Mainstay Medical annonce ses résultats financiers du premier semestre

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

Mainstay Medical International plc (« **Mainstay** », ou la « **Société** », cotée sur Euronext Paris: MSTY.PA et sur l'ESM de la Bourse irlandaise: MSTY.IE), société de dispositifs médicaux dédiée au développement et à la commercialisation de ReActiv8®, un nouveau dispositif implantable destiné au traitement de la lombalgie chronique invalidante, annonce aujourd'hui la publication de son rapport semestriel 2015.

Faits marquants

- Le 31 août 2015, la Société a annoncé des résultats cliniques positifs de l'Essai Clinique ReActiv8-A, résultats que la Société prévoit d'utiliser pour appuyer sa demande d'approbation du marquage CE, à la suite de laquelle la commercialisation en Europe pourra débuter. Le communiqué détaillé des Résultats Cliniques est disponible sur le site Internet de la Société à l'adresse suivante : http://www.mainstay-medical.com/news/press_releases.
- Le 24 août 2015, Mainstay a annoncé la finalisation d'une ligne de crédit d'un montant maximum de 15 millions de dollars (13,3 millions d'euros). La ligne de crédit sur nantissement est non-dilutive pour les actionnaires existants, et est consentie par IPF Partners, organisme de financement de premier plan spécialisé dans le secteur européen de la santé.

Les fonds peuvent être mis à disposition en trois tranches, et le premier versement d'un montant de 4,5 millions de dollars (4 millions d'euros) a été effectué. Les deuxième et troisième tranches du prêt seront disponibles lorsque les objectifs relatifs au marquage CE de ReActiv8 auront été atteints.

- En juillet et août 2015, Mainstay a annoncé l'obtention de trois nouveaux brevets américains :
  - Le brevet U.S. n° 9,072,897 intitulé « Systèmes et Méthodes destinés à la Restauration de la Fonction Musculaire de la Colonne Vertébrale »,
  - Le brevet U.S. n° 9,079,019 intitulé « Dispositifs et Méthodes d'Ancrage d'Electrodes destinées au Fonctionnement d'un Stimulateur Neuromusculaire Electrique Implantable », et
  - Le brevet U.S. n° 9,108,053 intitulé « Dispositifs et Méthodes de Réhabilitation d'un Muscle et Evaluation du Processus de Rééducation ».
- En mai 2015, Mainstay a reçu l'autorisation de la Food and Drug Administration (FDA) de débuter l'Essai Clinique de ReActiv8 sous exemption des dispositifs expérimentaux (*Investigational Device Exemption*, ou IDE). L'autorisation de la FDA concerne ReActiv8-B, l'Essai Clinique international, multicentrique, simulé (*sham-controlled*) et comparatif à répartition aléatoire dont l'objectif est de démontrer l'innocuité et l'efficacité de ReActiv8 pour le traitement d'adultes souffrant de lombalgie chronique et n'ayant pas subi d'opération chirurgicale du dos au préalable.

L'autorisation permet de mener l'Essai Clinique ReActiv8-B sur un maximum de 40 sites et d'une cohorte pivot de 128 patients qui recevront ReActiv8 de façon aléatoire. L'autorisation sous IDE permet à la Société d'engager avec les chercheurs, les sites d'Essais Cliniques, et les Comités d'Examen Institutionnel (IRB ou comités d'éthiques) menant aux premiers recrutements des patients qui recevront l'implant. Une fois l'Essai Clinique ReActiv8-B mené à terme et si les résultats sont probants, la Société prévoit de soumettre une demande d'approbation de pré-commercialisation (*Pre-Market Approval*, ou PMA), qui est nécessaire pour permettre le début de la commercialisation aux États-Unis.

- Les charges d'exploitation ont représenté un montant de 6,3 millions de dollars, en hausse de 1,5 million de dollars par rapport au premier semestre 2014 en raison de la hausse des coûts liés à l'Essai Clinique ReActiv8-A, et du renforcement de nos équipes.
- La trésorerie disponible au 30 juin 2015 représente un montant de 12,5 millions de dollars, et les flux de trésorerie liés aux activités d'exploitation de la période ont représenté un montant de 5,7 millions de dollars.

- End -

A propos de Mainstay Medical

Mainstay est une société irlandaise de dispositifs médicaux qui développe un dispositif implantable innovant de neurostimulation, ReActiv8, pour les personnes souffrant de lombalgie chronique invalidante. La société est basée à Dublin, en Irlande, elle dispose d'activités basées aux États-Unis et en Australie, et est cotée sur Euronext Paris et sur l'ESM de l'Irish Stock Exchange.

A propos de l'essai clinique du ReActiv8-A

ReActiv8-A, l'Essai Clinique de ReActiv8, est une étude clinique prospective à une seule branche à un maximum de 96 patients sur des sites en Australie et en Europe. Les instruments de mesures de l'Essai Clinique ReActiv8-A sont évalués trois mois après le début de la stimulation et sont comparés aux valeurs de base pré-implantation. Des informations complémentaires sont disponibles à l'adresse https://clinicaltrials.gov/show/NCT01985230

A propos de la lombalgie chronique

Une des causes reconnues de la lombalgie chronique est un affaiblissement du contrôle par le système nerveux central des muscles qui stabilisent en permanence la colonne vertébrale dans le bas du dos, puisqu'une colonne vertébrale instable peut provoquer des maux de dos. ReActiv8 est conçu pour stimuler électriquement les nerfs responsables de la contraction de ces muscles et ainsi de contribuer à restaurer le contrôle musculaire et d'améliorer la stabilité de la colonne vertébrale, ce qui permet au corps de récupérer de la lombalgie chronique.

Les personnes atteintes de lombalgie chronique invalidante ont généralement une qualité de vie réduite et ressentent une douleur très importante, peuvent être handicapées, souffrir de dépression, d'anxiété et de troubles du sommeil. Leur douleur et leur handicap peuvent persister malgré les meilleurs traitements médicaux disponibles, et seulement un faible pourcentage de cas résulte d'un état pathologique identifié, ou d'un défaut anatomique qui peut être corrigé par la chirurgie rachidienne. Leur capacité à travailler ou à être productifs est sérieusement affectée par ce mal, et les journées de travail perdues, les prestations d'invalidité et le recours aux prestations de santé pèsent sur l'économie.

Des informations complémentaires sont disponibles sur le site www.mainstay-medical.com

ReActiv8 est un dispositif d'essai et n'est pas approuvé pour la commercialisation dans le monde.

ATTENTION - aux États-Unis, ReActiv8 est limitée par la loi fédérale uniquement à l'usage d'essai.

La Société tiendra une conférence téléphonique retransmise en direct sur le site web de la Société (en anglais) pour les analystes et les investisseurs, le lundi 31 août 2015 à 15h30 heure de Paris (14h30 à Dublin-Londres, 09h30 à New York).

Les numéros à composer pour assister à cette conférence sont :

Irlande (numéro sans frais) :	1800 936 842
France (numéro sans frais) :	0805 101 988
Finlande (numéro sans frais) :	0800 523 133
Pays-Bas (numéro sans frais):	0800 265 8619
Amérique (numéro sans frais) :	1866 928 7517
Numéro international avec frais :	+44 203 139 4830
Mot de passe:	**70678930#**

La présentation sera retransmise en direct sur la page « Investisseurs » du site web de Mainstay Medical : http://www.mainstay-medical.com/fr/investors

Déclarations prospectives

Le présent communiqué contient des déclarations qui sont ou pourraient être comprises comme étant prospectives. Ces déclarations peuvent souvent être identifiées par les mots tels que « anticiper », « croire », « estimer », « s'attendre à », « ambitionner », « avoir l'intention de », « planifier », à travers l'utilisation le cas échéant du conditionnel ou dans chaque cas, la forme négative de ces mêmes termes, ou toute autre variante ou terminologie similaire, ou par une discussion de la stratégie, des objectifs, événements futurs ou intentions. Ces déclarations prospectives intègrent tous les éléments qui ne constituent pas un fait historique. Ces déclarations sont mentionnées dans différents paragraphes du présent communiqué et contiennent, mais ne sont pas limitées à, des déclarations relatives aux intentions, aux estimations et aux attentes de la Société concernant, notamment, ses résultats d'exploitation, sa situation financière, ses perspectives, ses objectifs, sa stratégie de financement, ses attentes en termes de recherche et de développement produit, les approbations par les autorités compétentes, le système de remboursement pour le produit, les coûts de vente et le taux de pénétration de ses produits.

Par leur nature, ces déclarations prospectives sont soumises à de nombreux risques et incertitudes dans la mesure où elles concernent les évènements et circonstances futurs. Les déclarations prospectives ne constituent pas une garantie de résultats futurs et les résultats actuels de la Société (ainsi que le développement du marché et de l'industrie au sein desquels la Société évolue) pourraient différer significativement de ceux qui sont exprimés, induits ou prévus dans les informations et déclarations prospectives mentionnées dans le présent communiqué. Même si les résultats opérationnels, la situation financière et la croissance future de la Société ainsi que le développement des marchés et de l'industrie où la Société opère sont en ligne avec ces déclarations prospectives, ces résultats et développements ne seront pas nécessairement un indicateur de résultats ou développements futurs. Les facteurs importants susceptibles d'entraîner des différences entre les objectifs énoncés et les réalisations effectives comprennent notamment l'évolution globale de l'activité économique et industrielle, les conditions du marché pour les équipements médicaux, l'évolution de l'industrie, la concurrence, les changements règlementaires et législatifs, les modifications de dispositifs fiscaux, la disponibilité et le coût de financement, les fluctuations des taux de change, les changements dans la stratégie de la Société, et les incertitudes politiques ou économiques. Les déclarations prospectives mentionnées dans le présent communiqué sont données uniquement à la date de ce communiqué.

Mainstay Medical International plc and its subsidiaries
Half Year Financial Report comprising Interim Management Report and condensed consolidated Financial Statements
for the half year ended 30 June 2015

Mainstay Medical International plc
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Forward looking statements

This Half Year 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" or "will", 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 Half Year Report and include, but are not limited to, statements regarding the Company's intentions, beliefs or current expectations concerning, among other things, the Company's results of operations, financial position, prospects, financing strategies, expectations for product design and development, regulatory applications and approvals, reimbursement arrangements, costs of sales and market penetration.

By their nature, forward looking statements involve risk and uncertainty because they relate to future events and circumstances. Forward looking statements are not guarantees of future performance and the actual results of the Company's operations, and the development of 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 Half Year Report. In addition, even if the Company's results of operations, financial position and growth, and the development of the markets and the industry in which the Company operates, are consistent with the forward looking statements contained in this Half Year Report, those results or developments may not be indicative of results or developments in subsequent periods. A number of factors could cause results and developments of the Company to differ materially from those expressed or implied by the forward looking statements including, without limitation, 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, currency fluctuations, changes in its business strategy, political and economic uncertainty. The forward-looking statements herein speak only at the date of this Half Year Report.

Mainstay Medical International plc
Corporate and shareholder information

Directors	Oern Stuge MD, Independent Non-Executive Chairman Peter Crosby, Chief Executive Officer and Executive Director David Brabazon, Independent Non-Executive Director Antoine Papiernik, Non-Executive Director James A. 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/ 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

We 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") for the half year ended 30 June 2015.

Principal activities

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

The Company is incorporated and registered in Ireland as a public limited company. The Company together with its operating subsidiaries Mainstay Medical Limited, MML US, Inc. and Mainstay Medical (Australia) Pty. Limited form the Mainstay Medical Group.

Business review

ReActiv8-A trial - On 31 August 2015, the Company announced positive clinical results of the ReActiv8-A Clinical Trial, which the Company plans to use to support its submission for CE Mark approval, after which commercialization in Europe can commence. The detailed Clinical Results announcement is available on the Company's website at http://www.mainstay-medical.com/news/press_releases.

US clinical trial and regulatory process - In January 2015, the Company submitted an application to the United States Food and Drug Administration ("FDA") for approval to start a clinical trial of ReActiv8 under an Investigational Device Exemption ("IDE").

In May 2015, Mainstay announced it had received approval from the FDA to begin a clinical trial of ReActiv8 under an IDE. The FDA approval is for the planned ReActiv8-B Clinical Trial, an international, multi-centre, prospective randomized sham-controlled trial designed to evaluate the safety and efficacy of ReActiv8 for the treatment of adults with CLBP and no prior back surgery.

The approval is to conduct the ReActiv8-B Clinical Trial at up to 40 clinical trial sites and for 128 randomized subjects to be implanted with ReActiv8 in the pivotal cohort. The IDE approval allows the Company to engage with investigators, clinical trial sites, and Institutional Review Boards ("IRBs" or "Ethics Committees") leading towards the first subject recruitment and implant. Upon successful completion of the ReActiv8-B Clinical Trial and if the results support it, the Company plans to submit an application for a Pre-Market Approval ("PMA") which is required to allow the start of commercialisation in the United States.

In the approval letter, the FDA provided some helpful study design recommendations and the Company is engaging with the FDA in relation to these comments.

US Patent Filing - In July and August 2015, Mainstay announced the issuance of three new U.S. Patents:

- U.S. Patent No. 9,072,897 entitled "Systems and Methods for Restoring Muscle Function to the Lumbar Spine"
- U.S. Patent No. 9,079,019 entitled "Apparatus and Methods for Anchoring Electrode Leads for Use with Implantable Neuromuscular Electrical Stimulator".
- U.S. Patent No. 9,108,053 entitled Apparatus and Methods for Rehabilitating a Muscle And Assessing Progress of Rehabilitation

Financial review

Income statement – Mainstay is at a pre-revenue stage. Operating expenses related to on-going activities were $6.3 million during the period ended 30 June 2015 (30 June 2014: $4.8 million before exceptional items). On-going activities include clinical and regulatory activities, research and development, and general and administrative expenses.

Research and development expenses reflect costs incurred for research, design and development of the Group's product ReActiv8. Research and development expenses were $1.2 million during the period ended 30 June 2015 (30 June 2014: $1.2 million). Clinical and regulatory expenses relate to the ongoing ReActiv8-A Clinical Trial and regulatory activities. Clinical and regulatory expenses were $2.3 million during the period ended 30 June 2015 (30 June 2014: $1.7 million). Non-cash expense in relation to share options for the period ended 30 June 2015 was $0.8 million increased from $0.2 million for the period ended 30 June 2014 due to the increase in the Company's share price with the IPO.

Statement of financial position – Cash on hand at 30 June 2015 was $12.5 million (31 December 2014: $18.3 million). Operating cash out flows for the period ended 30 June 2015 were $5.7 million (30 June 2014: $6.2 million). Total assets of the Group were $13.2 million (31 December 2014: $18.8 million).

On 24 August 2015, Mainstay 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.

The facility can be drawn in three tranches, and an initial tranche of $4.5 million has been called. The second and third tranches can be drawn upon achievement of milestones related to progress through the CE Mark process for ReActiv8.

Principal risks and uncertainties

The principal risks and uncertainties faced by the Group for the remaining six months of 2015 remain substantially unchanged from the disclosures included in the 2014 Annual Report. Those risks and uncertainties should be read in conjunction with this report and the Company's press releases and other public disclosures (copies of which can be found on the Company's website).

Related party transactions

Refer to note 14.

Outlook and future developments

Mainstay looks forward to continuing to work towards obtaining CE Mark and commencing commercialization in Europe.

Going concern

The Group has incurred losses of $67.9 million to date (includes the losses of Mainstay Medical Limited and MML, US Inc. incurred prior to the incorporation of Mainstay Medical International plc and includes losses attributable to the Company's 2014 Corporate Reorganisation). As at 30 June 2015, the Group reported shareholders' equity of $11.4 million and cash of $12.5 million. As detailed in the Financial Review above the Group is at a pre-revenue stage in the development of ReActiv8 and expects to incur further losses in the medium term. Progress on the development of ReActiv8 is detailed in the Business Review and the Company's press release in respect of results of the ReActiv8-A Clinical Trial released on 31 August 2015.

To fund the further development 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. The Group is carefully monitoring 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 approval of these Interim Financial Statements.

Accordingly the Directors believe it is appropriate that these Interim Financial Statements are prepared on the going concern basis.

Auditors

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

On behalf of the Board on 29 August 2015,

Oern Stuge — *Chairman*
MD Peter Crosby — *CEO*

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 interim 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 set of 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.

Mainstay Medical International plc
Condensed consolidated statement of profit or loss and other comprehensive income
for the half year ended 30 June 2015

($'000)	Notes	**6 month period to 30 June 2015** Unaudited	Before exceptional items 2014 Unaudited	Exceptional items 2014 Unaudited	6 month period to 30 June 2014 Unaudited
Revenue		-	-	-	-
Operating expenses	5	(6,280)	(4,780)	-	(4,780)
IPO related expenses	6	-	-	(4,040)	(4,040)
Operating loss		(6,280)	(4,780)	(4,040)	(8,820)
Finance income		-	20	-	20
Fair value (loss)/ gain on derivative financial instruments	6	-	-	(66,468)	(66,468)
Finance expense		(15)	(734)	-	(734)
Net finance expense		(15)	(714)	(66,468)	(67,182)
Loss before income taxes		**(6,295)**	**(5,494)**	**(70,508)**	**(76,002)**
Income taxes	8	(61)	(2)	96	94
Loss for the period and comprehensive loss for the period		**(6,356)**	**(5,496)**	**(70,412)**	**(75,908)**
Net loss attributable to equity holders		**(6,356)**	**(5,496)**	**(70,412)**	**(75,908)**
Basic and diluted loss per share (in $)	7	(1.48)	(3.54)	(45.31)	(48.85)

The accompanying notes form an integral part of these Condensed Consolidated Interim Financial Statements.

Mainstay Medical International plc
Condensed consolidated statement of financial position
at 30 June 2015

($'000)	Notes	**30 June 2015** Unaudited	31 December 2014 Audited
Non-current assets			
Property, plant and equipment		236	72
Current assets			
Prepayments and other receivables		325	263
Income tax receivable	8	141	150
Cash and cash equivalents		12,530	18,283

Total current assets		12,996	18,696
Total assets		**13,232**	**18,768**
Equity			
Share capital		61	61
Share premium		72,584	72,584
Share based payment reserve	13	1,976	1,162
Other reserves	11	4,700	4,700
Retained loss		(67,937)	(61,581)
Surplus/(deficit) on shareholders' equity		11,384	16,926
Current liabilities			
Trade and other payables		1,848	1,842
Total current liabilities		1,848	1,842
Total liabilities		**1,848**	**1,842**
Total equity and liabilities		**13,232**	**18,768**

The accompanying notes form an integral part of these Condensed Consolidated Interim Financial Statements.

Mainstay Medical International plc
Condensed consolidated statement of changes in shareholders' equity
for the half year ended 30 June 2015

($'000)	Share capital	Share premium	Capital conversion reserve	Reorgani-sation reserve	Share based payment reserve	Retained loss	Total equity
	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited	Unaudited
Balance at 1 January 2014	1	250	-	(9,609)	534	(13,146)	(21,970)
Loss for the period	-	-	-	-	-	(75,908)	(75,908)
Share based payments	-	-	-	-	232	-	232
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 as at 30 June 2014	**61**	**72,584**	**49,273**	**(44,573)**	**766**	**(55,024)**	**23,087**
Loss for the period	-	-	-	-	-	(6,557)	(6,557)
Share based payments	-	-	-	-	396	-	396
Balance at 31 December 2014	**61**	**72,584**	**49,273**	**(44,573)**	**1,162**	**(61,581)**	**16,926**
Balance at 1 January 2015	61	72,584	49,273	(44,573)	1,162	(61,581)	16,926
Loss for the period	-	-	-	-	-	(6,356)	(6,356)
Share based payments	-	-	-	-	814	-	814
Balance at 30 June 2015	**61**	**72,584**	**49,273**	**(44,573)**	**1,976**	**(67,937)**	**11,384**

The accompanying notes form an integral part of these Condensed Consolidated Interim Financial Statements.

Mainstay Medical International plc
Condensed consolidated statement of cash flows
for the half year ended 30 June 2015

($'000)	Notes	**6 month period to 30 June 2015**	6 month period to 30 June 2014
		Unaudited	Unaudited
Cash flow from operating activities			
Net loss attributable to equity holders		(6,356)	(75,908)
Add/(less) non-cash items			
Depreciation		24	12
Fair value of derivative financial instruments		-	66,468
Finance income		-	(20)
Finance expense		15	734
Income taxes	8	61	(94)
Share-based compensation	13	814	232
Add/(less) changes in working capital			
Prepayments and other receivables		(56)	(116)
Trade and other payables		(118)	(509)
Initial public offering and reserves related expenses	6	-	3,003
Taxes paid		(73)	-
Interest paid		-	(18)
Net cash used in operations		**(5,689)**	**(6,216)**
Cash flow from investing activities			
Acquisition of property and equipment		(64)	(15)
Net cash used in investing activities		**(64)**	**(15)**
Cash flow from financing activities			
Net proceeds from issue of shares		-	20,919
Repayment of borrowings	9	-	(800)
Net cash from financing activities		**-**	**20,119**
Net (decrease)/ increase in cash and cash equivalents		**(5,753)**	**13,888**
Cash and cash equivalents at beginning of period		18,283	9,590
Cash and cash equivalents at end of period		**12,530**	**23,478**

The accompanying notes form an integral part of these Condensed Consolidated Interim Financial Statements.

Mainstay Medical International plc

Notes to the 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 half year report and Condensed Consolidated Interim Financial Statements ("the Interim Financial Statements") in this report for the six month period ended 30 June 2015 comprise the results of the Company and of its subsidiaries (together the "Group"). At 30 June 2015, the Group comprises the Company and its operating subsidiaries Mainstay Medical Limited, MML US, Inc. and Mainstay Medical (Australia) Pty. Limited.

The Company 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®, a new implantable neurostimulation system to treat disabling Chronic Low Back Pain ("CLBP").

2 Basis of preparation

Statement of compliance

The Interim 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 2014.

The Interim 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 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 Interim Financial Statements relating to the periods ended 30 June 2014 and 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.

In addition, the following new standards were adopted by the Company for the first time in the current accounting period: Through the Annual Improvements to IFRSs 2011-2013 Cycle, the amendments to IFRS 3, IFRS 13 and IAS 40. None of these had a material impact on the Group's financial results.

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

The Interim Financial Statements were authorised for issue by the Board of Directors on 31 August 2015.

Going concern

The Group has incurred losses of $67.9 million to date (including the losses of Mainstay Medical Limited and MML, US Inc. incurred prior to the incorporation of Mainstay Medical International plc). As at 30 June 2015, the Group reported shareholders' equity of $11.4 million and cash of $12.5 million. As detailed in the Interim Management Report the Group is at a pre-revenue stage in the development of ReActiv8 and expects to incur further losses in the medium term. Progress on the development of ReActiv8 is detailed in the Interim Management Report and the Company's press release in respect of results of the ReActiv8-A Clinical Trial released on 31 August 2015.

To fund the further development 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. The Group is carefully monitoring 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 approval of these Interim Financial Statements.

Accordingly the Directors believe it is appropriate that these Interim Financial Statements are prepared on the going concern basis.

Currency

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

Basis of consolidation

The introduction of Mainstay Medical International plc as the new parent company in the Group during 2014 was accounted for as a continuation of Mainstay Medical Limited's business. Consequently the comparative financial information presented represents that of the Group headed by Mainstay Medical Limited for the period from 1 January 2014 to 2 April 2014 and of the Group headed by the Company for the period from 3 April 2014 to 30 June 2014 and for the period from 1 January 2015 to 30 June 2015. Further information is provided in Note 3 below.

3 2014 Corporate reorganisation

This note provides information on the Corporate Reorganisation which occurred during the 6 month period to 30 June 2014.

On 3 April 2014, the Company acquired all 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.

Both prior to and subsequent to the 2014 Corporate Reorganisation no individual shareholder or party had control of the Group. As the 2014 Corporate Reorganisation effectively 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.

As IFRS 3 Business Combinations did not apply to the 2014 Corporate Reorganisation, the Company, as referred by IAS 8, used guidance set by other standard-setting bodies and adopted merger accounting treatment. As a result, the Company accounted for the introduction of Mainstay Medical International plc as a continuation of the business of Mainstay Medical Limited. Consequently, even though the Company was not incorporated until 17 February 2014 and did not become a Group company until 3 April 2014, the disclosures in the Financial Statements include the consolidated financial statements of Mainstay Medical Limited prior to the date of the 2014 Corporate Reorganisation.

In addition, in accordance with the provisions of section 149(5) of the Companies Acts 1963, the Directors determined that the pre-acquisition losses of subsidiaries should be transferred to a reorganisation reserve on consolidation in the Group accounts.

As a result, in the consolidated financial statements of the Group, the difference between the carrying amount of preference shares and other equity items, including retained losses previously held by Mainstay Medical Limited and MML US, Inc, and the fair value of the shares issued by the Company is reflected in the Statement of Changes in Equity where it is recorded in the reorganisation reserve.

The impact of the above on the reorganisation reserve was a transfer of $34,030,000 from retained losses, representing the accumulated losses of Mainstay Medical Limited and MML US, Inc at 3 April 2014, and a fair value increase in ordinary shares in issue of $934,000, resulting in a total transfer to the reorganisation reserve of $34,964,000. This classification within a reorganisation reserve in the Group's consolidated financial statements does not impact on the distributable reserves of any individual subsidiary. See note 11 for further information.

4 Segment reporting

Due to the nature of the Group's current activities, the Company 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 condensed 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 2015**	**31 December 2014**
Europe	196	35
United States	40	37
Australia	-	-
Total non-current assets	**236**	**72**

5 Operating expenses

($'000)	**Period ended 30 June 2015**	Period ended 30 June 2014
Research and development expenses	1,219	1,242
Clinical and regulatory expenses	2,258	1,663
General and administration expenses	1,989	1,643
Share-based compensation expenses	814	232
Total operating expenses	**6,280**	**4,780**

6 Exceptional items

For the period ended 30 June 2015 there are no matters presented as exceptional.

For the period ended 30 June 2014, the Directors presented the following matters as exceptional as they relate to matters arising as a result of the Company's IPO on 2 May 2014.

($'000)	**Period ended 30 June 2015**	Period ended 30 June 2014
Fair value adjustment of derivative financial instruments	-	66,468
IPO related expenses	-	4,040
	-	**70,508**

On 3 April 2014, pursuant to the 2014 Company Reorganisation (refer to note 3) the Company acquired all outstanding ordinary and preference shares in Mainstay Medical Limited. The preference shares having equivalent rights in Mainstay Medical Limited had been classified as non-current liabilities and derivative financial instruments in the statement of financial position of the Group at 31 December 2013. Immediately prior to the reorganisation, a fair value expense adjustment of $17,193,978 was recorded in Mainstay Medical Limited's statement of profit or loss representing the difference between the carrying value at 31 December 2013 and the carrying value at 3 April 2014. There was a corresponding change in the derivative liability.

Immediately prior to completion of the IPO, all issued Series A, Series B and Series Z preference shares in the Company converted on a one-for-one basis into ordinary shares of €0.001 in the Company. Prior to the conversion of the preference shares in the Company to ordinary shares, a fair value adjustment was recorded in the statement of profit or loss of $49,273,644 representing the difference between the carrying value at 3 April 2014 and the fair value as at 28 April 2014. There was a corresponding change in the derivative liability.

On conversion of the preference shares to ordinary shares, the debt and derivative components of the preference shares were then derecognised from the statement of financial position as the Company's liability had been settled. The fair value of the preference shares as at 28 April 2014 was allocated to share premium and capital conversion reserve based on the carrying value of the preference shares pre and post the acquisition of these shares by the Company on 3 April 2014.

The combined impact of the above events resulted in a total fair value expense adjustment of $66,467,622 recorded in the Group statement of profit or loss. Following conversion of all preference shares during the period to 30 June 2014, the Company will not incur such fair value movements through the statement of profit or loss in future periods in relation to these preference shares.

Expenses directly associated with the Company listing its existing shares on the ESM and Euronext Paris of $4,039,681 were charged directly to profit or loss during the period ended 30 June 2014.

The adjustment for initial public offering and reserves related expenses of $3,003,000 in the cash flow statement includes these IPO expenses and the impact of the 2014 Corporate Reorganisation expenses (accounted for in share premium). In the Half Year report published on 28 August 2014, the impact of the 2014 Corporate Reorganisation expenses was included in the movement in prepayments and other receivables.

7 Earnings per share

Earnings/ losses per share are calculated by dividing net loss attributable to equity holders for the period by the weighted average number of ordinary shares outstanding during the period. As the Group is incurring operating losses, there is no difference between the basic and the diluted earnings per share.

The weighted average number of ordinary shares for the period ended 30 June 2015 (denominator) amounted to 4,294,141 (30 June 2014: 1,553,957, the weighted average during this period reflects the number of ordinary shares in issue pre and post the Company's IPO). There are no adjustments between reported profit or loss from continuing operations and earnings used for the purposes of earnings per share.

The loss per share before exceptional items for the period ended 30 June 2015 was $1.48 (30 June 2014: $3.54). The loss per share for the period ended 30 June 2015 after exceptional items was $1.48 (30 June 2014: $48.85).

8 Taxes

Current income tax assets and liabilities for the current and prior period 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)	**Period ended 30 June 2015**	Period ended 30 June 2014
Irish tax	-	-
Income tax in other jurisdictions	61	2
Deferred tax	-	(96)
Total income tax charge/(credit)	**61**	**(94)**

Certain companies within the Group provide services on a "cost plus" basis to other group companies, and consequently generate profits that are subject to corporation tax in the United States and Australia.

Tax receivable was classified within prepayments and other receivables as at 31 December 2014. The Company has included this disclosure on to a separate line in the Balance Sheet in the current report.

9 Borrowings

On 2 December 2011, Silicon Valley Bank provided the Group with a loan of $2,000,000 with a fixed annual interest rate of 10% to be serviced by interest-only payments until 1 July 2012, followed by monthly principal and interest payments until 1 December 2014. The bank 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.

10 Called up share capital

The Company's ordinary shares are quoted in Euro and have been translated into US Dollars at the rates ruling at the date of transactions. 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 the Euronext Paris. As at 5 May 2014, the issued share capital of the Company consisted of 4,294,141 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).

Authorised	**30 June 2015 €**	**30 June 2014 €**
20,000,000 ordinary shares of €0.001 each (Note 1)	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 $**
4,294,141 ordinary shares of €0.001 each	5,949	5,949
40,000 deferred shares of €1.00 each	55,268	55,268
	61,217	**61,217**

Note 1:

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 and 40,000 deferred shares of €1.00 each, 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.

Authority to allot shares

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

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

The Directors in their absolute discretion and without assigning any reason therefor may decline to register any transfer of a deferred share. The Company is authorized at any time to appoint any person to execute on behalf of the holder(s) of deferred shares a transfer thereof and/or an agreement to transfer the same, without making any payment to the holder(s) thereof and persons so entitled, to such person(s) as the Company may determine as holder(s) thereof and beneficially entitled thereto.

Details of movement in issued shares:

	Number of shares				
	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
Effect of reorganisation:					
Deconsolidation of Mainstay Medical Limited shares	(1,628,000)	-	(15,868,520)	(39,343,640)	(10,000,000)
Issue of Mainstay Medical International plc shares	102,400	40,000	793,425	2,008,877	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 30 June 2014	**4,294,141**	**40,000**	**-**	**-**	**-**
At 31 December 2014	**4,294,141**	**40,000**	**-**	**-**	**-**
At 30 June 2015	**4,294,141**	**40,000**	**-**	**-**	**-**

Series A, Series B and Series Z shares were classified as non-current liabilities and derivative financial instruments as at 1 January 2014. Immediately prior to the Company's IPO, all Series A, Series B, and Series Z preference shares converted on a one-for-one basis into ordinary shares of €0.001 each in the Company.

11 Other reserves

($'000)	**30 June 2015**	**31 December 2014**
Reorganisation reserve	(44,573)	(44,573)
Capital conversion reserve	49,273	49,273
Total other reserves	**4,700**	**4,700**

The reorganisation reserve represents (i) fair value differences arising as a result of group restructurings in 2012 and 2014; and (ii) the pre-acquisition historical losses of subsidiaries at the date of the 2012 and 2014 restructurings. This classification within a reorganisation reserve in the Group's consolidated financial statements does not impact on the distributable reserves of any individual subsidiary. All pre-acquisition losses of individual subsidiaries will need to be offset by sufficient subsequent distributable profits before subsidiaries will be in a position to make distributions.

The capital conversion reserve represents fair value uplifts in preference shares between issue and conversion. This reserve is not distributable.

12 Financial instruments

The Group's financial risk management strategy is described in the annual Consolidated Financial Statements for the year ended 31 December 2014. There have been no changes to the risk management procedures or policies since the 2014 year end.

As at 30 June 2015 the Group's only financial instruments were trade payables and cash which can be settled within 30 days. The fair value of these items is equivalent to their carrying value in accordance with IFRS 13.

Credit risk

The Group's only exposure to significant credit risk relates to cash on deposit. The Group maintained its cash balances with its principal financial institutions throughout the period. The Group's principal financial institutions carry investment grade rating.

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 AUD functional currency. The translation differences on the Australian subsidiary are not material.

The Group did not have material asset or liability amounts in foreign currencies at 30 June 2015 other than €18,000 and AUD$5,800 held in cash. A strengthening (or weakening) of the US Dollar against Euro of 5 per cent would have (decreased)/ increased the loss for the period by $1,000 (30 June 2014: $35,000). Any reasonable or likely movement between the US Dollar and the Australian Dollar are 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 50bps change in the rate of interest would not have had a material impact on the Group's statement of profit or loss and other comprehensive income in the period.

13 Share based payments

Stock Incentive Plan

The Group operates an employee share option plan (the "Plan"). As at 30 June 2015, the Plan allows for the Company to grant various classes of share options to employees of the Group companies, Directors, consultants and other contractors. As at 30 June 2015, 533,020 share options over ordinary shares of the Company have been granted under the Plan.

The Plan allows for flexibility in the grant conditions of each individual option, including variations on the amounts of options granted, the vesting requirements for each option and the expiration terms of the options.

Share Options

Details of share options granted as at 30 June 2015.

	Number of instruments in thousands	**Contractual life of options**
Options granted in 2010	41	10 years from vesting
Options granted in 2011	17	10 years from vesting
Options granted in 2012	3	10 years from vesting
Options granted in 2013	242	10 years from vesting
Options granted in 2014	91	10 years from vesting
Options granted in 2015	139	10 years from vesting
Total share options in issue	**533**	

Total non-cash expense charged to profit and loss in relation to share options for the period ended 30 June 2015 was $814,000 (30 June 2014: $232,000).

No share options have expired unexercised or have been exercised during the period ended 30 June 2015. No share options have been forfeited during the period ended 30 June 2015. The above options all include service vesting conditions and vest over periods ranging from one to four years.

Options granted prior to 2013 have an exercise price of $0.80. Options granted in 2013 have an exercise price of $1.00. Options granted in 2014 have exercise prices of either $1.00 or in the range of €14.90 to €18.51. Options granted in 2015 have exercise prices of €14.90.

At 30 June 2015, 221,938 options were exercisable.

The value of services received in return for the share options granted to employees and non-employees was based on the fair value of the options granted, measured using a Black-Scholes model with the following inputs:

	2015	**2014**	**2013**	**2012**	**2011**
Weighted average share price ($)	17.53	3.00 – 25.05	3.60	0.80	0.80
Weighted average exercise price ($)	17.53	3.00 – 25.05	1.00	0.80	0.80
Weighted average expected share volatility	60%	60%	60%	60%	60%
Expected term (years)	7	7	7	7	7
Expected dividends	-	-	-	-	-
Risk free rate (average)	0.50%	0.86%	1.60%	0.85%	0.85%
Fair value of option ($)	10.17	3.00 – 14.80	3.00	0.40	0.40

14 Related party transactions

During the period to 30 June 2015, the Group purchased services of $33,364 (30 June 2014: $36,527) from Orsco Life Sciences AG, a company controlled by Oern Stuge MD, a Director of Mainstay.

There were no balances outstanding to/from Orsco Life Sciences AG as at 30 June 2015 (31 December 2014: Nil).

Key management compensation and Directors' remuneration

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

($'000)	**Period ended 30 June 2015**	Period ended 30 June 2014
Salaries and fees	850	808
Other remuneration	249	221
Share based payments	645	183
Pension	11	5
Total remuneration	**1,755**	**1,217**

15 Events subsequent to 30 June 2015

As referred to in the Interim Management Report, on 24 August 2015 Mainstay 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.

The facility can be drawn in three tranches, and an initial tranche of $4.5 million has been called. The second and third tranches can be drawn upon achievement of milestones related to progress through the CE Mark process for ReActiv8.

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