Mainstay Medical Provides Company Update and Publishes 2018 Full Year Results

- *ReActiv8-B study results received; pre-PMA submission meeting with FDA expected during the second quarter*
- *European commercialization continues to advance*
- *Cash on hand of $15.5m at 31 December 2018*

Dublin – Ireland, 18 April 2019 – Mainstay Medical International plc ("Mainstay" or the "Company", Euronext Paris: MSTY.PA and Euronext Growth operated by Euronext Dublin (MSTY.IE), a medical device company focused on bringing to market ReActiv8, an implantable restorative neurostimulation system to treat disabling Chronic Low Back Pain, today provides a company update and announces the publication of its 2018 Full Year results and Annual Report.

Jason Hannon, CEO of Mainstay, said: *"I believe fully in ReActiv8 as a therapeutic option for patients suffering from disabling Chronic Low Back Pain, and I believe that the value we can deliver to both our physician customers and their patients, as well as the investing market, will be demonstrated in the months and years to come. The primary endpoint of our ReActiv8-B clinical trial was not achieved due to a higher response (at 120 days) in the control (active sham) patient group than was expected. However, we believe the overall results from the trial represent solid evidence of the efficacy and safety of ReActiv8. This belief is based on, among other things:*

- *A pre-specified analysis of the primary endpoint where we adjusted for patients who increased their pain medications for reasons unrelated to their back pain. As a reminder, to be considered a "Responder" in the clinical trial, a patient must have reported 30% or greater pain relief on the VAS scale and not increased their pain medications leading up to the 120 day measurement point;*
- *Statistically significant differences between the treatment and control groups on key secondary efficacy endpoints at 120 days;*
- *A responder rate of 72% in the patients in the treatment and control groups combined that have reached one year since implantation; and*
- *A significant reduction in the use of pain medications (including opioids) by patients at one year.*

We believe these results will support sales growth in Germany and other markets under our existing CE Mark, as well as our plan to file a Pre-Market Approval Application with the U.S. Food and Drug Administration. We plan to submit a PMA to the FDA in mid-2019, with a decision on approval expected in late 2020."

Business Update

- In November 2018, Mainstay announced top line results from the ReActiv8-B clinical study, its international, multi-center, prospective, randomized, active sham-controlled, blinded trial with

one-way cross-over, conducted under an Investigational Device Exemption (IDE) from the U.S. Food & Drug Administration (FDA). A total of 204 patients with chronic low back pain refractory to physical therapy were implanted with ReActiv8 at leading clinical sites in the U.S., Europe and Australia and randomized 1:1 to therapy or control. The average duration of symptoms was 14 years. In the treatment group, the ReActiv8 pulse generator was programmed to deliver electrical stimulation expected to elicit contractions of the multifidus muscle. In the control group, the ReActiv8 device was programmed to provide a low level of electrical stimulation. Following assessment of the primary endpoint at 120 days, patients in the control group crossed-over to receive levels of electrical stimulation similar to those in the treatment group. A summary of the clinical trial results is as follows:

  - The primary efficacy endpoint of the study was a comparison of responder rates between the treatment and control groups as measured on the visual analog scale (VAS) of pain, with responders defined as having a 30% or greater improvement on this measure between baseline and 120 days after randomization, without any increase in pain medication and/or muscle relaxants taken in the two weeks prior to the primary endpoint assessment visit. In the treatment group the responder rate at 120 days was 57%, compared to 47% in the control group, resulting in a difference that is not statistically significant.
  - Statistically significant differences on a number of key secondary endpoints were observed in the treatment group as compared to the control group at 120 days, including change from baseline in disability measured by the Oswestry Disability Index (ODI), change from baseline in quality of life measured by the European Quality of Life Score on Five Dimensions (EQ-5D), percent pain relief (PPR) compared to baseline and subject global impression of global change (SGIC).
  - Improvements in the percentage of patients reporting pain reduction continued beyond the 120-day assessment through one year for both groups. The percentage of the 116 patients in the treatment group and control groups that had completed the one-year assessment having a 30% or greater reduction in low back pain VAS at that assessment without a significant increase in pain medication was 72%. These data are subject to change as the remaining patients reach the one-year assessment.
  - The protocol permitted patients to adjust their back pain medication usage after the 120-day assessment point. At one year, 44% of the 50 patients in both groups combined who were on opioids at baseline had voluntarily eliminated (28%) or significantly reduced (16%) their use of opioids. These results are subject to change as the remaining patients reach the one-year assessment.
  - The incidence and type of adverse events (AEs), including serious AEs, were comparable to AEs in clinical trials reported for other neurostimulation devices, with no unanticipated AEs related to the device, procedure or stimulation.

- Mainstay is preparing to submit a PMA application to the FDA based upon the totality of its clinical data for ReActiv8. The Company expects to have a pre-PMA submission meeting with

the FDA during the second quarter to obtain feedback on its filing content and strategy. A PMA application filing is expected in mid-2019 after that meeting, with a decision on approval expected in late 2020. The FDA's review of the PMA may result in the FDA not agreeing with Mainstay's interpretation of its clinical data, including whether statistical significance was achieved for one or more endpoints.

- In Germany, Mainstay's initial European market, the commercial team was repositioned in order to better focus efforts on key physician targets. Commercialization efforts in line with this strategy began in earnest in late-2018. We are beginning to see the early fruits of these efforts as we regularly onboard new implanting physicians. We expect this early momentum to continue, leading to meaningful sales and revenue by the end of this year and the beginning of 2020.

Financial Update

- Since the beginning of 2018, Mainstay has conducted significant financing activities:
    - On 18 April 2019, Mainstay and its subsidiary, Mainstay Medical Limited, entered into an amendment to its agreement with IPF Partners relating to their existing debt facility. Pursuant to the amendment:
        - The repayment schedule for the three existing tranches drawn under the debt facility was amended such that no principal or interest will be repaid until 2021, with the principal and accrued interest to be amortized over the period from January 1, 2021 through September 30, 2023.
        - A new tranche of €3.0 million (approximately $3.34 million) was made available to Mainstay, conditioned upon Mainstay raising at least $10 million in gross proceeds from one or more offerings of equity prior to June 30, 2019. The repayment schedule for the new tranche will be the same as the amended repayment schedule for the three existing tranches.
        - The interest rate for all tranches will be 8% per annum, with interest accruing but capitalized prior to January 1, 2021.
        - The 5% repayment fee applicable to each existing tranche was eliminated.
        - All principal and accrued interest from all tranches will automatically convert into ordinary shares of the Company at a price per share of €8 upon the earlier of (a) FDA approval of Mainstay's PMA application for ReActiv8, (b) the date by which at least 900,000 ordinary shares of the Company are publicly sold on-market by non-affiliates of Mainstay since 18 April 2019 at a price per share of at least €8, or (c) IPF Partners' election to undertake such conversion, in each case unless the Company elects to satisfy such obligation in whole or in part in cash.
        - The minimum cash covenant was amended so that Mainstay is required to hold cash at least equal to its projected cash expenditures for operations and debt repayment for the next three months, and the covenant relating to the achievement of commercial milestones was eliminated.
        - Mainstay issued to IPF Partners warrants to purchase 1.5 million of its ordinary shares at a price per share of €6 at any time prior to the 6th anniversary of the amendment date. Mainstay has issued further conditional warrants to IPF Partners that will become exercisable only to the extent Mainstay elects to repay the debt in cash rather than issue ordinary shares when a conversion of the debt is triggered. As such, the conditional warrants are intended to ensure that, notwithstanding any such election to repay in cash, IPF Partners retains the right to subscribe for ordinary shares of the Company on the terms and conditions that would otherwise have applied.

  - On 15 February 2018, the Company announced the completion of a €30.1 million financing (approximately $37.5 million) through a placement of 2,151,332 new ordinary shares to new and existing shareholders.
- Revenue during the year ended 31 December 2018 was $0.7 million (2017: $0.3 million).
- Operating expenses related to on-going activities were $29.6 million during the year ended 31 December 2018 (2017: $27.9 million).
- Cash on hand as at 31 December 2018 was $15.5 million (2017: $10 million).

Investor Conference Call

Jason Hannon, Chief Executive Officer, and Matthew Onaitis, Chief Financial Officer, will host a conference call and Q&A for analysts and investors at 13:00 BST (08:00 EDT, 14:00 CEST) on 30 April 2019. The call will be conducted in English and a replay will be available for 30 days. Dial-in details for the call are:

UK/Europe: +44 333 300 0804

Ireland: +353 1 431 1252

France: +33 1 7075 0711

Germany: +49 69138 03430

USA: +1 631 913 1422

Participant PIN: 67816857#

– End –

This announcement contains inside information within the meaning of the EU Market Abuse Regulation 596/2014.

About Mainstay

Mainstay is a medical device company focused on commercializing 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, Germany and the Netherlands, and is listed on the regulated market of Euronext Paris (MSTY.PA) and the ESM of Euronext Dublin (MSTY.IE).

About Chronic Low Back Pain

One of the root causes of CLBP is impaired control by the nervous system of the muscles that dynamically stabilize the spine. ReActiv8 is designed to electrically stimulate the nerves responsible for contracting these muscles to 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 data from the ReActiv8-B clinical study, the Company’s plans in relation to that data, and 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 and other commercial performance.

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, the development of its main product, and 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 final outcome

of the ReActiv8-B Clinical Study, the outcome of the Company's interactions with the FDA on a PMA application for ReActiv8, general economic and business conditions, 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, and 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 2018

Mainstay Medical International plc
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Forward looking statements

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

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 Company's actual results, events, levels of activity, performance or achievement may differ materially from those described in, or suggested by, the forward looking statements contained in this annual report. In addition, even if the Company's actual results, events, levels of activity, performance or achievement are consistent with the forward looking statements contained in this annual report, they may not be indicative of 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 ability to raise additional capital to fund the Company's business and the cost of such capital, the outcome of the ReActiv8-B Clinical Study, the outcome of the Company's interactions with the FDA on a PMA application for ReActiv8, general economic and business conditions, global medical device market conditions, industry trends, competition, changes in law or regulation, changes in taxation regimes, the time required to complete clinical trials and to obtain regulatory approvals, currency fluctuations, changes in its business strategy, and political and economic uncertainty. The forward-looking statements herein speak only at the date of this annual report.

Mainstay Medical International plc
Corporate and shareholder information

Directors	Oern Stuge MD, Independent Non-Executive Chairman 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 Dan Sachs MD, Non-Executive Director
Secretary	Matthew Onaitis
Registered office	77 Sir John Rogerson's Quay Block C, Grand Canal Docklands Dublin 2, 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 Latham Watkins 885 3rd Avenue, NY 10022, USA
Independent Auditor	KPMG Chartered Accountants 1 Stokes Place St Stephen's Green Dublin 2, Ireland
Principal Bankers	HSBC Bank of Ireland
Euronext Growth 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

I am pleased to present the 2018 Annual Report for Mainstay Medical and its subsidiaries. 2018 was challenging year, but we believe the Company is positioned for success in 2019 and beyond.

Business review

We announced headline results from the ReActiv8-B Clinical Trial in November. Whilst the difference between the treatment and control groups on the primary endpoint of responder rate at 120 days as measured on the visual analog scale (VAS) of pain was not statistically significant due to a higher than expected response rate in the control group, we believe the overall results from the trial represent solid evidence of the efficacy and safety of ReActiv8. These overall results include additional, pre-specified analyses of the primary efficacy endpoint, as well as high responder rates in the patients that have reached one year since implantation, and a significant reduction in the use of pain medications by patients at one year.

We believe these results will support sales growth in Germany and other markets under our existing CE Mark, as well as our plan to file a Pre-Market Approval ("PMA") Application with the U.S. Food and Drug Administration.

A detailed review of the Company's corporate activity in 2018 can be found in the Directors' Report on page 8 of this Annual Report.

Finance review

Cash on hand as at 31 December 2018 was $15.5 million (2017: $10 million). Operating expenses were $29.6 million during the year ended 31 December 2018 (2017: $27.9 million) and the change relates primarily to commercialization activities.

Outlook

The completion of and results from the ReActiv8-B Trial have caused us to set two main corporate objectives for 2019: continuing to make progress growing sales in Germany and other markets and pursuing regulatory approval in the U.S. On the commercial front, we have been encouraged by the reaction of implanting physicians to the ReActv8-B Trial clinical data. On the regulatory front, we plan to submit a PMA to the FDA in mid-2019, with an approval decision expected in late 2020.

Directors and Staff

I would like to thank our current and former 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
18 April 2019

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

Prior to founding ORSCO, Dr. Stuge worked for 12 years for Medtronic, Inc. in different roles including Senior Vice President ("SVP") & President Europe & Central Asia, and SVP & President Cardiac Surgery. He was a member of the Medtronic Executive Committee & Operating Committee. Dr. Stuge 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

Mr. Jason Hannon joined Mainstay Medical as Chief Executive Officer and as a Director in October 2017. Mr. Hannon has extensive experience in the medical devices industry, particularly in the areas most critical to the future success of Mainstay: commercialization of new products, penetration of new markets, product innovation, strategic and financial planning, raising capital, regulatory and clinical management, and the building of a high-performance culture. Mr. Hannon previously served as President and Chief Operating Officer of NuVasive (NASDAQ:NUVA), a leading medical device company focused on transforming spine surgery with minimally disruptive, procedurally-integrated solutions. During his 12 years at the company, he helped grow NuVasive from a small U.S.-centric business with a handful of products into the third largest spine company in the world.

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

David Brabazon

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

Mr. Brabazon is a chartered accountant and holds a Masters of Accounting degree from University College Dublin, Ireland and a Master of Business Administration degree from INSEAD, France. 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 JD degree from McGeorge School of Law, University of the Pacific.

Nael Karim Kassar

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

Mr. Kassar serves as a non-executive director of OnePhone Holding AB and as a director of KCK Ltd., KCK Properties Ltd., Future Finance Loan Corporation Limited, Timeshare Finance Investments Limited, Specialty Finance ICAV Limited, Sentient Energy, Inc., Citizens Parking Inc., Affirmed Networks, Inc., SiGNa Chemistry, Inc., HPS Del Mar Holdings LLC, and BioInspire Technologies, Inc. He previously served as a Director of Tunnel Capital City Partners Inc and Hibernia NSG Limited.

Mr. Kassar holds a bachelor's 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 Mr. Papiernik has been an active board member in public companies like Actelion, ProQR, Shockwave Medical, 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), Ethical Oncology Science (EOS, sold to Clovis Oncology), and Recor Medical (sold to Otsuka). He is also a board member of private companies Rgenix, Gecko, Highlife, SafeHeal, MD Start, Medday and Reflexion Medical. Mr. Papiernik has an MBA from the Wharton School of Business, University of Pennsylvania. In 2012 and 2011 he was selected by Forbes for its "Midas List" of the world's top venture capital investors. Mr. Papiernik is one of the only Europeans to have appeared on the list, and one of the few life science investors.

James Reinstein

James A. Reinstein is a non-executive director of the Company with more than 25 years of medical device experience. Mr. Reinstein was the President, CEO and board member of Cutera, Inc. a NASDAQ listed global device company at the forefront of the medical aesthetics space, until January 2019. Just prior to Cutera, he was the President and CEO of Drawbridge Health, a joint venture of GE Healthcare and GE Venture. Previous to Drawbridge, Mr. Reinstein was the President and CEO of Aptus Endosystems Inc., where he led the sale of the company to Medtronic for over $100 million. Prior to joining Aptus, Mr. Reinstein served as Executive Vice-President and Chief Commercial Officer at Cyberonics, a neuromodulation company focused on helping patients with epilepsy, depression and chronic heart failure. Mr. Reinstein spent 17 years at Boston Scientific in various roles and functions including business development, marketing and general management. Most of his career at Boston Scientific was spent working and living in Europe, Asia and Latin America.

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

Dan Sachs MD

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

Dr. Sachs previously served as Instructor in Medicine on the faculty of Harvard Medical School in the Division of Emergency Medicine. Dr. Sachs earned 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 2018.

Principal activities

Mainstay is a medical device company focused on commercializing ReActiv8®, an implantable restorative neurostimulation system designed to treat an underlying cause of 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 Euronext Growth operated by Euronext Dublin (MSTY.IE).

As at 31 December 2018, 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 debt funding, private placement or public offering of equity or debt securities, and/or strategic partnering.

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 to support marketing approval 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 2018 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 ReActiv8-B Trial is an international, multi-center, prospective randomized sham controlled triple blinded trial with one-way crossover, conducted under an IDE from the FDA. The ReActiv8-B Trial is intended to gather data in support of a PMA application, 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.

A total of 204 subjects were implanted with ReActiv8 at leading clinical sites in the U.S., Europe and Australia and randomized 1:1 to therapy or control 14 days after implant. In the treatment group, the ReActiv8 pulse generator was programmed to deliver electrical stimulation expected to elicit contractions of the multifidus muscle. In the control group, the ReActiv8 device was programmed to provide a low level of electrical stimulation. Following assessment of the primary endpoint at 120 days, subjects in the control group crossed-over to receive levels of electrical stimulation similar to those in the treatment group.

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

The primary efficacy endpoint of the study was a comparison of responder rates between the treatment and control groups as measured on the visual analog scale (VAS) of pain, consisting a 0-10 scale with 0 being no pain and 10 being the worse imaginable pain. Responders defined as having a 30% or greater improvement on this measure between baseline and 120 days after baseline, without any increase in pain medication and/or muscle relaxants taken in the two weeks prior to the primary endpoint assessment visit. The following table shows the result on the primary efficacy endpoint:

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

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

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

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

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

Numerous secondary endpoints were collected to assess improvements in the treatment group as compared to the control group at 120 days, including change from baseline in disability measured by the Oswestry Disability Index (ODI), change from baseline in quality of life measured by the European Quality of Life Score on Five Dimensions (EQ-5D), percent pain relief (PPR) compared to baseline, subject global impression of global change (SGIC), and pain resolution. As shown in the following table, when evaluating the therapy across multiple dimensions of subject outcomes, the treatment effect is significant in four of the five secondary endpoints: ODI, EQ-5D, PPR, and SGIC:

Endpoint	Treatment N=102 N	Treatment N=102 Mean ± SD (Min, Max) or N (%)	Control N=102 N	Control N=102 Mean ± SD (Min, Max) or N (%)	Difference p-value
Change in ODI	100	-17.5 ± 15.0 (-58.0, 20.0)	101	-12.0 ± 14.5 (-46.0, 32.0)	5.5 p = 0.008
Change in EQ-5D	100	0.186 ± 0.199 (-0.365, 0.782)	100	0.115 ± 0.178 (-0.640, 0.665)	0.071 p = 0.009
Percent Pain Relief	100	52 ± 32 (0, 100)	101	35 ± 36 (0, 100)	17 p ≤ 0.001
Subject Global Impression of Change					NA p = 0.003
Much better	100	32 (32%)	101	18 (18%)	
Better	100	22 (22%)	101	16 (16%)	
A little better	100	25 (25%)	101	29 (29%)	
No change	100	10 (10%)	101	24 (24%)	
A little worse	100	6 (6%)	101	5 (5%)	
Worse	100	4 (4%)	101	6 (6%)	
Much worse	100	1 (1%)	101	3 (3%)	
Remitters (VAS ≤ 2.5)	100	34 (34%)	101	28 (28%)	6.3% p = 0.335

At the 120-day visit, subjects in the control group were allowed to cross-over to receive stimulation at a therapeutic level. All control subjects elected to cross-over at this timepoint. At the one-year timepoint, all endpoints demonstrated clinically meaningful improvements in the treatment group and the crossover group (8 months of therapy).

- VAS Responders:
  - 75% in the treatment group
  - 68% in the crossover group
- Average ODI Change:
  - 19.6-point reduction in the treatment group
  - 19.2-point reduction in the crossover group
- Average EQ-5D Change:
  - 0.201-point increase in the treatment group
  - 0.189-point increase in the crossover group
- Average Percent Pain Relief:
  - 67% in the treatment group
  - 64% in the crossover group
- Average SGIC:
  - 77% Better or Much Better in the Treatment group
  - 72% Better or Much Better in the Crossover group
- Remitters (VAS ≤ 2.5):

- 50% in the Treatment group
- 53% in the Crossover group

Although the study was not designed to reduce medications after the 120-day visit, subjects were allowed to change medications after that timepoint. Since titration of medications may not constitute a significant increase or decrease, the Company worked with an independent physician committee to define clinically meaningful changes. The following table shows the percentage of subjects at one year that significantly decreased or removed all pain medications or all pain opioids:

Medication Change Status	Any Pain Medication % (n/N)	Opioid % (n/N)
Removed or Decreased	36% (35/97)	44% (22/50)
No Change	59% (57/97)	54% (27/50)
Increased or Added	4% (4/97)	2% (1/50)

The incidence and type of adverse events (AEs), including serious AEs, were comparable to AEs in clinical trials reported for other neurostimulation devices, with no unanticipated AEs related to the device, procedure or stimulation.

The Company believes that the totality of the data will support the submission of a PMA application for ReActiv8 to the FDA. The Company expects to hold a pre-PMA meeting with the FDA within the second quarter of 2019 to obtain guidance on its filing content and strategy.

Commercialization – In Germany, Mainstay's initial European market, the commercial team was repositioned in 2018 to better focus efforts on key physician targets. The German sales team consisted of 6 members at the end of 2018, two of whom are new to the Company. The team's focus is driving adoption in a select number of high volume spine care centres.

We have continued to add to our investment in commercial infrastructure to expand commercialization in Europe, and in preparation to enter other markets in the future. We also increased our investment in the training of physicians; the education of referring physicians regarding the potential of ReActiv8; and the collection and dissemination of clinical data regarding use of ReActiv8.

US Patents – Since our last Annual Report we were issued four new US Patents, bringing the total current number of issued US issued Patents in the Mainstay portfolio to thirteen. 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 was an international, multi-center, prospective, single arm clinical trial of ReActiv8 that formed the basis of our CE mark for ReActiv8.

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 PMCF Study is a continuation of the ReActiv8-A Clinical Trial (but using CE Marked ReActiv8). Subjects enrolled in the ReActiv8–A Clinical Trial in the UK were converted to the ReActiv8-A PMCF Study. Physicians commenced with these implants in late 2017, and 43 implants were completed by the end of 2018.

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

Funding – On 15 February 2018, we announced the completion of a €30.1 million financing (approximately $37.5 million) through a placement of 2,151,332 new ordinary shares to new and existing shareholders. On 4 May 2018, we announced the publication of a prospectus (the Prospectus) in connection with the Placement and admission to trading on ESM (now Euronext Growth) and Euronext Paris. The funds are being used to complete the ReActiv8-B Clinical Trial, seek regulatory approval in the U.S. and other markets and advance the initial commercialization of ReActiv8 in Germany and other

markets. The Prospectus comprises a Summary Document, a Securities Note and a Registration Document. These documents are available on our website www.mainstay-medical.com).

Financial review

Income statement –Revenue during the twelve-month period ending 31 December 2018 was $0.7 million (2017: $0.3 million). Revenue was primarily generated from sales of ReActiv8 systems to customers in Germany and Ireland.

Operating expenses related to on-going activities were $29.6 million during the year ended 31 December 2018 (2017: $27.9 million). On-going activities during the financial year included research and development, clinical and regulatory activities, selling, general and administrative activities.

Research and development expenditure during the 2018 period included the salaries of engineers, technicians, and quality and regulatory specialists; the cost of outsourced development and manufacturing activities; biocompatibility and pre-clinical studies; and quality costs including the maintenance of our quality system. Research and development expenses were $3.5 million during the year ended 31 December 2018 (2017: $4.2 million). A decrease of $0.7 million is primarily driven by the reduction of certain quality and regulatory costs to support the Group's commercial strategy and a reclassification of 2018 IP legal costs of $0.4 million to selling, general and administrative expenses.

Clinical and regulatory expenses were $11 million during the year ended 31 December 2018 and decreased by $1.9 million from $12.9 million during the same period in 2017. This is primarily driven by decreased direct trial costs relating to activities for the ReActiv-8 B Trial, following the announcement in July 2018 on the completion of all implants.

Our selling, general and administrative expenses were $15.1 million during year ended 31 December 2018, and $10.9 million during the same period in 2017. The increase of $4.2 million is primarily driven by commercialization and the related increase in our direct sales force (impacting payroll, travel and training costs), as well as marketing, reimbursement consulting and market research costs. This increase is also impacted by a non-cash expense for share options granted.

Statement of financial position – Total assets of the Group at year end were $19.4 million (2017: $13.3 million). Cash on hand at 31 December 2018 was $15.5 million (2017: $10 million). Cash used in operating activities was $27.4 million during the year ended 31 December 2018 (2017: $24.9 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 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 2018, the Group made principal repayments of $3 million.

Since inception the Group has funded its operations primarily through the issuance of equity securities and debt funding. The Group continues to explore funding strategies (e.g., equity, debt, partnering) to support its activities into the future.

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 dilutive to current investors, specifically favorable to new investors, or to restrictions significantly limiting our access to additional capital or other activities.
- Our future financial performance is entirely dependent on the commercial success of ReActiv8, our only product as of the date of this Report, obtaining adequate reimbursement for ReActiv8, and rates of product adoption and market penetration.
- We operate in a highly regulated environment and regulatory approval is required before we can market or sell ReActiv8 in any market.
- To date, the only regulatory approval to market ReActiv8 is our CE Mark relating to the European Economic Area, or EEA, and Switzerland. Seeking and obtaining regulatory approval for medical devices in the United States and elsewhere can be a long and uncertain process. The failure to

achieve regulatory approval in the United States or in other key markets, the loss of our CE Mark, or strict or changing regulatory regimes, government policies and legislation in any of our target markets may delay, prohibit or reduce potential sales.

- Failure to comply with debt covenants or failure to make repayments on our debt facility could have a material adverse effect. 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.
- Any inability to fully protect and exploit our intellectual property may adversely impact our financial condition, business, prospects and results of operations.

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 24 to 56, 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. Risk management systems and policies will be reviewed regularly as conditions affecting the Group change.

The Group has no significant concentrations of financial risk other than concentration of cash with individual banks. Other than liquidity risk based on the Company's use of cash during the year, there has been no significant change during the year or since 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.

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.

Credit and financial 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.

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

The completion of and results from the ReActiv8-B Trial have caused us to set two main corporate objectives for 2019: continuing to make progress growing sales in Germany and other markets, and pursuing regulatory approval in the U.S. On the commercial front, we have been encouraged by the reaction of implanting physicians to the ReActv8-B Trial clinical data. On the regulatory front, we plan to submit a PMA to the FDA in mid-2019, with an approval decision expected in 2020.

Directors and Secretary and their interests

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

Dr Manus Rogan retired as an Executive Director on 24 September 2018.

Mr. Greg Garfield, Mr. James Reinstein and Dr. Manus Rogan retired at the Company's Annual General Meeting ("AGM") held on 21 September 2018 and submitted themselves for re-election by the shareholders. Jason Hannon, who was co-opted to the Board on 9 October 2017, submitted himself for election by the shareholders. The resolutions to re-elect and elect each Director were passed at the Company's AGM on 21 September 2018.

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.

Tom Maher ceased serving as Company Secretary on 30 January 2019 and Matthew Onaitis was appointed as Company Secretary on 30 January 2019.

The beneficial interest of the Directors and Company Secretary, who held office at 31 December 2018, 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 2018**	**At 31 December 2017**
David Brabazon	Ordinary shares of €0.001 each	57,828	27,828
Dan Sachs MD	Ordinary shares of €0.001 each	515,000	515,000
Jason Hannon	Ordinary shares of €0.001 each	30,000	-
Greg Garfield	Ordinary shares of €0.001 each	2,912	-
Tom Maher	Ordinary shares of €0.001 each	13,059	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 2018**	**No. of ordinary shares under option as at 31 December 2017**	**No. of vested options as at 31 December 2018**
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	8,498
Jason Hannon	6 Sept 2017	€14.85	10 years from vesting	401,862	401,862	125,581
Jason Hannon	23 March 2018	€16.90	10 years from vesting	118,628	-	-
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	2,841
James A. Reinstein	2 Sep 2015	€16.87	10 years from vesting	20,000	20,000	16,232
James A. Reinstein	13 Dec 2016	€15.50	10 years from vesting	6,200	6,200	3,098
Tom Maher	24 Jun 2014	€17.08	10 years from vesting	32,000	32,000	32,000
Tom Maher	8 Jan 2015	€14.90	10 years from vesting	5,000	5,000	4,890
Tom Maher	2 Sep 2015	€16.87	10 years from vesting	6,000	6,000	4,848
Tom Maher	17 Dec 2015	€17.95	10 years from vesting	15,000	15,000	11,238
Tom Maher	19 Oct 2016	€16.20	10 years from vesting	20,000	20,000	10,824

Tom Maher	23 Mar 2018	€16.90	10 years from vesting	20,000	20,000	-

Except as disclosed in this report, none of the Directors who held office at 31 December 2018, 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 2018, Sofinnova Capital VI FCPR owned 2,415,813 ordinary shares amounting to approximately 27.5% of the entire issued ordinary share capital of the Company. As 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.

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 2018, KCK Limited owned 1,152,418 ordinary shares amounting to approximately 18.0% of the entire issued ordinary share capital of the Company. 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.

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 relating to 2018:

2018:	**Fees**	**Salary**	**Annual Incentive**	**Benefits in Kind**	**Total**
Executive Directors					
Jason Hannon (Note 1)	$40,000	$473,474	-	$83,167	$596,641
Non-Executive Directors					
Oern Stuge MD	$106,292	-	-	-	$106,292
David Brabazon	$61,417	-	-	-	$61,417
Greg Garfield	-	-	-	-	-
Nael Karim Kassar	-	-	-	-	-
Antoine Papiernik	-	-	-	-	-
James A. Reinstein	$61,417	-	-	-	$61,417
Manus Rogan PhD (Note 2)	-	-	-	-	-
Dan Sachs MD	-	-	-	-	-

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 3)	-	$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	-	-	-	-	-

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. Manus Rogan retired as an Executive Director on 24 September 2018.
3. Peter Crosby retired as an Executive Director on 22 September 2017.

None of the directors exercised any share options in either 2018 or 2017.

Issued share capital

At 31 December 2018, 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 2018 AGM held on 21 September 2018:

- 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 114% of the Company's issued ordinary share capital (by number of shares) as at 29 August 2018. This authority will expire on 21 September 2023.
- 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 114% of the Company's issued ordinary share capital (by number of shares) as at 29 August 2018. This authority will expire on 21 September 2023.

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 2018 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 2018, 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.

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

Substantial shareholders

As at 31 December 2018 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	2,415,813	27.5%
KCK Limited	1,152,418	18.0%
Fountain Healthcare Partners Fund 1, L.P.	935,220	10.7%
The Ireland Strategic Investment Fund (ISIF)	714,285	8.1%
Dan Sachs MD	515,000	5.9%
Seamus Mulligan (Note 1)	372,039	4.2%
Capricorn Health-Tech Fund NV	352,718	4.0%
Perceptive Life Sciences Master Fund, Ltd	321,513	3.7%

Notes:

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

Going concern

The Directors have evaluated whether there are conditions and events, considered in aggregate, that raise doubt about the Group's ability to continue as a going concern. The Directors note the following relevant matters:

- The Group had cash of $15.5 million as at 31 December 2018 ($10 million as at 31 December 2017).
- The Group had operating cash out-flows of $27.3 million for the year ended 31 December 2018 (year ended 31 December 2017: $24.9 million).
- Due to the phase of development of the Group, the Group expects to continue to incur losses in the medium term due to the ongoing investment required in research and development, clinical and commercial activities and expects to continue to seek funding from investors or other finance providers as required.
- The Group has funded operations to date through the proceeds of equity funding of approximately $123.5 million and debt with an outstanding principal of $10.2 million as at 31 December 2018.

Subsequent to the year end, the Group has successfully extended the repayment terms of its debt arrangements to 2021 and will seek additional equity financing in 2019 in order to continue to fund its ongoing research and development, clinical and commercial activities. Under the terms of its amended debt facility, if the Group raises at least $10 million in equity financing prior to June 30, 2019, an additional €3 million will become available to the Group from its lender. As of the date of approval of these financial statements, the terms of any such additional equity finance have not yet been finalised. As there can be no certainty that this finance will be raised, or of the terms on which such finance will be raised, and because the Group is reliant on such finance in order to continue to operate at its current level into the future, this represents an uncertainty that may impact on the Group's ability to continue as a going concern. However the Directors are confident, based on discussions with investors, that additional equity funding and resultant debt funding will be received and that the amount of such funding will be sufficient to enable to the company to continue its current level of activity and to ensure that the Group is in a position to service its liabilities as they fall due for a period of at least 12 months from the date of approval of these financial statements. As a result, the Directors have prepared the financial statements on the 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 consolidated Financial Statements.

Subsidiary undertakings

At 31 December 2018, the Company (Mainstay Medical International plc) had the following subsidiaries:

- 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. Please refer to page 21 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, 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.

Auditor

The auditor, 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 21 September 2018.

On behalf of the Board on 18 April 2019,

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 Euronext Growth of Euronext Dublin 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 eight Directors, including one Executive Director, six Non-Executive Directors and the Non-Executive Chairman. The roles of Chairman and Chief Executive Officer are not exercised by the same individual.

The Board meets regularly (no less than four times per year) to consider strategy, performance and the framework of internal controls. The Directors have also established an Audit, Risk and Compliance Committee, a Remuneration Committee, and a Nominations Committee, each having 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 next succeeding paragraph 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), Mr. James Reinstein (Independent) and Dr. Oern Stuge (Independent);
- Nominations Committee - Dr. Oern Stuge (Independent Chairman), Mr. David Brabazon (Independent), Mr. Antoine Papiernik and Mr. James Reinstein (Independent);
- Remuneration Committee - Mr. James Reinstein (Independent Chairman), Mr. David Brabazon (Independent), Mr. Antoine Papiernik and Dr. Oern Stuge (Independent).

Audit, Risk and Compliance Committee

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

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.

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.

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.

Diversity Policy

The Board is keen to ensure the Group benefits from the existence of a high-quality Board comprising of individuals with an appropriate balance of skills and experience. In considering nominations to the Board, the Nomination Committee takes into account the benefit of Board diversity, including diversity of business background, geographical diversity and gender diversity.

The Board does not currently have a formal diversity policy in place due to the early stage of development of the Group. During 2019 the Board will continue to focus attention on considering nominations to the Board that re-affirms the Board's commitment to diversity across the Group.

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 Business

We have incurred significant operating losses and may not be able to achieve or subsequently maintain profitability or meet our financial obligations.

We have incurred significant net losses since we were founded. For the year ended 31 December 2018, we had a comprehensive loss of $31 million (and a comprehensive loss of $30 million for the year ended 31 December 2017). We have funded our operations through equity capital and debt. We have devoted substantially all of our resources to the research and development of ReActiv8, including to our feasibility study, our ReActiv8-A clinical trial and our ReActiv8-B clinical trial; initial commercialization efforts; and expansion of our intellectual property portfolio. Even if we do become profitable in the short or medium 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. In addition, a failure to raise sufficient capital could cause us to fail to meet contractual or other financial obligations, which could lead to legal liability or insolvency.

If we are unable to obtain or maintain additional regulatory approvals for ReActiv8 in the United States and elsewhere, we may never generate significant revenue or become profitable.

ReActiv8 is an active implantable medical device, or AIMD, which requires regulatory approval before it can be marketed or sold by us. The only regulatory approval we have received is the CE conformity assessment, or CE Marking, for ReActiv8, which allows commercialization of ReActiv8 in the European Economic Area, or EEA, and in Switzerland. 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, or that commercialization in the EEA, Switzerland or any other jurisdiction will be successful or will generate sufficient revenue and profits to cover expenses or fund future growth. Any such regulatory approval may also experience delays.

The ReActiv8-B Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on a pre-specified alternative analysis of that endpoint and on multiple secondary endpoints. We cannot be certain whether the totality of the data from the ReActiv8-B Trial will be sufficient to demonstrate safety and efficacy to the satisfaction of the FDA to allow for the granting of a PMA, or that it will be sufficient to maintain our current CE Marking.

Since our inception, we have devoted substantially all of our efforts to the development and commercialization of ReActiv8 for the treatment of CLBP. Failure to obtain FDA regulatory approval or other additional regulatory approvals, or the failure to maintain regulatory approvals once obtained, may result in our financial condition being adversely affected, and our ability to grow domestically and internationally would likely be limited. Because we do not have any other products currently in development, if we are unable to market ReActiv8 as a result of a failure to obtain FDA approval, or to obtain or maintain additional regulatory approvals, we would lose our only source of revenue, and our business would be materially adversely affected.

The FDA requires manufacturers of medical devices to obtain regulatory approval prior to commercializing products in the United States. Failing to obtain approval from the FDA could result in significant costs for us and consume management's time and other resources. The FDA could ask us to improve or augment manufacturing processes or generate and provide additional data on the quality,

efficacy or safety of ReActiv8, which could include additional clinical data. Additionally, even if we obtain FDA approval to commercialize ReActiv8 in the United States, we would be required to obtain further FDA approval prior to making any modification to ReActiv8, and we may be required to generate and provide additional data on the quality, efficacy or safety of ReActiv8 as a condition to maintaining approval. There can be no assurance that FDA approval will be ever obtained for ReActiv8.

Regulatory approval in the United States is via a pre-market approval, or PMA, issued by the FDA. We plan to submit a PMA to the FDA for ReActiv8 in mid-2019, but the timing of the PMA process is uncertain. 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 ReActiv8 no longer acceptable to the FDA.

The PMA process requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The FDA can delay, limit or deny approval of a device for many reasons, including:

- inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of clinical trials or the interpretation of data from pre-clinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- data from pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities used may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering clinical data or regulatory filings insufficient for clearance or approval.

In addition, the FDA's policies, and policies of foreign regulatory agencies, may change and additional regulations may be enacted that could prevent, limit or delay regulatory approval of our devices. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new approvals, increase the costs of compliance or restrict our ability to maintain our current approval. For example, as part of the Food and Drug Administration Safety and Innovation Act, enacted in 2012, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms, which are further intended to clarify and improve medical device regulation both pre- and post-clearance and approval. In addition, the planned withdrawal of the United Kingdom from the European Union, commonly known as Brexit, could cause additional or changed regulatory requirements relating to our products in the United Kingdom. Some of these proposals and reforms could impose additional regulatory requirements upon us that could delay our ability to obtain new approvals, increase the costs of compliance or restrict our ability to maintain our current approval.

The regulatory approval process may delay or prevent the launch of ReActiv8 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.

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 CLBP. Such acceptance will depend on medical professionals being convinced of the clinical performance, benefits, safety and cost-effectiveness of ReActiv8 and being prepared to undertake special training in certain cases.

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

Medical professionals may be hesitant to change their medical treatment practices or accept and adopt ReActiv8, including for the following reasons:

- general conservatism about adoption of new and innovative treatment practices;
- lack of awareness or acceptance of the role of inhibition of the multifidus muscle in causing CLBP and the suitability of neurostimulation therapy to address this inhibition;
- lack of experience with ReActiv8 and with neurostimulation as a treatment alternative;
- lack or perceived lack of long-term evidence, including that provided by the results of our ReActiv8-B Trial, supporting additional patient benefits;
- perceived clinical risk of a new treatment;
- inability to convince key opinion leaders to provide recommendations regarding ReActiv8, or to convince patients, physicians, or payers that ReActiv8 is an attractive alternative to other products;
- a lack of willingness to tolerate the surgical procedure required to implant ReActiv8;
- perceived liability risks associated with the use of new a product and procedures;
- limited or lack of coverage or inadequate reimbursement within healthcare payment systems;
- preference to provide other treatments which may be more lucrative for the medical professional;
- 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 to use ReActiv8.

Communicating the benefits of ReActiv8 to these physicians and hospitals requires a significant commitment by our commercial organization. Physicians and hospitals may be slow to change their practices because of perceived risks arising from the use of a new system. Physicians may not recommend or use ReActiv8 until there is more long-term commercial experience to convince them to alter their existing treatment methods, or until they receive additional recommendations from other physicians that our product is effective. We cannot predict when, if ever, physicians and hospitals may adopt use of our product.

We only recently began commercializing ReActiv8 in the EEA and have no history of commercializing ReActiv8 in the United States.

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

- established alternatives to ReActiv8 with strong relationships with customers, including physicians, hospitals and third-party suppliers;

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

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

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

A substantial portion of our current and potential future revenue depends or will depend, in part, on the extent to which the costs of ReActiv8, or procedures using ReActiv8, purchased by our customers are reimbursed by third-party payers, including Medicare, Medicaid, other U.S. government-sponsored programs, non-U.S. governmental payers and private payers. Our customers' ability to obtain adequate reimbursement for products and services from these third-party payers affects the selection of products they purchase and the prices they are willing to pay. Some of our target customers may be unwilling to adopt ReActiv8 in light of the additional associated cost. If we are forced to lower the price we charge for ReActiv8, our profit margins will decrease, which will adversely affect our ability to invest in and grow our business.

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 inpatient and ambulatory (outpatient) care. These codes and coding systems vary from country to country, including from country to country within the European Union, or EU. Payment for ReActiv8 is dependent on classification of the procedure that utilizes ReActiv8 within these coding systems.

There are existing reimbursement codes applicable to ReActiv8, which hospitals can use in Germany, Switzerland and Austria. However, there is a risk that the rules and procedures governing reimbursement may change such that hospitals cannot access reimbursement through existing codes. Additionally, payers may dispute the appropriateness of utilizing the existing reimbursement codes. If ReActiv8, or the procedures using ReActiv8, are not covered, or if reimbursement is not adequate, we may work with the relevant authorities to obtain a dedicated reimbursement code specific to ReActiv8, but there is no guarantee that we will be successful in these efforts. This can be a lengthy process and there is no guarantee that coverage or adequate reimbursement 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.

Securing coverage and adequate reimbursement depends on sufficient clinical evidence of safety and efficacy of a product. The ReActiv8-B Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on a pre-specified alternative analysis of that endpoint and on multiple secondary endpoints. Government and other third party payers may not deem the results of the ReActiv8-B Trial, or other data generated by us, to be sufficient to provide coverage or

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

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

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

We believe that the potential number of people with CLBP who could benefit from ReActiv8 therapy is significant, based on our estimate of persons suffering with CLBP 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 CLBP, as well as the global trend to reduce healthcare costs. If, as a result of these or other factors, the market for ReActiv8 does not develop as currently anticipated, our ability to generate revenue could be materially adversely affected.

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

While we 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 clinical trials for a number of reasons, including less control over the selection of people suitable to use 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 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 ReActiv8 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.

Active implantable medical devices such as ReActiv8 carry risks associated with the surgical procedure for implant or removal of the device, failure of the device, or 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 and 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.

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 our devices.

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. ReActiv8 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. We may be subject to product liability claims if ReActiv8 causes, or merely appears to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us. A product liability claim may be raised with or without merit, and as a result of factors outside our control, such as product failure, off-label use of ReActiv8, or failure of the medical practitioners or patients to follow the instructions for use. It is possible that a product liability lawsuit may be brought or 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 our clinical trials may lead to suspension or termination of the trial, which could have a material adverse effect on our business.

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

Consolidation of product liability claims into a class action lawsuit may require large dedication of resources for 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 we 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. We regularly review the level and appropriateness of the product liability insurance in place.

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

If we obtain FDA approval, we will be subject to FDA's medical device reporting regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is

an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device approval, seizure of our products or delay in clearance or approval of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, a regulatory authority may require, or we may decide, that we will need to obtain new approvals for the device before we may market or distribute the corrected device. Seeking such approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA or other regulatory authorities. We may initiate voluntary withdrawals or corrections for ReActiv8 in the future that we determine do not require notification of a regulatory authority. If a regulatory authority disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

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

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

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. While we 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 ReActiv8, which could present competition for ReActiv8.

Treatment for CLBP is potentially a very large market and may attract 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 ReActiv8 or could reach commercialization before ReActiv8. Such occurrences could have a material adverse effect on our ability to generate sufficient revenues to sustain our business.

During a clinical trial for regulatory approval, products are generally provided at no charge. Entry by a competitive product into clinical trials, while ReActiv8 is being commercialized, could have an adverse effect on our sales (for example, where ReActiv8 is approved for use and released to the market and the competitor is still in clinical development), or may inhibit timely enrollment in our on-going clinical trials.

In addition, the commercial availability of any approved competing product could potentially inhibit recruitment and enrollment in our clinical trials. We may successfully conclude our clinical trials and obtain regulatory approval but may fail to compete against potential competitors or alternative treatments for CLBP 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.

New or competing treatments for CLBP may emerge.

ReActiv8 therapy is designed as treatment for people with CLBP. Alternative therapies for this patient group may include, among others, physical therapy, 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, or TENS, osteopathic therapy, thermotherapy, lumbar stabilization exercises, spine surgery and SCS. 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 therapy, possibly at a lower cost. Patients might also prefer such new therapies to ReActiv8 therapy if such therapies do not require the patient to undergo a surgical procedure. Emergence of such new therapies that are safer, more effective, less costly, easier to use or otherwise more attractive than ReActiv8 therapy 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.

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

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

Manufacturing issues may arise that are detrimental to us.

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

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

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

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

Compliance with regulations for quality systems for medical device companies is difficult, time consuming and costly. If we or our third-party manufacturers are 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, our business could be significantly adversely affected.

We have developed and maintained a Quality Management System, or 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, or 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 generally must also comply with the QSR and ISO 13485. Any of our external vendors may become non-compliant with QSR, ISO 13485 or other applicable requirements, 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 United States and the AIMD Directive for Europe), which compliance may cause interruption to or delays in the marketing and sale of ReActiv8. 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 ReActiv8, 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.

We are dependent on access to raw materials and products and manufacturing of ReActiv8 is not guaranteed by the third parties with whom we contract.

Although we do not manufacture ReActiv8, 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 our supply chain. Disruption in our supply chain via our third-party manufacturers may result in interruption of supply of ReActiv8, which could have a material adverse impact on our ability to proceed with commercialization, continue clinical trials, and our financial condition, and could require product redesign and/or engagement with alternative manufacturers, which could be expensive and time consuming.

We depend on a limited number of third-party suppliers, and in some cases, sole suppliers, for the manufacture of ReActiv8, including the components and materials included in ReActiv8.

Disruption of the supply chain, degradation in performance of these suppliers or failure to achieve economies of scale could have a material adverse effect on our business.

We depend on a limited number of third-party suppliers for the manufacture of the ReActiv8 system and the loss of one or more of these third-party suppliers or their inability or unwillingness to supply us with adequate quantities of products could harm our business in the future. Certain of our suppliers, including Oscor Inc. and CCC del Uruguay S.A, are sole suppliers. These sole suppliers and any of our other suppliers may be subject to circumstances which impact their 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, and 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 timely meet our demand for product or components or fail to respect their contractual commitments to us or enter into relationships on commercially reasonable terms, or if the components or finished products that they supply do not meet quality and other specifications, clinical trials or commercialization of ReActiv8 could be delayed, limited or prevented. 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. Furthermore, our contract manufacturers could require us to move to another one of their production facilities. An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these components, materials or services and if we cannot then obtain an acceptable substitute.

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

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

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

In addition, our suppliers may discontinue supply of components or materials upon which we rely before the end of the product life of ReActiv8. 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, if we are able to do so at all. We may have to obtain alternative suppliers or buy substantial inventory to last until the scheduled end of life of ReActiv8 or through such time as we have an alternative product developed and approved by the regulatory authorities. We may have to temporarily cease supplying ReActiv8 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.

In some markets we may depend on distributors over which we have little or no control for the market and sale of ReActiv8. If we or our distributors do not obtain and maintain regulatory registrations or approvals for ReActiv8, we will be unable to market or sell ReActiv8.

For some markets in which we may obtain approval 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 substantially 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.

While the regulations of some countries may not impose barriers to marketing and selling ReActiv8 or only require notification, others require that we or our distributors obtain the approval of a specified regulatory body. Complying with regulatory requirements, including obtaining registrations or approvals, can be expensive and time-consuming, and we or our distributors may not receive regulatory approvals in each country in which we plan to market ReActiv8 or we may be unable to do so on a timely basis. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for FDA approval or CE Marking, and requirements for such registrations, clearances or approvals may significantly differ from FDA or EMA requirements. If we modify ReActiv8, we or our distributors may need to apply for additional regulatory approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we or our distributors have received. If we or our distributors are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

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.

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

In addition, because healthcare professionals and third-party payers will play a primary role in the recommendation and use of any product candidates for which we obtain marketing approval, our current and future arrangements with healthcare professionals and third-party payers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research on and commercialize our products. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Interpretations of standards of compliance under these laws and regulations are rapidly changing and subject to varying interpretations, and it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare 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 United States and the EU, which are complex and may be violated inadvertently.

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

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

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

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

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

We may be unable to manage our growth effectively.

Our past growth has provided, and our future growth may create, challenges for our organization. In the future, we expect to hire and train new personnel as we continue to grow and expand our operations. As a public company, we will need to support managerial, operational, financial and other resources. This growth may place significant strain on us. Successful growth is also dependent upon our ability to implement appropriate financial and management controls and systems and procedures. If we fail to manage these challenges effectively, there may be an adverse effect on our business, financial condition and results of operations.

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

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

Under rules contained in U.S. tax law (Section 7874 of the Internal Revenue Code of 1986, as amended, or the 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% of the non-U.S. company’s stock by reason of their holding stock in the U.S. corporation.

In 2014 we undertook a corporate reorganization during which we acquired the assets (being shares in Mainstay Medical Limited, or MML, one of our wholly owned subsidiaries) of Mainstay Medical Inc., a U.S. corporation, and former shareholders of Mainstay Medical Inc. became shareholders of Mainstay Medical International plc. The ownership of equity that former shareholders of Mainstay Medical Inc. received in the 2014 corporate reorganization is substantially below the 80% standard for application of the above U.S. rules. Accordingly, we do not believe these rules should apply. There can, however, be no assurance that the U.S. Internal Revenue Service, or IRS, will not challenge the determination that these rules are inapplicable. In addition to the 2014 corporate reorganization, there was an earlier reorganization in 2012, which, if viewed as integrated with the 2014 corporate reorganization, could lead the IRS to assert that the above 80% test was met. We do not believe such integrated treatment to be appropriate because there were 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.

The anti-tax avoidance directive could negatively affect our results.

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

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, 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.

If our ordinary shares cease to be listed on the Euronext Growth operated by Euronext Dublin, certain transfers of our ordinary shares will be subject to Irish stamp duty.

Our ordinary shares are currently listed on the Euronext Growth operated by Euronext Dublin. Under Irish law, stamp duty is generally payable on transfers of shares of an Irish company (other than transfers between spouses) whenever a document of transfer is executed. Stamp duty is generally charged at a rate of 1%, rounded to the nearest euro, and is payable by the transferee (or, in some cases, all parties to the transfer). Under Irish law, transfers of shares of Irish companies listed on the Euronext Growth operated by Euronext Dublin are exempt from stamp duty. As a result, stamp duty is not currently chargeable on transfers of our ordinary shares. If our ordinary shares cease to be listed on the Euronext Growth operated by Euronext Dublin, however, stamp duty would be payable on such transfers to the extent they involve an instrument of transfer, subject to certain exceptions.

Risks Relating to Intellectual Property

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.

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. It is difficult for industry participants, including us, to identify all third-party patent rights relevant to ReActiv8 or our services and technologies. Moreover, because some patent applications are maintained as confidential for a certain period of time, we cannot be certain that third parties have not filed patent applications that cover ReActiv8 or our services and technologies. Potential competitors may have or develop patents and other intellectual property that they assert ReActiv8 infringes.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file one or more lawsuits and assert infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable or may refuse to enjoin the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly in differing jurisdictions or as new technologies develop. As a result, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Further, even if we prevail against an infringer in U.S. district court, there is always the risk that the infringer will file an appeal and the district court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted in a manner insufficient to achieve our business objectives.

Any infringement claim against us, even if without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources and/or divert the time and efforts of management from our core business. Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, we may indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our products. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers or distributors, or may be required to obtain licenses to third-party intellectual property rights for the products or services they use. 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.

In addition, any potential intellectual property litigation could force us to do one or more of the following: stop selling/using our product or using technology that contains the allegedly infringing intellectual property; forfeit the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others; pay substantial damages to the party whose intellectual property rights we may be found to be infringing; redesign those products that contain or utilize the allegedly infringing intellectual property; or attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all. Any intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology. Any of these circumstances may have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our financial condition, business, results of operations or prospects, as our customers may be forced to stop using our products or services.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a material adverse effect on the price of our ordinary shares. The occurrence of any of these events may have a material adverse effect on our business, results of operation, financial condition or cash flows.

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

As is the case with other medical device companies, our success is heavily dependent on intellectual property protection, particularly from patents. Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to 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, or 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 March 16, 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 defense of our issued patents, all of which could have a material adverse effect on our 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 defense 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 U.S. patent laws 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 United States or other countries. Those changes may affect our patents or patent applications and our ability to obtain additional patent protection in the future.

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

The USPTO and various 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 ReActiv8 or other inventions, we may not be able to stop a potential competitor from marketing products that are the same as, or similar, to our own, which would have a material adverse effect on our financial condition, business, prospects and results of operations.

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

Filing, prosecuting and defending patents on ReActiv8 in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in some or all countries outside the United States. 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 but 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 could put 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 ReActiv8 and our competitive position in those countries could be materially harmed.

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 nondisclosure, confidentiality and other contractual agreements to protect our intellectual property rights against third-party challenges and enforce our intellectual property rights to prevent third-party infringement. We generally seek patent protection where possible for those aspects of our technology and product that, we believe, provide significant competitive advantages. 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, is expensive and may take many years. We may choose not to seek patent protection for certain innovations of products and may choose not to pursue patent protection in certain jurisdictions. 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 United States, 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, or for the reasons indicated above, we choose not to obtain a patent in one or more other jurisdictions. As a result, ReActiv8 may not be protected by patents in some jurisdictions. We generally apply for patents in those countries where we intend to make, have made, use, offer for sale, or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we sell products and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a

patent application in any such country or major market, we may be precluded from doing so at a later date. 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 but that may not be sufficient to terminate infringing activities. In addition, adverse patent decisions in one jurisdiction may adversely impact the ability to succeed in another jurisdiction or may adversely impact another, related patent or patent application we hold. 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.

The patent positions of medical device companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly. Changes in either the patent laws, implementing regulations or the interpretation of patent laws may diminish the value of our rights. The legal systems of certain countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions.

Because patent applications in the United States, Europe and many other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to conceive or reduce to practice the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or pending patent applications. We can give no assurance that all of the potentially relevant art relating to our patents and patent applications has been found and overlooked prior art could be used by a third party to challenge the validity, enforceability and scope of our patents or prevent a patent from issuing from a pending patent application. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the validity, enforceability and scope of our patents in the United States, Europe and in other countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against our competitors.

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 invention 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 ReActiv8, we might be required to cease such development or sale, pay damages to the owners or negotiate a license arrangement, which may not be available on reasonable terms or at all.

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. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or reexamination by the USPTO if a third party asserts a substantial question of patentability against any claim of a U.S. patent we own or license. The adoption of the Leahy-Smith Act in September 2011 established additional opportunities for third parties to invalidate U.S. patent claims, including inter partes review and post-grant review proceedings. Outside of the United States, patents we own or license may become subject to patent opposition or similar proceedings, which may result in loss of scope of some claims or the entire patent. In addition, such proceedings are very complex and expensive, and may divert our management's attention from our core

business. If any of our patents are challenged, invalidated, circumvented by third parties or otherwise limited or expire prior to the commercialization of ReActiv8, and if we do not own or have exclusive rights to other enforceable patents protecting ReActiv8 or other technologies, competitors and other third parties could market products and use processes that are substantially similar to, or superior to, ours and our business would suffer.

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 ReActiv8 but that are not covered by our patents. Third parties may also have blocking patents that could prevent us from marketing ReActiv8 or practicing our own patented technology. We may also not develop additional proprietary technologies that are patentable.

Much of our 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 us. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage.

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

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

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

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 ReActiv8 and our 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 and that those employees or third parties will not breach such agreements and disclose our trade secrets and other unpatented or unregistered proprietary information. Once disclosed, we would be likely to lose trade secret protection. Unauthorized use or disclosure of our confidential and proprietary information may have a material adverse effect on our financial condition, business, prospects and results of operations. Monitoring such disclosures is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to enforce trade secret protection.

Further, our competitors may independently develop knowledge, methods and know-how similar, equivalent, or superior to our proprietary technology. Competitors could purchase ReActiv8 and attempt to reverse engineer and replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology, or develop their own competitive technologies that fall outside of our intellectual property rights. In addition, our key employees, consultants, suppliers or other individuals with access to our proprietary technology and know-how may incorporate that technology and know-how into projects and inventions developed independently or with third parties. As a result, disputes may arise regarding the ownership of the proprietary rights to such technology or know-how, and any such dispute may not be resolved in our favor. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us, and our competitive position could be adversely

affected. If our intellectual property is not adequately protected so as to protect our market against competitors' products and processes, our competitive position could be adversely affected, as could our business.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market ReActiv8.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are accurate, complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of ReActiv8 in any jurisdiction. For example, U.S. patent applications filed before November 29, 2000 and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover ReActiv8 or the use of ReActiv8. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market ReActiv8. We may incorrectly determine that ReActiv8 is not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products and services. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products and services.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our products that are held to be infringing. We might, if possible, also be forced to redesign products or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

The patent protection for ReActiv8 may expire before we are able to maximize its commercial value, which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue.

Patents have a limited lifespan. In the United States, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. The patents for ReActiv8 have varying expiration dates and, if these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. For example, U.S. Patent No. 8,606,358 is set to expire March 10, 2028, if all maintenance fees are paid timely. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our patent rights may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Intellectual property rights do not necessarily address all potential threats to our business.

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

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

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

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

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We do and may employ individuals who were previously employed at universities or other medical device companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims.

Litigation may be necessary to defend against these claims. If we fail in defending against any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees and could result in customers seeking other sources for the technology, or in ceasing from doing business with us.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology or affect financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

We may not be successful in obtaining necessary intellectual property rights to future products through acquisitions and in-licenses.

Although we intend to develop products and technology through our own internal research, we may also seek to acquire or in-license technologies to grow our product offerings and technology portfolio. We may be unable to acquire or in-license intellectual property rights relating to, or necessary for, any such products or technology from third parties on commercially reasonable terms or at all. In that event, we may be unable to develop or commercialize such products or technology. We may also be unable to identify products or technology that we believe are an appropriate strategic fit for our company and protect intellectual property relating to, or necessary for, such products and technology.

The in-licensing and acquisition of third-party intellectual property rights for product candidates is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for products that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. If we are unable to successfully obtain rights to additional technologies or products, our business, financial condition, results of operations and prospects for growth could suffer.

In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for products and technologies that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in-license or acquire the third-party intellectual property rights for products or technology on terms that would allow us to make an appropriate return on our investment.

Risks Relating to Our Financial Condition and Capital Requirements

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 dilutive to existing shareholders or 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 continue 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, primarily being, at this point, our 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.

Our future financial performance is entirely dependent on the commercial success of ReActiv8, our only product, obtaining regulatory approvals of ReActiv8 in additional markets, obtaining adequate reimbursement for ReActiv8 in markets where ReActiv8 is or becomes approved, and rates of product adoption and market penetration.

Our only product, ReActiv8, is designed to treat people suffering from 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.

Our 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, MML, a wholly owned subsidiary of MMI, entered into a debt facility of up to $15 million with IPF Fund I SCA SICAV-FIS, or IPF, as the Lender. As of 31 December 2018, the aggregate principal amount outstanding under the debt facility was $10.2 million. On 18 April 2019, MML entered into an amendment agreement with IPF relating to the debt facility. The debt facility is guaranteed by MMI and is secured by certain assets and undertakings of MML and by the equity interests of MML held by MMI. Our debt facility also contains various covenants that limit our ability to engage in specified types of transactions. Subject to limited exceptions, these covenants limit our ability to, among other things:

- sell, lease, transfer, exclusively license or dispose of our assets;
- create, incur, assume or permit to exist additional indebtedness or liens;
- make restricted payments, including paying dividends on, repurchasing or making distributions with respect to our capital stock;
- make specified investments (including loans and advances);
- merge, consolidate or liquidate; and
- enter into any transaction or agreement with anyone except on arm's length terms.

In addition, our debt facility includes certain financial covenants, including a requirement that MML hold a minimum cash balance sufficient to cover at least three months of forecasted cash outflows. The debt facility also specifies that it will be an event of default if, among other things, any event or circumstance occurs which would have a material adverse effect (as defined in the facility agreement) or if our independent auditor qualifies its opinion on our annual audited financial statements in a manner that IPF determines is materially adverse to the debt facility. The agreement also includes monthly and quarterly reporting requirements. If we fail to comply with the covenants or fail to make repayments of principal or interest or otherwise experience or commit an event of default, IPF may accelerate repayment of the loan, with penalties, and may enforce its security interest, either of which would have a material adverse effect on our financial condition, business, prospects and/or results of operations.

Risks Relating to Regulation of Our Industry

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 must comply with complex regulatory requirements in our target markets before we can market or sell ReActiv8 in each market. Once initial regulatory approval is gained for ReActiv8 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, or the AIMD Directive, as implemented in applicable national laws of the respective EU member states, 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, the New EU Medical Device Regulations, a package of EU legislation replacing the existing regulatory framework for medical devices in the EU, including for AIMD, entered into force. The New EU Medical Device Regulations will apply in full as of 2020 but require implementing action and strategic decisions as of now.

The New EU Medical Device Regulations mean a more centralized 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 United States, 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 PMA application, which in our case is the ReActiv8-B Trial. 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. The ReActiv8-B Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on a pre-specified alternative analysis of that endpoint and on multiple secondary endpoints. We cannot be certain whether the totality of the data from the ReActiv8-B Trial will be sufficient to demonstrate safety and efficacy to the satisfaction of 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.

We are required to conduct clinical trials for regulatory approvals and other purposes. The clinical trial process required to obtain regulatory approvals carries substantial risks and is lengthy and expensive with uncertain outcomes. If clinical studies of ReActiv8 or our future products do not produce results necessary to support regulatory clearance or approval in the United States or elsewhere, we will be unable to expand the indications for or commercialize these products and may incur additional costs or experience delays in completing, or ultimately be unable to complete, the commercialization of those products.

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

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

In order to obtain PMA approval for a device, the sponsor must conduct well-controlled clinical trials designed to assess the safety and efficacy of the product candidate. Conducting clinical trials is a complex and expensive process, can take many years, and outcomes are inherently uncertain. We incur substantial expense for, and devote significant time to, clinical trials but cannot be certain that the trials will ever result in commercial sales. We may suffer significant setbacks in clinical trials, even after earlier clinical trials showed promising results, and failure can occur at any time during the clinical trial process. Any of our products may malfunction or may produce undesirable adverse effects that could cause us or regulatory authorities to interrupt, delay or halt clinical trials. We, the FDA or another regulatory authority may suspend or terminate clinical trials at any time to avoid exposing trial participants to unacceptable health risks. The ReActiv8-B Trial did not achieve statistical significance on its primary endpoint, but it did achieve statistical significance on a pre-specified alternative analysis of that endpoint and on multiple secondary endpoints. We cannot be certain whether the totality of the data from the ReActiv8-B Trial will be sufficient to demonstrate safety and efficacy to the satisfaction of the FDA to allow for the granting of a PMA. Failure to achieve FDA approval may require product redesign, new or additional clinical trials, additional testing, and other measures which typically require significant additional cost and time.

Successful results of pre-clinical studies are not necessarily indicative of future clinical trial results, and predecessor clinical trial results may not be replicated in subsequent clinical trials. Additionally, the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the clearance or approval of our products. The data we collect from our pre-clinical studies and clinical trials may not be sufficient to support FDA clearance or approval, and if we are unable to demonstrate the safety and efficacy of our future products in our clinical trials, we will be unable to obtain regulatory clearance or approval to market our products.

In addition, we may estimate and publicly announce the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals, which are often referred to as milestones. These milestones could include the enrollment of patients in clinical trials; the release of data from clinical trials; and other clinical and regulatory events. The actual timing of these milestones could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot assure you that we will meet our projected milestones and if we do not meet these milestones as publicly announced, the commercialization of ReActiv8 may be delayed and, as a result, our stock price may decline.

Clinical trials are necessary to support PMA applications and may be necessary as a condition to the initial approval or to support PMA supplements for modified versions of our marketed device products. This would require the enrollment of large numbers of suitable subjects, which may be difficult to identify, recruit and maintain as participants in the clinical trial. Adverse outcomes in the post-approval studies could also result in restrictions or withdrawal of approval of the PMA.

We are required to conduct post-approval clinical studies, we may face similar requirements in the future, and we may need to conduct additional clinical studies in the future to support new indications for ReActiv8 or for approvals or clearances of new product lines, or for the approval of the use of ReActiv8 in some foreign countries. All clinical investigations of investigational devices must be conducted in accordance with FDA's IDE regulations. Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed or halted for numerous reasons. We may experience a number of events during, or as a result of, clinical trials that could adversely affect the costs, timing or successful completion of our clinical trials, including:

- we may be required to submit an IDE application to FDA, which must become effective prior to commencing human clinical trials, and FDA may reject our IDE application and notify us that we may not begin investigational trials;

- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators and/or institutional review boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- regulators may determine that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself;
- we may not reach agreement on acceptable terms with clinical trial sites or other contractors, the terms of which can be subject to extensive negotiation and may vary significantly;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might to have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- regulators, IRBs or other parties may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials may be greater than we anticipate;
- regulators, IRBs or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- the potential for approval policies or regulations of FDA or applicable foreign regulatory agencies to change in a manner rendering our clinical data insufficient for approval; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product candidate. In addition, patients participating in our clinical trials may drop out before completion of the trial or suffer adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions at which such studies are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using the investigational product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial, the approval and commercial prospects of our device may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down the approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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; 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 enrollment, have adverse regulatory impact, prevent us from securing patent protection, result in diminished competitive position or damage our reputation.

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, or PMCF, to gather additional data on long term performance and safety of ReActiv8, 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 United States (if granted), the FDA may require us to conduct one or more post-approval studies, which could be extensive, expensive and time consuming.

Any post-approval studies conducted by us or on our behalf 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.

The misuse or off-label use of ReActiv8 may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

ReActiv8 received a CE Mark for a specific indication for use, and if ReActiv8 receives FDA approval, that approval will be limited to specific indications for use. We train our current sales and marketing personnel, and if ReActiv8 receives FDA approval we will train any future U.S. marketing and sales personnel, to not promote ReActiv8 for uses outside of the approved indications for use, known as “off-label uses.” We cannot, however, prevent a physician from using ReActiv8 off-label, when in the physician’s independent professional medical judgment he or she deems it appropriate. There may be

increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of ReActiv8 for indications other than those approved by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, physicians may misuse ReActiv8 or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If ReActiv8 is misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described below, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

We are or will become subject to certain fraud and abuse laws, health information privacy and security laws and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

We are or will become subject to healthcare fraud and abuse regulation and enforcement, which could significantly impact our business. Fraud and abuse laws can vary significantly by jurisdiction, complicating our compliance effort. In the United States, the laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate the Anti-Kickback statute itself to have committed a violation. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of manufacturers and distributors like us. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $74,792 for each violation, plus up to three times the remuneration involved. Violations of the federal Anti-Kickback Statute can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. In addition, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government. These laws may apply to manufacturers and distributors who provide information on coverage, coding, and reimbursement of their products to persons who do bill third-party payers. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties ranging from $11,181 to $22,363 for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of these statutes or specific intent to violate them to have committed a violation;
- the federal Physician Sunshine Act requirements under the 2010 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or, collectively, the ACA, which impose reporting and disclosure requirements on device and drug manufacturers for any "transfer of value" made or distributed by certain manufacturers of drugs, devices, biologics, and medical supplies to physicians (including doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers; and
- state and foreign law equivalents of each of the above federal laws, such as state anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, pricing transparency laws, and permitting laws.

Similar laws will apply to us and our operations in Europe and other jurisdictions. These laws and regulations constrain our promotional and other business activities by limiting the kinds of financial interactions, including discount and other commercial transactions, we may have with individuals or entities that use, order, purchase or recommend ReActiv8 such as patients and healthcare providers. The scope and enforcement of these laws are uncertain and subject to change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations and vary by jurisdiction. Due to the breadth of these laws, the narrowness of exceptions and/or safe harbors available, and the range of interpretations to which the laws are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

Enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us now or in the future, we may be subject to penalties, including civil and criminal penalties, damages, fines, disgorgement, exclusion from governmental health care programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Our use and disclosure of individually identifiable information, including health information, is subject to privacy and security regulations, and our failure to comply with those regulations or to adequately secure the information we hold could result in significant liability or reputational harm.

We are or may become subject to foreign, federal, and state laws and regulations regarding the processing (including disclosure and use) of personal data. The privacy and security of personally identifiable information stored, maintained, received or transmitted electronically is a major issue in Europe, the United States and elsewhere. While we strive to comply with all applicable privacy and security laws and regulations, as well as our own posted privacy policies, legal standards for privacy, continue to evolve and any failure or perceived failure to comply may result in proceedings or actions against us by government entities or others, or could cause us to lose audience and customers, which could have a material adverse effect on our business. Recently, there has been an increase in public awareness of privacy issues in the wake of revelations about the activities of various government

agencies and in the number of private privacy-related lawsuits filed against companies. Concerns about our practices with regard to the collection, use, disclosure or security of personally identifiable information or other privacy-related matters, even if unfounded and even if we are in compliance with applicable laws, could damage our reputation and harm our business.

HIPAA establishes a set of national privacy and security standards for the protection of individually identifiable health information, including what is known as protected health information, by health plans, healthcare clearinghouses and healthcare providers that submit certain covered transactions electronically, or covered entities, and their "business associates," which are persons or entities that perform certain services for, or on behalf of, a covered entity that involve the use or disclosure of protected health information. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties up to $55,910 per violation, not to exceed $1.68 million per calendar year for non-compliance of an identical provision and, in certain circumstances, criminal penalties with fines up to $250,000 and/or imprisonment. In addition, HIPAA authorizes state attorneys general to file suit under HIPAA on behalf of state residents. Courts can award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for HIPAA violations, its standards have been used as the basis for a duty of care claim in state civil suits such as those for negligence or recklessness in the misuse or breach of protected health information, or PHI.

Numerous other laws and regulations govern collection, dissemination, use and confidentiality of personally identifiable health information, including (i) U.S. state privacy and confidentiality laws (including state laws requiring disclosure of breaches); and (ii) European and other foreign data protection laws, including the GDPR (as defined below). We therefore must comply with strict data protection and privacy laws and regulations, including the Data Protection Acts 1988 and 2003 and the European Communities (Electronic Communications Networks and Services) (Privacy and Electronic Communications) Regulations 2011.

The EU General Data Protection Regulation, or GDPR, came into force in May 2018 and contains numerous requirements and changes from existing EU law, including more robust obligations on data processors and data controllers and heavier documentation requirements for data protection compliance programs. Specifically, the GDPR introduced numerous privacy-related changes for companies operating in the EU, including greater control over personal data by data subjects (e.g., the "right to be forgotten"), increased data portability for EU consumers, data breach notification requirements and increased fines. In particular, under the GDPR, fines of up to €20 million or up to 4% of the annual global revenue of the noncompliant company, whichever is greater, could be imposed for violations of certain of the GDPR's requirements. The GDPR requirements apply not only to third-party transactions, but also to transfers of information between us and our subsidiaries, including employee information. We are required to comply with the GDPR as a "Data Controller" and a "Data Processor."

We are also subject to evolving EU laws on data export, as we may transfer personal data from the European Union to other jurisdictions. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. In addition, these rules are constantly under scrutiny. For example, following a decision of the Court of Justice of the European Union in October 2015, transferring personal data to U.S. companies that had certified as members of the U.S. Safe Harbor Scheme was declared invalid. In July 2016 the European Commission adopted the U.S.-EU Privacy Shield Framework which replaces the Safe Harbor Scheme. However, this Framework is under review and there is currently litigation challenging other EU mechanisms for adequate data transfers (i.e., the standard contractual clauses). It is uncertain whether the Privacy Shield Framework and/or the standard contractual clauses will be similarly invalidated by the European courts. We rely on a mixture of mechanisms to transfer personal data from our EU business to the United States and could be impacted by changes in law as a result of a future review of these transfer mechanisms by European regulators under the GDPR, as well as current challenges to these mechanisms in the European courts.

Any failure or perceived failure by us to comply with privacy or security laws, policies, legal obligations or industry standards or any security incident that results in the unauthorized release or transfer of personally identifiable information may result in governmental enforcement actions and investigations, fines and penalties, litigation and/or adverse publicity, including by consumer advocacy groups, and could cause our customers to lose trust in us, which could have an adverse effect on our reputation and business. Such failures could have a material adverse effect on our financial condition and operations. If the third parties we work with violate applicable laws, contractual obligations or suffer a security

breach, such violations may also put us in breach of our obligations under privacy laws and regulations and/or could in turn have a material adverse effect on our business.

Healthcare reform may have a material adverse effect on our industry and our results of operations.

In March 2010, the ACA was signed into law in the United States. The ACA made changes that significantly affected the healthcare industry, including medical device manufacturers. The ACA included new fees or taxes on certain health-related industries, including medical device manufacturers. Beginning in 2013, entities that manufacture, produce or import medical devices were required to pay an excise tax in an amount equal to 2.3% of the price for which such devices are sold in the United States. Through a series of legislative amendments, the tax was suspended for 2016 through 2019, but is scheduled to return beginning in 2020, absent further Congressional action. The ACA also included, among other things, demonstrations to develop organizations that are paid under a new payment methodology for voluntary coordination of care by groups of providers, such as physicians and hospitals, and the establishment of a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research. The increased funding and focus on comparative clinical effectiveness research, which compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products, may result in lower reimbursements by payers for ReActiv8 in the U.S., if ReActiv8 is approved by the FDA, and decreased profits to us.

Other federal legislative changes have been proposed and adopted since the ACA was enacted. These changes included an aggregate reduction in Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The full impact on our business of the ACA and other new laws, including any outside of the U.S., is uncertain. Healthcare reform measures that may be adopted in the future, singularly or in the aggregate, could have a material adverse effect on our business, financial condition and results of operations.

Risks Relating to Our Ordinary Shares

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, and your investment in us could suffer a decline in value.

Although our ordinary shares have been traded on the regulated market of Euronext Paris and the Euronext Growth operated by Euronext Dublin since May 2014, an active trading market for our ordinary shares may never develop or be sustained In the absence of an active trading market for our ordinary shares, investors may not be able to sell their ordinary shares at a price that is satisfactory or at the time that they would like to sell. The market price of ordinary shares could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- our failure to obtain regulatory approval for ReActiv8 beyond CE Marking;
- our failure to successfully 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 ReActiv8;
- 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 regulated market operated by Euronext Paris or the Euronext Growth operated by Euronext Dublin;
- 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 us of ordinary shares or transfers or sales of ordinary shares by shareholders;
- issue or exercise of share warrants or share awards;
- new legislation in the markets in which we operate relating to the development or commercialization of ReActiv8; and
- general economic and market conditions in the markets in which we operate.

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.

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

Our executive officers, directors, current 5% or greater shareholders and affiliated entities beneficially owned approximately 71.3% of our ordinary shares outstanding at 31 December 2018. 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 shareholders, including those who purchase ordinary shares in this offering, oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other shareholders may view as beneficial.

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

The trading market for the 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 the ordinary shares would be negatively impacted. If one or more of the analysts who covers us downgrades the ordinary shares or publishes unfavorable research about our business, the price of the ordinary shares would likely decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly or downgrades the ordinary shares demand for the ordinary shares could decrease, which could cause the price of the ordinary shares or trading volume to decline.

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

We have never declared or paid any cash dividends on our ordinary shares and do not currently intend to do so for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your ordinary shares for the foreseeable future and the success of an investment in the ordinary shares will depend upon any future appreciation

in our value. Consequently, investors may need to sell all or part of their holdings of the ordinary shares after price appreciation, which may never occur, as the only way to realize any future gains on their investment. Investors seeking cash dividends should not purchase our ordinary shares.

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

We do not currently expect to declare or pay dividends on our ordinary shares for the foreseeable future. To the extent that we determine in the future to pay dividends, in certain limited circumstances, dividend withholding tax (currently at a rate of 20%) may arise in respect of dividends paid on our ordinary shares. A number of exemptions from the obligation to operate 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 United States, should generally be entitled to receive dividends without deduction of 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 for many of the exemptions to apply.

Any sale, purchase or exchange of the ordinary shares may become subject to the European Financial Transaction Tax, or FTT.

On February 14, 2013 the European Commission published a proposal, or the Commission Proposal, for a Council Directive implementing enhanced cooperation for a FTT requested by Austria, Belgium, Estonia, France, Germany, Greece, Italy, Portugal, Slovakia, Slovenia and Spain, which we refer to collectively (except for Estonia) as the Participating Member States. However, on March 16, 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. The FTT would impose a charge at generally not less than 0.1% of the sale price on such transactions.

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. The mechanism by which the tax would be applied and collected is not yet known, but if the proposed directive or any similar tax is adopted, transactions in shares would be subject to higher costs, and the liquidity of the market for our ordinary shares might decrease.

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 January 1, 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. In addition, other EU member states may decide to participate. Moreover, once a final agreement on such FTT proposal is reached, which would be referred to as 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 advisors in relation to the consequences of the FTT associated with subscribing for, purchasing, holding and disposing of ordinary shares.

A takeover offer for our 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 our securities.

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, we are, for the purposes of Directive 2004/25/EC of the European Parliament and the Council dated April 21, 2004, or the Takeover Bids Directive, a shared jurisdiction company. This means that a takeover offer or bid for our securities would be subject to the 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 in most other respects.

In the case of a takeover offer for a shared jurisdiction company, the Takeover Bids 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 directors 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 we have our registered office, in this case, Ireland.

We believe we are currently the only shared jurisdiction company (current or previous) for the purposes of the Takeover Bids 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 us 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. We believe 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.

If we raise additional capital in the future, your level of ownership in us could be diluted or require us to relinquish rights.

Any issuance of securities we may undertake in the future to raise additional capital could cause the price of our ordinary shares to decline or require us to issue shares at a price that is lower than that paid by holders of our ordinary shares in the past, which would result in those newly issued shares being dilutive.

Further, if we obtain funds through a debt financing or through the issuance of debt or preference securities, these securities would likely have rights senior to your rights as an ordinary shareholder, which could impair the value of our ordinary shares. Any debt financing, we enter into may include covenants that limit our flexibility in conducting our business. We also could be required to seek funds through arrangements with collaborators or others, which might require us to relinquish valuable rights to our intellectual property or product candidates that we would have otherwise retained.

Sales of a substantial number of our ordinary shares in the public market could cause our share price to fall.

Sales of a substantial number of our ordinary shares in the public market could occur at any time. These sales, or the perception in the market that these sales may occur, could result in a decrease in the market price of our ordinary shares.

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, the Directors are required to prepare the Group Financial Statements in accordance with IFRS as adopted by the European Union and applicable law including Article 4 of the IAS Regulation. The Directors have elected to prepare the Company Financial Statements in accordance with IFRS as adopted by the European Union as applied in accordance with the provisions of 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 or loss for that 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 whether applicable Accounting Standards have been followed, subject to any material departures disclosed and explained in the Financial Statements;
- assess the Group and Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern; and
- use the going concern basis of accounting unless they either intend to liquidate the Group or Company or to cease operations or have no realistic alternative but to do so.

The Directors are also required by the Transparency (Directive 2004/109/EC) Regulations 2007 and the Transparency Rules of the Central Bank of Ireland to include a management report containing a fair review of the business and a description of the principal risks and uncertainties facing the Group.

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 provision 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 including Article 4 of the IAS Regulation. They are responsible for such internal controls as they determine is necessary to enable the preparation of Financial Statements that are free from material misstatement, whether due to fraud or error, and have general 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 Group's and Company's website http://www.mainstay-medical.com. Legislation in Ireland concerning the preparation and dissemination of Financial Statements may differ from legislation in other jurisdictions.

Each of the Directors, whose names and functions are listed on page 3 of this Annual Report, confirm that, to the best of each person's knowledge and belief:

- The Group Financial Statements, prepared in accordance with IFRS as adopted by the European Union and the Company Financial Statements prepared in accordance with IFRS as adopted by the European Union as applied in accordance with the provisions of Companies Act 2014, give a true and fair view of the assets, liabilities, and financial position of the Group and Company at 31 December 2018 and of the loss of the Group for the year then ended;
- The Directors' Report contained in the Annual Report includes a fair review of the development and performance of the business and the position of the Group and Company, together with a description of the principal risk and uncertainties that they face; and

- The Annual Report and Financial Statements, taken as a whole, provides the information necessary to assess the Group's performance, business model and strategy and is fair, balanced and understandable and provides the information necessary for shareholders to assess the Company's position and performance, business model and strategy.

On behalf of the Board on 18 April 2019,

Oern Stuge MD	**Jason Hannon**
Chairman	*CEO*

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

Report on the audit of the financial statements

Opinion

We have audited the Group and Company Financial Statements of Mainstay Medical International plc ('the Company') for the year ended 31 December 2018 set out on pages 64 to 97, which comprise the Consolidated statement of profit or loss and other comprehensive income, the Consolidated and Company statements of financial position, the Consolidated and Company statements of changes in equity, the Consolidated and Company statements of cash flows, and related notes, including the summary of significant 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 Financial Statements give a true and fair view of the assets, liabilities and financial position of the Group and Company as at 31 December 2018 and of the Group's loss for the year then ended;
- 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, and as applied in accordance with the provisions of the Companies Act 2014; and
- the Group 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 under those standards are further described in the Auditor's Responsibilities section of our report. We believe that the audit evidence we have obtained is a sufficient and appropriate basis for our opinion. Our audit opinion is consistent with our report to the audit committee.

We were appointed as auditor by the directors on 2 May 2014. The period of total uninterrupted engagement is the 5 years ended 31 December 2018. 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 public interest entities. No non-audit services prohibited by that standard were provided.

Material uncertainty related to going concern

In forming our opinion, which is not qualified, we have considered the adequacy of the disclosures provided in the basis of preparation note to the financial statements. As discussed in that note, the Group will seek additional equity and debt finance in 2019 to fund its future operations. That the receipt of such funding cannot be certain as of the date of approval of the financial statements represents a material uncertainty that may cast doubt on the Group's ability to continue as a going concern. The directors have considered this uncertainty and are satisfied, based on the current status of funding discussions, that such finance will be received and will be sufficient to fund the ongoing activities of the Group. On this basis they have prepared the financial statements on the going concern basis.

Key audit matters: our assessment of risks of material misstatement

Key audit matters are those matters that, in our professional judgment, 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 of 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, in decreasing order of audit significance, were as follows (unchanged from 2017):

Revenue recognition $0.66 million (2017 - $0.35 million)

Refer to page 70 (accounting policy) and page 75 (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 related to the transfer of substantial risks to the customer, particularly where there are master supply arrangements.	We obtained and documented our understanding of the Group's revenue process, and tested the design and implementation of the relevant controls therein. 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 recognised in the year: - We tested the existence and accuracy of a sample of revenue transactions in the period, by agreeing revenues to customer 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 that the performance obligations had been satisfied and that control had been transferred to the customer; and - We performed procedures to confirm the appropriate authorisation of manual journals entries posted to the revenue account. Based on the procedures performed we identified no material misstatements and found the disclosures relating to revenue to be sufficient.

Share based payment expense $4.103 million (2017 - $3.045 million)

Refer to page 73 (accounting policy) and pages 88 to 89 (financial disclosures)

The key audit matter	How the matter was addressed in our audit
The Group operates a share option plan. The accounting for this plan involves making judgements in respect of the inputs to the valuation model, including assessment of the expected term of options to exercise and expected share price volatility. Changes in the assumptions and	In this area our procedures included, but were not limited to: - We obtained an understanding of the Group's share based incentive scheme process, and tested the design and implementation of the relevant controls therein; - As certain inputs to the model are factual, we tested a sample of this data to source documentation. This consisted of

estimates used could have a material impact on the results and financial position of the Group.	agreeing information, including the 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. - We assessed the adequacy of the group's disclosures when compared to the requirements of IFRS 2. Based on the procedures performed over share based payments, we did not identify any material misstatements in the calculation of the charge, and consider the judgements used to be reasonable. We found the disclosures relating to the share based payments per the financial statements to be appropriate. *Share based payment expense – 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.

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 $0.15 million (2017: $0.14 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 (2017: $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 $0.15 million (2017: $0.14 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.

Other information

The directors are responsible for the other information presented in the Annual Report together with the Financial Statements. The other information comprises the information included in the Directors' Report, Chairman's statement, Corporate governance report, and Risk factors. The Financial Statements and our auditor's report thereon do not comprise part of the other information. 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 our work on the other information:

- we have not identified material misstatements in the Other Information;

- in our opinion, the information given in the Other Information is consistent with the Financial Statements;
- in our opinion, the Directors' Report has been prepared in accordance with the Companies Act 2014.

Other corporate governance disclosures

In addition as required by the Companies Act 2014, we report, in relation to information given in the Corporate Governance Statement on pages 20 to 23, 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;
- 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; and
- the Corporate Governance Statement contains the information required by the European Union (Disclosure of Non-Financial and Diversity Information by certain large undertakings and groups) Regulations 2017.

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

Our opinions on other matters prescribed by 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 Group Financial Statements and the Company statement of financial position to be readily and properly audited and the Group and Company's statement of financial position and the Group's profit and loss account is in agreement with the accounting records.

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.

Respective responsibilities and restrictions on use

Directors' responsibilities

As explained more fully in their statement set out on page 57, 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 and 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

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 18 April 2019
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 2018

($'000)	Notes	Year ended 31 December 2018	Year ended 31 December 2017
Revenue	5	663	348
Cost of sales		(359)	(190)
Gross profit		304	158
Operating expenses	6	(29,589)	(27,877)
Operating loss		(29,285)	(27,719)
Finance income	9	-	46
Finance expense	10	(1,890)	(1,932)
Net finance expense		(1,890)	(1,886)
Loss before income taxes		**(31,175)**	**(29,605)**
Income taxes	12	98	(230)
Loss for the year		**(31,077)**	**(29,835)**
Net loss attributable to equity holders		**(31,077)**	**(29,835)**
Basic and diluted loss per share (in $)	11	($3.65)	($4.51)
Other Comprehensive Income			
Items that may be reclassified subsequently to the statement of profit or loss:			
Foreign currency translation differences of foreign operations		33	(142)
Total comprehensive loss for the year		**(31,044)**	**(29,977)**
Total comprehensive loss attributable to equity holders		**(31,044)**	**(29,977)**

The accompanying notes form an integral part of these condensed consolidated Financial Statements.

Mainstay Medical International plc
Consolidated statement of financial position
at 31 December 2018

($'000)	Notes	31 December 2018	31 December 2017
Non-current assets			
Property, plant and equipment	13	235	201
Current assets			
Trade and other receivables	14	813	571
Income tax receivable		213	205
Inventory	15	2,575	2,395
Cash and cash equivalents	16	15,545	9,975
Total current assets		19,146	13,146
Total assets		**19,381**	**13,347**
Equity			
Share capital	19	67	64
Share premium	19	143,897	106,414
Share based payment reserve	22	11,716	7,613
Other reserves	20	4,626	4,593
Retained loss		(157,022)	(124,505)
Shareholders' equity		**3,284**	**(5,821)**
Non-current liabilities			
Loans and borrowings	17	8,791	11,177
Total non-current liabilities		8,791	11,177
Current liabilities			
Loans and borrowings	17	3,158	3,214
Income tax payable		18	124
Trade and other payables	18	4,130	4,653
Total current liabilities		7,306	7,991
Total liabilities		**16,097**	**19,168**
Total equity and liabilities		**19,381**	**13,347**

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

On behalf of the Board on 18 April 2019,

Oern Stuge MD
Chairman

Jason Hannon
CEO

Mainstay Medical International plc
Consolidated statement of changes in shareholders' equity
for the year ended 31 December 2018

($'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 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)**
Balance as at 1 January 2018	64	106,414	49,273	(44,573)	(107)	7,613	(124,505)	(5,821)
Profit and loss	-	-	-	-	-	-	*(31,077)*	*(31,077)*
Other comprehensive income	-	-	-	-	*33*	-	-	*33*
Total comprehensive loss for the year	**-**	**-**	**-**	**-**	**33**	**-**	**(31,077)**	**(31,044)**
Transactions with owners of the Company:								
Issue of Shares	3	37,483	-	-	-	-	(1,440)	36,046
Share based payments	-	-	-	-	-	4,103	-	4,103
Balance at 31 December 2018	**67**	**143,897**	**49,273**	**(44,573)**	**(74)**	**11,716**	**(157,022)**	**3,284**

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 2018

($'000)	Notes	Year ended 31 December 2018	Year ended 31 December 2017
Cash flow from operating activities			
Loss for the year		(31,077)	(29,835)
Add/(less) non-cash items			
Depreciation	13	89	107
Finance income		-	(46)
Finance expense	10	1,890	1,932
Share-based compensation	22	4,103	3,044
Income taxes		(98)	230
Add/(less) changes in working capital			
Trade and other receivables		(242)	318
Inventory		(180)	(1,272)
Trade and other payables		(517)	2,176
Taxes paid		(188)	(265)
Interest paid		(1,133)	(1,285)
Net cash used in operations		**(27,353)**	**(24,896)**
Cash flow from investing activities			
Acquisition of property and equipment	13	(123)	(53)
Net cash used in investing activities		**(123)**	**(53)**
Cash flow from financing activities			
Gross proceeds from issue of shares	19	37,486	54
Transaction costs on issue of shares		(1,440)	-
Repayment of borrowings		(3,000)	(1,800)
Net cash from financing activities	28	**33,046**	**(1,746)**
Net increase/(decrease) in cash and cash equivalents		**5,570**	**(26,695)**
Cash and cash equivalents at beginning of year		9,975	36,670
Cash and cash equivalents at end of year	16	**15,545**	**9,975**

Mainstay Medical International plc
Notes to the consolidated Financial Statements

1 General information and reporting entity

Mainstay Medical International plc (the "Company") is a public limited 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 2018 and 31 December 2017 comprise the results of the Company and of its subsidiaries (together the "Group").

At 31 December 2018, 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 Euronext Growth operated by Euronext Dublin.

Mainstay is a medical device company focused on commercializing ReActiv8, an implantable restorative neurostimulation system designed to treat an underlying cause of disabling Chronic Low Back Pain.

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 Euronext Growth rules of Euronext Dublin. 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 2018 with no early adoption of forthcoming requirements.

The Financial Statements were authorized for issue by the Board of Directors on 15 April 2019.

Going concern

The Directors have evaluated whether there are conditions and events, considered in aggregate, that raise doubt about the Group's ability to continue as a going concern. The Directors note the following relevant matters:

- The Group had cash of $15.5 million as at 31 December 2018 ($10 million as at 31 December 2017).
- The Group had operating cash out-flows of $27.3 million for the year ended 31 December 2018 (year ended 31 December 2017: $24.9 million).
- Due to the phase of development of the Group, the Group expects to continue to incur losses in the medium term due to the ongoing investment required in research and development, clinical and commercial activities and expects to continue to seek funding from investors or other finance providers as required.
- The Group has funded operations to date through the proceeds of equity funding of approximately $123.5 million and debt with an outstanding principal of $10.2 million as at 31 December 2018.

Subsequent to the year end, the Group has successfully extended the repayment terms of its debt arrangements to 2021 and will seek additional equity financing in 2019 in order to continue to fund its ongoing research and development, clinical and commercial activities. Under the terms of its amended

debt facility, if the Group raises at least $10 million in equity financing prior to June 30, 2019, an additional €3 million will become available to the Group from its lender. As of the date of approval of these financial statements, the terms of any such additional equity finance have not yet been finalised. As there can be no certainty that this finance will be raised, or of the terms on which such finance will be raised, and because the Group is reliant on such finance in order to continue to operate at its current level into the future, this represents an uncertainty that may impact on the Group's ability to continue as a going concern. However the directors are confident, based on discussions with investors, that additional equity funding and resultant debt funding will be received and that the amount of such funding will be sufficient to enable to the company to continue its current level of activity and to ensure that the Group is in a position to service its liabilities as they fall due for a period of at least 12 months from the date of approval of these financial statements. As a result, the directors have prepared the financial statements on the 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 estimates have 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.

Adoption of newly effective accounting standards and amendments

In addition, the Group applied the following standards for the first time in the current year:

- IFRS 15 - Revenue from Contracts with Customers (effective date 1 January 2018)
- IFRS 9 - Financial Instruments (effective date 1 January 2018)
- Classification and Measurement of Share-based Payment Transactions (Amendments to IFRS 2) (effective date 1 January 2018)
- Applying IFRS 9 Financial Instruments with IFRS 4 Insurance Contracts (Amendments to IFRS 4) (effective date 1 January 2018)
- Transfers of Investment Property (Amendments to IAS 40) (effective date 1 January 2018)
- Annual Improvements to IFRSs 2014-2016 Cycle (Amendments to IFRS 1 and IAS 28) (effective date 1 January 2018)
- IFRIC 22 Foreign Currency Transactions and Advance Consideration (effective date 1 January 2018)

None of the above has had any material impact on the Group's implementation of its accounting policies or on its reported results. The impacts of the change in accounting policies arising from the implementation of IFRS 15 and IFRS 9 are set out below:

- IFRS 15 - Revenue from Contracts with Customers:
  The Group has initially adopted IFRS 15 Revenue from Contracts with Customers from 1 January 2018. Under IFRS 15, revenue is measured based on the consideration specified in a contract with a customer. 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 has not had a material impact on the Group. Due to the transition method chosen in applying IFRS 15 (cumulative effect method), comparative information has not been re-stated to reflect the new requirements.

- IFRS 9 - Financial Instruments:
  The Group has initially adopted IFRS 9 Financial Instruments from 1 January 2018. The change in accounting policy to comply with the requirements of IFRS 9 has had no impact on the amounts disclosed in the financial statements other than immaterial changes to impairment of trade and other receivables. Trade and other receivables and cash and cash equivalents were previously classified as loans and receivables under IAS 39. There has been no change in the classification of trade and other payables or interest-bearing borrowings. The changes in classification of financial assets and liabilities to IFRS 9 classification has had no impact on the accounting for those assets and liabilities.

The new accounting policies for revenue and financial instruments are provided at (a) and (h) below, respectively.

New standards and amendments not yet effective

A number of new standards and amendments to standards have an effective date of 1 January 2019. These standards and amendments to standards are not yet effective and have not been early adopted.

- IFRS 16 Leases
- IFRIC 23 Uncertainty over Income Tax Treatments (effective date 1 January 2019)
- Prepayment Features with Negative Compensation (Amendments to IFRS 9) (effective date 1 January 2019)

None of the above are expected to have a material impact on the Group's implementation of its accounting policies or on its reported results. IFRS 16 provides a single lessee accounting model, requiring lessees to recognize assets and liabilities for all leases unless the lease term is 12 months or less or the underlying asset has a low value. IFRS 16 is not expected to have a material impact to the Group's reported results and the group will continue to monitor its current leases.

A number of new standards and amendments to standards have an effective date after 1 January 2019. The new standards and amendments to standards with an effective date after 1 January 2019 are under review by the Group:

- Long-term interest in associates and joint ventures - Amendments to IAS 28 (IASB effective 1 January 2019, not yet endorsed by the EU)
- Plan Amendment, Curtailment or Settlement - Amendments to IAS 19 (IASB effective 1 January 2019, not yet endorsed by the EU)
- Amendments to References to Conceptual Framework in IFRS Standards (IASB effective 1 January 2020, not yet endorsed by the EU)
- Definition of a Business - Amendments to IFRS 3 (IASB effective 1 January 2020, not yet endorsed by the EU)
- Definition of Material - Amendments to IAS 1 and IAS 8 (IASB effective 1 January 2020, not yet endorsed by the EU)
- IFRS 17 Insurance Contracts (IASB effective 1 January 2021, not yet endorsed by the EU)

a) Revenue recognition

The Group recognizes revenue when it transfers control over a product or service to a customer. This may arise on shipment, on delivery or in accordance with specific terms and conditions agreed with customers and provided there are no material remaining performance obligations required of the Group.

Revenue is measured at the fair consideration received/receivable for the sale of goods to external customers net of value added tax and discounts. Expected discounts are estimated and provided for as a reduction in revenue based on agreements with customers, agreed promotional arrangements and accumulated experience. Accumulated experience is used to estimate and provide for the discounts, using the expected value method, and revenue is only recognized to the extent that it can be reliably measured and when it is probable that future economic benefits of the transaction will flow to the Group. 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 specified within the contract 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 asset as at 31 December 2018.

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; 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 rates. 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

Accounting policy in 2018, following adoption of IFRS 9

Classification and measurement of financial assets and liabilities

On initial recognition a financial asset is classified as measured at Amortized Cost, or Fair Value Through Other Comprehensive Income (FVOCI), or Fair Value Recognized Through Profit and Loss (FVTPL). Financial assets are not reclassified after initial recognition unless the related business model changes. A financial asset is measured at amortized cost if it is held in a business model whose objective is to hold assets to collect contractual cashflows and its contractual terms give rise on specific dates to cash flows that are solely payments of principal or interest.

Trade and other receivables

Trade and other receivables are classified by the Group as amortized cost assets under IFRS 9. These assets are recognized initially at fair value. Subsequent to initial recognition, they are measured at amortized cost using the effective interest method, less any impairment losses.

Cash and cash equivalents

Cash and cash equivalents are classified by the Group as amortized cost assets under IFRS 9. Cash and cash equivalents comprise cash balances and call deposits with maturities of three months or less, which are carried at amortized cost.

Trade and other payables

Trade and other payables are classified by the Group as other financial liabilities under IFRS 9. These liabilities recognized initially at fair value. Subsequent to initial recognition, they are measured at amortized cost using the effective interest method.

Interest-bearing borrowings

Interest-bearing borrowings are classified by the Group as other financial liabilities under IFRS 9 and are recognized initially at fair value including any attributable transaction costs. Subsequent to initial recognition, interest-bearing borrowings are stated at amortized cost using the effective interest method over the contractual term.

Accounting policy in 2017 under IAS 39

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.

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

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.

Impairment of financial assets

At each reporting date, in accordance with IFRS 9, the Group assesses whether its financial assets, comprising accounts receivable and cash, are impaired. 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. As at 31 December 2018, our trade receivables balances amounted to $143,000, and we have not recognized any material impairment losses at this time. Further information on the Group's credit risk is detailed in Note 21. The Company measures loss allowances at an amount equal to lifetime expected credit losses, except for cash which is measured at 12-month expected credit losses. The maximum period considered when estimating expected credit losses is the maximum contractual period of exposure to credit risk.

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 22. 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 2018**	31 December 2017
Ireland	101	47
Germany	2	5
United States	132	149
Australia	-	-
Total non-current assets	**235**	**201**

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

($'000)	**Year ended 31 December 2018**	Year ended 31 December 2017
Ireland	109	18
Germany	536	330
Other Europe	18	-
Total revenue by country	**663**	**348**

5 Revenue

($'000)	**Year ended 31 December 2018**	Year ended 31 December 2017
Revenue arising from the sale of goods	663	348
Total revenue	**663**	**348**

Revenues from four customers represented approximately $437,000 of the Group's total revenues.

6 Operating expenses

($'000)	**Year ended 31 December 2018**	Year ended 31 December 2017
Research and development expenses	3,447	4,170
Clinical and regulatory expenses	11,047	12,850
Selling, general and administration expenses	15,095	10,857
Total operating expenses	**29,589**	**27,877**

7 Employee numbers and benefits

As of 31 December 2018, 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 2018**	Year ended 31 December 2017
Research and development and quality	12	13
Clinical and regulatory	9	10
Selling, general and administration	16	16
Total employee numbers	**37**	**39**
Parent company employees		
General and administration	4	5

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

($'000)	Year ended 31 December 2018	Year ended 31 December 2017
Wages and salaries	6,002	5,050
Other remuneration	474	1,504
Social security costs/ payroll taxes	441	440
Share based payments	4,103	3,044
Pension	84	80
	11,104	**10,118**

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 2018	Year ended 31 December 2017
Audit services	200	60
Other assurance services	125	10
Taxation advisory services	60	38
Total auditor's remuneration	**385**	**108**
Depreciation of plant and equipment	89	107
Rentals payable under operating leases	355	272
Research and development expenditure	3,447	4,170

9 Finance income

($'000)	Year ended 31 December 2018	Year ended 31 December 2017
Finance income		
Foreign exchange gain	-	46
Total finance income	**-**	**46**

10 Finance expense

($'000)	Year ended 31 December 2018	Year ended 31 December 2017
Finance expense		
Foreign exchange loss	(198)	-
Interest expense on borrowings	(1,692)	(1,932)
Total finance expense	**(1,890)**	**(1,932)**

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 2018	Year ended 31 December 2017
Net Loss for the year ($'000) attributable to equity holders	31,077	29,835
Weighted average number of ordinary shares in issue	8,504,996	6,615,447
Loss per share	**$3.65**	**$4.51**

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 share options outstanding as at 31 December 2018 and 31 December 2017.

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, the Netherlands and Germany.

($'000)	**Year ended 31 December 2018**	Year ended 31 December 2017
Irish income tax	-	-
Income tax in other jurisdictions:		
Foreign current tax	94	178
Adjustments in respect of prior years	(192)	52
Total income tax (credit)/charge	**(98)**	**230**

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, the Netherlands and Germany.

Reconciliation of effective tax rate

($'000)	**Year ended 31 December 2018**	Year ended 31 December 2017
Loss before tax	(31,175)	(29,605)
Taxed at tax rate in Ireland of 12.5%	(3,897)	(3,700)
Non-deductible expenses	690	408
Tax credits	(178)	(205)
Foreign rate differential	148	234
Adjustments in respect of prior periods	(192)	52
Unrecognized tax losses	3,331	3,441
Total income tax (credit)/charge	**(98)**	**230**

Unrecognized deferred tax assets

The Group has unrecognized potential deferred tax assets. These potential assets are not recognized because future taxable profits against which they can be utilized are not sufficiently certain. The availability of these assets 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 21%.

Gross timing differences:	At 1 January 2017	Arising in year	Adjustment in respect of prior years	**At 31 December 2017**	Arising in year	Adjustment in respect of prior years	**At 31 December 2018**
Unrecognized tax losses	52,680	27,528	419	80,627	26,648	387	107,662
Intangible assets	15,000	-	-	15,000	-	-	15,000
Share based payments	1,245	72	-	1,317	(401)	-	916
Total gross timing differences	**68,925**	**27,600**	**419**	**96,944**	**26,247**	**387**	**123,578**
Unrecognized deferred tax asset							
Unrecognized tax losses	6,585	3,441	52	10,078	3,331	48	13,457
Intangible assets	1,875	-	-	1,875	-	-	1,875
Share based payments	423	16	(149)	290	(89)	-	201
Total unrecognized deferred tax asset	**8,883**	**3,457**	**(97)**	**12,243**	**3,242**	**48**	**15,533**

13 Property, plant & equipment

($'000)	**Computer and office equipment Year ended 31 December 2018**	Computer and office equipment Year ended 31 December 2017
Cost		
At beginning of year	502	449
Additions	123	53
At end of year	625	502
Depreciation		
At beginning of year	301	194
Charge for the year	89	107
At end of year	390	301
Carrying value at end of year	**235**	**201**

14 Trade and other receivables

($'000)	**Year ended 31 December 2018**	Year ended 31 December 2017
Trade receivables	143	90
VAT and sales tax receivable	169	71
Prepaid expenses and other current assets	501	410
Total trade and other receivables	**813**	**571**

Information about the Group's exposure to credit and market risks and impairment losses for trade receivables is included in Note 21.

15 Inventory

($'000)	**Year ended 31 December 2018**	Year ended 31 December 2017
Raw Materials	52	57
Work in Progress	136	154
Finished Goods	2,387	2,184
Total inventory	**2,575**	**2,395**

There were no provisions netted against inventory as at 31 December 2018. The cost of inventory used in cost of sales during 2018 was $344,000 (2017: $186,000).

16 Cash and cash equivalents

($'000)	**Year ended 31 December 2018**	Year ended 31 December 2017
Cash in bank accounts – USD	15,170	9,888
Cash in bank accounts – Euro	187	82
Cash in bank accounts – AUD	188	5
Total cash and cash equivalents	**15,545**	**9,975**

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 2018 and has not been in breach at any reporting date.

($'000)	**Year ended 31 December 2018**	Year ended 31 December 2017
Loans and borrowings – current		
Term loan	3,000	3,000
Deferred finance cost	(90)	(90)
Accrued interest	248	304
Total current loans and borrowings	**3,158**	**3,214**
Loans and borrowings – non-current		
Term loan	7,200	10,200
Deferred finance cost	(103)	(194)
Accrued interest	1,694	1,171
Total non-current loans and borrowings	**8,791**	**11,177**
Total loans and borrowings	**11,949**	**14,391**

18 Trade and other payables

($'000)	Year ended 31 December 2018	Year ended 31 December 2017
Trade and other payables	1,789	2,633
Payroll tax liability	74	136
Accrued expenses	2,267	1,884
Total trade and other payables	**4,130**	**4,653**

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

Authorized	**31 December 2018 €**	31 December 2017 €
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**

Issued, called up and fully paid	**2018 $**	**2017 $**
8,770,229 (2017: 6,618,897) ordinary shares of €0.001 each	11,240	8,562
40,000 deferred shares of €1.00 each	55,268	55,268
	66,508	**63,830**
In $'000	**67**	**64**

Details of movement in issued shares:

On 15 February 2018, Mainstay raised gross proceeds of €30.1 million (approximately $37.5 million) through a placement of 2,151,332 new ordinary shares. This issuance of new ordinary shares was recorded in the Statement of Financial Position in USD at the rate on the date of the transaction. Transaction costs directly attributable to the issue of the new ordinary shares of approximately $1.4 million have been offset against retained earnings (in accordance with the Companies Act 2014).

	Movement of shares	
Number of shares	Ordinary shares	Deferred shares
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**
At 1 January 2018	**6,618,897**	**40,000**
Issue of shares	2,151,332	-
Issue of ordinary shares on exercise of share warrants	-	-
At 31 December 2018	**8,770,229**	**40,000**

	Movement of shares	
$'000	Share capital	Share premium
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**
At 1 January 2018	64	106,414
Issue of shares	3	37,483
Issue of ordinary shares on exercise of share warrants	-	-
At 31 December 2018	**67**	**143,897**

20 Other reserves

($'000)	**31 December 2018**	31 December 2017
Reorganization reserve	(44,573)	(44,573)
Undenominated capital reserve	49,273	49,273
Foreign currency translation reserve	(74)	(107)
Total other reserves	**4,626**	**4,593**

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.

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

21 Financial instruments

The effect of initially applying IFRS 9 on the Group's financial instruments is described in Note 3.

A. Accounting classifications and fair value

The following table shows the carrying amounts and fair values of financial assets and financial liabilities as at 31 December 2018 and 31 December 2017:

2018 ($'000)	**Financial assets at amortized cost**	**Other financial liabilities**	**Total carrying value**	**Fair value**
Financial assets not measured at fair value				
Cash and cash equivalents	15,545	-	15,545	N/A
Trade and other receivables	143	-	143	N/A
Financial liabilities not measured at fair value				
Trade and other payables	-	(4,130)	(4,130)	N/A
Interest bearing loans and borrowings	-	(11,949)	(11,949)	(11,988)
At December 2018	15,688	(16,079)	(391)	**N/A**

2017 ($'000)	**Loans and receivables**	**Financial liabilities at amortized cost**	**Total carrying value**	**Fair value**
Financial assets not measured at fair value				
Cash and cash equivalents	9,975	-	9,975	N/A
Trade and other receivables	90	-	90	N/A
Financial liabilities not measured at fair value				
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**

B. Measurement of fair values

Valuation techniques and significant unobservable inputs

We disclose our financial instruments that are fair value using the following fair values 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. These are classified as level 3 fair value instruments.

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 value disclosures for financial instruments held at amortized cost as at 31 December 2018 and 31 December 2017 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.

C. 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.

I. 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. The Group is also exposed to credit risk arising on trade receivables, with further information provided under credit risk below. Other than liquidity risk based on the Company's use of cash during the year, there has been no significant change during the year or since 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.

II. 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.

Trade and other receivables

Trade receivables comprise of amounts due from customers, all of which were past due as at 31 December 2018 and 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, considering their financial position, past experience and other factors.

The Company does not have exposure to significantly different categories of customer and accordingly details of credit risk by customer type or jurisdictions is not provided.

There were no material impairment losses recorded in the period and the provision for expected credit losses at 31 December 2018 is also immaterial. The carrying value of trade receivables of $0.1 million at 31 December 2018 (2017: $0.1 million) represents the maximum exposure to credit risk.

The below table provides an analysis of aging of receivables as at 31 December 2018 and the total balance outstanding relates to 4 customers.

2018 ($'000)	Current	1 - 30 Days	31 - 60 Days	61 – 90 Days
Trade and other receivables	93	50	-	-

2017 ($'000)	Current	1 - 30 Days	31 - 60 Days	61 – 90 Days
Trade and other receivables	90	-	-	-

Cash and cash equivalents

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 cash and cash equivalents are held with bank and financial institution counterparties, which are rated Baa1 to AA-, based on Moody and Standard and Poor's ratings. 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 $15.5 million as at 31 December 2018.

Impairment on cash and cash equivalents has been measured on a 12-month expected loss basis and reflects the short maturities of the exposures. The Group considers that its cash and cash equivalents have low credit risk based on the external credit ratings of the counterparties.

Guarantees

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 2018 and 31 December 2017.

III. Liquidity risk

Liquidity risk is the risk that the Group will encounter difficulty in meeting the obligations associated with its financial liabilities 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 2018 and as at 31 December 2017.

($'000)	Carrying value	Cash flow (total)	Less than 1 year	Between 1-2 years	Between 2-5 years
31 December 2018:					
Non-derivative financial Liabilities					
Trade and other payables	4,130	4,130	4,130		
Interest bearing loans and borrowings	11,949	14,635	3,893	10,742	-
At 31 December 2018	**16,079**	**18,765**	**8,023**	**10,742**	**-**

($'000)	Carrying value	Cash flow (total)	Less than 1 year	Between 1-2 years	Between 2-5 years
31 December 2017:					
Non-derivative financial Liabilities					
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**

IV. Foreign currency risk

The Group is exposed to transactional foreign currency risk to the extent that there is a mismatch between the currencies in which sales, purchases, receivables and borrowings are denominated and the respective functional currencies of Group companies. The Group's reporting currency is the US Dollar. 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 following table sets forth, for the years indicated, certain information concerning the exchange rate between: (i) the Euro and the US Dollar; and (ii) the Australian Dollar and the US Dollar:

Euro per USD1.00	**End of year**	**Average**
Year ended 31 December 2017	1.1993	1.1297
Year ended 31 December 2018	1.145	1.1793

Australian Dollar per USD1.00	**End of year**	**Average**
Year ended 31 December 2017	0.7815	0.7668
Year ended 31 December 2018	0.7059	0.7453

The Group did not have material asset or liability amounts in foreign currencies at year end, other than trade payables and accruals (net of cash) of €747,000 (2017: €1 million)

Sensitivity analysis

A strengthening (or weakening) of the US Dollar against the Euro of 5% would have (decreased)/ increased the loss for the year by $35,000 (2017: $61,000). 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.

V. Interest rate risk

At 31 December 2018, the principal outstanding on MML's loan from IPF was $10,200,000 (2017: $13,200,000). 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 $25,500 on a full year basis based on the drawn down loan balance as at 31 December 2018 (2017: $33,000 on a full year basis based on the drawn down loan balance as at 31 December 2017).

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.

22 Share based payments

Stock Incentive Plan

The Group operates a share option plan (the "Plan"). As at 31 December 2018, 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 2018, 1,784,855 (2017: 1,422,843) share options over ordinary shares of the Company that had been granted under the Plan were 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 2018:

	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	292	10 years from vesting
Options granted in 2016	263	10 years from vesting
Options granted in 2017	418	10 years from vesting
Options granted in 2018	433	10 years from vesting
Total share options in issue	**1,784**	

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 2018**	**Weighted average exercise price 2018**	Year ended 31 December 2017	Weighted average exercise price 2017
At beginning of year	1,423	€12.53	993	€11.53
Options granted during the year	448	€16.17	436	€14.92
Options expired unexercised	-	-	-	-
Options forfeited	(87)	€16.47	(6)	€16.20
Options exercised	-	-	-	-
Outstanding at end of year	**1,784**	**€13.23**	**1,423**	**€12.53**
Exercisable at end of year	**922**	**€10.95**	**643**	**€8.94**

Total non-cash expense charged to profit and loss in relation to share options for the year ended 31 December 2018 was $4,103,227 (2017: 3,044,508).

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	
	2018	**2017**
Weighted average share price (€)	16.17	14.92
Weighted average exercise price (€)	16.17	14.92
Weighted average expected share volatility	53.21%	52.35%
Expected term (years)	7	7
Expected dividends	-	-
Risk free rate (average)	0.03%	0.03%
Fair value of option ($)	10.95	8.94

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 for the purposes of section 357 of the Companies 2014 Act for the years ended 31 December 2018 and 31 December 2017.

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 $355,407 for the year ended 31 December 2018 (2017: $271,674).

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

($'000)	**31 December 2018**	31 December 2017
Within one year	256	157
After one year but no more than five years	247	405
More than five years	-	-
Total operating leases	**503**	**562**

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 2018 amounted to $83,570 (2017: $80,354). There were no accruals or prepayments in respect of the pension costs at 31 December 2018 (2017: None).

25 Subsidiary undertakings

At 31 December 2018, 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 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

26 Related party transactions

There were no balances due to or from related parties as at 31 December 2018 (2017: 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 2018**	31 December 2017
Salaries	1,958	1,909
Directors' fees	269	233
Other remuneration	915	1,093
Payroll taxes	130	217
Share based payments	3,591	2,369
Pension	26	24
Total remuneration	**6,889**	**5,845**

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

($'000)	**31 December 2018**	31 December 2017
Salaries	473	656
Directors' fees	269	233
Other remuneration	83	225
Payroll taxes	12	76
Share based payments	2,540	1,386
Total remuneration	**3,377**	**2,576**

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 2018 Carrying Value	*Cashflow* Issue of ordinary shares	*Cashflow* Repayment of borrowings	*Cashflow* Transaction costs on issue of ordinary shares	*Loss for the year*	As at 31 December 2018 Carrying Value
Liabilities						
Term Loan	13,200	-	(3,000)	-	-	10,200
Total	**13,200**	**-**	**(3,000)**	**-**	**-**	**10,200**
Equity						
Share Premium	106,414	37,483	-	-	-	143,897
Share Capital	64	3	-	-	-	67
Retained loss	(124,505)	-	-	(1,440)	(31,044)	(156,989)
Total	**(18,027)**	**37,486**	**-**	**(1,440)**	**(31,044)**	**(13,025)**

29 Events subsequent to 31 December 2018

Amendment to Debt Facility with IPF

On 18 April 2019, Mainstay Medical Limited entered into an amendment to its agreement with IPF Partners relating to the existing debt facility. Pursuant to the amendment:

- The repayment schedule for the three existing tranches drawn under the debt facility was amended such that no principal or interest will be repaid until 2021, with the principal and accrued interest to be amortized over the period from January 1, 2021 through September 30, 2023.
- A new tranche of €3.0 million was made available to Mainstay, conditioned upon Mainstay raising at least $10 million in gross proceeds from one or more offerings of equity prior to June 30, 2019. The repayment schedule for the new tranche will be the same as the amended repayment schedule for the three existing tranches.
- The interest rate for all tranches will be 8% per annum, with interest accruing but capitalized prior to January 1, 2021.
- The 5% repayment fee applicable to each existing tranche was eliminated.
- All principal and accrued interest from all tranches will automatically convert into ordinary shares of Mainstay Medical International plc at a price per share of €8 upon the earlier of (a) FDA approval of Mainstay's PMA application for ReActiv8, (b) the date by which at least 900,000 ordinary shares of Mainstay Medical International plc are publicly sold on-market by non-affiliates of Mainstay after 18 April 2019 at a price per share of at least €8, or (c) IPF Partners' election to undertake such conversion, in each case unless Mainstay elects to satisfy such obligation in whole or in part in cash.
- The minimum cash covenant was amended so that Mainstay is required to hold cash at least equal to its projected cash expenditures for operations and debt repayment for the next three months, and the covenant relating to the achievement of commercial milestones was eliminated.

- Mainstay Medical International plc issued to IPF Partners a warrant to purchase 1.5 million of its ordinary shares at a price per share of €6 at any time prior to the 6th anniversary of the amendment date. Medical International plc has issued further conditional warrants to IPF Partners that will become exercisable only to the extent Mainstay elects to repay the debt in cash rather than issue ordinary shares when a conversion of the debt is triggered. As such, the conditional warrants are intended to ensure that, notwithstanding any such election to repay in cash, IPF Partners retains the right to subscribe for ordinary shares of the Company on the terms and conditions that would otherwise have applied.

All tranches under the facility will continue to be secured by way of fixed and floating charges over the assets and undertakings of Mainstay Medical Limited, and the fixed first charge created by Mainstay Medical International plc in favor of IPF over its present and future shares held in Mainstay Medical Limited continues in effect.

Parent Company Financial Statements
Mainstay Medical International plc

Company statement of financial position
At 31 December 2018

($'000)	Notes	31 December 2018	31 December 2017
Non-current assets			
Investment in subsidiary	(d)	56,965	52,849
Current assets			
Prepayments and other receivables	(a)	131	158
Amounts due from subsidiary undertakings	(c)	81,380	49,876
Cash and cash equivalents	(b)	6,189	2,387
Total current assets		87,700	52,421
Total assets		144,665	105,270
Equity			
Share capital	19	67	64
Share premium	19	143,897	106,414
Share based payment reserve	22	11,716	7,613
Undenominated capital reserve		49,273	49,273
Retained loss		(61,780)	(58,749)
Surplus/(deficit) on shareholders' equity		143,173	104,615
Current liabilities			
Trade and other payables	(e)	1,492	655
Total current liabilities		1,492	655
Total liabilities		**1,492**	**655**
Total equity and liabilities		**144,665**	**105,270**

On behalf of the Board on 18 April 2019,

Oern Stuge MD
Chairman

Jason Hannon
CEO

Company statement of changes in equity
At 31 December 2018

($'000)	Share capital	Share premium	Un-denominated capital reserve	Share based payment reserve	Retained loss	Total equity
Balance at 1 January 2017	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**
Balance at 1 January 2018	64	106,414	49,273	7,613	(58,749)	104,615
Comprehensive loss for the year	-	-	-	-	(1,591)	(1,591)
Transactions with owners of the Company:						
Issue of Shares	3	37,483	-	-	(1,440)	36,046
Share based payments	-	-	-	4,103	-	4,103
Issue of ordinary shares on exercise of share options and warrants	-	-	-	-	-	-
Balance at 31 December 2018	**67**	**143,897**	**49,273**	**11,716**	**(61,780)**	**143,173**

Company statement of cash flows
At 31 December 2018

($'000)	Notes	Year ended 31 December 2018	Year ended 31 December 2017
Cash flow from operating activities			
Net loss attributable to equity holders		(1,591)	(1,365)
Add/(less) non-cash items			
Share-based compensation		(9)	1,565
Add/(less) changes in working capital			
Prepayments and other receivables		(31,481)	(22,996)
Trade and other payables		837	(17)
Net cash used in operations		**(32,244)**	**(22,813)**
Cash flow from financing activities			
Gross Proceeds from issue of shares		37,486	54
Transaction costs on issue of shares		(1,440)	-
Net cash from financing activities		**36,046**	**54**
Net increase/(decrease) in cash and cash equivalents		**3,802**	**(22,759)**
Cash and cash equivalents at beginning of year	(b)	2,387	25,146
Cash and cash equivalents at end of year		**6,189**	**2,387**

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 2018	31 December 2017
Prepayments	118	154
VAT recoverable	13	4
	131	**158**

(b) Cash and cash equivalents

($'000)	31 December 2018	31 December 2017
Cash in bank accounts – USD	6,132	2,368
Cash in bank accounts – Euro	57	18
Cash in bank accounts – AUD	-	1
	6,189	**2,387**

(c) Amounts due from subsidiary undertakings

($'000)	31 December 2018	31 December 2017
Mainstay Medical Limited	75,636	47,249
Mainstay Medical Distribution Limited	4,546	2,566
Mainstay Medical BV	1,198	61
	81,380	**49,876**

(d) Investment in subsidiary

($'000)	31 December 2018	31 December 2017
Opening balance	52,849	51,370
Investment in subsidiary	-	-
Effect of group share based payments	4,116	1,479
Closing balance	**56,965**	**52,849**

(e) Trade and other payables

($'000)	31 December 2018	31 December 2017
Trade and other payables	150	425
Payroll tax liability	23	60
Accrued expenses	1,319	170
	1,492	**655**

(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 $290,000 (31 December 2017: $106,000). The carrying value of the Company's cash is the same as its fair value.

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