Mainstay Medical Publishes 2017 Full Year Results

Dublin – Ireland, 15 February 2018 – Mainstay Medical International plc ("Mainstay" or the "Company", Euronext Paris: MSTY.PA and ESM of the Irish Stock Exchange: MSTY.IE), a medical device company focused on bringing to market ReActiv8, an implantable restorative neurostimulation system to treat disabling Chronic Low Back Pain, announces today the publication of its 2017 Full Year results and Annual Report.

Business Update

- In December 2017, we announced the positive outcome of the Interim Analysis of the ReActiv8-B Study. The Independent Data Monitoring Committee recommended the continuation of the Study with a definitive size of 168 evaluable patients. The DMC also reported that they had no safety concerns in the Study.
- The ReActiv8-B Study is expected to be fully enrolled by the end of the second quarter of 2018, with a full data readout expected towards the end of 2018. The ultimate number of patients in the Study will be higher than 168 due to the nature of the enrollment process.
- Mainstay has continued to advance the initial commercialization of ReActiv8 in Europe. Our European commercial activities are initially focused on Germany, where we are working to drive adoption in a select number of high volume spine care centers to develop reference sites.
- To date, 5 centers in Germany and Ireland have implanted patients with ReActiv8, and several additional sites have been trained.
- We were recently issued a new US Patent, U.S. Patent No. 9,861,811 "Electrical Stimulator for Treatment of Back Pain and Methods of Use", bringing the total current number of US issued patents in the Mainstay portfolio to nine.

Financial Update

- Revenue during the year ended 31 December 2017 was $0.3 million (2016: nil).
- Operating expenses related to on-going activities were $27.9 million during the year ended 31 December 2017 (2016: $16.8 million).
- Cash on hand as at 31 December 2017 was $10 million (2016: $36.7 million) and operating net cash outflows for the year ended 31 December 2017 were $24.9 million (2016: $16.7 million). This operating cash outflow reflects the cost of the research and development of ReActiv8, undertaking our clinical trials, commercialization expenditure, the ongoing costs of being a public company, and running the Group.
- The Company had $7.8 million cash on hand at 31 January 2018.

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About Mainstay

Mainstay is a medical device company focused on bringing to market an innovative implantable restorative 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 its ordinary shares are admitted to trading on Euronext Paris (MSTY.PA) and the ESM of the Irish Stock Exchange (MSTY.IE).

About Chronic Low Back Pain

One of the recognized root causes of CLBP is impaired control by the nervous system of the muscles that dynamically stabilize the spine in the low back, and an unstable spine can lead to 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 the condition and the resulting days lost from work, disability benefits and health resource utilization put a significant burden on individuals, families, communities, industry and governments.

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

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

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Forward looking statements

This announcement 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 announcement 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 announcement. 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 announcement, those results or developments may not be indicative of results or developments in subsequent periods. A number of factors could cause results and developments of the Company to differ materially from those expressed or implied by the forward looking statements including, without limitation, the successful launch and commercialization of ReActiv8, the progress and success of the ReActiv8-B Clinical Trial, 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 announcement.

Mainstay Medical International plc and its subsidiaries

Annual Report

for the year ended 31 December 2017

Mainstay Medical International plc
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Forward looking statements

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Mainstay Medical International plc
Corporate and shareholder information

Directors	Oern Stuge MD, Independent Non-Executive Chairman Jason Hannon, Chief Executive Officer and Executive Director David Brabazon, Independent Non-Executive Director Greg Garfield, Non-Executive Director Nael Karim Kassar, 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 Peter Crosby, Executive Director (retired 22 September 2017)
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

2017 was a year of significant progress for Mainstay Medical International on the path to the international commercialization of ReActiv8 and I am pleased to present the Annual Report for the Company and its subsidiaries.

Business review

The successful result of the Interim Analysis of our ReActiv8-B Clinical Trial was announced in December 2017 and enrollment to reach the definitive size of evaluable patients is underway. We expect the Clinical Trial to be fully enrolled by the end of the second quarter of 2018, and to have a full data readout towards the end of the year. Additionally, we continue to advance initial commercialization in Germany and have a clear plan to invest further in commercial infrastructure, to expand commercialization in Europe, and in preparation for commercialization in other markets.

I am delighted to welcome Jason Hannon, our new Chief Executive Officer, who has been with the Company since October 2017. Jason has made an immediate and significant impact on the business. I have full confidence in his ability to drive the Company forward by bringing his extensive experience in the medical devices industry to bear.

A detailed review of the Company's corporate activity in 2017 can be found in the Directors' Report on page 8 of this Annual Report.

Finance review

Cash on hand as at 31 December 2017 was $10 million (2016: $36.7 million). Operating expenses were $27.9 million during the year ended 31 December 2017 (2016: $16.8 million) and the change relates primarily to the commencement and ramp up of the ReActiv8-B Clinical Trial and to commercialization activities.

Outlook

2018 is set to be a pivotal year for the Company. We anticipate the completion of enrolment in the ReActiv8-B Clinical Trial in the coming months and announcement full data towards the end of 2018. We intend to add to our investment in commercialization activities and infrastructure in Europe, and in preparation for commercialization in other markets. Our goal is to build our commercial presence in 2018 for meaningful commercial expansion starting in 2019.

Directors and Staff

I would like to thank the staff, consultants, clinical trial investigators and all my fellow Directors for their support and dedication, which has enabled the continued success of the Company. Of course, we also owe a debt of gratitude to all those people who agreed to be subjects in our Clinical Trials, and helped to advance ReActiv8 as an option for the millions of people suffering from Chronic Low Back Pain. I look forward to the future with optimism.

Yours faithfully,

Oern Stuge MD
Chairman
14 February 2018

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 25 years of experience in the life science sector. Dr. Stuge is the owner of ORSCO Life Sciences AG through which he holds several executive & non-executive board memberships & advisory roles.

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, an MBA from IMD, Switzerland and an INSEAD Certificate of Corporate Governance.

Jason Hannon

Jason Hannon joined Mainstay Medical as Chief Executive Officer and as a Director in October 2017. Mr. Hannon has extensive experience in the medical devices industry, particularly in the areas most critical to the future success of Mainstay: commercialization of new products, penetration of new markets, product innovation, strategic and financial planning, raising capital, regulatory and clinical management, and the building of a high-performance culture. Mr. Hannon previously served as President and Chief Operating Officer of NuVasive (NASDAQ:NUVA), a leading medical device company focused on transforming spine surgery with minimally disruptive, procedurally-integrated solutions. He helped grow NuVasive from a small U.S.-centric business with a handful of products into the third largest spine company in the world. During his 12 years at the company, and prior to becoming COO, Mr. Hannon led the international business, was responsible for business development and strategy, and also served as general counsel. During his tenure, the company's commercial presence was expanded globally to more than 40 countries, revenue grew from $61M to almost $1 billion, and the product portfolio expanded to over 100 products.

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

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 U.S. focused speciality pharmaceuticals business with its corporate headquarters in Ireland. Mr. Brabazon previously was a co-founder and Chief Financial Officer of Azur Pharma plc, which merged with Jazz Pharmaceuticals plc in early 2012. Mr. Brabazon continued to serve in the merged business as Senior Vice President of Finance and Company Secretary until late 2012. Prior to Azur Pharma, 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. Mr. Brabazon serves as a director of Headway (Ireland) Limited which provides support and services to people affected by brain injury.

Greg Garfield

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

Nael Karim Kassar

Nael Karim Kassar is an investment partner of KCK Group which follows a multi-asset strategy including venture capital and private equity.

Mr. Kassar has been a Director on the board of RefleXion Medical Inc. since April 14, 2016 and Mainstay Medical International plc since 17 June 2016. He serves as a Non-Executive Director of OnePhone Holding AB and as a Director of Aerin Medical Inc., KCK Ltd., KCK Properties Ltd., Future Finance Loan Corporation Limited, Timeshare Finance Investments Limited, Specialty Finance ICAV Limited, Judgment Acquisition Corporation Limited, High Sealed and Coupled “HSC” FZCO, Sentient Energy, Inc., Citizens Parking Inc., Affirmed Networks, Inc., GFL Environmental Holdings Inc., SiGNa Chemistry, Inc., Murosa Development S.a r.l., HPS Del Mar Holdings LLC, BioInspire Technologies, Inc., QM Power Inc., and Sonitus Technologies, Inc. He served as a Director of Tunnel Capital City Partners Inc and Hibernia NSG Limited.

Nael holds a bachelor degree in Pure Mathematics from Imperial College London together with a Masters in Advanced Studies in Mathematics from Cambridge University.

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 Corwave, Rgenix, Gecko, 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, CEO and board member of Cutera, Inc. a NASDAQ listed global device company at the forefront of the medical aesthetics space. Just prior to Cutera, he was the President and CEO of Drawbridge Health, a joint venture of GE Healthcare and GE Venture. Previous to Drawbridge, 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 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, MBA

Dr. Manus Rogan is a Managing Partner and co-founder of Fountain Healthcare Partners. He has over 27 years of investment and operating experience in the life science sector in both the U.S. and Europe. Manus earned a PhD in chemistry from the University of York (sponsored by GlaxoSmithKline) and an MBA from Trinity College Dublin.

Manus 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, Manus 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 7 years at Elan, Manus concluded over twenty-five investment and technology licensing transactions involving companies in the U.S., Europe and Japan. Manus led Fountain's investment in Innocoll Inc. and currently serves on the board of Opsona Therapeutics, Mainstay Medical (IPO, 2014), Neuromod Devices and Inflazome Ltd. He was formerly Chairman of the Irish Venture Capital Association ('IVCA') and previously represented Fountain 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 serves as Associate Director of the Innovation Fellows Program within the Institute for Engineering in Medicine at the University of Minnesota. 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 a MD from the University of Michigan, and an 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 2017.

Principal activities

Mainstay is a medical device company focused on bringing to market ReActiv8®, a new implantable restorative neurostimulation system to treat 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, the Netherlands and Germany, and its ordinary shares are admitted to trading on EuroNext Paris (MSTY.PA) and the ESM of the Irish Stock Exchange (MSTY.IE).

As at 31 December 2017, the Company together with its operating subsidiaries Mainstay Medical Limited, MML US, Inc., Mainstay Medical (Australia) Pty Limited, Mainstay Medical Distribution Limited, Mainstay Medical B.V. and Mainstay Medical GmbH 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 conduct a clinical trial of ReActiv8 in the US (the "ReActiv8-B Trial")
- Conducting the ReActiv8-B Trial 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 2017 on the relevant areas above, including updates on progress towards milestones, and analysis of expenditure and use of funds during the year.

Business review

US Pivotal ReActiv8-B Clinical Trial - The US Pivotal ReActiv8-B Clinical Trial (the "Clinical Trial") is an international, multi-center, prospective randomized sham controlled triple blinded trial with one-way crossover, conducted under an IDE from the US FDA. The Clinical Trial is intended to gather data in support of an application PMA from the FDA, a key step towards the commercialization of ReActiv8 in the US. Information about the Clinical Trial can be found at https://clinicaltrials.gov/ct2/show/study/NCT02577354.

The primary efficacy endpoint of the Clinical Trial is a comparison of responder rates between the treatment and control arms. The Clinical Trial will be considered a success if there is a statistically significant difference in responder rates between the treatment and control arms. The Clinical Trial, if successful, will provide Level 1A Evidence of efficacy of ReActiv8, which may be used to support applications for favorable reimbursement in the USA. Evidence from the Trial will also be used to support market development activities worldwide.

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

In December 2017, the independent Data Monitoring Committee "DMC" completed the Interim Analysis, which was based on data from the first 58 patients in the pivotal cohort to complete the primary endpoint. The DMC recommended continuation of the Clinical Trial with a definitive size of 168 evaluable patients. The ultimate number of patients in the Clinical Trial will be slightly higher than 168 due to the nature of the enrollment process. The DMC also reported that they have observed no safety concerns in the Clinical Trial.

The Clinical Trial is expected to be fully enrolled by the end of the second quarter of 2018. We expect to announce full data readout towards the end of 2018.

Commercialization – Mainstay has continued to advance the initial commercialization of ReActiv8 in Europe. Our European commercial activities are initially focused on Germany, where we are working to drive adoption in a select number of high volume spine care centers to develop reference sites.

To date, 5 centers in Germany and Ireland have implanted patients with ReActiv8, and several additional sites have been trained. We have begun recruiting an experienced market development and sales team of direct Mainstay employees.

We intend to add to our investment in commercial infrastructure to expand commercialization in Europe, and in preparation for commercialization in other markets including Australia and the U.S. We will be building a market development team of clinical experts to drive market penetration, identify the right physician partners, help educate the market about Reactiv8, and support implants. We will also increase our investment in the training of physicians; the education of referring physicians regarding the potential of ReActiv8; and in the collection and dissemination of clinical data regarding the expanding use of ReActiv8.

US Patents – Since our last Annual Report we were issued one new US Patent. U.S. Patent No. 9,861,811 "Electrical stimulator for treatment of back pain and methods of use" was issued bringing the total current number of issued US issued Patents in the Mainstay portfolio to nine. Mainstay continues to add to its portfolio of issued patents and pending patent applications.

ReActiv8-A Clinical Trial/PMCF Study – The ReActiv8-A Clinical Trial is an international, multi-center, prospective, single arm Clinical Trial of ReActiv8. We announced the results of the first 47 subjects implanted in this Clinical Trial, of whom, 46 reached the 90-day end point in August 2015. On 20 September 2016, we announced the one-year results from the ReActiv8-A Clinical Trial, which showed long term sustained performance. During September to November 2015, 6 additional subjects were implanted in the ReActiv8–A Clinical Trial.

Following CE marking approval, a range of activities is required for Post Market Clinical Follow Up to gather additional data on the long-term performance and safety of ReActiv8. The ReActiv8–A Post Market Clinical Follow-up ("PMCF") Study is a continuation of the ReActiv8-A Clinical Trial (but with CE Marked ReActiv8). All subjects enrolled in the ReActiv8–A Clinical Trial in Belgium and the UK will be converted to the ReActiv8-A PMCF Study. As part of the continuation of the ReActiv8-A PMCF Study, 40 additional subjects are planned to be implanted at sites in the UK.

ReActiv8-C Registry – In addition to the ReActiv8-A PMCF Study, the Group will conduct a registry. The ReActiv8-C Registry is an international, multi-center, data collection registry. All patients who will be implanted with ReActiv8 during commercialization will be invited to enroll in the ReActiv8-C Registry until the target enrollment numbers have been reached. The purpose is to gather additional summary data on the long-term performance of ReActiv8 in at least 50 patients.

Funding – The Group's debt facility provided by IPF was announced on 24 August 2015 for up to $15 million. The Group had drawn down $4.5 million on 9 September 2015, $6 million on 3 December 2015 and $4.5 million on 28 July 2016. During 2017, the Group made principal repayments of $1.8 million.

Financial review

Income statement – The first sales of ReActiv8 were recorded in the period ending 31 December 2017. Our customers are hospitals in Germany and Ireland, and are served through our direct sales force. Revenue during the twelve-month period ending 31 December 2017 was $0.3 million (2016: nil).

Cost of sales increased from nil during the year ended 31 December 2016 to $0.2 million during 2017 as a result of sales of ReActiv8 systems to customers. We purchase all elements of our product (e.g.: implantable pulse generator, leads, patient activators, surgical tools, and programmers) from third party manufacturers. Consequently, cost of sales consists primarily of acquisition costs of the elements of ReActiv8, and distribution-related expenses.

Operating expenses related to on-going activities were $27.9 million during the year ended 31 December 2017 (2016: $16.8 million). On-going activities during the financial year included research and development, clinical and regulatory activities, selling, general and administrative activities.

Research and development expenses reflect costs incurred for research, ongoing development and design. 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 on-going maintenance of our quality system. Research and development expenses were $4.2 million during the year ended 31 December 2017 (2016: $3.6 million). An increase of $0.6 million is primarily driven by expansion of the team, who will support the extensive work required to prepare the regulatory submission to the FDA following the completion of the ReActiv8-B Clinical Trial.

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

All clinical and regulatory costs are expensed as incurred. Clinical and regulatory expenses were $12.9 million during the year ended 31 December 2017 (2016: $5.6 million). The increase of $7.3 million is primarily driven by the ReActiv8-B Clinical Trial direct costs during 2017 (c. $6m of the increase), and additional payroll and consulting costs to support the implants (c. $1m of the increase). As at 31 December 2017, 137 patients had been implanted (as at 31 December 2016 4 subjects had been implanted).

Selling, general and administration expenses include costs relating to the executive, legal, finance and commercial functions. Executive, legal, and finance expenses include the salaries and other related costs for personnel, professional fees for accounting, audit and legal services, general and facilities costs such as rent, insurances and IT costs. Selling costs include the salaries of our direct sales force, costs related to the development of the Group's commercial strategy, and costs related to obtaining and expanding reimbursement for the Group's products.

Selling expenses are expected to increase as we add to our investment in commercial infrastructure in Europe, build a market development team, increase our investment in training of physicians and education of the referral network. Selling, general and administration expenses were $10.9 million during the year (2016: $7.6 million). The increase of $3.3 million is primarily driven by commercialization and the related increase in our direct sales force during 2016 and 2017 (impacting recruitment fees, payroll, travel and training costs), as well as marketing, consulting and market research costs.

Statement of financial position – Cash on hand at 31 December 2017 was $10 million (2016: $36.7 million). Total assets of the Group at year end were $13.3 million (2016: $39 million). The decrease in cash is primarily due to continuing ongoing operating expenditure and further buildup of inventory held for commercialization.

The Group's debt facility provided by IPF was announced on 24 August 2015 for up to $15 million. The Group had drawn down $4.5 million on 9 September 2015, $6 million on 3 December 2015 and $4.5 million on 28 July 2016. During 2017, the Group made principal repayments of $1.8 million.

Operating net cash outflows for the year ended 31 December 2017 were $24.9 million (2016: $16.7 million). This operating cash outflow reflects the cost of the research and development of ReActiv8, undertaking our clinical trials, commercialization expenditure, the ongoing costs of being a public company, and running the Group.

Principal risks and uncertainties

A summary of the principal risks relating to the Group and Company and/or its industry include the following:

- We have incurred significant operating losses and may not be able to achieve or subsequently maintain profitability.
- 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.
- Our future financial performance is entirely dependent on the commercial success of ReActiv8 (our only product as of the date of this Annual Report), obtaining adequate reimbursement for ReActiv8, and rates of product adoption and market penetration.
- Failure to comply with debt covenants or failure to make repayments on our debt facility could have a material adverse effect.
- We operate in a highly regulated environment and regulatory approval is required before we can market or sell ReActiv8 in any market.
- Seeking and obtaining regulatory approval for medical devices can be a long and uncertain process. Strict or changing regulatory regimes, government policies and legislation in any of our target markets may delay, prohibit or reduce potential sales.
- We are 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.

A more extensive description of the existing and future potential risks to Mainstay's business and to the Company's ordinary shares are outlined in the Risk Factors section of this report, on pages 22 to 41, and should be considered carefully by Shareholders and prospective investors.

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. Further information can be reviewed in Note 21.

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.

The Group has no significant concentrations of financial risk other than concentration of cash with individual banks. In January 2017 the Group made its first commercial sale of ReActiv8, and consequently the year ended 31 December 2017 is the first year during which the Group is exposed to credit risk arising from trade receivables. There has been no other significant change during the year or since the year end to the types or extent 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 and trade and other receivables.

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, and three of the Group's subsidiaries located in Ireland, Germany and the Netherlands have a Euro 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 10.5% to 12.5%.

Any change in the Euribor rate above zero will directly affect the amount of interest repayable on this debt.

Outlook and future developments

2018 is set to be a pivotal year for the Company. We anticipate the completion of enrolment in the ReActiv8-B Clinical Trial in the coming months and announcement full data towards the end of 2018. We intend to add to our investment in commercialization activities and infrastructure in Europe, and in preparation for commercialization in other markets. Our goal is to build our commercial presence in 2018 for meaningful commercial expansion starting in 2019.

Directors and Secretary and their interests

The names of the persons who were Directors during the year are set out on page 3.

Jason Hannon was appointed to the board as an Executive Director on 9 October 2017. Peter Crosby retired as an Executive Director on 22 September 2017.

The following Directors, Dr Oern Stuge, Dr Dan Sachs and Mr David Brabazon retired at the Company's Annual General Meeting ("AGM") held on 22 September 2017 and submitted themselves for re-election by the shareholders. The resolutions to re-elect each Director were passed at the Company's AGM on 22 September 2017.

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 2017, 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 2017**	**At 31 December 2016**
David Brabazon	Ordinary shares of €0.001 each	27,828	27,828
Dan Sachs MD	Ordinary shares of €0.001 each	515,000	515,000
Tom Maher	Ordinary shares of €0.001 each	7,702	7,702

Share options	Deemed date of grant	Exercise price per ordinary share	Expiry date	No. of ordinary shares under option as at 31 December 2017	No. of ordinary shares under option as at 31 December 2016	No. of vested options as at 31 December 2017
Oern Stuge MD	23 Jan 2013	US$1.00	10 years from vesting	55,014	55,014	55,014
Oern Stuge MD	13 Dec 2016	€15.50	10 years from vesting	17,000	17,000	4,250
Jason Hannon	6 Sept 2017	€14.85	10 years from vesting	401,862	-	-
David Brabazon	5 Dec 2013	US$1.00	10 years from vesting	18,427	18,427	18,427
David Brabazon	13 Dec 2016	€15.50	10 years from vesting	5,700	5,700	1,425
James A. Reinstein	2 Sep 2015	€16.87	10 years from vesting	20,000	20,000	11,240
James A. Reinstein	13 Dec 2016	€15.50	10 years from vesting	6,200	6,200	1,550
Tom Maher	24 Jun 2014	€17.08	10 years from vesting	32,000	32,000	27,980
Tom Maher	8 Jan 2015	€14.90	10 years from vesting	5,000	5,000	3,642
Tom Maher	2 Sep 2015	€16.87	10 years from vesting	6,000	6,000	3,360
Tom Maher	17 Dec 2015	€17.95	10 years from vesting	15,000	15,000	7,494
Tom Maher	19 Oct 2016	€16.20	10 years from vesting	20,000	20,000	5,832

Except as disclosed in this report, none of the Directors, who held office at 31 December 2017, 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 held 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 2017, Sofinnova Capital VI FCPR owned 2,165,813 ordinary shares amounting to approximately 32.7% of the entire issued ordinary share capital of the Company. As at 31 December 2016, Sofinnova Capital VI FCPR owned 2,165,813 ordinary shares amounting to approximately 32.8% of the entire issued ordinary share capital of the Company.

Manus Rogan held 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 2017, Fountain Healthcare Partners Fund 1 LP owned 796,940 ordinary shares amounting to approximately 12% of the entire issued ordinary share capital of the Company. At 31 December 2016, Fountain Healthcare Partners Fund 1 LP owned 796,940 ordinary shares amounting to approximately 12.1% of the entire issued ordinary share capital of the Company.

Nael Karim Kassar held 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 KCK Limited. At 31 December 2017, KCK Limited owned 1,153,846 ordinary shares amounting to approximately 17.4% of the entire issued ordinary share capital of the Company. At 31 December 2016, KCK Limited owned 1,153,846 ordinary shares amounting to approximately 17.5% 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:

2017:	Fees	Salary	Annual Incentive	Benefits in Kind	Total
Executive Directors					
Jason Hannon (Note 1)	$9,206	$147,269	$54,506	$4,500	$215,481
Peter Crosby (Note 2)	-	$508,634	$141,452	$24,917	$675,003
Non-Executive Directors					
Oern Stuge MD	$105,523	-	-	-	$105,523
David Brabazon	$59,094	-	-	-	$59,094
Greg Garfield	-	-	-	-	-
Nael Karim Kassar	-	-	-	-	-
Antoine Papiernik	-	-	-	-	-
James A. Reinstein	$59,094	-	-	-	$59,094
Manus Rogan PhD	-	-	-	-	-
Dan Sachs MD	-	-	-	-	-

2016:	Fees	Salary	Annual Incentive	Benefits in Kind	Total
Executive Directors					
Peter Crosby (Note 3)	-	$551,673	$140,106	$25,110	$716,889
Non-Executive Directors					
Oern Stuge MD	$102,015	-	-	-	$102,015
David Brabazon	$55,288	-	-	-	$55,288
Greg Garfield	-	-	-	-	-
Nael Karim Kassar	-	-	-	-	-
Antoine Papiernik	-	-	-	-	-
James A. Reinstein	$55,288	-	-	-	$55,288
Manus Rogan PhD	-	-	-	-	-
Dan Sachs MD	-	-	-	-	-

Notes:

1. Jason Hannon was appointed to the Board on 9 October 2017. The terms of Jason Hannon's appointment letter include $40,000 Directors Fees per annum.
2. Peter Crosby retired as an Executive Director on 22 September 2017.
3. Peter Crosby's salary and bonus in 2016 includes amounts relating to the years 2013, 2014 and 2015 of approximately $130,000 arising from adjustments related to currency and tax equalization.

None of the directors exercised any share options in either 2016 or 2017.

Issued share capital

At 31 December 2017, 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). 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 19.

At the Company's 2017 AGM held on 22 September 2017:

- 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 151% of the Company's issued ordinary share capital (by number of shares) as at the 30 August 2017. This authority will expire on 22 September 2022.
- 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 151% of the Company's issued ordinary share capital (by number of shares) as at 30 August 2017. This authority will expire on 22 September 2022.

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 2017 were any ordinary or deferred shares in the Company held or acquired by the Company or any subsidiary of the Company.

Share Option Plan 2016

The Group operates a share option plan (the "Plan"). As at 31 December 2017, 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 2017 AGM held on 22 September 2017, a special resolution was passed to amend the Articles of Association of the Company 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 at 31 December 2017 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	2,165,813	32.7%
KCK Limited	1,153,846	17.4%
Fountain Healthcare Partners Fund 1, L.P.	796,940	12.0%
Dan Sachs MD	515,000	7.8%
Perceptive Life Sciences Master Fund, Ltd	321,513	4.9%
Capricorn Health-Tech Fund NV	317,004	4.8%
Seamus Mulligan (Note 1)	281,050	4.2%
Medtronic, Inc.	235,209	3.6%

Notes:

1. Includes Ordinary Shares held by Barrymore Investments Limited (a company controlled by Seamus Mulligan)

Going concern

The Directors note the following relevant matters:

- The Group has an accumulated retained losses reserve of $124.5 million and a reorganization reserve of $44.6 million as at 31 December 2017 (31 December 2016: $94.7 million and $44.6 million respectively).
- The Group had operating cash out-flows of $24.9 million for the year ended 31 December 2017 (year ended 31 December 2016: $16.7 million).
- The group expects to incur losses due to the ongoing investment in research and development, expenditure on clinical trials and investment in commercial infrastructure.
- The Group has raised debt and equity and as it continues to explore funding strategies to support the Group's activities into the future it is confident that sufficient funding will be received to support these activities for a period of at least 12 months.

The Directors have considered the conditions noted above and other factors, and believe 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 6 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 26 to the consolidated Financial Statements.

Political and charitable donations

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

Post balance sheet events

Details of important events affecting the Company which have taken place since the end of the year are given in Note 29 to the Financial Statements.

Subsidiary undertakings

At 31 December 2017, the Company (Mainstay Medical International plc) 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.
- Mainstay Medical Distribution Limited ("MMD") was incorporated in Ireland and its principal activity is the provision of sales and distribution services.
- Mainstay Medical GmbH ("MMG") is registered in Germany and its principal activity is the provision of sales support services.
- Mainstay Medical BV ("MMBV") is registered in the Netherlands and its principal activity is the provision of management and 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's and the Group's obligation to keep adequate accounting records under section 281-285 of the Companies Act, 2014. The books of account of the Company and the Group are maintained at its registered office.

Relevant audit information

The Directors believe they have taken all steps necessary to make themselves aware of any relevant audit information and have established that the Group's statutory auditors are aware of that information. In so far as they are aware, there is no relevant audit information of which the Group's statutory auditors are unaware.

Audit Committee

The Company has established an Audit Committee, refer to page 19 for further information.

Directors Compliance Statement:

The Directors, in accordance with Section 225(2) of the Companies Act 2014, acknowledge that they are responsible for securing the Company's compliance with the Relevant Obligations (as defined by the Companies Act 2014), and the Directors confirm that:

(a) a compliance policy statement has been drawn up setting out the Company's policies that are, in their opinion, appropriate with regard to such compliance;

(b) appropriate arrangements or structures are in place that are, in their opinion designed to provide reasonable assurance of compliance in all material respects with those Relevant Obligations; and

(c) a review has been conducted, during the financial year, of those arrangements or structures.

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.

Auditors

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

A resolution authorizing the Directors to fix the auditors remuneration was passed at the Company's AGM on 22 September 2017.

On behalf of the Board on 14 February 2018,

Oern Stuge MD
Chairman

Jason Hannon
CEO

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 nor is there any specific corporate governance regime mandated in France for companies who are listed on Euronext but not incorporated in France, the Company applies 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 Company. 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 nine Directors, including one Executive Director, seven 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 each Director retire at the annual general meeting held in the third calendar year following the year in which he was appointed or last re-appointed but unless he falls within the paragraph immediately below he shall be eligible for re-appointment.

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

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 and Half-Yearly Report;
- 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 (Independent Chairman), Dr. Manus Rogan, Mr. James Reinstein (Independent) and Dr. Oern Stuge (Independent);
- Nominations Committee - Dr. Oern Stuge (Independent Chairman), Mr. David Brabazon (Independent), Mr. Antoine Papiernik and Mr. James Reinstein (Independent);
- Remuneration Committee - Mr. James Reinstein (Independent Chairman), Mr. David Brabazon (Independent), Mr. Antoine Papiernik, Dr. Manus Rogan and Dr. Oern Stuge (Independent).

Audit, Risk and Compliance Committee

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

Remuneration Committee

The Remuneration Committee is chaired by Mr. James Reinstein. It meets at least three times a year and considers and recommends to the Board the framework for the remuneration of the Chief Executive Officer, Chairman, Company Secretary, Chief Financial Officer, executive Directors and such other officers as it is designated to consider and, within the terms of the agreed policy, considers and recommends to the Board the total individual remuneration package of each executive Director including bonuses, incentive payments and share awards. It reviews the design of all incentive plans for approval by the Board and (if required) shareholders and, for each such plan, recommends whether awards are made and, if so, the overall amount of such awards, the individual awards to executive Directors and the performance targets to be used. 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 requisitions, 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 Directors 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.

Mainstay Medical International plc

Risk factors

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

RISKS RELATING TO OUR FINANCIAL CONDITION AND CAPITAL REQUIREMENTS

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

We have incurred significant net losses since we were founded. For the year ended 31 December 2017, we had a comprehensive loss of $30 million (and a comprehensive loss of $18.7 million for the year ended 31 December 2016 and $13.2 million for the year ended 31 December 2015). We fund our operations through equity capital and debt, and have raised more than $85 million of equity capital and we have drawn the full amount of the $15 million debt facility that we announced in August 2015 (the outstanding principal on this debt is $13.2 million as at 31 December 2017). We have devoted substantially all of our resources to the research and development of ReActiv8, including completion of our feasibility study in October 2012, progress on our ReActiv8-A Clinical Trial (which commenced in 2014 and led to CE Marking in May 2016), progress of our U.S. Pivotal ReActiv8-B Clinical Trial (the purpose of which is to gather data in support of an application for Pre-Market Approval ("**PMA**") from the US Food and Drug Administration ("**FDA**")), initial commercialization, 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 Annual Report is our only product) in our target markets. We have obtained CE Marking of ReActiv8, which allows for commercialization of ReActiv8 in the European Economic Area (the "**EEA**", which includes the EU, Iceland, Liechtenstein and Norway) and Switzerland. CE Marking also allows more rapid regulatory approval in certain other countries (e.g.: Australia). In January 2017 we applied for ReActiv8 to be admitted to the Australian Register of Therapeutic Goods ("**ARTG**") which would allow for commercialization in Australia. There is no assurance that commercialization in the EEA, Switzerland or Australia (if approval is obtained) will be successful or will generate sufficient revenue (and profits) to cover expenses or fund future growth.

We have not yet obtained regulatory approval for ReActiv8 in the U.S.. If U.S. regulatory approval is not obtained, then it will not be possible to commercialize ReActiv8 in the U.S.

If we are unable to obtain additional regulatory approvals for ReActiv8 in the U.S. and elsewhere, or if product development, manufacture, marketing, sales or 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.

(b) We expect to require additional funds in the future in order to meet our capital and expenditure needs and further financing may not be available when required or, if available, could require us to agree to terms which are specifically 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 pay our financial obligations as they fall due, continue research and development,

conduct Clinical Trials, continue our work to obtain regulatory approval and other activities necessary to bring ReActiv8 to target markets and to establish marketing and sales capabilities. However, we may not be able to obtain additional financing on terms 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, being, at this point, the Group's intellectual property.

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

(c) Our future financial performance is entirely dependent on the commercial success of ReActiv8, our only product as of the date of this Annual Report

Our only product as of the date of this Annual 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 manufacturing, research and development, rates of product adoption and market penetration and low sales in target markets. Because our business currently relies on the success of a single product, any factors that negatively impact the regulatory approval and commercialization of ReActiv8 would adversely affect our financial condition, business, prospects and /or results of operations.

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

On 24 August 2015, Mainstay Medical Limited entered into the IPF Facility Agreement for a debt facility of up to $15 million. Each tranche has a repayment term of 60 months from drawdown, with interest only payments for the first 12 months. As at 31 December 2017, the principal outstanding was $13.2 million.

The terms of the agreement include covenants, including a requirement that Mainstay Medical Limited hold a minimum cash balance of $2 million, or achieve revenue targets within an agreed timeframe. It also includes monthly and quarterly reporting requirements.

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

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

1.2 RISKS RELATING TO OUR BUSINESS AND INDUSTRY

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

ReActiv8 is an active implantable medical device ("**AIMD**"), which requires regulatory approval before it can be marketed or sold by us. At the date of this Annual Report, the only regulatory approval we have received is the CE conformity assessment or CE Marking for ReActiv8, which allows commercialization of ReActiv8 in the EEA and in Switzerland. In January 2017 we applied for ReActiv8 to be admitted to the ARTG which would allow for commercialization in Australia; however there is no guarantee that this application will be successful.

Regulatory approval in the U.S. is via a PMA issued by the FDA. Timing of a PMA is uncertain, as it depends on the progress and results of the Clinical Trial to gather data for a Pre-Market Approval Application ("**PMAA**"). The process typically takes significantly longer than CE Marking. Once granted, the PMA does not have an expiry date; however, regulatory approvals may be withdrawn if, for example,

a new and unexpected risk emerges that would make continued marketing of our product no longer acceptable to the FDA. There is no guarantee that further regulatory approval will be obtained for ReActiv8 or any other product we develop, either now or in the future. Any such regulatory approval may also experience delays.

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

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

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

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

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

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

In the U.S., regulatory approval is obtained via a PMA issued by the FDA. Regulatory approval can be a lengthy, expensive and uncertain process. Timing of a PMA is uncertain, as it depends on the progress and results of the Clinical Trial to gather data for a PMAA. The process typically takes significantly longer than obtaining CE Marking. Applications for regulatory approval require extensive pre-clinical, clinical and technical testing, all of which must be undertaken in accordance with the requirements of regulations and guidance for the FDA. During 2016, the Company commenced the U.S. Pivotal ReActiv8-B Clinical Trial which is intended to gather data in support of an application for PMA from the FDA.

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

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

The outcomes of Clinical Trials are by their nature uncertain and dependent on a number of variables inherent to clinical research, such as the suitability of the Clinical Trial patients for the therapy, the

experience and the expertise of the referring and implanting medical professionals, the ability and willingness of the Clinical Trial patients to perform the activities required from their participation in the trial, and the quality of the clinical follow up.

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

The U.S. Pivotal 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 patients. The costs of the Clinical Trials may exceed the resources available to us, in the medium to long term, possibly resulting in delayed completion, cost overruns, or failure to complete.

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

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

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

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

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

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

Performing Clinical Trials requires the engagement of many hospitals, clinics, and clinicians. In particular, we must engage a physician at each Clinical Trial 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 patients or perform surgery or other procedures). We may not be able to attract a sufficient number of qualified Investigators to conduct Clinical Trials within an adequate time, and those Investigators may not be able to attract or enroll a sufficient number of patients to meet our Clinical Trial objectives.

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

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

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

While the Company will take steps including physician training and certification, and having company sales representatives or field clinical specialists attend some or all implant procedures, ReActiv8 clinical performance in commercialization may be different from the clinical performance observed during the Clinical Trials for a number of reasons, including less control on the selection of people suitable for use of the product, use by physicians with different experience and/or training, and failure to adhere to a follow up regimen in the absence of Clinical Trial oversight.

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

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

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

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

(h) 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 or related concerns may limit general acceptance and adoption of ReActiv8. Lack of acceptance and adoption of ReActiv8 by a significant number of medical professionals may limit our future revenues and profitability.

(i) 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 (labelling) provided with the device to both physicians and patients.

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

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

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

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

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

Following regulatory approval and market release, device failures or malfunctions may result in a recall of the product, which may be restricted to a specific manufacturing lot or may impact all products in the field. Recalls may occur at any time during the life cycle of a device once regulatory approval has been obtained for the commercial distribution of the device. In most markets including the U.S. and the EU, authorities may request a manufacturer to carry out a recall, irrespective of whether the manufacturer itself deems this is required. Recalls can impact our business as they can be expensive, time consuming

and can divert resources and management from normal operations. Replacement of product subject to recall can be free of charge under warranty and is therefore a potential expense for us. In some cases, the cost of a recall can include the cost of the surgical procedure to replace or remove a product. In addition, a recall may impact our future sales, or may lead to the loss of key suppliers or legal action against us by people affected by a recall and/or regulatory authorities whose role it is to supervise the distribution and sale of medical devices.

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

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

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

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

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

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

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

ReActiv8 is an AIMD designed as treatment for people with Chronic Low Back Pain. Alternative therapies for this patient group may include, among others, spine surgery, physical therapy (such as lumbar extensor strengthening exercises), watchful waiting (i.e. no therapy), traction therapy, the McKenzie Method of exercise therapy, massages, drugs (including analgesics, opioids, sleep aids, muscle relaxants and anti-depressants), acupuncture, steroid injections, back schools, various types of energy application including ultrasound, transcutaneous electrical nerve stimulation ("**TENS**"), osteopathic therapy, and thermotherapy, spinal cord stimulation ("**SCS**"), and lumbar 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.

(m) 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.

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

In many countries, a series of codes is used to classify diagnoses and clinical procedures performed, and there are separate coding systems for delivery of stationary (inpatient) and ambulatory (outpatient) care. Payment for ReActiv8 is dependent on classification of the procedure that utilises ReActiv8 within these coding systems.

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

There are existing reimbursement codes applicable to ReActiv8, which hospitals can use in Germany, Switzerland and Austria.

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

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

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

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

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

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

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

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

In addition, 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.

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

We depend on a limited number of third party suppliers for the manufacture of ReActiv8 and the loss of one or more of these third party suppliers or their inability or unwillingness to supply us with adequate quantities of products could harm our business in the future. 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 have a material adverse effect on our financial condition, business, prospects and/or results of operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

adversely affected if a member of senior management transferred to another company seeking to develop a rival product.

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

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

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

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

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

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

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

(v) 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, clinical and regulatory functions, manufacturing processes, and our research and development functions.

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

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

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

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

(w) Rules relating to data privacy laws

The Company is subject to regulation regarding the processing (including disclosure and use) of personal data. The Company therefore must comply with strict data protection and privacy laws and regulations, including the Data Protection Acts 1988 and 2003 (the "**DPA**") and the European Communities (Electronic Communications Networks and Services) (Privacy and Electronic Communications) Regulations 2011 (the "**ePrivacy Regulations**").

Regulation 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (the "**GDPR**") will take effect from 25 May 2018, and will replace the DPA as the primary legislation governing the use of personal data. GDPR introduces substantial changes to data protection law, including an increased emphasis on businesses being able to demonstrate compliance with their data protection obligations, which will require investment by the Company in its compliance strategies. In addition, relevant supervisory authorities are given the power to issue fines of up to 4 per cent. of an undertaking's annual global group turnover or €20 million (whichever is the greater) for failure to comply with certain provisions of the GDPR. The EC recently released its proposal for a new European ePrivacy Regulation.

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

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

In 2014 the Group undertook the 2014 Corporate Reorganization during which the Company acquired the assets (being shares in MML) of Mainstay Medical Inc. ("**MMI**") (a U.S. corporation), and former shareholders of MMI became shareholders of the Company. The ownership of equity that former shareholders of MMI received in the 2014 Corporate Reorganization is substantially below the 80 per cent. standard for application of the above U.S. rules. Accordingly, the Directors do not believe these rules should apply. There can, however, be no assurance that the IRS will not challenge the determination that these rules are inapplicable. In addition to the 2014 Corporate Reorganization, there was an earlier Group reorganization transaction in 2012. The Directors do not believe integrated treatment of this transaction with the 2014 Corporate Reorganization to be appropriate because there are independent business reasons for undertaking these transactions. In the event that the U.S. anti-

inversion rules are held to apply to us, we would be subject to the U.S. federal income tax on our worldwide income, which would negatively impact the cash available for distribution and the value of the Ordinary Shares.

(y) We are exposed to foreign exchange risk

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

1.3 RISKS RELATING TO INTELLECTUAL PROPERTY

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

Our success depends significantly on our ability to protect our proprietary rights, including the intellectual property related to and incorporated in ReActiv8. We rely on a combination of patent protection, trademarks and trade secrets, and we use confidentiality and other contractual agreements to protect our intellectual property. We generally seek patent protection where possible for those aspects of our technology and product that, the Directors believe, provide significant competitive advantages. As at the date of this report, our patent portfolio includes nine granted U.S. patents, 41 patents outside the U.S. and 33 U.S. and foreign patent applications in the patent families. However, we may be unable to adequately protect our intellectual property rights or may become subject to a claim of infringement or misappropriation, which we may be unable to settle on commercially acceptable terms. We cannot be certain that our pending or future patent applications will result in issued patents. In addition, we do not know whether any issued patents will be upheld as valid or will be proven to be enforceable against alleged infringers or that they will prevent the development of competitive patents or provide meaningful restriction against potential competitors or against potential competitive technologies.

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

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

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

There is no assurance that our intellectual property rights will not be challenged, invalidated, circumvented or rendered unenforceable. Parties seeking to compete with us (directly or indirectly) or other third parties may successfully challenge and invalidate or render unenforceable our issued

patents, including any patents that may be issued in the future or could develop competitor products to ReActiv8. This could prevent or limit our ability to stop potential competitors from marketing products that are identical or substantially equivalent to ours. In addition, such parties may be able to design around our patents, obtain competitive patents or other intellectual property rights regardless of prior art in our patents or patent applications, or develop products that provide outcomes that are comparable to our product but that are not covered by our patents.

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

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

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

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

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

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

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

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

substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on 16 March 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defence of our issued patents, all of which could have a material adverse effect on financial condition, business, prospects and results of operations.

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

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

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

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

Filing, prosecuting and defending patents on 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 U.S.. Consequently, we may not be able to prevent third parties from practicing our inventions in some or all countries outside the U.S.. Potential competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities.

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

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

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

1.4 RISKS RELATING TO OUR SHARES

(a) We may be a passive foreign investment company ("PFIC") for 2018 or subsequent years, which could result in adverse U.S. federal income tax consequences to U.S. investors

For U.S. federal income tax purposes, a non-U.S. corporation will be considered a passive foreign investment company, or PFIC, for any taxable year if either (1) at least 75% of its gross income for such year is passive income or (2) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during such year) is attributable to assets that produce or are held for the production of passive income. If we are a PFIC for any taxable year during which a U.S. holder holds shares, the U.S. holder may be subject to adverse tax consequences, including (1) the treatment of any gain on disposition as ordinary income, rather than capital gain qualifying for preferential rates, (2) the application of an interest charge with respect to such gain and certain dividends and (3) compliance with certain reporting requirements. The Directors do not believe that the Company was a PFIC for its 2017 taxable year, although the U.S. Internal Revenue Service ("**IRS**") may disagree with this conclusion in the event it audits any U.S. shareholder's tax reporting. Based on the value and composition of our assets, we may, however, be a PFIC for 2018 and potentially for future taxable years. The determination of PFIC status is fact-specific, and a separate determination must be made for each taxable year (after the close of each such taxable year). Each U.S. shareholder is strongly urged to consult its tax advisors regarding these issues.

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

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

- actual or anticipated fluctuations in our financial condition and operating results;
- our failure to obtain regulatory approval for ReActiv8 beyond CE Marking;
- our failure to commercialize ReActiv8;
- adverse results or delays in our Clinical Trials;
- actual or anticipated changes in our growth rate;
- competition from existing products or new products that may emerge;
- announcements by us, our collaborators or our potential competitors of significant acquisitions, strategic partnerships, joint ventures, strategic alliances, or capital commitments;
- adverse regulatory decisions;
- the inability to establish potential strategic alliances;
- unanticipated serious safety concerns related to the use of our product;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;

- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- price and volume fluctuations in trading of our Ordinary Shares on 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;
- issuances by the Company of Ordinary Shares or transfers or sales of Ordinary Shares by shareholders;
- issue or exercise of share warrants or share options; and
- general economic and market conditions.

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

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

Our eight largest Shareholders together own approximately 87.6% of our Ordinary Shares in issue at the date of this report. As a result, these Shareholders (or a combination of some of these Shareholders), if they were to act together, would have significant influence over all matters that require approval by our ordinary Shareholders, including the election of directors and approval of significant corporate transactions. Subject to customary Shareholder protections on takeovers and related party transactions, corporate action might be taken even if other ordinary shareholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other ordinary Shareholders may view as beneficial.

(d) 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 downgrades this 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.

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

Company. 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.

(f) 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% for Irish tax residents) 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 U.S., 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.

(g) 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 generally 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 or ordinarily resident for tax purposes in Ireland). Shareholders who are not resident or ordinarily resident for tax purposes in Ireland who receive dividends subject to Irish dividend withholding tax will generally have no further liability to Irish income tax on those dividends.

(h) Any sale, purchase or exchange of the Ordinary Shares may become subject to the European Financial Transaction Tax

In February 2013 the European Commission published a proposal for a Council Directive implementing enhanced cooperation for a financial transaction tax ("**FTT**") requested by Austria, Belgium, Estonia, France, Germany, Greece, Italy, Portugal, Slovakia, Slovenia and Spain (the "Participating Member States"). However, on 16 March 2016, Estonia completed the formalities required to cease participation in the enhanced cooperation on FTT.

Under the Commission Proposal, the proposed FTT would apply to certain financial transactions where at least one party is a financial institution, and at least one party is established in a Participating Member State or the financial instrument in which the parties are dealing is issued in a Participating Member State. The FTT may apply to both transaction parties where one of these circumstances applies.

Under the Commission Proposal, the FTT would not apply to (inter alia) primary market transactions referred to in Article 5(c) of Regulation (EC) No 1287/2006, including the activity of underwriting and subsequent allocation of financial instruments in the framework of their issue.

Certain aspects of the Commission Proposal are controversial and, while the Commission Proposal initially identified the date of introduction of the FTT across the Participating Member States as being 1 January 2014, this anticipated introduction date has been extended on several occasions due to disagreement among the Participating Member States regarding a number of key issues concerning the scope and application of the FTT. However, the details and timing of the FTT remain to be agreed.

The FTT proposal is still subject to negotiation between the Participating Member States and therefore may be changed at any time. Moreover, once a final agreement on such FTT proposal is reached (the "**FTT Directive**"), it will need to be implemented into the respective domestic laws of the Participating Member States and the domestic provisions implementing the FTT Directive might deviate from the FTT Directive itself.

In any case, investors should consult their own advisers in relation to the consequences of the FTT associated with subscribing for, purchasing, holding and disposing of Ordinary Shares.

(i) The rights of our shareholders in respect of our corporate affairs may differ from the rights typically offered to shareholders of a typical U.S. corporation or other non-Irish corporations, 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 U.S. corporations or other non-Irish corporations and these differences may make our shares less attractive to investors. The principal differences, regarded by the Board, 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 dis-applied 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 2017, shareholders approved, for a period ending on 22 September 2022, the disapplication of statutory pre-emption rights with respect to the issuance of share capital with a nominal value of €10,000, representing approximately 151% of our issued Ordinary Shares as at 30 August 2017. 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 dis-apply 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;
- 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; and
- 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.

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

As an Irish company, we are governed by the Irish Companies Act 2014 and Irish company law generally, which differ in some material respects from laws generally applicable to typical U.S. corporations and other non-Irish corporations and their shareholders, including, among others, differences relating to interested director and officer transactions and shareholder lawsuits. Likewise, the duties of directors and officers of an Irish company generally are owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or other officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. You should also be aware that Irish law does not allow for any terms of legal

proceedings directly equivalent to the class action available in U.S. courts. Accordingly, holders of our shares may have more difficulty protecting their interests than would holders of shares of a company organised in a jurisdiction of the U.S..

(k) 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 *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.

The Company is currently the only shared jurisdiction company (current or previous) for the purposes of the Takeover Directive where, in the case of a takeover offer, the relevant competent authorities 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.

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

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

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 also 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. Under company law the directors must not approve the Group and Company financial statements unless they are satisfied that they give a true and fair view of the assets, liabilities and financial position of the Group and Company and of the Group's profit and loss for the year.

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, and as regards the Company 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 adequate accounting records which disclose with reasonable accuracy at any time the assets, liabilities, financial position and profit or loss of the Company and which enable them to ensure that the financial statements of the Company comply with the provisions of the Companies Act 2014. The Directors are also responsible for taking all reasonable steps to ensure such records are kept by its subsidiaries which enable them to ensure that the financial statements of the Group comply with the provisions of the Companies Act 2014. They are also responsible for safeguarding the assets of the Company and the Group, and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities. The Directors are also responsible for preparing a Directors' Report that complies with the requirements of the Companies Act 2014.

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 as at 31 December 2017 and of the loss of the Group for the year then ended; and
- the Directors' Report contained in the Annual Report includes a fair review of the development and performance of the business for the year then ended and the position of the Company and Group as at 31 December 2017, together with a description of the principal risks and uncertainties that they face.

The statutory Directors' Report is deemed to comprise pages 8 to 21.

On behalf of the Board on 14 February 2018,

Oern Stuge MD
Chairman

Jason Hannon
CEO

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

1 Opinion: our opinion is unmodified

We have audited the financial statements of Mainstay Medical International plc ("the Company") for the year ended 31 December 2017 which comprise the consolidated statement of comprehensive income, the consolidated and Company statements of financial position, the consolidated and Company statement of changes in equity, the consolidated and Company statements of cash flows, and the related notes, including the accounting policies set out in note 3.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.

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 2017 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 2017;
- 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 and, as regards the Group financial statements, Article 4 of the IAS Regulation.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (Ireland) ("ISAs (Ireland)") and applicable law. Our responsibilities are described below in the Auditor's responsibilities section of our report. We have fulfilled our ethical responsibilities under, and we remained independent of the Group in accordance with, ethical requirements applicable in Ireland, including the Ethical Standard issued by the Irish Auditing and Accounting Supervisory Authority (IAASA) as applied to listed public interest entities. We believe that the audit evidence we have obtained is a sufficient and appropriate basis for our opinion.

2 Key audit matters: our assessment of risks of material misstatement

Key audit matters are those matters that, in our professional judgement, were of most significance in the audit of the financial statements and include the most significant assessed risks of material misstatement (whether or not due to fraud) identified by us, including those which had the greatest effect on: the overall audit strategy; the allocation of resources in the audit; and directing the efforts of the engagement team. These matters were addressed in the context of our audit on the financial statements as a whole and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

In arriving at our audit opinion above, the key audit matters were as follows. Revenue recognition and share based payments have been identified as key audit matters for the first time in 2017:

Revenue recognition $0.35 million (2016 - $Nil)
Refer to note 3(a) (accounting policy) and note 5 (financial disclosures)

The key audit matter	How the matter was addressed in our audit
Revenue recognition contains an inherent fraud risk relating to the judgement in respect of the timing of revenue recognition and the transfer of substantial risks to the customer, particularly where there are master supply arrangements.	We obtained an understanding of the company's revenue process, which included the identification of anti-fraud controls and testing the design and implementation of these controls. Our substantive audit procedures included, among others, performing the following audit tests for a sample of transactions selected based on magnitude of the individual transaction and/or the amount of revenue recognized in the year: - We tested the existence and accuracy of a sample of revenue transactions in the period, by agreeing revenues to orders, invoices and cash receipts where appropriate and assessed the appropriateness of the timing of transactions close to the period end by agreeing individual transactions to documents confirming the timing of revenue recognition; and - We performed procedures to confirm the appropriate authorization of manual journals entries posted to the revenue account. Based on the procedures performed we identified no material errors and found the disclosures relating to revenue to be sufficient.

Share Based Payment Charge $3.045 million (2016 - $1.959 million)
Refer to note 3(m) (accounting policy) and note 22 (financial disclosures)

The Group operates a share option plan. The accounting for this plan involves making judgements in respect of the inputs to the valuation models, including assessments of the expected term of options to exercise and expected share price volatility. Changes in the assumptions and estimates used could have a material impact on the results and financial position of the Group.	In this area our audit procedures included - We obtained an understanding of the Group's Share based incentive scheme process, which included the testing of the design and implementation of the controls forming part of the process; - As certain inputs to the model are factual, we tested a sample of this data to source documentation. This included verifying information, such as share price, to external sources; - We assessed the reasonableness of the key assumptions used by management, which included a comparison of these key assumptions against externally derived data, where available. We also considered the adequacy of the Group's disclosures in respect of these assumptions.

Based on the procedures performed over share based payments, we did not identify any material management bias in the calculation of the charge. We found the disclosures relating to the share based payments per the financial statements to be appropriate.

Share based payment charge – Parent Company

The parent company's activities are to act as a holding company with limited transactions with its subsidiaries and as the principal in the Group's share based payment arrangements. There were no key audit matters related to our audit of the Parent Company financial statements other than in respect of share based payments as discussed above.

3 Our application of materiality and an overview of the scope of our audit

The materiality for the Group financial statements as a whole was set at $0.14 million (2016: $0.09 million). This was calculated with reference to a benchmark of operating expenses. Materiality represents 0.5% of this benchmark.

We report to the Audit and Risk Committee all corrected and uncorrected misstatements we identified through our audit with a value in excess of $0.02 million (2016: $0.02 million), in addition to other audit misstatements below that threshold that we believe warrant reporting on qualitative grounds.

Materiality for the parent company financial statements as a whole was set at $0.14 million (2016: $0.09 million). This was initially determined with reference to a benchmark of total assets, of which it represents 0.5%, but restricted to the absolute amount of Group materiality.

The Group audit team performed the audit of the Group as if it was a single aggregated set of financial information which included the audit of the parent company. The audit was performed using the materiality level set out above.

4 We have nothing to report on going concern

We are required to report to you if we have concluded that the use of the going concern basis of accounting is inappropriate or there is an undisclosed material uncertainty that may cast significant doubt over the use of that basis for a period of at least twelve months from the date of approval of the financial statements. We have nothing to report in these respects.

5 We have nothing to report on the other information in the annual report

The directors are responsible for the other information presented in the financial statements. The other information comprises the information other than the financial statements and our auditor's report thereon which is included in the directors' report, the chairman's statement, the corporate governance report and the report on risk factors. Our opinion on the financial statements does not cover the other information and, accordingly, we do not express an audit opinion or, except as explicitly stated below, any form of assurance conclusion thereon.

Our responsibility is to read the other information and, in doing so, consider whether, based on our financial statements audit work, the information therein is materially misstated or inconsistent with the financial statements or our audit knowledge. Based solely on that work we have not identified material misstatements in the other information.

Based solely on that work, we report that

- we have not identified material misstatements in the directors' report or other accompanying information;
- in our opinion, the information given in the directors' report and other accompanying information is consistent with the financial statements;
- in our opinion, the directors' report has been prepared in accordance with the Companies Act 2014.

In addition as required by the Companies Act 2014, we report, in relation to information given in the Corporate Governance Statement on pages 18 to 21, that:

- based on the work undertaken for our audit, in our opinion, the description of the main features of internal control and risk management systems in relation to the financial reporting process, and information relating to voting rights and other matters required by the European Communities (Takeover Bids (Directive 2004/EC) Regulations 2016 and specified for our consideration, is consistent with the financial statements and has been prepared in accordance with the Act; and
- based on our knowledge and understanding of the company and its environment obtained in the course of our audit, we have not identified any material misstatements in that information.

We also report that, based on work undertaken for our audit, other information required by the Act is contained in the Corporate Governance Statement.

6 Our opinions on other matters prescribed the Companies Act 2014 are unmodified

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

In our opinion, the accounting records of the Group and Company were sufficient to permit the financial statements to be readily and properly audited and the Group's statement of financial position and the profit and loss account is in agreement with the accounting records.

7 We have nothing to report on other matters on which we are required to report by exception

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

8 Respective responsibilities

Directors' responsibilities

As explained more fully in their statement set out on page 42, the directors are responsible for: the preparation of the financial statements including being satisfied that they give a true and fair view; such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error; assessing the Group and parent Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern; and using the going concern basis of accounting unless they either intend to liquidate the Group or the parent Company or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue our opinion in an auditor's report. Reasonable assurance is a high level of assurance, but does not guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud, other irregularities or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements. The risk of not detecting a material misstatement

resulting from fraud or other irregularities is higher than for one resulting from error, as they may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control and may involve any area of law and regulation not just those directly affecting the financial statements.

A fuller description of our responsibilities is provided on IAASA's website at https://www.iaasa.ie/getmedia/b2389013-1cf6-458b-9b8f-a98202dc9c3a/Description_of_auditors_responsiblities_for_audit.pdf

9 The purpose of our audit work and to whom we owe our responsibilities

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 our report, or for the opinions we have formed.

Sean O'Keefe *14 February 2018*
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 2017

($'000)	Notes	Year ended 31 December 2017	Year ended 31 December 2016
Revenue	5	348	-
Cost of sales		(190)	-
Gross profit		158	-
Operating expenses	6	(27,877)	(16,828)
Operating loss		(27,719)	(16,828)
Finance income	9	46	-
Finance expense	10	(1,932)	(1,808)
Net finance expense		(1,886)	(1,808)
Loss before income taxes		**(29,605)**	**(18,636)**
Income taxes	12	(230)	(122)
Loss for the year		**(29,835)**	**(18,758)**
Net loss attributable to equity holders		**(29,835)**	**(18,758)**
Basic and diluted loss per share (in $)	11	($4.51)	($3.38)
Other Comprehensive Income			
Items that may be reclassified subsequently to the statement of profit or loss:			
Foreign currency translation differences of foreign operations		(142)	35
Total comprehensive loss for the year		**(29,977)**	**(18,723)**
Total comprehensive loss attributable to equity holders		**(29,977)**	**(18,723)**

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

Mainstay Medical International plc
Consolidated statement of financial position
at 31 December 2017

($'000)	Notes	31 December 2017	31 December 2016
Non-current assets			
Property, plant and equipment	13	201	255
Current assets			
Trade and other receivables	14	571	889
Income tax receivable		205	103
Inventory	15	2,395	1,123
Cash and cash equivalents	16	9,975	36,670
Total current assets		13,146	38,785
Total assets		**13,347**	**39,040**
Equity			
Share capital	19	64	64
Share premium	19	106,414	106,360
Share based payment reserve	22	7,613	4,606
Other reserves	20	4,593	4,735
Retained loss		(124,505)	(94,707)
Shareholders' equity		**(5,821)**	**21,058**
Non-current liabilities			
Loans and borrowings	17	11,177	13,276
Total non-current liabilities		11,177	13,276
Current liabilities			
Loans and borrowings	17	3,214	2,268
Income tax payable		124	58
Trade and other payables	18	4,653	2,380
Total current liabilities		7,991	4,706
Total liabilities		**19,168**	**17,982**
Total equity and liabilities		**13,347**	**39,040**

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

On behalf of the Board on 14 February 2018,

Oern Stuge MD
Chairman

Jason Hannon
CEO

Mainstay Medical International plc
Consolidated statement of changes in shareholders' equity
for the year ended 31 December 2017

($'000)	Share capital	Share premium	Unde-nominated capital reserve	Reorgani-zation reserve	Foreign currency translation reserve	Share based payment reserve	Retained loss	Total equity
Balance as at 1 January 2016	61	72,588	49,273	(44,573)	-	2,691	(74,816)	5,224
Profit and loss	-	-	-	-	-	-	*(18,758)*	*(18,758)*
Other comprehensive income	-	-	-	-	*35*	-	-	*35*
Total comprehensive loss for the year	**-**	**-**	**-**	**-**	**35**	**-**	**(18,758)**	**(18,723)**
Transactions with owners of the Company:								
Issue of Shares	3	33,725	-	-	-	-	(1,177)	32,551
Share based payments	-	-	-	-	-	1,959	-	1,959
Issue of shares on exercise of share options or warrants	-	47	-	-	-	(44)	44	47
Balance at 31 December 2016	**64**	**106,360**	**49,273**	**(44,573)**	**35**	**4,606**	**(94,707)**	**21,058**
Balance as at 1 January 2017	64	106,360	49,273	(44,573)	35	4,606	(94,707)	21,058
Profit and loss	-	-	-	-	-	-	*(29,835)*	*(29,835)*
Other comprehensive income	-	-	-	-	*(142)*	-	-	*(142)*
Total comprehensive loss for the year	**-**	**-**	**-**	**-**	**(142)**	**-**	**(29,835)**	**(29,977)**
Transactions with owners of the Company:								
Issue of Shares	-	-	-	-	-	-	-	-
Share based payments	-	-	-	-	-	3,044	-	3,044
Issue of shares on exercise of share options or warrants	-	54	-	-	-	(37)	37	54
Balance at 31 December 2017	**64**	**106,414**	**49,273**	**(44,573)**	**(107)**	**7,613**	**(124,505)**	**(5,821)**

The undenominated capital reserve, reorganization reserve and foreign currency translation reserve are shown as "other reserves" in the statement changes of financial position and within Note 20.

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

Mainstay Medical International plc
Consolidated statement of cash flows
for the year ended 31 December 2017

($'000)	Notes	Year ended 31 December 2017	Year ended 31 December 2016
Cash flow from operating activities			
Loss for the year		(29,835)	(18,758)
Add/(less) non-cash items			
Depreciation	13	107	120
Finance income		(46)	-
Finance expense	10	1,932	1,808
Share-based compensation	22	3,044	1,959
Add/(less) changes in working capital			
Trade and other receivables		318	(454)
Inventory		(1,272)	(929)
Trade and other payables		2,406	561
Taxes paid		(265)	(117)
Interest paid		(1,285)	(934)
Net cash used in operations		**(24,896)**	**(16,744)**
Cash flow from investing activities			
Acquisition of property and equipment	13	(53)	(195)
Net cash used in investing activities		**(53)**	**(195)**
Cash flow from financing activities			
Gross proceeds from issue of shares	19	54	33,775
Transaction costs on issue of shares		-	(1,177)
Proceeds of borrowings		-	4,500
Repayment of borrowings		(1,800)	
Transaction costs on issue of borrowings		-	(113)
Net cash from financing activities	28	**(1,746)**	**36,985**
Net (decrease)/increase in cash and cash equivalents		**(26,695)**	**20,046**
Cash and cash equivalents at beginning of year		36,670	16,624
Cash and cash equivalents at end of year	16	**9,975**	**36,670**

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 Consolidated Financial Statements ("the Financial Statements") for the years ended 31 December 2017 and 31 December 2016 comprise the results of the Company and of its subsidiaries (together the "Group").

At 31 December 2017, the Group comprises the Company and its operating subsidiaries Mainstay Medical Limited, MML US, Inc., Mainstay Medical (Australia) Pty. Limited, Mainstay Medical Distribution Limited, Mainstay Medical BV and Mainstay Medical GmbH.

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 restorative 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, 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 2017 with no early adoption of forthcoming requirements.

The Financial Statements were authorized for issue by the Board of Directors on 14 February 2018.

Going concern

The Directors note the following relevant matters:

- The Group has an accumulated retained losses reserve of $124.5 million and a reorganization reserve of $44.6 million as at 31 December 2017 (31 December 2016: $94.7 million and $44.6 million respectively).
- The Group had operating cash out-flows of $24.9 million for the year ended 31 December 2017 (year ended 31 December 2016: $16.7 million).
- The group expects to incur losses due to the ongoing investment in research and development, expenditure on clinical trials and investment in commercial infrastructure.
- The Group has raised debt and equity and as it continues to explore funding strategies to support the Group's activities into the future it is confident that sufficient funding will be received to support these activities for a period of at least 12 months.

The Directors have considered the conditions noted above and other factors, and believe 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.

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

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 22).

Basis of consolidation

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

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 following standards for the first time in the current year:

- Disclosure initiative (amendments to IAS 7) (effective date 1 January 2017)
- IAS 12 (amended) – recognition of deferred tax assets for unrealized losses (IASB effective 1 January 2017)

None of the above 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 have an effective date of 1 January 2018. These standards and amendments to standards are not yet effective and have not been early adopted.

- IFRS 15 - Revenue from Contracts with Customers (effective date 1 January 2018):

This standard is a converged standard from the IASB and the Financial Accounting Standards Board ('FASB') on revenue recognition. The standard will improve the financial reporting of revenue and improve comparability of the top line in Financial Statements globally. Due to the stage of development of the Group, and the nature of the Group's current activities (the Group has only one product, ReActiv8, and some related accessories and services available for sale), this new standard is not expected to have a material impact on the group.

- IFRS 9 – Financial Instruments - (effective date 1 January 2018):

This standard replaces the guidance in IAS 39 'Financial Instruments: Recognition and Measurement'. It includes requirements on the classification and measurement of financial assets and liabilities; it also includes an expected credit losses model that replaces the current incurred loss impairment model for financial assets. IFRS 9 contains three new principal classification categories for financial assets (measured at amortized cost; FVOCI; and FCTPL), IFRS 9 largely retains the existing requirements in IAS 39 for the classification of financial liabilities. This standard is not expected to have a material impact on the Group's reported results and the Group will continue to monitor any potential future bad debt provisions that may arise.

- Annual Improvements to IFRSs 2014 – 2016 Cycle: Amendments to IFRS 1 First time Adoption of IFRSs and IAS 28 Investment in Associates and Joint Ventures (IASB effective date 1 January 2018, not yet endorsed by the EU):

A number of small amendments IAS 28, and removal of outdated exemptions for first-time adopters of IFRS from IFRS 1. These amendments are not expected to have a material impact on the Group.

A number of new standards and amendments to standards have an effective date after 1 January 2018. The new standards and amendments to standards with an effective date after 1 January 2018 are under review by the Group:

- IFRS 16 – Leases (IASB effective 1 January 2019, endorsed by the EU)
- IFRIC 23 Uncertainty over Income Tax Treatments (IASB effective 1 January 2019, not yet endorsed by the EU)
- Prepayment Features with Negative Compensation - Amendments to IFRS 9 (IASB effective 1 January 2019, not yet endorsed by the EU)
- Long-term interest in associates and joint ventures - Amendments to IAS 28 (IASB effective 1 January 2019, not yet endorsed by the EU)
- IFRS 17 Insurance Contracts (IASB effective 1 January 2021, not yet endorsed by the EU)

a) Revenue recognition

Revenue is measured at the fair value of the consideration received/receivable for the sale of goods to external customers net of value added tax and discounts. The Group recognizes revenue when the amount of revenue can be reliably measured and when it is probable that future economic benefits of the transaction will flow to the Group. Revenue from the sale of goods is recognized when significant risks and rewards of ownership of the goods are transferred to the buyer. This may arise on shipment, delivery or in accordance with specific terms and conditions agreed with customers and provided there are no material remaining performance obligations required of the Group. Discounts are provided for based on agreements or contracts with customers, agreed promotional arrangements and accumulated experience. Discounts are recorded in the same period as the original revenue. Service revenues (relating to training and implant support) are recognized when the related services are rendered.

When a customer is invoiced or cash is received but conditions for recognition of the related revenues have not been met, revenue is deferred until all conditions are met.

The Group occasionally sells goods and services as a bundled arrangement. Such sales are unbundled based on the relative fair value of the individual goods and services components and each component is recognized separately in accordance with the Group's recognition policy.

b) 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. Intra-group balances and transactions, and any unrealized income and expenses arising from intra-group transactions, are eliminated on consolidation.

c) Pension costs

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

d) 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

e) 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.

f) 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 has no recognized deferred tax as at 31 December 2017.

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.

g) 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.

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

- assets and liabilities at each reporting date are translated at the closing rate at the reporting date of the balance sheet; and
- income and expenses in the income statement and statement of comprehensive income are translated at average exchange rates for the year. Average exchange rates are only permissible if they approximate actual. The average exchange rates are a reasonable approximation of the cumulative effect of the exchange rates on transaction dates.
- All resulting exchange differences are recognized in other comprehensive income, and are taken to a separate currency reserve within equity, the foreign currency translation reserve.

h) 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.

Trade and other receivables

Trade and other receivables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method less provision for impairment.

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.

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

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

j) 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.

Impairment of trade and other receivables
The Group evaluates customer accounts with past-due outstanding balances, and analyses customer credit worthiness, payment patterns and trends. Based upon a review of these accounts and management's analysis and judgement, we estimate the future cash flows expected to be recovered from these receivables. The amount of the impairment on doubtful receivables is measured individually and recorded as a specific allowance against the customer's receivable balance. The allowance is re-evaluated and adjusted periodically as additional information is received. The net movement in the provision for impairment of receivables is included within the income statement.

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.

k) 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.

l) Finance income and expense
Finance income comprises foreign exchange gains on financial items and deposit interest. Interest income is recognized as it accrues. Finance costs comprise interest on borrowings and foreign exchange losses.

m) 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 is 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 20. 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.

n) 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.

o) 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.

p) 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.

q) Inventories

Inventories are stated at the lower of cost and net realizable value. The cost of inventories is based on the first in – first out principle and includes expenditure in acquiring the inventories and bringing them to their existing location and condition. Net realizable value is the estimated selling price less the estimated costs of completion and the estimated costs necessary to make the sale. Provision is made, where necessary, for aged, slow moving, obsolete and defective inventories.

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 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 2017**	31 December 2016
Ireland	47	75
Germany	5	-
United States	149	180
Total non-current assets	**201**	**255**

The Group's total revenue by country is detailed below:

($'000)	**Year ended 31 December 2017**	Year ended 31 December 2016
Germany	330	-
Ireland	18	-
Total revenue by country	**348**	**-**

5 Revenue

($'000)	Year ended 31 December 2017	Year ended 31 December 2016
Revenue arising from the sale of goods	348	-
Total revenue	**348**	**-**

Revenues from four customers represented approximately $330,000 of the Group's total revenues.

6 Operating expenses

($'000)	Year ended 31 December 2017	Year ended 31 December 2016
Research and development expenses	4,170	3,582
Clinical and regulatory expenses	12,850	5,599
Selling, general and administration expenses	10,857	7,647
Total operating expenses	**27,877**	**16,828**

7 Employee numbers and benefits

As of 31 December 2017, the Group's employees were based in Ireland, Germany, the United States, the Netherlands 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 2017	Year ended 31 December 2016
Research and development and quality	13	12
Clinical and regulatory	10	8
Selling, general and administration	16	12
Total employee numbers	**39**	**32**
Parent company employees		
General and administration	5	7

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

($'000)	Year ended 31 December 2017	Year ended 31 December 2016
Wages and salaries	5,050	3,731
Other remuneration	1,504	921
Social security costs/ payroll taxes	440	306
Share based payments	3,044	1,959
Pension	80	62
	10,118	**6,979**

8 Statutory information and Auditor's 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 2017**	Year ended 31 December 2016
Audit of these financial statements	60	65
Other assurance services	10	132
Taxation advisory services	38	65
Total auditor's remuneration	**108**	**262**
Depreciation of plant and equipment	107	120
Rentals payable under operating leases	272	205
Research and development expenditure	4,170	3,582

9 Finance income

($'000)	**Year ended 31 December 2017**	Year ended 31 December 2016
Finance income		
Foreign exchange gain	46	-
Total finance income	**46**	**-**

10 Finance expense

($'000)	**Year ended 31 December 2017**	Year ended 31 December 2016
Finance expense		
Foreign exchange loss	-	(107)
Interest expense on borrowings	(1,932)	(1,701)
Total finance expense	**(1,932)**	**(1,808)**

11 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 2017	Year ended 31 December 2016
Net Loss for the year ($'000) attributable to equity holders	29,835	18,758
Weighted average number of ordinary shares in issue	6,615,447	5,548,880
Loss per share	**$4.51**	**$3.38**

In accordance with IFRS, share options are not included in the weighted average number of ordinary shares for the purposes of calculating diluted earnings per share as they are anti-dilutive. Refer to note 22, for information on shares options outstanding as at 31 December 2017 and 31 December 2016.

12 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, Australia and Germany.

($'000)	**Year ended 31 December 2017**	Year ended 31 December 2016
Irish income tax	-	-
Income tax in other jurisdictions:		
Foreign current tax	178	106
Adjustments in respect of prior years	52	16
Total income tax charge	**230**	**122**

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, United States and Germany.

Reconciliation of effective tax rate

($'000)	**Year ended 31 December 2017**	Year ended 31 December 2016
Loss before tax	(29,605)	(18,636)
Taxed at tax rate in Ireland of 12.5%	(3,700)	(2,329)
Non-deductible expenses	408	288
Tax credits	(205)	(103)
Foreign rate differential	234	183
Adjustments in respect of prior periods	52	16
Unrecognized tax losses	3,441	2,067
Total income tax charge/(credit)	**230**	**122**

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.

The unrecognized deferred tax asset relating to share based payments arises principally in our US subsidiary. The adjustment in respect of prior years' arising on the unrecognized deferred tax asset on share based payments in 2017 relates to a change in the expected applicable US tax rate from 34% to 22%. The adjustment in respect of prior years' arising on the unrecognized deferred tax asset on share based payments in 2016 relates to a change in the expected applicable US tax rate from 40% to 34%.

Gross timing differences:

	At 1 January 2016	Arising in year	Adjustment in respect of prior years	**At 31 December 2016**	Arising in year	Adjustment in respect of prior years	**At 31 December 2017**
Unrecognized tax losses	36,360	16,541	(221)	52,680	27,528	419	80,627
Intangible assets	15,000	-	-	15,000	-	-	15,000
Share based payments	930	315	-	1,245	72	-	1,317
Total gross timing differences	**52,290**	**16,856**	**(221)**	**68,925**	**27,600**	**419**	**96,944**
Unrecognized deferred tax asset							
Unrecognized tax losses	4,545	2,068	(28)	6,585	3,441	52	10,069
Intangible assets	1,875	-	-	1,875	-	-	1,875
Share based payments	372	107	(56)	423	16	(149)	290
Total unrecognized deferred tax asset	**6,792**	**2,175**	**(84)**	**8,883**	**3,457**	**(97)**	**12,243**

13 Property, plant & equipment

($'000)	**Computer and office equipment Year ended 31 December 2017**	Computer and office equipment Year ended 31 December 2016
Cost		
At beginning of year	449	378
Additions	53	195
Transfer to inventory	-	(124)
At end of year	502	449
Depreciation		
At beginning of year	194	136
Charge for the year	107	120
Transfer to inventory	-	(62)
At end of year	301	194
Carrying value at end of year	**201**	**255**

During 2016, computer equipment which had been purchased for use in Clinical Trials, and which had been recognized as Property, Plant and Equipment during 2015, was transferred at its written down value into inventory, as it is intended now that this equipment will be sold in the normal course of business.

14 Trade and other receivables

($'000)	Year ended 31 December 2017	Year ended 31 December 2016
Trade receivables	90	-
VAT and sales tax receivable	71	100
Prepaid expenses and other current assets	410	789
Total trade and other receivables	**571**	**889**

15 Inventory

($'000)	Year ended 31 December 2017	Year ended 31 December 2016
Raw Materials	57	137
Work in Progress	154	108
Finished Goods	2,184	878
Total inventory	**2,395**	**1,123**

There were no provisions netted against inventory as at 31 December 2017. The cost of inventory used in cost of sales during 2017 was $186,000 (2016: $nil).

16 Cash and cash equivalents

($'000)	Year ended 31 December 2017	Year ended 31 December 2016
Cash in bank accounts – USD	9,888	36,615
Cash in bank accounts – Euro	82	53
Cash in bank accounts – AUD	5	2
Total cash and cash equivalents	**9,975**	**36,670**

17 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 was 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%.

A third tranche (“Tranche C”) of $4.5 million was received on 28 July 2016. The interest rate on Tranche C is 3-month Euribor plus a margin of 10.5%.

Other expenses directly associated with the facility of $466,000 were deferred 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. The Group is not in breach of any covenants at 31 December 2017 and has not been in breach at any reporting date.

($'000)	**Year ended 31 December 2017**	Year ended 31 December 2016
Loans and borrowings – current		
Term loan	3,000	2,025
Deferred finance cost	(90)	(91)
Accrued interest	304	334
Total current loans and borrowings	**3,214**	**2,268**
Loans and borrowings – non-current		
Term loan	10,200	12,975
Deferred finance cost	(194)	(142)
Accrued interest	1,171	443
Total non-current loans and borrowings	**11,177**	**13,276**
Total loans and borrowings	**14,391**	**15,544**

18 Trade and other payables

($'000)	**Year ended 31 December 2017**	Year ended 31 December 2016
Trade and other payables	2,633	1,570
Payroll tax liability	136	113
Accrued expenses	1,884	697
Total trade and other payables	**4,653**	**2,380**

19 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.

Authorized and Issued Share Capital

	31 December 2017	31 December 2016
Authorized	**€**	€
20,000,000 ordinary shares of €0.001 each	20,000	20,000
40,000 deferred shares of €1.00 each	40,000	40,000
	60,000	**60,000**

	2017	**2016**
Issued, called up and fully paid	**$**	**$**
6,618,897 (2016: 6,611,952) ordinary shares of €0.001 each	8,562	8,555
40,000 deferred shares of €1.00 each	55,268	55,268
	63,830	**63,823**
In $'000	**64**	**64**

Details of movement in issued shares:

On 17 June 2016, the Company raised gross proceeds of €30 million (approximately $33.7 million) through a placement of 2,307,694 new ordinary shares. This issuance of new ordinary shares was recorded in the Statement of Financial Position in USD at the rate ruling on the date of the transaction. Transaction costs directly attributable to the issue of the new ordinary shares, of approximately $1.2 million, have been offset against retained earnings (in accordance with the Companies Act 2014).

During 2016, 6,055 warrants over ordinary shares were exercised by the holders and the Company issued 6,055 ordinary shares. Proceeds of $46,624 were received on issue of the shares.

During 2017, 6,945 warrants over ordinary shares were exercised by the holders and the Company issued 6,945 ordinary shares. Proceeds of $53,477 were received on issue of the shares.

	Movement of shares	
Number of shares	Ordinary shares	Deferred shares
At 1 January 2016	4,298,203	40,000
Issue of shares	2,307,694	-
Issue of ordinary shares on exercise of share warrants	6,055	-
At 31 December 2016	**6,611,952**	**40,000**
At 1 January 2017	**6,611,952**	**40,000**
Issue of shares	-	-
Issue of ordinary shares on exercise of share warrants	6,945	-
At 31 December 2017	**6,618,897**	**40,000**

	Movement of shares	
$'000	Share capital	Share premium
At 1 January 2016	61	72,588
Issue of shares	3	33,725
Issue of ordinary shares on exercise of share warrants	-	47
At 31 December 2016	**64**	**106,360**
At 1 January 2017	64	106,360
Issue of shares	-	-
Issue of ordinary shares on exercise of share warrants	-	54
At 31 December 2017	**64**	**106,414**

20 Other reserves

($'000)	**31 December 2017**	31 December 2016
Reorganization reserve	(44,573)	(44,573)
Undenominated capital reserve	49,273	49,273
Foreign currency translation reserve	(107)	35
Total other reserves	**4,593**	**4,735**

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. Further information on these transactions are available in our 2015 Annual Report and our 2014 IPO Prospectus, available on the Group's website.

Undenominated capital reserve

The undenominated capital reserve represents the fair value movement on embedded derivatives associated with preference shares between the issue of the shares and their conversion (during 2014) which does not meet the definition of Share Premium under the Irish Companies Act. The Company therefore recorded this fair value movement in a "Undenominated Capital Reserve" on conversion. This reserve is not distributable. Further information on these transactions are available in our 2015 Annual Report.

Foreign currency translation reserve

The currency reserve reflects the foreign exchange gains and losses that arise on foreign operations that have a functional currency that differs from the presentation currency of the Company. The assets and liabilities of these subsidiaries are translated at the closing rate at the reporting date, income and expenses in the income statement are translated at the average rate for the year and resulting exchange differences are taken to the currency reserve within equity. Refer to Note 3 for further information.

The Group has three subsidiary companies with a Euro functional currency and one subsidiary company with an AUD functional currency.

21 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.

The Group has no significant concentrations of financial risk other than concentration of cash with individual banks. During January 2017, the Group made its first commercial sale of ReActiv8, and consequently the year ended 31 December 2017 is the first period during which the group is exposed to credit risk arising on trade receivables. Further information is provided under credit risk below. There has been no other significant change during the year end, or since the end of the year end 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 and trade and other receivables. Credit risk is managed on a Group basis. The maximum exposure to credit risk is represented by the carrying amount of each asset. The carrying value of receivables is a reasonable approximation of fair value. The Group's objective is to manage credit risk.

The Group maintained its cash balances with its principal financial institutions throughout the year, and the Group limits its exposure to any one financial institution by holding cash balances across several financial institutions. The Group's principal financial institutions have investment grade ratings at 31 December 2017. The credit rating status of the Group's principal financial institutions is reviewed by the Audit Committee or the Board annually. The cash balance is reported to the Board of Directors on a monthly basis, and a monthly review of all cash balances held at each institution is carried out by the CFO. The Group maintains most of its cash in USD denominated accounts. The Group held cash and cash equivalents of $10 million as at 31 December 2017.

The Group's credit risk management policy and process in relation to trade receivables involves carrying out credit checks where appropriate, and by active credit management. The utilization of credit limits is regularly monitored. In addition, it involves periodically assessing the financial reliability of customers, taking into account their financial position, past experience and other factors. As at 31 December 2017 our trade and other receivables balances amounted to $90,000 (2016: $nil), and we have not recognized any impairment at this time. The total outstanding balance as at 31 December 2017 was received post period end.

The below table provides an analysis of aging of receivables as at 31 December 2017 and the total balance outstanding relates to one customer.

($'000)	Current	1 - 30 Days	31 - 60 Days	61 – 90 Days
Trade and other receivables	90	-	-	-

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 2017 and as at 31 December 2016.

($'000)	Carrying value	Cash flow (total)	Less than 1 year	Between 1-2 years	Between 2-5 years
31 December 2017:					
Trade and other payables	4,777	4,777	4,777	-	-
Interest bearing loans and borrowings	14,391	18,756	4,121	3,893	10,742
At 31 December 2017	**19,168**	**23,533**	**8,898**	**3,893**	**10,742**
31 December 2016:					
Trade and other payables	2,438	2,438	2,438	-	-
Interest bearing loans and borrowings	15,544	21,574	3,323	4,121	14,130
At 31 December 2016	**17,982**	**24,012**	**5,761**	**4,121**	**14,130**

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, and three of the Group's subsidiaries located in Ireland, Germany and the Netherlands have a Euro functional currency.

The Group did not have material asset or liability amounts in foreign currencies at year end other than net receivables, trade payables and accruals of €1 million (2016: €468,000) 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 $61,000 (2016: $23,000). 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 2016	1.0541	1.1069
Year ended 31 December 2017	1.1993	1.1297

Australian Dollar per USD1.00	**End of year**	**Average**
Year ended 31 December 2016	0.7222	0.7430
Year ended 31 December 2017	0.7815	0.7668

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 2017, the principal outstanding on MML's loan from IPF was $13,200,000 (2016: $15,000,000). This loan carries a variable rate of 3-month Euribor plus a margin ranging from 10.5% 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 have increased the loss by $33,000 on a full year basis based on the drawn down loan balance as at 31 December 2017 (2016: $37,500 on a full year basis based on the drawn down loan balance as at 31 December 2016).

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 2017 and 31 December 2016:

($'000)	Designated at fair value	Loans and receivables	Financial liabilities at amortized cost	Total carrying value	Fair value
Assets					
Cash and cash equivalents	-	9,975	-	9,975	N/A
Trade and other receivables	-	90	-	90	N/A
Liabilities					
Trade and other payables	-	-	(4,777)	(4,777)	N/A
Interest bearing loans and borrowings	-	-	(14,391)	(14,391)	(14,336)
At December 2017	**-**	**10,065**	**19,168**	**(9,103)**	**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	-	36,670	-	36,670	N/A
Liabilities					
Trade and other payables	-	-	(2,438)	(2,438)	N/A
Interest bearing loans and borrowings	-	-	(15,544)	(15,544)	(15,400)
At December 2016	**-**	**36,670**	**(17,982)**	**18,688**	**N/A**

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.

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 2017 and 31 December 2016 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 margin 12.3%-15.0%	An increase in the interest rate would reduce the fair value of the liability.

22 Share based payments

Stock Incentive Plan

The Group operates a share option plan (the "Plan"). As at 31 December 2017, the Plan allows for the Company to grant options over ordinary shares of Mainstay Medical International plc to employees of the Group companies, directors, consultants and other contractors. As at 31 December 2017, 1,422,843 (2016: 992,388) 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 2017:

	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	232	10 years from vesting
Options granted in 2014	85	10 years from vesting
Options granted in 2015	300	10 years from vesting
Options granted in 2016	309	10 years from vesting
Options granted in 2017	436	10 years from vesting
Total share options in issue	**1,423**	

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.

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 2017**	**Weighted average exercise price 2017**	Year ended 31 December 2016	Weighted average exercise price 2016
At beginning of year	993	€11.53	690	€9.32
Options granted during the year	436	€14.92	315	€15.93
Options expired unexercised	-	-	(5)	€0.95
Options forfeited	(6)	€16.20	(7)	€17.18
Options exercised	-	-	-	-
Outstanding at end of year	**1,423**	**€12.53**	**993**	**€11.53**
Exercisable at end of year	**643**	**€8.94**	**445**	**€6.25**

Total non-cash expense charged to profit and loss in relation to share options for the year ended 31 December 2017 was $3,044,508 (2016: $1,959,000).

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	
	2017	**2016**
Weighted average share price (€)	14.92	15.93
Weighted average exercise price (€)	14.92	15.93
Weighted average expected share volatility	52.35%	60%
Expected term (years)	7	7
Expected dividends	-	-
Risk free rate (average)	0.03%	0.03%
Fair value of option ($)	8.94	9.96

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.

During 2017, 6,945 warrants were exercised (2016: 6,055). As at 31 December 2017, no further warrants remained unexercised.

23 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 payment of the liabilities and commitments of its subsidiaries in Ireland (as defined in section 357 of the Companies 2014 Act) for the years ended 31 December 2017 and 31 December 2016.

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 $271,674 for the year ended 31 December 2017 (2016: $205,353).

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

($'000)	**31 December 2017**	31 December 2016
Within one year	157	254
After one year but no more than five years	405	664
More than five years	-	-
Total operating leases	**562**	**918**

24 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 2017 amounted to $80,354 (2016: $62,333). There were no accruals or prepayments in respect of the pension costs at 31 December 2017 (2016: None).

25 Subsidiary undertakings

At 31 December 2017, 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.
- Mainstay Medical Distribution Limited is registered in Ireland.
- Mainstay Medical GmbH is registered in Germany.
- Mainstay Medical BV is registered in the Netherlands (incorporated in September 2017) and its principal activity is the provision of management and sales support services.

26 Related party transactions

There were no balances due to or from related parties as at 31 December 2017 (2016: 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 2017**	31 December 2016
Salaries	1,909	1,644
Directors' fees	233	213
Other remuneration	1,093	760
Payroll taxes	217	181
Share based payments	2,369	1,556
Pension	24	22
Total remuneration	**5,845**	**4,376**

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

($'000)	**31 December 2017**	31 December 2016
Salaries	656	552
Directors' fees	233	213
Other remuneration	225	165
Payroll taxes	76	71
Share based payments	1,386	540
Total remuneration	**2,576**	**1,541**

27 Capital management

Please refer to our discussion on key performance indicators within the Directors Report and the disclosure relating to risk management within Note 21.

28 Net cash from financing activities reconciliation

Reconciliation of term loan and equity to cashflow:

($'000)	**As at 1 January 2017 Carrying Value**	**Issue of ordinary shares on exercise of share warrants**	***Cashflow* Repayment of borrowings**	***Non-cashflow* Reallocation to current**	**As at 31 December 2017 Carrying Value**
Liabilities					
Term Loan – current	2,025	-	(1,800)	2,775	3,000
Term Loan – non current	12,975	-	-	(2,775)	10,200
Total	**15,000**	**-**	**(1,800)**	**-**	**13,200**
Equity					
Share Premium	106,360	54	-	-	106,414
Total	**106,360**	54	**-**	**-**	**106,414**

29 Events subsequent to 31 December 2017

There were no events subsequent to the year ended 31 December 2017 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 2017

($'000)	Notes	31 December 2017	31 December 2016
Non-current assets			
Investment in subsidiary	(d)	52,849	51,370
Current assets			
Prepayments and other receivables	(a)	158	204
Amounts due from subsidiary undertakings	(c)	49,876	26,834
Cash and cash equivalents	(b)	2,387	25,146
Total current assets		52,421	52,184
Total assets		**105,270**	**103,554**
Equity			
Share capital	19	64	64
Share premium	19	106,414	106,360
Share based payment reserve	22	7,613	4,606
Undenominated capital reserve		49,273	49,273
Retained loss		(58,749)	(57,421)
Surplus/(deficit) on shareholders' equity		104,615	102,882
Current liabilities			
Trade and other payables	(e)	655	672
Total current liabilities		655	672
Total liabilities		**655**	**672**
Total equity and liabilities		**105,270**	**103,554**

On behalf of the Board on 14 February 2018,

Oern Stuge MD
Chairman

Jason Hannon
CEO

Company statement of changes in equity
At 31 December 2017

($'000)	Share capital	Share premium	Un-denominated capital reserve	Share based payment reserve	Retained loss	Total equity
Balance at 31 December 2015	61	72,588	49,273	2,691	(55,580)	69,033
Comprehensive loss for the year	-	-	-	-	(708)	(708)
Transactions with owners of the Company:						
Issue of Shares	3	33,725	-	-	(1,177)	32,551
Share based payments	-	-	-	1,959	-	1,959
Issue of ordinary shares on exercise of share options and warrants	-	47	-	(44)	44	47
Balance at 31 December 2016	**64**	**106,360**	**49,273**	**4,606**	**(57,421)**	**102,882**
Balance at 31 December 2016	64	106,360	49,273	4,606	(57,421)	102,882
Comprehensive loss for the year	-	-	-	-	(1,365)	(1,365)
Transactions with owners of the Company:						
Issue of Shares	-	-	-	-	-	-
Share based payments	-	-	-	3,044	-	3,044
Issue of ordinary shares on exercise of share options and warrants	-	54	-	(37)	37	54
Balance at 31 December 2017	**64**	**106,414**	**49,273**	**7,613**	**(58,749)**	**104,615**

Company statement of cash flows
At 31 December 2017

($'000)	Notes	Year ended 31 December 2017	Year ended 31 December 2016
Cash flow from operating activities			
Net loss attributable to equity holders		(1,365)	(708)
Add/(less) non-cash items			
Share-based compensation		1,565	821
Add/(less) changes in working capital			
Prepayments and other receivables		(22,996)	(15,132)
Trade and other payables		(17)	77
Net cash used in operations		**(22,813)**	**(14,942)**
Cash flow from financing activities			
Proceeds from issue of shares		54	33,775
Transaction costs on issue of shares		-	(1,177)
Net cash from financing activities		**54**	**32,598**
Net (decrease)/increase in cash and cash equivalents		**(22,759)**	**17,656**
Cash and cash equivalents at beginning of year	(b)	25,146	7,490
Cash and cash equivalents at end of year		**2,387**	**25,146**

Notes to the Company Financial Statements

Notes 1, 2, 3, 22 and 29 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 2017	31 December 2016
Prepayments	154	189
VAT recoverable	4	15
	158	**204**

(b) Cash and cash equivalents

($'000)	31 December 2017	31 December 2016
Cash in bank accounts – USD	2,368	25,142
Cash in bank accounts – Euro	18	3
Cash in bank accounts – AUD	1	1
	2,387	**25,146**

(c) Amounts due from subsidiary undertakings

($'000)	31 December 2017	31 December 2016
Mainstay Medical Limited	47,249	26,246
Mainstay Medical Distribution Limited	2,566	588
Mainstay Medical BV	61	-
	49,876	**26,834**

(d) Investment in subsidiary

($'000)	31 December 2017	31 December 2016
Opening balance	51,370	50,233
Investment in subsidiary	-	-
Effect of group share based payments	1,479	1,137
Closing balance	**52,849**	**51,370**

(e) Trade and other payables

($'000)	31 December 2017	31 December 2016
Trade and other payables	425	488
Payroll tax liability	60	80
Accrued expenses	170	104
	655	**672**

(f) 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 detailed in note (b)), and intercompany receivables denominated in Euro. 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 $106,000 (31 December 2016: $18,300). 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 (e). All amounts fall due for payment within 30 days and the carrying value represents the fair value of these liabilities.