Mainstay Medical annonce ses résultats du premier semestre 2018 et fait le point sur ses activités

- *L'essai clinique ReActiv8-B suit son cours ; l'ensemble des données de l'étude est attendu en cette fin d'année*
- *Levée de fonds réussie de 37,5 millions de dollars (30 millions d'euros) pour financer l'achèvement de l'essai ReActiv8-B et la poursuite de la commercialisation en Europe*
- *La trésorerie disponible s'élève à 29,7 millions de dollars au 30 juin 2018*

Dublin – Irlande, le 21 septembre 2018 – Mainstay Medical International plc (« Mainstay » ou « la Société », Euronext Paris : MSTY.PA et Euronext Dublin : MSTY.IE), société de dispositifs médicaux consacrée à la commercialisation de ReActiv8®, un dispositif de neurostimulation implantable destiné à traiter la lombalgie chronique invalidante, annonce aujourd'hui la publication de ses résultats semestriels au 30 juin 2018 et fait le point sur ses activités.

M. Jason Hannon, Directeur Général de Mainstay, indique : *« Nous avons réalisé dernièrement de nombreux progrès notamment avec l'annonce de la fin du cycle des implantations pour l'étude ReActiv8-B, dont l'ensemble des résultats est toujours attendu pour la fin de cette année. Il s'agit d'une étape significative alors que nous redoublons d'efforts pour mettre ReActiv8 à la disposition des patients aux États-Unis.*

Nous mettons tout en œuvre pour accélérer l'adoption de ReActiv8 en Allemagne, notre premier marché. Nous y avons, depuis mars dernier, affiné notre stratégie commerciale, restructuré nos équipes de vente, apporté une formation plus ciblée à l'ensemble de nos commerciaux (nouveaux et existants) et étendu notre communication aux médecins susceptibles de pratiquer l'implantation. Nous avons également nommé un nouveau directeur exécutif Allemagne, chargé de notre développement commercial outre-Rhin, de la mise en place des relations avec les principaux médecins pratiquant l'implantation et du renforcement de notre équipe avec l'arrivée de commerciaux expérimentés, à même d'augmenter rapidement la présence de ReActiv8 sur le marché. Nous constatons aujourd'hui les premiers signes témoignant du succès de ces initiatives. Nous soulignons que nous restons en bonne voie pour atteindre notre objectif d'au moins dix médecins partenaires pratiquant des implantations multiples d'ici à la fin de l'année. Nous estimons que cette dynamique nous ouvre la voie d'un développement commercial accru en 2019, au fur et à mesure que davantage de clients adopteront notre dispositif et n'hésiteront pas à le proposer aux patients pour lesquels cette thérapie est la plus adaptée. »

État d'avancement des activités

- Au premier semestre 2018, nous avons enregistré des avancées significatives dans l'étude clinique pivot IDE de Mainstay sur ReActiv8-B, qui doit recueillir des données pour étayer la demande d'approbation préalable à la commercialisation (PMA) envoyée à la FDA (*Food and Drug Administration*), une étape clé vers la vente de ReActiv8 aux États-Unis. La fin du cycle des implantations a été annoncée au début du troisième trimestre 2018. En tout, 204 patients ont reçu un générateur d'impulsions implantable dans le cadre de l'étude, ce qui témoigne de l'intérêt suscité par celle-ci. La fin du cycle d'implantations de l'étude clinique signifie que la Société devrait pouvoir, comme prévu, annoncer une revue des données complètes vers la fin de l'année 2018.
- En Allemagne, le premier marché européen sur lequel Mainstay s'est implanté, l'équipe commerciale a été réorganisée afin de mieux cibler les efforts sur la recherche de médecins clés. Les opérations

commerciales prévues dans le cadre de cette nouvelle stratégie ont commencé effectivement en mars 2018, après la levée de fonds annoncée en février 2018, et sont en plein déploiement. Le nombre d'implantations et de nouveaux sites a fortement augmenté en juillet-août 2018 par rapport aux six premiers mois de l'année.

- Wolfgang Frisch a été nommé vice-président et directeur exécutif pour l'Allemagne le 20 juin 2018. M. Frisch a plus de 30 ans d'expérience dans l'industrie des technologies médicales. Il jouera un rôle déterminant dans le développement de nos activités commerciales en Allemagne, en visant en priorité l'adoption de nos produits par des centres de soins de la colonne vertébrale soigneusement sélectionnés, traitant un nombre important de patients.
- Matthew Onaitis a été nommé directeur financier avec effet au 20 août 2018. Fort de plus de 20 ans d'expérience au sein d'entreprises dynamiques dans le secteur de la santé, Matthew nous apporte sa connaissance approfondie du financement d'entreprises innovantes en croissance telles que Mainstay.

Situation financière

- Le 15 février 2018, la Société a annoncé la levée d'un financement de 30,1 millions d'euros (environ 37,5 millions de dollars) via l'émission de 2 151 332 nouvelles actions ordinaires auprès d'actionnaires nouveaux et existants. Les fonds ainsi levés permettent d'achever l'étude clinique pivot ReActiv8-B, de poursuivre le lancement de ReActiv8 en Allemagne et dans d'autres pays, et d'investir dans des activités commerciales préalables à la vente aux États-Unis.
- Le chiffre d'affaires des six premiers mois de l'année au 30 juin 2018 s'établit à 0,4 million de dollars (contre 0,3 million de dollars au premier semestre 2017).
- Les charges d'exploitation ont atteint 15,8 millions de dollars (contre 12,3 millions de dollars au premier semestre 2017). Cette augmentation provient principalement des frais générés par l'étude ReActiv8-B et des investissements dans la commercialisation.
- La trésorerie disponible au 30 juin 2018 s'établissait à 29,7 millions de dollars (contre 10 millions de dollars au 31 décembre 2017).

Conférence téléphonique pour les investisseurs

Le directeur général, Jason Hannon, et le directeur financier, Matthew Onaitis, tiendront une conférence téléphonique et répondront aux questions des analystes et des investisseurs à 13h00, heure de Dublin (8h00 heure de New York, 14h00, heure de Paris) le vendredi 21 septembre 2018. La conférence se tiendra en anglais, et pourra être réécoutée pendant 30 jours. Les numéros à composer sont les suivants :

Europe : +44 333 300 0804

Irlande : +353 1 431 1252

France : +33 170750711

Allemagne : +49 6913803430

États-Unis : +1 6319131422

Code participant : 87237611#

– Fin du communiqué –

À propos de Mainstay
Mainstay est une société de dispositifs médicaux axée sur la commercialisation d'un système implantable innovant de neurostimulation réparatrice, ReActiv8®, pour les personnes souffrant de lombalgie chronique invalidante (Chronic Low Back Pain(CLBP)). Le siège social de la Société est situé à Dublin, en Irlande. La Société dispose de filiales basées en Irlande, aux États-Unis, en Australie, en Allemagne et aux Pays-Bas, et elle est cotée sur le marché réglementé d'Euronext Paris (MSTY.PA) et sur l'ESM d'Euronext Dublin (MSTY.IE).

À propos de la lombalgie chronique invalidante

L'une des causes fondamentales reconnues de la lombalgie chronique invalidante est l'altération du contrôle par le système nerveux des muscles qui stabilisent dynamiquement la colonne vertébrale dans le bas du dos, et une colonne vertébrale instable peut entraîner des douleurs dorsales. ReActiv8 est conçu pour stimuler électriquement les nerfs responsables de la contraction de ces muscles et ainsi aider à restaurer le contrôle musculaire et à améliorer la stabilité dynamique de la colonne vertébrale, permettant au corps de récupérer de la lombalgie chronique invalidante.
Les personnes atteintes de lombalgie chronique invalidante ont généralement une qualité de vie grandement réduite et ont des résultats significativement plus élevés sur les échelles de douleur, d'invalidité, de dépression, d'anxiété et de troubles du sommeil. Leur douleur et leur incapacité peuvent persister malgré les meilleurs traitements médicaux disponibles, et seul un faible pourcentage des cas résulte d'un état pathologique ou d'un défaut anatomique identifié qui peut être corrigé par la chirurgie de la colonne vertébrale. Leur capacité de travailler ou d'être productif est sérieusement affectée par la maladie et les journées de travail perdues, les prestations d'invalidité et le coût des prestations médicales représentent un fardeau important pour les individus, les familles, les collectivités, l'industrie et les gouvernements.

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

ATTENTION - aux États-Unis, ReActiv8 est limité 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 lancer et commercialiser avec succès 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 and its subsidiaries

Half Year Report comprising Interim Management Report and condensed consolidated Financial Statements for the half year ended 30 June 2018

Mainstay Medical International plc
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Forward looking statements

This report includes statements that are, or may be deemed to be, forward looking statements. These forward looking statements can be identified by the use of forward looking terminology, including the terms "anticipates", "believes", "estimates", "expects", "intends", "may", "plans", "projects", "should", "will", or "explore" or, in each case, their negative or other variations or comparable terminology, or by discussions of strategy, plans, objectives, goals, future events or intentions. These forward looking statements include all matters that are not historical facts. They appear throughout this report and include, but are not limited to, statements regarding the Company's intentions, beliefs or current expectations concerning, among other things, the Company's results of operations, including commercial performance, financial position, prospects, financing strategies, expectations for product design and development, regulatory applications and approvals, commercialization plans, 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, including commercial performance, and the development of its main product, the markets and the industry in which the Company operates, may differ materially from those described in, or suggested by, the forward looking statements contained in this report. In addition, even if the Company's results of operations, commercial performance, financial position and growth, and the development of its main product and the markets and the industry in which the Company operates, are consistent with the forward looking statements contained in this 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, the successful launch and commercialization of ReActiv8, the progress and success of the ReActiv8-B Clinical Trial, general economic and business conditions, global medical device market conditions, industry trends, competition, changes in law or regulation, changes in taxation regimes, the availability and cost of capital, the time required to commence and complete clinical trials, the time and process required to obtain regulatory approvals, currency fluctuations, changes in its business strategy, and political and economic uncertainty. The forward-looking statements herein speak only at the date of this report.

Mainstay Medical International plc
Corporate and shareholder information

Directors	Oern Stuge MD, Independent Non-Executive Chairman Jason Hannon, Chief Executive Officer and Executive Director David Brabazon, Independent Non-Executive Director Greg Garfield, Non-Executive Director Nael Karim Kassar, Non-Executive Director Antoine Papiernik, Non-Executive Director James Reinstein, Independent Non-Executive Director 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/ Lawyers	McCann FitzGerald Riverside One Sir John Rogerson's Quay Dublin 2, Ireland Latham Watkins 885 3rd Avenue, NY 10022, USA
Independent Auditor	KPMG Chartered Accountants 1 Stokes Place St Stephen's Green Dublin 2, Ireland
Principal Bankers	HSBC Bank of Ireland
ESM Adviser and Broker	J&E Davy Davy House 49 Dawson Street Dublin 2, Ireland
Registrar	Computershare Investor Services (Ireland) Limited Heron House Corrig Road Sandyford Industrial Estate Dublin 18, Ireland
Paying Agent (in France)	Caceis Corporate Trust 1/3, Place Valhubert 75013 Paris, France

Mainstay Medical International plc
Interim Management Report

The Board of Directors is pleased to report on the progress of Mainstay Medical International plc (Mainstay or the Company) and present the Half Year Report for the half year ended 30 June 2018 of the Company and its subsidiaries (the Group or we).

Principal activities

Mainstay is a medical device company focused on commercializing ReActiv8®, an implantable restorative neurostimulation system designed to treat an underlying cause of disabling Chronic Low Back Pain (CLBP). ReActiv8 is designed to electrically stimulate the nerves responsible for contracting a muscle which stabilizes the lumbar spine. Activation of this muscle to restore functional stability has been shown to facilitate recovery from CLBP. Mainstay received CE Marking for ReActiv8 based on positive results from the ReActiv8-A Clinical Trial which demonstrated a statistically significant and lasting improvement in pain, disability and quality of life in people with disabling CLBP.

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

As at 30 June 2018, the Company and its operating subsidiaries Mainstay Medical Limited, MML US, Inc., Mainstay Medical (Australia) Pty Limited, Mainstay Medical Distribution Limited, Mainstay Medical B.V. and Mainstay Medical GmbH form the Mainstay Medical Group.

Business review

ReActiv8-B Clinical Trial – The ReActiv8-B Clinical Trial (the Trial) is an international, multi-center, prospective, randomized, sham-controlled, triple blinded trial with one-way crossover, conducted under an Investigational Device Exemption (IDE) from the US Food and Drug Administration (FDA).

The Trial is intended to gather data in support of an application for pre-market approval (PMA) from the FDA, a key step towards the commercialization of ReActiv8 in the US. Information about the trial can be found at https://clinicaltrials.gov/ct2/show/study/NCT02577354.

The primary efficacy endpoint of the Trial is a comparison of responder rates between the treatment and control arms. The Trial will be considered a success if there is a statistically significant difference in responder rates between the treatment and control arms. The Trial, if successful, will provide Level 1 Evidence of efficacy of ReActiv8, which may be used to support applications for reimbursement in the US. Data from the Trial will also be used to support market development activities worldwide.

In December 2017, the independent Data Monitoring Committee (DMC) completed the pre-planned interim analysis of the Trial, which was based on data from the first 58 patients in the pivotal cohort to complete the primary endpoint. The DMC recommended continuation of the Trial with a definitive size of 168 evaluable patients. The DMC also reported that they had observed no safety concerns in the Trial.

During the first half of 2018, significant further progress was made to advance the Trial. In July 2018, we announced completion of all implants in the Trial. Because of enrollment momentum at our clinical sites at the time of and following the interim review of the data, and reflecting the strength of interest in the Trial, a total of 204 patients were implanted. The completion of implants in the Trial means the Company remains on track to announce full data towards the end of 2018.

Commercialization – In Germany, Mainstay's initial European market, the commercial team was repositioned in order to better focus efforts on key physician targets. Commercialization efforts in line with this strategy began in earnest in March 2018, post our financing announced in February 2018, and are gaining traction. Our strategy is to focus on adoption in a select number of high volume spine care centres. The rates of implants and new implanting sites have increased sharply in July and August 2018 as compared to the first six months of the year.

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

Funding – On 15 February 2018, we announced the completion of a €30.1 million financing (approximately $37.5 million) through a placement of 2,151,332 new ordinary shares to new and existing shareholders. On 4 May 2018, we announced the publication of a prospectus (the Prospectus) in connection with the Placement. The funds are being used to complete the ReActiv8-B Clinical Trial, advance the initial commercialization of ReActiv8 in Germany and other markets and invest in early commercial activities in preparation for launch in the US. The Prospectus comprises a Summary Document, a Securities Note and a Registration Document. These documents are available on our website (www.mainstay-medical.com).

ReActiv8-A Post Market Clinical Follow up (PMCF) Study – The ReActiv8-A Clinical Trial was an international, multi-center, prospective, single arm clinical trial of ReActiv8 that formed the basis of our CE mark for ReActiv8.

Following CE marking approval, a range of activities is required for post market clinical follow up to gather additional data on the long-term performance and safety of ReActiv8. The ReActiv8–A PMCF Study is a continuation of the ReActiv8-A Clinical Trial (but using CE Marked ReActiv8). All subjects enrolled in the ReActiv8–A Clinical Trial in Belgium and the UK are being converted to the ReActiv8-A PMCF Study. Physicians commenced with these implants in late 2017, and the full 40 implants are expected to be completed by the end of 2018.

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

Financial review

Income Statement – Revenue during the six-month period ending 30 June 2018 was $0.36 million ($0.25 million during the same period in 2017). Revenue was generated from sales of ReActiv8 systems to customers in Germany and Ireland.

Operating expenses related to on-going activities were $15.8 million during the half year ended 30 June 2018 (same period in 2017: $12.3 million). On-going activities during the financial year included research and development, clinical and regulatory activities, selling, general and administrative activities.

Research and development expenses were $2 million during the six-month period ended 30 June 2018, which is consistent with expenditure of $2 million during the same period in 2017. Expenditure during the 2018 period included the salaries of engineers, technicians, and quality and regulatory specialists; the cost of outsourced development and manufacturing activities; biocompatibility and pre-clinical studies; and quality costs including the maintenance of our quality system.

Clinical and regulatory expenses were $7.2 million during the six-month period ended 30 June 2018 and increased by $2 million from $5.2 million during the same period in 2017. This is primarily driven by increased direct trial costs, consulting, training and travel costs relating to activities for the Trial, which has sites in the U.S., Australia and Europe.

Our selling, general and administrative expenses were $6.6 million during the six-month period ended 30 June 2018, and $5.1 million during the same period in 2017. The increase of $1.5 million is primarily driven by commercialization and the related increase in our direct sales force (impacting recruitment fees, payroll, travel and training costs), as well as marketing, reimbursement consulting and market research costs. This increase is also impacted by a non-cash expense for share options granted. Selling, general and administrative expenses are expected to increase in future years, as we increase our direct sales team to drive activities to promote growth.

Statement of financial position – Total assets of the Group at 30 June 2018 were $33.6 million (31 December 2017: $13.3 million). Cash on hand at 30 June 2018 was $29.7 million (31 December 2017: $10 million). Cash used in operating activities was $14.8 million during the period (30 June 2017: $11.4 million) and is reflective of our increased operating expenses.

The Group's debt facility provided by IPF Partners was entered into on 24 August 2015 for up to $15 million. The Group had drawn down $4.5 million on 9 September 2015, $6 million on 3 December 2015 and $4.5 million on 28 July 2016. During 2018, the Group made principal repayments of $1.5 million.

Since inception the Group has funded its operations primarily through the issuance of equity securities and debt funding. The Group continues to explore funding strategies (e.g., equity, debt, partnering) to support its activities into the future, including the possibility of a listing on NASDAQ or other US stock exchange and a related public or other offer of securities.

Principal risks and uncertainties

The principal risks and uncertainties faced by the Group and/or its industry for the remaining six months of 2018 remain substantially unchanged from the risks disclosed in the Prospectus, which is available on our website.

A summary of the principal risks relating to the Company and/or its industry include the following:

- We have incurred significant operating losses and may not be able to achieve or subsequently maintain profitability.
- We expect to require additional funds in the future in order to meet our capital and expenditure needs and further financing may not be available when required or, if available, could require us to agree to terms which are specifically favourable to new investors, or to restrictions significantly limiting our access to additional capital.
- Our future financial performance is entirely dependent on the commercial success of ReActiv8, our only product as of the date of this Report, obtaining adequate reimbursement for ReActiv8, and rates of product adoption and market penetration.
- Failure to comply with debt covenants or failure to make repayments on our debt facility could have a material adverse effect.
- We operate in a highly regulated environment and regulatory approval is required before we can market or sell ReActiv8 in any market.
- Seeking and obtaining regulatory approval for medical devices can be a long and uncertain process. Strict or changing regulatory regimes, government policies and legislation in any of our target markets may delay, prohibit or reduce potential sales.
- We are required to conduct clinical trials for regulatory approvals and other purposes. Clinical trials carry substantial risks and are costly and time consuming, with uncertain results.
- Any inability to fully protect and exploit our intellectual property may adversely impact our financial condition, business, prospects and results of operations.

A more extensive description of the existing and future potential risks to Mainstay's business and to the Company's ordinary shares are outlined in the Risk Factors section of the Prospectus, on pages 4 to 25, and should be considered carefully by shareholders and prospective investors.

Outlook and future developments

During the first half of 2018, significant further progress was made in Mainstay's pivotal IDE Clinical Trial, ReActiv8-B, which is intended to gather data in support of a pre-market approval (PMA) application to the FDA, a key step towards the commercialization of ReActiv8 in the US. Completion of all implants was announced at the start of the third quarter of 2018. The completion of implants in the Trial means the Company remains on track to announce full data towards the end of 2018.

If successful, the ReActiv8-B Clinical Trial will yield data in support of an application for pre-market approval (PMA) from the FDA. The data will also comprise Level 1 Evidence of efficacy, which may be used to support applications for favorable reimbursement in the US. Data from the ReActiv8-B Trial will also be used to support market development activities worldwide.

Our refined commercialization strategy and repositioned commercial team is gaining traction. Our strategy is to focus on adoption in a select number of high volume spine care centers to develop key reference sites, and then build on that experience and data from the ReActiv8-B Trial to expand commercialization to additional centers and other countries.

Related party transactions

Refer to note 12.

Going concern

The Directors have evaluated whether there are conditions and events, considered in aggregate, that raise doubt about the Group's ability to continue as a going concern within one year of the date of issue of the consolidated financial statements. The Directors note the following relevant matters:

- The Group had cash of $29.7 million as at 30 June 2018 ($10 million as at 31 December 2017).
- The Group had operating cash out-flows of $14.8 million for the 6 months ended 30 June 2018 (year ended 31 December 2017: $24.9 million).
- Due to the phase of development of the Group, the Group expects to continue to incur losses in the medium term due to the ongoing investment in research and development, clinical and commercial activities.
- The Group has an accumulated retained loss reserve of $142.5 million and a reorganization reserve of $44.6 million as at 30 June 2018 (31 December 2017: $124.5 million and $44.6 million, respectively).
- The Group has funded operations to date through the proceeds of equity funding of approximately $123.5 million and as at 30 June 2018, debt with an outstanding principal of $11.7 million.

In the event that additional funding is not secured in the 12 months from the approval of these Financial Statements, the Directors believe that the Group has the ability, based on its currently available cash resources, to consider alternative budgets to manage its cash outflows so as to match those available cash resources, 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 the Financial Statements. On that basis the Directors are satisfied that there is no substantial doubt about the Group's ability to continue as a going concern and that the Financial Statements should be prepared on a going concern basis.

Auditors

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

Mainstay Medical International plc
Directors' responsibilities statement

Statement of the Directors in respect of Half Year Financial Report

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

(a) the condensed consolidated Financial Statements comprising the condensed consolidated statement of profit or loss and other comprehensive income, the condensed consolidated statement of financial position, the condensed consolidated statement of changes in equity, the condensed consolidated statement of cash flows and related notes 1 to 13 have been prepared in accordance with IAS 34 *Interim Financial Reporting* as adopted by the EU.

(b) the interim management report includes a fair review of the information required by:

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

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

On behalf of the Board on 19 September 2018,

Oern Stuge MD
Chairman

Jason Hannon
CEO

Mainstay Medical International plc
Condensed consolidated statement of profit or loss and other comprehensive income
for the half year ended 30 June 2018

($'000)	Notes	Half year ended 30 June 2018 Unaudited	Half year ended 30 June 2017 Unaudited
Revenue	4	358	250
Cost of sales		(170)	(136)
Gross profit		188	114
Operating expenses		(15,849)	(12,282)
Operating loss		(15,661)	(12,168)
Finance income		-	10
Finance expense		(1,018)	(986)
Net finance expense		(1,018)	(976)
Loss before income taxes		**(16,679)**	**(13,144)**
Income taxes	6	156	(131)
Loss for the half year		**(16,523)**	**(13,275)**
Net loss attributable to equity holders		**(16,523)**	**(13,275)**
Basic and diluted loss per share (in $)	5	(2.01)	(2.01)
Other Comprehensive Income			
Items that are or may be reclassified subsequently to the statement of profit or loss:			
Foreign currency translation differences of foreign operations		56	(50)
Total comprehensive loss for the half year		**(16,467)**	**(13,325)**
Total comprehensive loss attributable to equity holders		**(16,467)**	**(13,325)**

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 2018

($'000)	Notes	30 June 2018	31 December 2017
		Unaudited	Audited
Non-current assets			
Property, plant and equipment		177	201
Current assets			
Inventory		2,474	2,395
Trade and other receivables		875	571
Income tax receivable		345	205
Cash and cash equivalents		29,711	9,975
Total current assets		33,405	13,146
Total assets		**33,582**	**13,347**
Equity			
Share capital	8	67	64
Share premium		143,897	106,414
Other reserves		4,649	4,593
Share based payment reserve		9,465	7,613
Retained loss		(142,468)	(124,505)
Surplus/ (deficit) on shareholders' equity		**15,610**	**(5,821)**
Non-current liabilities			
Loans and borrowings	7	9,991	11,177
Total non-current liabilities		9,991	11,177
Current liabilities			
Loans and borrowings	7	3,182	3,214
Income tax payable		12	124
Trade and other payables		4,787	4,653
Total current liabilities		7,981	7,991
Total liabilities		**17,972**	**19,168**
Total equity and liabilities		**33,582**	**13,347**

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 2018

($'000)	Share capital	Share premium	Other reserves	Share based payment reserve	Retained loss	Total equity
Balance as at 1 January 2017	64	106,360	4,735	4,606	(94,707)	21,058
Loss for the half year	-	-	-	-	*(13,275)*	*(13,275)*
Other comprehensive income for the half year	-	-	*(50)*	-	-	*(50)*
Total comprehensive loss for the half year	-	-	(50)	-	(13,275)	(13,325)
Transactions with owners of the Company:						
Share based payments	-	-	-	1,296	-	1,296
Issue of shares on exercise of share options or warrants	-	4	-	(3)	3	4
Balance at 30 June 2017 (Unaudited)	**64**	**106,364**	**4,685**	**5,899**	**(107,979)**	**9,033**
Loss for the half year	-	-	-	-	*(16,560)*	*(16,560)*
Other comprehensive income	-	-	*(92)*	-	-	*(92)*
Total comprehensive loss for the half year	-	-	(92)	-	(16,560)	(16,652)
Transactions with owners of the Company:						
Share based payments	-	-	-	1,748	-	1,748
Issue of shares on exercise of share options or warrants	-	50	-	(34)	34	50
Balance at 31 December 2017	**64**	**106,414**	**4,593**	**7,613**	**(124,505)**	**(5,821)**
Loss for the half year	-	-	-	-	*(16,523)*	*(16,523)*
Other comprehensive income for the half year	-	-	*56*	-	-	*56*
Total comprehensive loss for the half year	-	-	56	-	(16,523)	(16,467)
Transactions with owners of the Company:						
Share based payments	-	-	-	1,852	-	1,852
Issue of shares	3	37,483	-	-	(1,440)	36,046
Balance at 30 June 2018 (Unaudited)	**67**	**143,897**	**4,649**	**9,465**	**(142,468)**	**15,610**

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 2018

($'000)	Notes	Half year ended 30 June 2018 Unaudited	Half year ended 30 June 2017 Unaudited
Cash flow from operating activities			
Net loss for the half year		(16,523)	(13,275)
Add/(less) non-cash items			
Depreciation		50	52
Finance income		-	(10)
Finance expense		1,018	986
Share-based compensation	10	1,852	1,296
Income taxes	6	(156)	131
Add/(less) changes in working capital			
Trade and other receivables		(306)	12
Inventory		(80)	(831)
Trade and other payables		76	1,143
Taxes paid		(112)	(238)
Interest paid		(603)	(656)
Net cash used in operations		**(14,784)**	**(11,390)**
Cash flow from investing activities			
Acquisition of property and equipment		(26)	(35)
Net cash used in investing activities		**(26)**	**(35)**
Cash flow from financing activities			
Gross proceeds from issue of shares		37,486	4
Transaction costs on issue of shares		(1,440)	-
Repayment of borrowings	7	(1,500)	(750)
Net cash inflow/(outflow) from financing activities		**34,546**	**(746)**
Net increase/(decrease) in cash and cash equivalents		**19,736**	**(12,171)**
Cash and cash equivalents at beginning of year		9,975	36,670
Cash and cash equivalents at 30 June 2018		**29,711**	**24,499**

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

The Half Year Report and condensed consolidated Financial Statements for the periods ended 30 June 2018 and 30 June 2017 comprise the results of the Company and of its subsidiaries (together the Group).

At 30 June 2018, the Group comprises the Company and its operating subsidiaries Mainstay Medical Limited, Mainstay Medical Distribution Limited, Mainstay Medical GmbH, Mainstay Medical B.V., MML US, Inc. and Mainstay Medical (Australia) Pty. Limited.

The Company's shares are quoted on Euronext Paris and the ESM of Euronext Dublin.

Mainstay is a medical device company focused on developing and commercializing ReActiv8®, an implantable restorative neurostimulation system designed to treat an underlying casuse of disabling Chronic Low Back Pain (CLBP).

2 Basis of preparation

Statement of compliance

The condensed consolidated Financial Statements have been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the EU. They do not include all the information and disclosures necessary for a complete set of IFRS Financial Statements. However, selected explanatory notes are included to explain events and transactions that are significant to an understanding of the changes in the Group's financial position and performance since the last annual consolidated financial statements as at and for the year ended 31 December 2017.

The comparative information provided in the condensed consolidated Financial Statements relating to the periods ended 30 June 2017 and 31 December 2017 does not comprise the statutory financial statements of the Group. Those statutory financial statements for the year ended 31 December 2017 on which the auditors gave an unqualified audit opinion, have been delivered to the Companies Registry Office.

There are no significant or material changes to judgements or estimates used in these condensed consolidated Financial Statements compared with those used in the consolidated Financial Statements for the year ended 31 December 2017.

The condensed consolidated Financial Statements were authorized for issue by the Board of Directors, on 19 September 2018.

Going concern

The Directors have evaluated whether there are conditions and events, considered in aggregate, that raise doubt about the Group's ability to continue as a going concern within one year of the date of issue of the consolidated financial statements. The Directors note the following relevant matters:

- The Group had cash of $29.7 million as at 30 June 2018 ($10 million as at 31 December 2017).
- The Group had operating cash out-flows of $14.8 million for the 6 months ended 30 June 2018 (year ended 31 December 2017: $24.9 million).
- Due to the phase of development of the Group, the Group expects to continue to incur losses in the medium term due to the ongoing investment in research and development, clinical and commercial activities.
- The Group has an accumulated retained loss reserve of $142.5 million and a reorganization reserve of $44.6 million as at 30 June 2018 (31 December 2017: $124.5 million and $44.6 million, respectively).
- The Group has funded operations to date through the proceeds of equity funding of approximately $123.5 million and as at 30 June 2018, debt with an outstanding principal of $11.7 million.

In the event that additional funding is not secured in the 12 months from the approval of these Financial Statements, the Directors believe that the Group has the ability, based on its currently available cash resources, to consider alternative budgets to manage its cash outflows so as to match those available cash resources, 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 the Financial Statements. On that basis the Directors are satisfied that there is no substantial doubt about the Group's ability to continue as a going concern and that the Financial Statements should be prepared on a going concern basis.

Currency

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

Basis of consolidation

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

Significant accounting policies

With the exception of the newly implemented policies noted below, the condensed consolidated Financial Statements have been prepared applying the accounting policies that were applied in the preparation of the Group's consolidated Financial Statements for the year ended 31 December 2017, which were prepared in accordance with IFRS and are available on the Company's website (www.mainstay-medical.com) except as detailed below. These accounting policies have been applied consistently for all periods presented.

The Group has initially adopted IFRS 15 Revenue from Contracts with Customers and IFRS 9 Financial Instruments from 1 January 2018. The implementation of these standards had no material impact on the Group's reported results.

a) Revenue recognition

The Group has initially adopted IFRS 15 Revenue from Contracts with Customers from 1 January 2018. Under IFRS 15, revenue is measured based on the consideration specified in a contract with a customer. The Group recognises revenue when it transfers control over a product or service to a customer. This may arise on shipment, delivery or in accordance with specific terms and conditions agreed with customers and provided there are no material remaining performance obligations required of the Group.

Revenue is measured at the fair consideration received/receivable for the sale of goods to external customers net of value added tax and discounts. Expected discounts are estimated and provided for as a reduction in revenue based on agreements with customers, agreed promotional arrangements and accumulated experience. Accumulated experience is used to estimate and provide for the discounts, using the expected value method, and revenue is only recognised to the extent that it can be reliably measured and when it is probable that future economic benefits of the transaction will flow to the Group. Service revenues (relating to training and implant support) are recognized when the related services are rendered. When a customer is invoiced, or cash is received but conditions for recognition of the related revenues have not been met, revenue is deferred until all conditions are met. The Group occasionally sells goods and services as a bundled arrangement. Such sales are unbundled based on the relative fair value of the individual goods and services components and each component is recognized separately in accordance with the Group's recognition policy.

Due to the stage of development of the Group, and the nature of the Group's current activities (the Group has only one product, ReActiv8, and some related accessories and services available for sale), this new standard has not had a material impact on the Group and there has been no restatement of previously reported amounts.

b) Financial Instruments

The change in accounting policy to comply with the requirements of IFRS 9 has had no impact on the amounts disclosed in the financial statements other than immaterial changes to impairment of trade and other receivables as discussed below. The changes in classification of financial assets and liabilities to IFRS 9 classification has had no impact on the accounting for those assets and liabilities.

Classification and measurement of financial assets and liabilities

On initial recognition a financial asset is classified as Measured at Amortised Cost, FVOCI or FVTPL. Financial assets are not reclassified after initial recognition unless the related business model changes. A financial asset is measured at amortised cost if it is held in a business model whose objective is to hold assets to collect contractual cashflows and its contractual terms give rise on specific dates to cash flows that are solely payments of principal or interest.

Trade and other receivables

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

Cash and cash equivalents

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

Trade and other payables

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

Interest-bearing borrowings

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

Trade and other receivables and cash and cash equivalents were previously classified as loans and receivables under IAS 39. There has been no change in the classification of trade and other payables or interest-bearing borrowings.

Impairment of financial assets

At each reporting date, in accordance with IFRS 9, the Group assesses whether its financial assets, comprising of accounts receivable and cash are impaired. The Group evaluates customer accounts with past-due outstanding balances, and analyses customer credit worthiness, payment patterns and trends. Based upon a review of these accounts and management's analysis and judgement, we estimate the future cash flows expected to be recovered from these receivables. As at 30 June 2018, our trade and other receivables balances amounted to $16,000, and we have not recognized any material impairment losses at this time. The total outstanding balance as at 30 June 2018 was received post period end. Further information on the Group's credit risk is detailed in Note 9. The Company measures loss allowances at an amount equal to lifetime expected credit losses, except for cash which is measured at 12-month expected credit losses. The maximum period considered when estimating expected credit losses is the maximum contractual period of exposure to credit risk.

c) Other new standards and interpretations

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

- IFRS 2 (amended) - Share Based Payments (effective 1 January 2018)
- Annual Improvements to IFRSs 2014 – 2016 Cycle: Amendments to IFRS 1 First time Adoption of IFRSs and IAS 28 Investment in Associates and Joint Ventures (IASB effective date 1 January 2018, not yet endorsed by the EU)
- Transfers of Investment Property (Amendments to IAS 40) (effective 1 January 2018)

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

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)	**30 June 2018**	31 December 2017
Ireland	30	47
Germany	3	5
United States	144	149
Total non-current assets	**177**	**201**

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

($'000)	**Half year ended 30 June 2018**	Half year ended 30 June 2017
Germany	250	231
Ireland	90	19
Other Europe	18	-
Total revenue by country	**358**	**250**

4 Revenue

($'000)	**Half year ended 30 June 2018**	Half year ended 30 June 2017
Revenue arising from the sale of goods	358	250
	358	**250**

5 Earnings per share

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

	Half year ended 30 June 2018	Half year ended 30 June 2017
Weighted average number of ordinary shares in issue	8,235,367	6,612,012
Loss per share	**2.01**	**2.01**

6 Taxes

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

7 Interest bearing loans and borrowings

IPF Debt Financing

The Group's debt facility is secured by way of fixed and floating charges over the assets and undertakings of Mainstay Medical Limited, and the Mortgage Debenture includes customary terms and conditions. In addition, Mainstay Medical International plc has created a first fixed charge in favor of IPF over its present and future shares held in Mainstay Medical Limited.

The terms of the agreement include a requirement that Mainstay Medical Limited hold a minimum cash balance of $2 million or achieve revenue targets within an agreed timeframe. The Group is not in breach of any covenants at 30 June 2018 and has not been in breach at any reporting date.

($'000)	**30 June 2018**	31 December 2017
Loans and borrowings - current		
Term loan	3,000	3,000
Deferred finance cost	(90)	(90)
Accrued interest	272	304
Total current loans and borrowings	**3,182**	**3,214**
Loans and borrowings – non-current		
Term loan	8,700	10,200
Deferred finance cost	(149)	(194)
Accrued interest	1,440	1,171
Total non-current loans and borrowings	**9,991**	**11,177**
Total loans and borrowings	**13,173**	**14,391**

8 Called up share capital

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

Authorized and Issued Share Capital

	30 June 2018	31 December 2017
Authorized	**€**	€
20,000,000 ordinary shares of €0.001 each	20,000	20,000
40,000 deferred shares of €1.00 each	40,000	40,000
	60,000	**60,000**

	2018	**2017**
Issued, called up and fully paid	**$**	**$**
8,770,229 (31 December 2017: 6,618,897) ordinary shares of €0.001 each	11,240	8,562
40,000 deferred shares of €1.00 each	55,268	55,268
	66,508	**63,830**
In $'000	**67**	**64**

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

9 Financial instruments

Financial risk management

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

Risk management framework

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

The Group has no significant concentrations of financial risk other than concentration of cash with individual banks. The Group is also exposed to credit risk arising on trade receivables, with further information provided under credit risk below. There has been no other significant change during the half year or since the end of the half year to the types or quantum of financial risks faced by the Group or the Group's approach to the management of those risks.

Credit and financial risk

Credit risk is the risk of financial loss to the Group if a customer or counterparty to a financial instrument fails to meet contractual obligations and arises principally from the Group's cash and cash equivalents and trade and other receivables. Credit risk is managed on a Group basis. The maximum exposure to

credit risk is represented by the carrying amount of each asset. The carrying value of receivables is a reasonable approximation of fair value.

Trade receivables comprise of amounts due from customers, all of which were current at 30 June 2018 and 31 December 2017. The Company does not have exposure to significantly different categories of customer and accordingly details of credit risk by customer type or jurisdictions is not provided.

There were no material impairment losses recorded in the period and the provision for expected credit losses at 30 June 2018 is also immaterial. The carrying value of trade receivables of $16,000 at 30 June 2018 ($90,000 at 31 December 2017) represents the maximum exposure to credit risk. The Group maintained its cash balances with its principal financial institutions throughout the year, and the Group limits its exposure to any one financial institution by holding cash balances across several financial institutions. The Group's principal financial institutions have investment grade ratings at 30 June 2018. The credit rating status of the Group's principal financial institutions is reviewed by the Audit Committee or the Board annually. The cash balance is reported to the Board of Directors on a monthly basis, and a monthly review of all cash balances held at each institution is carried out by the CFO. The Group maintains most of its cash in USD denominated accounts. The Group held cash and cash equivalents of $29.7 million as at 30 June 2018.

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 the issuance of equity securities and debt funding. The Group continues to explore funding strategies (e.g., equity, debt, partnering) to support its activities into the future, including the possibility of a listing on NASDAQ or other US stock exchange and a related public or other offer of securities. 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 expenditures incurred in Euros, Great British Pounds (GBP) and Australian Dollars.

The Group's Australian subsidiary has an Australian Dollar functional currency and three of the Group's subsidiaries located in Ireland, Germany and the Netherlands have a Euro functional currency. Additionally, GBP expenditure is mainly incurred from the UK based sites relating to the ReActiv8-A Post Market Clinical Follow-Up ("PMCF") Study and U.S. Pivotal ReActiv8-B Clinical Trial.

The Group did not have material asset or liability amounts in foreign currencies at 30 June 2018 other than trade payables and accruals (net of cash) of €1.2 million and £321,000.

Interest rate risk

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

At 30 June 2018, the principal outstanding on MML's loan from IPF was $11,700,000. This loan carries a variable rate of 3-month Euribor plus a margin ranging from 10.5% to 12.5%.

10 Share based payments

Share Options

The terms and conditions of the Group's share option plan are disclosed in the 2017 Annual Report. The charge of $1.9 million for the half year ended 30 June 2018 (30 June 2017: $1.3 million) is the grant date fair value of various share options granted in the current and prior years, which are being recognized within the statement of profit or loss and other comprehensive income over the vesting period related to service. 279,878 options were granted in the six months ended 30 June 2018 (30 June 2017: 30,000 options).

11 Contingencies

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

12 Related party transactions

There were no balances due to or from related parties as at 30 June 2018 and 30 June 2017.

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 for the six-month reporting period are provided below:

($'000)	**30 June 2018**	30 June 2017
Salaries	817	876
Non-executive directors' fees	135	111
Other remuneration	915	595
Payroll taxes	92	102
Share based payments	1,825	931
Pension	14	11
Total remuneration	**3,798**	**2,626**

13 Events subsequent to 30 June 2018

There were no events subsequent to the half year ended 30 June 2018 that would have a material impact on the condensed consolidated interim Financial Statements.