Résultats préliminaires 2015 et rapport d'activité de Mainstay Medical

Dublin, Irlande – le 8 février 2016 : Mainstay Medical International plc (« **Mainstay** » ou la « **Société** » cotée sur Euronext Paris: MSTY.PA et l'ESM de la Bourse irlandaise: MSTY.IE), une société de dispositifs médicaux dédiée au développement et à la commercialisation de ReActiv8®, un nouveau dispositif de neurostimulation implantable destiné à traiter la lombalgie chronique invalidante, annonce aujourd'hui la publication de ses résultats préliminaires pour l'exercice clos le 31 décembre 2015.

Faits marquants de l'activité

La démarche engagée pour la commercialisation de ReActiv8 continue à avancer. Nous annoncions, le 2 novembre 2015, avoir sollicité le marquage CE à notre Organisme Notifié. Nous avons depuis échangé à plusieurs reprises avec l'Organisme Notifié dans le but de faire progresser notre demande.

Une fois le marquage CE obtenu, nous prévoyons d'initier la phase de commercialisation en Allemagne, notre premier marché cible. Les préparatifs en vue de la commercialisation sont en cours, dont notamment des interactions avec les premiers clients médecins ainsi que le recrutement d'une équipe chargée de la vente directe et de personnels auxiliaires. En Allemagne, nous prévoyons d'utiliser une équipe de vente directe restreinte afin de nous concentrer sur un groupe identifié de centres multidisciplinaires recevant un grand nombre de personnes souffrant de lombalgie chronique. Au fil de l'expérience acquise grâce à cette stratégie de commercialisation, nous envisagerons à l'avenir de nous étendre à de nouveaux clients et d'autres pays.

Des résultats positifs de l'Essai Clinique ReActiv8-A ont été publiés le 31 août 2015, et le 4 décembre 2015, nous avons publié des données supplémentaires qui confirment les résultats positifs de cet essai clinique. Ces résultats ont été présentés lors de la réunion scientifique de la *North American Neuromodulation Society* par le professeur Sam Eldabe (Middlesbrough, Royaume-Uni), un investigateur de l'Essai Clinique ReActiv8-A. Lors de cet événement, ReActiv8 est également apparu dans un certain nombre d'autres présentations sur le mal de dos, animées par d'éminents médecins spécialisés en neuromodulation.

Le 29 mai 2015, nous avons annoncé l'approbation de la FDA pour commencer l'Essai Clinique ReActiv8-B sous exemption des dispositifs expérimentaux (*Investigational Device Exemption*, IDE). Nous avons depuis cette date travaillé avec la FDA pour affiner le protocole et nous progressons dans la sélection et le démarrage des sites d'essai clinique, ainsi que dans la formation des médecins, et les soumissions de dossiers aux comités d'éthique habilités (*Institutional Review Boards*, ou IRBs, aux États-Unis). L'Essai Clinique ReActiv8-B est conçu pour générer des données destinées à constituer une partie de la demande adressée à la FDA d'autorisation « pré-commercialisation » de ReActiv8 (*Pre Market Approval Application*, PMAA). Suite à l'autorisation de

« pré-commercialisation » (si délivrée), nous avons l'intention de commercialiser ReActiv8 aux États-Unis.

L'Essai Clinique ReActiv8-B est constitué d'une simulation contrôlée, à répartition aléatoire, à simple insu, prospective, internationale, multi-sites, à permutation unique. En résumé, après vérification que les critères de recrutement sont satisfaits, les données de référence des sujets seront collectées et ReActiv8 sera implanté. Lors de la visite de contrôle 14 jours post-implantation, une moitié des sujets sera sélectionnée sur une base aléatoire pour recevoir un programme de stimulation adapté (le volet traitement), tandis que l'autre moitié recevra une stimulation minimale (le volet témoin). Les sujets ne seront pas informés de leur affectation au volet traitement ou au volet témoin, et tous seront informés qu'ils peuvent ou non ressentir les effets de la stimulation. Tous les sujets seront encouragés à continuer à utiliser ReActiv8 au moins jusqu'à la visite primaire d'évaluation des résultats au bout de 120 jours et seront informés de la nécessité de ne pas utiliser d'autres traitements contre la lombalgie chronique à partir de leur recrutement jusqu'après la collecte des résultats lors de la visite primaire d'évaluation des résultats. Les sujets reçoivent des instructions de maintenir constante l'utilisation de médicaments prescrits et utilisés pour la lombalgie jusqu'à la visite primaire d'évaluation des résultats. Le paramètre principal d'efficacité de l'Essai est une comparaison entre les taux des répondants des volets traitement et témoin. L'Essai sera considéré comme réussi si une différence statistiquement significative est constatée entre les taux des répondants du volet traitement et ceux du volet témoin. Un répondant est défini comme un sujet ayant une amélioration d'au moins 30% de sa douleur au dos, rapportée sur une échelle visuelle analogique (EVA) de 100mm, entre les données de référence et les résultats de la visite primaire d'évaluation au bout de 120 jours, sans augmentation des médicaments prescrits et utilisés contre la douleur au cours des 14 jours qui précèdent la visite. Des données pour la mesure de multiples critères d'évaluation secondaires seront également recueillies. A la suite de la visite primaire d'évaluation des résultats, les sujets du volet témoin seront échangés pour se voir administrer un programme de stimulation complet et adapté, et tous les sujets continueront à être suivis.

La méthodologie statistique de l'Essai nécessite la collecte de données provenant de 128 sujets au stade de la visite primaire d'évaluation des résultats à 120 jours. D'autres sujets seront vraisemblablement recrutés et implantés dans le cadre de la phase de développement chirurgical et afin d'obtenir des données de 128 sujets de la cohorte pivot. L'Essai comprend une « observation intermédiaire » qui est effectuée lorsque les données des résultats primaires sont disponibles pour la moitié des sujets, et si nécessaire, le nombre de sujets de la cohorte pivot pourra être augmenté afin d'atteindre le niveau de pertinence statistique recherché. Jusqu'à 40 sites d'essais cliniques pourraient être impliqués dans l'Essai, certains d'entre eux pouvant être des sites référents et d'autres des sites d'implantation.

Un résumé du protocole est disponible à l'adresse suivante : https://clinicaltrials.gov/show/NCT02577354.

Sur la base de notre expérience des recrutements dans le cadre de l'Essai ReActiv8-A, nous estimons que le recrutement complet de la cohorte pivot de l'Essai Clinique ReActiv8-B durera de 12 à 18 mois à partir de son lancement, avec des résultats qui devraient être disponibles environ six mois après l'accomplissement de la phase de recrutement. Le travail nécessaire pour compléter la demande d'autorisation « pré-commercialisation » adressée à la FDA est estimé à six mois environ à compter de la date de disponibilité des données.

L'Essai ReActiv8-B, en cas de succès, fournira ce qui est appelé « Preuve de sécurité et efficacité de niveau 1 » de ReActiv8 (*Level 1 Evidence of safety and efficacy*), et une preuve de niveau 1 peut être utilisée pour justifier des demandes de remboursement avantageux aux États-Unis.

Nous prévoyons une accélération des recrutements pour l'Essai ReActiv8-B lorsque nous aurons déterminé que nous disposons de ressources financières suffisantes pour mener à terme l'Essai jusqu'au stade de la mise à disposition des données. Un nombre restreint de sujets pourrait être recruté pour l'Essai ReActiv8-B avant la sécurisation de ces ressources financières.

Nous sommes également heureux d'annoncer l'obtention de deux nouveaux brevets américains, portant à sept le nombre total de brevets américains dans le portefeuille de Mainstay :

- Le brevet US n° 9 186 501 intitulé « *Dispositifs et méthodes pour l'implantation de câbles d'électrodes pour usage avec un stimulateur électrique neuromusculaire implantable* », et
- Le brevet US n° 9 248 278 intitulé « *Stimulateur modulaire pour le traitement du mal de dos, système d'ablation à radiofréquence implantable et méthodes d'utilisation* ».

Des demandes correspondantes ont été déposées dans d'autres pays. Mainstay continue d'augmenter le nombre de brevets et de demandes de brevet en cours d'examen constituant son portefeuille.

Situation financière

Le 24 août 2015, nous avons annoncé l'octroi d'une ligne de crédit d'un montant maximum de 15 millions de dollars. 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. Au 31 décembre 2015, 10,5 millions de dollars ont été mis à disposition de la Société. La dernière tranche de 4,5 millions de dollars pourra être tirée à tout moment à la suite de l'approbation du marquage CE de ReActiv8 à la discrétion de la Société, et ce jusqu'au 31 juillet 2016.

Les charges d'exploitation se sont élevées à 12,9 millions de dollars pour l'année, en diminution de 2,3 millions de dollars par rapport à 2014 en raison des coûts liés à l'introduction en bourse en Europe imputés en 2014 et non plus en 2015, et compensés par les coûts liés à l'agrandissement de l'équipe de Mainstay.

Au 31 décembre 2015, la trésorerie disponible était de 16,6 millions de dollars et les sorties de trésorerie liées à l'exploitation en 2015 s'élevaient à 11,6 millions de dollars.

Perspectives et développements futurs

Alors que nous attendons l'approbation du marquage CE pour ReActiv8, nous nous préparons à sa commercialisation en Europe. Nous préparons également l'Essai Clinique ReActiv8-B et, sous réserve de la disponibilité de ressources financières suffisantes, envisageons d'accélérer les recrutements pour l'Essai.

Les principaux risques et incertitudes concernant le Groupe sont, pour l'essentiel, inchangés par rapport à ceux publiés dans le rapport annuel de 2014. Les risques et incertitudes présentées dans le rapport doivent être lus en combinaison avec ce communiqué, les communiqués de presse de la Société et les autres informations publiquement disponibles (dont des copies sont librement accessibles sur le site internet de la Société) et pourraient, de fait, conduire des événements à différer sensiblement par rapport à ceux décrits dans le présent communiqué et nos autres déclarations.

- Fin -

À propos de Mainstay

Mainstay est une société de dispositifs médicaux axée sur la mise sur le marché d'un système 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 (MSTY.PA) et sur l'ESM de l'Irish Stock Exchange (MSTY.IE).

A propos de l'Essai ReActiv8-A

L'Essai Clinique ReActiv8-A est un essai clinique prospectif à volet unique avec un maximum de 96 sujets sur des sites en Australie et en Europe. Les données des 47 premiers sujets de l'Essai ReActiv8-A ont été soumises dans le cadre d'une application pour marquage CE. Des informations complémentaires sont disponibles à l'adresse https://clinicaltrials.gov/show/NCT01985230.

A propos de la première instance ReActiv8-B

L'Essai Clinique ReActiv8-B est une simulation contrôlée, à répartition aléatoire, à simple insu, prospective, internationale, multi-sites, à permutation unique, développée sous exemption des dispositifs expérimentaux (*Investigational Device Exemption*, IDE). L'Essai Clinique ReActiv8-B est conçu pour générer des données destinées à constituer une partie de la demande adressée à la FDA d'autorisation « pré-commercialisation » (*Pre Market Approval Application*, PMAA) de ReActiv8. Des informations complémentaires sont disponibles à l'adresse https://clinicaltrials.gov/show/NCT02577354.

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 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 la lombalgie chronique, et les journées de travail perdues, les prestations d'invalidité et le recours aux prestations de santé pèsent de façon significative sur les individus, les familles, les communautés, l'industrie et sur les gouvernements.

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.

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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 « anticipe », « croit », « estime », « s'attend à », « a l'intention de », « planifie », « ambitionne », « explore » ou 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. En outre, même si les résultats opérationnels, la situation financière et la croissance future de la Société ainsi que le développement de son produit principal, 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, la capacité de la Société à obtenir le marquage CE pour le dispositif ReActiv8®, le lancement et succès de l'Essai Clinique ReActiv8-B®, 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, le temps nécessaire pour commencer et achever les essais cliniques, le temps et les procédures nécessaires à l'obtention des approbations réglementaires, 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

Directors' responsibilities statement

Statement of the Directors in respect of the Preliminary Results

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

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

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

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

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

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

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

The directors' responsibility for the financial statements

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

Our responsibility

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

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

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

Conclusion

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

Emphasis of matter

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

Limitations

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

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

5 February 2016

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 General information and reporting entity

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

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

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

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

2 Basis of preparation

Statement of compliance

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

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

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

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

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

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

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

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

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

Going concern

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

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

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

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

Basis of measurement

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

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

Currency

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

2014 Corporate Reorganisation

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

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

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

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

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

3 Segment reporting

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

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

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

4 Operating expenses

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

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

5 Net finance expense

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

Note (i):

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

6 Earnings per share

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

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

7 Taxes

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

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

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

8 Interest bearing loans and borrowings and shares classified as debt

IPF Debt Financing

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

The initial tranche (“Tranche A”) of $4,500,000 was received on 9 September 2015. The interest rate on Tranche A is 3-month Euribor plus a margin of 12.5%.

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

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

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

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

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

9 Called up share capital

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

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

Authorised and Issued Share Capital of Mainstay Medical International plc:

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

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

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

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

Details of movement in issued shares:

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

10 Financial instruments

Financial risk management

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

Risk management framework

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

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

Credit risk
Credit risk is the risk of financial loss to the Group if a customer or counterparty to a financial instrument fails to meet contractual obligations, and arises principally from the Group's cash and cash equivalents.
The Group maintained its cash balances with its principal financial institutions throughout the year. The Group's principal financial institutions have investment grade ratings at year end.

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

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

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

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

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

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

11 Share based payments

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

12 Contingencies

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

13 Related party transactions

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

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

Key management compensation and Directors' remuneration

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

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

14 Events subsequent to 31 December 2015

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

Mainstay Medical International plc
Corporate and shareholder information

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