Mainstay Medical Announces Half Year Financial Results

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

Mainstay Medical International plc ("**Mainstay", "We"** or the "**Company"**, Euronext Paris: MSTY.PA and ESM of the Irish Stock Exchange: MSTY.IE), a medical device company focused on bringing to market ReActiv8®, an implantable neurostimulation system to treat disabling Chronic Low Back Pain ("**CLBP**"), today announces the publication of its report for the Half Year ended 30 June 2016.

Highlights

- On 14 September 2016, Mainstay announced the enrollment of the first subject in the ReActiv8-B Clinical Trial. The purpose of the ReActiv8-B Clinical Trial is to gather data in support of an application for pre-market approval ("PMA") from the US Food and Drug Administration ("FDA"), a key step towards commercialization of ReActiv8 in the US. The Clinical Trial, if successful, will provide Level 1 Evidence of efficacy of ReActiv8, which may be used to support applications for favorable reimbursement in the USA. In addition, evidence from the ReActiv8-B Clinical Trial will be used to support market development activities worldwide.
- On 25 May 2016, Mainstay announced the receipt of CE Marking approval for ReActiv8. The CE Marking approval is based on positive results from the ReActiv8-A Clinical Trial which demonstrated clinically important, statistically significant and lasting improvement in pain, disability and quality of life in people with disabling chronic low back pain and few other treatment options. On 20 September 2016 we announced the one-year results from the ReActiv8-A Clinical Trial, which showed long term sustained performance.
- Our commercial launch of ReActiv8 is focused on Germany. We aim to drive adoption of ReActiv8 in a select number of hospitals with a large population of patients with chronic low back pain and with a multi-disciplinary approach to treatment. Our initial customers in Germany (neurosurgeons and orthopedic spine surgeons) have been trained, contract negotiations are well under way, and ethics committee submissions have been made for the ReActiv8-C Registry. We have recruited a direct sales force, which is supported by our team of experienced field clinical specialists. As we gain experience and momentum, we will expand our commercialization efforts to other countries and centers.
- On 17 June 2016, Mainstay announced the completion of a private placement of €30 million (approximately $33.7 million) through a placement of 2,307,694 new ordinary shares with new and existing shareholders.
- In February 2016, a new US Patent was issued bringing the total number of issued US Patents in the Mainstay portfolio to seven.
- Operating expenses were $8.0 million ($6.3 million in 1H15) and the increase was primarily driven by expansion of our team, preparation for the ReActiv8-B Clinical Trial and preparation for our commercial launch.
- Cash on hand at 30 June was $42.8 million and operating cash out flows for the period were $7.5 million.

About Mainstay

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

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

About the ReActiv8-C Registry

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

About Chronic Low Back Pain

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

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

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

The Company will host a live conference call for analysts and investors at 3:00pm Dublin time (4:00pm Paris, 10:00am New York) on the day. The call will be conducted in English and a replay will be available for 30 days.

Dial-ins for the call are outlined below:

Ireland Toll Free Number:	1800 931 806
France Toll Free Number:	0805 111 542
Finland Toll Free Number:	0800 778 968
Netherlands Toll Free Number:	0800 023 3590
Germany Toll Free Number:	0800 101 4051
USA Toll Free Number:	1866 793 4273
International Non Toll Free Number:	+44 203 425 3098
Passcode:	**849195#**

Forward looking statements

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

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

Half Year Report 2016

Mainstay Medical International plc and its subsidiaries
Half Year Report comprising Interim Management Report and condensed consolidated Financial Statements for the half year ended 30 June 2016

Mainstay Medical International plc

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Forward looking statements

This 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 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.

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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 Greg Garfield, Non-Executive Director Nael Karim Kassar, Non-Executive Director Antoine Papiernik, Non-Executive Director James Reinstein, Independent Non-Executive Director Manus Rogan PhD, Non-Executive Director Dan Sachs MD, Non-Executive Director
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
Legal Advisors	McCann FitzGerald Riverside One Sir John Rogerson's Quay Dublin 2, Ireland Jones Day 2, rue Saint-Florentin 75001 Paris, France
Independent Auditor	KPMG Chartered Accountants 1 Stokes Place St Stephen's Green Dublin 2, Ireland
Principal Bankers	HSBC Bank of Ireland
ESM Adviser and Broker	J&E Davy Davy House 49 Dawson Street Dublin 2, Ireland
Registrar	Computershare Investor Services (Ireland) Limited Heron House Corrig Road Sandyford Industrial Estate Dublin 18, Ireland
Paying Agent (in France)	Caceis Corporate Trust 1/3, Place Valhubert 75013 Paris France

Mainstay Medical International plc

Interim Management Report

The Board of Directors are pleased to report on the progress of Mainstay Medical International plc ("Mainstay" or the "Company") and present the Half Year Report of the Company and its subsidiaries (the "Group" or "we") for the half year ended 30 June 2016.

Principal activities

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

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

As at 30 June 2016, the Company together with its operating subsidiaries Mainstay Medical Limited, Mainstay Medical Distribution Limited, Mainstay Medical GmbH, MML US, Inc. and Mainstay Medical (Australia) Pty. Limited form the Mainstay Medical Group.

Business review

ReActiv8-B Clinical Trial – On 14 September 2016, Mainstay announced the enrolment of the first subject in the ReActiv8-B Clinical Trial. The purpose of the ReActiv8-B Clinical Trial is to gather data in support of an application for pre-market approval ("PMA") from the US Food and Drug Administration ("FDA"), a key step towards commercialization of ReActiv8 in the US. The Clinical Trial, if successful, will provide Level 1 Evidence of efficacy of ReActiv8, which may be used to support applications for favorable reimbursement in the USA. In addition, evidence from the ReActiv8-B Clinical Trial will be used to support market development activities worldwide.

The design of the Clinical Trial requires data from 128 randomized subjects in the Pivotal Cohort at the 120-day primary outcome assessment visit. Based on experience with enrolment in the ReActiv8-A Clinical Trial, it is estimated that full enrolment in the ReActiv8-B Clinical Trial will take 12 to 18 months from first enrolment, with results anticipated to be available approximately six months following full enrolment.

CE Marking and Initial Commercial Launch – On 25 May 2016, Mainstay announced the receipt of CE Marking approval for ReActiv8. The CE Marking approval is based on positive results from the ReActiv8-A Clinical Trial which demonstrated a clinically important, statistically significant and lasting improvement in pain, disability and quality of life in people with disabling chronic low back pain and few other treatment options.

Our commercial launch of ReActiv8 is focused on Germany. We aim to drive adoption of ReActiv8 in a select number of hospitals with a large population of patients with chronic low back pain and with a multi-disciplinary approach to treatment. Our initial customers in Germany (neurosurgeons and orthopedic spine surgeons) have been trained, contract negotiations are well under way, and ethics committee submissions have been made for the ReActiv8-C Registry. We have recruited a direct sales force, which is supported by our team of experienced field clinical specialists. As we gain experience and momentum, we will expand our commercialization efforts to other countries and centers.

Funding – On 17 June 2016, we announced the completion of a private placement of €30 million (approximately $33.7 million) through a placement of 2,307,694 new ordinary shares with new and existing shareholders (the "Placement").

On 11 August 2016, we announced the publication of a prospectus (the "Prospectus") in connection with the Placement. The Prospectus comprises a Summary Document, a Securities Note and a Registration Document. These documents are available on our website (www.mainstay-medical.com).

The Group's debt facility provided by IPF was announced on 24 August 2015 for up to $15 million. As at 30 June 2016, the Group had drawn down $10.5 million. During July 2016, we received the last tranche of $4.5 million.

US Patents - In February 2016, one new US Patent was issued (listed below), which brings the total number of issued US Patents in the Mainstay portfolio to seven:

- 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.

ReActiv8-A Clinical Trial –The ReActiv8-A Clinical Trial is an international, multi-center, prospective, single arm Clinical Trial of ReActiv8, for the purpose of gathering data to form part of the submission for CE Mark approval. We announced the results of the first 46 subjects in this Clinical Trial to reach the 90-day end point in August 2015, and additional data were announced in December 2015 and September 2016. On 20 September 2016 we announced the one-year results from the ReActiv8-A Clinical Trial, which showed long term sustained performance.

The results show clinically important, statistically significant and lasting improvement in pain, disability and quality of life in a population of people with few treatment options. As detailed above, the submission for CE Mark approval included the results of the ReActiv8-A Clinical Trial.

As part of the CE Marking approval process, we agreed to conduct a range of activities to gather additional data on the long term performance and safety of ReActiv8. The ReActiv8-A Post Market Clinical Follow-up (PMCF) Study is a continuation of the ReActiv8-A Clinical Trial (but with CE Marked ReActiv8).

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

Financial review

Income Statement – Mainstay is at a pre-revenue stage. Operating expenses related to on-going activities were $8.0 million during the half year ended 30 June 2016 (30 June 2015: $6.3 million). On-going activities include clinical and regulatory activities, research and development, preparation for our initial commercial launch and general and administrative activities. The increase of $1.7 million is primarily driven by expansion of our team, preparation for our commercial launch and preparation for the ReActiv8-B Clinical Trial.

Research and development expenses reflect costs incurred for research, ongoing development and design of the Group's product ReActiv8 and related accessories. These expenses include the salaries of engineers, technicians, quality and regulatory specialists; the cost of outsourced early-stage development and manufacturing activities; biocompatibility and pre-clinical studies; and quality costs including the set-up and maintenance of our quality system. Research and development expenses also include the costs of developing and maintaining our intellectual property portfolio, including legal costs and associated filing and maintenance fees. Research and development expenses were $1.6 million during the half year ended 30 June 2016 (30 June 2015: $1.2 million). The increase of $0.4 million is primarily driven by expansion of our team.

Clinical and regulatory expenses relate to the ongoing ReActiv8-A Clinical Trial, and preparation for the ReActiv8-B Clinical Trial. Also included in clinical and regulatory expenses are expenses relating to clinical consulting; regulatory consulting; and, salary costs for our clinical team members. All clinical and regulatory costs are expensed as incurred. We expect clinical and regulatory expenses to increase significantly when enrollment in the ReActiv8-B Clinical Trial ramps up, as further subjects continue to be recruited, as we collect data for both clinical trials, and as we undertake post market clinical follow-up activities. Clinical and regulatory expenses were $2.6 million during the half year ended 30 June 2016 (30 June 2015: $2.3 million). The increase of $0.3 million is primarily driven by increased consulting and clinical costs as we prepare for the ReActiv8-B Clinical Trial.

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

Commercial activities to date have been focused on the development of the Group's commercial strategy and on planning and managing the process to obtain reimbursement for the Group's products after regulatory approvals have been obtained and the products become available to be sold commercially. Commercial expenses are expected to increase with the expansion of our resources to include new personnel in a direct sales team as we move toward commercialization in Germany. General and administration expenses were $2.9 million during the half year (30 June 2015: $2.0 million). The increase of $0.9 million is primarily driven by expansion of our team, and expenditure on activities for our initial commercial launch.

Non-cash expense in relation to share options for the half year ended 30 June 2016 was $0.9 million (30 June 2015: $0.8 million). This increase is primarily due to grants of additional options to employees and consultants.

Statement of financial position – On 17 June 2016, we announced that we had raised gross proceeds of €30 million (approximately $33.7 million) through a placement of 2,307,694 new ordinary shares with new and existing shareholders (the "Placement"). Transaction costs of approximately $1 million have been allowed for and have been offset against retained earnings (in accordance with the Company's Act 2014).

Following CE Marking approval which was received by the Group in May 2016, as part of our preparation for our commercial launch, we have built up inventory of $0.4 million as at 30 June 2016.

Cash on hand at 30 June 2016 was $42.8 million (31 December 2015: $16.6 million). The increase in cash is primarily due to the proceeds received on the placement completed in June 2016, offset by ongoing operating expenditure. Total assets of the Group at period end were $44.0 million (31 December 2015: $17.6 million).

Operating net cash out flows for the half year ended 30 June 2016 were $7.5 million (30 June 2015: $5.7 million). This operating cash out flow reflects the cost of the research and development of ReActiv8, undertaking our clinical trials, preparation for our commercial launch, the ongoing costs of being a public company, and running the Group. The increase during the half year ended 30 June 2016 is primarily due to increased operating expenditure.

Principal risks and uncertainties

The principal risks and uncertainties faced by the Group and/or its industry for the remaining six months of 2016 remain substantially unchanged from the risks disclosed in the Prospectus published on 11 August 2016. Section D1 of the Summary Document of the Prospectus sets out on pages 12 and 13 some key information on the key risks specific to the Company and its industry.

Outlook and future developments

We look forward to ramping up the ReActiv8-B Clinical Trial and our commercial launch of ReActiv8 in Germany.

Related party transactions

Refer to note 14.

Going concern

The condensed consolidated Financial Statements have been prepared on the basis that the Group is a going concern.

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 30 June 2016, following a private placement which generated gross proceeds of €30 million (approximately $33.7 million), the Group has reported cash of $42.8 million and the last tranche of the IPF debt facility of $4.5 million was received by the Group in July 2016.

After making enquiries and having considered the conditions noted above and the options available to the Group, the Directors are satisfied that Group will have sufficient funds to be able to meet its liabilities as they fall due for a period of at least 12 months from the date of the condensed consolidated Financial Statements and are satisfied that the condensed consolidated Financial Statements should be prepared on a going concern basis.

Auditors

The condensed consolidated Financial Statements have not been reviewed by the Company's auditors.

Mainstay Medical International plc

Directors' responsibilities statement

Statement of the Directors in respect of Half Year Financial Report

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 condensed consolidated Financial Statements comprising the condensed consolidated statement of profit or loss and other comprehensive income, the condensed consolidated statement of financial position, the condensed consolidated statement of changes in equity, the condensed consolidated statement of cash flows and related notes 1 to 15 have been prepared in accordance with IAS 34 *Interim Financial Reporting* as adopted by the EU.

(b) the interim management report 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 first six months of the financial year and their impact on the condensed consolidated Financial Statements; and a description of the principal risks and uncertainties for the remaining six months of the year; and

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

On behalf of the Board on 20 September 2016,

Oern Stuge MD, Chairman — Peter Crosby, CEO

Mainstay Medical International plc

Condensed consolidated statement of profit or loss and other comprehensive income for the half year ended 30 June 2016

($'000)	Notes	**Half year ended 30 June 2016** Unaudited	**Half year ended 30 June 2015** Unaudited
Revenue		-	-
Operating expenses	4	(7,987)	(6,280)
Operating loss		(7,987)	(6,280)
Finance income	5	-	-
Finance expense	5	(784)	(15)
Net finance expense		(784)	(15)
Loss before income taxes		**(8,771)**	**(6,295)**
Income taxes	7	(71)	(61)
Loss for the half year and comprehensive loss for the half year		**(8,842)**	**(6,356)**
Net loss attributable to equity holders		**(8,842)**	**(6,356)**
Basic and diluted loss per share (in $)	6	(1.98)	(1.48)

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

Mainstay Medical International plc

Condensed consolidated statement of financial position at 30 June 2016

($'000)	Notes	**30 June 2016** Unaudited	**31 December 2015** Unaudited
Non-current assets			
Property, plant and equipment		209	242
Current assets			
Prepayments and other receivables		552	661
Inventory	8	381	-
Income tax receivable		127	70
Cash and cash equivalents		42,768	16,624
Total current assets		43,828	17,355
Total assets		**44,037**	**17,597**
Equity			
Share capital	10	64	61
Share premium	10	106,322	72,588
Undenominated capital reserve		49,273	49,273
Share based payment reserve	12	3,633	2,691
Reorganization reserve		(44,573)	(44,573)
Retained loss		(84,711)	(74,816)
Surplus on shareholders' equity		**30,008**	**5,224**
Non-current liabilities			
Loans and borrowings	9	9,283	10,084
Total non-current liabilities		9,283	10,084
Current liabilities			
Loans and borrowings	9	1,445	305
Income tax payable		29	17
Trade and other payables		3,272	1,967
Total current liabilities		4,746	2,289
Total liabilities		**14,029**	**12,373**
Total equity and liabilities		**44,037**	**17,597**

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

Mainstay Medical International plc

Condensed consolidated statement of changes in shareholders' equity for the Period ended 30 June 2016

($'000)	Share capital Un-audited	Share premium Un-audited	Undeno-minated capital reserve Un-audited	Reorgani-zation reserve Un-audited	Share based payment reserve Un-audited	Retained loss Un-audited	Total equity Un-audited

Balance as at 1 January 2015	61	72,584	49,273	(44,573)	1,162	(61,581)	16,926
Comprehensive loss for the half year	-	-	-	-	-	(6,356)	(6,356)
Transactions with owners of the Company:							
Share based payments	-	-	-	-	814	-	814
Balance at 30 June 2015	**61**	**72,584**	**49,273**	**(44,573)**	**1,976**	**(67,937)**	**11,384**
Comprehensive loss for the half year	-	-	-	-	-	(6,879)	(6,879)
Transactions with owners of the Company:							
Share based payments	-	-	-	-	715	-	715
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**
Balance as at 1 January 2016	61	72,588	49,273	(44,573)	2,691	(74,816)	5,224
Comprehensive loss for the half year	-	-	-	-	-	(8,842)	(8,842)
Transactions with owners of the Company:							
Issue of shares	3	33,725	-	-	-	(1,053)	32,675
Share based payments	-	-	-	-	942	-	942
Issue of shares on exercise of share warrants	-	9	-	-	-	-	9
Balance at 30 June 2016	**64**	**106,322**	**49,273**	**(44,573)**	**3,633**	**(84,711)**	**30,008**

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

Mainstay Medical International plc

Condensed consolidated statement of cash flows for the Period ended 30 June 2016

($'000)	Notes	**Half year ended 30 June 2016** Unaudited	**Half year ended 30 June 2015** Unaudited
Cash flow from operating activities			
Net loss for the half year		(8,842)	(6,356)
Add/(less) non-cash items			
Depreciation		54	24
Finance expense	5	784	15
Share-based compensation	12	942	814
Add/(less) changes in working capital			
Prepayments and other receivables		(273)	(56)
Trade and other payables		293	(57)
Taxes paid		(114)	(73)
Interest paid		(389)	-
Net cash used in operations		**(7,545)**	**(5,689)**
Cash flow from investing activities			
Acquisition of property and equipment		(21)	(64)
Net cash used in investing activities		**(21)**	**(64)**
Cash flow from financing activities			
Gross proceeds from issue of shares	10	33,737	-
Transaction costs on issue of shares	10	(27)	-
Net cash from financing activities		**33,710**	**-**
Net increase/(decrease) in cash and cash equivalents		**26,144**	**(5,753)**
Cash and cash equivalents at beginning of year		16,624	18,283
Cash and cash equivalents at 30 June 2016		**42,768**	**12,530**

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

Mainstay Medical International plc

Notes to the condensed consolidated Financial Statements

1 General information and reporting entity

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

The Half Year Report and condensed consolidated Financial Statements for the periods ended 30 June 2016 and 30 June 2015 comprise the results of the Company and of its subsidiaries (together the "Group").

At 30 June 2016, the Group comprises the Company and its operating subsidiaries Mainstay Medical Limited, Mainstay Medical Distribution Limited, Mainstay Medical GmbH, 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

The condensed consolidated Financial Statements have been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the EU. They do not include all the information and disclosures necessary for a complete set of IFRS 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 2015.

The comparative information provided in the condensed consolidated Financial Statements relating to the periods ended 30 June 2015 and 31 December 2015 does not comprise the statutory financial statements of the Group. Those statutory financial statements for the year ended 31 December 2015 on which the auditors gave an unqualified audit opinion, have been delivered to the Registrar of Companies.

The half year ended 30 June 2016 is the first period in which the Group has recognized inventory, following CE Marking approval for the Group's product in May 2016. Therefore, except for estimates of provision for inventories (refer to significant accounting policies below, and note 8), there are no significant or material changes to judgements or estimates used in these condensed consolidated Financial Statements compared with those used in the full Financial Statements for the year ended 31 December 2015.

The condensed consolidated Financial Statements were authorized for issue by the Audit, Risk and Compliance Committee, as delegated by the Board of Directors, on 20 September 2016.

Going concern

The condensed consolidated Financial Statements have been prepared on the basis that the Group is a going concern.

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 30 June 2016, following a private placement which generated gross proceeds of €30 million (approximately $33.7 million), the Group has reported cash of $42.8 million and the last tranche of the IPF debt facility of $4.5 million was received by the Group in July 2016.

After making enquiries and having considered the conditions noted above and the options available to the Group, the Directors are satisfied that Group will have sufficient funds to be able to meet its liabilities as they fall due for a period of at least 12 months from the date of the condensed consolidated Financial Statements and are satisfied that the condensed consolidated Financial Statements should be prepared on a going concern basis.

Currency

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

Basis of consolidation

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

Significant accounting policies

The condensed consolidated Financial Statements have been prepared applying the accounting policies that were applied in the preparation of the Group's published consolidated financial information for the year ended 31 December 2015 prepared in accordance with IFRS, as adopted by the EU and available from the Company's website (www.mainstay-medical.com). These accounting policies have been applied consistently for all periods presented. New accounting policies implemented during the half year ended 30 June 2016 are listed below:

Inventories - Inventories are stated at the lower of cost and net realisable 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 realisable 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.

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

- Annual Improvements to IFRSs 2012-2014 cycle (effective date 1 January 2016)
- Disclosure initiative (amendments to IAS 1) (effective date 1 January 2016)
- IAS 16 and IAS 38 (amended) – Property, Plant and Equipment and Intangible Assets (effective date 1 January 2016)
- IAS 16 and 41 - Bearer Plants (effective date 1 January 2016)
- IFRS 11 (amended) – Accounting for acquisitions of interests in Joint Operations (effective date 1 January 2016)

- IAS 27 (amended) – Equity method in separate financial statements

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

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

- IFRS 9 – Financial Instruments (1 January 2018)
- IFRS 15 – Revenue from contracts with customers (1 January 2018)
- Disclosure initiative (amendments to IAS 7) (1 January 2017)
- IAS 12 (amended) – recognition of deferred tax assets for unrealized losses (1 January 2017)
- IFRS 16 – Leases (1 January 2019)
- IFRS 2 (amended) – Share based payments (1 January 2018)

The above listed new standards and amendments to standards with an effective date of 1 January 2017 are not expected to have a material impact on the Group.

The above listed new standards and amendments to standards with an effective date after 1 January 2017 are under review by the Group.

3 Segment reporting

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

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

($'000)	**30 June 2016**	31 December 2015
Europe	167	207
United States	42	35
Australia	-	-
Total non-current assets	**209**	**242**

4 Operating expenses

($'000)	**Half year ended 30 June 2016**	Half year ended 30 June 2015
Research and development expenses	1,588	1,219
Clinical and regulatory expenses	2,606	2,258
General and administration expenses	2,851	1,989
Share-based compensation expenses	942	814
Total operating expenses	**7,987**	**6,280**

5 Net finance expense

($'000)	**Half year ended 30 June 2016**	Half year ended 30 June 2015
Finance income		
Fair value gain on derivative financial instruments	-	-
Foreign exchange gain	-	-
Total finance income	**-**	**-**
Finance expense		
Foreign exchange loss	(56)	(15)
Interest expense on borrowings	(728)	-
Total finance expense	**(784)**	**(15)**
Net finance expense	**(784)**	**(15)**

6 Earnings per share

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

	Half year ended 30 June 2016	Half year ended 30 June 2015
Weighted average number of ordinary shares in issue	4,476,421	4,294,141
Loss per share	**1.98**	**1.48**

7 Taxes

Current income tax assets and liabilities for the current and prior periods are measured at the amount expected to be recovered from or paid to the relevant taxation authorities. The tax charge has been prepared based on the Group's best estimate of the weighted average tax rate that is expected for the full financial year. The tax rates and tax laws used to compute the amount are those used in Ireland, the United States and Australia.

($'000)	**Half year ended 30 June 2016**	Half year ended 30 June 2015
Income tax in Ireland	-	-
Income tax in other jurisdictions	71	61
Total income tax charge	**71**	**61**

8 Inventory

($'000)	**Half year ended 30 June 2016**	Half year ended 30 June 2015
Finished goods	381	-
Inventories	**381**	**-**

There were no provisions netted against inventory as at 30 June 2016.

9 Interest bearing loans and borrowings

IPF Debt Financing

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

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

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

Other expenses directly associated with the facility of $353,412 were deferred and are amortized to profit or loss over the term of the loan 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. It also includes monthly and quarterly reporting requirements. The Group is not in breach of any covenants at 30 June 2016 and has not been in breach at any reporting date.

($'000)	**30 June 2016**	31 December 2015
Loans and borrowings - current		
Term loan	1,275	225
Deferred finance cost	(71)	(71)
Accrued interest	241	151
Total current loans and borrowings	**1,445**	**305**
Loans and borrowings – non-current		
Term loan	9,225	10,275
Deferred finance cost	(161)	(248)
Accrued interest	219	57
Total non-current loans and borrowings	**9,283**	**10,084**
Total loans and borrowings	**10,728**	**10,389**

10 Called up share capital

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

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

Authorized and Issued Share Capital

	30 June 2016	31 December 2015
Authorized	**€**	€
20,000,000 ordinary shares of €0.001 each	20,000	20,000
40,000 deferred shares of €1.00 each	40,000	40,000
	60,000	**60,000**

	2016	2015
Issued, called up and fully paid	**$**	**$**
6,607,000 (31 December 2015: 4,298,203) ordinary shares of €0.001 each	8,549	5,954
40,000 deferred shares of €1.00 each	55,268	55,268
	63,817	**61,222**
In $'000	**64**	**61**

Details of movement in issued shares:

During the year ended 31 December 2015, 4,062 options over ordinary shares were exercised by the holders and the Company issued 4,062 ordinary shares. Proceeds of $4,062 were received on issue of the shares.

During the half year to 30 June 2016, 1,103 warrants over ordinary shares were exercised by the holders and the Company issued 1,103 ordinary shares. Proceeds of $8,493 were received on issue of the shares.

On 17 June 2016, raised gross proceeds of €30 million (approximately $33.7 million) through a placement of 2,307,694 new ordinary shares. This issuance of new ordinary shares was recorded in the Statement of Financial Position in USD at the rate ruling on the date of the transaction. Transaction costs directly attributable to the issue of the new ordinary shares, of approximately $1 million, have been offset against retained earnings (in accordance with the Company's Act 2014).

	Movement of shares	
Number of shares	Ordinary shares	Deferred shares
At 1 January 2015	4,294,141	40,000
At 30 June 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**
At 1 January 2016	**4,298,203**	**40,000**
Issue of shares	2,307,694	-
Issue of ordinary shares on exercise of share warrants	1,103	-
At 30 June 2016	**6,607,000**	**40,000**

	Movement of shares	
$'000	Share capital	Share premium
At 1 January 2015	61	72,584
At 30 June 2015	61	72,584
Issue of ordinary shares on exercise of share options	-	4
At 31 December 2015	**61**	**72,588**
At 1 January 2016	61	72,588
Issue of shares	3	33,725
Issue of ordinary shares on exercise of share warrants	-	9
At 30 June 2016	**64**	**106,322**

11 Financial instruments

Financial risk management

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

Risk management framework

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

Due to the current pre-revenue nature of the Group's activities, there are no significant concentrations of financial risk other than concentration of cash with individual banks and there has been no significant change during the half year, or since the end of the half 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 maximum credit risk is represented by the carrying value of cash held with the Group's financial institutions. The Group's objective is to minimize credit risk.

The Group maintained its cash balances with its principal financial institutions throughout the half year, and the Group limits its exposure to any one financial institution by holding cash balances across a number of financial institutions. The Group's principal financial institutions have investment grade ratings at 30 June 2016.

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 the majority of its cash in USD denominated accounts. Approximately $3,000 was held in AUD as at 30 June 2016 and approximately $300,000 was held in Euro as at 30 June 2016.

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. Mainstay Medical Distribution Limited and Mainstay Medical GmbH have a Euro functional currency. The translation differences related to the consolidation of these subsidiaries are not material.

The Group did not have material asset or liability amounts in foreign currencies at 30 June 2016 other than trade payables and accruals (net of cash) of €1,527,000 and AU$201,000. A strengthening (or weakening) of the US Dollar against the Euro of 5% would have (decreased)/ increased the loss for the period by $84,000 (2015: $1,000). 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.

Interest rate risk

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

At 30 June 2016, 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 have increased the loss for the period by $13,125.

12 Share based payments

Share Options

The terms and conditions of the Group's share option plan are disclosed in the most recent, published, consolidated financial statements. The charge of €0.9 million for the half year ended 30 June 2016 (30 June 2015: $0.8 million) is the grant date fair value of various share options granted in the current and prior years, which are being recognized within the statement of profit or loss and other comprehensive income over the vesting period related to service.

Warrants

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

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

As at 30 June 2016 11,897 warrants were outstanding.

13 Contingencies

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

14 Related party transactions

During the half year ended 30 June 2015, the Group purchased services of $33,364 from Orsco Life Sciences AG, a company controlled by Oern Stuge MD, a Director of Mainstay Medical International plc. This agreement was terminated on 31 December 2015.

There were no balances due to or from related parties as at 30 June 2016 and 31 December 2015.

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)	**30 June 2016**	30 June 2015
Salaries	715	679
Non-executive directors' fees	108	31
Other remuneration	512	389
Payroll taxes	63	60
Share based payments	788	645
Pension	11	11
Total remuneration	**2,197**	**1,815**

15 Events subsequent to 30 June 2016

As referred to in the Interim Management Report, the Group received the last tranche of the IPF debt facility ($4.5 million) during July 2016.

Contacts

Mainstay Medical
PR and IR Enquiries:
Consilium Strategic Communications
Chris Gardner, Mary-Jane Elliott, Jessica Hodgson, Hendrik Thys
Tel: +44 203 709 5700 / +44 7921 697 654
Email: mainstaymedical@consilium-comms.com
or
FTI Consulting (for Ireland)
Jonathan Neilan
Tel: +353 1 663 3686
Email: jonathan.neilan@fticonsulting.com
or
NewCap (for France)
Julie Coulot
Tel: +33 1 44 71 20 40
Email: jcoulot@newcap.fr
or
LifeSci Advisors, LLC
Brian Ritchie
Tel: + 1 (212) 915-2578
Email: britchie@lifesciadvisors.com
or
ESM Advisers:
Davy
Fergal Meegan or Barry Murphy
Tel: +353 1 679 6363
Email: fergal.meegan@davy.ie or barry.murphy2@davy.ie

Source: Mainstay Medical