Mainstay Medical Publishes its 2015 Annual Report

DUBLIN--(BUSINESS WIRE)-- Regulatory News:

Mainstay Medical International plc ("**Mainstay**" or the "**Company**" listed on *Euronext Paris: MSTY.PA and ESM of the Irish Stock Exchange: MSTY.IE)* today announces that it has published its 2015 Annual Report.

The Annual Report is attached to this press release and is also available on the "Investors" section of the Mainstay Medical website at: http://www.mainstay-medical.com/investors/annual_reports

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About Mainstay

Mainstay is a medical device company focused on bringing to market an innovative implantable neurostimulation system, ReActiv8®, for people with disabling Chronic Low Back Pain (CLBP). The Company is headquartered in Dublin, Ireland. It has subsidiaries operating in Ireland, the United States, Australia and Germany and is listed on Euronext Paris (MSTY.PA) and the ESM of the Irish Stock Exchange (MSTY.IE).

About Chronic Low Back Pain

One of the recognised root causes of CLBP is disruption of control by the nervous system of the muscles that dynamically stabilise the spine in the lower back, and an unstable spine can result in back pain. ReActiv8 is designed to electrically stimulate the nerves responsible for contracting these muscles and thereby help to restore muscle control and improve dynamic spine stability, allowing the body to recover from CLBP.

People with CLBP usually have a greatly reduced quality of life and score significantly higher on scales for pain, disability, depression, anxiety and sleep disorders. Their pain and disability can persist despite the best available medical treatments, and only a small percentage of cases result from an identified pathological condition or anatomical defect that may be correctable with spine surgery. Their ability to work or be productive is seriously affected by CLBP and the resulting days lost from work, disability benefits and health resource utilisation put a significant burden on individuals, families, communities, industry, and governments.

Further information can be found at www.mainstay-medical.com

ReActiv8 is an investigational device and is not approved for commercialisation anywhere in the world.

CAUTION – in the United States, ReActiv8 is limited by federal law to investigational use only.

Mainstay Medical International plc and its subsidiaries
Annual Report

for the year ended 31 December 2015

Mainstay Medical International plc

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Forward looking statements

This Annual Report 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", "will" or "explore" or, in each case, their negative or other variations or comparable terminology, or by discussions of strategy, plans, objectives, goals, future events or intentions. These forward looking statements include all matters that are not historical facts. They appear throughout this Annual Report and include, but are not limited to, statements regarding the Company's intentions, beliefs or current expectations concerning, among other things, the Company's results of operations, financial position, prospects, financing strategies, expectations for product design and development, regulatory applications and approvals, reimbursement arrangements, costs of sales and market penetration.

By their nature, forward looking statements involve risk and uncertainty because they relate to future events and circumstances. Forward looking statements are not guarantees of future performance and the actual results of the Company's operations, and the development of its main product, the markets and the industry in which the Company operates, may differ materially from those described in, or suggested by, the forward looking statements contained in this Annual Report. In addition, even if the Company's results of operations, financial position and growth, and the development of its main product and the markets and the industry in which the Company operates, are consistent with the forward looking statements contained in this Annual Report, those results or developments may not be indicative of results or developments in subsequent periods. A number of factors could cause results and developments of the Company to differ materially from those expressed or implied by the forward looking statements including, without limitation, the Company's ability to obtain CE Marking for ReActiv8, the initiation and success of the ReActiv8-B Clinical Trial, the successful launch and commercialization of ReActiv8, 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, the time required to commence and complete clinical trials, the time and process required to obtain regulatory approvals, currency fluctuations, changes in its business strategy, political and economic uncertainty. The forward-looking statements herein speak only at the date of this Annual Report.

Mainstay Medical International plc

Corporate and shareholder information

Directors	Oern Stuge MD, Independent Non-Executive Chairman Peter Crosby, Chief Executive Officer and Executive Director David Brabazon, Independent Non-Executive Director Antoine Papiernik, Non-Executive Director James Reinstein, Independent Non-Executive Director Manus Rogan PhD, Non-Executive Director Dan Sachs MD, Non-Executive Director
Secretary	Tom Maher
Registered office	Clonmel House Forster Way Swords, K67F2K3 County Dublin, Ireland
Registered number	539688
Website	www.mainstay-medical.com
ISIN / Symbol	IE00BJYS1G50 / MSTY.PA (Paris) and MSTY.IE
Solicitors/ Lawyers	McCann FitzGerald Riverside One Sir John Rogerson's Quay Dublin 2, Ireland Jones Day 2, rue Saint-Florentin 75001 Paris, France
Independent Auditor	KPMG Chartered Accountants 1 Stokes Place St Stephen's Green Dublin 2, Ireland
Principal Bankers	HSBC Bank of Ireland
ESM Adviser and Broker	J&E Davy Davy House 49 Dawson Street Dublin 2, Ireland
Registrar	Computershare Investor Services (Ireland) Limited Heron House Corrig Road Sandyford Industrial Estate Dublin 18, Ireland
Paying Agent (in France)	Caceis Corporate Trust 1/3, Place Valhubert 75013 Paris France

Mainstay Medical International plc

Chairman's Statement

Dear Shareholder

2015 was a year of continued progress on the path to commercialization of ReActiv8®, and I am pleased to present the Annual Report for Mainstay Medical International plc and its subsidiaries.

Business review

On 2 November 2015 we announced that we had submitted an application for CE Marking to our Notified Body. We have since had several interactions with the Notified Body and we are awaiting CE Marking approval. Our application was based on positive results from our ReActiv8-A trial which were announced on 31 August 2015, and on 4 December 2015 we announced additional data confirming the positive results from this clinical trial.

In May 2015 we also announced we had received approval from the US Food and Drug Administration to begin the ReActiv8-B Clinical Trial under an Investigational Device Exemption. We have since worked with the FDA to refine the protocol, and we are progressing clinical trial site selection and initiation, physician training, and submissions to Ethics Committees (Institutional Review Boards in the US).

A detailed review of our 2015 activities can be found in the Directors' Report on page 7 of this Annual Report.

Finance

Cash on hand as at 31 December 2015 was $16.6 million. Operating expenses were $12.9 million during the year ended 31 December 2015 (2014: $11.1 million before exceptional items) and relate to clinical trial activities, research and development, and commercial, general and administrative expenses.

Outlook

While we await CE Marking approval for ReActiv8, we are preparing for commercialization in Europe. We are also preparing for the ReActiv8-B Clinical Trial and, subject to the availability of sufficient financial resources, we look forward to ramping up enrollment in the Trial.

Directors and Staff

I would like to thank all my fellow Directors, staff, consultants and study investigators for their support and dedication, which has enabled the continued success of the Company. I look forward to the future with confidence.

Yours faithfully,

Oern Stuge MD

Chairman

27 April 2016

Mainstay Medical International plc

Board of Directors

Biographies of Directors

Oern Stuge MD

Dr. Oern R. Stuge is the independent non-executive Chairman of the Board. He is an international executive with more than 25 years of experience in the life science sector. Dr. Stuge is the owner of Orsco Lifesciences AG, through which he holds several executive and non-executive board memberships and advisory roles.

Prior to founding Orsco, Oern Stuge worked for 12 years for Medtronic, Inc. in different roles including Senior Vice President ("SVP") & President Europe & Central Asia, and SVP & President Cardiac Surgery. He was a member of the Medtronic Executive Committee & Operating Committee. Dr. Stuge has been credited for successfully transforming Medtronic's global Cardiac Surgery business and accelerating the growth in its neurological and cardiovascular business in Europe, Middle East & Africa.

Dr. Stuge earned an MD from University of Oslo, and an MBA from IMD, Switzerland.

Peter Crosby

Mr. Peter Crosby has been a Board member of the ultimate holding company of the Group since he was appointed CEO of Mainstay Medical in mid-2009. Mr. Crosby was instrumental in founding the Group, raising the 2010 and 2012 financing rounds, and completing the 2014 IPO. He is an internationally experienced medical device executive who has been chief executive officer or chairman of seven medical device companies (public and private) in four countries.

Mr. Crosby has contributed to the development and introduction to the global market 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, and continued his career with executive roles in many more companies. He has direct experience in active implantable medical devices, including cardiac pacemakers and defibrillators (Telectronics Pacing Systems), cochlear implants (Cochlear), left ventricular assist devices (Ventracor), Neuromodulation (Mainstay Medical), ultrasound (Ausonics, NeoVision), software (Cardicomm Solutions), and in-vitro diagnostics (First Medical, Ischemia Technologies). 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 Electrical Engineering and a Masters in Engineering Science (Biomedical Engineering) from the University of Melbourne, Australia. He is a named inventor on over 25 patents and patent applications, primarily in the field of biomedical engineering.

David Brabazon

Mr. David Brabazon is a co-founder of Adapt Pharma Limited and serves as Chief Financial Officer and a board member. Adapt Pharma Limited is a US 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, Mr. Brabazon served as Vice President of Finance and Group Financial Controller of Elan Corporation plc.

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

Antoine Papiernik

Mr. Antoine Papiernik is a Non-Executive Director of the Company and is a Managing Partner at Sofinnova Partners, which he joined in 1997. Sofinnova has been an initial investor and Antoine has been an active board member in public companies like Actelion, Auris, ProQR, Novus Pharma (then sold to CTI), Movetis (then sold to Shire), Mainstay Medical, Pixium Vision and Stentys which went public respectively on the Zürich stock exchange, the NASDAQ, the Milan Nuovo Mercato, the Belgium Stock Exchange, the Irish Stock Exchange and EuroNext Paris, in Cotherix (initially NASDAQ listed, then sold to Actelion), CoreValve (sold to Medtronic), Fovea (sold to Sanofi Aventis) and Ethical Oncology Science (EOS sold to Clovis Oncology). He has also invested, for Sofinnova, in and is a board member of private companies ReCor, MD Start, Shockwave Medical, and Reflexion Medical. Antoine has an MBA from the Wharton School of Business, University of Pennsylvania. In 2012 and 2011 Antoine was selected by Forbes for its "Midas List" of the world's top venture capital investors. Antoine is one of the only Europeans on the list, and one of the few life science investors.

James Reinstein

James A. Reinstein has more than 25 years of medical device experience. James is currently the President and CEO of Drawbridge Health, a medical technology company which fuses the science of chemistry with the fundamentals of logistics to access and immediately stabilize the blood sampling process. Previous to Drawbridge, he was the President and CEO of Aptus Endosystems Inc. where he led the sale of the company to Medtronic for over $100 million. Prior to joining Aptus, James served as Executive Vice-President and Chief Commercial Officer at Cyberonics, a neuromodulation company focused on helping patients with epilepsy, depression and chronic heart failure. James spent 17 years at Boston Scientific in various roles and functions including business development, marketing and general management. Most of his career at Boston Scientific was spent working and living in Europe, Asia and Latin America.

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

Manus Rogan PhD

Dr. Manus Rogan is Managing Partner and co-founder of Fountain Healthcare Partners. He has over 26 years of investment and operating experience in the life science sector in both the US and Europe. Dr. Rogan earned a PhD in chemistry from the University of York (sponsored by GlaxoSmithKline) and an MBA from Trinity College Dublin.

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.

Dan Sachs MD

Dr. Dan Sachs is a physician entrepreneur and founder of KSpine Inc., Respicardia, Inc., Mainstay Medical Inc., 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 MBA from Harvard Business School.

Mainstay Medical International plc

Directors' Report

The Board of Directors are pleased to report on the progress of Mainstay Medical International plc ("Mainstay" or the "Company") and present the annual report of the Company and its subsidiaries (the "Group" or "we") for the year ended 31 December 2015.

Principal activities

Mainstay is a medical device company focused on bringing to market ReActiv8®, a new implantable neurostimulation system to treat disabling Chronic Low Back Pain ("CLBP").

The Company is incorporated in Ireland as a public limited company. The Company's ordinary shares are listed on the ESM of the Irish Stock Exchange and Euronext Paris.

As at 31 December 2015, the Company together with its operating subsidiaries Mainstay Medical Limited, MML US, Inc. and Mainstay Medical (Australia) Pty. Limited form the Mainstay Medical Group.

Key performance indicators

Current key performance indicators, used by management to measure performance and exercise control over operations are summarized below:

Securing funds - The Group has financed its operations to date principally through the issuance of equity securities and debt funding. The management team continues to develop and strengthen relationships to explore further financing options. These may include strategic partnering, private placement or public offering of equities or debt.

Effective monitoring of use of funds - Management prepares budgets and rolling forecasts to track and monitor use of funds. Actual expenditure is measured against budget, and is reported to and evaluated by the Directors on a monthly basis.

Achieving milestones - The Group has defined the strategic activities and milestones leading to commercialization of ReActiv8. These include:

- Product design and development of ReActiv8
- Conducting the ReActiv8-A Clinical Trial
- Quality System certification
- Obtaining CE Marking
- European commercialization of ReActiv8
- Obtaining approval for an Investigational Device Exemption (an "IDE") from the US Food and Drug Administration (the "FDA") to start a clinical trial of ReActiv8 in the US
- Conducting a clinical trial of ReActiv8 under the IDE to generate data to file a Pre-Market Approval Application (a "PMAA") with the FDA
- Following Pre-Market Approval ("PMA"), starting the US commercialization of ReActiv8.

Progress towards and achievement of these milestones is reported by the management team to the Board on a regular basis. Outlined in the following business and financial review sections of this report, we describe our performance during the year ended 31 December 2015 on the relevant areas above, including updates on progress towards milestones, and analysis of expenditure and use of funds during the year.

Business review

Commercialization – We continue to make progress towards commercialization of ReActiv8. On 2 November 2015 we announced that we had submitted an application for CE Marking to our Notified Body. We have since had several interactions with the Notified Body to progress the application and we are awaiting CE Marking approval.

Following CE Marking, we plan to commence commercialization in Germany, our first target market. Preparations for commercialization are ongoing, including interaction with initial physician customers, and recruiting direct sales and support staff. In Germany we plan to use a small direct sales force to focus on a select group of multi-disciplinary centers who see a large number of people with CLBP. As we gain experience with this commercialization strategy, we will consider expanding to additional customers and additional countries.

ReActiv8-A Trial - Positive results of the ReActiv8-A Clinical Trial were announced on 31 August 2015, and on 4 December 2015 we announced additional data confirming the positive results from this clinical trial. These results were presented at the scientific meeting of the North American Neuromodulation Society in December by Professor Sam Eldabe (Middlesbrough, UK), an investigator in the ReActiv8-A Clinical Trial. ReActiv8 also featured in a number of other presentations on back pain presented by leading neuromodulation physicians at this meeting.

ReActiv8-B Trial - On 29 May 2015, we announced FDA approval to begin the ReActiv8-B Clinical Trial under an IDE. We have since worked with the FDA to refine the protocol, and we are progressing clinical trial site selection and initiation, physician training, and submissions to Ethics Committees (Institutional Review Boards ("IRB"s) in the US). The ReActiv8-B Clinical Trial is designed to generate data to form part of the PMAA of ReActiv8 to the FDA. Following PMA (if obtained), we plan to commercialize ReActiv8 in the US.

The ReActiv8-B Clinical Trial is an international, multi-center, prospective randomized sham-controlled blinded trial with one-way crossover. In summary, eligible subjects will have baseline data collected and then following verification that the enrollment criteria are met, ReActiv8 will be implanted. At the 14-day post implant follow up visit, half the subjects will be randomized to receive appropriately programmed stimulation (the treatment arm), and half will be randomized to receive minimal stimulation (the control arm). Subjects will not be informed about their allocation to the treatment or control arm, and all subjects will be told that

they may or may not feel something with stimulation, and all will be encouraged to continue using ReActiv8 at least until the 120-day primary outcome assessment visit. Subjects will be instructed to not use any other therapies for CLBP from the time of enrollment until after data collection at the primary outcome assessment visit. Subjects will also be instructed to keep constant the use of medications prescribed and used for low back pain until the primary outcome assessment visit. The primary efficacy endpoint of the Trial is a comparison of responder rates between the treatment and control arms. The Trial will be considered a success if there is a statistically significant difference in responder rates between the treatment and control arms. A responder is defined as having at least a 30% improvement in low back pain reported on a 100mm Visual Analog Scale (VAS) between baseline and the 120-day primary outcome assessment visit, with no increase in medications prescribed and taken for pain in the 14 days prior to the visit. Data for multiple secondary outcome measures will also be gathered. After the primary outcome assessment visit, subjects in the control arm will be crossed over to receive appropriately programmed full strength stimulation, and all subjects will continue to be followed.

The statistical design of the Trial requires data from 128 subjects at the 120-day primary outcome assessment visit. Additional subjects will likely be enrolled and implanted as part of the surgical roll-in phase and to achieve data from 128 subjects in the pivotal cohort. The Trial is designed with an "interim look" when primary outcome data are available from half the subjects, and if necessary the number of subjects in the pivotal cohort may be increased to achieve the targeted statistical significance. Up to 40 clinical trial sites may be involved in the Trial, some of which may be referring sites and some may be implanting sites.

A summary of the protocol can be found at https://clinicaltrials.gov/show/NCT02577354.

Based on our experience with enrollment in the ReActiv8-A Trial, we estimate that full enrollment of the pivotal cohort in the ReActiv8-B Trial will take 12-18 months from ramp up of enrollment, with results anticipated to be available approximately six months following full enrollment. The work required to complete a PMAA submission to the FDA is estimated to take approximately six months from data availability.

The ReActiv8-B Trial, if successful, will provide what is referred to as Level 1 Evidence of safety and efficacy of ReActiv8, and Level 1 evidence may be used to support applications for favorable reimbursement in the US.

We plan to ramp up enrollment in the ReActiv8-B Trial once we determine that we have sufficient financial resources to complete the Trial through data availability. A small number of subjects may be enrolled in the ReActiv8-B Trial prior to securing such financial resources.

US Patent Filing - During 2015 we also announced the issuance of five new US Patents (listed below), bringing the total current number of issued US issued Patents in the Mainstay portfolio to seven:

- US Patent No. 9,072,897 entitled "Systems and Methods for Restoring Muscle Function to the Lumbar Spine";
- US Patent No. 9,079,019 entitled "Apparatus and Methods for Anchoring Electrode Leads for Use with Implantable Neuromuscular Electrical Stimulator";
- US Patent No. 9,108,053 entitled "Apparatus and Methods for Rehabilitating a Muscle And Assessing Progress of Rehabilitation";
- US Patent No. 9,186,501 entitled "Systems and Methods for Implanting Electrode Leads for Use with Implantable Neuromuscular Electrical Stimulator"; and
- US Patent No. 9,248,278 entitled "Modular Stimulator for Treatment of Back Pain, Implantable RF Ablation System and Methods of Use";

Corresponding applications have been filed for other countries. Mainstay continues to add to its portfolio of issued patents and pending patent applications.

Financial review

Income Statement – Mainstay is at a pre-revenue stage. Operating expenses related to on-going activities were $12.9 million during the year ended 31 December 2015 (2014: $15.1 million including exceptional items, and $11.1 million excluding exceptional items). On-going activities include clinical and regulatory activities, research and development, preparation for commercialization and general and administrative activities.

Research and development expenses reflect costs incurred for research, ongoing development and design of the Group's product ReActiv8. These expenses include the salaries of engineers, technicians, quality and regulatory specialists; the cost of outsourced development and manufacturing activities; biocompatibility and pre-clinical studies; and quality costs including the set-up and maintenance of our quality system. Research and development expenses also include the costs of prosecuting and maintaining our intellectual property portfolio, including legal costs and associated filing and maintenance fees. Research and development expenses were $2.7 million during the year ended 31 December 2015 (2014: $2.6 million).

Clinical and regulatory expenses relate to the ongoing ReActiv8-A Clinical Trial, and preparation for the ReActiv8-B US Clinical Trial. Also included in clinical and regulatory expenses are expenses relating to clinical consulting; regulatory consulting; and, salary costs for our clinical team members. All clinical and regulatory costs are expensed as incurred. We expect clinical and regulatory expenses to increase significantly when enrollment in the ReActiv8-B Clinical Trial ramps up, as further subjects continue to be recruited, as we collect data for both clinical trials, and as we undertake post market clinical follow-up activities. Clinical and regulatory expenses were $4.4 million during the year ended 31 December 2015 (2014: $4.0 million).

General and administration expenses consist of salaries and other related costs for personnel in executive, commercial, finance and legal functions. Commercial costs consist primarily of consulting and related costs. General and administration expenses include the professional fees for accounting, audit and legal services; general and facilities costs such as rent; insurances and IT costs.

Commercial activities to date have been 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 become available to be sold commercially. Commercial expenses are expected to increase with the expansion of our resources to include new personnel in a direct sales team as we move toward commercialization in key target markets in Europe. General and administration expenses were $4.3 million during the year (2014: $3.9 million).

Non-cash expense in relation to share options for the year ended 31 December 2015 was $1.5 million, which increased from $0.6 million for the year ended 31 December 2014 due to the increase in the Company's share price following the IPO.

Statement of financial position – Cash on hand at 31 December 2015 was $16.6 million (2014: $18.3 million). Total assets of the Group at year end were $17.6 million (2014: $18.8 million).

On 24 August 2015, we announced the closing of debt financing for up to $15 million. The secured debt facility is non-dilutive to existing shareholders, and is being provided by IPF Partners, a leading financing provider focused on the European healthcare sector. As at 31 December 2015, the Group had drawn down $10.5 million. The last tranche of $4.5 million can be drawn down at the Company's discretion up to 31 July 2016 following CE Marking approval of ReActiv8.

Operating net cash out flows for the year ended 31 December 2015 were $11.6 million (2014: $11.4 million). This operating cash out flow reflects the cost of the research and development of ReActiv8, undertaking our clinical trials, preparation for commercialization, the ongoing costs of being a public company, and running the Group.

Principal risks and uncertainties

The principal risks and uncertainties faced by the Group are outlined on pages 16 to 33 of this report, and include risks relating to the Group's financial position and capital requirements, risks relating to its business and industry, risks relating to intellectual property and risks relating to the Company's shares.

Financial risk management

The Group is exposed to a variety of financial risks including credit risks, liquidity risks, interest rate risks and foreign currency risks.

Risk management framework - Mainstay'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 analyze the risks faced by the Group, to set appropriate risk limits and controls and to monitor risks and adherence to the limits.

Due to the current pre-revenue nature of the Group's activities, there are no significant concentrations of financial risk other than concentration of cash with individual banks 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 - Credit risk is the risk of financial loss to the Group if a customer or counterparty to a financial instrument fails to meet contractual obligations, and arises principally from the Group's cash and cash equivalents.

Liquidity risk - Liquidity risk is the risk that the Group will not be able to meet its financial obligations as they fall due. Since inception the Group has funded its operations primarily through (i) the issuance of equity securities and (ii) debt funding. The Group continues to explore funding strategies (e.g.: equity, debt, partnering) to support its activities into the future. Adequate additional financing may not be available on acceptable terms, or at all. The Group's inability to raise capital as and when needed would have a negative impact on the Group's financial position and its ability to pursue its business strategy.

Foreign currency risk - The Group's reporting currency is the US Dollar. The Group's exposure to foreign currency risk arises through expenditure incurred in Euro and Australian Dollars. The Group's Australian subsidiary has an Australian Dollar functional currency.

Interest rate risk - The Group's cash balances are maintained in short term access accounts and carry a floating rate of interest.

The Group's debt carries a variable rate of 3-month Euribor plus a margin ranging from 11.5% to 12.5%. Any change in the Euribor rate above zero will directly affect the amount of interest repayable on this debt.

Further details regarding financial risks are set out in Note 18 to the consolidated Financial Statements.

Outlook and future developments

While we await CE Marking approval for ReActiv8, we are preparing for commercialization in Europe. We are also preparing for the ReActiv8-B Clinical Trial and, subject to the availability of sufficient financial resources, we look forward to ramping up enrollment in the Trial.

Directors and Secretary and their interests

The names of currently serving Directors are set out on page 3.

James A. Reinstein was appointed as an additional independent Director on 22 June 2015.

All the other Directors retired at the Company's Annual General Meeting ("AGM") held on 18 June 2015 and submitted themselves for re-election by the shareholders. The resolutions to re-elect each Director were passed at the Company's AGM on 18 June 2015.

It is the Board's current intention that one third of all Directors will retire at each AGM, subject to any additional requirements under Articles 90 to 94 of the Company's Articles of Association.

The beneficial interest of the Directors and Company Secretary, who held office at 31 December 2015, in the ordinary share capital of the Company at the dates below were as follows:

Ordinary shares		*Ordinary shares at par value of €0.001 each*	
Name		**At 31 December 2015**	**At 31 December 2014**
Peter Crosby	Ordinary shares of €0.001 each	81,400	81,400
David Brabazon	Ordinary shares of €0.001 each	4,728	4,728
Dan Sachs MD	Ordinary shares of €0.001 each	515,000	515,000
Tom Maher	Ordinary shares of €0.001 each	10	10

Share options	**Deemed date of grant**	**Exercise price per ordinary share**	**Expiry date**	**No. of ordinary shares under option 31 December 2015**	**No. of ordinary shares under option 31 December 2014**	**No. of vested options as at 31 December 2015**
Oern Stuge MD	23 Jan 2013	US$1.00	10 years from vesting	55,014	55,014	40,111
Peter Crosby	23 Jan 2013	US$1.00	10 years from vesting	75,000	75,000	54,676
Peter Crosby	8 Jan 2015	€14.90	10 years from vesting	65,000	-	-
Peter Crosby	17 Dec 2015	€17.95	10 years from vesting	35,000	-	-
David Brabazon	5 Dec 2013	US$1.00	10 years from vesting	18,427	18,427	9,202
James A. Reinstein	2 Sep 2015	€16.87	10 years from vesting	20,000	-	-
Tom Maher	24 Jun 2014	€17.08	10 years from vesting	32,000	32,000	11,996
Tom Maher	8 Jan 2015	€14.90	10 years from vesting	5,000	-	-
Tom Maher	2 Sep 2015	€16.87	10 years from vesting	6,000	-	-
Tom Maher	17 Dec 2015	€17.95	10 years from vesting	15,000	-	-

Except as disclosed in this report, none of the Directors, who held office at 31 December 2015, had a beneficial interest in the share capital of the Company or its subsidiaries and no such interest, the existence of which is known or could with reasonable diligence be ascertained by the relevant Director, is held by any connected person.

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. At 31 December 2015, Sofinnova Capital VI FCPR owned 1,775,829 ordinary shares amounting to approximately 41.32% of the entire issued ordinary share capital of the Company. As at 31 December 2014, Sofinnova Capital VI FCPR owned 1,775,829 ordinary shares amounting to approximately 41.35% of the entire issued ordinary share capital of the Company.

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 the interests that he holds in Fountain Healthcare Partners Fund 1 LP. At 31 December 2015, Fountain Healthcare Partners Fund 1 LP owned 566,171 ordinary shares amounting to approximately 13.17% of the entire issued ordinary share capital of the Company. As at 31 December 2014, Fountain Healthcare Partners Fund 1 LP owned 556,171 ordinary shares amounting to approximately 13.18% of the entire issued ordinary share capital of the Company.

Directors' remuneration

The following table shows the amount of remuneration paid and benefits in kind granted to the Directors by the Group for services in all capacities:

2015:	**Fees**	**Salary**	**Annual Incentive**	**Benefits in Kind**	**Total**
Executive Directors					
Peter Crosby	-	$411,535	$127,650	$24,728	$563,913
Non-Executive Directors					
Oern Stuge MD (Note 1)	$41,678	-	-	-	$41,678
David Brabazon	$26,860	-	-	-	$26,860
Antoine Papiernik	-	-	-	-	-
James A. Reinstein	$25,991	-	-	-	$25,991
Manus Rogan PhD	-	-	-	-	-
Dan Sachs MD	-	-	-	-	-

2014:	**Fees**	**Salary**	**Annual Incentive**	**Benefits in Kind**	**Total**
Executive Directors					
Peter Crosby	-	$448,167	$89,244	$4,395	$541,806

Non-Executive Directors					
Oern Stuge MD (Note 1)	$44,326	-	-	-	$44,326
David Brabazon	$21,439	-	-	-	$21,439
Antoine Papiernik	-	-	-	-	-
Manus Rogan PhD	-	-	-	-	-
Dan Sachs MD	-	$8,500	-	-	$8,500

Notes:

1. In addition to the Directors fees above, the Group made payments under a consultancy agreement to ORSCO Life Sciences AG (the "ORSCO Consulting Agreement"), a Swiss company which is controlled by Oern Stuge. Details of payment to ORSCO Life Sciences AG are included in Note 23. On 31 December 2015, Mainstay Medical Limited and ORSCO Life Sciences AG agreed to terminate the ORSCO Consultancy Agreement with effect from 31 December 2015.

Issued share capital

At 31 December 2015 the authorized share capital of the Company was €60,000, comprised of 20,000,000 ordinary shares of €0.001 each, representing 99.8% of total authorized shares (by number) and 40,000 deferred shares of €1.00 each, representing 0.2% of total authorized shares (by number). At 31 December 2015, the issued share capital of the Company was 4,298,203 ordinary shares of €0.001 each and 40,000 deferred shares of €1.00 each (which do not carry voting rights, are not entitled to receive any dividend or distribution and have in effect no right to a return of capital on a winding up). A full description of the rights attached to the ordinary and deferred shares of the Company is available in the Articles of Association on the Company's website. Further information on share movements is provided in Note 16.

At the Company's 2015 AGM held on 18 June 2015:

- the Directors were authorized, pursuant to Section 1021 of the Companies Act 2014 (**"2014 Act**"), to allot "relevant securities" up to an aggregate nominal value of €10,000, representing approximately 233% of the Company's issued ordinary share capital as at 15 May 2015. This authority will expire on 18 June 2020, being five years from the date on which the resolution was passed.
- the Directors were authorized, pursuant to Section 1023 of the 2014 Act, to dis-apply statutory pre-emption provisions in the event of a rights issue or other pro rata offer of equity securities to shareholders for cash; or other issue of equity securities for cash up to an aggregate nominal value of €10,000 representing approximately 233% of the Company's issued ordinary share capital as at 15 May 2015. This authority will expire on 18 June 2020, being five years from the date on which the resolution was passed.

The Company is not aware of any agreements between holders of securities that may result in restrictions in the transfer of ordinary shares or voting rights over ordinary shares. The Directors in their absolute discretion and without assigning any reason therefor may decline to register any transfer of a deferred share. The Company is authorized at any time to appoint any person to execute on behalf of the holder(s) of deferred shares a transfer thereof and/or an agreement to transfer the same, without making any payment to the holder(s) thereof and persons so entitled, to such person(s) as the Company may determine as holder(s) thereof and beneficially entitled thereto.

At no time during 2015 were any ordinary or deferred shares in the Company held or acquired by the Company or any subsidiary of the Company.

Share Option Plan 2014

The Group operates a share option plan (the "Plan"). As at 31 December 2015, the Plan allows for the Company to grant share options to employees of the Group companies, and other eligible persons. Shares are issued when share options are exercised in accordance with the Plan.

Memorandum and Articles of Association

The Company's Articles of Association detail the rights attached to the shares; and the rules relating to the Directors, including their appointment, retirement, re-election and powers. Changes to the Articles of Association must be approved by the shareholders in accordance with the legislation in force from time to time.

At the Company's AGM held on 18 June 2015, two special resolutions were passed to amend the Articles of Association of the Company to take account of the Companies Act 2014 and to make some "housekeeping" changes.

A copy of the Memorandum and Articles of Association can be obtained from the Group's website.

Substantial shareholders

As of 27 April 2016 being the latest practicable date before publication of this Directors' Report, in so far as was notified to the Company, the following were holders of 3% or more of the Company's issued ordinary share capital:

Shareholder	**No. of ordinary shares**	**Percentage**
Sofinnova Capital VI FCPR	1,775,829	41.3%
Fountain Healthcare Partners Fund 1, L.P.	566,171	13.2%
Dan Sachs MD	515,000	12.0%
Perceptive Life Sciences Master Fund, Ltd	321,513	7.5%
Capricorn Health-Tech Fund NV	259,312	6.0%
Medtronic, Inc.	235,209	5.5%
Seventure Partners Managed Funds	194,333	4.5%

Going concern

The Financial Statements have been prepared on the basis that the Group is a going concern. The Directors note the following relevant matters:

- The Group has an accumulated retained losses reserve of $74.8 million and a reorganization reserve of $44.6 million (which is in substance primarily retained losses). These losses include a non-cash expense of $66.5 million incurred in 2014 related to fair valuing of embedded derivatives arising on preference shares
- The Group has not generated revenue from its operations to date and expects to continue to incur losses in the medium term
- The Group had operating cash out flows of $11.6 million during the year ended 2015 (2014: $11.4 million)
- Regulatory approval for the commercialization of ReActiv8 is not guaranteed and in the US is dependent on the successful completion of the ReActiv8-B Clinical Trial and obtaining PMA approval from the FDA

To fund the clinical trials and commercialization of ReActiv8 the Group has raised debt and equity and it continues to explore funding strategies (e.g.: equity, debt, partnering) to support the Group's activities into the future. As at 31 December 2015, the Group reported cash of $16.6 million and the last tranche of the IPF debt facility of $4.5 million can be drawn down at the Group's discretion up to 31 July 2016, following CE Marking approval of ReActiv8.

After making enquiries and having considered the conditions noted above and the options available to the Group, the Directors have a reasonable expectation that the Group can carefully monitor its cash flows and has the ability to consider alternative strategies and budgets to ensure that the Group will have sufficient funds to be able to meet its liabilities as they fall due for a period of at least 12 months from the date of the Financial Statements and are satisfied that the Financial Statements should be prepared on a going concern basis.

Dividends

The Directors do not recommend the payment of a dividend.

Research and development

Certain Group undertakings are engaged in ongoing research and development aimed at continuous improvement of the Group's product and processes. Research and development expenditure is set forth in Note 5 to the consolidated Financial Statements.

Related party transactions

Details of related party transactions that have taken place during the reporting period are set forth in Note 23 to the consolidated Financial Statements.

Political donations

During the year, the Group and Company made no donations requiring disclosure.

Post balance sheet events

Details of important events affecting the Group and Company which have taken place since the end of the year are given in Note 24 to the Financial Statements.

Subsidiary undertakings

At 31 December 2015, the Company had the following subsidiaries and owns 100% of the called up ordinary share capital of each such subsidiary:

- Mainstay Medical Limited ("MML") is registered in Ireland and its principal activities include research, development, clinical and regulatory activities and support services to other Group companies.
- MML US, Inc. is registered in the United States of America and its principal activity is the provision of support services to other Group companies.
- Mainstay Medical (Australia) Pty. Limited ("MMA") is registered in Australia and its principal activity is the provision of support services to other Group companies

Subsequent to 31 December 2015 and prior to the date of this report, the Company incorporated the following two subsidiaries:

- Mainstay Medical Distribution Limited was incorporated in Ireland and its principal activity is the provision of sales and distribution services.
- Mainstay Medical GmbH is registered in Germany and its principal activity is the provision of sales support services.

The Company owns 100% of the called up share capital of each of the above subsidiaries

Accounting records

The Directors, through the use of appropriate procedures, personnel and systems have ensured that measures are in place to secure compliance with the Company and the Group's obligation to keep adequate accounting records. The books of account of the Company and the Group are maintained at its registered office.

Auditors

The auditors, KPMG, Chartered Accountants, will continue in office accordance with Section 383 (2) of the 2014 Act.

A resolution authorizing the Directors to fix the auditors remuneration was passed at the Company's AGM on 18 June 2015.

On behalf of the Board on 27 April 2016,

Oern Stuge MD Peter Crosby

Chairman CEO

Mainstay Medical International plc

Principal risks and uncertainties

RISKS RELATING TO OUR FINANCIAL CONDITION AND CAPITAL REQUIREMENTS

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

We have incurred significant net losses since we were founded. For the year ended 31 December 2015, we had a comprehensive loss of $13.2 million (and a comprehensive loss of $82.5 million in 2014). We fund our operations through equity capital and debt, and have raised more than $52 million of equity capital and as of 31 December 2015, we have drawn $10.5 million of debt from a $15 million debt facility which we announced in August 2015. We have devoted substantially all of our resources to the research and development of ReActiv8, including completion of our feasibility study in October 2012, progress on our ReActiv8-A Clinical Trial which commenced in 2014, preparations for our ReActiv8-B Clinical Trial, and expansion of our intellectual property portfolio.

To implement our business strategy and generate revenue and profit in the future we need to, among other things, obtain regulatory approvals for ReActiv8 (which on the date of this report is our only product) in our target markets. We have not yet obtained CE Marking of ReActiv8, which allows for commercialization of ReActiv8 in the European Union, Switzerland and other European Economic Area countries (the "EU") and certain other countries (e.g.: Australia). If we obtain CE Marking for ReActiv8, there is no assurance that commercialization in the EU will be successful or will generate sufficient revenue (and profits) to cover expenses or fund future growth. We have not yet obtained regulatory approval for ReActiv8 in the US. If US regulatory approval is not obtained, then it will not be possible to commercialize ReActiv8 in the US.

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

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

We expect to require additional funds in the future in order to meet our capital and expenditure needs, including funds to continue research and development, conduct clinical trials, continue our work to obtain regulatory approval and other activities necessary to bring ReActiv8 to target markets and to establish marketing and sales capabilities. However, we may not be able to obtain additional financing on terms favorable to us, if at all, when needed. If we are unable to obtain adequate financing or financing on terms satisfactory to us, when we require it, we may cease to have operations and may need to liquidate some or all of our assets.

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

We have a variable interest rate secured debt facility, which in the event of the occurrence of an event of default, could become immediately repayable and subject to the enforcement of the related security

On 24 August 2015, we entered into an agreement with IPF Partners for a debt facility of up to $15 million. The facility can be drawn in three tranches. Each tranche has a repayment term of 60 months from drawdown, with interest only payments for the first 12 months. As at 31 December 2015, the Group had drawn down $10.5 million. The last tranche of $4.5 million can be drawn down at the Company's discretion up to 31 July 2016 following CE Marking approval of ReActiv8.

Failure to achieve CE Marking on or before 31 July 2016 could result in our being unable to draw the third tranche of this facility which could have an adverse impact on our future financial position.

This facility carries a variable rate of 3-month Euribor plus a margin ranging from 11.5% to 12.5%. Any change in the Euribor rate above zero will directly affect the amount of interest repayable on this facility and could have an adverse impact on our financial performance and/or financial position.

The facility is secured by way of fixed and floating charges over the assets and undertakings of Mainstay Medical Limited, and the Mortgage Debenture includes customary terms and conditions. In addition, Mainstay Medical International plc has created a first fixed charge in favor of IPF over its present and future shares held in Mainstay Medical Limited. Failure to make payments or the occurrence of an event of default under the facility could result in a demand for immediate repayment of the facility by the lender and enforcement of its security under the Mortgage Debenture, which could have a material adverse impact on our financial performance and/or financial position.

Our future financial performance is entirely dependent on the commercial success of ReActiv8, our only product as of the date of this report

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

RISKS RELATING TO OUR BUSINESS AND INDUSTRY

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

ReActiv8 is an active implantable medical device ("AIMD"), which requires regulatory approval before it can be marketed or sold by us. Currently we have not received approval from any regulatory authority for ReActiv8 and there is no guarantee that regulatory approvals will be obtained for ReActiv8 or any other product we develop, either now or in the future. Any such regulatory approval may also experience delays.

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

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

We currently do not have regulatory approval to market ReActiv8 in any country, and regulatory approval can be a lengthy, expensive and uncertain process. We are primarily targeting commercialization in markets in the EU and the US and we must comply with complex regulatory requirements in these markets before we can market or sell our product in each market. Once initial regulatory approval is gained for our product for a particular market, any subsequent products or product modifications may also require further regulatory approval before we can market the subsequent or modified products.

In the EU, regulatory approval is obtained via the CE Marking 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 US, regulatory approval is obtained via a Pre-Market Approval ("PMA") issued by the US Food and Drug Administration ("FDA"). Timing of a PMA is uncertain, as it depends on the progress and developments of the clinical trial to gather data for a Pre-Market Approval Application ("PMAA"). The process typically takes significantly longer than obtaining CE Marking. Applications for regulatory approval require extensive pre-clinical, clinical and technical testing, all of which must be undertaken in accordance with the requirements of regulations and guidance for the FDA. We have not yet started the ReActiv8-B Clinical Trial to gather data for a PMAA.

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

We are required to conduct clinical trials for regulatory approvals and other purposes. Clinical trials carry substantial risks and are costly and time consuming, with uncertain results

The outcomes of clinical trials are by their nature uncertain and dependent on a number of variables inherent to clinical research, such as the 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, and related or unrelated to the device, occur in clinical trials. Significant unanticipated adverse events associated with ReActiv8 could result in damage to our reputation, lawsuits, suspension or delay of clinical trials, and/or enrollment difficulties. Errors in associating adverse events with ReActiv8 could result in damage to our reputation, lawsuits, suspension or delay of clinical trials, and/or enrollment difficulties. Any delay or suspension of clinical trials may delay the filings of regulatory submissions and ultimately the ability to commercialize ReActiv8 and to generate revenues.

The ReActiv8-B Clinical Trial to gather data on ReActiv8 for a PMAA may not achieve the anticipated endpoints to demonstrate safety and efficacy to the satisfaction of the FDA to allow for the granting of a PMA. 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.

We are required to fund clinical trials. This typically includes the payment of professional fees for physicians; hospital costs; fees for one or more contract research organizations ("CROs"); data collection, retention and management; fees for consultants to run committees; and clinical trial insurance premiums. Medical device companies are usually required to provide products and services at no charge during clinical trials leading to regulatory submissions, and therefore we will not generate revenue from product sales from the use of ReActiv8 in such clinical trials. We may be required to fund the cost of surgical procedures to replace or remove the device in clinical subjects. The costs of the clinical trials may exceed the resources available to us, 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 enrollment, have adverse regulatory impact, prevent us from securing patent protection, result in diminished competitive position or damage our reputation.

We may be required to conduct one or more post-approval studies which could be expensive and fail to produce the desired results

Following CE Marking approval (if granted), a range of activities will be required for Post Market Clinical Follow-up ("PMCF"). It is possible that the PMCF may uncover problems that did not emerge during the clinical trials of ReActiv8 which may result in product recall, suspension of sales, and/or restrictions on commercialization.

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

The PAS may uncover problems with ReActiv8 and may result in a need to redesign certain aspects of ReActiv8 and/or conduct additional studies and includes possible suspension from sale. Such consequences would have a material adverse effect on our business and financial performance.

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, we must engage a physician at each clinical trial center to maintain overall responsibility for the conduct of the clinical trial (the "Investigator"). Each Investigator may have additional physicians or other medical professionals working under his or her direction to conduct a trial (e.g., to recruit clinical trial subjects or perform surgery or other procedures). We may not be able to attract a sufficient number of qualified Investigators to conduct clinical trials within an adequate time, and those Investigators may not be able to attract or enroll a sufficient number of subjects to meet our 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 enrollment 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 certain tests. Some subjects may not comply with the requirements of the trial, or could at any time withdraw from the trial, which could lead to poor or unusable data, which may compromise the results of the clinical trial.

Failure to attract a sufficient number of eligible clinical trial 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 our ability to achieve regulatory approval, and thereby our ability to market our product and achieve revenues and profits.

There is no guarantee that the performance of ReActiv8 when commercialized will match the performance of ReActiv8 in clinical trials.

ReActiv8 clinical performance when commercialized may be different from the clinical performance observed during the clinical trials for a number of reasons, including less control on the selection of people suitable for use of the product, use by physicians with different experience and/or training, and failure to adhere to a follow up regimen in the absence of clinical trial oversight.

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

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

There is no certainty that the market for ReActiv8 will develop as currently anticipated by us or at all

We believe the potential number of people with Chronic Low Back Pain who could benefit from ReActiv8 is large, based on our estimate of persons suffering with Chronic Low Back Pain in our key target markets. However, development of the market depends on several factors including regulatory approvals, availability and level of reimbursement, acceptance of the treatment by the medical profession, product performance after approval, emergence of other current and future treatments for Chronic Low Back Pain, as well as the global trend to reduce healthcare costs. If, as a result of these or other factors, the market for our product does not develop as currently anticipated, our ability to generate revenue could be materially adversely affected.

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

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

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

- general conservatism about adoption of new and innovative treatment practices;
- lack or perceived lack of long-term evidence supporting additional patient benefits;
- perceived clinical risk of a new treatment;
- perceived liability risks associated with the use of new a product and procedures;
- limited or lack of reimbursement and coverage within healthcare payment systems,
- cost associated with the purchase of new product and equipment;
- other procedures competing for physician time and attention; and
- the time commitment that may be required for special training.

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

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

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

Adverse events associated with these risks may lead some patients to blame us, the physician or other parties for such occurrences. This may result in product liability lawsuits, medical malpractice lawsuits, investigations by regulatory authorities, adverse publicity, criminal charges or other harmful circumstances for us. Any of those circumstances may have a material adverse effect on our ability to conduct our business, to sell ReActiv8 (if and when approved), or to develop future products (if any).

Our business exposes us to an inherent risk of potential product liability claims relating to the manufacturing, clinical trials, marketing and sale, or recall of an active implantable medical device

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

Medical device manufacturers are exposed to the risk of potential product liability claims arising from device failures and malfunctions, product use and associated surgical procedures. A product liability claim may be raised as a result of factors outside the control of the manufacturer, such as off-label use of our product, or failure of the medical practitioners or patients to follow the instructions for use. It is possible that a product liability lawsuit may be lost through no fault of ours, which could result in reputational risk, increased insurance premiums, and depression of future sales, all of which may have an adverse effect on our financial performance and/or financial position.

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

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

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

Prior to first sale of our product, we intend to purchase product liability insurance to help cover the costs of defense of product liability lawsuits and for damages. Until that time, clinical trial insurance helps cover defense of lawsuits relating to the product which is the subject of clinical trials and for damages if awarded. We may not be able to maintain or increase product liability insurance on acceptable terms, and such insurance may not provide adequate coverage against potential liabilities. A successful claim brought against us in excess, or outside, of our insurance coverage could have an adverse effect on our financial performance and/or financial position.

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

Competition from medical device companies is intense and we expect it to further increase. We may not be able to compete successfully against our current and future competitors, including competitors with larger financial capabilities. Competitors may develop new products or adapt existing products or their uses for the same patient group targeted by our product, which could present competition for ReActiv8.

Treatment for CLBP is potentially a very large market, and is attracting potential competitors. 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 our product or could reach commercialization before our product. Such occurrences could adversely affect our ability to generate sufficient revenues to sustain our business.

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

In addition, the commercial availability of any approved competing product could potentially inhibit recruitment and enrollment in our clinical trials. We may successfully conclude our 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 us to compete effectively against other medical device companies or to effectively manage the risks related to competition may have a material adverse effect on our financial condition and business.

New or competing treatments for Chronic Low Back Pain may emerge

ReActiv8 is an AIMD designed as treatment for people with Chronic Low Back Pain. Alternative therapies for this patient group may include among others physical therapy (such as lumbar extensor strengthening exercises), watchful waiting (i.e., no therapy), traction therapy, the McKenzie method of exercise therapy, massages, drugs (including analgesics, opioids, sleep aids, muscle relaxants and anti-depressants), acupuncture, steroid injections, back schools, various types of energy application including ultrasound, transcutaneous electrical nerve stimulation ("TENS"), osteopathic therapy, and thermotherapy, spinal cord stimulation ("SCS"), and lumbar stabilization exercises. New treatment options, or modifications of existing treatments or their uses, may emerge which yield clinical results equal to or better than those achieved with ReActiv8, possibly at a lower cost. Emergence of such new therapies may inhibit our ability to develop and grow the market for ReActiv8, which would have a material adverse effect on our financial condition, business, prospects and results of operations.

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

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

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

In many countries, payment for our product 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 utilize our product. There is no guarantee that such coverage can be obtained, or if obtained, that it will be adequate to enable us to build a profitable business selling ReActiv8.

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

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

We are dependent on access to raw materials and products necessary for the conduct of clinical trials and manufacturing of our product is not guaranteed

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

Manufacturing issues may arise that are detrimental to us

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

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

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

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

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

We depend on a limited number of third party suppliers for the manufacture of ReActiv8 and the loss of one or more of these third party suppliers or their inability to supply us with adequate quantities of products could harm our business in the future. A third party supplier may be subject to circumstances which impact our ability to supply, including enforcement action by regulatory authorities, natural disasters (e.g., hurricanes and earthquakes), industrial action (e.g., strikes), financial difficulties including insolvency, pressure or demands on manufacturing capacity (e.g.: by products for other customers that compete for manufacturing capacity), among a variety of other internal or external factors.

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

Our suppliers, in turn, depend on their own suppliers and supply chain. Any disruption of the supply chain could adversely affect us.

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

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

Any of these interruptions to the supply of materials or components could result in substantial reduction in our available inventory and an increase in our production costs, which may have an adverse effect on our financial performance and/or our financial position.

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

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

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

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

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

In some markets we may depend on distributors over which we have little or no control

For some markets our intended distribution strategy may be to rely on third party distributors for ReActiv8.

In such markets where we may depend on distributors, we would not directly control the performance of a distributor. Thus our success in those markets may depend on the efforts of others. A distributor's failure to perform according to expectations and/or contractual obligations may have an adverse effect on our reputation, financial performance or our financial position.

We may be unable to attract and retain management and other personnel we need to succeed

We rely on the expertise and experience of our Directors, senior management and other key employees and contractors in management, research and development, clinical and regulatory matters, sales and marketing, and other functions. The retention and performance of our Directors, senior management and other key employees are therefore significant factors in our ability to achieve our objectives. The departure of any of these individuals (in particular our CEO or COO) without timely and adequate replacement or the loss of any of our senior management may have a material adverse effect on our financial condition, business, prospects and results of operations and there can be no guarantee that we would be able to find and attract other individuals with similar levels of expertise and experience or similar relationships with commercial partners and other market participants. In addition, our competitive position could be materially adversely affected if a member of senior management transferred to a competitor.

If we receive future regulatory approval for ReActiv8 in our target markets, we expect to expand our operations and grow our research and development, product development, commercial operations and administrative operations. Our growth will require hiring a number of qualified clinical, scientific, commercial and administrative personnel. If we are unable to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development, commercialization or growth.

We have entered into indemnification agreements with our Directors and senior management, including certain contractors. As a consequence of such indemnification agreements, we may have to use our resources to indemnify such persons which could have an adverse effect on our future financial performance.

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

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

We may be at risk for non-compliance with applicable laws and regulations.

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

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

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

The Company is incorporated as an Irish public limited company and is listed on Euronext Paris and the ESM of the Irish Stock Exchange, and accordingly is subject to compliance with the rules of these stock exchanges and applicable laws and regulations of Ireland, France and the European Union. If the Company fails to comply with any of these rules, laws or regulations, we could be subject to enforcement actions by the relevant stock exchanges or regulators, legal sanctions and/or the imposition of fines or penalties which could have an adverse effect on our reputation, financial performance and/or financial position.

As at the date of this report, the Company also has subsidiaries incorporated in Ireland, the US, Australia and Germany. The Company and its subsidiaries have operations in multiple countries and are subject to the applicable laws and regulations of those countries. If the Company or any of its subsidiaries fail to comply with the laws and regulations of any of these countries, we could be subject to enforcement actions by the relevant authorities, legal sanctions and/or the imposition of fines or penalties which could have an adverse effect on our reputation, financial performance and/or financial position.

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

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

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

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

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

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

U.S. "anti-inversion" tax laws could negatively affect our results

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

In the 2014 Corporate Reorganization, MMIplc acquired the assets (being shares in MML) of Mainstay Medical Inc. (a US corporation), and former shareholders of MMI became shareholders of MMIplc. The ownership of equity that former shareholders of MMI received in the 2014 Corporate Reorganization is substantially below the 80 per cent. standard for application of the above US rules. Accordingly, we do not believe these rules should apply. There can, however, be no assurance that the IRS will not challenge the determination that these rules are inapplicable. In addition to the 2014 Reorganization, there was an earlier Group reorganization transaction in 2012. We do not believe integrated treatment of this transaction with the 2014 Reorganization to be appropriate because there are independent business reasons for undertaking these transactions. In the event that the US anti-inversion rules are held to apply to us, we would be subject to the US federal income tax on our worldwide income, which would negatively impact the cash available for distribution and the value of the ordinary shares.

We are exposed to foreign exchange risk

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

RISKS RELATING TO INTELLECTUAL PROPERTY

Any inability to fully protect and exploit our intellectual property may adversely impact our financial performance and prospects

Our success depends significantly on our ability to protect our proprietary rights, including the intellectual property related to and incorporated in ReActiv8. We rely on a combination of patent protection, trademarks and trade secrets, and we use non-disclosure, confidentiality and other contractual agreements to protect our intellectual property. We generally seek patent protection where possible for those aspects of our technology and product that we believe provide significant competitive advantages. At the date of this report, our patent portfolio includes seven issued US patents, ten patents granted outside the US and thirty patent applications pending US and other countries. However, we may be unable to adequately protect our intellectual property rights or may become subject to a claim of infringement or misappropriation, which we may be unable to settle on commercially acceptable terms. We cannot be certain that our pending or future patent applications will result in issued patents. In addition, we do not know whether any issued patents will be upheld as valid or will be proven to be enforceable against alleged infringers or that they will prevent the development of competitive patents or provide meaningful restriction against 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 US, but such patents cannot be applied for in Europe. Therefore, there may be circumstances where an invention is patented in one jurisdiction but a patent cannot be obtained in one or more other jurisdictions.

In responding to our patent application, a patent office may reject one or more (or sometimes all) claims. This may lead to an extensive dialogue between our patent attorneys and the patent office in an effort to reach agreement and grant of a patent. There is no assurance that such efforts will be successful, and thus no assurance that all patent applications will result in an issued patent.

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

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

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

Third party patents or other intellectual property may emerge which may adversely impact our ability to commercialize our product and there is no assurance that such third party patents or intellectual property will not emerge.

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

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

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

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

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to US patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switched the US patent system from a "first-to-invent" system to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The US Patent and Trademark Office (the "USPTO") recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the US Supreme Court and the US Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the US are interpreted. Similarly, non-US courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by the US and other legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

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

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

We may not be able to adequately protect our intellectual property rights throughout the world

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

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

We depend on confidentiality agreements with third parties to maintain confidential information

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

RISKS RELATING TO OUR SHARES

We may be a passive foreign investment company ("PFIC") for 2016 or subsequent years, which could result in adverse US federal income tax consequences to US investors

For US federal income tax purposes, a non-US corporation will be considered a passive foreign investment company, or PFIC, for any taxable year if either (1) at least 75% of its gross income for such year is passive income or (2) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during such year) is attributable to assets that produce or are held for the production of passive income. We do not believe we were a PFIC for our 2015 taxable year, although the US Internal Revenue Service ("IRS") may disagree with this conclusion. Based on the value and composition of our assets, we may, however, be a PFIC for 2016 and potentially for future taxable years. The determination of PFIC status is fact-specific, and a separate determination must be made for each taxable year (after the close of each such taxable year). If we are a PFIC for any taxable year during which a US holder holds shares, the US holder may be subject to adverse tax consequences, including (1) the treatment of any gain on disposition as ordinary income, rather than capital gain qualifying for preferential rates, (2) the application of an interest charge with respect to such gain and certain dividends and (3) compliance with certain reporting requirements. Each US holder is strongly urged to consult its tax advisors regarding these issues.

The market price of our securities may fluctuate widely in response to various factors, which could harm the market price of our shares

The market price of ordinary shares could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

-- actual or anticipated fluctuations in our financial condition and operating results;

-- our failure to obtain regulatory approval for any of our product candidates and commercialize our products;

-- adverse results or delays in our clinical trials;

-- actual or anticipated changes in our growth rate;

-- competition from existing products or new products that may emerge;

-- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, strategic alliances, or capital commitments;

-- adverse regulatory decisions;

-- the inability to establish potential strategic alliances;

-- unanticipated serious safety concerns related to the use of our product;

-- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;

-- issuance of new or updated research or reports by securities analysts;

-- fluctuations in the valuation of companies perceived by investors to be comparable to us;

-- price and volume fluctuations in trading of our ordinary shares on the ESM of the Irish Stock Exchange or Euronext Paris;

-- additions or departures of key management or scientific personnel;

-- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;

-- our inability to obtain reimbursement by commercial third-party payers and government payers and any announcements relating to coverage policies or reimbursement levels;

-- announcement or expectation of additional debt or equity financing efforts;

-- sales of our ordinary shares by us, our insiders or our other shareholders;

-- issue or exercise of share warrants or share options; and

-- general economic and market conditions.

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

Our ordinary share ownership is concentrated in the hands of our principal shareholders and management, who may be able to exercise a direct or indirect controlling influence on us

Our executive officers, Directors, 5% or greater shareholders and affiliated entities beneficially own approximately 87% of our ordinary shares in issue at the latest practicable date before publication of this report. As a result, these ordinary shareholders, acting together, have significant influence over all matters that require approval by our ordinary shareholders, including the election of directors and approval of significant corporate transactions. Corporate action might be taken even if other ordinary shareholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other ordinary shareholders may view as beneficial.

If securities or industry analysts do not publish research or publish unfavorable research about our business, the price of our ordinary shares and trading volume could decline

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

We do not currently intend to pay dividends, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of the shares

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

Any dividends paid by us may be subject to Irish dividend withholding tax

We do not currently expect to declare or pay dividends on our ordinary shares for the foreseeable future. To the extent that we determine in the future to pay dividends, in certain limited circumstances, dividend withholding tax (currently at a rate of 20%) may arise in respect of dividends paid on our ordinary shares. A number of exemptions from dividend withholding tax exist, such that shareholders resident in EU member states (other than Ireland) or other countries with which Ireland has signed a double tax treaty, which would include the US, should generally be entitled to exemptions from dividend withholding tax provided that the appropriate documentation is in place. Shareholders should note the requirement to complete certain dividend withholding tax forms in order to qualify for many of the exemptions.

Dividends received by Irish residents and certain other shareholders may be subject to Irish income tax

We do not currently expect to declare or pay dividends on our ordinary shares for the foreseeable future. However, if we do decide to pay dividends, then dividends received by Irish residents and certain other shareholders may be subject to Irish income tax. However, shareholders entitled to an exemption from Irish dividend withholding tax on dividends received from us will not be subject to Irish income tax in respect of those dividends, unless they have some connection with Ireland other than their shareholding in us (for example, they are resident in Ireland). Shareholders who are not Irish tax residents who receive dividends subject to Irish dividend withholding tax will generally have no further liability to Irish income tax on those dividends.

A future transfer of your ordinary shares, may be subject to Irish stamp duty

Any transfer of your ordinary shares could be subject to Irish stamp duty (currently at the rate of 1% of the higher of the price paid or the market value of the shares acquired). Payment of Irish stamp duty is generally a legal obligation of the transferee. The potential for stamp duty to arise could adversely affect the value of your shares.

The rights of our shareholders in respect of our corporate affairs may differ from the rights typically offered to shareholders of a typical US corporation or other non-Irish corporation, and these differences may make our shares less attractive to investors

We are incorporated under Irish law and, therefore, certain of the rights of holders of our shares are governed by Irish law, including the provisions of the Irish Companies Act 2014, and by our memorandum and articles of association. These rights differ in certain respects from the rights of shareholders in typical US corporation or other non-Irish corporations and these differences may make our shares less attractive to investors. The principal differences include the following:

• under Irish law, dividends may only be declared if we have, on an individual entity basis, profits available for distribution, within the meaning of the Irish Companies Act 2014

• under Irish law, each shareholder present at a meeting has only one vote unless a poll is called, in which case each holder gets one vote per share owned. Under Irish law, it is only on a poll that the number of shares determines the number of votes a holder may cast

• under Irish law, each shareholder generally has pre-emptive rights to subscribe on a proportionate basis to any issuance of new shares. Pre-emptive rights may be disapplied under Irish law for renewable periods of up to five years by Irish companies by way of a provision in their articles of association or special resolution of their shareholders (being a resolution approved by no less than 75% of the votes cast by shareholders in general meeting). At our AGM in 2015, shareholders approved, for a period ending on 18 June 2020, the disapplication of statutory pre-emption rights with respect to the issuance of share capital with a nominal value of €10,000, representing approximately 233% of our issued ordinary shares as at 15 May 2015. However, we cannot guarantee that the existing disapplication of pre-emption rights will not in future be revoked or that, following expiry of the existing disapplication, that shareholders will approve any future resolution to disapply pre-emption rights and, in any of those events, future equity fundraisings would be more cumbersome, costly and time consuming

• under Irish law, certain matters require the approval of 75% of the shareholders, including amendments to our Articles of Association. This may make it more difficult for us to complete corporate transactions deemed advisable by our Board of Directors

• under Irish law, a bidder seeking to acquire all issued ordinary shares in a tender offer would need to receive shareholder acceptance in respect of 90% of our issued ordinary shares (other than ordinary shares already in the beneficial ownership of the bidder) in order to proceed to "squeeze out" the remaining ordinary shareholders. If this 90% threshold is not achieved in the offer, under Irish law, the bidder cannot complete a "second step merger" to obtain 100% control of us. Accordingly, receipt of acceptances in respect of 90% of our issued ordinary shares (other than ordinary shares already in the beneficial ownership of the bidder) would typically be a condition in a tender offer to acquire our ordinary shares.

• under Irish law, shareholders may be required to disclose information regarding their equity interests upon our request, and the failure to provide the required information could result in the loss of rights or a restriction of rights attaching to the shares, including prohibitions on the transfer of the shares.

Irish law may afford fewer remedies in the event shareholders suffer losses compared to the US or other jurisdictions

As an Irish company, we are governed by the Irish Companies Act 2014 and Irish company law generally, which differ in some material respects from laws generally applicable to typical US corporations and other non-Irish corporations and their shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or other officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. You should also be aware that Irish law does not allow for any terms of legal proceedings directly equivalent to the class action available in US courts. Accordingly, holders of our shares may have more difficulty protecting their interests than would holders of shares of a company organized in a jurisdiction of the US.

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

As a company with its registered office in Ireland and whose securities are admitted to trading on a regulated market (within the meaning of Directive 93/22/EEC) in France only, the Company is, for the purposes of Directive 2004/25/EC of the European Parliament and the Council dated 21 April 2004 (the "**Takeover Directive**"), a shared jurisdiction company. This means that a takeover offer or bid for its securities would be subject to the Irish Takeover Rules of the Irish Takeover Panel in some respects, but also subject to the General Regulation (Règlement Général) (the "**French Takeover Rules**") of the French L'Autorité des marchés financiers (the "**AMF**") in most other respects.

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

As far as the Company is aware, it is currently the only shared jurisdiction company for the purposes of the Takeover Directive (and it is generally not aware of other applicable precedent) where the relevant competent authorities in the case of a takeover offer would be those of France and Ireland. Accordingly, a takeover offer for the Company would be supervised by two competent authorities, who would need to agree amongst themselves the correct delineation, with respect to such takeover offer, between the application of their respective takeover rules, as well as between their respective responsibilities and powers. The Company believes that this could lead to additional complexity in planning, making and/or completing any such takeover offer, which in turn could result in an extension of the transaction timetable and increased transaction costs.

The referendum on UK membership of the European Union ("Brexit") may introduce uncertainties which may impact our business

A referendum on UK membership of the European Union (to be held on 23 June 2016) may introduce potentially significant new uncertainties and instability in financial markets ahead of the date of the referendum and, depending on the outcome, after the event. It is unclear at this stage what the consequences would be for our business should the UK leave the European Union.

Mainstay Medical International plc

Corporate Governance Report

The Board recognizes 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 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 applies recognized 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 authorizations to the extent they are appropriate for a company of its size, stage of development and resources.

The Board

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

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

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

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

All the Directors bring independent judgment to bear on issues affecting the Group and all have full and timely access to information necessary to enable them to discharge their duties. The Articles require that at each annual general meeting of the Company one-third of the Directors retire by rotation.

Internal control

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

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

- Board approval of the annual budget and strategy;
- Monitoring of performance against the annual budget through monthly Board reports detailing actual results versus budget, analysis of material variances, and re-forecasting where required;
- Finance function resourced to facilitate segregation of duties;
- Audit, Risk and Compliance Committee review of the integrity of the Annual Report, Half-Yearly Report and Interim Management Statements;
- Board review and approval of the Annual Report and Half-Yearly Report; and
- Board approved authorization limits and investment policy.

Board Committees

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

- Audit, Risk and Compliance Committee – Mr. David Brabazon (Chairman), Dr. Manus Rogan, Mr. James Reinstein and Dr. Oern Stuge;
- Nominations Committee - Dr. Oern Stuge (Chairman), Mr. David Brabazon, Mr. Antoine Papiernik and Mr. James Reinstein;
- Remuneration Committee - Mr. James Reinstein (Chairman), Mr. David Brabazon, Mr. Antoine Papiernik, Dr. Manus Rogan and Dr. Oern Stuge.

Audit, Risk and Compliance Committee

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

Remuneration Committee

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

Nominations Committee

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

General meeting

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 Companies Act 2014.

Subject to the provisions of the Companies Act 2014 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 Companies Act 2014, be called by at least 14 clear days' notice.

The Directors shall specify in the notice of a general meeting the voting record date, being a date not more than 48 hours before the general meeting to which it relates. 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 Company's statutory financial statements and reports of the Directors and auditors, the appointment of Directors in the place of those retiring, the appointment or re-appointment of the auditors (subject to sections 380 and 382 to 385 of the Companies Act 2014) 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 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
- 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.

The Company's AGM gives shareholders the opportunity to question the Directors. The Company must answer any question a member asks relating to the business being dealt with at the meeting unless answering the question would interfere unduly with the preparation for the general meeting or the confidentiality and business interests of the Company, or the answer has already been given on a website in the form of an answer to a question, or it appears to the Chairman of the meeting that it is undesirable in the interests of good order of the meeting that the question be answered.

The business of the Company is managed by the Directors who may exercise all the powers of the Company, subject to the Companies Act 2014, the Articles of Association and to any directions given by the members by special resolution.

Votes

The Companies Act 2014 require that resolutions of the general meeting be passed by the majority of votes cast (ordinary resolution) unless the Companies Act 2014 or the Company's Articles of Association provide for 75% majority of votes cast (special resolution). The Company's Articles of Association provide that the Chairman has a casting vote in the event of a tie.

At meetings, unless a poll is demanded, all resolutions are determined on a show of hands, with every shareholder who is present in person or by proxy having 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. At the meeting, after each resolution has been dealt with, details will be given of the level of proxy votes lodged for and against that resolution and also the level of votes withheld on that resolution.

Subject to the Companies Act 2014 and to such requirements and restrictions as the Directors may, in accordance with the Companies Act 2014 specify, the Company at its discretion may provide for participation and voting in a general meeting by electronic means.

Subject to the Companies Act 2014 and to such requirements and restrictions as the Directors may, in accordance with the Companies Act 2014 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.

European Communities (Takeover Bids (Directive 2004/25/EC)) Regulations 2006

The Company and a subsidiary of the company, Mainstay Medical Limited ("MML") are party to a Facility Agreement dated 24 August 2015 with IPF Fund I SCA SICAV-FIS ("IPF") whereby IPF provided a debt facility to MML of up to $15 million. In certain circumstances in the event of a change of control of the Company or of MML, the debt facility may become immediately repayable at IPF's option.

Mainstay Medical International plc

Directors' responsibilities statement

Statement of the Directors in respect of the Annual Report and Financial Statements

The Directors are responsible for preparing the Annual Report and the Group and Company Financial Statements, in accordance with applicable law and regulations.

Company law requires the Directors to prepare group and company financial statements for each financial year. Under that law and in accordance with the ESM Rules, the Directors have prepared the Group Financial Statements in accordance with International Financial Reporting Standards ("IFRS") as adopted by the European Union ("EU") and have elected to prepare the Company Financial Statements in accordance with IFRS as adopted by the EU, as applied in accordance with the Companies Act 2014. The Financial Statements are required by law to give a true and fair view of the state of affairs of the Group and the Company and of the profit or loss of the Group.

In preparing each of the Group and Company Financial Statements, the Directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and estimates that are reasonable and prudent;
- state that the Financial Statements comply with IFRS as adopted by the EU, as applied in accordance with the Companies Act 2014; and
- prepare the Financial Statements on the going concern basis unless it is inappropriate to presume that the Group and the Company will continue in business.

The Directors are responsible for keeping proper books of account that disclose with reasonable accuracy at any time the financial position of the Group and Company and enable them to ensure that its Financial Statements comply with the Companies Act 2014. They have general responsibility for taking such steps as are reasonably open to them to safe guard the assets of the Group and to prevent and detect fraud and other irregularities. Under applicable law, the Directors are responsible for the maintenance and integrity of the corporate and financial information included on the Company's website. Legislation in the Republic of Ireland governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

Each of the current Directors, whose names are listed in the Corporate Information confirms that they consider that the Annual Report and Financial Statements, taken as a whole is fair, balanced and understandable and provides the information necessary for shareholders to assess the Company's and the Group's performance, business model and strategy. Each of the current Directors also confirms that to the best of each person's knowledge and belief:

- the Financial Statements prepared in accordance with IFRS as adopted by the EU give a true and fair view of the assets, liabilities and financial position of the Company and the Group and of the loss of the Group; and
- the Directors' Report contained in the Annual Report includes a fair review of the development and performance of the business and the position of the Company and Group, together with a description of the principal risks and uncertainties that they face.

The statutory Directors' Report is deemed to comprise pages 7 to 37.

On behalf of the Board on 27 April 2016,

Oern Stuge MD Peter Crosby

Chairman CEO

INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF MAINSTAY MEDICAL INTERNATIONAL PLC

We have audited the Group and Company financial statements (''financial statements'') of Mainstay Medical International plc for the year ended 31 December 2015 which comprise the consolidated statement of profit or loss and other income, the consolidated and parent company statements of financial position, the consolidated and parent company statements of changes in equity, the consolidated and parent company statements of changes in cash flows and the related notes. The financial reporting framework that has been applied in their preparation is Irish law and International Financial Reporting Standards ("IFRS") as adopted by the European Union and as regards the Company financial statements, as applied in accordance with the provisions of the Companies Act 2014.

Opinions and conclusions arising from our audit

In our opinion:

- the Group financial statements give a true and fair view of the assets, liabilities and financial position of the Group as at 31 December 2015 and of its loss for the year then ended;
- the Company statement of financial position gives a true and fair view of the assets, liabilities and financial position of the Company as at 31 December 2015;
- the Group financial statements have been properly prepared in accordance with IFRS as adopted by the European Union;
- the Company financial statements have been properly prepared in accordance with IFRS as adopted by the European Union as applied in accordance with the provisions of the Companies Act 2014; and
- the Group financial statements and Company financial statements have been properly prepared in accordance with the requirements of the Companies Act 2014.

2 Our conclusions on other matters on which we are required to report by the Companies Act 2014 are set out below

We have obtained all the information and explanations which we consider necessary for the purposes of our audit.

In our opinion the accounting records of the Company were sufficient to permit the financial statements to be readily and properly audited and the financial statements are in agreement with the accounting records.

In our opinion the information given in the Directors' Report is consistent with the financial statements.

3 We have nothing to report in respect of matters on which we are required to report by exception

ISAs (UK & Ireland) require that we report to you if, based on the knowledge we acquired during our audit, we have identified information in the annual report that contains a material inconsistency with either that knowledge or the financial statements, a material misstatement of fact, or that is otherwise misleading.

In addition, the Companies Act 2014 requires us to report to you if, in our opinion, the disclosures of directors' remuneration and transactions required by sections 305 to 312 of the Act are not made.

INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF MAINSTAY MEDICAL INTERNATIONAL PLC (*continued*)

Basis of our report, responsibilities and restrictions on use

As explained more fully in the Statement of Directors' Responsibilities set out on page 38, the Directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view and otherwise comply with the Companies Act 2014. Our responsibility is to audit and express an opinion on the financial statements in accordance with Irish law and International Standards on Auditing (UK and Ireland). Those standards require us to comply with the Financial Reporting Council's Ethical Standards for Auditors.

An audit undertaken in accordance with ISAs (UK & Ireland) involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of: whether the accounting policies are appropriate to the Group and Company's circumstances and have been consistently applied and adequately disclosed; the reasonableness of significant accounting estimates made by the Directors; and the overall presentation of the financial statements.

In addition, we read all the financial and non-financial information in the Annual Report to identify material inconsistencies with the audited financial statements and to identify any information that is apparently materially incorrect based on, or materially inconsistent with, the knowledge acquired by us in the course of performing the audit. If we become aware of any apparent material misstatements or inconsistencies we consider the implications for our report.

Whilst an audit conducted in accordance with ISAs (UK & Ireland) is designed to provide reasonable assurance of identifying material misstatements or omissions it is not guaranteed to do so. Rather the auditor plans the audit to determine the extent of testing needed to reduce to an appropriately low level the probability that the aggregate of uncorrected and undetected misstatements does not exceed materiality for the financial statements as a whole. This testing requires us to conduct significant audit work on a broad range of assets, liabilities, income and expense as well as devoting significant time of the most experienced members of the audit team, in particular the engagement partner responsible for the audit, to subjective areas of the accounting and reporting.

Our report is made solely to the Company's members, as a body, in accordance with section 391 of the Companies Act 2014. Our audit work has been undertaken so that we might state to the Company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the Company and the Company's members as a body, for our audit work, for this report, or for the opinions we have formed.

27 April 2016

Sean O'Keefe

for and on behalf of

KPMG

Chartered Accountants, Statutory Audit Firm

1 Stokes Place, St. Stephen's Green. Dublin 2

Mainstay Medical International plc

Consolidated statement of profit or loss and other comprehensive income

for the year ended 31 December 2015

	Year	Year

($'000)	Notes	ended 31 December 2015	ended 31 December 2014
Revenue		-	-
Operating expenses	5	(12,864)	(15,160)
Operating loss		(12,864)	(15,160)
Finance income	8	-	-
Finance expense	8	(323)	(67,247)
Net finance expense		(323)	(67,247)
Loss before income taxes		**(13,187)**	**(82,407)**
Income taxes	10	(48)	(58)
Loss for the year and comprehensive loss for the year		**(13,235)**	**(82,465)**
Net loss attributable to equity holders		**(13,235)**	**(82,465)**
Basic and diluted loss per share (in $)	9	($3.08)	($28.09)

The accompanying notes form an integral part of these financial statements.

Mainstay Medical International plc

Consolidated statement of financial position

at 31 December 2015

($'000)	Notes	31 December 2015	31 December 2014
Non-current assets			
Property, plant and equipment	11	242	72
Current assets			
Prepayments and other receivables	12	661	263
Income tax receivable		70	150
Cash and cash equivalents	13	16,624	18,283
Total current assets		17,355	18,696
Total assets		**17,597**	**18,768**
Equity			
Share capital	16	61	61
Share premium	16	72,588	72,584
Share based payment reserve	19	2,691	1,162
Capital conversion reserve	17	49,273	49,273
Reorganization reserve	17	(44,573)	(44,573)
Retained loss		(74,816)	(61,581)
Surplus/(deficit) on shareholders' equity		**5,224**	**16,926**
Non-current liabilities			
Loans and borrowings	14	10,084	-
Total non-current liabilities		10,084	-
Current liabilities			
Loans and borrowings	14	305	-
Income tax payable		17	15
Trade and other payables	15	1,967	1,827
Total current liabilities		2,289	1,842
Total liabilities		**12,373**	**1,842**
Total equity and liabilities		**17,597**	**18,768**

The accompanying notes form an integral part of these financial statements.

On behalf of the Board on 27 April 2016,

Oern Stuge MD Peter Crosby

Chairman CEO

Mainstay Medical International plc

Consolidated statement of changes in shareholders' equity

for the year ended 31 December 2015

($'000)	Share capital	Share premium	Capital conversion reserve	Reorgani-zation reserve	Share based payment reserve	Retained loss	Total equity
Balance at 1 January 2014	1	250	-	(9,609)	534	(13,146)	(21,970)
Comprehensive loss for the year	-	-	-	-	-	(82,465)	(82,465)
Transactions with owners of the Company:							
Share based payments	-	-	-	-	628	-	628
Effect of reorganization	55	879	-	(34,964)	-	34,030	-
Effect of European IPO:							
Issue of shares	1	23,922	-	-	-	-	23,923
Conversion of preference shares	4	47,533	49,273	-	-	-	96,810
Balance at 31 December 2014	**61**	**72,584**	**49,273**	**(44,573)**	**1,162**	**(61,581)**	**16,926**
Balance as at 1 January 2015	61	72,584	49,273	(44,573)	1,162	(61,581)	16,926
Comprehensive loss for the year	-	-	-	-	-	(13,235)	(13,235)
Transactions with owners of the Company:							
Share based payments	-	-	-	-	1,529	-	1,529
Issue of shares on exercise of share options	-	4	-	-	-	-	4
Balance at 31 December 2015	**61**	**72,588**	**49,273**	**(44,573)**	**2,691**	**(74,816)**	**5,224**

The accompanying notes form an integral part of these financial statements.

Mainstay Medical International plc

Consolidated statement of cash flows

for the year ended 31 December 2015

($'000)	Notes	Year ended 31 December 2015	Year ended 31 December 2014
Cash flow from operating activities			
Net loss attributable to equity holders		(13,235)	(82,465)
Add/(less) non-cash items			
Depreciation	11	78	32
Finance income	8	-	-
Finance expense	8	323	67,247
Share-based compensation	5	1,529	628
Add/(less) reclassifications			
Initial public offering expenses reclassified to financing activities	16	-	4,040
Reorganization costs recognized in equity reclassified to operating cash flows	16	-	(1,037)
Add/(less) changes in working capital			
Prepayments and other receivables		(391)	27
Trade and other payables		142	297
Taxes paid		19	(195)
Interest paid		(27)	(18)
Net cash used in operations		**(11,562)**	**(11,444)**
Cash flow from investing activities			
Acquisition of property and equipment	11	(248)	(36)
Net cash used in investing activities		**(248)**	**(36)**
Cash flow from financing activities			
Net proceeds from issue of shares	16	4	20,973
Net proceeds of borrowings	14	10,147	-
Repayment of borrowings	14	-	(800)
Net cash from financing activities		**10,151**	**20,173**

Net (decrease)/increase in cash and cash equivalents		**(1,659)**	**8,693**
Cash and cash equivalents at beginning of year		18,283	9,590
Cash and cash equivalents at end of year	13	**16,624**	**18,283**

The accompanying notes form an integral part of these financial statements.

Mainstay Medical International plc

Notes to the consolidated Financial Statements

1 General information and reporting entity

Mainstay Medical International plc (the "Company") is a company incorporated and registered in Ireland. Details of the registered office, the officers and advisers to the Company are presented on the Corporate and Shareholder Information page. The Company was incorporated on 17 February 2014.

The Consolidated Financial Statements ("the Financial Statements") for the years ended 31 December 2015 and 31 December 2014 comprise the results of the Company and of its subsidiaries (together the "Group").

Following a reorganization (the "2014 Corporate Reorganization" detailed in Note 2 below) on 3 April 2014, the Company became the new parent company of the Group. At 31 December 2015, the Group comprises the Company and its operating subsidiaries Mainstay Medical Limited, MML US, Inc. and Mainstay Medical (Australia) Pty. Limited. Prior to 3 April 2014, Mainstay Medical Limited was the ultimate parent company of the Group.

The Company's shares are quoted on Euronext Paris and ESM of the Irish Stock Exchange.

Mainstay is a medical device company focused on bringing to market ReActiv8®, an implantable neurostimulation system to treat disabling Chronic Low Back Pain ("CLBP").

2 Basis of preparation

Statement of compliance

The Financial Statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"), as endorsed by the European Union ("EU") and in accordance with the ESM rules of the Irish Stock Exchange. The Company Financial Statements have also been prepared in accordance with IFRS as adopted by the EU, in accordance with ESM rules and as applied in accordance with the Companies Act 2014 (the "2014 Act"), which permits a company that publishes its company and group financial statements together to take advantage of the exemption in Section 304 of the 2014 Act from presenting to its members both its company statement of profit or loss and other comprehensive income and related notes which form part of the approved company financial statements.

The Financial Statements are available on the Group's website.

The IFRSs adopted by the EU applied by the Group in the preparation of these Financial Statements are those that were effective for accounting periods beginning on or after 1 January 2015 with no early adoption of forthcoming requirements.

The Financial Statements were authorized for issue by the Board of Directors on 27 April 2016.

Going concern

The Financial Statements have been prepared on the basis that the Group is a going concern. The Directors note the following relevant matters:

- The Group has an accumulated retained losses reserve of $74.8 million and a reorganization reserve of $44.6 million (which is in substance primarily retained losses). These losses include a non-cash expense of $66.5 million incurred in 2014 related to fair valuing of embedded derivatives arising on preference shares
- The Group has not generated revenue from its operations to date and expects to continue to incur losses in the medium term
- The Group had operating cash out flows of $11.6 million during the year ended 2015 (2014: $11.4 million)
- Regulatory approval for the commercialization of ReActiv8 is not guaranteed and in the US is dependent on the successful completion of the ReActiv8-B Clinical Trial and obtaining PMA approval from the FDA

To fund the clinical trials and commercialization of ReActiv8 the Group has raised debt and equity and it continues to explore funding strategies (e.g.: equity, debt, partnering) to support the Group's activities into the future. As at 31 December 2015, the Group reported cash of $16.6 million and the last tranche of the IPF debt facility of $4.5 million can be drawn down at the Group's discretion up to 31 July 2016, following CE Marking approval of ReActiv8.

After making enquiries and having considered the conditions noted above and the options available to the Group, the Directors have a reasonable expectation that the Group can carefully monitor its cash flows and has the ability to consider alternative strategies and budgets to ensure that the Group will have sufficient funds to be able to meet its liabilities as they fall due for a period of at least 12 months from the date of the Financial Statements and are satisfied that the Financial Statements should be prepared on a going concern basis.

Basis of measurement

The Financial Statements are prepared on the historic cost method, except for:

- Share based payments, which are initially measured at grant date fair value;
- Derivative financial instruments, which are measured at fair value through profit or loss and other comprehensive income; and
- The issue of shares in the Company as part of the 2014 Corporate Reorganization as defined and discussed below, which were accounted for at fair value at the date of the 2014 Corporate Reorganization as required by the Irish Companies Act 1963.

Currency

The Financial Statements are presented in US Dollars ("$"), which is the functional and presentational currency of the Company. Balances in the Financial Statements are rounded to the nearest thousand ("$'000") except where otherwise indicated.

Use of estimates and judgements

The preparation of the Financial Statements 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 recognized in the Financial Statements are:

- Initial fair value measurement of equity-settled share based payments (Note 19);
- Measurement of derivative financial instruments held at fair value (Note 18);
- Determination of the carryover basis of accounting for the 2014 Corporate Reorganization (Note 2);
- Fair value determination of preference shares issued by the Company for the purposes of calculating the reorganization reserve following the 2014 Corporate Reorganization (Note 2 and Note 17);

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 18.

Basis of consolidation

The Financial Statements comprise the consolidated results of Mainstay Medical International plc and its subsidiaries.

2014 Corporate Reorganization

On 3 April 2014, the Company, which had no prior activity and was incorporated solely to allow the Group to apply to be listed in Europe, acquired all the issued ordinary and preference shares in Mainstay Medical Limited in exchange for issuing 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 Mainstay Medical Limited, in each case on the basis of one share in the Company in place of 20 shares of the same class in Mainstay Medical Limited. There was no change in control as a result of this transaction (the "2014 Corporate Reorganization").

As the 2014 Corporate Reorganization changed the parent company of the Group from a legal perspective only, no business combination in accordance with IFRS 3 was deemed to have occurred.

The Company accounted for this transaction as a continuation of the business of Mainstay Medical Limited on a carryover basis with assets and liabilities recorded at their historic book values, whereby the income statement is presented on a continuous basis as if no change of parent company had occurred.

The only exception to the carryover basis of accounting relates to the Company's ordinary shares that were issued as part of the 2014 Corporate Reorganization. The Irish Companies Act 1963, required that all shares issued by an Irish company must be issued at fair value. As a result, the Company recorded this required increase in the fair value of the Company's ordinary shares against their previous carrying value as an increase in Share Capital and Share Premium, with the corresponding entry recorded in the Reorganization Reserve in equity, which resulted in no change to net equity. Further details of the components of the Reorganization Reserve are provided in Note 17.

3 Significant accounting policies

The Financial Statements have been prepared applying the accounting policies as set out below. These have been applied consistently for all years presented. In addition the Group applied the standards listed below for the first time in the current year:

- Annual improvements to IFRSs 2010-2012 (effective date 1 February 2015)
- Annual improvements to IFRSs 2011-2013 (effective date 1 January 2015)
- Amendments to IAS 19 - Defined Benefit Plans: Employee Contributions (effective date 1 July 2014)

None of these have had any material impact on the Group's implementation of accounting policies or on its reported results.

A number of new standards and amendments to standards are effective for future periods. The date noted is the EU effective date:

- Annual Improvements to IFRSs 2012-2014 cycle (effective date 1 January 2016)
- Disclosure initiative (amendments to IAS 1) (effective date 1 January 2016)
- IAS 16 and IAS 38 (amended) – Property, Plant and Equipment and Intangible Assets (effective date 1 January 2016)
- IAS 16 and 41 - Bearer Plants (effective date 1 January 2016)
- IAS 27 (amended) – Separate financial statements (effective date 1 January 2016)
- IFRS 9 – Financial Instruments
- IFRS 11 (amended) – Accounting for acquisitions of interests in Joint Operations (effective date 1 January 2016)
- IFRS 15 – Revenue from contracts with customers
- Amendments to IFRS 10, IFRS 12 and IAS 28: Investment Entities: Applying the consolidation exception
- IFRS 14 – Regulatory Deferral Accruals

The above listed new standards and amendments to standards with an effective date of 1 January 2016 are not expected to have a material impact on the Group.

The above listed new standards and amendments to standards with an effective date after 1 January 2016 are under review by the Group.

a) Subsidiaries

Subsidiaries are entities controlled by the Group. The Group controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect these returns through its power over the entity. The financial statements of subsidiaries are included in the Financial Statements from the date that control commences until the date that control ceases.

b) Pension costs

The Group provides pensions to its employees in Ireland and Australia under three defined contribution schemes. Obligations for contributions to the defined contribution schemes are expensed as the related service is provided.

c) 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

d) 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.

e) Taxation

Tax expense comprises current and deferred tax. Current and deferred taxes are recognized 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 recognized 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 recognized 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 recognized 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 recognized to the extent that it is probable that there will be taxable profits in the foreseeable future against which they can be utilized.

The Group recognizes tax credits as a component of income tax in jurisdictions where the tax credit regime is not, in substance a government grant.

f) Foreign currency transactions and balances

Transactions in foreign currencies are recorded at the rate prevailing 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 consolidated profit or loss.

g) Financial instruments

I) Non-derivative financial assets

Financial assets are initially recognized on the date they are originated and when the Group obtains contractual rights to receive cash flows. The Group derecognizes 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.

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 amortized cost using the effective interest method over the contractual term of the associated liability.

Preference share liabilities

Preference shares classified as liabilities were initially recognized at fair value and subsequently measured at amortized cost using the effective interest rate method over the expected life of the associated liability.
Preference shares were classified as financial liabilities if they were redeemable on a specific date or at the option of the shareholders, if dividend payments were not discretionary, or if the conversion rights attaching to the shares required a variable number of ordinary shares be delivered by the Company in the event of conversion. The conversion option was treated as an embedded derivative and separately recognized.

Trade and other payables

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

III) Derivative financial instruments

Series A, series B and series Z shares included conversion rights which were settleable in a variable number of ordinary shares. These conversion rights were classified as derivative financial instruments in accordance with IAS 39 and were 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 18.

Embedded derivatives that meet the separation criteria of IAS 32 are recorded separately at fair value through profit or loss.

h) Equity

Ordinary share capital is recognized directly in equity at fair value on issue and is not subsequently re-measured.

i) 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 recognized 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 recognized 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 cash flows associated with the asset are discounted to their present value using a pre-tax discount rate that reflects current market conditions.

j) Provisions

A provision is recognized 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.

k) 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 recognized as it accrues. Finance costs comprise interest on borrowings, dividends on series A and series B shares recognized on an effective interest rate basis and fair value losses on derivative financial instruments.

l) Share based payments

The grant date fair value of equity-settled share based awards made to employees and non-employees is recognized as an expense, with a corresponding adjustment to equity, over the vesting period of the award. The amount recognized 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 recognized represents only vested awards.

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 option, or where such a value is not available, based on the same model as used for employee options. Options can only be settled by way of share issues.

On 3 April 2014, all outstanding share options in Mainstay Medical Limited were surrendered by the holders. In return the Company granted one share option in place of 20 share options on substantially the same terms. As this exchange reflected the terms of the 2014 Corporate Reorganization and was not beneficial to the holders, there was no impact on shareholder's equity or statement of profit or loss and comprehensive income.

m) Warrants

Warrants issued alongside debt instruments are initially recognized at fair value with a corresponding reduction in the debt instrument liability whereon this adjustment to the liability is amortized 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 equity instruments. Equity instruments are not re-measured over the life of the instrument.

n) Earnings per ordinary share

Basic earnings per share are calculated by dividing net profit/ (loss) attributable to equity holders for the year by the weighted average number of ordinary shares in issue during the year.

Diluted earnings per share are calculated by dividing net profit attributable to equity holders for the year by the weighted average number of ordinary shares in issue during the year after adjusting for the effects of all potential dilutive ordinary shares that were outstanding during the financial period.

o) Research and development expenditure

Expenditure on research is charged to the income statement in the year in which it is incurred.

Expenditure on development is charged to the income statement in the year in which it is incurred with the exception of development expenditure that is incurred in the development of an intangible asset that is available for sale; is intended to be developed for sale; and for which the likelihood of development and sale is probable; which is capitalized. No costs have been capitalized to date.

4 Segment reporting

Due to the current nature of the Group's current activities, the Group considers there to be one operating segment Active Implantable Medical Devices ("AIMD"s). The results of the Group are reported on a consolidated basis to the Chief Operating Decision Maker of the Group, the Chief Executive Officer. 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 US and Australia. The non-current assets held in these jurisdictions are detailed below:

($'000)	**31 December 2015**	31 December 2014
Europe	207	35
United States	35	37
Australia	-	-
Total non-current assets	**242**	**72**

5 Operating expenses

($'000)	**Year ended 31 December 2015**	Year ended 31 December 2014
Research and development expenses	2,694	2,601
Clinical and regulatory expenses	4,376	3,978
General and administration expenses	4,265	3,913
European IPO related expenses	-	4,040
Share-based compensation expenses	1,529	628
Total operating expenses	**12,864**	**15,160**

Expenses directly associated with the Company listing its existing shares on the ESM and Euronext Paris of $4,039,681 in May 2014, were charged directly to profit or loss in the year ended 31 December 2014.

6 Employee numbers and benefits

As of 31 December 2015, the Group's employees were based in Ireland, the United States and Australia.

The table below sets out the number of employees of the Group for each financial year shown, analyzed by category:

($'000)	**Year ended 31 December 2015**	Year ended 31 December 2014
Research and development and quality	9	5
Clinical and regulatory	6	5
General and administration	8	7
Total employee numbers	**23**	**17**
Parent company employees		
General and administration	6	5

The aggregate payroll costs of these employees, including Directors, were as follows for each financial year shown:

($'000)	**Year ended 31 December 2015**	Year ended 31 December 2014
Wages and salaries	2,812	2,396
Other remuneration	823	695

Social security costs/ payroll taxes	213	210
Share based payments	1,529	628
Pension	51	41
	5,428	**3,970**

7 Statutory information and Auditors remuneration

The loss before income tax has been arrived at after charging the following items for each financial year shown:

($'000)	**Year ended 31 December 2015**	Year ended 31 December 2014
Audit of these financial statements	47	72
Other assurance services	21	618
Taxation advisory services	42	165
Total auditor's remuneration	**110**	**855**
Depreciation of plant and equipment	78	32
Rentals payable under operating leases	176	191
Research and development expenditure	2,694	2,601

8 Net finance expense

($'000)	**Year ended 31 December 2015**	Year ended 31 December 2014
Finance income		
Fair value gain on derivative financial instruments	-	-
Foreign exchange gain	-	-
Total finance income	**-**	**-**
Finance expense		
Foreign exchange loss	(53)	(45)
Interest expense on borrowings	(270)	(33)
Fair value loss on derivative financial instruments (Note (i))	-	(66,468)
Interest on preference shares	-	(701)
Total finance expense	**(323)**	**(67,247)**
Net finance expense	**(323)**	**(67,247)**

Note (i):

The fair value loss on derivative financial instruments in 2014 represents the increase in the fair value of the embedded derivatives in the Group's preference shares between 31 December 2013 and their conversion to ordinary shares on 28 April 2014. Following conversion of these preference shares, the Company will no longer report such fair value movements through the statement of profit or loss in relation to these preference shares.

Details of the inputs into the fair value of preference shares are provided in Note 18.

9 Earnings per share

As the Group is incurring operating losses, there is no difference between basic and diluted earnings per share.

	Year ended 31 December 2015	Year ended 31 December 2014
Weighted average number of ordinary shares in issue	4,294,617	2,935,310
Loss per share	**$3.08**	**$28.09**

10 Taxes

Current income tax assets and liabilities for the current and prior years 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.

($'000)	**Year ended 31 December 2015**	Year ended 31 December 2014
Irish tax	-	146
Income tax in other jurisdictions	48	8
Deferred tax	-	(96)
Total income tax charge	**48**	**58**

Certain companies within the Group provide services to other group companies, and consequently generate revenues and profits that are subject to corporation tax in Australia and the United States.

Reconciliation of effective tax rate

($'000)	**Year ended 31 December 2015**	Year ended 31 December 2014
Loss before tax	(13,187)	(82,407)
Taxed at tax rate in Ireland of 12.5%	(1,648)	(10,301)
Non-deductible expenses	202	509
Fair value movements on derivative financial instruments	-	8,404
Tax credits	(69)	34
Foreign rate differential	35	79
Adjustments in respect of prior periods	254	-
Unrecognized tax losses	1,274	1,333
Total income tax charge/(credit)	**48**	**58**

Unrecognized deferred tax assets

The Group has unrecognized potential deferred tax assets as follows. These potential assets are not recognized because future taxable profits against which they can be utilized are not sufficiently certain. The availability of these losses does not expire.

Capital allowances on intellectual property which is recognized as an asset for tax purposes but is not capitalized under IFRS will be available should the Group generate relevant income in future periods against which the capital allowances are deductible.

($'000)	**Year ended 31 December 2015**	Year ended 31 December 2014
Carry forward tax losses:		
Opening balance	26,168	15,504
Arising during the year	10,192	10,664
Closing balance	**36,360**	**26,168**
Tax effected closing balance	**4,545**	**3,271**
Timing differences on intangible assets:		
Opening balance	15,000	15,000
Arising during the year	-	-
Closing balance	**15,000**	**15,000**
Tax effected closing balance	**1,875**	**1,875**
Share-based payments:		
Opening balance	1,158	248
Movement during the year	(228)	910
Closing balance	**930**	**1,158**
Tax effected closing balance	**372**	**463**
Total unrecognized deferred tax asset	**6,792**	**5,609**

11 Property, plant & equipment

	Computer and office equipment	Computer and office equipment
($'000)	**Year ended 31 December 2015**	Year ended 31 December 2014
Cost		
At beginning of year	130	107
Additions	248	36
Disposals	-	(13)
At end of year	378	130
Depreciation		
At beginning of year	58	39
Charge for the year	78	32
Disposals	-	(13)
At end of year	136	58
Carrying value at end of year	**242**	**72**

12 Prepayments and other receivables

($'000)	**Year ended 31 December 2015**	Year ended 31 December 2014
Prepayments	588	188
VAT recoverable	42	44
Other receivables	31	31

Total prepayments and other receivables	**661**	**263**

13 Cash and cash equivalents

($'000)	**Year ended 31 December 2015**	Year ended 31 December 2014
Cash in bank accounts – USD	16,584	18,188
Cash in bank accounts – Euro	35	83
Cash in bank accounts – AUD	5	12
Total cash and cash equivalents	**16,624**	**18,283**

14 Interest bearing loans and borrowings

IPF Debt Financing

On 24 August 2015, Mainstay Medical Limited entered into an agreement with IPF Partners for a debt facility of up to $15 million. The facility can be drawn in three tranches. Each tranche has a repayment term of 60 months from drawdown, with interest only payments for the first 12 months.

The initial tranche ("Tranche A") of $4.5 million was received on 9 September 2015. The interest rate on Tranche A is 3-month Euribor plus a margin of 12.5%.

A second tranche ("Tranche B") of $6 million was received on 3 December 2015. The interest rate on Tranche B is 3-month Euribor plus a margin of 11.5%.

Other expenses directly associated with the facility of $353,412 are capitalized and are amortized to profit or loss over the commitment term on an effective interest rate basis.

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

The terms of the agreement include a requirement that Mainstay Medical Limited hold a minimum cash balance of $2 million, or achieve revenue targets within an agreed timeframe, starting with $1 million. It also includes monthly and quarterly reporting requirements. The Group is not in breach of any covenants at 31 December 2015 and has not been in breach at any reporting date.

($'000)	**Year ended 31 December 2015**	Year ended 31 December 2014
Loans and borrowings - current		
Term loan	225	-
Deferred finance cost	(71)	-
Accrued interest	151	-
Total current loans and borrowings	**305**	**-**
Loans and borrowings – non-current		
Term loan	10,275	-
Deferred finance cost	(248)	-
Accrued interest	57	-
Total non-current loans and borrowings	**10,084**	**-**
Total loans and borrowings	**10,389**	**-**

15 Trade and other payables

($'000)	**Year ended 31 December 2015**	Year ended 31 December 2014
Trade and other payables	1,204	1,200
Payroll tax liability	81	67
Accrued expenses	682	560
Total trade and other payables	**1,967**	**1,827**

16 Called up share capital

The Company's ordinary shares are quoted in Euro and have been translated in US Dollars at the rates prevailing at the date of issue.

On 2 May 2014, the Company listed its ordinary shares on the ESM of the Irish Stock Exchange and on 5 May 2014, the Company listed its ordinary shares on Euronext Paris.

Authorized and Issued Share Capital

	31 December 2015	31 December 2014
Authorized	**€**	€
20,000,000 (2014:10,000,000) ordinary shares of €0.001 each (Note (i))	20,000	10,000
40,000 deferred shares of €1.00 each	40,000	40,000
	60,000	**50,000**

	2015	**2014**
Issued, called up and fully paid	**$**	**$**
4,298,203 (2014: 4,294,141) ordinary shares of €0.001 each	5,954	5,949
40,000 deferred shares of €1.00 each	55,268	55,268
	61,222	**61,217**
In $'000	**61**	**61**

Note (i):

At the Company's 2015 AGM on 18 June 2015, the authorized share capital of the Company was increased from €50,000 divided into 10,000,000 ordinary shares of €0.001 each (which carry voting rights) and 40,000 deferred shares of €1.00 each (which do not carry voting rights, are not entitled to receive any dividend or distribution and have in effect no right to a return of capital on a winding up), to €60,000, divided into 20,000,000 ordinary shares of €0.001 each and 40,000 deferred shares of €1.00 each following the passing of Resolution 4, set out in the Company's 2015 Notice of AGM.

Details of movement in issued shares:

On incorporation of Mainstay Medical International plc on 17 February 2014, the Company had an issued share capital of €38,500 divided into 38,500 "A" ordinary shares. Those 38,500 "A" ordinary shares were subsequently converted into 38,500 redeemable shares and redeemed at par and cancelled on 21 April 2014. On 2 April 2014, a further 41,700 Series B preference shares and 21,000 ordinary shares were issued. Gross proceeds of $53,000 were received on issue.

On 3 April 2014, Mainstay Medical International plc acquired all issued ordinary and preference shares in Mainstay Medical Limited in exchange for issuing 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 Mainstay Medical Limited, in each case on the basis of one share in the Company in place of 20 shares of the same class in Mainstay Medical Limited. The preference shares had conversion and other rights which under IFRS required that they be accounted for in part as debt liabilities and in part as derivative financial instruments. There were no cash proceeds received on the issue of these shares. Transaction costs incurred of $1,037,000 were offset against share premium. In the Consolidated Statement of Cash Flows these transaction costs are included in operating activities.

Immediately prior to the Company's European IPO, all Series A, Series B, and Series Z preference shares converted on a one-for-one basis into ordinary shares of €0.001 each in the Company. On conversion the debt and derivative components of the preference shares were derecognized from the Statement of Financial Position as the Company's liability had been settled, with the corresponding entry allocated to share capital, share premium and capital conversion reserve based requirements of the Irish Companies Act as discussed in Note 17.

On 21 April 2014 by way of a written resolution of the members of Mainstay Medical International plc, 40,000 deferred shares were issued by way of bonus issue of shares. There were no proceeds received on the issue of these shares, instead the share premium account of the Company was used to pay up the deferred shares as fully paid bonus shares.

On 2 May 2014, the Company completed an initial public offering (the "European IPO"), issuing 851,175 new ordinary shares and listing its ordinary shares on the ESM of the Irish Stock Exchange and Euronext Paris. On 28 May 2014 the underwriters for the European IPO partially exercised their over-allotment option, resulting in the issue of a further 38,264 new ordinary shares. Gross proceeds of $26 million were raised. Transaction costs of $5.1 million were incurred of which $1.1 million was included in share premium as this portion of the costs related to new ordinary shares issued, and $4 million was expensed in the statement of profit and loss and other comprehensive income. The net proceeds of $20.9 million are included in the Statement of Cash Flows in financing activities.

During 2015, 4,062 options over ordinary shares were exercised by the holders and the Company issued 4,062 ordinary shares. Proceeds of $4,062 were received on issue of the shares.

	Movement of shares					
	Number of shares					
	Ordinary shares	"A" Ordinary Shares	Deferred shares	Series A shares	Series B shares	Series Z shares
At 1 January 2014	1,628,000	-	-	15,868,520	39,343,640	10,000,000
Issue of Mainstay Medical International plc shares on incorporation	-	38,500	-	-	-	-
Issue of additional shares	21,000	-	-	-	41,700	-
Issue of deferred shares and redemption of "A" ordinary shares	-	(38,500)	40,000	-	-	-
Effect of reorganization:						
Exchange of Mainstay Medical Limited shares	(1,628,000)	-	-	(15,868,520)	(39,343,640)	(10,000,000)
Issue of Mainstay Medical International plc shares	81,400	-	-	793,425	1,967,177	500,000
Effect of European IPO						
Issue of new shares	889,439	-	-	-	-	-
Conversion of preference shares to ordinary shares	3,302,302	-	-	(793,425)	(2,008,877)	(500,000)
At 31 December 2014	**4,294,141**	-	**40,000**	**-**	**-**	**-**
At 1 January 2015	4,294,141	-	40,000	**-**	**-**	**-**
Issue of ordinary shares on exercise of share options	4,062	-	-	-	-	-
At 31 December 2015	**4,298,203**	-	**40,000**	**-**	**-**	**-**

17 Other reserves

($'000)	**31 December 2015**	31 December 2014
Reorganization reserve	(44,573)	(44,573)
Capital conversion reserve	49,273	49,273
Total other reserves	**4,700**	**4,700**

Reorganization reserve

The reorganization reserve represents a reserve related to requirements of Irish Companies Acts. It comprises (i) fair value differences on ordinary shares arising as a result of group restructurings in 2012 and 2014; and (ii) the pre-acquisition retained losses of subsidiaries at the date of the 2012 and 2014 restructurings.

Details of the movements in the Reorganization Reserve in the period are as follows:

($'000)	**Year ended 31 December 2015**	Year ended 31 December 2014
At beginning of year	44,573	9,609
Fair value movement on ordinary shares	-	934
Pre-acquisition losses of subsidiaries	-	34,030
At end of year	44,573	44,573

Fair value movement in ordinary shares

As detailed in the Group's accounting policies, the 2014 Corporate Reorganization was accounted for on a carryover basis, whereby all assets, liabilities and equity accounts continued to be accounted for using their historic book values with the exception of ordinary shares. The Irish Companies Act 1963, which applied at the date of the transaction, required that all ordinary shares issued by a Company must be issued at fair value. The difference between the previous carrying value of Mainstay Medical Limited's ordinary shares and their fair value at the date of the 2014 Corporate Reorganization was $934,000.

In accordance with the provisions of the Companies Act 1963, this amount was recorded as Share Capital and Share Premium within equity. The contra-entry was recorded within the Reorganization Reserve, also within equity.

The fair value of the ordinary shares issued was calculated in accordance with the valuation models described in Note 18.

Pre-acquisition losses of subsidiaries

The Irish Companies Act 1963, Section 149, states a holding company must not treat the pre-acquisition profits and losses of its subsidiaries as "revenue profits and losses". With reference to this, the Company determined that following the insertion of Mainstay Medical International plc as the parent company of the Group, the retained profits and losses of Mainstay Medical Limited and subsidiaries should be transferred within equity from retained earnings to the Reorganization Reserve. The retained losses as of 3 April 2014 were $34,030,000. This classification within a reorganization reserve in the Group's consolidated financial statements does not impact the distributable reserves of Company or its subsidiaries. All pre-acquisition losses of individual subsidiaries will need to be offset by sufficient subsequent distributable profits before subsidiaries will be in a position to make distributions.

Capital conversion reserve

On 28 April 2014, the Series A, Series B and Series Z preference shares of the Company were converted to ordinary shares. On that date, the carrying amount of these preference shares was determined by reference to the Company's share price for its European IPO and the number of ordinary shares into which the preference shares converted. On conversion, the preference shares which were recorded as liabilities, accumulated unpaid interest and embedded derivatives were derecognized in the statement of financial position and an equivalent amount was recognized in equity.

This was then recorded in equity reserves in accordance with the provisions of the Irish Companies Act as follows:

($'000)	
Amount recognized as share capital	4
Amount recognized as share premium	47,533
Amount recognized as capital conversion reserve	49,273
Total amount recognized in equity	**96,810**

Share capital

This represents the par value of the converted shares.

Share premium

The legal form of the Mainstay Medical International plc Series A, B and Z preference shares were issued on 4 April 2014 as part of the 2014 Corporate Reorganization. In accordance with the provisions of the Irish Companies Act 1963, this issue was required to be at fair value. The fair value of these shares on that date was $47,537,000, determined on the valuation basis outlined in Note 18. The difference between the issue price and the par value of shares must be recorded as Share Premium under the Irish Companies Act and accordingly once these shares converted to ordinary shares, this amount was presented as such within equity.

Capital conversion reserve

The fair value movement on the embedded derivatives associated with the preference shares between the issue of the shares and their conversion does not meet the definition of Share Premium under the Irish Companies Act. The Company therefore recorded this fair value movement in a "Capital Conversion Reserve" on conversion. This reserve is not distributable.

18 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
Mainstay'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 analyze 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 financial risk other than concentration of cash with individual banks 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

Credit risk is the risk of financial loss to the Group if a customer or counterparty to a financial instrument fails to meet contractual obligations, and arises principally from the Group's cash and cash equivalents.
The Group maintained its cash balances with its principal financial institutions throughout the year. The Group's principal financial institutions have investment grade ratings at year end.

Liquidity risk

Liquidity risk is the risk that the Group will not be able to meet its financial obligations as they fall due.

Since inception the Group has funded its operations primarily through (i) the issuance of equity securities and (ii) debt funding. The Group continues to explore funding strategies (e.g.: equity, debt, partnering) to support its activities into the future. Adequate additional financing may not be available on acceptable terms, or at all. The Group's inability to raise capital as and when needed would have a negative impact on the Group's financial position and its ability to pursue its business strategy.

The following is an analysis of the maturity of the contractual (undiscounted) outflows associated with the Group's financial liabilities at 31 December 2015

($'000)	Carrying value	Cash flow (total)	Less than 1 year	Between 1-2 years	Between 2-5 years
31 December 2015:					
Trade and other payables	1,984	1,984	1,984	-	-
Interest bearing loans and borrowings	10,389	15,757	1,099	3,026	11,632
At 31 December 2015	**12,373**	**17,741**	**3,083**	**3,026**	**11,632**
31 December 2014					
Trade and other payables	1,842	1,842	1,842	-	-
At 31 December 2014	**1,842**	**1,842**	**1,842**	**-**	**-**

Foreign currency risk

The Group's reporting currency is the US Dollar. The Group's exposure to foreign currency risk arises through expenditure incurred in Euro and Australian Dollars. The Group's Australian subsidiary has an Australian Dollar functional currency. The translation differences related to the consolidation of the Australian subsidiary are not material.

The Group did not have material asset or liability amounts in foreign currencies at year end other than trade payables and accruals of €394,000 arising in companies with US Dollar functional currencies. A strengthening (or weakening) of the US Dollar against the Euro of 5% would have (decreased)/ increased the loss for the year by $53,000 (2014: $3,400). Any reasonable or likely movement between the US Dollar and the Australian Dollar is considered not likely to have a material impact on the Group's statement of profit or loss and other comprehensive income.

The following table sets forth, for the years indicated, certain information concerning the exchange rate between: (i) the Euro and the US Dollar; (ii) the Australian Dollar and the US Dollar:

Euro per USD1.00	**End of year**	**Average**
Year ended 31 December 2014	1.2141	1.3211
Year ended 31 December 2015	1.0887	1.1045
Australian Dollar per USD1.00	**End of year**	**Average**
Year ended 31 December 2014	0.8187	0.8981
Year ended 31 December 2015	0.7308	0.7463

Interest rate risk

The Group's cash balances are maintained in short term access accounts and carry a floating rate of interest. A 50 basis points change in the rate of interest applied to the cash balance held by the Group would not have had a material impact on the Group's statement of profit or loss in the year.

At 31 December 2015, the principal outstanding on MML's loan from IPF was $10,500,000. This loan carries a variable rate of 3-month Euribor plus a margin ranging from 11.5% to 12.5%. The terms of the debt agreement stipulate that if Euribor is less than zero, it is deemed to be zero. Any change in the Euribor rate above zero will directly affect the amount of interest repayable on this debt.

A 25 basis point increase in Euribor above zero would not have materially increased the loss for the year (increase in loss by $26,250 on a full year basis, based on drawn down borrowings).

Fair values and carrying amounts for all financial instruments:

The following table shows the carrying amounts and fair values of financial assets and financial liabilities as at 31 December 2015 and 31 December 2014:

($'000)	Designated at fair value	Loans and receivables	Financial liabilities at amortized cost	Total carrying value	Fair value
Assets					
Cash and cash equivalents	-	16,624	-	16,624	N/A
Liabilities					
Trade and other payables	-	-	(1,984)	(1,984)	N/A
Interest bearing loans and borrowings	-	-	(10,389)	(10,389)	(10,389)
At December 2015	**-**	**16,624**	**(12,373)**	**4,251**	N/A
($'000)	**Designated at fair value**	**Loans and receivables**	**Financial liabilities at amortized cost**	**Total carrying value**	**Fair value**
Assets					
Cash and cash equivalents	-	18,283	-	18,283	N/A
Liabilities					
Trade and other payables	-	-	(1,842)	(1,842)	N/A
At December 2014	**-**	**18,283**	**(1,842)**	**(16,441)**	**N/A**

Series A, Series B and Series Z shares were classified as non-current liabilities and derivative financial instruments as at 31 December 2013. Immediately prior to the Company's European IPO in 2014, all Series A, Series B, and Series Z preference shares converted on a one-for-one basis into ordinary shares of €0.001 each in the Company.

A reconciliation of the fair values of derivative financial instruments is provided below:

($'000)	**Year ended 31 December 2015**	Year ended 31 December 2014
At beginning of year	-	4,622
Fair value movement recognized in profit or loss	-	66,468
Conversion to ordinary shares	-	(71,090)
At end of year	-	-

There were no derivative financial instruments held at 31 December 2014. The fair value of derivatives embedded in the Group's debt at 31 December 2015 was not material.

Estimation of fair values:

We disclose our financial instruments that are measured in the statement of financial position at fair value using the following fair value hierarchy for valuation inputs. The hierarchy prioritizes the inputs into three levels based on the extent to which inputs used in measuring fair value are observable in the market. Each fair value measurement is reported in one of three levels which are determined by the lowest level input that is significant to the fair value measurement in its entirety. These levels are:

- Level 1: Inputs are based upon quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: Inputs are based upon other than quoted prices included in Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices).

- Level 3: Inputs for the asset or liability that are not based on observable market data (unobservable inputs).

Cash and trade payables are settleable within 30 days and accordingly fair value is deemed to be equal to carrying value.

The fair value of interest bearing loans and borrowings is calculated based on the present value of future contractual principal plus interest cash flows discounted at appropriate market rates of interest. The fair value of interest-related embedded derivatives in the Group's debt, which were not material as at 31 December 2015, are calculated by reference to scheduled cash flows and market interest rates. These are classified as Level 2.

There were no transfers into or out of any classification of financial instruments in any period.

Details of key unobservable inputs and the 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 amortized cost as at 31 December 2015 are detailed in the table below

Type	Valuation approach	Key unobservable inputs	Interaction between key unobservable inputs and fair value
Loans and borrowings	Discounted cash flows based on contractual cash flows at a market rate of interest.	• Interest rate 13.6%-15.2%	An increase in the interest rate would reduce the fair value of the liability.

The Group held no financial instruments at amortized cost or fair value as at 31 December 2014. Series A, Series B and Series Z preference shares were classified as non-current liabilities and derivative financial instruments as at 31 December 2013. Immediately prior to the Company's 2014 European IPO, all Series A, Series B, and Series Z preference shares converted on a one-for-one basis into ordinary shares of €0.001 each in the Company. The valuation basis for these shares on conversion is outlined below:

Type	Valuation approach	Key unobservable inputs	Interaction between key unobservable inputs and fair value
Gross value of series A, B and Z shares	Option model based on probability assessment of liquidation preferences derived from the series A and series B funding rounds.	• Risk free rate (1.6%) • Volatility (60%) • 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 amortized cost	Discounted cash flows based on contractual cash flows at a market rate of interest.	• Term (5 years) • Interest rate (10%)	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 amortized cost above.	• Input as above	As above.
Loans and borrowings (excluding shares classified as liabilities)	Discounted cash flows based on contractual cash flows at a market rate of interest.	• Interest rate (10%)	An increase in the interest rate would reduce the fair value of the liability.

19 Share based payments

Stock Incentive Plan

The Group operates a share option plan (the "Plan"). As at 31 December 2015, the Plan allows for the Company to grant various classes of share options to employees of the Group companies, directors, consultants and other contractors. As at 31 December 2015, 689,424 share options over ordinary shares of the Company that have been granted under the Plan are outstanding.
The Plan allows for flexibility in the grant conditions of each individual option, including variations on the amounts of options granted, the vesting requirements for each option and the expiration terms of the options.

Share Options

Details of share options granted that are outstanding as at 31 December 2015:

	Number of instruments in thousands	Contractual life of options
Options granted in 2010	41	10 years from grant
Options granted in 2011	17	10 years from grant
Options granted in 2012	3	10 years from grant
Options granted in 2013	237	10 years from vesting
Options granted in 2014	85	10 years from vesting
Options granted in 2015	307	10 years from vesting
Total share options in issue	**690**	

The above options all include service vesting conditions related to employee and non-employee service and vest over periods ranging from one to four years. At 31 December 2015, 264,631 (2014: 168,785) options were exercisable.

The following table provides a reconciliation of the total share options in issue at the end of each year shown:

(Number of instruments in thousands)	Year ended 31 December 2015	Year ended 31 December 2014
At beginning of year	394	330
Options granted during the year	307	93
Options expired unexercised	(1)	-
Options forfeited	(6)	(29)
Options exercised	(4)	-
At end of year	**690**	**394**

Total non-cash expense charged to profit and loss in relation to share options for the year ended 31 December 2015 was $1,529,000 (2014: $628,000).

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:

	Year of Grant 2015	2014
Weighted average share price ($)	16.43-19.46	17.53 – 25.05
Weighted average exercise price ($)	16.43-19.46	17.53 – 25.05
Weighted average expected share volatility	60%	60%
Expected term (years)	7	7
Expected dividends	-	-
Risk free rate (average)	0.57%	0.86%
Fair value of option ($)	9.55 – 11.32	3.00 – 14.80

Warrants

On 2 December 2011, Silicon Valley Bank provided the Company with a loan of $2,000,000, the loan was repaid in full on 7 March 2014.

In connection with these borrowings, MML issued immediately exercisable warrants to purchase up to 13,000 shares at $7.70 per share with an expiration date of 2 December 2021. The fair value of these warrants on the date of issue was $69,000.

As at 31 December 2015 none of these warrants have been exercised.

20 Contingencies

The Directors and management are not aware of any contingencies that may have a significant impact on the financial position of the Group.

Subsidiary guarantee

The Company has guaranteed the liabilities of its subsidiary in Ireland in respect of any losses or liabilities (as defined section 357 of the 2014 Act) for the years ended 31 December 2015 and 31 December 2014.

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 $175,595 for the year ended 31 December 2015 (2014: $191,070).

The future aggregate minimum lease payments under non-cancellable operating leases are payable as follows:

($'000)	31 December 2015	31 December 2014
Within one year	121	142
After one year but no more than five years	208	17
More than five years	-	-
Total operating leases	**329**	**159**

21 Pension schemes

Defined contribution schemes

The Group operates defined contribution pension schemes for certain employees in Ireland and Australia. 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 year ended 31 December 2015 amounted to $50,781 (2014: $40,729). There were no accruals or prepayments in respect of the pension costs at 31 December 2015 (2014: None).

22 Subsidiary undertakings

At 31 December 2015, the Company had the following subsidiaries and owns 100% of the called up ordinary share capital of each such subsidiary:

- Mainstay Medical Limited is registered in the Republic of Ireland.
- MML US, Inc. is registered in the United States of America.
- Mainstay Medical (Australia) Pty. Limited is registered in Australia.

Subsequent to 31 December 2015 and prior to the date of this report, the Company incorporated the following two subsidiaries. The Company owns 100% of the called up share capital of each such subsidiary:

- Mainstay Medical Distribution Limited is registered in Ireland
- Mainstay Medical GmbH is registered in Germany

23 Related party transactions

During 2015, the Group purchased services of $64,878 (2014: $67,406) from Orsco Life Sciences AG, a company controlled by Oern Stuge MD, a Director of Mainstay Medical International plc.

There were no balances due to or from related parties as at 31 December 2015 (2014: None).

Key management compensation and Directors' remuneration

The Group defines key management as its non-executive directors, executive directors and senior management. Details of remuneration for key management personnel are provided below:

($'000)	**31 December 2015**	31 December 2014
Salaries	1,355	1,088
Non-executive directors fees	95	66
Other remuneration	818	786
Payroll taxes	137	118
Share based payments	1,248	496
Pension	21	16
Total remuneration	**3,674**	**2,570**

Aggregate amount of emoluments paid to or receivable by the Directors during the year:

($'000)	**31 December 2015**	31 December 2014
Salaries	412	457
Non-executive directors fees	95	66
Other remuneration	152	94
Payroll taxes	31	11
Share based payments	548	124
Total remuneration	**1,238**	**752**

24 Events subsequent to 31 December 2015

There were no events subsequent to the year ended 31 December 2015 that would have a material impact on the Financial Statements.

Parent Company Financial Statements

Mainstay Medical International plc

Company statement of financial position

At 31 December 2015

($'000)	Notes	**31 December 2015**	**31 December 2014**
Non-current assets			
Investment in subsidiary	(c)	50,233	49,434
Current assets			
Prepayments and other receivables	(a)	112	54
Amounts due from subsidiary undertakings		11,793	1,786
Cash and cash equivalents	(b)	7,490	17,410
Total current assets		19,395	19,250
Total assets		**69,628**	**68,684**
Equity			
Share capital	16	61	61
Share premium	16	72,588	72,584
Share based payment reserve	19	2,691	1,162
Capital conversion reserve		49,273	49,273
Retained loss		(55,580)	(54,962)
Surplus/(deficit) on shareholders' equity		69,033	68,118
Current liabilities			
Trade and other payables	(d)	595	566
Total current liabilities		595	566
Total liabilities		**595**	**566**
Total equity and liabilities		**69,628**	**68,684**

On behalf of the Board on 27 April 2016,

Oern Stuge MD Peter Crosby

Chairman CEO

Company statement of changes in equity

At 31 December 2015

($'000)	**Share capital**	**Share premium**	**Capital conversion reserve**	**Share based payment reserve**	**Retained loss**	**Total equity**
Issue of shares on incorporation	**55**	**-**	**-**	**-**	**-**	**55**
Loss for the period	-	-	-	-	(54,962)	(54,962)
Transactions with owners of the Company:						
Share based payments	-	-	-	396	-	396
Effect of reorganization	1	1,129	-	766	-	1,896
Effect of IPO:						
Issue of shares	1	23,922	-	-	-	23,923
Conversion of preference shares	4	47,533	49,273	-	-	96,810
Balance at 31 December 2014	**61**	**72,584**	**49,273**	**1,162**	**(54,962)**	**68,118**
Balance at 31 December 2014	61	72,584	49,273	1,162	(54,962)	68,118
Comprehensive loss for the year	-	-	-	**-**	(618)	(618)
Transactions with owners of the Company:						
Share based payments	-	-	-	1,529	-	1,529
Issue of ordinary shares on exercise of share options	-	4	-	-	-	4
Balance at 31 December 2015	**61**	**72,588**	**49,273**	**2,691**	**(55,580)**	**69,033**

Company statement of cash flows

At 31 December 2015

($'000)	Notes	**31 December 2015**	**31 December 2014**
Cash flow from operating activities			
Net loss attributable to equity holders		(618)	(54,962)
Add/(less) non-cash items			
Fair value of derivative financial instruments		-	49,274
Share-based compensation		730	396
Add/(less) changes in working capital			
Prepayments and other receivables		(10,065)	(1,840)
Trade and other payables		29	566
Add/(less) reclassifications			
Initial public offering expenses reclassified to financing activities		-	4,040
Reorganization costs recognized in equity reclassified to operating cash flows		-	(1,037)
Net cash used in operations		**(9,924)**	**(3,563)**
Cash flow from financing activities			
Net proceeds from issue of shares		4	20,973
Net cash from financing activities		**4**	**20,973**
Net (decrease)/increase in cash and cash equivalents		**(9,920)**	**17,410**
Cash and cash equivalents at beginning of period	(b)	17,410	-
Cash and cash equivalents at end of period		**7,490**	**17,410**

Notes to the Company Financial Statements

Notes 1, 2, 3, 16, 19, 24 to the Consolidated Financial Statements (as provided earlier herein) also directly apply to the Company Financial Statements. The accounting policies of the Company are the same as the accounting policies of the Group as set out in Note 3 to the consolidated Financial Statements, with the exception of:

Business Combinations

The Company was incorporated to be the parent company of the Group for the purposes of the initial public offering. This was accounted for in accordance with IAS 27, whereby the Company measured in its separate Financial Statements its interest in subsidiaries at the fair value of the ordinary and preference shares in issue by MML at 3 April 2014, the date of the 2014 Reorganization.

In addition, the following notes are specific to the Company statement of financial position:

(a) Prepayments and other receivables

($'000)	31 December 2015	31 December 2014
Prepayments	98	51
VAT recoverable	14	3
	112	**54**

(b) Cash and cash equivalents

($'000)	31 December 2015	31 December 2014
Cash in bank accounts – USD	7,483	17,383
Cash in bank accounts - Euro	6	26
Cash in bank accounts - AUD	1	1
	7,490	**17,410**

(c) Investment in subsidiary

($'000)	31 December 2015	31 December 2014
Opening balance	49,434	-
Investment in subsidiary	-	48,668
Effect of group share based payments	799	766
Closing balance	**50,233**	**49,434**

(d) Trade and other payables

($'000)	31 December 2015	31 December 2014
Trade and other payables	-	73
Payroll tax liability	61	43
Accrued expenses	534	450
	595	**566**

(e) Financial instruments

The Company's policies for managing financial instruments risks are the same as those for the Group. The Company's primary financial instruments and their associated risks are as follows:

Financial assets

The Company's only financial assets are cash and cash equivalents, which are held in the currencies details in note (c). A 5% change in the exchange rate between the US dollar and the Euro would have altered the Company's loss for the year by $19,500 (31 December 2014: $1,000). The carrying value of the Company's cash is the same as its fair value.

Financial liabilities

The Company's only financial liabilities are trade payables and accruals as set out in Note (d). All amounts fall due for payment within 30 days and the carrying value represents the fair value of these liabilities.

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