Mainstay Medical fait le point sur ses avancées, et publie ses résultats semestriels 2019

- *Demande soumise à la FDA en août 2019 pour ReActiv8; acceptation pour examen attendue en octobre 2019*
- *Poursuite de la validation commerciale en Europe*
- *Succès des opérations de financement, accroissant le volant de trésorerie d'environ 28 millions de dollars*

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

Mainstay Medical International plc (Mainstay ou la Société, Euronext Paris : MSTY.PA et Euronext Growth opéré par Euronext Dublin (MSTY.IE), société de dispositifs médicaux dédiée à la commercialisation de ReActiv8®, un dispositif de neurostimulation implantable pour traiter la lombalgie chronique invalidante, fait aujourd'hui le point sur ses avancées et annonce la publication de ses résultats pour le semestre clos au 30 juin 2019.

Jason Hannon, CEO de Mainstay, déclare : *«Nous poursuivons nos avancées considérables conformément à nos objectifs prioritaires d'obtenir l'approbation des autorités américaines et de continuer la validation commerciale en Allemagne et sur d'autres marchés européens triés sur le volet. Je suis heureux d'annoncer que nous avons déposé au mois d'août la demande d'approbation préalable à la commercialisation de ReActiv8 auprès de la FDA (Food and Drug Administration) aux États-Unis. En attendant l'acceptation pour examen, qui devrait intervenir en octobre 2019, nous tablons sur une décision autour de la fin 2020. Nous poursuivons également nos avancées en Allemagne en œuvrant aux côtés de référents clés qui intègrent ReActiv8 dans leurs protocoles afin d'en valider l'adoption commerciale, affinent les stratégies de sélection des patients et assurent un suivi des progrès des patients.*

Faits marquants

- En août 2019, Mainstay a déposé une demande de PMA (pre-market approval) auprès de la FDA sur la base de l'ensemble de ses données cliniques pour ReActiv8. En attendant l'acceptation de la demande pour examen, qui devrait intervenir en octobre 2019, une décision concernant l'approbation est escomptée autour de la fin 2020. L'essai clinique pivot sur lequel se fonde la demande de PMA est une étude clinique de ReActiv8-B portant sur 204 patients. Voici une synthèse des résultats cliniques de cet essai :
  - Le principal paramètre d'évaluation de l'essai consistait à comparer le taux de réponse du groupe de traitement avec celui du groupe de contrôle, tel que mesuré sur l'échelle de douleur visuelle analogique (EVA), la réponse s'entendant comme une amélioration d'au moins 30 % 120 jours après la date de randomisation sans augmentation des analgésiques et/ou relaxants musculaires au cours des deux semaines précédant l'évaluation. Dans le groupe de traitement, le taux de réponse à 120 jours s'établit à 57 %, contre 47 % dans le groupe de contrôle, soit un écart non significatif statistiquement.
  - Le protocole de l'essai comprenait une analyse prédéterminée des données relatives au paramètre d'évaluation principal permettant de prendre en compte le taux de réponse cumulé. Une comparaison des classements préservant de façon inhérente les informations a ainsi permis d'améliorer l'efficacité statistique en scindant le paramètre d'évaluation. Cette analyse a mis en évidence un écart statistiquement significatif entre le groupe de traitement et le groupe de contrôle, le groupe de traitement obtenant un taux de réponse supérieur, pour toutes les valeurs seuil.
  - Le protocole incluait en outre une analyse préspécifiée du paramètre principal après ajustement pour prendre en compte les changements de médication antalgique des patients pour des raisons sans lien avec leur lombalgie. Cette analyse a montré que dans le groupe de traitement, le taux de réponse à 120 jours s'est établi à 61 %, contre 47 % dans le groupe de contrôle, soit un écart statistiquement significatif.
  - Des améliorations statistiquement significatives de plusieurs paramètres secondaires principaux et des analyses complémentaires ont été notées dans le groupe de traitement depuis la pose de l'implant par rapport au groupe de contrôle après 120 jours, notamment la diminution de la douleur, mesurée par la réduction moyenne du score sur l'échelle visuelle analogue (EVA) et par le pourcentage de soulagement de la douleur, l'amélioration de la capacité fonctionnelle sur l'échelle d'incapacité d'Oswestry, l'amélioration de la qualité de vie mesurée par EQ-5D (European Quality of Life Score on Five Dimensions), l'impression globale du patient sur l'évolution de son état, l'impression globale du médecin sur l'évolution de l'état du patient et la satisfaction du patient vis-à-vis de son traitement, mesurée par le questionnaire de satisfaction du traitement.
  - Le pourcentage de patients faisant état de diminutions de la douleur a continué de s'améliorer après l'évaluation à 120 jours, jusqu'à un an, dans les deux groupes. Un an après la pause du stimulateur, 66 % des 160 patients du groupe de traitement et du groupe de contrôle rapportent une diminution d'au moins 30 % de leur lombalgie sur l'échelle EVA, sans augmentation significative de leur

traitement antalgique. Ces données ne sont pas encore définitives, car tous les patients n'ont pas encore passé la visite d'évaluation à un an.
    - Le protocole autorisait les patients à ajuster leur traitement antalgique après l'évaluation à 120 jours. Un an après la pause du stimulateur, 49 % des 61 patients des deux groupes combinés sous opioïdes au jour de la pause avaient volontairement éliminé ou réduit significativement l'utilisation de ces analgésiques. Ces données ne sont pas encore définitives, car tous les patients n'ont pas encore passé la visite d'évaluation à un an.
    - L'incidence et la typologie des Événements Indésirables (EI), même graves, se comparent favorablement à celles rapportées pour d'autres dispositifs de neurostimulation, sans EI imprévu lié à l'appareil, au traitement ou à la procédure.

- En Allemagne, premier marché de Mainstay, les efforts de validation commerciale ont bénéficié d'un recentrage tout au long de 2018. Mainstay s'attache désormais entièrement à accompagner un nombre réduit de sites de référence où un grand nombre de patients sont traités avec ReActiv8, ce qui facilite la collecte des données cliniques, l'affinement des processus de sélection des patients pour les marchés commerciaux et la constitution d'un corpus d'enseignements pour accélérer le lancement commercial sur d'autres marchés à l'avenir.

Situation financière

- Depuis le début de 2019, Mainstay a réalisé des activités de financement significatives qui lui ont permis de renforcer son volant de trésorerie d'environ 28 millions de dollars :
    - le 29 juillet 2019, Mainstay a finalisé des opérations de financement consistant en l'émission de 4649775 nouvelles actions ordinaires à un prix d'émission de 3,00 € par action et le tirage de 3,0 millions d'euros d'emprunts supplémentaires auprès du prêteur existant de la Société, IPF Partners, lui procurant un produit brut total de 16,9 millions d'euros (18,9 millions de dollars).
    - Le 18 avril 2019, Mainstay et sa filiale Mainstay Medical Limited ont conclu un avenant à l'accord signé avec IPF Partners relatif à leur convention de crédit existante. En vertu de cet avenant :
        - l'échéancier de remboursement des trois tranches existantes tirées dans le cadre de cette convention de crédit a été modifié de sorte qu'aucun remboursement de principal ou d'intérêt n'interviendra avant 2021, le principal et les intérêts échus devant être amortis à partir du 1er janvier 2021 et jusqu'au 30 septembre 2023;
        - une nouvelle tranche de 3,0 millions d'euros (environ 3,34 millions de dollars) a été débloquée au profit de Mainstay, qui a été tirée par Mainstay le 29 juillet 2019. L'échéancier de remboursement de cette nouvelle tranche sera le même que l'échéancier amendé de remboursement des trois tranches existantes;
        - toutes les tranches portent intérêt à un taux annuel de 8 %, les intérêts étant échus, mais capitalisés avant le 1er janvier 2021. Les taux d'intérêt précédemment applicables au trois tranches initiales étaient compris entre 10,5 % et 12,5 %.
        - la pénalité de remboursement de 5 % applicable à chacune des tranches existantes a été éliminée;
        - le montant en principal et les intérêts échus de l'ensemble des tranches seront automatiquement convertis en actions ordinaires de la Société à un cours de 8 euros par action dès que l'un des événements suivants surviendra : (a) l'approbation par la FDA de la demande de mise sur le marché de ReActiv8, (b) la date à laquelle au moins 900000 actions ordinaires de la Société auront été cédées publiquement sur le marché par des actionnaires non affiliés de Mainstay depuis avril 2019 à un cours égal ou supérieur à 8 euros, ou (c) la décision de IPF Partners de procéder à la conversion, sous réserve dans chaque cas, que la Société puisse décider d'honorer en numéraire tout ou partie de cette obligation;
        - l'engagement de montant de trésorerie minimum a été amendé de sorte que Mainstay est tenu de détenir des liquidités égales ou supérieures aux dépenses de trésorerie projetées pour ses activités et le remboursement de sa dette sur trois mois, et l'engagement relatif au franchissement des étapes commerciales a été éliminé;
        - Mainstay a émis au profit d'IPF Partners des bons de souscription d'actions pour l'achat de 1,5 million de ses actions ordinaires à un cours de 6 euros par action à tout moment jusqu'au sixième anniversaire de la date de l'avenant.
- Le chiffre d'affaires du semestre clos au 30 juin 2019 s'est établi à 0,6 million de dollars (0,36 million de dollars au S1 2018).
- Les charges d'exploitation du semestre se sont élevées à 9,5 millions de dollars (15,8 millions de dollars au S1 2018). Cette diminution des charges d'exploitation traduit principalement la baisse du coût de l'essai ReActiv-8 B, tous les implants ayant été réalisés, et l'abaissement des frais de personnels suite à la réduction des effectifs mise en œuvre en 2019.

- La trésorerie disponible ressort à 5,8 millions de dollars au 30 juin 2019 (29,7 millions de dollars au 31 décembre 2018). La trésorerie disponible atteint 23,5 millions de dollars au 31 juillet 2019.

Prévisions concernant l'essai clinique ReActiv8-B

L'essai clinique ReActiv8-B est un essai international multicentrique randomisé prospectif en aveugle contre placébo avec permutation, réalisé dans le cadre d'une dispense (*Investigational Device Exemption* - IDE) des autorités américaines (US Food and Drug Administration - FDA). Au total, 204 patients souffrant de lombalgie chronique invalidante et ne réagissant pas à la kinésithérapie ont reçu ReActiv8 en implant dans des centres de recherche de pointe aux États-Unis, en Europe et en Australie, et ont été randomisés à parité pour traitement ou contrôle. Dans le groupe de traitement, le générateur d'impulsions ReActiv8 a été programmé pour délivrer des stimulations électriques visant à stimuler la contraction du muscle multifidus. Dans le groupe de contrôle, l'appareil a été programmé pour des stimulations électriques de faible niveau. Suite à l'évaluation du paramètre principal à 120 jours, les patients du groupe de contrôle ont rejoint le groupe de traitement pour y recevoir le même protocole de traitement. À l'issue de son examen de la demande de PMA, il est possible que la FDA ait une interprétation des données cliniques divergente de celle de Mainstay, notamment en ce qui concerne la signification statistique d'un ou plusieurs paramètres.

Conférence téléphonique à l'intention des investisseurs

Jason Hannon, président-directeur général, et Matthew Onaitis, Directeur financier de Mainstay, animeront une conférence téléphonique et une séance de questions-réponses à l'intention des investisseurs et des analystes, le 20 septembre 2019 à 14 heures, heure de Paris (8 heures à New York). Cette conférence aura lieu en anglais et sera disponible en réécoute pendant 30 jours. Voici les informations qui vous permettront de vous connecter :

Europe : +44 333 300 0804

Irlande : +353 1 431 1252

France : +33 170750711

Allemagne : +49 6913803430

États-Unis : +1 6319131422

Code d'accès : 34020721#

– Fin du communiqué –

Le présent communiqué contient des informations privilégiées au sens de la réglementation européenne 596/2014 contre les abus de marchés.

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 le marché Euronext Growth d'Euronext Dublin (MSTY.IE).

À propos de la lombalgie chronique invalidante

L'une des causes de la lombalgie chronique invalidante est une perturbation de la fonction musculaire des stabilisateurs de la colonne lombaire, muscles contrôlés par le système nerveux. ReActiv8 est conçu pour stimuler électriquement les nerfs responsables de la contraction de ces muscles pour améliorer la stabilité dynamique de la colonne lombaire, ce qui permet de guérir 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.

Déclarations prospectives

Le présent communiqué contient des déclarations à caractère prospectif ou susceptibles d'être considérées comme telles. Ces déclarations prospectives se reconnaissent à l'emploi d'une terminologie à caractère prospectif, avec des verbes comme «prévoir», «croire», «estimer», «tabler sur», «avoir l'intention de», «pouvoir», «projeter de», «devoir», «envisager», du futur ou du conditionnel, ou d'expressions semblables ou dérivées, à la forme affirmative ou négative, ou en ce qu'elles ont trait à des stratégies, projets, objectifs, buts, événements futurs ou intentions. Ces déclarations prospectives incluent tout ce qui n'est pas un fait historique. Présentes à différents endroits du communiqué, elles peuvent concerner, sans caractère limitatif, les intentions, croyances ou anticipations actuelles de la Société concernant notamment l'examen par la FDA de la demande de PMA de la Société pour ReActiv8, les données cliniques relatives à ReActiv8, la probabilité d'approbation par la FDA de la commercialisation de ReActiv8 aux États-Unis, la visibilité financière dont la Société estime qu'elle bénéficie, ainsi que le résultat des opérations de la Société, sa situation financière, ses perspectives, ses stratégies de financement, ses anticipations à propos de la conception et du développement des produits, des dépôts auprès des autorités et approbations d'ordre réglementaire, des arrangements de remboursement, du coût des ventes et de l'implantation sur les marchés, et autres performances commerciales.

Les déclarations prospectives sont empreintes par nature de risques et d'incertitudes, car elles ont trait à des événements et circonstances à venir. Elles ne constituent pas des garanties de la performance future et les résultats réels des opérations de la Société et l'évolution de son principal produit, les marchés et le secteur d'activité de la Société peuvent différer considérablement de ceux décrits ou suggérés par les déclarations prospectives contenues dans le présent communiqué. En outre, quand bien même les résultats des opérations de la Société, sa situation financière et sa croissance, et l'évolution de son principal produit et des marchés et du secteur d'activité de la Société seraient conformes aux déclarations prospectives contenues dans le présent communiqué, ces résultats ou évolutions pourraient ne pas être indicatifs des résultats ou évolutions ultérieurs. Plusieurs facteurs pourraient engendrer des divergences considérables entre les résultats et évolutions de la Société et ceux énoncés ou impliqués par ces déclarations prospectives, y compris, sans caractère limitatif, les résultats complets de l'essai clinique ReActiv8-B entrepris par la Société, l'issue des démarches de la Société auprès de la FDA en vue de la demande de PMA pour ReActiv8, le succès du lancement et de la commercialisation de ReActiv8, la conjoncture économique et le climat des affaires, la conjoncture du marché mondial des dispositifs médicaux, les tendances du secteur, la concurrence, l'évolution du droit ou de la réglementation, l'évolution des régimes fiscaux, la disponibilité et le coût des capitaux, le temps nécessaire pour démarrer ou terminer les essais cliniques, le temps et les démarches nécessaires à l'obtention des autorisations prévues par la réglementation, les fluctuations de parités monétaires, l'évolution de la stratégie d'entreprise, les incertitudes politiques et économiques. Les déclarations prospectives contenues dans le présent communiqué ne valent qu'à la date du présent 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 2019

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 FDA’s review of the Company’s PMA application for ReActiv8, the clinical data relating to ReActiv8, the potential for the FDA to approve ReActiv8 for marketing in the United States, the Company’s expected cash runway and the Company’s results of operations, financial position, prospects, financing strategies, expectations for product design and development, regulatory applications and approvals, reimbursement arrangements, costs of sales and market penetration and other commercial performance.

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, the development of its main product, and 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, 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 final outcome of the Company’s ReActiv8-B clinical study, the outcome of the Company’s interactions with the FDA on a PMA application for ReActiv8, the Company’s cash position, the successful launch and commercialization of ReActiv8, 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 Dan Sachs MD, Non-Executive Director
Secretary	Matthew Onaitis
Registered office	77 Sir John Rogerson’s Quay Block C, Grand Canal Docklands Dublin 2, 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 2019 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).

The Company is headquartered in Dublin, Ireland. It has subsidiaries operating in Ireland, the United States, Australia, the Netherlands and Germany, and its ordinary shares are admitted to trading on Euronext Paris (MSTY.PA) and Euronext Growth operated by Euronext Dublin (MSTY.IE). As at 30 June 2019, the Company together with 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 update

In August 2019, the Company submitted a pre-market approval (PMA) application to the United States Food & Drug Administration (FDA) for ReActiv8. Assuming acceptance of the submission by the FDA in October 2019, a decision on approval is expected in late 2020. The FDA's review of the PMA may result in the FDA not agreeing with the Company's interpretation of its clinical data, including whether statistical significance was achieved for one or more endpoints.

The pivotal clinical trial upon which the PMA submission was based is the ReActiv8-B clinical trial is an international, multi-center, prospective randomized sham controlled triple blinded trial with one-way crossover, conducted under an IDE from the FDA. Information about the Clinical Trial can be found at https://clinicaltrials.gov/ct2/show/study/NCT02577354.

A total of 204 subjects were implanted with ReActiv8 at leading clinical sites in the U.S., Europe and Australia and randomized 1:1 to therapy or control 14 days after implant. In the treatment group, the ReActiv8 pulse generator was programmed to deliver electrical stimulation expected to elicit episodic contractions of the multifidus muscle. In the control group, the ReActiv8 device was programmed only to provide a low level of electrical stimulation. Following assessment of the primary endpoint at 120 days, subjects in the control group crossed-over to receive levels of electrical stimulation similar to those in the treatment group.

The subjects in the study had an average age of 47, and an average duration of chronic low back pain of 14 years. This patient population had tried many other treatment alternatives, including physical therapy and drugs, with limited success, and 79% of the subjects were on pain medication at baseline.

The primary efficacy endpoint of the study was a comparison of responder rates between the treatment and control groups as measured on the visual analog scale (VAS) of pain, consisting a 0-10 scale with 0 being no pain and 10 being the worst imaginable pain. Responders are defined as having a 30% or greater improvement on this measure between baseline and 120 days after baseline, without any increase in pain medication and/or muscle relaxants taken in the two weeks prior to the primary endpoint assessment visit. The following table shows the result on the primary efficacy endpoint:

Primary Efficacy Endpoint	**Treatment N=102**	**Control N=102**	**Difference p-value**
Responder (30% Reduction in Low Back Pain VAS and no Increase in Pain Medications)	57.1%	46.6%	10.4% p=0.138

The same data as above, presented in a cumulative proportion of responders analysis that was pre-specified in the investigational plan, demonstrated a statistically significant difference ($p<0.05$) between the treatment and control groups, with the treatment group showing a higher proportion of responders across all threshold levels. This analysis, which is a comparison of ranks, inherently preserves information over a dichotomized endpoint, thereby improving statistical power.

In addition, the analysis of difference in mean low back pain VAS reduction between the treatment group and the control group was statistically significant ($p<0.05$) at the 120-day visit.

The investigational plan for the study also includes a pre-specified analysis, assessing the impact of medication and/or muscle relaxant increases to treat acute, unrelated pain conditions on the primary endpoint. Such patients, as a result of increasing pain medication and/or muscle relaxants, are deemed non-responders under the study protocol.

The specific implementing methods of this supplementary analysis were defined by the independent statistician advisors prior to the unblinding of the data. In consultation with its advisors, the Company determined that a valid way to handle the subjects with pain medication increases for reasons unrelated to low back pain would be to analyze the endpoint with these subjects removed, as pain medication use for reasons unrelated to low back pain was an exclusion criterion in the study. By doing so, inference is limited to the population of subjects taking pain medication only for reasons related to low back pain, as intended by the patient selection criteria in the trial protocol.

Six subjects had increases in pain medications for reasons other than low back pain. The following table presents the results of the primary efficacy endpoint in the subjects not requiring an increase in pain medications for reasons other than for low back pain, showing a clinically-meaningful and statistically-significant difference:

Primary Efficacy Endpoint	**Treatment N=96**	**Control N=102**	**Difference p-value**
Responder (30% Reduction in Low Back Pain VAS and no Increase in Pain Medications)	60.6%	46.7%	14.0% p=0.048

Numerous secondary endpoints and supporting analyses were collected to assess improvements in the treatment group as compared to the control group at 120 days, including reduction from baseline in pain as measured by both mean reduction in VAS and percent pain relief (PPR), change from baseline in disability measured by the Oswestry Disability Index (ODI), change from baseline in quality of life measured by the European Quality of Life Score on Five Dimensions (EQ-5D), subject global impression of change (SGIC), clinician global impression of change (CGI), patient treatment satisfaction as measured by the treatment satisfaction questionnaire (TSQ) and pain resolution (VAS 2.5 cm). As shown in the following table, when evaluating the therapy across multiple dimensions of subject outcomes, the treatment effect is significant in seven of the eight secondary endpoints/supporting analyses: mean reduction in VAS, PPR, ODI, EQ-5D, SGIC, treatment satisfaction and CGI:

	Treatment N=102		**Control N=102**		**Difference**
Endpoint	**N**	**Mean ± SD (Min, Max) or N (%)**	**N**	**Mean ± SD (Min, Max) or N (%)**	**p-value**
Change in Low back pain VAS	100	-3.3 ± 2.7 (-8.5, 3.0)	101	-2.4 ± 2.9 (-8.8, 3.5)	0.9 p = 0.032
Percent Pain Relief	100	52 ± 32 (0, 100)	101	35 ± 36 (0, 100)	17 p 0.001
Change in ODI	100	-17.5 ± 15.1 (-58.0, 20.0)	101	-12.2 ± 14.6 (-48.0, 32.0)	5.4 p = 0.011
Change in EQ-5D	100	0.186 ± 0.199 (-0.365, 0.782)	100	0.115 ± 0.178 (-0.640, 0.665)	0.071 p = 0.009
Subject Global Impression of Change					
Much better	100	32 (32%)	101	18 (18%)	
Better	100	22 (22%)	101	16 (16%)	
A little better	100	25 (25%)	101	29 (29%)	NA p = 0.003
No change	100	10 (10%)	101	24 (24%)	
A little worse	100	6 (6%)	101	5 (5%)	
Worse	100	4 (4%)	101	6 (6%)	
Much worse	100	1 (1%)	101	3 (3%)	
Satisfied with Treatment					
Definitely Yes	100	61 (61%)	101	40 (40%)	NA
Maybe	100	29 (29%)	101	37 (37%)	p 0.001
Definitely Not	100	10 (10%)	101	24 (24%)	
Clinician Global Impression					
Much Better	100	57 (57%)	100	22 (22%)	
Slightly Better	100	26 (26%)	100	29 (29%)	NA
About the Same	100	16 (16%)	100	42 (42%)	p 0.001
Slightly Worse	100	1 (1%)	100	5 (5%)	
Much Worse	100	0 (0%)	100	2 (2%)	
Remitters (VAS 2.5)	100	34 (34%)	101	28 (28%)	6.3% p = 0.335

At the 120-day visit, subjects in the control group were allowed to cross-over to receive stimulation at a therapeutic level. All control subjects elected to cross-over at this timepoint. At the time of filing of the PMA, 160 subjects had completed the 1-year assessment visit, consisting of 80 in each group. In this population, all efficacy outcomes for the treatment group and for the control group post crossover progressively improved through the 1-year assessment visit, consistent with the rehabilitative nature of the therapy (8 months of therapy for the crossover group). These results are subject to change as additional subjects complete the 1-year assessment visit.

Outcomes at 1 year (8 months of therapy for the crossover group):

- VAS Responders:
  - 69% in the treatment group
  - 63% in the crossover group
- Change in VAS:

    - -4.4 in the treatment group
    - -4.4 in the crossover group
- Average Percent Pain Relief:
    - 67% in the treatment group
    - 66% in the crossover group

- Average ODI Change:
    - 21-point reduction in the treatment group
    - 20-point reduction in the crossover group
- Average EQ-5D Change:
    - 0.218-point increase in the treatment group
    - 0.183-point increase in the crossover group
- Average SGIC:
    - 76% Better or Much Better in the treatment group
    - 72% Better or Much Better in the crossover group
- Average Treatment Satisfaction:
    - 82% Definitely Satisfied in the treatment group
    - 76% Definitely Satisfied in the crossover group
- Average CGI:
    - 78% Much Better in the treatment group
    - 71% Much Better in the crossover group

Although the study was not designed to reduce medications after the 120-day visit, subjects were allowed to change medications after that timepoint. As the following table shows, of the 61 patients (treatment and crossover groups combined) who were on at least one opioid-containing medication at baseline and had a 1-year visit, 28% had discontinued use of opioids, and an additional 21% had decreased opioid use, for an overall rate of 49% of patients who decreased or discontinued opioids by the 1-year visit.

Medication Change Status	Opioid % (n/N)
Discontinued or Decreased	49% (30/61)
No Change	44% (27/61)
Increased or Added	7% (4/61)

Notably, patients who decreased or discontinued opioids had similar efficacy results as the overall population. In addition, 97% of those who were not on an opioid at baseline and had a 1-year visit remained off opioids.

The incidence and type of adverse events (AEs), including serious AEs, compares favorably to that of spinal cord stimulator devices, with no unanticipated AEs related to the device, procedure or stimulation.

Funding – On 29 July 2019, we announced the completion of a €16.9 million financing (approximately $18.9 million). The financing transactions consist of the issuance of 4,649,775 new ordinary shares at a purchase price of €3.00 per New Share and the drawdown of €3.0 million (approximately $3.34 million) in additional debt from the Company's existing lender, IPF Partners. The funds are being used to advance the PMA review process with the FDA and continue the commercial validation effort in Germany and other select European markets.

On 18 April 2019, the Company and its subsidiary, Mainstay Medical Limited, entered into an amendment to its agreement with IPF Partners relating to their existing debt facility. Pursuant to the amendment:

- The repayment schedule for the three existing tranches drawn under the debt facility was amended such that no principal or interest will be repaid until 2021, with the principal and accrued interest to be amortized over the period from January 1, 2021 through September 30, 2023.
- A new tranche of €3.0 million (approximately $3.34 million) was made available to the Company, conditioned upon the Company raising at least $10 million in gross proceeds from one or more offerings of equity prior to 30 June 2019, which date was amended to 31 July 2019. The repayment schedule for the new tranche will be the same as the amended repayment schedule for the three existing tranches.
- The interest rate for all tranches is 8% per annum.
- The 5% repayment fee applicable to each existing tranche was eliminated.
- All principal and accrued interest from all tranches will automatically convert into ordinary shares of the Company at a price per share of €8 upon the earlier of (a) FDA approval of the Company's PMA application for ReActiv8, (b) the date by which at least 900,000 ordinary shares of the Company are publicly sold on-market by non-affiliates of the Company since 18 April 2019 at a price per share of at least €8, or (c) IPF

Partners' election to undertake such conversion, in each case unless the Company elects to satisfy such obligation in whole or in part in cash.

- The minimum cash covenant was amended so that the Company is required to hold cash at least equal to its projected cash expenditures for operations and debt repayment for the next three months, and the covenant relating to the achievement of commercial milestones was eliminated.
- The Company issued to IPF Partners warrants to purchase 1.5 million of its ordinary shares at a price per share of €6 at any time prior to the 6th anniversary of the amendment date. The Company has issued further conditional warrants to IPF Partners that will become exercisable only to the extent the Company elects to repay the debt in cash rather than issue ordinary shares when a conversion of the debt is triggered. As such, the conditional warrants are intended to ensure that, notwithstanding any such election to repay in cash, IPF Partners retains the right to subscribe for ordinary shares of the Company on the terms and conditions that would otherwise have applied.

Commercialization – In Germany, the Company's initial European market, commercial repositioning efforts in order to better focus efforts on key physician targets were undertaken throughout 2018. The Company continues to focus on commercial validation by working with key physician partners who identify appropriate ReActiv8 patients in their centres in order to validate commercial adoption, refine patient selection strategies and follow ongoing patient progress.

Financial review

Income Statement – Revenue during the six-month period ending 30 June 2019 was $0.6 million ($0.4 million during the same period in 2018). Revenue was generated from sales of ReActiv8 systems to customers in Germany, Ireland and the UK.

Operating expenses related to on-going activities were $9.5 million during the half year ended 30 June 2019 (same period in 2018: $15.8 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 $1 million during the six-month period ended 30 June 2019 ($2 million during the same period in 2018). The decrease of $1 million is primarily driven by reduced payroll related costs following a reduction in headcount in 2019.

Clinical and regulatory expenses were $2.9 million during the six-month period ended 30 June 2019 ($7.2 million during the same period in 2018). The decrease of $4.3 million is primarily driven by decreased direct trial costs relating to activities for the ReActiv-8 B clinical trial, following the announcement in July 2018 of the completion of all implants.

Selling, general and administrative expenses were $5.6 million during the half year ended 30 June 2019 ($6.6 million during the half year ended 30 June 2018). The decrease of $1 million is primarily driven by the reduction in recruitment fees, travel and training costs, as well as certain marketing and market research costs.

Statement of financial position – Total assets of the Group at 30 June 2019 were $9.7 million (31 December 2018: $19.4 million). Cash on hand at 30 June 2019 was $5.8 million (31 December 2018: $15.5 million). Cash used in operating activities was $8.8 million during the period (30 June 2018: $14.8 million) and is reflective of our decreased operating expenses.

Since inception the Group has funded its operations primarily through the issuance of equity securities and debt funding. The Group intend to continue to explore funding strategies (e.g., equity, debt, partnering) to support its activities into the future.

Principal risks and uncertainties

The principal risks and uncertainties faced by the Group and/or its industry for the remaining six months of 2019 remain unchanged from the risks disclosed in the 2018 Annual Report, 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 cash outflows 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 which are dilutive to current investors, specifically favorable to new investors, or to restrictions significantly limiting our access to additional capital or other activities.
- 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.
- We operate in a highly regulated environment and regulatory approval is required before we can market or sell ReActiv8 in any market.
- To date, the only regulatory approval to the market ReActiv8 is our CE Mark relating to the European Economic Area, or EEA, and Switzerland. Seeking and obtaining regulatory approval for medical devices in the United States and elsewhere can be a long and uncertain process. The failure to achieve regulatory approval in the United States or in other key markets, the loss of our CE Mark, or strict or changing regulatory regimes, government policies and legislation in any of our target markets may delay, prohibit or reduce potential sales.
- Failure to comply with debt covenants or failure to make repayments on our debt facility could have a material adverse effect.
- 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 Annual Report, on pages 24 to 56, and should be considered carefully by shareholders and prospective investors.

Outlook and future developments

Our objectives for the remainder of 2019 and into 2020 are to advance the PMA review process with the FDA following filing in August 2019; and to continue the commercial validation effort in Germany and other select European markets by working with key physician partners who identify appropriate ReActiv8 patients in their centers in order to validate commercial adoption, refine patient selection strategies and follow ongoing patient progress.

Related party transactions

Refer to note 11.

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 $5.8 million as at 30 June 2019 ($15.5 million as at 31 December 2018).
- The Group had operating cash out-flows of $8.8 million for the 6 months ended 30 June 2019 (year ended 31 December 2018: $27.3 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 required in research and development, clinical and commercial activities and expects to continue to seek funding from investors or other finance providers as required.
- The Group has an accumulated retained loss reserve of $168.2 million and a reorganization reserve of $44.6 million as at 30 June 2019 (31 December 2018: $157 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 2019, debt with an outstanding principal of $9.45 million.
- On 29 July 2019, we announced the completion of a €16.9 million financing (approximately $18.9 million). The financing transactions consist of the issuance of 4,649,775 new ordinary shares at a purchase price of €3.00 per share and the drawdown of €3.0 million (approximately $3.34 million) in additional debt from the Company's existing lender.

The Directors have considered the conditions noted above and other factors, and believe 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 and are satisfied 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 12 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 2019,

Oern Stuge MD Jason Hannon

Chairman CEO

Mainstay Medical International plc
Condensed consolidated statement of profit or loss and other comprehensive income
for the half year ended 30 June 2019

($'000)	Notes	**Half year ended 30 June 2019** Unaudited	**Half year ended 30 June 2018** Unaudited
Revenue	4	552	358
Cost of sales		(316)	(170)
Gross profit		236	188
Operating expenses		(9,559)	(15,849)
Operating loss		(9,323)	(15,661)
Finance expense (net)		(1,760)	(1,018)
Net finance expense		(1,760)	(1,018)
Loss before income taxes		**(11,083)**	**(16,679)**
Income taxes	6	(63)	156
Loss for the half year		**(11,146)**	**(16,523)**

Net loss attributable to equity holders		**(11,146)**	**(16,523)**
Basic and diluted loss per share (in $)	5	(1.27)	(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		(20)	56
Total comprehensive loss for the half year		**(11,166)**	**(16,467)**
Total comprehensive loss attributable to equity holders		**(11,166)**	**(16,467)**

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 2019

($'000)	Notes	**30 June 2019** Unaudited	**31 December 2018** Audited
Non-current assets			
Property, plant and equipment		191	235
Right of use asset		414	-
Total non-current assets		**605**	**235**
Current assets			
Inventory		2,251	2,575
Trade and other receivables		871	813
Income tax receivable		212	213
Cash and cash equivalents		5,806	15,545
Total current assets		9,140	19,146
Total assets		**9,745**	**19,381**
Equity			
Share capital	8	67	67
Share premium		143,898	143,897
Other reserves		4,606	4,626
Share based payment reserve		15,797	11,716
Retained loss		(168,219)	(157,022)
Surplus/ (deficit) on shareholders' equity		**(3,851)**	**3,284**
Non-current liabilities			
Loans and borrowings	7	9,684	8,791
Derivative financial instruments	7	1,098	-
Total non-current liabilities		**10,782**	**8,791**
Current liabilities			
Loans and borrowings	7	215	3,158
Income tax payable		64	18
Deferred revenue		62	-

Trade and other payables	2,473	4,130
Total current liabilities	**2,814**	**7,306**
Total liabilities	**13,596**	**16,097**
Total equity and liabilities	**9,745**	**19,381**

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 2019

($'000)	Share capital	Share premium	Other Reserves	Share based payment reserve	Retained loss	Total equity
Balance as at 1 January 2018	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 on exercise of share options or warrants	3	37,483	-	-	(1,440)	36,046
Balance at 30 June 2018 (Unaudited)	**67**	**143,897**	**4,649**	**9,465**	**(142,468)**	**15,610**
Loss for the half year	-	-	-	-	*(14,554)*	*(14,554)*
Other comprehensive income	-	-	(23)	-	-	*(23)*
Total comprehensive loss for the half year	**-**	**-**	**(23)**	**-**	**(14,554)**	**(14,577)**
Transactions with owners of the Company:						
Share based payments	-	-	-	2,251	-	2,251
Issue of shares on exercise of share options or warrants	-	-	-	-	-	-
Balance at 31 December 2018	**67**	**143,897**	**4,626**	**11,716**	**(157,022)**	**3,284**
Opening adjustment on initial application of IFRS 16	-	-	-	-	(51)	(51)
Adjusted balance at 1 January 2019	*67*	*143,897*	*4,626*	*11,716*	*(157,073)*	*3,233*
Loss for the half year	-	-	-	-	*(11,146)*	*(11,146)*
Other comprehensive income for the half year	-	-	*(20)*	-	-	*(20)*
Total comprehensive loss for the half year	**-**	**-**	**(20)**	**-**	**(11,146)**	**(11,166)**
Transactions with owners of the Company:						
Share based payments	-	-	-	4,081	-	4,081
Issue of shares	-	1	-	-	-	1
Balance at 30 June 2019 (Unaudited)	**67**	**143,898**	**4,606**	**15,797**	**(168,219)**	**(3,851)**

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 2019

($'000)	Notes	Half year ended 30 June 2019 Unaudited	Half year ended 30 June 2018 Unaudited
Cash flow from operating activities			
Net loss for the half year		(11,146)	(16,523)
Add/(less) non-cash items			
Depreciation		174	50
Finance expense		1,760	1,018
Share-based compensation	10	2,102	1,852
Income taxes	6	63	(156)
Add/(less) changes in working capital			
Trade and other receivables		(58)	(306)
Inventory		324	(80)
Trade and other payables		(1,793)	76
Taxes paid		(16)	(112)
Interest paid		(245)	(603)
Net cash used in operations		**(8,835)**	**(14,784)**
Cash flow from investing activities			
Acquisition of property and equipment		(6)	(26)
Net cash used in investing activities		**(6)**	**(26)**
Cash flow from financing activities			
Gross proceeds from issue of shares		-	37,486
Transaction costs on issue of shares		-	(1,440)
Repayment of borrowings	7	(750)	(1,500)
Payment of lease liabilities	7	(148)	-
Net cash (outflow)/inflow from financing activities		**(898)**	**34,546**
Net (decrease)/increase in cash and cash equivalents		**(9,739)**	**19,736**
Cash and cash equivalents at beginning of period		15,545	9,975
Cash and cash equivalents at 30 June 2019		**5,806**	**29,711**

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 2019 and 30 June 2018 comprise the results of the Company and of its subsidiaries (together the Group).

At 30 June 2019, 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 Euronext Growth operated by Euronext Dublin.

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).

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 2018.

The comparative information provided in the condensed consolidated Financial Statements relating to the periods ended 30 June 2018 and 31 December 2018 does not comprise the statutory financial statements of the Group. Those statutory financial statements for the year ended 31 December 2018 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 2018.

The condensed consolidated Financial Statements were authorized for issue by the Board of Directors, on 19 September 2019.

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 $5.8 million as at 30 June 2019 ($15.5 million as at 31 December 2018).
- The Group had operating cash out-flows of $8.8 million for the 6 months ended 30 June 2019 (year ended 31 December 2018: $27.3 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 required in research and development, clinical and commercial activities and expects to continue to seek funding from investors or other finance providers as required.
- The Group has an accumulated retained loss reserve of $168.2 million and a reorganization reserve of $44.6 million as at 30 June 2019 (31 December 2018: $157 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 2019, debt with an outstanding principal of $9.45 million.
- On 29 July 2019, Mainstay announced the completion of a €16.9 million financing (approximately $18.9 million). The financing transactions consist of the issuance of 4,649,775 new ordinary shares at a purchase price of €3.00 per share and the drawdown of €3.0 million (approximately $3.34 million) in additional debt from the Company's existing lender.

The Directors have considered the conditions noted above and other factors, and believe 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 and are satisfied 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 2018, which were prepared in accordance with IFRS and are available on the Company's website (www.mainstay-medical.com). These accounting policies have been applied consistently for all periods presented.

The Group has initially adopted IFRS 16 Leases from 1 January 2019. A number of other new standards are effective from 1 January 2019, but they do not have a material effect on the Group's financial statements

a) Leases

The Group has initially adopted IFRS 16 Leases from 1 January 2019. IFRS 16 introduced a single, on-balance sheet accounting model for lessees. As a result, the Group, as a lessee, has recognized right-of-use assets representing its rights to use the underlying assets and lease liabilities representing its obligation to make lease payments.

The Group has applied IFRS 16 using the modified retrospective approach, under which the cumulative effect of initial application is recognized in retained earnings at 1 January 2019. Accordingly, the comparative information presented for 2018 has not been restated. The details of the changes in accounting policies are disclosed below.

Definition of a Lease

As a lessee, the Group previously classified leases as operating or finance leases based on its assessment of whether the lease transferred substantially all of the risks and rewards of ownership. Under IFRS 16, the Group recognizes right-of-use assets and lease liabilities for leases. The Group has elected not to recognize right-of-use assets and lease liabilities for some leases of low-value assets and has applied the exemption not to recognize right-of-use assets and liabilities for leases with less than 12 months of lease term.

The Group recognizes a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, and subsequently at cost less any accumulated depreciation and impairment losses, and adjusted for certain remeasurements of the lease liability.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Generally, the Group uses its incremental borrowing rate as the discount rate.

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 2019**	31 December 2018
Ireland	227	101
Germany	2	2
United States	376	132
Total non-current assets	**605**	**235**

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

	Half year ended	
($'000)	**30 June 2019**	Half year ended 30 June 2018

Ireland	39	90
Germany	387	250
Other Europe	126	18
Total revenue by country	**552**	**358**

4. Revenue

($'000)	**Half year ended 30 June 2019**	Half year ended 30 June 2018
Revenue arising from the sale of goods	552	358
	552	**358**

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 2019	Half year ended 30 June 2018
Weighted average number of ordinary shares in issue	8,771,472	8,235,367
Loss per share		
	1.27	**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

On 24 August 2015, MML entered into the IPF debt facility for up to $15.0 million. The facility was drawn down in three tranches. As at 31 December 2018 and 30 June 2019, the principal outstanding was $10.2 million and $9.45 million respectively. In April 2019 a new tranche of €3.0 million (approximately $3.34 million) was made available to Mainstay, conditional upon Mainstay raising at least $10 million in gross proceeds from one or more offerings of equity prior to June 30, 2019. This deadline was extended to July 31, 2019 by agreement with IPF. On 29 July Mainstay completed an equity offering, raising gross proceeds of €13.9 million, and announced the drawdown of €3.0 million in additional debt from the new tranche of the existing debt facility.

In April 2019, the Company and IPF amended the terms of their existing agreements such that all the principal and interest payments are deferred until 2021, the loan term was extended to 2023 and the interest rate on all tranches was changed to 8%. The loan is also convertible in certain circumstances to ordinary shares at a price of €8 per share.

The Company considers the amendment to be a significant modification of the terms of the debt. Accordingly the previous loans and associated accruals were de-recognized and the new loan was recognized at fair value, resulting in a loss recognized in the period of $1.1 million. The Company accounts for the conversion option as a derivative financial instrument carried at fair value through the statement of profit or loss.

The fair value of the conversion option is determined using a Black-Scholes model whose principal assumptions at 30 June 2019 were:

Stock price ($)	4.14
Exercise price (€)	8
Volatility	58.95%
Expected term (years)	4

In connection with the amendment to the debt facility, the Company also granted 1.5 million warrants over ordinary shares to IPF with an exercise price of €6. The fair value of the warrants on the grant date of $1.9 million, which was also calculated using a Black-Scholes model, was recognized in finance costs as part of the net cost of modification of the debt.

($'000)	**30 June 2019**	31 December 2018
Loans and borrowings - current		
Term loan	-	3,000
Deferred finance cost	-	(90)
Accrued interest	-	248
Lease liabilities	215	-
Total current loans and borrowings	**215**	**3,158**
Loans and borrowings – non-current		
Term loan	9,247	7,200
Deferred finance cost	-	(103)
Accrued interest	190	1,694
Lease liabilities	247	-
Total non-current loans and borrowings	**9,684**	**8,791**
Total loans and borrowings	**9,899**	**11,949**

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 2019	31 December 2018
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**

	2019	**2018**
Issued, called up and fully paid	**$**	**$**
8,771,729 (31 December 2018: 8,770,229) ordinary shares of €0.001 each	11,242	11,240
40,000 deferred shares of €1.00 each	55,268	55,268
	66,510	**66,508**
In $'000	**67**	**67**

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 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, other than in connection with the revised terms negotiated with IPF as disclosed in note 7.

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 and other receivables

Trade receivables comprise amounts due from customers, all of which were current at 30 June 2019 and 31 December 2018. The Group's credit risk management policy and process in relation to trade receivables involves carrying out credit checks where appropriate, and by active credit management. The utilization of credit limits is regularly monitored. In addition, it involves periodically assessing the financial reliability of customers, considering their financial position, past experience and other factors.

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 2019 is immaterial. The carrying value of trade receivables of $0.2 million at 30 June 2019 ($0.1 million at 31 December 2018) represents the maximum exposure to credit risk.

Cash and cash equivalents

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 2019. 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 $5.8 million as at 30 June 2019.

Guarantees

The Company has guaranteed the payment of the liabilities and commitments of its subsidiaries in Ireland (as defined in section 357 of the Companies 2014 Act) for the years ended 31 December 2018 and 31 December 2017.

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 intends to continue 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 expenditures incurred in Euros 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.

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 2019, the principal outstanding on MML's loan from IPF was $9,450,000. The repayment schedule for the four existing tranches drawn under the debt facility is such that no principal or interest will be repaid until 2021, with the principal and accrued interest to be amortized over the period from 1 January 2021 through 30 September 2023. The interest rate for all tranches will be 8% per annum, with interest accruing but capitalized prior to January 1, 2021.

10. Share based payments

Share Options

The terms and conditions of the Group's share option plan are disclosed in the 2018 Annual Report. The charge of $2.1 million for the half year ended 30 June 2019 (30 June 2018: $1.9 million) is the grant date fair value of various share options and RSUs 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. 7,500 options were granted in the six months ended 30 June 2019 (30 June 2018: 279,878 options). The Company also recognized $1.9 million in the profit and loss related to the fair value of warrants granted to IPF as disclosed in Note 7. This amount has been recorded in finance expense as it related to the modification of the debt.

The Employee Incentive Plan was amended in January 2019 to allow for the issue of RSUs, being rights to receive Ordinary Shares at no cost to the relevant employee, director or consultant. The Company has granted 381,000 RSUs as at 30 June 2019.

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 2019 and 30 June 2018.

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 2019**	30 June 2018
Salaries	604	428
Non-executive directors' fees	130	135
Other remuneration	65	223
Payroll taxes	27	23
Share based payments	1,288	1,609
Pension	-	-
Total remuneration	**2,114**	**2,418**

13. Events subsequent to 30 June 2019

On 29 July 2019, we announced the completion of a €16.9 million financing (approximately $18.9 million). The financing transactions consist of the issuance of 4,649,775 new ordinary shares at a purchase price of €3.00 per share and the drawdown of €3.0 million (approximately $3.34 million) in additional debt from the Company's existing lender.

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