Mainstay Medical Full Year 2015 Preliminary Results and Business Update

Dublin, Ireland – 8 February 2016: Mainstay Medical International plc ("**Mainstay**" or the "**Company**" listed on Euronext Paris: MSTY.PA and ESM of the Irish Stock Exchange: MSTY.IE), a medical device company focused on bringing to market ReActiv8®, a new implantable neurostimulation system to treat disabling Chronic Low Back Pain ("CLBP"), today announced the publication of preliminary results for the year ended 31 December 2015.

Business Highlights

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

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

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

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

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

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

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

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

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

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

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

We are also pleased to announce the issuance of two new U.S. Patents, bringing the total current number of issued U.S. issued Patents in the Mainstay portfolio to seven:

– U.S. Patent No. 9,186,501 entitled "Systems and Methods for Implanting Electrode Leads for Use with Implantable Neuromuscular Electrical Stimulator"; and

– U.S. Patent No. 9,248,278 entitled “Modular Stimulator for Treatment of Back Pain, Implantable RF Ablation System and Methods of Use”.

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

Financial Update

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

Operating expenses were $12.9 million for the year and have decreased by $2.3 million compared to 2014 due to costs associated with the European IPO included in 2014 not arising in 2015, offset by costs related to the expansion of the Mainstay team.

Cash on hand at 31 December 2015 was $16.6 million and operating cash outflows for 2015 were $11.6 million.

Outlook and future developments

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

The principal risks and uncertainties faced by the Group remain substantially unchanged from the disclosures included in the 2014 Annual Report. Those risks and uncertainties should be read in conjunction with this announcement and the Company’s press releases and other public disclosures (copies of which can be found on the Company’s website) and could cause actual events to differ materially from those described in this announcement and our disclosures.

- End -

About Mainstay

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

About the ReActiv8-A Trial

The ReActiv8-A Clinical Trial is a prospective single arm clinical trial with up to 96 subjects at sites in Australia and Europe. Data from the first 47 subjects in ReActiv8-A Trial have been submitted as part of an application for CE Marking. Further details can be obtained at https://clinicaltrials.gov/show/NCT01985230.

About the ReActiv8-B Trial

The ReActiv8-B Clinical Trial is an international, multi-center, prospective randomized sham controlled blinded trial with one-way crossover conducted under an Investigational Device Exemption (IDE). The ReActiv8-B Clinical Trial is designed to generate data to form part of the Pre-Market Approval Application (PMAA) of ReActiv8 to the FDA. Further details can be found at https://clinicaltrials.gov/show/NCT02577354.

About Chronic Low Back Pain (CLBP)

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

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

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

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

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

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

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Mainstay Medical International plc

Directors' responsibilities statement

Statement of the Directors in respect of the Preliminary Results

Each of the Directors of the Company (the "Directors"), whose names and functions are listed in the Corporate and Shareholder Information, confirm that, to the best of each person's knowledge and belief:

(a) the unaudited condensed consolidated financial statements comprising the unaudited condensed consolidated statement of profit or loss and other comprehensive income, the unaudited condensed consolidated statement of financial position, the unaudited condensed consolidated statement of changes in shareholders' equity, the unaudited condensed consolidated statement of cash flows and related notes have been prepared in accordance with IAS 34 *Interim Financial Reporting* as adopted by the EU.

(b) the preliminary results announcement includes a fair review of the information required by:

   a. *Regulation 8(2) of the Transparency (Directive 2004/109/EC) Regulations 2007*, being an indication of important events that have occurred during the financial year and their impact on the unaudited condensed consolidated set of financial statements; and a description of the principal risks and uncertainties for the next six months; and

   b. *Regulation 8(3) of the Transparency (Directive 2004/109/EC) Regulations 2007*, being related party transactions that have taken place in the current financial year and that have materially affected the financial position or performance of the entity during that year; and any changes in the related party transactions described in the last annual report that could do so.

INDEPENDENT STATUTORY AUDITOR'S REVIEW REPORT TO THE DIRECTORS OF MAINSTAY MEDICAL INTERNATIONAL PLC

We have been engaged by Mainstay Medical International plc to review the condensed consolidated financial statements of Mainstay Medical International plc, contained within the accompanying preliminary announcement, comprising the statement of financial position as at 31 December 2015, and the statement of comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, and a summary of significant accounting policies and other explanatory information prepared in accordance with International Accounting Standard 34 *Interim Financial Reporting* as adopted by the European Union (EU) as applied by the Transparency (Directive 2004/109/EC) Regulations 2007 as amended (the TD Regulations).

The directors' responsibility for the financial statements

The directors are responsible for the preparation and fair presentation of these condensed consolidated financial statements in accordance with the International Accounting Standard 34 *Interim Financial Reporting* as adopted by the EU as applied by the TD Regulations and for such internal controls as management determines are necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

Our responsibility

Our responsibility is to express a conclusion on the accompanying condensed consolidated financial statements. We conducted our review in accordance with International Standard on Review Engagements (ISRE) 2400 (Revised), *Engagements to Review Historical Financial Statements*. ISRE 2400 (Revised) requires us to conclude whether anything has come to our attention that causes us to believe that the condensed consolidated financial statements, taken as a whole, are not prepared in all material respects in accordance with the applicable financial reporting framework. This Standard also requires us to comply with relevant ethical requirements.

A review of financial statements in accordance with ISRE 2400 (Revised) is a limited assurance engagement. We perform procedures, primarily consisting of making inquiries of management and others within the entity, as appropriate, and applying analytical procedures, and evaluates the evidence obtained.

The procedures performed in a review are substantially less than those performed in an audit conducted in accordance with International Standards on Auditing. Accordingly, we do not express an audit opinion on these financial statements.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that these condensed consolidated financial statements do not present fairly, in all material respects, the financial position of Mainstay Medical International plc as at 31 December 2015, and its financial performance and cash flows for the year then ended, in accordance with the International Accounting Standard 34 *Interim Financial Reporting* as adopted by the EU as applied by the TD Regulations.

Emphasis of matter

We are the statutory auditor of Mainstay Medical International plc and we are currently conducting the audit of Mainstay Medical International plc's annual financial statements upon which this preliminary announcement is based. We are not yet in a position to sign our auditor's report on the annual financial statements as they have not yet been approved by the directors and certain audit procedures are not yet complete. Consequently, there can be no absolute certainty that we will be in a position to issue an unmodified audit report on Mainstay Medical International plc's annual financial statements consistent with the result and financial position reported in the preliminary announcement. However, at the present time, we are not aware of any matters that may give rise to a modification of our report.

Limitations

Our review report has been prepared for the directors solely in connection with assisting the Company in meeting the requirements of the TD Regulations with respect to its preliminary announcement.

Our review report was designed to meet the agreed requirements of the directors determined by the Company's needs at the time. Our review report should not therefore be regarded as suitable to be used or relied on by any party wishing to acquire rights against us other than the Company for any purpose or in any context. Any party other than the Company who chooses to rely on our review report (or any part of it) will do so at its own risk. To the fullest extent permitted by law, KPMG will accept no responsibility or liability in respect of our review work, for this report, or for the conclusions we have reached to any other party.

5 February 2016

Sean O'Keefe
For and on behalf of
KPMG
Chartered Accountants
1 Stokes Place, St. Stephen's Green, Dublin 2

Mainstay Medical International plc
Unaudited condensed consolidated statement of profit or loss and other comprehensive income
for the year ended 31 December 2015

($'000)	Notes	**Year ended 31 December 2015 Unaudited**	Year ended 31 December 2014 Audited
Revenue		-	-
Operating expenses	4	(12,864)	(15,160)
Operating loss		(12,864)	(15,160)
Finance income	5	-	-
Finance expense	5	(323)	(67,247)
Net finance expense		(323)	(67,247)
Loss before income taxes		**(13,187)**	**(82,407)**
Income taxes		(48)	(58)
Loss for the year and comprehensive loss for the year		**(13,235)**	**(82,465)**
Net loss attributable to equity holders		**(13,235)**	**(82,465)**
Basic and diluted loss per share (in $)	6	($3.08)	($28.09)

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

Mainstay Medical International plc
Unaudited condensed consolidated statement of financial position at 31 December 2015

($'000)	Notes	**31 December 2015 Unaudited**	31 December 2014 Audited
Non-current assets			
Property, plant and equipment		242	72
Current assets			
Prepayments and other receivables		661	263
Income tax receivable		70	150
Cash and cash equivalents		16,624	18,283
Total current assets		17,355	18,696
Total assets		**17,597**	**18,768**
Equity			
Share capital		61	61
Share premium		72,588	72,584
Share based payment reserve		2,691	1,162
Capital conversion reserve		49,273	49,273
Reorganisation reserve		(44,573)	(44,573)
Retained loss		(74,816)	(61,581)
Shareholders' equity		5,224	16,926
Non-current liabilities			
Loans and borrowings	8	10,084	-
Total non-current liabilities		10,084	-
Current liabilities			
Loans and borrowings	8	305	-
Income tax payable		17	15
Trade and other payables		1,967	1,827
Total current liabilities		2,289	1,842
Total liabilities		**12,373**	**1,842**
Total equity and liabilities		**17,597**	**18,768**

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

Mainstay Medical International plc
Unaudited condensed consolidated statement of changes in shareholders' equity
for the year ended 31 December 2015

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

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

Mainstay Medical International plc
Unaudited condensed consolidated statement of cash flows for the year ended 31 December 2015

($'000)	Notes	**Year ended 31 December 2015 Unaudited**	Year ended 31 December 2014 Audited
Cash flow from operating activities			
Net loss attributable to equity holders		(13,235)	(82,465)
Add/(less) non-cash items			
Depreciation		78	32
Finance expense	5	323	67,247
Share-based compensation	11	1,529	628
Add/(less) reclassifications			
Initial public offering expenses reclassified to financing activities		-	4,040
Reorganisation costs recognised in equity reclassified to operating cash flows		-	(1,037)
Add/(less) changes in working capital			
Prepayments and other receivables		(391)	27
Trade and other payables		142	297
Taxes paid		19	(195)
Interest paid		(27)	(18)
Net cash used in operations		**(11,562)**	**(11,444)**
Cash flow from investing activities			
Acquisition of property and equipment		(248)	(36)
Net cash used in investing activities		**(248)**	**(36)**
Cash flow from financing activities			
Net proceeds from issue of shares		4	20,973
Net proceeds of borrowings		10,147	-
Repayment of borrowings		-	(800)
Net cash from financing activities		**10,151**	**20,173**
Net (decrease)/increase in cash and cash equivalents		**(1,659)**	**8,693**
Cash and cash equivalents at beginning of year		**18,283**	9,590
Cash and cash equivalents at end of year		**16,624**	**18,283**

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

Mainstay Medical International plc
Notes to the unaudited condensed consolidated Financial Statements

1 General information and reporting entity

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

The unaudited condensed consolidated preliminary financial statements (the "preliminary financial statements") for the years ended 31 December 2015 and 31 December 2014 comprise the results of the Company and of its subsidiaries (together the "Group"). At 31 December 2015, the Group comprises the Company and its operating subsidiaries Mainstay Medical Limit, MML US, Inc and Mainstay Medical (Australia) Pty. Limited.

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

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

2 Basis of preparation

Statement of compliance

These preliminary financial statements have been prepared in accordance with IAS 34 Interim Financial Reporting, as adopted by the EU. The preliminary financial statements set out in this document do not constitute full statutory financial statements. However, selected explanatory notes are included to explain events and transactions that are significant to an understanding of the changes in the Group's financial position and performance since the last annual consolidated financial statements as at and for the year ended 31 December 2014.

The audited financial statements as required by statute have not yet been completed. Consequently, there is no absolute certainty that the final financial statements for the year ended 31 December 2015 will be consistent with these preliminary financial statements.

Except as described below, the preliminary financial statements have been prepared applying the accounting policies that were applied in the preparation of the Group's published consolidated financial statements for the year ended 31 December 2014 prepared in accordance with IFRS, as adopted by the EU and available from the Company's website (www.mainstay-medical.com).

The comparative information provided in the preliminary financial statements relating to the year ended 31 December 2014 does not comprise the statutory financial statements of the Group. Those statutory financial statements for the year ended 31 December 2014 on which the auditors gave an unqualified audit opinion, have been delivered to the Registrar of Companies.

The IFRSs applied by the Group in the preparation of these preliminary financial statements are those that were effective for accounting periods beginning on or after 1 January 2015 with no early adoption of forthcoming requirements. The Group applied the standards listed below for the first time in the current year:

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

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

There are no significant or material changes to judgements or estimates used in these preliminary financial statements versus those used in the full financial statements for the year ended 31 December 2014.

The Board of Directors approved these preliminary financial statements on 5 February 2016.

Going concern

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

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

To fund the clinical trials and commercialization of ReActiv8 the Group has raised debt and equity and it continues to explore funding strategies (e.g.: equity, debt, partnering) to support the Group's activities into the future. As at 31 December 2015, the Group reported cash of $16.6 million.

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

Basis of measurement

The condensed consolidated financial statements are prepared on the historic cost method, except for:

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

Currency

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

2014 Corporate Reorganisation

On 3 April 2014, the Company, which had no prior activity and was incorporated solely to allow the Group to apply to be listed in Europe, acquired all the outstanding ordinary and preference shares in Mainstay Medical Limited in exchange for issuing 793,425 series A shares, 1,967,177 series B shares, 500,000 series Z shares and 81,400 ordinary shares to former shareholders in Mainstay Medical Limited, in each case on the basis of one share in the Company in place of 20 shares of the same class in Mainstay Medical Limited. There was no change in control as a result of this transaction (the "2014 Corporate Reorganisation").

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

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

The only exception to the carryover basis of accounting relates to the Company's ordinary shares that were issued as part of the 2014 Corporate Reorganisation. The Irish Companies Act, 1963, requires that all shares issued by an Irish company must be issued at fair value. As a result, the Company

recorded this required uplift in the fair value of the Company's ordinary shares against their previous carrying value as an increase in Share Capital and Share Premium, with the corresponding entry recorded in the Reorganisation Reserve in equity, which resulted in no change to net equity.

3 Segment reporting

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

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

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

4 Operating expenses

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

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

5 Net finance expense

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

Note (i):

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

6 Earnings per share

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

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

7 Taxes

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

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

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

8 Interest bearing loans and borrowings and shares classified as debt

IPF Debt Financing

On 24 August 2015, Mainstay Medical Limited entered into an agreement with IPF Partners for a debt facility of up to $15,000,000. The facility can be drawn in three tranches. Each tranche has a repayment term of 60 months from drawdown, with interest only payments for the first 12 months.

The initial tranche (“Tranche A”) of $4,500,000 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 $6,000,000 was received on 3 December 2015. The interest rate on Tranche B is 3-month Euribor plus a margin of 11.5%.

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

The facility is secured by a floating debenture over the assets and undertakings of Mainstay Medical Limited, excluding Intellectual Property, and the debenture includes customary terms and conditions. In addition Mainstay Medical International plc has created a first fixed charge in favour of IPF Fund 1 SCA SICAV-FIS over its present and future shares held in Mainstay Medical Limited.

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

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

9 Called up share capital

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

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

Authorised and Issued Share Capital of Mainstay Medical International plc:

The following table discloses the authorised and issued share capital of Mainstay Medical International plc, which was incorporated on 17 February 2014 and became the ultimate parent company of the Group on 3 April 2014:

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

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

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

Details of movement in issued shares:

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

10 Financial instruments

Financial risk management

In terms of financial risks, the Group has exposure to credit risk, liquidity risk and market risk (comprising foreign currency risk and interest rate risk). This note presents information about the Group's exposure to each of the above risks together with the Group's objectives, policies and processes for measuring and managing those risks.

Risk management framework

Mainstay's Board of Directors has overall responsibility for the establishment and oversight of the Group's risk management framework. The Group's risk management policies are established to identify and analyse the risks faced by the Group, to set appropriate risk limits and controls and to monitor risks and adherence to the limits. Risk management systems and policies will be reviewed regularly as the Group expands its activities and resource base to take account of changing conditions.

Due to the current pre-revenue nature of the Group's activities, there are no significant concentrations of financial risk other than concentration of cash with individual banks and there has been no significant change during the financial year, or since the end of the year to the types or quantum of financial risks faced by the Group or the Group's approach to the management of those risks.

Credit risk
Credit risk is the risk of financial loss to the Group if a customer or counterparty to a financial instrument fails to meet contractual obligations, and arises principally from the Group's cash and cash equivalents.

The Group maintained its cash balances with its principal financial institutions throughout the year. The Group's principal financial institutions have investment grade ratings at year end.

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

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

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

The Group did not have material asset or liability amounts in foreign currencies at year end other than trade payables and accruals of €394,000.

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

A 25 basis point increase in Euribor above zero would not have materially increased the loss for the year.

11 Share based payments

The terms and conditions of the employee share option plan are disclosed in the most recent, published, consolidated financial statements. The charge of €1.5 million for the year ended 31 December 2015 is the grant date fair value of various share options granted in the current and prior years, which are being recognised within the statement of profit or loss and other comprehensive income in accordance with employee services rendered.

12 Contingencies

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

13 Related party transactions

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

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

Key management compensation and Directors' remuneration

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

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

14 Events subsequent to 31 December 2015

There were no events subsequent to 31 December 2015 that would have a material impact on the condensed consolidated financial statements.

Mainstay Medical International plc
Corporate and shareholder information

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