned for 28 April 2014, unless the Offer period is closed early (it being specified however that the subscription period of the Retail Offer may not be less than three Euronext Paris trading days – see paragraph 14.3.2 of this Part 14 (*The Offer*) below), in which case the press release and the Pricing Statement and the Euronext notice would be published the day after the day the Offer period closes.

14.1.10 ***Preferential subscription rights***

The capital increase carried out as part of the Offer will be conducted without preferential subscription rights.

14.2 SECURITY DISTRIBUTION AND ALLOCATION PLAN

14.2.1 ***Category of potential investors – Countries in which the offering will be open – Restrictions applicable to the Offer***

14.2.1.1 *Category of potential investors and countries in which the Offer will be open*

The Offer includes:

- a Retail Offer to the retail public in France carried out by means of an open price offering (*offre à prix ouvert*) primarily intended for individuals.
- An Institutional Placement principally intended for institutional investors including:
  - a placement in France; and

- an international private placement outside of France (excluding, Canada, Australia and Japan); and

14.2.1.2 *Selling and transfer restrictions applicable to the Offer*

No action has been or will be taken in any jurisdiction (other than France) that would give rise to a public offer of the Ordinary Shares, or that would permit possession or distribution of this Prospectus or any other Offer material, in any country or jurisdiction where action for that purpose is required. Accordingly, the Ordinary Shares may not be offered or sold, directly or indirectly, and this Prospectus may not be distributed or published in or from any country or jurisdiction, except under circumstances that will result in compliance with any and all applicable rules and regulations of any such country or jurisdiction. Persons into whose possession this Prospectus comes must inform themselves about and observe any restrictions on the distribution of this Prospectus and the offer of Ordinary Shares contained in this Prospectus. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdiction.

Authorised intermediaries may not accept any order from clients having an address located in a country having such restrictions and the corresponding orders will be deemed null and void. No person (including trustees and nominees) receiving this Prospectus, its summary or any other document or information relating to the Offer, may distribute it in or send it to such countries, except in compliance with applicable laws and regulations. Any person who, for whatever reason, transmits or permits the transmission of the aforementioned documents to such countries must draw the attention of the recipient to the terms of this paragraph.

This Prospectus does not constitute an offer to acquire any of the Ordinary Shares to any person in any jurisdiction to whom it is unlawful to make such offer or solicitation in such jurisdiction.

United States

Restrictions on Offer under the U.S. Securities Act

The Ordinary Shares have not been and will not be registered under the U.S. Securities Act or under the securities laws of any state or other jurisdiction of the United States and, subject to certain exceptions, may not be offered or sold, directly or indirectly, within the United States, except pursuant to an exemption from, or in transactions not subject to, the registration requirements of the U.S. Securities Act and applicable state or local securities laws.

The new Ordinary Shares are being offered and sold outside of the United States only in offshore transactions in reliance on and in accordance with Regulation S. The Placing Agreement provides that the Joint Bookrunners and the Co-lead Manager may, directly or through their respective U.S. broker-dealer affiliates, arrange for the offer and sale of new Ordinary Shares within the United States only to QIBs or IAIs in reliance on and in accordance with an available exemption from, or in a transaction not subject to, the registration requirements of the U.S. Securities Act, and applicable state or local securities laws.

Each person that is subscribing for new Ordinary Shares and that is located within the United States prior to any such subscription, will be required to execute a U.S. investor's letter in the form prescribed by either of the Joint Bookrunners ("**U.S. Investor's Letter**") and deliver the letter to the Joint Bookrunners, the Co-lead Manager and the Company. The U.S. Investor's Letter will require each such person to represent, agree and acknowledge that, among other things:

(a) it is a QIB or an IAI; and

(b) it will offer, resell, transfer, assign, pledge or otherwise dispose of the Ordinary Shares only (i) outside the U.S. in an offshore transaction complying with the provisions of Regulation S (including, for the avoidance of doubt, a bona fide sale on Euronext Paris or the ESM) to a person not known to be a U.S. Person (by pre-arrangement or otherwise), (ii) inside the U.S. to persons reasonably believed to be QIBs or IAIs, in reliance on and in accordance with an exemption from, or in transactions not subject to, the registration requirements of the U.S. Securities Act, which may include Rule 144A in the case of QIBs or (iii) the Company or a subsidiary (if any) thereof. The transferor will notify any subsequent transferee or executing broker, as applicable, of the restrictions that are applicable to the Ordinary Shares being sold.

The U.S. Investor's Letter contains additional written representations, agreements and acknowledgements relating to the transfer restrictions applicable to the Ordinary Shares.

Restrictions on Offer in reliance on Regulation S

Each subscriber to whom the new Ordinary Shares are distributed, offered or sold outside the United States will be deemed by its subscription for new Ordinary Shares, to have represented, agreed and acknowledged as follows:

(a) it is not the Company's affiliate or a person acting on behalf of such an affiliate;

(b) it is subscribing for the new Ordinary Shares in an offshore transaction meeting the requirements of Regulation S;

(c) it is aware that the Ordinary Shares have not been and will not be registered under the U.S. Securities Act and may not be offered or sold in the United States or to, or for the account or benefit of, U.S. Persons, absent registration or an exemption from, or in a transaction not subject to, registration under the U.S. Securities Act;

(d) if in the future it decides to offer, sell, transfer, assign or otherwise dispose of the Ordinary Shares, it will do so only in compliance with an exemption from the registration requirements of the U.S. Securities Act;

(e) it has carefully read and understands this Prospectus, and has not, directly or indirectly, distributed, forwarded, transferred or otherwise transmitted this Prospectus or any other presentation or Offer materials concerning the Ordinary Shares to any persons within the United States or to any U.S. Persons, nor will it do any of the foregoing;

(f) (i) it is not, and is not acting on behalf of, a Benefit Plan Investor or a Controlling Person unless, in the case of Benefit Plan Investors, it acquires the Ordinary Shares on or prior to ESM Admission with the written consent of the Company, and, in the case of Controlling Persons, it acquires the Ordinary Shares with the written consent of the Company, and (ii) (A) if it is, or is acting on behalf of, a Benefit Plan Investor, its acquisition, holding and disposition of such Ordinary Share does not and will not constitute or result in a non-exempt prohibited transaction under ERISA or Section 4975 of the Internal Revenue Code and (B) if it is a governmental, church, non-U.S. or other plan which is subject to any federal, state, local or non-U.S. law that is similar to the prohibited transaction provisions of section 406 of ERISA and/or section 4975 of the Internal Revenue Code ("**Similar Law**"), (1) it is not, and for so long as it holds such Ordinary Shares or interest therein will not be, subject to any federal, state, local, non-U.S. or other laws or regulations that could cause the underlying assets of the Company to be treated as assets of a shareholder by virtue of its interest in the Ordinary Shares and thereby subject the Company (or any persons responsible for the investment and operation of the Company's assets) to laws or regulations that are substantially similar to the prohibited transaction

provisions of section 406 of ERISA or section 4975 of the Internal Revenue Code and (2) its acquisition, holding and disposition of such Ordinary Shares will not constitute or result in a non-exempt violation of any Similar Law and (iii) it will agree to certain transfer restrictions regarding its interest in such Ordinary Shares;

(g) the Company, the Joint Bookrunners, the Co-lead Manager and their respective directors, officers, agents, employees, advisors and others will rely upon the truth and accuracy of the foregoing acknowledgements, representations and agreements; and

(h) if any of the representations or agreements made by it are no longer accurate or have not been complied with, it will immediately notify the Company, the Joint Bookrunners and the Co-lead Manager if it is acquiring any Ordinary Shares as a fiduciary or agent for one or more accounts, it has sole investment discretion with respect to each such account and it has full power to make such foregoing representations and agreements on behalf of each such account.

Prospective purchasers are hereby notified that sellers of the Ordinary Shares may be relying on the exemption from the provisions of section 5 of the U.S. Securities Act provided by Rule 144A.

European Economic Area ("EEA")

This Prospectus has been approved by the Central Bank of Ireland, being the competent authority in Ireland for the purposes of the Prospectus Directive. The Company has requested that the Central Bank of Ireland provide a certificate of approval and a copy of this Prospectus to the competent authority in France.

In relation to each member state of the EEA that has implemented the Prospectus Directive (each, a "**Relevant Member State**") except for France, with effect from and including the date on which the Prospectus Directive was implemented in that relevant member state (the "**Relevant Implementation Date**"), no new Ordinary Shares have been offered or will be offered pursuant to the Offer to the public in that Relevant Member State prior to the publication of a prospectus in relation to the Ordinary Shares that has been approved by the competent authority in that Relevant Member State, or where appropriate approved in another Relevant Member State and notified to the competent authority in that Relevant Member State all in accordance with the Prospectus Directive, except that an offer to the public in that Relevant Member State of any Ordinary Shares may be made at any time with effect from and including the relevant implementation date under the following exemptions under the Prospectus Directive if they have been implemented in the Relevant Member State:

(a) to any legal entity which is a qualified investor as defined under the Prospectus Directive;

(b) to fewer than 100, or, if the Relevant Member State has implemented the relevant provisions of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive); or

(c) in any other circumstances falling within Article 3(2) of the Prospectus Directive

provided that no such offer of Ordinary Shares shall result in a requirement for the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive or any measure implementing the Prospectus Directive in a Relevant Member State and each person who initially acquires any Ordinary Shares or to whom any offer is made on the basis of (a), (b) or (c) above will be deemed to have represented, acknowledged and agreed that it is a "**qualified investor**" within the meaning of Article 2(1)(e) of the Prospectus Directive.

The expression "**offer of any Ordinary Shares to the public**" in relation to any Ordinary Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the Ordinary Shares to be offered so as to enable an investor to decide to purchase or subscribe for any Ordinary Shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State.

In the case of any Ordinary Shares being offered to a financial intermediary as that term is used in Article 3(2) of the Prospectus Directive, such financial intermediary will also be deemed to have represented, acknowledged and agreed that the Ordinary Shares acquired by it in the Offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to persons in circumstances which may give rise to an offer of any Ordinary Shares to the public other than their offer or resale in a Relevant Member State to qualified investors (as so defined) or in circumstances in which the prior consent of the Joint Bookrunners has been obtained to each such proposed offer or resale. The Company, the Joint Bookrunners and the Co-lead Manager will rely upon the truth and accuracy of the foregoing representation, acknowledgement and agreement.

Italy

The Offer has not been registered pursuant to Italian securities legislation and, accordingly, no Ordinary Shares may be offered, sold or delivered, nor may copies of this Prospectus or of any other document relating to the Ordinary Shares be distributed in the Republic of Italy, except:

(i) to qualified investors (investitori qualificati), as defined in Article 26, first paragraph, letter d), of Commissione Nazionale per le Società e la Borsa ("**CONSOB**") Regulation No. 16190, pursuant to Article 34-ter, first paragraph, letter b) of CONSOB Regulation No. 11971 of May 14, 1999, as amended from time to time ("**Issuers' Regulation**"), implementing Article 100 of Legislative Decree No. 58 of February 24, 1998, as amended (the "**Financial Services Act**"); or

(ii) in other circumstances which are exempted from the rules on public offerings pursuant to Article 100 of the Financial Services Act and its implementing CONSOB regulations, including the Issuers' Regulation.

Any offer, sale or delivery of the Ordinary Shares or distribution of copies of this Prospectus or any other document relating to the Ordinary Shares in Italy under (i) or (ii) above must be:

(a) made by investment firms, banks or financial intermediaries permitted to conduct such activities in the Republic of Italy in accordance with the relevant provisions of the Legislative Decree No. 385 of September 1, 1993, as amended (the "**Banking Act**"), the Financial Services Act and the Issuers' Regulation (as amended from time to time) and any other applicable law and regulations; and

(b) in accordance with any Italian securities, tax, exchange control and any other applicable laws, including any requirements or limitations which may be imposed by CONSOB, the Bank of Italy or by any other Italian authority from time to time.

Any investor acquiring new Ordinary Shares is solely responsible for ensuring that any offer, sale, delivery or resale of new Ordinary Shares by such investor occurs in compliance with applicable Italian laws and regulations.

United Kingdom

This document is only being distributed to and is only directed at (i) persons who are outside the United Kingdom, (ii) to investment professionals falling within Article 19(5) of

the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "**Order**") or (iii) high net worth entities falling within Article 49(2)(a) to (d) of the Order, and other persons to whom it may be lawfully communicated (all such persons together being referred to as "**relevant persons**"). Ordinary Shares are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such Ordinary Shares will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this Prospectus or any of its contents.

Switzerland

The distribution of the new Ordinary Shares in or from Switzerland will be exclusively made to, and directed at, regulated qualified investors (the "**Regulated Qualified Investors**"), as defined in Article 10(3)(a) and (b) of the Swiss Collective Investment Schemes Act of 23 June 2006, as amended ("**CISA**"). Accordingly, the Company has not been and will not be registered with the Swiss Financial Market Supervisory Authority ("**FINMA**") and no Swiss representative or paying agent have been or will be appointed in Switzerland. This Prospectus and/or any other Offer materials relating to the Ordinary Shares may be made available in Switzerland solely to Regulated Qualified Investors.

Australia

This Prospectus does not constitute a disclosure document under Part 6D.2 of the Australian Corporations Act and has not been, and will not be, lodged with the Australian Securities and Investments Commission. The offer of Ordinary Shares under this Prospectus to investors in Australia will only be made to the extent that such offers of Ordinary Shares for issue or sale do not need disclosure to investors under Part 6D.2 of the Australian Corporations Act. In particular, any person who receives an offer of Ordinary Shares under this Prospectus in Australia represents and warrants to the Company, the Joint Bookrunners and the Co-lead Manager that they are a person who falls within an exemption from disclosure to investors provided by section 708 of the Australian Corporations Act, including a "sophisticated investor" within the meaning of section 708(8) of the Corporations Act, or a "professional investor" within the meaning of section 708(11) of the Australian Corporations Act. Any offer of Ordinary Shares received in Australia is void to the extent that it needs disclosure to investors under the Australian Corporations Act.

Any person to whom Ordinary Shares are issued or sold pursuant to an exemption provided by section 708 of the Australian Corporations Act must not, within 12 months after the issue, offer those Ordinary Shares for sale in Australia unless that offer is itself made pursuant to a disclosure document under Part 6D.2 of the Australian Corporations Act or is made in reliance on an exemption from the disclosure requirements provided by section 708 of the Australian Corporations Act.

Canada

The Ordinary Shares have not been nor will they be qualified for sale to the public under applicable Canadian securities laws and, accordingly, any offer and sale of the Ordinary Shares in Canada will be made on a basis which is exempt from the prospectus requirements of Canadian securities laws.

Any resale of the Ordinary Shares must be made in accordance with, or pursuant to an exemption from, or in a transaction not subject to, the prospectus requirements of those laws. In addition, in order to comply with the dealer registration requirements of Canadian securities laws, any resale of the Ordinary Shares must be made either by a person not required to register as a dealer under applicable Canadian securities laws, or through an appropriately registered dealer or in accordance with an exemption from the dealer registration requirements.

These Canadian resale restrictions may in some circumstances apply to resales made outside of Canada. Purchasers of Ordinary Shares are advised to seek Canadian legal advice prior to any resale of Ordinary Shares.

Japan

No registration pursuant to Article 4, paragraph 1 of the financial instruments and exchange law of Japan (the ''**FIEL**'') has been made or will be made with respect to the Ordinary Shares offered in the Offer on the ground that Article 2, paragraph 3, item 2-(i) of the FIEL is applied to such solicitation. As described in this Prospectus, the offering of the Ordinary Shares is limited to and made only to the qualified institutional investors (''**QIIS**'') as defined in Article 2, paragraph 3, item 1 of the FIEL and article 10 of the cabinet order regarding the definitions under Article 2 of the FIEL. No transfer of the Ordinary Shares may be made to persons other than QIIS, as described in this Prospectus.

14.2.2 ***Intention to subscribe of the existing Shareholders of the Company or members of its administrative, managerial or supervisory bodies or of anyone intending to place a subscription order of more than 5 per cent.***

Sofinnova Partners, a Shareholder of the Company, undertook to place an order to subscribe, at the Offer Price, for such number of Offered Shares as would give rise to a total subscription amount of €4,628,267. This order is intended to be served in full if demand makes this possible, however this amount may be reduced based on market demand and pursuant to usual allocation practice (see paragraph 14.2.6 of Part 14 (*The Offer*).

Fountain Healthcare Partners, a Shareholder of the Company, undertook to place an order to subscribe, at the Offer Price, for such number of Offered Shares as would give rise to a total subscription amount of €1,475,594. This order is intended to be served in full if demand makes this possible, however this amount may be reduced based on market demand and pursuant to usual allocation practice (see paragraph 14.2.6 of Part 14 (*The Offer*).

Capricorn Health-Tech Fund NV, a Shareholder of the Company, undertook to place an order to subscribe, at the Offer Price, for such number of Offered Shares as would give rise to a total subscription amount of €675,837. This order is intended to be served in full if demand makes this possible, however this amount may be reduced based on market demand and pursuant to usual allocation practice (see paragraph 14.2.6 of Part 14 (*The Offer*).

Seventure Partners Managed Funds, a Shareholder of the Company, undertook to place an order to subscribe, at the Offer Price, for such number of Offered Shares as would give rise to a total subscription amount of €495,302. This order is intended to be served in full if demand makes this possible, however this amount may be reduced based on market demand and pursuant to usual allocation practice (see paragraph 14.2.6 of Part 14 (*The Offer*).

Medtronic, Inc., a Shareholder of the Company, undertook to place an order to subscribe, at the Offer Price, for such number of Offered Shares as would give rise to a total subscription amount of €725,000. This order is intended to be served in full if demand makes this possible, however this amount may be reduced based on market demand and pursuant to usual allocation practice (see paragraph 14.2.6 of Part 14 (*The Offer*).

Further details are given at paragraph 15.13.5 of Part 15 (*Additional Information*) of this Prospectus.

To the Company's knowledge, its other existing Shareholders and the members of its Board or Senior Managers do not, as of the date of this Prospectus, intend to submit a subscription order in the context of the Offer.

14.2.3 ***Pre-allocation information***

This information appears in paragraphs 14.1.1 and 14.1.3 of this Part 14 (*The Offer*).

Notice to subscribers

As part of the Retail Offer, the financial intermediary of those investors who have submitted subscription orders will be responsible for notifying such investors regarding the amount of their allocations.

As part of the Institutional Placement, the Joint Bookrunners will be responsible for notifying investors who submitted subscription orders regarding the amount of their allocations.

14.2.4 ***Extension Clause***

Depending on demand, following consultation with the Joint Bookrunners, the Company may decide to increase the number of new Ordinary Shares by a maximum 15 per cent., i.e. a maximum of 127,676 additional new Ordinary Shares, at the Offer Price (as this term is defined in paragraph 14.3.1 of this Part 14 (*The Offer*) below).

The decision to exercise the Extension Clause will be taken when the price is set, which is planned for 28 April 2014 and will be detailed in the Company's press release and the Pricing Statement scheduled to be published on 28 April 2014 and the notice of Euronext Paris announcing the result of the Offer expected to be published on 28 April 2014.

14.2.5 ***Over-allotment Option***

The Company will grant the Joint Bookrunners an over-allotment option (the "**Over-allotment Option**"), such option to be facilitated by the Stock Loan Agreement detailed in paragraph 15.13.1 of Part 15 (*Additional Information*) of this Prospectus, enabling the subscription of additional new Ordinary Shares up to a limit of 15 per cent. of the number of new Ordinary Shares issued pursuant to the Offer, including after the possible exercise of the Extension Clause (the "**Over-allotment Shares**"), at the Offer Price (as this term is defined in paragraph 14.3.1 of this Part 14 (*The Offer*) below).

This Over-allotment Option, which will make it possible to cover any over-allotments and to facilitate stabilisation transactions, may be exercised in a single instalment at any time, in full or in part, for a period of 30 calendar days from the date commencing on the date of the conditional dealings of the Ordinary Shares on Euronext Paris and on the ESM and ending no later than 30 calendar days thereafter.

Société Générale (as Stabilising Manager), in agreement with Kempen & Co, on behalf and for the account of the Joint Bookrunners and the Co-lead Manager, may effect other transactions with a view to supporting the market price of the Ordinary Shares at a higher level than that which might otherwise prevail in the open market. The Stabilising Manager is not required to enter into such transactions and such transactions may be effected on any securities market, over-the-counter market, stock exchange or otherwise and may be undertaken at any time during the period commencing on the date of the conditional dealings of the Ordinary Shares on Euronext Paris and on the ESM and ending no later than 30 calendar days thereafter. However, there will be no obligation on the Stabilising Manager or any of its agents to effect stabilisation transactions and there is no assurance that stabilisation transactions will be undertaken. Such stabilisation, if commenced, may be discontinued at any time without prior notice. In no event will measures be taken to stabilise the market price of the Ordinary Shares above the Offer Price. Except as required by law or regulation, neither the Stabilising Manager nor any of its agents intends to disclose the extent of any over-allotments made and/or stabilisation transactions conducted in relation to the Offer.

To allow the Stabilising Manager to cover short positions resulting from any such over-allotment and/or from sales of Ordinary Shares effected by it during the stabilising period, it will enter, on behalf and for the account of the Joint Bookrunners and the Co-lead Manager, into the Over-allotment Option with the Company pursuant to which it may subscribe (or nominate subscribers for) additional new Ordinary Shares representing up to 15 per cent of the total number of new Ordinary Shares comprised in the Offer (before utilisation of the Over-allotment Option) (the "**Over-allotment Shares**", together with the new Ordinary Shares being the "**Offered Shares**") at the Offer Price. The

Over-allotment Option may be exercised in whole or in part upon notice by the Stabilising Manager at any time on or before the 30th calendar day after the commencement of conditional dealings of the Ordinary Shares on Euronext Paris and the ESM of the Irish Stock Exchange. Any Over-allotment Shares made available pursuant to the Over-allotment Option will be sold on the same terms and conditions as the new Ordinary Shares being offered pursuant to the Offer and will rank *pari passu* in all respects with, and form a single class with, the other Ordinary Shares (including for all dividends and other distributions declared, made or paid on the Ordinary Shares).

In case of exercise of the Over-allotment Option, the information relating to this exercise and to the number of Over-allotment Shares to be issued will be brought to the public's attention by means of a press release by the Company and a notice published by Euronext Paris.

14.2.6 ***Allocations under the Offer***

The allocation of new Ordinary Shares between the investors will be made by the Joint Bookrunners following consultation with the Company.

Applicants under the Offer may be allocated new Ordinary Shares having a value which is less than the sum applied for. A number of factors will be considered in determining the basis of allocation, including the level and nature of demand for new Ordinary Shares and the objective of establishing an orderly after-market in the new Ordinary Shares. New Ordinary Shares issued pursuant to the Offer will be issued, payable in full, at the Offer Price. Each purchaser will be required to undertake to pay the Offer Price for the new Ordinary Shares issued to such purchaser in such manner as set out in paragraph 14.1.8 of this Part 14 (*The Offer*).

Upon notification of any allocation, prospective investors will be contractually committed to acquire the number of Ordinary Shares allocated to them at the Offer Price and, to the fullest extent permitted by law, will be deemed to have agreed not to exercise any rights to rescind or terminate or, subject to any statutory withdrawal rights, otherwise withdraw from such commitment. Dealing may not begin before notification is made.

14.3 DETERMINATION OF THE OFFER PRICE AND COMPLETION

14.3.1 ***Method for determining the price***

The price of the new Ordinary Shares in the Retail Offer will be equal to the price of the Offered Shares in the Institutional Placement (the "**Offer Price**").

The Offer Price will be determined by the Board following consultation with Joint Bookrunners and is expected to be announced on or around 28 April 2014, via a Regulatory Information Service, together with details of the final number of new Ordinary Shares subject to the Offer. This information will also be set out in a press release, the Pricing Statement and in a Euronext Paris notice. The press release and the Pricing Statement will not automatically be sent to persons who receive this Prospectus, but will be available free of charge at the registered office of the Company at Clonmel House, Forster Way, Swords, Co. Dublin, Ireland. In addition, the press release and the Pricing Statement will, subject to certain access restrictions for parties in certain foreign jurisdictions, be published in electronic form and be available on the Company's website at www.mainstay-medical.com. The Offer Price announcement date could be postponed or set earlier as indicated in paragraph 14.3.2 of this Part 14 (*The Offer*) below.

It is currently expected that the Offer Price will be within the Price Range, but this range is indicative only and the Offer Price may be set within, above or below it. A number of factors will be considered in determining the Offer Price, including the level and the nature of the demand for Ordinary Shares, the prevailing market conditions and the objective of establishing an orderly and liquid after-market in the Ordinary Shares. The Offer Price will be established at a level determined in accordance with these arrangements, taking into account indications of interest received (whether before or after the times and/or dates stated) from market-makers, fund managers and other persons. The Company and the Joint Bookrunners reserve the right to increase or decrease the aggregate number of Ordinary Shares offered pursuant to the Offer. If the Price Range changes prior to the announcement of the final

Offer Price, the revised Price Range will be announced and advertised as soon as possible, including by Euronext Paris, and the Company will publish a supplementary prospectus and each applicant may exercise their withdrawal rights as set out in paragraph 14.3.2.5 of this Part 14 (*The Offer*).

The Joint Bookrunners will solicit from prospective investors indications of interest in acquiring Ordinary Shares under the Institutional Placement. Prospective institutional investors will be required to specify the number of Ordinary Shares which they would be prepared to acquire either at specified prices or at the Offer Price (as finally determined). There is no minimum or maximum number of Ordinary Shares which can be applied for under the Institutional Placement.

In addition, applications are expected to be sought from individuals or retail investors in France under the Retail Offer on the basis that the number of Offered Shares which may be allocated will vary depending on the final Offer Price. Applications will then be made by the authorised intermediaries on behalf of their clients and this demand will be taken into account by the Company and the Joint Bookrunners, alongside indications of interest in the Institutional Placement, in conducting the bookbuilding process described above in respect of the Offer.

The basis of the allocation under the Institutional Placement and the Retail Offer shall be determined in accordance with paragraph 14.2.6 above. A number of factors will be considered in determining the basis of allocation, including the level and nature of demand for the Ordinary Shares in the Offer and the objective of establishing an orderly and liquid after-market in the Ordinary Shares, provided however that if the level of demand expected (in the context of the Retail Offer) is sufficient the number of new Ordinary Shares allocated to Retail Offer investors will be at least equal to 10 per cent. of the Offer (before any exercise of the Extension Clause or the Over-allotment Option) as defined in paragraph 14.1.1 of Part 14 (*The Offer*). If there is excess demand for Ordinary Shares, allocations may be scaled down and applicants may be allocated Ordinary Shares having an aggregate value which is less than the sum applied for. Such Ordinary Shares may be allocated in accordance with paragraph 14.2.6 above. In such event, there is no obligation for such Ordinary Shares to be allocated proportionately (and some applicants may receive no Ordinary Shares).

Completion of the Offer will be subject to the determination of the Offer Price and the Board's decision to proceed with the Offer. It will also be subject to the satisfaction of conditions contained in the Placing Agreement, including Settlement and ESM Admission occurring and to the Placing Agreement being executed and not having been terminated. The Offer cannot be terminated once unconditional dealings in the Ordinary Shares have commenced. Further details of the Placing Agreement are set out in Part 15 (*Additional Information*).

14.3.2 ***Procedure for publication of the Offer Price and changes to the parameters of the Offer***

14.3.2.1 *Date of the setting of the Offer Price*

It is expected that the Offer Price will be set on 28 April 2014, it being specified that this date may be postponed if the market conditions and results of the order bookbuilding do not allow for the Offer Price to be set under satisfactory conditions (refer to paragraph 14.3.2.3 of this Part 14 (*The Offer*) below).

14.3.2.2 *Publication of the Offer Price and of the number of Offered Shares*

The Offer Price and the final number of Offered Shares will be announced to the public by way of both press release and the Pricing Statement issued by the Company and a notice to be published by Euronext Paris on 28 April 2014 according to the indicative timetable, unless the Offer Price is set early, in which case the press release and the Pricing Statement and notice should be published on the day the Offer Price is set.

14.3.2.3 *Adjusting the range, determination of the Offer Price outside of the Price Range and changes to the number of Offered Shares*

Changes enabling the orders issued in the context of the Retail Offer to be revoked

If the upper limit of the Price Range is raised or if the Offer Price is set above the upper limit of the (initial or, as the case may be, amended) Price Range, the following procedure will apply:

- New terms: the new terms of the Offer will be brought to the public's knowledge by means of a press release by the Company and a notice published by Euronext Paris. The press release of the Company and the notice of Euronext Paris referred to above will indicate the new price range, and as the case may be, the new timetable, together with the new closing date of the Retail Offer, the new date planned for the setting of the Offer Price and the new Settlement date.
- Closing date of the Retail Offer: the closing date of the Retail Offer will be postponed or a new subscription period for the Retail Offer will be opened, as the case may be, such that there are at least two Euronext Paris Business Days between the publication date of the aforementioned press release and the new closing date of the Retail Offer.
- Revocability of orders issued in the context of the Retail Offer: the orders issued in the context of the Retail Offer before publication of the press release referred to above will be maintained unless they have been expressly revoked before and including the new closing date of the Retail Offer. New irrevocable orders may be issued until and including the new closing date of the Retail Offer (these orders may however be expressly revoked before and including the new closing date of the Retail Offer in case of another postponement of the date for setting the Offer Price and/or a new amendment to the terms of the Offer).

Changes not enabling the orders issued in the context of the Retail Offer to be revoked

- The Offer Price could be freely set below the lower limit of the Price Range or the Price Range could be freely adjusted downward. The Offer Price or the new indicative price range would then be released to the public under conditions provided for in paragraph 14.3.2.2 of this Part 14 (*The Offer*) below, failing any material impact on the other characteristics of the Offer.

  Accordingly, if the setting of the Offer Price below the lower limit of the Price Range or if the downward adjustment of the Price Range did not have a material impact on the other characteristics of the Offer, the Offer Price will be brought to the public's knowledge by the press release and the Pricing Statement issued by the Company and the notice of Euronext Paris referred to in paragraph 14.3.2.2 of this Part 14 (*The Offer*) above, which should be distributed, according to the indicative timetable, on 28 April 2014, unless the Offer Price is set earlier, in which case the press release and the Pricing Statement and the notice should be published on the day the Offer Price is set.

  However, if the setting of the Offer Price below the lower limit of the Price Range or if the downward adjustment of the Price Range has a material impact on the other characteristics of the Offer, the provisions of paragraph 14.3.2.5 of this Part 14 (*The Offer*) below would apply.
- The number of Offered Shares could also be adjusted if the adjustment described in the preceding paragraph had no material impact on the other characteristics of the Offer. If the contrary is true, the provisions of paragraph 14.3.2.5 of this Part 14 (*The Offer*) below would apply.

14.3.2.4 *Early closing or extension of the Offer*

The closing dates of the Institutional Placement and of the Retail Offer may be brought forward (however the subscription period of the Retail Offer must not be shorter than three Euronext Paris trading days) or extended under the following conditions:

- If the closing date of the Offer is brought forward, the new closing date will be the subject of a press release by the Company and a notice published by Euronext Paris announcing this change at the latest the day before the new closing date.
- If the closing date is extended, the new closing date will be the subject of a press release by the Company and a notice published by Euronext Paris announcing this change at the latest the day before the initial closing date. In this case, the orders issued in the context of the Retail Offer before publication of the Company's press release and the notice of Euronext Paris referred to above will be maintained unless they have been expressly revoked before and including the new closing date of the Retail Offer.

14.3.2.5 *Material changes to the terms of the Offer and withdrawal rights*

In the case of material changes to the terms and conditions initially set for the Offer not provided for by this Prospectus, an addendum to the Prospectus called a supplementary prospectus will be submitted to the Central Bank for approval. The Central Bank will, upon approval and request from the Company, transmit the supplemental prospectus, together with a certificate of approval to the AMF. The orders issued in the context of the Retail Offer and of the Institutional Placement will be void if the Central Bank does not approve such addendum to this Prospectus.

The orders issued in the context of the Retail Offer and of the Institutional Placement before the release of the supplementary prospectus with the approval of the Central Bank may be revoked for at least two clear Business Days after its release (see paragraph 14.3.2.3 of this Part 14 (*The Offer*) above for a description of cases in which this paragraph would apply).

If the Company is required to publish any supplementary prospectus, applicants who have applied for Offered Shares in the Offer shall have at least two clear Business Days following the publication of the relevant supplementary prospectus within which to withdraw their application to subscribe for Ordinary Shares in the Offer in its entirety. The right to withdraw an application to subscribe for Ordinary Shares in the Offer in these circumstances will be available to all investors in the Offer. If the application is not withdrawn within the stipulated period, any application to subscribe for Ordinary Shares in the Offer will remain valid and binding.

In the event that the Offer Price is set above the Price Range or if the Price Range is revised higher, then applicants who have applied to subscribe for Ordinary Shares in the Offer would have a statutory right to withdraw their offer to subscribe for Ordinary Shares in the Offer in its entirety before the end of a period of two Business Days commencing on the first Business Day after the date on which an announcement of this is published via a Regulatory Information Service announcement (or such later date as may be specified in that announcement).

In addition, in the event that the Offer Size is set above the Offer Size Range, then prospective investors would have a statutory right to withdraw their offer to subscribe for Ordinary Shares in the Offer in its entirety before the end of a period of two Business Days commencing on the first Business Day after the date on which an announcement of this is published via a Regulatory Information Service announcement (or such later date as may be specified in that announcement).

Any supplementary prospectus will not automatically be distributed to prospective investors but will be published in accordance with the Prospectus Rules (and notification thereof will

be made to a Regulatory Information Service). Any such supplementary prospectus will be available in printed form free of charge at the registered office of the Company and at the offices of the Joint Bookrunners and the Co-lead Manager until 28 days after Settlement and ESM Admission.

Details of how to withdraw an application will be made available if a supplementary prospectus is published. **Applicants who have applied in the Retail Offer via an intermediary should contact the relevant intermediary for details of how to withdraw an application.**

14.3.3 ***Restrictions or elimination of the preferential subscription right***

The Offered Shares will be allotted and issued pursuant to resolutions of the Shareholders of the Company passed on 2 April 2014 (see paragraph 15.3.5 of Part 15 (*Additional Information*).

14.3.4 ***Completion of the Offer***

Completion of the Offer will be subject to the determination of the Offer Price and the Board's decision to proceed with the Offer. It will also be subject to the satisfaction of conditions contained in the Placing Agreement, including Settlement and ESM Admission occurring and to the Placing Agreement being executed and not having been terminated in accordance with its provisions. The Offer cannot be terminated once unconditional dealings in the Ordinary Shares have commenced. Further details of the Placing Agreement are set out in Part 15 (*Additional Information*).

Should the Offer fail to yield the Minimum Net Proceeds, the Offer will be cancelled and no Ordinary Shares will be issued pursuant to the Offer.

14.4 PLACEMENT

14.4.1 ***Contact information of the listing financial institutions***

JOINT BOOKRUNNERS

Kempen & Co
Beethovenstraat 300
1077 WZ Amsterdam
Postbus 75666
1070 AR Amsterdam
The Netherlands

Société Générale
29 boulevard Haussmann
75009 Paris
France

CO-LEAD MANAGER, PROSPECTUS ADVISER AND ESM ADVISER

Davy
Davy House
49 Dawson Street
Dublin 2
Ireland

14.4.2 ***Contact information of the institution in charge of the securities services and the financial service***

The securities services to be provided to the Company (keeping the register of registered shareholders) and the financial services (payment of dividends) will be provided by the Registrar (Computershare) and the Paying Agent in France (Société Générale Security Services (SGSS)). SGSS will issue the certificate of deposit of the funds relating to this capital increase.

14.4.3 ***Placing Agreement***

The Company, the Directors, the Joint Bookrunners and the Co-lead Manager will be subject to the Placing Agreement under which the Joint Bookrunners will severally but not jointly with one another agree, subject to certain conditions that are typical for an agreement of this nature (the last condition

being ESM Admission) to procure subscribers for the new Ordinary Shares offered under the Offer at the Offer Price and failing which, to subscribe and pay for those new Ordinary Shares themselves. The Placing Agreement will be executed on the day on which the Offer Price is set, which according to the indicative timetable is expected to take place on 28 April 2014. Further details of the Placing Agreement are set out in paragraph 15.13.3 of Part 15 (*Additional Information*).

In the case the Placing Agreement were not executed or were to be terminated in accordance with its terms and conditions, the Company will release a press release and immediately inform Euronext Paris, which will publish a notice. Paragraph 14.1.4 of this Part 14 (*The Offer*) above describes the consequences of terminating or not signing the Placing Agreement.

14.4.4 ***Lock-up Agreements***

The Company has agreed that it will not issue any new Ordinary Shares for a period of 360 days from the date of ESM Admission, except as required to comply with existing or permitted grants of Share Options or Share Warrants.

Each of the Shareholders at the date of this Prospectus, the Directors holding Ordinary Shares or Share Options as at the date of this Prospectus and the Senior Managers has agreed that, subject to certain customary exceptions, they will not dispose of any Ordinary Shares (other than Ordinary Shares subscribed for by these parties under the Offer) for a period of 365 days from the date of ESM Admission.

Further details of these arrangements are described in paragraph 15.13.5 of Part 15 (*Additional Information*).

14.4.5 ***Date of settlement-delivery of the Offered Shares***

Settlement of the new Ordinary Shares is planned for 2 May 2014.

14.5. DEALING ARRANGEMENTS

14.5.1 ***Admission to trading***

The Ordinary Shares have been created pursuant to the Irish Companies Acts. Each of the Ordinary Shares carries one vote on a poll at a meeting of the Company's Shareholders. There are no restrictions on the voting rights of the Ordinary Shares. The Ordinary Shares are freely transferable immediately following Settlement and ESM Admission. The Ordinary Shares will be in registered form and capable of being held in uncertified form.

Application will be made for the listing and admission to trading of all Ordinary Shares on Euronext Paris and on the ESM. Conditional dealings in the Ordinary Shares are expected to commence on Euronext Paris and the ESM at 8.00 a.m. GMT (9.00 a.m. CET) on 29 April 2014. When admitted to trading the Ordinary Shares will be registered with ISIN number IE00BJYS1G50, SEDOL number BJYS1G5 and will trade under the symbol MSTY. The Ordinary Shares will, on ESM Admission, comprise the entire issued and to be issued ordinary share capital of the Company.

The product name on Euronext Paris will be Mainstay Medical.

The company will belong to ICB Classification 4535 Medical Equipment.

Unconditional dealings before Settlement and ESM Admission will only be settled if Settlement and ESM Admission takes place. All dealings in Ordinary Shares prior to the commencement of unconditional dealings will be on a "as-if-and-when-issued-or-delivered" basis and of no effect if Settlement and ESM Admission does not take place and will be at the sole risk of the parties concerned. It is expected that Settlement and ESM Admission occur and that unconditional dealings will commence in the Ordinary Shares on the ESM and on Euronext Paris at 8.00 a.m. GMT (9.00 a.m. CET) on 2 May 2014 and 5 May 2014, respectively. No application has been, or is currently intended to be, made for the Ordinary Shares to be admitted to listing or trading on any other stock exchange .

The above-mentioned dates and times may be changed without further notice. Upon being allocated Ordinary Shares in accordance with the Offer, each investor agrees to pay the Offer Price for the Ordinary Shares allocated to it in such manner as shall be directed by the Joint Bookrunners.

14.5.2 ***CREST***

CREST is a paperless settlement system enabling securities to be transferred from one person's CREST account to another's without the need to use share certificates or written instruments of transfer. The Company has applied for the Ordinary Shares to be admitted to CREST with effect from the commencement of conditional dealings. The Articles permit the holding of Ordinary Shares under the CREST system. Accordingly, settlement of transactions in the Ordinary Shares following Settlement and ESM Admission may take place within the CREST system if any Shareholder so wishes. CREST is a voluntary system and holders of Ordinary Shares who wish to receive and retain share certificates will be able to do so.

14.5.3 ***Euronext Paris***

14.5.3.1 *General*

Euronext Paris is a regulated market operated and managed by Euronext, a market operator (entreprise de marché) responsible for the admission of securities and the supervision of trading in listed securities. Euronext publishes a daily official price list that includes price information on listed securities on Euronext Paris. Securities listed on Euronext Paris are classified in alphabetical order. In addition, Euronext created the following compartments for classification purposes:

- Compartment A for issuers with a market capitalization over €1 billion;
- Compartment B for issuers with a market capitalization between €150 million and €1 billion; and
- Compartment C for issuers with a market capitalization under €150 million.

The Company's shares will be listed on Compartment C.

14.5.3.2 *Trading on Euronext Paris*

Trading on Euronext Paris is subject to the prior approval of Euronext. Securities listed on Euronext Paris are officially traded through authorized financial institutions that are members of Euronext Paris. Euronext places securities listed on Euronext Paris in one of two main categories (continuous (or "**Continu**") or by auction), depending on whether they belong to certain Indices or Segments, and/or on their historical and expected trading volume and the presence of liquidity providers. The Company's shares will be traded in the Continu category, which includes the most actively traded securities. Shares pertaining to the Continu category are traded on each trading day from 9:00 a.m. to 5:30 p.m. (Paris time), with a pre-opening phase from 7.15 a.m. to 9.00 a.m. and a pre-closing phase from 5.30 p.m. to 5.35 p.m. (during which preopening and pre-closing trades are recorded but not executed until the opening auction at 9.00 a.m. and the closing auction at 5.35 p.m., respectively). In addition, from 5.35 p.m. to 5.40 p.m., trading can take place at the closing auction price (trading-at-last phase). Trading in a share traded continuously after 5.40 p.m. until the beginning of the pre-opening phase of the following trading day may occur off-market and be at a price that must be within the last quoted price plus or minus 1 per cent.

Euronext may temporarily suspend, freeze or restrict trading in a security if the buy or sell orders for this security would result in a price beyond certain thresholds defined by its regulations and referred to as a "reservation threshold" or a "collar." These thresholds are set at a percentage fluctuation from a reference price. In particular, if the quoted price of a Continu security, such as the Company's shares, varies by more than 6 per cent. for the opening auction, or 3 per cent. in continuous trading, Euronext may suspend trading for up

to two minutes. Euronext may also suspend trading of securities listed on Euronext Paris to prevent or stop disorderly market conditions. In addition, in certain circumstances, including, for example, in the context of a takeover bid, Euronext may suspend trading of the security concerned upon request of the AMF.

14.5.4 ***Euroclear France***

Prior to any transfer of securities held in registered form on Euronext Paris, the securities must be inscribed in an account maintained by an accredited intermediary with Euroclear France, a registered clearing agency. Transactions in securities are initiated by the owner giving instruction (through an agent, if appropriate) to the relevant accredited intermediary. Trades of securities listed on Euronext Paris are cleared through LCH Clearnet and settled through Euroclear France using a continuous net settlement system. A fee or commission is payable to the broker-dealer or other agent involved in the transaction.

14.6. DILUTION

Between 851,175 new Ordinary Shares (assuming no exercise of the Extension Clause or the Over-allotment Option) and 1,125,678 new Ordinary Shares (assuming full exercise of the Extension Clause and the Over-allotment Option) will be issued pursuant to the Offer. Therefore, the number of such new Ordinary Shares as a percentage of the Enlarged Issued Share Capital of the Company immediately following Settlement and ESM Admission will be between 20.0 and 24.8 per cent.

14.7. ADDITIONAL TERMS AND CONDITIONS OF THE OFFER

These terms and conditions apply to investors agreeing to subscribe for new Ordinary Shares under the Offer. Each investor agrees with each of the Company and the Joint Bookrunners to be bound by these terms and conditions as being the terms and conditions upon which new Ordinary Shares will be issued under the Offer.

14.7.1 ***Agreement to acquire Shares***

Conditional on (i) Settlement and ESM Admission occurring on or prior to 8.00 a.m. on 2 May 2014 (or such later date as the Joint Bookrunners and the Company may agree), and (ii) the investor being allocated Ordinary Shares, each investor agrees to become a member of the Company on the terms and conditions of the Articles and agrees to subscribe for new Ordinary Shares at the Offer Price. The number of Ordinary Shares allocated to such investor under the Offer will be in accordance with the arrangements described in paragraph 14.2 of this Part 14 (*The Offer*). To the fullest extent permitted by law, each investor acknowledges and agrees that subject to any orders that might be revoked under the Institutional Placement as described in paragraph 14.1.3.2 of Part 14 (*The Offer*), it will not be entitled to exercise any rights to rescind or terminate or, subject to any statutory rights, to withdraw an application for Ordinary Shares in the Offer, or otherwise to withdraw from, such commitment.

14.7.2 ***Payment for Shares***

Each investor undertakes to pay the Offer Price for the Ordinary Shares issued to or acquired by such investor in such manner as shall be directed by the Joint Bookrunners. In the event of any failure by any investor to pay as so directed by the Joint Bookrunners, the relevant investor will be deemed thereby to have appointed the Joint Bookrunners or any nominee of the Joint Bookrunners to sell (in one or more transactions) any or all of the Ordinary Shares in respect of which payment will not have been made as directed by the Joint Bookrunners and indemnifies on demand the Joint Bookrunners and/or any relevant nominee of the Joint Bookrunners in respect of any liability for stamp duty arising in respect of any such sale or sales.

14.7.3 ***Representations and warranties***

Each investor and, in the case of sub-paragraphs (j), (k) and (l) below, any person confirming an agreement to subscribe for Ordinary Shares on behalf of an investor or authorising the Joint Bookrunners (on behalf of themselves and the Co-lead Manager) to notify the investor's name to the

Registrars, represents, warrants and acknowledges to each of the Company, and the Joint Bookrunners and the Co-lead Manager:

(a) if the investor is a natural person, such investor is not under the age of majority (18 years of age in Ireland and France) on the date of such investor's agreement to subscribe for Ordinary Shares under the Offer;

(b) the content of this Prospectus is exclusively the responsibility of the Company and the Directors and that neither the Joint Bookrunners, the Co-lead Manager nor any person acting on their behalf is responsible for or will have any liability for any information, representation or statement contained in this Prospectus or any information previously published by or on behalf of the Company or any member of the Group and will not be liable for any decision by an investor to participate in the Offer based on any information, representation or statement contained in this Prospectus or otherwise;

(c) in agreeing to subscribe for Ordinary Shares under the Offer, the investor is relying on this Prospectus and any supplementary prospectus that may be issued by the Company, and not on any other information or representation concerning the Group, the Ordinary Shares or the Offer. Such investor agrees that none of the Company, the Joint Bookrunners, the Co-lead Manager nor any of their respective officers, partners or directors will have any liability for any such other information or representation and irrevocably and unconditionally waives any rights it may have in respect of any such other information or representation. This paragraph 14.7.3 of Part 14 (*The Offer*) will not exclude any liability for fraudulent misrepresentation;

(d) the Joint Bookrunners and the Co-lead Manager are not making any recommendations to investors or advising any of them regarding the suitability or merits of any transaction they may enter into in connection with the Offer, and each investor acknowledges that participation in the Offer is on the basis that it is not and will not be a client of any of either the Joint Bookrunners or the Co-lead Manager and that the Joint Bookrunners or the Co-lead Manager are acting for the Company and no one else, and they will not be responsible to anyone else for the protections afforded to their respective clients, and that the Joint Bookrunners and the Co-lead Manager will not be responsible to anyone other than the Company for providing advice in relation to the Offer, the contents of this Prospectus or any transaction, arrangements or other matters referred to herein, and the Joint Bookrunners and the Co-lead Manager will not be responsible to anyone other than the relevant party to the Placing Agreement in respect of any representations, warranties, undertakings or indemnities contained in the Placing Agreement or for the exercise or performance of the Joint Bookrunners and Co-lead Manager' rights and obligations thereunder, including any right to waive or vary any condition or exercise any termination right contained therein;

(e) if the laws of any place outside Ireland or France are applicable to the investor's agreement to subscribe for Ordinary Shares, such investor has complied with all such laws and none of the Company, the Joint Bookrunners and the Co-lead Manager will infringe any laws outside Ireland and France as a result of such investor's agreement to subscribe for Ordinary Shares or any actions arising from such investor's rights and obligations under the investor's agreement to subscribe for Ordinary Shares and under the Articles (and, in making this representation and warranty, the investor confirms that it is aware of the selling and transfer restrictions set out in paragraph 14.2.1.2 of Part 14 (*The Offer*)).

(f) it understands that no action has been or will be taken in any jurisdiction other than France by the Company or any other person that would give rise to a public offering of the Ordinary Shares, or that would permit possession or distribution of this Prospectus, in any country or jurisdiction where action for that purpose is required;

(g) if the investor is in any Relevant Member State, it is: (i) a legal entity which is a qualified investor as defined in the Prospectus Directive; or (ii) otherwise permitted by law to be offered

Ordinary Shares in circumstances which do not require the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive or other applicable laws;

(h) the investor is not a national, resident or citizen of Australia, Italy, United Kingdom, Switzerland, Canada or Japan or a corporation, partnership or other entity organised under the laws of Australia, Italy, United Kingdom, Switzerland, Canada or Japan; that the investor will not offer, sell, renounce, transfer or deliver, directly or indirectly, any of the Ordinary Shares in Australia, Italy, United Kingdom, Switzerland, Canada or Japan or to any national, resident or citizen of Australia, Italy, United Kingdom, Switzerland, Canada or Japan and the investor acknowledges that the Ordinary Sharers have not been and will not be registered under the applicable securities laws of Australia, Italy, United Kingdom, Switzerland, Canada or Japan and that the same are not being offered for subscription or sale, and may not, directly or indirectly, be offered, sold, transferred or delivered, in Australia, Italy, United Kingdom, Switzerland, Canada or Japan;

(i) the investor is liable for any capital duty, stamp duty, stamp duty reserve tax and all other stamp, issue, securities, transfer, registration, documentary or other duties or taxes (including any interest, fines or penalties relating thereto) payable outside Ireland by it or any other person on the acquisition by it of any Ordinary Shares or the agreement by it to acquire any Ordinary Shares;

(j) in the case of a person who confirms to the Joint Bookrunners or the Co-lead Manager, on behalf of an investor, an agreement to subscribe for Ordinary Shares and/or who authorises the Joint Bookrunners (on behalf of themselves and the Co-lead Manager) to notify the investor's name to the Registrars, that person represents and warrants that he, she or it has authority to do so on behalf of the investor;

(k) the investor has complied with its obligations in connection with relevant money laundering and terrorist financing legislation and, if it is making payment on behalf of a third party, it has obtained and recorded satisfactory evidence to verify the identity of the third party as required by such legislation;

(l) if the investor is acquiring Ordinary Shares as a fiduciary or agent for one or more investor accounts, it represents that it has sole investment discretion with respect to each such account and it has full power to make the foregoing acknowledgements, representations and agreements on behalf of each such account;

(m) each investor in a Relevant Member State (other than France) who acquires any Ordinary Shares under the Offer contemplated hereby will be deemed to have represented, warranted and agreed with each of the Joint Bookrunners and the Co-lead Manager and the Company that:

(i) it is a qualified investor as that term is defined under the Prospective Directive;

(ii) it is otherwise permitted by law to be offered shares in circumstances which do not require the publication by the Company of a prospectus pursuant to Article 3 of the Prospectus Directive or other applicable law; or

(iii) in the case of any Ordinary Shares acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, (i) it is one of the intermediaries; or (ii) the Ordinary Shares acquired by it in the Offer have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any relevant member state other than qualified investors, as that term is defined in the Prospectus Directive, or in other circumstances falling within Article 3(2) of the Prospectus Directive and the prior consent of the Joint Bookrunners and the Co-lead Manager has been given to the offer or resale; or (iii) where Ordinary Shares have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of those Ordinary Shares to it is not treated under the Prospectus Directive as having been made to such persons; For the purposes of this provision, the

expression an "offer" in relation to any of the Ordinary Shares in any Relevant Member States means the communication in any form and by any means of sufficient information on the terms of the offer and any Ordinary Shares to be offered so as to enable an investor to decide to subscribe for the Ordinary Shares, as the same may be varied in that relevant member state by any measure implementing the Prospectus Directive in that Relevant Member State; (iv) if the investor wishes to issue orders under the Retail Offer, it is an authorised person as set out in paragraph 14.1.3.2 in Part 14 (*The Offer*); (v) in the case of a person who confirms to either the Joint Bookrunners or the Co-lead Manager, on behalf of an investor which is an entity other than a natural person, an agreement to subscribe for Ordinary Shares and/or who authorises the notification of such investor's name to the Registrars, that person warrants that he, she or it has authority to do so on behalf of the investor.

The Company, the Joint Bookrunners and the Co-lead Manager will rely upon the truth and accuracy of the foregoing representations, warranties and undertakings.

14.7.4 ***Supply and disclosure of information***

If the Company or the Joint Bookrunners or any of their agents request any information about an investor's agreement to subscribe for Ordinary Shares, such investor must promptly disclose it to them and ensure that such information is complete and accurate in all respects.

PART 15

ADDITIONAL INFORMATION

15.1 RESPONSIBILITY

The Company and the Directors (whose names appear on page 46 of this Prospectus) accept responsibility for the information contained in this Prospectus. To the best of the knowledge and belief of the Company and the Directors (who have taken all reasonable care to ensure that such is the case), the information contained in this Prospectus is in accordance with the facts and does not omit anything likely to affect the import of such information.

15.2 INFORMATION ON THE COMPANY

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.

The principal legislation under which the Company operates, and under which the Ordinary Shares were created, are the Irish Companies Acts and the regulations made thereunder.

The registered office of the Company is at Clonmel House, Forster Way, Swords, Co. Dublin, Ireland.

The Company has not traded nor prepared any audited accounts since its incorporation. KPMG Chartered Accountants, whose address is 1 Stokes Place, St. Stephen's Green, Dublin 2, has been appointed as the auditors of the Company and are the only auditors of the Company since its incorporation.

The Company has not, since its incorporation, carried on business or incurred borrowings or liabilities save in connection with it undertaking the position of the new holding company of the Group.

15.3 SHARE CAPITAL AND AUTHORITY RELATING TO THE ORDINARY SHARES

15.3.1 The share capital history of the Company is as follows:

(a) On incorporation the authorised share capital of the Company was €40,000 divided into 40,000 "A" ordinary shares of €1.00 each (each of which is an "**A Ordinary Share**"), of which 38,994 A Ordinary Shares were held by MFSD Holdings Limited and six A Ordinary Shares were held by nominees of MFSD Holdings Limited. The shares were issued and fully paid at par. MFSD Holdings Limited is a nominee company of the Company's Irish solicitors that subscribed for shares on incorporation to allow the Company to satisfy the authorised minimum share capital requirements for a plc under Irish company law. The 38,500 issued A Ordinary Shares were converted into Redeemable Shares, redeemed at par and cancelled on 3 April 2014, on the basis described at sub-paragraphs (c) and (e) below.

(b) By written resolution of the shareholders of the Company dated 28 March 2014, it was resolved to increase the authorised share capital of the Company by the creation of new classes of shares in the Company, comprising Series A Shares, Series B Shares, Series Z Shares and Ordinary Shares, in addition to the class of A Ordinary Shares already in existence.

(c) By written resolution of the shareholders of the Company dated 2 April 2014 it was resolved to approve the conversion, on completion of the 2014 Corporate Reorganisation, of the A Ordinary Shares to redeemable shares ("**Redeemable Shares**") and by resolutions dated 28 March 2014, the directors of the Company resolved that, immediately upon completion of the 2014 Corporate Reorganisation, subject to the Irish Companies Acts, the Redeemable Shares be redeemed by the Company at par.

(d) Upon the adoption of new articles of association by the Company on 28 March 2014 ("**Pre-IPO Articles**"), the Company had an authorised share capital of €50,000 divided into 40,000 A Ordinary Shares of €1.00 each, 5,000,000 ordinary shares of €0.001 each, 1,000,000 Series A Shares of €0.001 each, 3,000,000 Series B Shares of €0.001 each and 1,000,000 Series Z Shares of €0.001 each.

(e) On 2 April 2014:

(i) Sofinnova Partners subscribed for 28,469 Series B Shares for an aggregate subscription price of €26,305.36;

(ii) Fountain Healthcare Partners subscribed for 9,074 Series B Shares for an aggregate subscription price of €8,384.38;

(iii) Capricorn Venture Partners subscribed for 4,157 Series B Shares for an aggregate subscription price of €3,841.07;

(iv) Dan Sachs subscribed for 15,000 Ordinary Shares at nominal value, giving an aggregate subscription price of €15.00; and

(v) Medtronic, Inc. subscribed for 6,000 Ordinary Shares at nominal value, giving an aggregate subscription price of €6.00,

giving aggregate subscription proceeds of €38,551.80, which proceeds were used to fund the redemption of the 38,500 Redeemable Shares on 3 April 2014.

(f) On 3 April 2014, in connection with the 2014 Corporate Reorganisation:

(i) the Company issued 793,425 Series A Shares, 1,967,177 Series B Shares, 500,000 Series Z Shares and 81,400 Ordinary Shares to former shareholders in MML, in each case on the basis of one share in the Company in place of each 20 shares in MML of the same class that had been transferred to the Company under the terms of the 2014 Corporate Reorganisation;

(ii) the 2014 Share Option Plan was adopted by the Company on substantially the same terms as the 2012 share option plan of MML, the 2008 stock option plan of MMI, the Share Option Instrument and each of the stock option agreements between MMI and option holders of MMI were terminated, and the Company issued options to subscribe for Ordinary Shares in the Company to each of the persons who had previously held options over common stock in MMI and/or ordinary shares in MML in substitution for and in replacement of the options previously held by them; and

(iii) the MML Warrants were cancelled and replaced by 13,000 Share Warrants having an exercise price of $7.70 per Share Warrant and the parties agreed that the terms of the Warrant Deed applied to the Share Warrants, save for any adjustments to reflect that from completion of the 2014 Corporate Reorganisation the Company was the holding company of the Group and to reflect certain other amendments, waivers and variations relevant in the context of the 2014 Corporate Reorganisation.

(g) On 1 April 2014, the board of directors and shareholders of MMI adopted a plan of reorganisation of MMI ("**Plan of Reorganisation**") pursuant to which, among other matters, on 5 April 2014 MMI distributed to MMI shareholders (other than holders of series c shares in MMI) the shares in the Company that had been issued to MMI under the allotment referred to at sub-paragraph 15.3.1(f)(i) above.

The authorised and issued share capital of the Company following completion of the steps described at paragraphs (a) to (g) above on 5 April 2014 is set out at paragraph 15.3.2 below. The only material change to the Company's authorised and issued share capital that is expected to occur during the period commencing on the date of this Prospectus and ending immediately prior to ESM Admission

(and prior to completion of the Offer) is the conversion of the issued and unauthorised but unissued Series A Shares, Series B Shares and Series Z Shares into Ordinary Shares (on a one-for-one basis), as described at paragraphs 15.3.3 and 15.3.5(k) below.

15.3.2 The authorised, issued and fully paid up share capital of the Company as at the date of this Prospectus is as follows:

Class	*Authorised Number*	*Nominal Value*	*Issued and fully paid up number*	*Nominal value aggregate*
Ordinary Shares	5,000,000	€0.001	102,400	€102.40
Series A Shares	1,000,000	€0.001	793,425	€793.43
Series B Shares	3,000,000	€0.001	2,008,877	€2,008.88
Series Z Shares	1,000,000	€0.001	500,000	€500.00

15.3.3 In accordance with the terms of the Pre-IPO Articles, all issued 793,425 Series A Shares, 2,008,877 Series B Shares and 500,000 Series Z Shares will convert into Ordinary Shares on a one-for-one basis shortly before ESM Admission.

15.3.4 Immediately prior to ESM Admission, the Company's share capital is expected to be as follows:

Class	*Authorised Number*	*Nominal Value*	*Issued and fully paid up number*	*Nominal value aggregate*
Ordinary Shares	10,000,000	€0.001	3,404,702	€3.404.70

The maximum number of Ordinary Shares that will be in issue immediately following completion of the Offer is expected to be as follows:

Maximum number of Ordinary Shares that may be issued under the Base Offer (A)	851,175	
Maximum number of Ordinary Shares that may be issued under the Extension Clause (B)	127,676	
Maximum number of Ordinary Shares that may be issued under the Over-allotment Option (C)	146,827	
Total number of Ordinary Shares that may be issued under the Offer (A + B + C = D)		1,125,678
Expected number of Ordinary Shares in issue immediately prior to ESM Admission (E)		3,404,702
Total Maximum number of issued Ordinary Shares following completion of the Offer (D + E)		4,530,380

15.3.5 Written resolutions of the shareholders of the Company were passed on 28 March 2014:

(a) approving an increase in the authorised share capital of the Company to €50,000.00 divided into 40,000 A Ordinary Shares of €1.00 each, 5,000,000 ordinary shares of €0.001 each, 1,000,000 Series A Shares of €0.001 each, 3,000,000 Series B Shares of €0.001 each and 1,000,000 Series Z Shares of €0.001 each;

(b) approving the adoption of the Pre-IPO Articles; and

(c) giving the Board authority to make the allotment and issuance of shares contemplated by paragraphs 15.3.1(e) and (f) above.

Written resolutions of the shareholders of the Company were passed on 2 April 2014:

(d) authorising the Board to allot and issue relevant securities (as defined by section 20 of the 1983 Act) up to: (i) an aggregate nominal value of €3,000 in connection with the Offer, such authority to expire 45 days following ESM Admission; and thereafter up to (ii) an aggregate

nominal value of €5,000, representing 117 per cent. of the expected nominal value of the Enlarged Issued Share Capital following ESM Admission (assuming that 851,175 new Ordinary Shares are issued under the Base Offer and no exercise of the Extension Clause or the Over-allotment Option), such authority to expire five years from the date on which this resolution is passed, save that the Company may before such expiry make an offer or agreement which would or might require relevant securities to be allotted after the expiration of such authority and the directors may allot relevant securities in pursuance of such offer or agreement as if the authority had not expired;

(e) empowering the Board to allot equity securities (as defined by section 23 of the 1983 Act) for cash pursuant to the authority conferred by the resolution at sub-paragraph (d) above as if sub-section (1) of section 23 of the 1983 Act did not apply to any such allotment, provided that this power shall be limited: (a) to the allotment of equity securities to be issued by the Company in connection with the Offer (b) 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 where the equity securities respectively attributable to the interests of such holders are proportional (as nearly as may be) to the respective numbers of Ordinary Shares held by them (but subject to such exclusions or other arrangements as the Board 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 authorised regulatory body or any stock exchange in, any territory, or otherwise howsoever); and (c) to the allotment (otherwise than pursuant to sub-paragraph (a) and (b) above) of equity securities up to an aggregate nominal amount of €2,500, representing 59 per cent. of the expected nominal value of the Enlarged Issued Share Capital following ESM Admission (assuming that 851,175 new Ordinary Shares are issued under the Base Offer and no exercise of the Extension Clause or the Over-allotment Option), and shall expire at the earlier of the conclusion of the annual general meeting of the Company in 2015 and close of business on the date that is 15 months from the 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 Board may allot equity securities in pursuance of such offer or agreement as if the power hereby conferred had not expired;

(f) authorising the Company to use electronic means to convey information to Shareholders or debt securities holders, in accordance with the Transparency Regulations;

(g) authorising the Company, in accordance with the Articles, to call certain general meetings on 14 clear days' notice;

(h) fixing the aggregate ordinary remuneration permitted to be paid to the Directors in accordance with the Articles at an amount not exceeding €10,000,000.00 per annum;

(i) authorising the Directors to fix the remuneration of the auditors of the Company;

(j) approving the conversion of the 38,500 issued A Ordinary Shares into redeemable shares and the redemption at par and cancellation of those shares;

(k) approving the conversion of all authorised but unissued Series A Shares, Series B Shares and Series Z Shares into authorised and unissued Ordinary Shares at the same time as the issued shares of those classes convert into Ordinary Shares (as provided for in the Pre-IPO Articles and as described at paragraph 15.3.3 above); and

(l) approving, subject to, and with effect from, ESM Admission (i) the adoption by the Company of the Articles of Association as described in paragraph 15.7 below; and (ii) the amendment and replacement of clause 5 of the Memorandum of Association of the Company so that, following cancellation of the 38,500 A Ordinary Shares previously held by MFSD Holdings Limited and its nominees, all authorised but unissued A Ordinary Shares are cancelled and the authorised share capital of the Company on ESM Admission will be as described in paragraph 15.3.4 above.

15.3.6 As at the Latest Practicable Date, the Company has issued the following Share Warrants:

Warrant Holder	*No. of Outstanding Share Warrants*	*Subscription Price*	*Expiry Date*
SVB Financial Group	13,000	$7.70	2 December 2021

As at the Latest Practicable Date, each Share Warrant is exercisable over one Series A Share. With effect from ESM Admission, each Share Warrant will become exercisable over one Ordinary Share.

15.3.7 As at the Latest Practicable Date, options over 331,074 Ordinary Shares are in issue and outstanding under the 2014 Share Option Plan. Under the terms of the 2014 Share Option Plan, the Board is entitled to issue a total of 794,734 options over Ordinary Shares.

15.3.8 Save as disclosed in this paragraph 15.3 of Part 15 and sub-paragraph 9.4 (d) of Part 9 (*Directors, Senior Management and Corporate Governance*) of this Prospectus and save as provided for under the terms and conditions of the Placing Agreement, 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.

15.3.9 Section 40 of the 1983 Act provides that where the net assets of a company are half or less of the amount of the company's called-up share capital, the directors of the company shall, not later than 28 days from the earliest day on which that fact is known to a director of the company, duly convene an extraordinary general meeting of the company for a date not later than 56 days from that day for the purpose of considering whether any, and if so what, measures should be taken to deal with the situation. At a meeting of the directors of MML on 1 April 2014, it was resolved to convene an extraordinary general meeting of MML in order to comply with the requirements of section 40 of the 1983 Act. It is not envisaged that any measures will be taken by MML to deal with the situation.

15.4 2014 CORPORATE REORGANISATION

15.4.1 Following the steps set out in sub-paragraph 15.3.1(a)-(e) above and in order to effect the changes to the share capital structure outlined in sub-paragraph 15.3.1(f), the shareholders of MML, the Company and MML entered into and completed a Re-organisation Agreement on 3 April 2014 under which the Company became the ultimate holding company of the Group and MML became a wholly-owned subsidiary of the Company, comprising the following principal transactions ("**2014 Corporate Reorganisation**"):

(a) each shareholder of MML transferred to the Company the legal and beneficial title to its shares in MML in order for all of the issued share capital of MML to be held by the Company;

(b) the former shareholders of MML were allotted and issued 793,425 Series A Shares, 1,967,177 Series B Shares, 500,000 Series Z Shares and 81,400 Ordinary Shares, to be apportioned amongst them in each case in place of each 20 issued shares of MML of the same class that had been transferred to the Company by the former shareholders of MML as described under sub-paragraph 15.4.1(a) above;

(c) the MML Warrants were cancelled and replaced by 13,000 Share Warrants having an exercise price of $7.70 per Warrant Share and the parties to the Reorganisation Agreement agreed that the terms of the Warrant Deed applied to the Share Warrants, save for any adjustments to certain provisions to reflect that from completion of the 2014 Corporate Reorganisation the Company will be the holding company of the Group and to reflect certain other amendments, waivers and variations relevant in the context of the 2014 Corporate Reorganisation;

(d) the 2014 Share Option Plan was adopted by the Company on substantially the same terms as those contained in the 2012 share option plan of MML; the 2008 stock option plan of MMI, the Share Option Instrument and each of the stock option agreements between MMI and option

holders of MMI were terminated; and the Company issued options to subscribe for Ordinary Shares in the Company to each of the persons who had previously held options over common stock in MMI and/or ordinary shares in MML in substitution for and in replacement of the options previously held by them and on a "one for twenty" basis so that each person received one option for every twenty options previously held by them;

(e) the Redeemable Shares were redeemed at par and cancelled by the Company;

(f) Antoine Papiernik, Manus Rogan, Dan Sachs and David Brabazon were appointed as directors of the Company, Oern Stuge was appointed as director and chairman of the Board and Hugh Kavanagh resigned as director of the Company; and

(g) MMI was liquidated and dissolved and MMI distributed to its shareholders (other than the holders of series C shares) the shares in the Company that it had acquired under the transactions described at sub-paragraph 15.4.1(b) above.

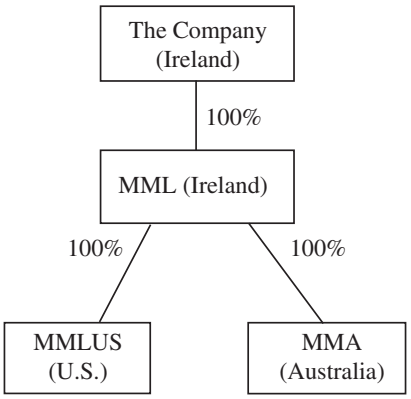
15.4.2 Upon the closing of the Series B Financing, certain shareholders held shares in MMI which in turn held shares in MML. This structure gave rise to possible double taxation of proceeds on any future change of control transaction involving MML, i.e. MMI would pay corporate taxes prior to distribution of proceeds, and shareholders in MMI would then pay their own taxes on the proceeds so distributed. The shareholders of MML and MMI had previously agreed that any tax liabilities imposed upon MMI as a result of such a transaction should be borne pro rata by all shareholders in MMI and MML, in proportion to the respective amounts of net sales proceeds that would have been received by such shareholder if no entity level tax liabilities had been imposed on MMI as a result of such transaction (the "**Tax Sharing Arrangements**").

The shareholders of MMI and MML decided that it was in the best interests of all parties to simplify the shareholder structure in MML. To that end, they agreed that (i) MMI would be liquidated; (ii) MMI and MML shareholders would subscribe for shares in MMI (on a basis to be agreed between the parties) to allow it to discharge its tax liabilities and other liabilities in connection with the liquidation; and (iii) the Tax Sharing Arrangements would be terminated.

In order to effect the liquidation of MMI, the U.S. tax liabilities of MMI had to be evaluated and paid to the U.S. tax authorities prior to liquidation. The principal tax liability of MMI was derived from the value of its deemed ownership interest in the intellectual property of MML. For the purpose of assessing that tax liability, the directors of MMI obtained an independent valuation of that ownership interest, which yielded an overall valuation of MML (subject to various assumptions and caveats) within the same general range as the implied valuation of MML following the Series B Financing. In order to raise capital to pay these tax liabilities and other liabilities, MMI offered to issue stock in MMI to existing shareholders of MMI and MML. In April 2014, the MMI and MML shareholders acquired series C shares in MMI. Immediately following the acquisition by MMI of shares in the Company as part of the 2014 Corporate Reorganisation, liquidation proceedings in respect of MMI were commenced. On 5 April 2014, MMI distributed to its shareholders (other than holders of series C shares) the shares in the Company that it had acquired as part of the 2014 Corporate Reorganisation.

In connection with the termination of the Tax Sharing Arrangements, it was also agreed that certain MMI and MML shareholders would subscribe for shares in the Company on the basis described at paragraph 15.3.1(e) above.

15.4.3 The 2014 Corporate Reorganisation did not affect the Group's operations, which will continue to be carried out through its operating subsidiaries. The following chart reflects the Group's corporate structure on ESM Admission, after giving effect to the 2014 Corporate Reorganisation:



15.5 INTERESTS OF MAJOR SHAREHOLDERS

As of the Latest Practicable Date, in so far as is known to the Company, the following persons have an interest which represents three per cent. or more of the issued share capital of the Company:

	As of the Latest Practicable Date		*After the Base Offer and before exercise of the Extension Clause and the Over-allotment Option*[2][3]	
Name	*Number of shares*[1]	*Percentage of Existing Issued Share Capital*	*Number of Ordinary Shares*	*Percentage of Enlarged Issued Share Capital*
Sofinnova Capital VI FCPR	1,556,999	45.7%	1,753,946	41.2%
Fountain Healthcare Partners Fund 1, L.P.	496,403	14.6%	559,194	13.1%
Dan Sachs	515,000	15.1%	515,000	12.1%
Capricorn Health-Tech Fund NV	227,358	6.7%	256,117	6.0%
Medtronic, Inc.	200,931	5.9%	231,782	5.4%
Seventure Partners Managed Funds	170,915	5.0%	191,991	4.5%

	After the Base Offer and exercise in full of the Extension Clause and before exercise of the Over-allotment Option[2][3]		*After the Base Offer and exercise in full the Extension Clause and of the Over-allotment Option*[2][3]	
Name	*Number of Ordinary Shares*	*Percentage of Enlarged Issued Share Capital*	*Number of Ordinary Shares*	*Percentage of Enlarged Issued Share Capital*
Sofinnova Capital VI FCPR	1,753,946	40.0%	1,753,946	38.7%
Fountain Healthcare Partners Fund 1, L.P.	559,194	12.8%	559,194	12.3%
Dan Sachs	515,000	11.7%	515,000	11.4%
Capricorn Health-Tech Fund NV	256,117	5.8%	256,117	5.7%
Medtronic, Inc.	231,782	5.3%	231,782	5.1%
Seventure Partners Managed Funds	191,991	4.4%	191,991	4.2%

Notes:

(1) As at the Latest Practicable Date the Shareholders listed above hold various classes of shares. All issued shares in the Company will convert to Ordinary Shares on a one for one basis shortly before admission to listing on Euronext Paris and prior to ESM Admission.

(2) Assuming the issue of 851,175 new Ordinary Shares, being the maximum number under the Base Offer.

(3) Assuming (where applicable) the aggregate subscription of these Shareholders under their respective Subscription and Lock-up Deeds of an amount of €8 million, corresponding to 340,424 new Ordinary Shares based on the mid-point of the Price Range.

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.

15.6 MANDATORY BIDS, COMPULSORY ACQUISITION RULES AND DISCLOSURE OF INFORMATION

15.6.1 *Mandatory Bids*

The Directive 2004/25/EC of the European Parliament and the Council dated April 21, 2004 on takeover bids (the "**Takeover Directive**") sets forth certain principles governing the laws applicable to the Company in the context of a takeover bid for the shares of the Company.

Article 5-1 of the Takeover Directive requires Member States to ensure that any person who, acting individually or in concert with other persons, acquires directly or indirectly a specified percentage of voting rights which confers on such person the control of a listed company, is required to make a takeover bid as a means of protecting the minority shareholders of that company, subject to certain exemptions provided by law. Article 5-3 of the Takeover Directive further specifies that the percentage of voting rights which confers control for the purposes of the foregoing rule, and the method of calculating the specified percentage, is determined by the rules of the Member State in which the company has its registered office.

Article 4-2(b) of the Takeover Directive provides that if the securities of the company subject to the takeover bid are not admitted to trading on a regulated market of the Member State in which the company has its registered office, the authority competent to supervise the takeover bid shall be that of the Member State on the regulated market of which the company's securities are admitted to trading. Under Article 4-2(e), the matters referred to such competent authority include the price and other consideration offered, and the takeover bid procedure, in particular the information on the offeror's decision to make a takeover bid, the contents of the offer document and the disclosure of the takeover bid.

Article 4-2(e) also specifies however, that the applicable rules and the competent authority shall be those of the Member State in which the offeree company has its registered office for matters relating to the information to be provided to the employees of the company that is the subject of the takeover bid and matters relating to company law, in particular the percentage of voting rights which confers control and any derogation from the obligation to launch a takeover bid, as well as the conditions under which the board of the company that is the subject of the takeover bid may undertake any action which might result in the frustration of the takeover bid.

Following admission of its Ordinary Shares to trading of Euronext Paris and the ESM, the Company will be a public limited company incorporated in Ireland (with its registered office in Ireland) and its Ordinary Shares will be admitted to trading on an EU regulated market (within the meaning of "regulated market" pursuant to the Directive 93/22/EEC), being Euronext Paris, and a market which is not an EU regulated market (within the same meaning of "regulated market", being the ESM). As a result, a takeover bid for the Company would be subject to rules from both the French AMF and the Irish Takeover Panel, as outlined above. Additional details on the French takeover rules and the Irish takeover rules are given below.

French Takeover Rules

Pursuant to Articles 4-2(b) and 4-2(e) of the Takeover Directive, for so long as the Ordinary Shares of the Company shall be admitted to trading on an EU regulated market in France only, (i) the AMF shall be competent to supervise any takeover bid filed for the Company's shares and (ii) matters relating to the consideration offered and 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 general regulation (règlement général) of the AMF (the "**French Takeover Rules**").

Takeover bids must be made for all of the Company's voting securities, as well as for all other securities issued by the Company that entitle the holders thereof to the subscription for, or the conversion in, voting securities. Prior to making a takeover bid, the offeror must issue and disseminate an offer document, which must be approved by the AMF. The offeror must also obtain approval of the relevant competition authorities, where such approval is legally required for the acquisition of the Company's shares.

In the event of a mandatory takeover bid, the offer price must be at least equal to the highest price paid by the offeror, acting alone or in concert, in the twelve-month period preceding the event that gave rise to the obligation to file a mandatory offer.

The acceptance period for the takeover bid must be at least 10 and not more than 30 trading days, and will depend on the specific circumstances.

For the avoidance of doubt, any French Takeover Rules on the percentage of voting rights that trigger the obligation to file a mandatory takeover bid or allowing the squeeze-out of the minority shareholders in certain circumstances will not apply in relation to the Ordinary Shares of the Company. Rather, these matters shall be dealt with in accordance with the Irish Takeover Rules and the 2006 Regulations (as defined below), which are described below.

Irish Takeover Rules

Pursuant to Article 4-2(e) of the Takeover Directive, the Irish Takeover Rules apply to the Company only in respect of matters relating to the information to be provided to its employees and matters relating to company law (in particular the percentage of voting rights which confers control and any derogation from the obligation to launch an offer, as well as the conditions under which the Board may undertake any action which might result in the frustration of an offer). Under the Irish Takeover Rules a person acquires control of a relevant company where that person acquires securities which, when taken together with securities held by concert parties, amount to 30 per cent. of more of the voting rights of the company.

There have been no mandatory takeover bids nor any public takeover bids by third parties in respect of the share capital of the Company in the last financial year or in the current financial year to date.

15.6.2 ***Squeeze Out***

The European Communities (Takeover Bids (Directive 2004/25/EC)) Regulations 2006 (the "**2006 Regulations**") set out a procedure enabling a bidder for an Irish company which has securities admitted to trading on an EU regulated market to acquire compulsorily the securities of those holders who have not accepted a general offer—the "**squeeze-out**" right—on the terms of the general offer.

The main condition that needs to be satisfied before the "**squeeze-out**" right can be exercised is that the bidder, pursuant to acceptance of a bid for the beneficial ownership of all the transferable voting securities (other than securities already in the beneficial ownership of the bidder) in the capital of the company, has acquired, or unconditionally contracted to acquire, securities that amount to not less than nine tenths of the nominal value of the securities affected and carry not less than nine tenths of the voting rights attaching to the securities affected.

15.6.3 ***Buy Out***

The 2006 Regulations also provide for rights of "**sell-out**" for shareholders in Irish companies which have securities admitted to trading on an EU regulated market. Holders of securities carrying voting rights in the company who have not accepted a bid by way of a general offer for the beneficial ownership of all of the voting securities in the company (other than securities already in the beneficial ownership of the bidder) have a corresponding right to oblige the bidder to buy their securities, on the terms of the general offer under which the beneficial ownership of the securities of the assenting

security holders was acquired by the bidder. The main condition to be satisfied to enable the exercise of ''sell-out'' rights is that the bidder has acquired, or unconditionally contracted to acquire, securities which amount to not less than nine tenths in nominal value of the securities affected and which carry not less than nine-tenths of the voting rights attaching to the securities affected.

15.6.4 ***Disclosure of Interests***

Under the Transparency Regulations and Transparency Rules, the shareholders of a listed company to which the Transparency Rules apply are required to notify the company (and at the same time the Central Bank of Ireland) within two trading days when their voting rights in the company reach, exceed or fall below 3 per cent. of the voting rights and also each time they increase or decrease by a whole integer (i.e., a whole number) above 3 per cent.. The Company is obliged, under the Transparency Rules, to publish any such notification received no later than the trading day following receipt.

The Transparency Regulations and Transparency Rules oblige listed companies to publish the total number of voting rights and capital at the end of each calendar month during which an increase or decrease of such total number occurs. Further disclosure is required where the company acquires or disposes of its own shares, either itself or through another person acting on its behalf, when the percentage of voting rights attributable to those shares exceeds or falls below the thresholds of 5 per cent. or 10 per cent.

The Transparency Regulations and Transparency Rules also oblige listed companies to notify a RIS as soon as possible after any decision to pay or withhold any dividend or interest payment on listed securities and of the results of any new issue of equity securities or preference shares or of a public offering of existing shares or other equity shares.

15.6.5 ***Disclosure of Information***

As the Company is incorporated in Ireland and its Ordinary Shares will be admitted to trading on Euronext Paris (which is an EU regulated market), under the Market Abuse Directive, both Irish and French market abuse laws (including the provisions under the laws of each jurisdiction relating to insider dealing and disclosure of inside information) will apply to the Company.

In addition, under the ESM Rules, the Company will be required to disclose without delay price sensitive information concerning the Company.

15.7 MEMORANDUM AND ARTICLES OF ASSOCIATION

The following is a summary of the Memorandum of Association and the Articles of Association of the Company to be effective on ESM Admission. Any Shareholder requiring further detail than that provided in the summary is advised to consult the copies of the Memorandum of Association and the Articles of Association of the Company to be effective on ESM Admission, which are available at the address specified in paragraph 15.2 of Part 15 (*Additional Information*).

15.7.1 ***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.

15.7.2 ***Articles of Association***

The Articles of Association of the Company to be effective on ESM Admission contain (among others) provisions to the following effect:

Allotment of shares

Subject to the provisions of the Irish Companies Acts and of any resolution of the Company in general meeting, the shares shall be at the disposal of the Directors who may allot (with or without conferring a right of renunciation), grant options over or otherwise dispose of them to such persons, on such terms and conditions and at such times as they may consider to be in the best interests of the Company and its members, but so that no share shall be allotted at a discount and so that, except in the case of shares allotted pursuant to an employees' share scheme, the amount payable on application on each share shall not be less than one-quarter of the nominal amount of the share and the whole of any premium thereon.

Without prejudice to the generality of the powers conferred on the Directors by the preceding paragraph and the powers and rights of the Directors under or in connection with any share option schemes or arrangements which were adopted or entered into by the Company prior to the adoption of the Articles, the Directors may from time to time grant options to subscribe for the unallotted shares in the capital of the Company to employees, consultants or customers of the Company or any subsidiary of the Company (including Directors holding executive offices) on such terms and subject to such conditions as the Directors may from time to time approve.

The Company may issue a warrant or certificate to any person to whom the Company has granted the right to subscribe for shares in the Company (other than under a share option scheme for employees), certifying the right of the holder thereof to subscribe for shares in the Company upon such terms and conditions as the right may have been granted.

Variation of rights

Whenever the share capital is divided into different classes of shares, the rights attached to any class may be varied or abrogated with the consent in writing of the holders of three-fourths in nominal value of the issued shares of that class, or with the sanction of a special resolution passed at a separate general meeting of the holders of the shares of the class, and may be so varied or abrogated either whilst the Company is a going concern or during or in contemplation of a winding-up. To every such separate general meeting the provisions of the Articles relating to general meetings shall apply except that the quorum at any such separate general meeting, other than an adjourned meeting, shall be two persons holding or representing by proxy at least one-third in nominal value of the issued shares of the class in question and the quorum at an adjourned meeting shall be one person holding shares of the class in question or his proxy.

The rights conferred upon the holders of the shares of any class shall not, unless otherwise expressly provided by the Articles or the terms of the issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking pari passu therewith or subordinate thereto or by the purchase or redemption by the Company of any of its shares.

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 81 of the 1990 Act.

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 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 regulated market (as such term is defined in the EU Markets in Financial Instruments Directive (2004/39/EC)) 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:

(a) 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 transfer by a Stock Exchange Nominee (as defined in the Articles) where no certificate has been issued in respect of the shares in question or 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;

(b) it is in respect of one class of share only; and

(c) it is in favour of not more than four persons jointly.

Alteration of capital

The Company may by ordinary resolution:

(a) increase its share capital;

(b) consolidate and divide all or any of its share capital into shares of a larger amount;

(c) subject to the provisions of the Irish Companies Acts, sub-divide its shares, or any of them, into shares of smaller amount; or

(d) cancel any shares which have not been taken or agreed to be taken by any person and reduce the amount of its share capital by the amount of the shares so cancelled.

Reduction of capital

The Company may, by special resolution, reduce its share capital, any capital redemption reserve fund, any share premium account or any capital conversion reserve fund in any manner and with, and subject to, any incident authorised, and consent required, by law.

Purchase of own shares

Subject to the provisions of the Irish Companies Acts and to any rights conferred on the holders of any class of shares, the Company may purchase all or any of its shares of any class including redeemable shares so that any shares so purchased may be cancelled or held by the Company as treasury shares. The Company shall not make a purchase of shares in the company unless the market purchase has first been authorised by a special resolution of the Company.

General meetings

The Company shall hold in each year a general meeting as its annual general meeting in addition to any other meeting in that year and shall specify the meeting as such in the notice calling it. Not more than 15 months shall elapse between the date of one annual general meeting and that of the next.

All general meetings other than annual general meetings shall be called extraordinary general meetings.

The Directors may convene general meetings. Extraordinary general meetings may also be convened on such requisition, or in default may be convened by such requisitionists, and in such manner as may be provided by the Irish Companies Acts.

Subject to the provisions of the Irish Companies Acts allowing a general meeting to be called by shorter notice, an annual general meeting and an extraordinary general meeting shall be called by at least 21 clear days' notice, except that an extraordinary general meeting that is not called for the passing of a special resolution may, subject to compliance with all applicable provisions of the Irish Companies Acts, be called by at least 14 clear days' notice.

The Directors shall specify in the notice of a general meeting the voting record date. A person shall be entered on the Register at the voting record date in order for that person to exercise the right of a member to participate and vote at the general meeting and any change to an entry on the Register after the voting record date shall be disregarded in determining the right of any person to attend and vote at the meeting.

No business other than the appointment of a chairman shall be transacted at any general meeting unless a quorum of members is present at the time when the meeting proceeds to business. Two persons entitled to attend and to vote upon the business to be transacted, each being a member or a proxy for a member, shall be a quorum.

If such a quorum is not present within half an hour from the time appointed for the meeting, the meeting, if convened upon the requisition of members, shall be dissolved; in any other case the meeting shall stand adjourned to the same day in the next week at the same time and place, or to such other day and at such other time and place as the Directors may determine.

All business shall be deemed special that is transacted at an extraordinary general meeting. All business that is transacted at an annual general meeting shall also be deemed special, with the exception of declaring a dividend, the consideration of the accounts, balance sheets and reports of the Directors and auditors, the appointment of Directors in the place of those retiring, the re-appointment of the retiring auditors and the fixing of the remuneration of the auditors.

Every member entitled to attend and vote at a general meeting may appoint a proxy to attend, speak and vote on his behalf provided, however, that:

(a) a member may appoint more than one proxy provided that each proxy is appointed to exercise the rights attached to shares held in different securities accounts; and

(b) a member acting as an intermediary on behalf of a client in relation to shares may appoint that client or any third party designated by that client as a proxy in relation to those shares,

subject to such requirements and restrictions as the Directors may from time to time specify.

Votes

Votes may be given either personally or by proxy. Subject to any rights or restrictions for the time being attached to any class or classes of shares and subject to any suspension or abrogation of rights pursuant to the Articles, on a show of hands every member present in person and every proxy shall have one vote, so, however, that no individual shall have more than one vote, and on a poll every member shall have one vote for every share carrying rights of which he is the holder. On a poll a

member entitled to more than one vote need not cast all his votes or cast all the votes he uses in the same way.

Subject to the Irish Companies Acts and to such requirements and restrictions as the Directors may, in accordance with the Irish Companies Acts, specify, the Company at its discretion may provide for participation and voting in a general meeting by electronic means.

Subject to the Irish Companies Acts and to such requirements and restrictions as the Directors may, in accordance with the Irish Companies Acts, specify, the Company may at its discretion provide for voting on a poll by correspondence. Where the Company permits votes to be cast on a poll by correspondence, it shall be required to count only those votes cast in advance by correspondence that are received before the date and time specified by the Company for that purpose, provided that such date and time is not more than 24 hours before the time at which the vote is to be concluded.

Default in payment of calls

Unless the Directors otherwise determine, no member shall be entitled to vote at any general meeting or any separate meeting of the holders of any class of shares in the Company, either in person or by proxy, or to exercise any privilege as a member in respect of any share held by him unless all moneys then payable by him in respect of that share have been paid.

Restriction of voting and other rights

(a) If at any time the Directors shall determine that a Specified Event (as defined in paragraph (i) 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:

  (i) 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

  (ii) the Directors shall, where the Specified Shares represent not less than 0.25 per cent. of the class of shares concerned, be entitled:

    a. 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

    b. where the Specified Event concerned is the event described in subparagraph (i) or (iii) of paragraph (g) below, to refuse to register any transfer (other than an Approved Transfer as defined in paragraph (h) below) of the Specified Shares or any renunciation of any allotment of new shares or debentures made in respect of the Specified Shares.

(b) 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.

(c) 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.

(d) Every determination of the Directors and every Restriction Notice served by them pursuant to the provisions of this Article 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 Article shall not be questioned by any person.

(e) 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 Article.

(f) 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.

(g) A "**Specified Event**" shall be deemed to have occurred in relation to a share if:

(i) 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;

(ii) 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 the Articles; or

(iii) 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 81 of the 1990 Act.

(h) For the purposes of the Articles:

(i) an "**Approved Transfer**" is a transfer of shares which:

a. 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

b. 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 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

c. 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.

(ii) 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 81 of the 1990 Act includes reference:

i. to his having failed or refused to give all or any part of the information required by the notice; or

ii. 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.

Directors

Numbers
Unless otherwise determined by Company in general meeting, the number of Directors shall not be more than 14 or less than two.

Qualification
A Director shall not require a share qualification.

Remuneration
The ordinary remuneration of the Directors shall not exceed such amount as may be determined from time to time by an ordinary resolution of the Company and shall be divisible (unless such resolution shall provide otherwise) among the Directors as they may agree, or, failing agreement, equally, except that any Director who shall hold office for part only of the period in respect of which such remuneration is payable shall be entitled only to rank in such division for a proportion of the remuneration related to the period during which he has held office. Any sums payable pursuant to this Article shall be distinct from any salary, remuneration (including share based remuneration) or other amounts payable to a Director pursuant to any other Article and shall accrue from day to day.

Any Director who holds any additional office (including for this purpose the office of chairman or deputy chairman whether or not such office is held in an executive capacity), who serves on any committee or who otherwise performs services which in the opinion of the Directors are outside the scope of the ordinary duties of a Director, may be paid such extra remuneration by way of salary, commission, participation in profits or otherwise as the Directors may determine.

The Directors may be paid all travelling, hotel and other expenses properly incurred by them in connection with their attendance at meetings of Directors or of committees of Directors or of general meetings or of separate meetings of the holders of any class of shares or of debentures of the Company or otherwise in connection with the discharge of their duties.

Delegation
The Directors may entrust to and confer upon a Director any of the powers, authorities and discretions exercisable by them (with power to sub-delegate) upon such terms and subject to such conditions and with such restrictions as they think fit, and either collaterally with or to the exclusion of their own powers and may from time to time revoke, withdraw, alter or vary all or any of such powers.

The Directors may delegate any of their powers, authorities and discretions (with power to sub-delegate) for such time, upon such terms and subject to such conditions and with such restrictions as they think fit to any committee consisting of one or more Directors and (if thought fit) one or more other persons, provided that:

(a) a majority of the members of a committee shall be Directors; and

(b) no resolution of a committee shall be effective unless a majority of those present when it is passed are Directors or alternate Directors.

Borrowing powers
The Directors may exercise all the powers of the Company to borrow or raise money and to mortgage or charge its undertaking, property, assets, and uncalled capital or any part thereof and, subject to Part III of the 1983 Act, to issue debentures, debenture stock and other securities whether outright or as collateral security for any debt, liability or obligation of the Company or of any third party, without any limitation as to amount.

Retirement

Each Director shall 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.

Appointment

No person other than a Director retiring at the meeting shall be appointed or re-appointed a Director at any general meeting unless he is recommended by the Directors or, not less than seven nor more than 42 days before the date appointed for the meeting, notice executed by a member qualified to vote at the meeting has been given to the Company of the intention to propose that person for appointment stating whether the person is proposed as an additional Director or to replace a Director who is retiring or being removed and the particulars which would be required, if he were so appointed, to be included in the Company's register of Directors, together with notice executed by that person of his willingness to be appointed.

Subject as aforesaid, the Company by ordinary resolution may appoint a person to be a Director either to fill a vacancy or as an additional Director provided that the appointment does not cause the number of Directors to exceed any number fixed by or in accordance with the Articles as the maximum number of Directors. The Directors may appoint a person who is willing to act to be a Director, either to fill a vacancy or as an additional Director, provided that the appointment does not cause the number of Directors to exceed any number fixed by or in accordance with the Articles as the maximum number of Directors. Subject to the provisions of the Irish Companies Acts and of the Articles, a Director so appointed shall retire at the next following annual general meeting and shall then be eligible for re-appointment.

Directors' interests

Subject to the provisions of the Irish Companies Acts and provided that he has complied with the Articles, a Director, notwithstanding his office:

(a) may be a party to, or otherwise interested in, any contract, arrangement, transaction or proposal with the Company or any subsidiary or associated company thereof or in which the Company or any subsidiary or associated company thereof is otherwise interested;

(b) may hold any other office or place of profit under the Company (except that of auditor or of auditor of a subsidiary of the Company) in conjunction with his office of Director, and may act by himself or through his firm in a professional capacity for the Company, and in any such case on such terms as to remuneration and otherwise as the Directors shall arrange;

(c) may be a director or other officer of, or employed by, or a party to any contract, arrangement, transaction or proposal with, or otherwise interested in, any body corporate promoted by the Company or in which the Company or any subsidiary or associated company of the Company is otherwise interested; and

(d) shall not be accountable, by reason of his office, to the Company for any profit, remuneration or other benefit which he derives from any such contract, arrangement, transaction, proposal, office, place of profit or employment or from any interest in any such body corporate,

and no such contract, arrangement, transaction or proposal entered into by or on behalf of the Company in which any Director is in any way interested shall be liable to be avoided on account of such interest.

A Director who is in any way, whether directly or indirectly, interested in any contract, arrangement, transaction or proposal with the Company shall declare the nature of his interest at the meeting of the Directors at which the question of entering into the contract, arrangement, transaction or proposal is

first considered, or, if the Director was not at the date of that meeting interested therein, at the next meeting of the Directors held after he became so interested, and, in a case where the Director becomes interested in a contract, arrangement, transaction or proposal after it is made, at the first meeting of the Directors held after he becomes so interested.

Interested Director not to vote or count for quorum

(a) Save as otherwise provided by the Articles, a Director shall not vote at a meeting of the Directors or a committee of Directors on any resolution concerning a matter in which he has an interest which (together with any interest of any person connected with him) is to his knowledge material (otherwise than by virtue of his interests in shares or debentures or other securities of or otherwise in or through the Company). A Director shall not be counted in the quorum present at a meeting in relation to any such resolution on which he is not entitled to vote.

(b) A Director shall be entitled (in the absence of any other material interest than is indicated below) to vote (and to be counted in the quorum) in respect of any resolution concerning any of the following matters, namely:

(i) the giving of any security, guarantee or indemnity to him in respect of money lent or obligations incurred by him or any other person at the request of or for the benefit of the Company or any of its subsidiary undertakings;

(ii) the giving of any security, guarantee or indemnity in respect of a debt or obligation of the Company or any of its subsidiary undertakings for which he himself has assumed responsibility in whole or in part under a guarantee or indemnity or by the giving of security;

(iii) any proposal concerning any offer of shares or debentures or other securities of or by the Company or any of its subsidiary undertakings in which offer he is or may be entitled to participate as a holder of securities or in the underwriting or sub-underwriting of which he is to participate;

(iv) any proposal concerning any other company in which he (together with any persons connected with him) does not to his knowledge have an interest (as that term is used in Chapter 2 of Part IV of the 1990 Act) in one per cent or more of either any class of the equity share capital of, or the voting rights in, such company;

(v) any proposal relating to any arrangement for the benefit of employees of the Company or any of its subsidiary undertakings which does not award him any privilege or benefit not generally awarded to the employees to which such arrangement relates; or

(vi) any proposal concerning the giving of any indemnity to the Directors or any of them pursuant to the Articles or the discharge of the cost of any insurance which the Company proposes to maintain or purchase for the benefit of the Directors or any of them or for the benefit of persons who include the Directors or any of them.

Voting at Directors' meetings

Questions arising at any meeting of Directors shall be decided by a majority of votes. Where there is an equality of votes, the chairman of the meeting shall have a second or casting vote. Subject as hereinafter provided, each Director present shall have one vote and in addition to his own vote shall be entitled to one vote in respect of each other Director not present at the meeting who shall have authorised him in respect of such meeting to vote for such other Director in his absence. Any such authority may relate generally to all meetings of the Directors or to any specified meeting or meetings and shall be in writing and may be sent by delivery, post, facsimile, electronic mail or any other means of communication approved by the Directors and may bear a printed or facsimile signature of the Director giving such authority. The authority must be delivered to the secretary for filing prior to, or

shall be produced at, the first meeting at which a vote is to be cast pursuant thereto provided that no Director shall be entitled to any vote at a meeting on behalf of another Director pursuant to this paragraph if the other Director shall have appointed an alternate Director and that alternate Director is present at the meeting at which the Director proposes to vote pursuant to this paragraph.

Indemnity

Subject to the provisions of and so far as may be permitted by the Irish Companies Acts but without prejudice to any indemnity to which the person concerned may otherwise be entitled, every Director, Managing Director, auditor, secretary or other officer of the Company shall be entitled to be indemnified by the Company against all costs, charges, losses, expenses and liabilities incurred by him in the execution or discharge of his duties or in relation thereto including (without prejudice to the generality of the foregoing) any liability incurred by him in defending any proceedings, civil or criminal, which relate to anything done or omitted to be done or alleged to have been done or omitted by him as an officer or employee of the Company and in which judgment is given in his favour (or the proceedings are otherwise disposed of without any finding or admission of any material breach of duty on his part) or in which he is acquitted or in connection with any application under any statute for relief from liability in respect of any such act or omission in which relief is granted to him by the court.

Dividends

Subject to the provisions of the Irish Companies Acts, the Company may by ordinary resolution declare dividends in accordance with the respective rights of the members, but no dividend shall exceed the amount recommended by the Directors. Subject to the provisions of the Irish Companies Acts, the Directors may declare and pay such interim dividends as appear to them to be justified by the profits of the Company available for distribution. The Directors may from time to time at their discretion, with or subject to the sanction of an ordinary resolution of the Company, offer to the holders of ordinary shares in the Company the right to elect to receive an allotment of additional ordinary shares, credited as fully paid, instead of cash in respect of all or part of any cash dividend or dividends specified by such resolution or such part of such dividend or dividends as the Directors may determine.

Distribution on winding up

If the Company shall be wound up and the assets available for distribution among the members as such shall be insufficient to repay the whole of the paid up share capital, such assets shall be distributed so that, as nearly as may be, the losses shall be borne by the members in proportion to the capital paid up at the commencement of the winding up on the shares held by them respectively; and if in a winding up the assets available for distribution among the members shall be more than sufficient to repay the whole of the share capital paid up at the commencement of the winding up, the excess shall be distributed among the members in proportion to the capital at the commencement of the winding up paid up on the shares held by them respectively; provided, however, that this paragraph shall not affect the rights of the holders of shares issued upon special terms and conditions.

15.8 EMPLOYEES

Employees of the Group

Details of the number of the Group's permanent employees (including the executive Director) during each of the three financial periods the last of which ended on 31 December 2013 are as follows:

Financial period ended	*Number of employees*
As at 31 December 2011	3
As at 31 December 2012	6
As at 31 December 2013	13
Latest Practicable Date	13

The table below sets out the number of employees of the Group for the financial period ended 31 December 2013, as well as a breakdown of the persons employed by category:

Job Function	*Ireland/ Europe*	*U.S.*	*Australia*	*Total*
Research & Development and Quality	1	6	–	7
Clinical & Regulatory	–	2	–	2
General & Administration	2	1	1	4

As of December 2013, the Group's employees are based in Ireland 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 2013, the Group employed the following consultants:

Job Function	*Ireland/ Europe*	*U.S.*	*Australia*	*Total*
Research & Development and Quality	–	1	–	1
Clinical & Regulatory	–	1	–	1
General & Administration	1	1	–	2

15.9 WORKING CAPITAL

The Company, having made due and careful enquiry, is of the opinion that, taking into account the Minimum Net Proceeds to be received by the Company from the Offer, 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.

15.10 NO SIGNIFICANT CHANGE

There has been no significant change in the financial or trading position of the Group since 31 December 2013 (the date to which the financial information reported on in the accountant's report in respect of the Company in Part 12 (*Historical Financial Information*) of this Prospectus was prepared).

15.11 RELATED PARTY TRANSACTIONS

15.11.1 ***Related Party Transactions***

Save as disclosed in this paragraph 15.11 of this Part 15 (*Additional Information*) and in the financial information set out in the related party transaction notes to the financial statements for the financial years ended 31 December 2011, 2012 and 2013 contained in *Section 12.1B: Consolidated Financial Information as at 31 December 2013, 2012 and 2011, and for the Three Years Ended 31 December 2013* of Part 12 (*Historical Financial Information*) of this Prospectus, the Company did not enter into any material transactions with related parties during the financial years ended 31 December 2011, 2012 and 2013.

The Group has received invoices from ORSCO Life Sciences AG, a company controlled by Oern Stuge, of U.S.$16,911 (converted from invoice currency CHF) since 31 December 2013. The Company did not enter into any other material transactions with related parties in the interim period up until the Latest Practicable Date.

See note 20 Related Party Transactions in *Notes to the consolidated financial information of Section 12.2B: Consolidated Financial Information as at 31 December 2013, 2012 and 2011, and for the Three Years Ended 31 December 2013* of Part 12 (*Historical Financial Information*).

15.11.2 ***Directors' shareholdings***

Paragraph 9.4 of Part 9 (*Directors, Senior Management and Corporate Governance*) of this Prospectus sets out the interests of the Directors in the share capital of the Company as at the Latest Practicable Date.

15.12 ISSUER'S SUBSIDIARIES

Name	*Country of Incorporation*	*Shareholding per cent.*
Subsidiaries		
Mainstay Medical Limited	Ireland	100
MML US, Inc.	United States	100
Mainstay Medical (Australia) Pty. Limited	Australia	100

15.13 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 Prospectus 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 Prospectus:

15.13.1 ***Stock Loan Agreement***

In connection with the over-allotment and stabilisation arrangements relating to the Offer, the Stabilising Manager will enter into a Stock Loan Agreement with Sofinnova Partners pursuant to which the Stabilising Manager will be able to borrow, from Sofinnova Partners free of charge, Ordinary Shares on Settlement and ESM Admission up to an amount equal to 15 per cent. of the size of the Offer for the purposes, amongst other things, of allowing the Stabilising Manager to settle, at Settlement and ESM Admission, overallocations, if any, made in connection with the Offer. If the Stabilising Manager borrows any Ordinary Shares pursuant to the Stock Loan Agreement it will be required to return equivalent securities to Sofinnova Partners by certain agreed dates.

15.13.2 ***ESM Adviser and Broker Agreement***

On 7 April 2014, the Company and Davy entered into an ESM Adviser and Broker Agreement pursuant to which Davy has agreed to act as ESM Adviser and Broker to the Company for the purposes of the ESM Rules and following ESM Admission. Pursuant to the agreement, Davy will receive a retainer fee of €50,000 per annum (exclusive of VAT). Either party may terminate the agreement forthwith in the event of the 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 an ESM Adviser or broker.

15.13.3 ***Placing Agreement***

It is expected that on or about 28 April 2014 (being the date on which the Offer Price and Offer Size will be announced), the Company will enter into an agreement with J&E Davy, Kempen & Co and Société Générale (together the "**Managers**"). Pursuant to the terms of this agreement, the Managers will severally agree, subject to certain conditions that are typical in an agreement of this nature, to procure subscribers for the Ordinary Shares to be offered by the Company at the Offer Price and, failing which, to subscribe and pay for those Ordinary Shares themselves.

The Company will agree to pay all costs, charges, fees and expenses of and, incidental to, the Offer and the issue of the new Ordinary Shares including a commission to the Managers of between approximately 5.5 per cent. and 6.5 per cent. of the aggregate proceeds from subscribers for new Ordinary Shares in the Offer based on the Price Range. A discretionary commission of up to 1 per cent. of the gross proceeds may also be paid solely at the discretion of the Company.

The agreement includes the Over-Allotment Option, being a provision whereby Société Générale (being the "**Stabilisation Manager**"), itself or through its agents will be entitled (but not obliged) to cover over-allotments made in the Offer on its behalf and on behalf of the other Managers pursuant to applicable laws and regulations, including EU Regulation 2273/2003 dated December 22, 2003.

Pursuant to the agreement, the Company and the Directors of the Company have given certain market standard warranties and the Company has given the Managers an indemnity concerning, amongst other items, the accuracy of the warranties given in the agreement.

The Company has also undertaken that it will not, for a period of 180 days beginning on the date of Settlement and ESM Admission (the "**Closing Date**") offer, issue, lend, sell, contract to sell, grant options in respect of or otherwise dispose of, directly or indirectly, any Ordinary Shares or any securities that are convertible into or exchangeable for, or enter into any swap or other agreement or any other transaction with the same economic effect as (or agree to do) any of the foregoing, except as required to comply with existing and permitted grants of Share Options or Share Warrants. The Company has also agreed not to do any of the foregoing without the prior written consent of the Managers during the period beginning 181 days after and continuing to and including the date 360 days after the Closing Date.

The agreement may be terminated by the Managers giving notice to the Company in certain circumstances including where any of certain specified conditions contained in the agreement have not been satisfied by the Closing Date (including Settlement and ESM Admission occurring).

The agreement is governed by the laws of the French Republic and the Tribunal de Commerce of Paris has non-exclusive jurisdiction for the purposes of any litigation or suit arising out of or relating to the agreement.

15.13.4 ***Re-organisation Agreement***

The shareholders of MML, the Company and MML entered into a Re-organisation Agreement on 3 April 2014 to put into effect the 2014 Corporate Reorganisation, under which the Company became the ultimate holding company of the Group and MML became a wholly-owned subsidiary of the Company, which comprised those transactions more particularly set out at sub-paragraph 15.3.1(f) and paragraph 15.4.1 of this Part 15 (*Additional Information*).

15.13.5 ***Lock-up Deeds and Lock-up and Subscription Deeds***

The Company is party to Lock-up Agreements with the Directors holding Ordinary Shares or Share Options, Senior Managers and Shareholders as at the date of the Prospectus.

The Directors holding Ordinary Shares or Share Options, Senior Managers and Shareholders as at the date of the Prospectus have agreed with the Company, the Joint Bookrunners, and the Co-lead Manager that, subject to certain customary exceptions, each of the relevant Directors, Shareholders and Senior Managers shall not, amongst other things, offer, sell, pledge or sell any option over, enter into or consummate any contract to sell, grant any option, right or warrant or otherwise transfer or dispose of, directly or indirectly any Ordinary Shares, or securities of the Company, or any securities that are convertible or redeemable into or exchangeable for, or that give the right to receive, acquire or subscribe, for Ordinary Shares in the Company, held by them at the date of ESM Admission for a period of 365 days from the date of ESM Admission (other than as described in the following paragraph).

The Company is party to Lock-up and Subscription Deeds with Sofinnova Partners, Fountain Healthcare Partners, Medtronic, Inc., Capricorn Health-Tech Fund NV and Seventure Partners Managed Funds. Under the terms of each Lock-up and Subscription Deed, the above named Shareholders have agreed to enter into the same lock-up terms, as described in the preceding paragraph, but that the lock-up terms shall not apply in respect of Ordinary Shares issued to the above named Shareholders under the Offer.

Details of the maximum amount that may be subscribed for by each above named Shareholder under its Lock-up and Subscription Deed are set out in paragraph 14.2.2 of Part 14 (*The Offer*).

Under the terms of each Lock-Up and Subscription Deed, the above named Shareholders have irrevocably undertaken to subscribe under the Offer for the issue of new Ordinary Shares with an aggregate subscription price of €8 million, and that this amount is intended to be served in full if demand makes this possible, provided that this amount may be reduced based on actual market demand and pursuant to usual allocation practice.

15.13.6 ***Amendment and Restatement Agreement to Shareholders Agreement***

As part of the 2014 Corporate Reorganisation, an Amendment and Restatement Agreement to Shareholders Agreement was entered into on 3 April 2014 between each of the shareholders of the Company, the Company, MML and MMI ("**Amendment and Restatement Agreement**").

Under the Amendment and Restatement Agreement, the parties agreed that the MML Shareholders Agreement was amended and restated so that, with effect from completion of the 2014 Corporate Reorganisation, the terms of the MML Shareholders Agreement were superseded and replaced by the Amendment and Restatement Agreement. As a result the MML Shareholders Agreement was terminated.

The Amendment and Restatement Agreement includes terms pursuant to which shareholders of the Company have agreed that their rights to certain tax and financial information under the terms of the Amendment and Restatement Agreement (see below) would be suspended pending the completion or termination of ESM Admission. The Amendment and Restatement Agreement also includes terms pursuant to which the Company assumed and became bound by certain contractual arrangements ("**Observer Rights**") that had been previously been agreed between MML and each of Medtronic, Inc., Seventure Partners Managed Funds and Capricorn Venture Partners ("**Observer Parties**"), The Observer Rights, among other things, included the grant of certain rights by MML to the Observer Parties to attend board meetings of MML in a non-voting observer capacity. Whilst the Observer Rights in respect of the Company are similar to the rights that the Observer Parties were entitled to in respect of MML, under the Amendment and Restatement Agreement it was acknowledged and agreed that certain of the Observer Rights would be suspended pending completion or termination of ESM Admission.

Under the Amendment and Restatement Agreement, the shareholders of the Company granted acknowledgements, consents, waivers and approvals in respect of the transactions contemplated by the 2014 Corporate Reorganisation, the Offer, admission to trading on Euronext Paris and the ESM Admission.

The Amendment and Restatement Agreement includes, amongst other things, provisions governing the composition of the board of directors of the Company, voting by the shareholders of the Company for the board of directors of the Company, voting by the shareholders of the Company in connection with a sale of the Company, and agreements and undertakings relating to rights of first refusal and co-sale with respect to certain proposed transfers of shares in the Company.

In addition, the Amendment and Restatement Agreement contains provisions which require the approval of a majority of the board of the Company in order for certain matters to be effected by the Company (or its subsidiaries). In the case of more specific matters identified in the Amendment and Restatement Agreement that are proposed to be effected by the Company (or its subsidiaries), the approval of the majority of the board of the Company must also include directors appointed by Fountain Healthcare Partners and Sofinnova Partners. These matters include (amongst other things) the issue of new shares, the amendment of the Company's Memorandum and Articles of Association, the liquidation, dissolution or any merger or acquisition of the Company, and the grant of employee options under employee stock or options plans.

The Amendment and Restatement Agreement also contains other categories of provisions that would customarily be included in a shareholders agreement, including co-sale, drag-along, tag-along and pre-emption provisions.

Subject to the suspension of rights referred to above, under the Amendment and Restatement Agreement, the Company must also provide to certain classes of shareholders in the Company particular tax and financial information in relation to the business and operations of the Company, such as audited annual accounts, management accounts, operating plans, budgetary information and tax returns.

The terms of the Amendment and Restatement Agreement provide that the agreement will terminate (i) where a change in control transaction occurs (being either (a) an acquisition of the Company after which the existing shareholders of the Company immediately prior to such a transaction, would own less than 50 per cent. of the voting rights and control of all classes of shares in the Company, or (b) a sale, lease or conveyance of all or substantially all of the assets of the Company) (ii) where the Company completes a listing of its ordinary shares; (iii) by written agreement of the Company (with the approval of the majority of the board of the Company which must also include directors appointed by Fountain Healthcare Partners and Sofinnova Partners) and the holders of 75 per cent. of the issued shares in the Company; or (iv) immediately on and simultaneously with the automatic conversion of all issued shares in the company to Ordinary Shares shortly before ESM Admission.

The terms of the Amendment and Restatement Agreement are governed by Irish law and the Irish courts have exclusive jurisdiction to hear, settle and/or decide any dispute which may arise out of the Amendment and Restatement Agreement.

15.13.7 ***Warrant Deed***

MML entered into a warrant deed with Silicon Valley Bank ("**SVB**") with an issue date of 21 September 2012 (the "**Warrant Deed**") giving SVB the right to subscribe for 260,000 series A convertible redeemable preference shares of $0.001 each in the capital of MML ("**MML Warrants**"). The exercise price was $0.385 per share, subject to adjustment in accordance with the terms and conditions of the Warrant.

In accordance with the terms of the Warrant Deed, on completion of the 2014 Corporate Reorganisation pursuant to the terms of the Re-organisation Agreement, the rights held by SVB under the Warrant Deed were replaced by rights over 13,000 Series A Shares of €0.001 each in the capital of the Company (the "**Warrant Shares**") to be held on the same terms and conditions except that the exercise price per Warrant Share became $7.70 and the parties agreed certain other amendments, waivers and variations relevant in the context of the 2014 Corporate Reorganisation.

The Warrant Deed provides that in the event that all outstanding Series A Shares are converted, automatically or by action of the holders thereof, into Ordinary Shares pursuant to the provisions of the Company's Articles of Association, then from and after the date on which all such outstanding shares have been so converted, the warrant shall be exercisable for such number of Ordinary Shares into which the Warrant Shares would have been converted had the Warrant Shares been outstanding on the date of such conversion. On such a conversion the warrant price shall equal the warrant price in effect as of immediately prior to the conversion divided by the number of Ordinary Shares into which one Warrant Share would have been converted (all subject to further adjustment thereafter from time to time in accordance with the provisions of the Warrant Deed).

The warrant may be exercised in whole or in part at any time and from time to time until and including 2 December 2021 ("**Expiration Date**") and will be void thereafter.

The Warrant Deed provides that, in lieu of exercising the warrant, the holder may up until the Expiration Date convert the warrant in whole or in part into a number of Warrant Shares. The number of Warrant Shares will be determined by dividing (a) the aggregate fair market value of all of the Warrant Shares issuable under the warrant minus the aggregate warrant price for all such Warrant Shares by (b) the fair market value of one Warrant Share; provided always that the holder

shall be required to subscribe in cash for the par value of the Warrant Shares to the extent that, if it did not do so, the Warrant Shares would be issued at a discount to the holder.

If the Company's ordinary shares are traded on a recognised investment exchange and the Warrant Shares are ordinary shares, the fair market value of each Warrant Share shall be the closing price of a Warrant Share reported for the business day immediately before the holder of the Warrant delivers its notice of exercise to the Company (or in the instance where the warrant is exercised immediately before the effectiveness of an initial public offering, the "price to the public" per share price specified in the final prospectus relating to such offering). If the Company's ordinary shares are traded on a public market and the Warrant Shares are preferred shares, the fair market value of a Warrant Share shall be the closing price of the Company's ordinary shares reported for the business day immediately before the holder of the Warrant delivers his notice of exercise to the Company multiplied by the number of shares into which a Warrant Share is then convertible. If the shares of the Company are not traded on a recognised investment exchange, the fair market value of a Warrant Share shall be determined by the Board acting reasonably and in good faith.

Upon the written request of the Company, in the event of an acquisition of the Company where the consideration to be received by Shareholders consists solely of cash, or solely of marketable securities or a combination of cash and marketable securities ("**Cash/Public Acquisition**"), the holder of the Warrant shall exercise its conversion or purchase right under the Warrant. If such right is not exercised, the Warrant will expire immediately upon the closing of such an acquisition.

Upon the closing of any acquisition other than a Cash/Public Acquisition, the acquiring, surviving or successor entity shall assume the obligations of the warrant and the warrant shall thereafter be exercisable for the same securities and/or other property as would have been paid for the shares issuable upon the exercise of the unexercised portion of the warrant as if such shares were outstanding on and as of the closing of such acquisition, subject to further adjustment in accordance with the warrant.

After (i) any allotment of fully paid shares by way of capitalisation of the Company's reserves (other than shares paid up out of distributable reserves and issued in lieu of a cash dividend) to holders of shares on a date before the end of the Expiration Date or (ii) upon any sub-division, consolidation or reduction of the Company's shares before the end of the Expiration Date, the number and/or nominal value of Warrant Shares to be subscribed on any subsequent exercise of the warrant will be increased, or as the case may be, reduced in due proportion so as to maintain the same relative subscription rights, and the warrant price will be adjusted accordingly with effect from the record date for such capitalisation, subdivision and consolidation. On any such capitalisation, subdivision or consolidation the auditors of the Company shall be requested by the Board to certify the appropriate adjustments.

The Warrant Shares and the number of ordinary shares issuable upon conversion of the Warrant Shares shall be subject to standard anti-dilution adjustments as set out in the Warrant Deed. On any such adjustment the auditors of the Company shall be required to certify the appropriate adjustments.

The Company shall not, by amendment of its Memorandum or Articles of Association or through a reorganisation, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms to be observed or performed under the warrant. In fact, the Company must, at all times in good faith assist in the carrying out of the provisions of the Warrant Deed and in taking all such action as may be necessary or appropriate to protect the holder's rights against impairment.

As part of the Warrant Deed, MML gave certain warranties and covenants to the warrant holder relating to the Warrant Shares issuable under the terms of the Warrant Deed.

The Company is required to give notice to the holder of the warrant in relation to proposals for certain changes to the share capital of the Company or for any public offering of the Company's shares.

Under the terms of the Warrant Deed, after receipt by SVB of the executed warrant, SVB agreed to transfer all of the warrants to its parent company, SVB Financial Group and upon providing written notice to the Company, SVB Financial Group and any subsequent holder may transfer all or part of the warrants or the shares issuable on exercise of the warrant, provided the required notice is given to the Company and provided that the transferee agree in writing with the Company to be bound by all of the terms and conditions of the warrant.

At all times prior to an initial public offering the holder of the warrant may not, without the Company's prior written consent, transfer the warrant, any portion thereof, any shares or securities issued upon the exercise thereof, to any person or entity who directly competes with the Company, except in connection with an acquisition of the Company by such a direct competitor.

In the event that, upon the Expiration Date, the fair market value of one Warrant Share (as determined in accordance with the above paragraphs) is greater than the warrant price in effect on such date, then the warrant shall automatically be deemed to be converted (also in accordance with the above paragraphs) as to all Warrant Shares for which it shall not previously have been exercised or converted.

The Warrant Deed is governed by Irish Law and any disputes are to be referred to the exclusive jurisdiction of the Irish courts, other than disputes in relation to the adjustment provisions or calculation of the market price of shares which are to be referred to expert determination.

15.13.8 ***MML Series B Preferred Subscription Agreement***

On 21 September 2012 and as part of the 2012 Corporate Reorganisation, MML entered into a subscription agreement (the "**Subscription Agreement**") with MMI, and certain other investors, including Sofinnova Partners, Fountain Healthcare Partners, Seventure Partners Managed Funds and Capricorn Venture Partners (the "**Investors**"). Under the Subscription Agreement, the Investors agreed to subscribe for, in aggregate, 38,986,354 series B redeemable convertible preference shares of U.S.$0.001 each in the capital of MML at a cash purchase price of U.S.$0.513 per share, for a total aggregate subscription price of U.S.$19,999,999.62.

The Subscription Agreement contains representations and warranties given by MML, MMI and the Investors (subject to certain limitations) typical for a subscription agreement of its nature. The Subscription Agreement contains various conditions to completion including a requirement that each of MML, MMI, the Investors and each of the existing shareholders of MML and MMI enter into a new shareholders' agreement regulating, amongst other things, the relationships between them concerning MML and MMI (see below summary of the MML Shareholders Agreement for further details). Under the terms of the Subscription Agreement it was agreed that, prior to completion of the subscription by the Investors for series B shares under the agreement, the loan and security agreement entered into between MMI with SVB was to be assigned to and assumed by MML. MML was also required to enter into an indemnification agreement with each member of the board of directors of MML pursuant to which MML was to indemnify, and to advance expenses to, the directors of MML in connection with any claims or actions arising against them in connection with their services to, and the activities of, MML.

The terms of the Subscription Agreement are governed by Irish law and the Irish courts have exclusive jurisdiction to hear, settle and/or decide any dispute which may arise out of the Subscription Agreement.

15.13.9 ***MML Shareholders' Agreement***

On 25 September 2012, a shareholders' agreement was entered into between MML, MMI and the shareholders of MML and MMI to regulate the relationship between the parties and certain other

matters in connection with the operation of the business of MML ("**MML Shareholders Agreement**").

The MML Shareholders Agreement was terminated with effect from completion of the 2014 Corporate Reorganisation under the terms of the Amendment and Restatement Agreement (see paragraph 15.13.6 of Part 15 (*Additional Information*)).

The MML Shareholders Agreement included, amongst other things, provisions governing the composition of the board of directors of MML and MMI, voting by the shareholders of MML or MMI for (respectively) the board of directors of MML or MMI, voting by the shareholders of MML in connection with a sale of MML, and agreements and undertakings relating to rights of first refusal and co-sale with respect to certain proposed transfers of shares in MML or MMI.

In addition, the MML Shareholders Agreement contained provisions requiring the approval of a majority of the board of MML in order for certain matters to be effected by MML (or its subsidiaries). In the case of more specific matters identified in the MML Shareholders Agreement that may have been proposed to be effected by MML (or its subsidiaries), the approval of the majority of the board of MML was also required to include directors appointed by Fountain Healthcare Partners and Sofinnova Partners. These matters included (amongst other things) the issue of new shares, the amendment of MML's Memorandum and Articles of Association, the liquidation, dissolution or any merger or acquisition of MML, and the grant of employee options under employee stock or options plans.

The MML Shareholders Agreement also contained other categories of provisions that would customarily be included in a shareholders agreement, including co-sale, drag-along, tag-along and pre-emption provisions. Under the MML Shareholders Agreement the parties also agreed that in the event of a change in control of MML, any tax liabilities imposed upon MML or MMI as a result of the change in control shall be borne pro-rata by all of the shareholders of the MML and MMI in proportion to the respective amounts of the net sales proceeds they would receive if there was no entity level tax liabilities.

Under the MML Shareholders Agreement, MML was obliged provide to certain classes of shareholders in MML and MMI particular tax and financial information in relation to the business and operations of MML, such as audited annual accounts, management accounts, operating plans, budgetary information and tax returns.

The terms of the MML Shareholders Agreement were governed by Irish law and the Irish courts had exclusive jurisdiction to hear, settle and/or decide any dispute which may arise out of the MML Shareholders Agreement provided however that, with respect to disputes solely among shareholders of MMI or MMI, the laws of Delaware governed such disputes and such shareholders consent to the exclusive jurisdiction of, and venue in, the courts of Delaware.

15.13.10 ***Contribution and Assumption Agreement***

On 21 September 2012, a contribution and assumption agreement was entered into between MMI and MML ("**Contribution and Assumption Agreement**") as part of the 2012 Corporate Re-organisation under which MMI agreed to contribute to MML substantially all of its assets, rights, properties and business of every kind and description (including all intellectual property rights such as patents, inventions, technology, know-how etc.) held or used by MMI primarily in the conduct of the development of medical devices for the treatment of Chronic Non-Specific Low Back Pain and for the sale and marketing of such devices. MML also agreed to assume certain liabilities from MMI which are set forth in the Contribution and Assumption Agreement, including trade account payables, obligations to furnish goods, services and other non-cash benefits to third parties, and obligations under a loan and security agreement dated 2 December 2011 between SVB and MMI.

In exchange for entering into the transactions under the Contribution and Assumption Agreement, MML agreed to issue to MMI (i) a promissory note convertible into equity securities of MML (see

below summary of the Convertible Promissory Note); and (ii) an option instrument to purchase shares in MML (see below summary of the Option Instrument).

The Contribution and Assumption Agreement contains a list of some assets or items that were excluded from the contribution of assets by MMI to MML, which included equipment, furniture and fittings located in the US, cash, employment agreements, option agreements, consultancy agreements, insurance policies and other contracts.

The Contribution and Assumption Agreement contains representations, warranties and covenants from both MML and MMI that would be typical for an agreement of its nature. The agreement is governed by and construed in accordance with the laws of the State of Delaware.

15.13.11 ***Convertible Promissory Note***

In connection with the Contribution and Assumption Agreement and as part of the 2012 Corporate Re-organisation, on 21 September 2012 a convertible promissory note was entered into between MML and MMI ("**Convertible Promissory Note**") pursuant to which MML promised to pay to the order of MMI the sum of U.S.$15,000,000 without interest, to be paid through the issuance of (i) 1,626,000 ordinary shares of U.S.$0.001 each, (ii) 15,868,520 series A preferred shares of U.S.$0.001 each, and (iii) 10,000,000 Z preferred shares of U.S$0.001 each in the share capital of the MML (collectively the "**Mainstay Securities**"). Under the terms of the Convertible Promissory Note, the entire principal amount could be converted at any time at the option of MMI. into the Mainstay Securities in accordance with the terms of that agreement.

The terms of the Convertible Promissory Note are governed by Irish law and the Irish courts have exclusive jurisdiction to hear, settle and/or decide any dispute which may arise out of the Convertible Promissory Note.

MMI effected an exercise of its rights under the Convertible Promissory Note on 24 September 2012.

15.13.12 ***Loan and Security Agreement***

Under a loan and security agreement dated 2 December, 2011 between MMI and SVB, SVB agreed to advance up to $2,000,000 to MMI ("**SVB Loan and Security Agreement**"). MMI agreed to repay the loan in 30 equal instalments of principal together with monthly payments of accrued interest. The SVB Loan and Security Agreement provides that the repayments of the loan commence on 1 July 2012 with the final repayment due on 1 December, 2014. MMI granted a security interest in certain properties, rights and assets to SVB as security for the payment and its obligations under the SVB Loan and Security Agreement. The SVB Loan and Security Agreement contains certain representations, warranties, covenants from MMI and events of default typical for an agreement of its nature.

In accordance with the terms of the Pay-Off Letter and Deed of Release summarised at paragraph 15.13.15 of this Part 15 (*Additional Information*) below, the amounts due to SVB under the SVB Loan and Security Agreement were repaid in full by MML and associated security (including the Debenture summarised below) was released.

15.13.13 ***Consent Agreement***

In connection with the Contribution and Assumption Agreement, MML agreed, amongst other things, to assume the liability of MMI for its obligations under the SVB Loan and Security Agreement. A Consent, Assumption and Amendment to the Loan and Security Agreement ("**Consent Agreement**") was entered into between MMI and SVB to, amongst other things, gives effect to the assumption by MML of the liabilities and obligations of MMI under the SVB Loan and Security Agreement. The Consent Agreement contains consents from SVB to the proposed transactions contemplated by the Contribution and Assumption Agreement and the Subscription Agreement.

The SVB Loan and Security Agreement was amended and supplemented by the terms of the Consent Agreement in order for, amongst other things, MML to become the borrower under the SVB Loan and Security Agreement and for MMI to become the guarantor of the obligations of MML under the SVB Loan and Security Agreement (as amended by the Consent Agreement). The terms of the Consent Agreement provided that MML execute and deliver a new warrant in favour of SVB to purchase stock, previously issued by MMI and that the warrant previously issued by MMI and held by SVB Financial Group be cancelled. It is also a term of the Consent Agreement that MML enter into a debenture with SVB as security for its obligations under the Loan and Security Agreement (as amended).

The terms of the Consent Agreement are governed by Californian law, except to the extent that the application of the laws of Ireland are expressly agreed to apply.

15.13.14 ***Debenture***

In connection with the Consent Agreement, on 21 September 2012 a debenture was entered into between SVB and MML ("**Debenture**") to secure the repayment obligations of MML to SVB under the Loan and Security Agreement (as amended by the Consent Agreement). The Debenture secured all sums due to SVB and was not limited to the obligations of the Loan and Security Agreement. Under the Debenture, MML created, amongst other things, the following security in favour of SVB over the following items:

(a) a first fixed charge over certain charged property, intellectual property proceeds, and book debts;

(b) a mortgage over all of the shares held by any of MML, MMI or any of their subsidiaries;

(c) an assignment of all MML's plant and machinery; and

(d) an assignment over certain security accounts.

The terms of the Debenture are governed by Irish law and the Irish courts were to have exclusive jurisdiction to hear, settle and/or decide any dispute which may arise out of the Debenture.

In accordance with the terms of the Pay-Off Letter and Deed of Release summarise in paragraph 15.13.15 of this Part 15 (*Additional Information*) below, the amounts due to SVB under the SVB Loan and Security Agreement were repaid in full by MML and associated security (including the Debenture) was released.

15.13.15 ***Pay-Off Letter and Deed of Release***

A Pay-Off Letter dated 5 March 2014 was entered into between SVB and MML ("**Pay-Off Letter**") pursuant to which, effective immediately upon SVB's receipt of payment in full in cash of the amount due and owing under the SVB Loan and Security Agreement, all indebtedness and payment obligations of MML to SVB under the SVB Loan and Security Agreement (together with security interests held by SVB in connection with the loan thereunder) were terminated and released, except in respect of the Warrant Deed and certain bank services being provided by SVB to MML. The Pay-Off Letter is governed by the laws of the State of California. The SVB loan has been paid-off in full.

Pursuant to a Deed of Release dated 7 March 2014 between SVB and MML ("**Deed of Release**"), SVB released and discharged all of the assets mortgaged, charged or assigned to SVB by MML and all obligations under the Debenture and any other documents securing payment obligations entered into between SVB and MML. However, the Deed of Release excluded any release in respect of the Warrant Deed and certain bank services being provided by SVB to MML. The Deed of Release is governed by the laws of Ireland and the parties irrevocably submit to the exclusive jurisdiction of the courts of Ireland.

15.13.16 ***Share Option Instrument***

Under the Share Option Instrument executed by MML ("**Share Option Instrument**"), MML created an option conferring on MMI the right to subscribe for 1,222,800 ordinary shares of $0.001 each in the capital of MML ("**Option Shares**") in cash at the option price of $0.04 per Option Share ("**Option Price**").

The Share Option Instrument was terminated with effect from completion of the 2014 Corporate Reorganisation under the terms of the Re-organisation Agreement.

15.13.17 ***Subscription Application***

Pursuant to a letter of application for subscription for shares dated 6 June 2013 from FCPI Biosanté to MML ("**Subscription Application**"), FCPI Biosanté applied to subscribe for 357,286 series B convertible redeemable preference shares of $0.001 each in the capital of MML at a price per share of $0.513, to be held subject to the articles of association of MML and the MML Shareholders Agreement. Pursuant to a letter to MML dated 11 June 2013, the shareholders of MML having pre-emption rights waived all of the pre-emptive rights they had under the articles of association of MML, the MML Shareholders Agreement or otherwise in relation to the issue of shares proposed under the Subscription Application. At a meeting of the board of directors of MML held on 14 June 2013, the directors of MML resolved that MML allot the shares specified, and on the terms set out, in the Subscription Application.

15.13.18 ***CCC Agreement***

CCC del Uruguay S.A. ("**CCC**") was founded by Dr. Fiandra, who performed the first successful pacemaker chronic implant in the world in February 1960, and started its operations in 1969 to manufacture implantable cardiac pacemakers. CCC has evolved into an established and well respected supplier of cardiac and neurostimulation devices to early stage and commercial OEM neurostimulation companies. CCC is certified to international quality standards including ISO 13485. CCC is the supplier of products and services to the Group under an agreement entered into in 2010 (the agreement, as subsequently amended, the "**CCC Agreement**") including the design, verification testing, assembly and manufacture of the IPG and accompanying technology including software.

The material terms of the CCC Agreement include:

- In consideration for the performance of the services by CCC, MML and MML US, Inc. agreed to make certain payments to CCC on the completion of certain milestones;
- The CCC Agreement shall continue in force until terminated or through the performance by the parties of their obligations under the CCC Agreement;
- Either party may terminate the agreement, by written notice, where the other party materially breaches the 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;
- MML is entitled to request technical information, training and other items allowing it to manufacture its product by a third party, subject to payment to CCC of an amount to be determined in good faith by the parties; and
- The CCC Agreement is governed by the laws of Minnesota and each party submits exclusively to the courts of Minnesota.

15.13.19 ***Oscor Agreement***

Oscor Inc. ("**Oscor**") was founded in 1982 and designs, develops and manufactures electrical stimulation leads for a number of medical applications including cardiac pacing and neurostimulation on an OEM basis for many customers and under its own name in over 70

countries around the world. Under a development agreement between 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 in which the defending party has its primary place of business.

15.13.20 ***Evergreen Agreement***

Evergreen Medical Technologies Inc. ("**Evergreen**") is a Minnesota (USA) based company founded in 2006 which develops and manufactures active implantable medical devices and provides a full spectrum of product development resources for medical device clients. A product development agreement was entered into between MMI and Evergreen in March 2012 under which Evergreen agreed to purchase, assemble, package and inventory the laptop computers which are the foundation of the ReActiv8 programmer, and the agreement was subsequently assigned to MML (the "**Evergreen Agreement**").

The material terms of the Evergreen Agreement include:

- MML pays Evergreen based on agreed hourly rates;
- The Evergreen Agreement will remain in force and shall continue until terminated;
- Evergreen may terminate the agreement at any time by providing 60 business days written notice, and may also terminate immediately if MML fails to maintain in good standing all required payments or ceases to conduct business in the normal course or in the case of certain insolvency events;
- MML may terminate the agreement at any time by providing 20 business days written notice, and may also terminate immediately if Evergreen fails to maintain in good standing all required licences or ceases to conduct business in the normal course or in the case of certain insolvency events;
- Both parties are also subject to various other termination provisions;

- MML indemnifies Evergreen from and against any loss, liability, damage or expense (including reasonable attorney fees) incurred by Evergreen in connection with any third party claim arising out of, relating to, or resulting from (a) MML's gross negligence, wilful misconduct or breach of any other performance obligation under the Evergreen Agreement (b) the alleged infringement of a third party's intellectual property rights by a Product that has been developed or manufactured for MML, and (c) personal injury or property damage from use of a Product;
- Neither party shall be liable to any person or entity for indirect, incidental, consequential or special damages or any description, whether arising out of warranty or contract, tort, or otherwise, including without limitation any damages resulting from lost profits or lost business opportunity, arising under or relating to any subject matter covered by the agreement (except for wilful misconduct or liability for indemnity, IP or confidentiality obligations); and
- The Evergreen Agreement is governed by the laws of Minnesota and each party submits exclusively to the courts of Minnesota.

Key Consultants

The Group engages a number of consultants in connection with the business, some of whom are considered to be key. The following consultancy agreements are considered material to the Group:

15.13.21 ***Consultancy Agreement with Jan Pieter Heemels***

A consultancy agreement was entered into between MMI and Jan Pieter Heemels (doing business as MedVenture BVBA) dated and effective from 1 November 2011 (the "**JPH Consultancy Agreement**") and this agreement was subsequently assigned to MML. Pursuant to the JPH Consultancy Agreement, Jan Pieter Heemels agreed to provide services to MML including: (a) assisting in conducting the European clinical trials of MML, (b) acting as the European business manager for MML specifically in relation to business development and sales management related matters, including providing direction for other employees or consultants of the Group, (c) collaborating with members of the MML team and all matters associated with MML's business and (d) any other matters as mutually agreed between the parties from time to time.

The material terms of JPH Consultancy Agreement include:

- The consultant is remunerated with an agreed monthly retainer for a minimum of 160 hours worked per month. Additional hours are not billed by the consultant but the consultant is entitled to all expenses reasonably incurred in connection with the performance of its duties. MML reserves the right to modify the agreement to offer incentive payments upon the achievement of certain milestones to be defined from time to time. The total remuneration to the consultant under the agreement is included in the aggregate amount of remuneration paid to Senior Managers, as described at paragraph 9.6 of Part 9 (*Directors, Senior Management and Corporate Governance*).
- Any of the consultant's inventions, discoveries, improvements and ideas which relate to MML's business, products or services and which are made during the term of the contract and for a period of six months following the termination of the contract are the property of the company.
- The initial term of the agreement is for 12 months. The agreement automatically renews for successive one month periods unless, prior to the renewal of the term, either party provides the other with 30 calendar days written notice detailing their intention to terminate the agreement.
- Either party may terminate the agreement with or without cause upon 30 days prior written notice to the other party. Certain terms of the agreement survive the termination of the contract.

- The consultant is not subject to restrictive covenants in connection with the provision of similar services to third parties. However, at the time of the contract the consultant represented and warranted that his obligations under the agreement did not conflict with his obligations under any other agreements to which he was a party.
- MML indemnifies the consultant from and against civil damages, penalties, or fines claimed or levied against the consultant arising from, or related to the consultant's actions as consultant to MML, including the consultant's reasonable attorney fees and costs, provided that the consultant was acting in the performance of the duties agreed to under the agreement and was not guilty of intentional misconduct, wilful neglect of duties, or bad faith.
- The JPH Consultancy Agreement is governed by the laws of the state of Minnesota.

15.13.22 ***Consultancy Agreement with KN Jaax Consulting Inc***

A consultancy agreement was entered into between MML and KN Jaax Consulting Inc ("**KN Jaax**") (the "**KJ Consultancy Agreement**") dated and effective from 1 November 2013. Pursuant to the KJ Consultancy Agreement KN Jaax agreed to provide services to MMI including (a) advising on clinical trials and regulatory strategy, (b) advising on and contributing to the Company's intellectual property portfolio and (c) any other matters as mutually agreed between the parties from time to time.

The material terms of the KJ Consultancy Agreement include:

- The consultant is compensated at an agreed rate per month for a minimum of 80 hours per month, and at an agreed hourly rate for services performed in excess of the initial 80 hours per month up to a total agreed maximum payment. The consultant is entitled to a minimum monthly payment notwithstanding it does not work for the contracted 80 hours per month. In addition, the consultant is entitled to all expenses reasonably incurred in connection with the performance of its duties
- The consultant is entitled to an annual bonus based on the achievement of certain annual performance goals applicable to the management team of the Company.
- Provided that the consultant is continuously engaged as a consultant to the company and the consultant shall be entitled to purchase a number of shares pursuant to the company's share option plan. The total remuneration to the consultant under the agreement is included in the aggregate amount of remuneration paid to Senior Managers, as described at paragraph 9.6 of Part 9 (*Directors, Senior Management and Corporate Governance*).
- Any of the consultant's inventions, discoveries, improvements and ideas which relate to MMI's business, products or services and which are made during the term of the contract and for a period of six months following the termination of the contract are the property of the company.
- The initial term of the agreement is for 24 months. The agreement automatically renews for successive one month periods unless, prior to the renewal of the term, either party provides the other with 30 calendar days written notice detailing their intention to terminate the agreement.
- Either party may terminate the agreement with or without cause upon 30 days prior written notice to the other party. Both parties are also subject to various other termination provisions.
- KN Jaax is subject to agreed restrictive covenants in connection with the provision of similar services to third parties. The restrictive covenants apply throughout the term of the contract and for a period of six months following the termination of the contract.
- MMI indemnifies the consultant from and against civil damages, penalties, or fines claimed or levied against the consultant arising from, or related to the consultant's actions as

consultant to MMI, including the consultant's reasonable attorney fees and costs, provided that the consultant was acting in the performance of the duties agreed to under the agreement and was not guilty of intentional misconduct, wilful neglect of duties, bad faith or a material breach of the agreement.

- KN Jaax is not liable under the agreement for any consequential, indirect, exemplary, special or punitive damages, including any damages for business interruption, loss of use, revenue or profit, whether arising out of breach of contract, tort (including negligence) or otherwise, except where such liability or damages arises out of or in connection with a breach by the consultant in respect of certain clauses of the agreement, including inventions, confidential information or restrictive covenants. The liability of the consultant is capped based on the liability insurance policy maintained by the consultant which, according the agreement should not be any less than $1.0 million.
- The KJ Consultancy Agreement is governed by the laws of Ireland and both parties submit to the non-exclusive jurisdiction of the courts of Ireland.

15.13.23 ***Consultancy Agreement with ORSCO Life Sciences AG***

ORSCO Life Sciences AG ("**ORSCO**") entered into a consultancy agreement with MML on 23 January 2013 (the "ORSCO Consultancy Agreement"). ORSCO is a Swiss company controlled by Dr. Oern Stuge. Pursuant to the ORSCO Consultancy Agreement, ORSCO has agreed to provide general strategic advice to MML, the Board and the CEO of MML.

The material terms of the ORSCO Consultancy Agreement include:

- The consultant is compensated at an agreed rate annual rate of CHF 60,000. The rate is payable quarterly in advance and ORSCO is to devote as much time is necessary for it to discharge the condition. ORSCO is also entitled to the reimbursement of expenses incurred in carrying out its duties under the agreement.
- Any of the consultant's inventions, discoveries, improvements and ideas which relate to MML's business, products or services and which are made during the term of the contract and for a period of six months following the termination of the contract are the property of MML.
- The ORSCO Consultancy Agreement terminates upon Dr. Oern Stuge's loss of office as the Company's Chairman.
- Either party may on written notice to the other party terminate the agreement where the other party makes an arrangement with its creditors or is adjudged insolvent, bankrupt or goes into liquidation or has a receiver appointed over most of its assets. Both parties are subject to various other termination provisions.
- The ORSCO Consultancy Agreement is governed by the laws of Ireland and both parties submit to the non-exclusive jurisdiction of the courts of Ireland.

15.13.24 ***Consultancy Agreement with Hugh Kavanagh***

Hugh Kavanagh, being the CFO of the Company, entered into a consultancy agreement with MML on 30 November 2012 (the "**HK Consultancy Agreement**") for the provisions of services common for a financial controller. The HK Consultancy Agreement was subsequently amended and became effective on 2 January 2013. Hugh Kavanagh became an employee of the Company, and ceased to be a consultant, on 17 June 2013.

The material terms of the HK Consultancy Agreement include:

- The consultant is compensated at an agreed monthly rate. The compensation covers the consultant's work for a retainer of up to 8 days per month. An hourly rate is payable for any

service provided over the retainer of 8 days in any month. The consultant is also entitled to the reimbursement of expenses incurred in carrying out its duties under the agreement.

- Any of the consultant's inventions, discoveries, improvements and ideas which relate to MML's business, products or services and which are made during the term of the agreement and for a period of six months following the termination of the contract are the property of the company.
- The HK Consultancy Agreement is for an initial term of six months. Thereafter, it automatically renews for one-month periods, unless 30 days prior to the expiration of the initial term or any renewal term, one party gives the other party written notice of their intention to terminate the agreement.
- Either party may terminate the agreement with or without cause upon 30 days prior written notice to the other party. Both parties are also subject to various other termination provisions.
- The consultant is subject to agreed restrictive covenants in connection with the provision of similar services to third parties. The restrictive covenants apply throughout the term of the agreement and for a period of six months following the termination of the agreement.
- The HK Consultancy Agreement is governed by the laws of Ireland and both parties submit to the non-exclusive jurisdiction of the courts of Ireland.

15.14 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 Prospectus which may have, or have had in the recent past (covering the 12 months preceding the date of this Prospectus) significant effects on Company's financial position or profitability.

15.15 ENVIRONMENTAL ISSUES

The Directors believe that the Group does not have any material environmental compliance costs or environmental liabilities.

15.16 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.

15.17 PROPERTY, PLANT AND EQUIPMENT

The Company as at the date of this Prospectus 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 2 (*Risk Factors*). All facilities are leased or licenced.

15.18 CONSENTS

Davy, which is regulated in Ireland by the Central Bank of Ireland, has given and has not withdrawn its written consent to the issue of this document with the inclusion herein of the references to its name in the form and context in which it appears.

KPMG, a firm authorised and regulated by, and whose partners include members of the Institute of Chartered Accountants in Ireland, has given and not withdrawn its written consent to the inclusion of its report on the Historical Financial Information of the Group and the Company set out in Part 12 (*Historical Financial Information*) and the inclusion in this Prospectus of the references to its name in the form and context in which they appear.

15.19 EXPENSES

The total costs and expenses (exclusive of VAT) of, or incidental to, the Offer and admission to listing and trading on Euronext Paris and to trading on the ESM, payable by the Company are estimated to be approximately €3,502,016.

15.20 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.

Paragraphs 7.4.1 and 7.6 of Part 7 (*Market Opportunity and Overview*), paragraphs 8.4 to 8.12 of Part 8 (*Information on the Company*) and paragraph 15.13 of Part 15 (*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 2 (*Risk Factors*), paragraphs 7.1, 7.2, 7.4, 7.5 and 7.6 of Part 7 (*Market Overview and Opportunity*), paragraphs 8.4 to 8.6 and 8.9 to 8.14 of Part 8 (*Information on the Company*), paragraphs 9.8 of Part 9 (*Directors, Senior Management and Corporate Governance*) and paragraph 15.13 of Part 15 (*Additional Information*), 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.

Benefits received from the Company

Save as disclosed in the Prospectus, no person (excluding professional advisers named in this document and trade suppliers) has received, directly or indirectly, from the Company within the twelve months preceding the application for admission to ESM; or entered into any contractual arrangement (not otherwise disclosed in this document) to receive, directly or indirectly, from the Company on or after ESM Admission, any fees totalling €14,000 or more, or securities in the Company with a value of €14,000 or more, or any other benefit to a value of €14,000 or more at the date of ESM Admission.

15.21 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 the Prospectus:

(a) the Memorandum and Articles of the Company;

(b) the written consent letters referred to in paragraph 15.18 of Part 15 (*Additional Information*);

(c) the historical financial information of the Group and the Company, included in Part 12 (*Historical Financial Information*) of this Prospectus together with the Accountant's Reports;

(d) the Summary of this Prospectus translated into French; and

(e) this Prospectus.

This Prospectus is dated 9 April 2014.

DEFINITIONS

The following definitions shall apply throughout this Prospectus 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**"	the lawful currency of the United States;
"**1983 Act**"	the Companies (Amendment) Act 1983;
"**1990 Act**"	the Companies Act 1990;
"**2005 Act**"	the Investment Funds, Companies and Miscellaneous Provisions Act 2005;
"**2006 Regulations**"	has the meaning given to that term in paragraph 15.6.2 of Part 15 (*Additional Information*);
"**2010 PD Amending Directive**"	European Parliament and Council Directive 2010/73/EU of 24 November 2010;
"**2012 Corporate Reorganisation**"	the transactions or series of transactions completed on or around 21 September 2012 pursuant to the Subscription Agreement, Contribution and Assumption Agreement and the Convertible Note and the execution of the MML Shareholders' Agreement and the Services Agreement (as each of the aforementioned agreements are defined in paragraph 15.13 of Part 15 (*Additional Information*));
"**2014 Corporate Reorganisation**"	has the meaning given to that term in paragraph 15.4.1 of Part 15 (*Additional Information*);
"**2014 Share Option Plan**"	has the meaning given to that term in paragraph 9.7 of Part 9 (*Directors, Senior Management and Corporate Governance*);
"**Amendment and Restatement Agreement**"	has the meaning given to that term in paragraph 15.13.6 of Part 15 (*Additional Information*) of this Prospectus;
"**AMF**"	The French Financial Markets Authority (*Autorité des marchés financiers*);
"**A Ordinary Share**"	has the meaning given to that term in paragraph 15.3.1 of Part 15 (*Additional Information*);
"**Applicable Employees**"	Any employee of an ESM company, its subsidiary or parent undertaking who: (a) together with that employee's family, has a holding interest, directly or indirectly, in 0.5 per cent. or more of a class of ESM securities (excluding treasury shares); or (b) is likely to be in possession of unpublished price-sensitive information in relation to the ESM company because of his or her employment in the ESM company, its subsidiary or parent undertaking, irrespective of his or her holding or interest.

"**Approved Transfer**"	has the meaning given to that term in paragraph 15.7.2 of Part 15 (*Additional Information*) of this Prospectus;
"**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 9.10.3 of Part 9 (*Directors, Senior Management and Corporate Governance*);
"**Base Offer**"	the issue of up to 851,175 new Ordinary Shares pursuant to the Offer;
"**Benefit Plan Investor**"	(a) an employee benefit plan (as defined in section 3(3) of ERISA) subject to Title I of ERISA, (b) a plan described in section 4975(e)(1) of the U.S. Internal Revenue Code to which section 4975 of such Code applies or (c) any other entity whose underlying assets could be deemed to include plan assets by reason of an employee benefit plan's or a plan's investment in the entity within the meaning of the Plan Asset Regulations or otherwise;
"**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;
"**Capricorn Venture Partners**"	means Capricorn Health-Tech Fund NV or Capricorn Venture Partners acting on behalf of Capricorn Health-Tech Fund NV;
"**Cash/Public Acquisition**"	has the meaning given to that term in paragraph 15.13.7 of Part 15 (*Additional Information*) of this Prospectus;
"**CCC"**	has the meaning given to that term in paragraph 15.13.18 of Part 15 (*Additional Information*);
"**CCC Agreement**"	has the meaning given to that term in paragraph 15.13.18 of Part 15 (*Additional Information*) of this Prospectus;
"**CE Mark**"	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;
"**Central Bank**" or "**CBI**"	the Central Bank of Ireland;
"**Co-lead Manager**"	Davy;
"**Company**"	Mainstay Medical International plc, a company incorporated under the laws of Ireland (registered under the number 539688), with its registered office at Clonmel House, Forster Way, Swords, Co. Dublin, Ireland;
"**Computershare**"	Computershare Investor Services (Ireland) Limited, Registrar for the Company;
"**Consent Agreement**"	has the meaning given to that term in paragraph 15.13.13 of Part 15 (*Additional Information*);
"**Contribution and Assumption Agreement**"	has the meaning given to that term in paragraph 15.13.10 of Part 15 (*Additional Information*);

"**Controlling Person**"	any person (other than a Benefit Plan Investor) that has discretionary authority or control with respect to the assets of the Company or that provides investment advice for a fee (direct or indirect) with respect to such assets or an ''affiliate'' (within the meaning of the Plan Asset Regulations) of such a person;
"**Convertible Promissory Note**"	has the meaning given to that term in paragraph 15.13.11 of Part 15 (*Additional Information*);
"**CREST**"	the system of paperless settlement of trades in securities and the holding of uncertificated securities operated by CRESTCo in accordance with the Uncertificated Securities Regulations;
"**CRESTCo**"	CRESTCo Limited, a company incorporated and registered in England and Wales (registered number 06179984), whose registered office is at 33 Cannon Street, London, EC4M 5SB, United Kingdom, and which is the operator of CREST;
"**CREST Regulations**"	the Companies Act 1990 (Uncertificated Securities) Regulations 1996 (S.1.68 of 1996);
"**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;
"**Debenture**"	has the meaning given to that term in paragraph 15.13.14 of Part 15 (*Additional Information*) of this Prospectus;
"**Deed of Release**"	has the meaning given to that term in paragraph 15.13.15 of Part 15 (*Additional Information*) of this Prospectus;
"**Directors**" or "**Board**"	the directors of the Company, whose names as at the date of this Prospectus are set out in Part 4 (*Directors, Company Secretary, Registered Office and Advisors*);
"**EEA Member States**"	European Union Member States, Iceland, Norway and Liechtenstein;
"**Enlarged Issued Share Capital**"	the issued share capital of the Company following completion of the Offer including (if applicable) any new Ordinary Shares issued pursuant to exercise of the Extension Clause or the Over-allotment Option;
"**ERISA**"	the US Employee Retirement Income Security Act of 1974;
"**ESM**"	the Enterprise Securities Market, an authorised multilateral trading facility under the European Communities (Markets in Financial Instruments Directive) Regulations 2007, operated by the Irish Stock Exchange;
"**ESM Admission**"	admission of Ordinary Shares to trading on the ESM;
"**ESM Rules**" or "**ESM Rules for Companies**"	the ESM Rules for Companies issued by the Irish Stock Exchange;
"**EU**"	the European Union;
"**EU Prospectus Regulations**"	Commission Regulation (EC) No. 809/2004;
"**Euronext Paris**"	the regulated market operated by Euronext Paris SA or where referring to the issuance of a notice, Euronext Paris S.A.;

"**Evergreen**"	has the meaning given to that term in paragraph 15.13.20 of Part 15 (*Additional Information*);
"**Evergreen Agreement**"	has the meaning given to that term in paragraph 15.13.20 of Part 15 (*Additional Information*);
"**Extension Clause**"	has the meaning given to that term in paragraph 14.1.1 of Part 14 (*The Offer*);
"**Existing Issued Share Capital**"	means the Series A Shares, Series B Shares, Series Z Shares and Ordinary Shares in issue in the capital of the Company at the date of this Prospectus;
"**Expiration Date**"	has the meaning given to that term in paragraph 15.13.7 of Part 15 (*Additional Information*) of this Prospectus;
"**Fountain Healthcare Partners**"	means 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**"	has the meaning given to that term in paragraph 15.6.1 of Part 15 (*Additional Information*) of this Prospectus;
"**Group**"	in the period: (a) prior to 21 September 2012, MMI; (b) from 21 September 2012 until immediately prior to completion of the 2014 Corporate Reorganisation, MML and its subsidiaries and its subsidiary undertakings; and (c) from completion of the 2014 Corporate Reorganisation, the Company and its subsidiaries and subsidiary undertakings;
"**Historical Financial Information**"	the historical financial information of the Group and the Company set out in Part 12 (*Historical Financial Information*);
"**IASB**"	International Accounting Standards Board;
"**IFRS**"	International Financial Reporting Standards;
"**Investors**"	has the meaning given to that term in paragraph 15.13.8 of Part 15 (*Additional Information*);
"**Institutional Placement**" or "**Placing**"	a private placement principally to institutional investors, as described in paragraph 14.1.3.2 of Part 14 (*The Offer*);
"**Ireland**"	the island of Ireland excluding Northern Ireland, and the word "Irish" shall be construed accordingly;
"**Irish Companies Acts**"	the Companies Acts 1963 to 2011 (as amended) of Ireland;
"**Irish Revenue**"	the Revenue Commissioners of Ireland;
"**Irish Stock Exchange**"	The Irish Stock Exchange plc;
"**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;
"**ISIN**"	International Security Identification Number;

"**Joint Bookrunners**"	Société Générale Corporate & Investment Banking and Kempen & Co;
"**JPH Consultancy Agreement**"	means has the meaning given to that term in paragraph 15.13.21 of Part 15 (*Additional Information*);
"**Kempen & Co**"	Kempen & Co N.V;
"**KJ Consultancy Agreement**"	means has the meaning given to that term in paragraph 15.13.22 of Part 15 (*Additional Information*);
"**KN Jaax**"	means has the meaning given to that term in paragraph 15.13.22 of Part 15 (*Additional Information*);
"**KPMG**"	KPMG Chartered Accountants, whose address is 1 Stokes Place, St. Stephen's Green, Dublin 2;
"**Latest Practicable Date**"	7 April 2014, being the latest practicable date prior to the publication of this Prospectus;
"**Lock-up Agreements**"	means the Lock-up Deeds and the Lock-up Subscription Deeds agreements described at paragraph 15.13.5 of Part 15 (*Additional Information*);
"**Mainstay Securities**"	has the meaning given to that term in paragraph 15.13.11 of Part 15 (*Additional Information*);
"**Market Abuse Directive**"	European Parliament and Council Directive 2003/6/EC of 28 January 2003;
"**Market Abuse Rules**"	Directive 2003/6/EC of the European Parliament and of the Council of 28 January 2003 on insider dealing and market manipulation and the rules issued by the Central Bank under section 34 of the Investment Funds, Companies and Miscellaneous Provisions Acts 2005;
"**Memorandum**" and "**Memorandum of Association**"	the memorandum of association of the Company, as amended from time to time;
"**Minimum Net Proceeds**"	the amount below which the Offer will not be completed, set at an aggregate amount of €12 million (net of fees and expenses of the Offer);
"**MMA**"	Mainstay Medical (Australia) Pty Limited CAN 164 049 281, a proprietary company limited by shares registered in New South Wales, Australia;
"**MMI**"	Mainstay Medical, Inc., a company incorporated under the laws of the State of Delaware;
"**MML**"	Mainstay Medical Limited, a private company limited by shares incorporated in Ireland with registered number 516089 having its registered office at Clonmel House, Forster Way, Swords, Co. Dublin, Ireland;
"**MML Shareholders Agreement**"	has the meaning given to that term in paragraph 15.13.9 of Part 15 (*Additional Information*) of this Prospectus;
"**MMLUS**"	MML US, Inc., a company incorporated under the laws of the State of Delaware;

"**MML Warrants**"	has the meaning given to that term in paragraph 15.13.7 of Part 15 (*Additional Information*) of this Prospectus;
"**Nominations Committee**"	the nominations committee of the Company as described in paragraph 9.10.3 of Part 9 (*Directors, Senior Management and Corporate Governance*) of this Prospectus;
"**Non-Executive Director**"	a non-executive Director;
"**Observer Rights**"	has the meaning given to that term in paragraph 15.13.6 of Part 15 (*Additional Information*) of this Prospectus;
"**Offer**"	the Retail Offer and the Institutional Placement;
"**Offer Price**"	the price of the Offered Shares as determined in accordance with paragraph 14.3 of Part 14 (*The Offer*);
"**Offer Size Range**"	between 851,175 new Ordinary Shares and 1,125,678 new Ordinary Shares;
"**Offer Size**"	the number of new Ordinary Shares to be issued under the Offer;
"**Offered Shares**"	the new Ordinary Shares pursuant to the Base Offer and the Extension Clause, together with the Over-allotment Shares;
"**Ordinary Shares**"	the ordinary shares of par value €0.001 each in the capital of the Company;
"**ORSCO**"	means ORSCO Life Sciences AG;
"**ORSCO Consultancy Agreement**"	has the meaning given to it in 15.13.23;
"**Oscor**"	has the meaning given to that term in paragraph 15.13.19 of Part 15 (*Additional Information*);
"**Oscor Agreement**"	has the meaning given to that term in paragraph 15.13.19 of Part 15 (*Additional Information*);
"**Over-allotment Option**"	the over-allotment option granted by the Company to the Stabilising Manager;
"**Over-allotment Shares**"	new Ordinary Shares issued in accordance with the Over-allotment Option;
"**Pay-Off Letter**"	has the meaning given to that term in paragraph 15.13.15 of Part 15 (*Additional Information*) of this Prospectus;
"**PEA**"	means a "*Plan d'Epargne en Actions*", a French stock-savings plan;
"**Placing Agreement**"	the placing agreement among the Company, the Joint Bookrunners and the Co-lead Manager defined in paragraph 14.4.3 of Part 14 (*The Offer*);
"**Plan Asset Regulations**"	U.S. Department of Labor regulation 29 C.F.R. Section 2510.3-101 (as modified by Section 3(42) of ERISA);
"**PME-ETI PEA**"	means a specific type of PEA or French stock savings plan, in which the eligible securities are those of certain small and medium sized businesses;
"**Pre-IPO Articles**"	has the meaning given to that term in paragraph 15.3.1 of Part 15 (*Additional Information*);

"**Price Range**"	the price range per Ordinary Share under the Offer of between €20.00 and €27.00;
"**Pricing Statement**"	a statement to be issued by the company confirming the Offer Price and the number of Ordinary Shares that are the subject of the Offer;
"**Prospectus**"	this document issued by the Company in relation to admission to trading on Euronext Paris and ESM, and approved under the Prospectus Directive;
"**Prospectus Directive**"	European Parliament and Council Directive 2003/71/EC of 4 November 2003 (and amendments thereto, including Directive 2010/73/EU);
"**Prospectus Regulations**"	the Prospectus (Directive 2003/71 EC) Regulations 2005 of Ireland;
"**Prospectus Rules**"	rules issued by the Central Bank from time to time under section 51 of 2005 Act;
"**QCA Corporate Governance Code for Small and Mid-Size Quoted Companies**"	the Corporate Governance Code for Small and Mid-Size Quoted Companies 2013 issued by the Quoted Companies Alliance (www.theqca.com) of 6 Kinghorn Street, London, EC1A 7HW;
"**qualified institutional buyer**" or "**QIB**"	a qualified institutional buyer within the meaning of Rule 144A under the U.S. Securities Act;
"**ReActiv8**"	means ReActiv8®;
"**Re-organisation Agreement**"	Means the agreement described at paragraph 15.13.4 of Part 15 (*Additional Information*);
"**Redeemable Shares**"	has the meaning given to that term in paragraph 15.3.1 of Part 15 (*Additional Information*);
"**Register**"	the Register of members of the Company;
"**Registrar**"	Computershare or such other registrar as the Company may appoint from time to time;
"**Regulation S**"	Regulation S under the U.S. Securities Act;
"**Regulatory Information Service**" or "**RIS**"	one of the regulatory information services authorised by the Irish Stock Exchange and/or the FCA to receive, process and disseminate regulated information from listed companies;
"**Relevant Member State**"	Has the meaning given to that term in paragraph 14.2.1.2 of Part 14 (*The Offer*);
"**Reporting Accountants**"	KPMG;
"**Restriction Notice**"	has the meaning given to that term in paragraph 15.7.2 of Part 15 (*Additional Information*);
"**Retail Offer**"	a public offering in France conducted by means of an open price offering (*offre à prix ouvert*), mainly intended for individuals or retail investors, as described in paragraph 14.1.3.1 of Part 14 (*The Offer*);
"**Rule 144A**"	Rule 144A under the U.S. Securities Act;
"**SEDOL**"	Stock Exchange Daily Official List;

"**sell-out**"	has the meaning given to that term in paragraph 15.6.3 of Part 15 (*Additional Information*);
"**Senior Managers**"	Hugh Kavanagh, Prashant Rawat, Jan Pieter Heemels, and Kristen Jaax;
"**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;
"Series A Shares"	series A convertible redeemable preference shares of €0.001 each in the capital of the Company;
"**Series B Shares**"	series B convertible redeemable preference shares of €0.001 each in the capital of the Company;
"**Series Z Shares**"	series Z convertible redeemable preference shares of €0.001 each in the capital of the Company;
"**Settlement**"	settlement of the new Ordinary Shares issued pursuant to the Offer on a delivery versus payment basis;
"**Seventure Partners Managed Funds**"	means Banque Populaire ISF 4, FCPI Biosanté and FCPI SG Innovation 2011 or Seventure Partners acting on behalf of each or any of those parties;
"**Shareholder**"	a holder of shares in the Company from time to time;
"**Share Options**"	options over the Ordinary Shares in the Company;
"**Share Option Instrument**"	has the meaning given to that term in paragraph 15.13.16 of Part 15 (*Additional Information*);
"**Share Warrants**"	warrants over the Ordinary Shares in the Company;
"**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 15.7.2 of Part 15 (*Additional Information*);
"**Specified Shares**"	has the meaning given to that term in paragraph 15.7.2 of Part 15 (*Additional Information*);
"**squeeze-out**"	has the meaning given to that term in paragraph 15.6.2 of Part 15 (*Additional Information*);
"**Stabilising Manager**"	Société Générale;
"**Subscription Agreement**"	has the meaning given to that term in paragraph 15.13.8 of Part 15 (*Additional Information*);
"**subsidiary**"	shall be construed in accordance with the Irish Companies Acts;

"**subsidiary undertaking**"	shall have the meaning given by the European Communities (Companies: Group Accounts) Regulations 1992;
"**Summary**"	the summary of this Prospectus set out in Part 1 of this Prospectus;
"**SVB**"	has the meaning given to that term in paragraph 15.13.7 of Part 15 (*Additional Information*) of this Prospectus;
"**SVB Financial Group**"	means SVB Financial Group, the parent company of SVB;
"**SVB Loan and Security Agreement**"	has the meaning given to that term in paragraph 15.13.12 of Part 15 (*Additional Information*) of this Prospectus;
"**Takeover Directive**"	the Directive 2004/25/EC of the European Parliament and the Council dated April 21, 2004 on takeover bids;
"**Transparency Regulations**"	the Transparency (Directive 2004/109/EC) Regulations 2007 (SI No. 277 of 2007);
"**Transparency Rules**"	the transparency rules issued by the Central Bank under section 22 of the Investment Funds, Companies and Miscellaneous Provisions Act, 2006 as amended 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;
"**Uncertificated Securities Regulations**"	the Uncertificated Securities Regulations 2001 (SI 2001/3755);
"**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. Investment Company Act**"	the U.S. Investment Company Act of 1940, as amended;
"**U.S. Person**"	a U.S. person within the meaning of Regulation S;
"**U.S. Securities Act**"	the U.S. Securities Act of 1933, as amended;
"**VAT**" or "**Value Added Tax**"	value added tax;
"**Warrant Deed**"	has the meaning given to that term in paragraph 15.13.7 of Part 15 (*Additional Information*);
"**Warrant Shares**"	has the meaning given to that term in paragraph 15.13.7 of Part 15 (*Additional Information*);
"**When-Issued Period**"	29 April to 2 May 2014, as denoted by "as-if-and-when-issued-or-delivered" in this Prospectus.

For the purpose of this Prospectus, 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 prospectus.

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 subjects, users or other persons, whether or not related to the investigational medical device.
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).
AIMD Directive	The European Active Implantable Medical Devices Directive 90/385/EEC and subsequent amendments, which sets out i.a. the approval requirements for an AIMD in the European Economic Area (which includes the EU, Iceland, Liechtenstein and Norway).
Acute Low Back Pain	Recent onset of an episode of Low Back Pain.
Angina Pectoris	Also known as "angina" – a condition marked by severe pain in the chest, often also spreading to the shoulders, arms, and neck, usually caused by an inadequate blood supply to the heart.
Arthrogenic muscle inhibition (AMI)	An impairment of muscle control caused by an ongoing 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.
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 trial	A program of investigation that involves human subjects to investigate a new therapy. Trials can be of multiple different designs, including: Prospective randomized controlled trial – the investigational therapy is compared to a control therapy (often a placebo) in which subjects are prospectively (i.e.: in advance) allocated in a statistically random manner ("randomized") to either the investigational therapy or the control therapy. 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 subjects outcomes are compared to the characteristics prior to application of the investigational therapy. Open label trial – a clinical trial in which subjects have knowledge of the investigational therapy (i.e.: they are not "blinded").
Competent Authority	A Competent Authority is the organization which has the authority to act on behalf of the government of a Member state of the EU to ensure that the requirements of the EU Directives are carried out in a particular Member State of the EU. The role of the Competent Authority is determined by the EU Directives and associated National Regulations. Its prime aim is to ensure that all medical devices meet the essential requirements laid down in the Directives. For example, in the UK it is the Medicines and Healthcare products Regulatory Agency (MHRA) and in France it is Agence nationale de sécurité du médicament et des produits de santé (ANSM) (the previous Agence française de sécurité sanitaire des produits de santé (AFSSAPS)).
Contract Research Organisation (CRO)	Person or organization contracted to perform one or more of the clinical investigation-related duties and functions.
Chronic Regional Pain Syndrome (CRPS)	An uncommon form of chronic pain that usually affects an arm or leg. CRPS typically develops after an injury, surgery, stroke or heart attack, but the pain is out of proportion to the severity of the initial injury, if any.
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 (EQ-5D)	A clinical assessment instrument of a subject's quality of life by use of a questionnaire.
Ethics committee (EC) (sometimes called Investigational 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 subjects 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.
Etiology (also "aetiology")	A term used to mean the cause, set of causes, or manner of causation of a disease or condition.
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.
Feasibility Study	A study designed and sponsored by the Group to investigate the scientific principles on which ReActiv8 is based.

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.
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.
Human cadavers	Bodies donated by people for scientific research after their death.
The Institute of Medicine (IOM)	A U.S. based independent, non-profit organization 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.
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 subjects 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.
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.

Minimally Important Clinical Change (MIC)	The amount of change in an outcome measure (e.g.: Back Pain NRS) that is considered clinically important to patients. See Dworkin 2008.
MF	Multifidus muscle.
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.
Neuro-Muscular Electrical Stimulation (NMES)	Electrical stimulation pulses applied generally to a nerve to elicit muscle contraction.
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.
Numerical Rating Scale (NRS)	A measurement instrument in which a subject 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.
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.
Palliative therapy	Treatment for clinical conditions that is given to decrease suffering.
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 (i.e. study subject) 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.
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.

Pivotal IDE trial	A clinical trial conducted under the Investigational Device Exemption (IDE) provisions of the U.S. Food Drug and Cosmetics Act. A pivotal trial is one in which the results will be used for regulatory submissions to the FDA, as opposed for example to a pilot study or feasibility study.
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.
Pre-Market Approval (PMA)	The action of the FDA which grants permission to sell a Class III medical device in the United States.
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.
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 subjects 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.
Subject	An individual who participates in a clinical investigation. A subject can be either a healthy volunteer or a patient.
Transcutaneous Electrical Nerve Stimulation (TENS)	The application of electrical stimulation pulses via electrodes applied directly to the skin.
Visual analogue scale (VAS)	A method of assessing an outcome. For example, to assess pain, a subject 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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