Mainstay Medical annonce ses résultats du premier semestre 2017

- *Avancée significative de l'essai clinique ReActiv8-B (achèvement du recrutement toujours prévu autour de la fin de l'exercice 2017)*
- *Début de la commercialisation de ReActiv8® actuellement en cours en Europe*
- *Trésorerie disponible de 24,5 millions de dollars au 30 juin 2017*

Dublin – Irlande, le 5 septembre 2017 – Mainstay Medical International plc (« **Mainstay** » ou la « **Société** », Euronext Paris : MSTY.PA et l'ESM de la Bourse irlandaise : MSTY.IE), une société de dispositifs médicaux dédiée à la commercialisation de ReActiv8®, un dispositif de neurostimulation implantable destiné à traiter la lombalgie chronique invalidante, annonce aujourd'hui la publication de son rapport semestriel clos au 30 juin 2017.

Peter Crosby, Directeur Général de Mainstay, a commenté : *« L'essai clinique ReActiv8-B constitue une étape clé vers la commercialisation aux États-Unis, notre marché cible le plus important. L'essai progresse bien et le rythme de recrutement des patients s'est accéléré suite à l'accroissement du nombre de sites actifs au cours de l'exercice 2017. D'après notre expérience, acquise à ce jour, nous estimons que le recrutement s'achèvera autour de la fin de l'exercice 2017 et que les résultats seront disponibles en 2018 ».*

En parallèle, nous avons initié la commercialisation de ReActiv8 en Europe. Dans le sillage de la vente et de la pose du premier implant, début 2017, nos premiers clients se familiarisent avec ReActiv8 et nous collaborons avec eux afin de faciliter l'intégration de ReActiv8 dans leurs soins quotidiens. Nous poursuivons le déploiement de notre stratégie consistant à cibler les principaux établissements prescripteurs en Allemagne, puis à mettre à profit l'expérience ainsi acquise et les données de l'essai ReActiv8-B, afin d'étendre la commercialisation à d'autres établissements et à d'autres pays ».

Faits marquants du premier semestre 2017 :

- L'essai clinique ReActiv8-B est un essai international multi-sites en triple aveugle, contrôlé, avec simulation aléatoire prospective, à permutation unique. Conduit avec une exemption de dispositif expérimental (*Investigational Device Exemption* - IDE), octroyé par les autorités américaines (*US Food and Drug Administration* - FDA), l'essai vise à recueillir des données pour étayer la demande d'approbation, préalable à la commercialisation (*pre-market approval* – PMA), auprès de la FDA, étape clé avant la distribution de ReActiv8® aux États-Unis. Des informations complémentaires à propos de l'essai peuvent être consultées à l'adresse suivante : https://clinicaltrials.gov/ct2/show/study/NCT02577354.

  En 2017, l'essai clinique ReActiv8-B s'est poursuivi pour atteindre plus de la moitié du nombre d'implantations requises.
- En février 2017, la première vente et pose de l'implant, réalisée à l'Hôpital catholique de Koblenz-Montabaur à Koblenz en Allemagne, ont été annoncées. La commercialisation se concentre dans

un premier temps sur l'Allemagne, où la Société a pour objectif de promouvoir l'adoption de ReActiv8® au sein d'un nombre défini de centres pluridisciplinaires très actifs, spécialisés dans la colonne vertébrale. À mesure que les premiers clients se familiarisent avec le traitement ReActiv8®, la Société apporte sa collaboration afin de les aider à intégrer ReActiv8® dans leurs soins quotidiens. Le dialogue avec d'autres établissements majeurs en Allemagne se poursuit et la formation des chirurgiens pour ces établissements est en cours. La stratégie consiste à cibler les principaux établissements prescripteurs en Allemagne, puis à mettre à profit l'expérience acquise et les données de l'essai ReActiv8-B pour étendre la commercialisation à d'autres établissements et à d'autres pays.

Plus récemment, en mai 2017, le début de la commercialisation en Irlande, le marché domestique de la Société, a été annoncée.

Principaux résultats financiers :

- Le chiffre d'affaires du premier semestre, clos le 30 juin 2017, s'établit à 0,25 million de dollars.
- Les charges d'exploitation s'élèvent à 12,3 millions de dollars, contre 8,0 millions de dollars au premier semestre 2016. Cette hausse reflète l'accélération des recrutements et des implantations dans le cadre de l'essai clinique ReActiv8-B, ainsi que les coûts liés à la commercialisation qui a démarré en 2017.
- La trésorerie disponible ressort à 24,5 millions de dollars au 30 juin 2017 et les flux de trésorerie liés aux activités d'exploitation ont représenté 11,4 millions de dollars sur le semestre.

— Fin du communiqué —

À propos de Mainstay
Mainstay est une société de dispositifs médicaux dédiée à la commercialisation d'un système de neurostimulation réparatrice implantable, ReActiv8®, pour les personnes souffrant de lombalgie chronique invalidante. La société est basée à Dublin, Irlande. Elle dispose d'activités basées en Irlande, aux États-Unis, en Australie et en Allemagne, et ses actions ordinaires sont admises à la négociation sur Euronext Paris (MSTY.PA) et sur l'ESM de l'Irish Stock Exchange (MSTY.IE).

À propos de l'Essai Clinique ReActiv8-B
L'Essai Clinique ReActiv-8 est un essai internationale, multicentrique, aléatoire en aveugle réglementé à segment unique effectué sous une exemption de dispositif expérimentale (IDE). L'Essai Clinique ReActive-8 est conçu pour générer des données pour un dossier d'autorisation d'avant commercialisation (PMAA) de ReActive-8 pour la FDA. Pour plus de détails, consulter le site https://clinicaltrials.gov/show/NCT02577354

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

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

Des informations complémentaires sont disponibles sur le site www.mainstay-medical.com
Attention – aux Etats-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 », « ambitionne », « a l'intention de », « planifie », « 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 événements 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 progrès 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 réglementaires 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 2017

Mainstay Medical International plc
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Forward looking statements

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

By their nature, forward looking statements involve risk and uncertainty because they relate to future events and circumstances. Forward looking statements are not guarantees of future performance and the actual results of the Company's operations, and the development of its main product, the markets and the industry in which the Company operates, may differ materially from those described in, or suggested by, the forward looking statements contained in this 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 annual 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, the global medical device market conditions, industry trends, competition, changes in law or regulation, changes in taxation regimes, the availability and cost of capital, the time required to commence and complete clinical trials, the time and process required to obtain regulatory approvals, currency fluctuations, changes in its business strategy, political and economic uncertainty. The forward-looking statements herein speak only at the date of this report.

Mainstay Medical International plc
Corporate and shareholder information

Directors	Oern Stuge MD, Independent Non-Executive Chairman Peter Crosby, Chief Executive Officer and Executive Director David Brabazon, Independent Non-Executive Director 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 Jones Day 2, rue Saint-Florentin 75001 Paris, France
Independent Auditor	KPMG Chartered Accountants 1 Stokes Place St Stephen's Green Dublin 2, Ireland
Principal Bankers	HSBC Bank of Ireland
ESM Adviser and Broker	J&E Davy Davy House 49 Dawson Street Dublin 2, Ireland
Registrar	Computershare Investor Services (Ireland) Limited Heron House Corrig Road Sandyford Industrial Estate Dublin 18, Ireland
Paying Agent (in France)	Caceis Corporate Trust 1/3, Place Valhubert 75013 Paris France

Mainstay Medical International plc
Interim Management Report

The Board of Directors 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 2017 of the Company and its subsidiaries (the Group or we).

Principal activities

Mainstay is a medical device company focused on bringing to market ReActiv8®, an implantable restorative neurostimulation system to treat disabling Chronic Low Back Pain (CLBP). ReActiv8 is designed to electrically stimulate the nerves responsible for contracting muscles which stabilize the lumbar spine. Activation of these muscles 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 clinically important, statistically significant and lasting improvement in pain, disability and quality of life in people with disabling CLBP and few other treatment options.

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

As at 30 June 2017, the Company together with its operating subsidiaries Mainstay Medical Limited, Mainstay Medical Distribution Limited, Mainstay Medical GmbH, MML US, Inc. and Mainstay Medical (Australia) Pty. Limited form the Mainstay Medical Group.

Business review

ReActiv8-B Clinical Trial – 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 statistical design of the Trial requires data from 128 subjects at the 120-day primary outcome assessment visit. Total subjects implanted will also include some enrolled and implanted as part of the surgical roll-in phase, in addition to subjects in the pivotal cohort.

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.

During the first half of 2017, we have continued to advance the Trial which commenced in September 2016. In August 2017, we announced that over half the required number of implants have been performed. The enrollment has been accelerating as the number of active sites increased during 2017.

The Trial is designed with an interim analysis of the primary efficacy end point (the Interim Analysis) for sample size re-estimation when primary outcome data are available from half the subjects in the pivotal cohort. The Interim Analysis will be performed by a third-party independent statistician under the direction of the Data Monitoring Committee (DMC), and the Interim Analysis, other than a DMC recommendation regarding the findings, will remain blinded to the Group, study subjects, investigators and Clinical Trial sites.

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 1A Evidence of efficacy of ReActiv8, which may be used to support applications for favorable reimbursement in the USA. Evidence from the Trial will be used to support market development activities worldwide.

Based on our experience to date, we anticipate that enrollment will complete around the end of 2017, with results available in 2018.

Commercialization – In February 2017, we announced the first sale and implant had been performed at the Catholic Hospital Koblenz-Montabaur in Koblenz, Germany. We are focusing commercialization of ReActiv8 initially on Germany, where we aim to drive adoption of ReActiv8 in a select number of high volume multi-disciplinary spine care centers. As our pioneering customers are gaining more experience with the ReActiv8 therapy we are working with them towards the goal of making ReActiv8 part of their

clinical practice. We are progressing discussions with other key centers in Germany, and implanter training for these centers is underway. Our strategy is to work with key reference centers in Germany, and then build on that experience and data from the ReActiv8-B Trial to expand commercialization to additional centers and other countries.

More recently, in May 2017, we announced that commercialization has begun in Ireland, Mainstay's home market.

On 12 January 2017, we announced we had applied for ReActiv8 to be admitted to the Australian Register of Therapeutic Goods (ARTG) to allow for commercialization in Australia. The ARTG application included the results of the ReActiv8-A Clinical Trial. The Therapeutic Goods Agency will review the application and may request additional data during the review process.

ReActiv8-A Clinical Trial/ PMCF Study – The ReActiv8-A Clinical Trial (the ReActiv8-A Trial) is an international, multi-center, prospective, single arm clinical trial of ReActiv8. We announced the results of the first 47 subjects implanted in the ReActiv8-A Trial, of whom, 46 reached the 90-day end point in August 2015. On 20 September 2016, we announced the one-year results from the ReActiv8-A Trial, which showed long term sustained performance. As at 30 June 2017, 6 additional subjects had been implanted in the ReActiv8-A Trial.

The results from 53 subjects at one year show clinically important, statistically significant and lasting improvement in pain, disability and quality of life in a population of people with few treatment options, with 94% of subjects showing a clinically important improvement in at least one of the three major endpoints at 90 days, which was substantially maintained through one year. The one year results of these 53 subjects implanted, were presented at the 13th World Congress of the International Neuromodulation Society in Edinburgh at the end of May 2017. The presentation was judged as one of the "best abstracts" presented in the plenary session.

Following CE Mark 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 Post Market Clinical Follow-up (PMCF) Study is a continuation of the ReActiv8-A Trial (but with CE Marked ReActiv8). 40 additional subjects are planned to be implanted as part of the continuation of the ReActiv8-A PMCF Study.

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

Financial review

Income Statement – The first sales of ReActiv8 were recorded in the six-month period ending 30 June 2017. Our customers are hospitals and are served through our direct sales force. Revenue during the six-month period ending 30 June 2017 was $0.25 million (nil during the same period in 2016). Revenue was generated from sales of ReActiv8 systems to customers in Germany and in Ireland.

Operating expenses related to on-going activities were $12.3 million during the half year ended 30 June 2017 (30 June 2016: $8.0 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 increased by $0.3 million to $2 million during the six-month period ended 30 June 2017. The increase is primarily due to additional team members engaged in research, quality and regulatory activities required for our ReActiv8-B Clinical Trial, and maintenance of our quality system as we expand commercial activities.

Clinical and regulatory expenses were $5.2 million during the six-month period ended 30 June 2017, and increased by $2.5 million from $2.7 million during the same period in 2016. The increase is primarily driven by the ramp up of enrollments in the ReActiv8-B Trial. As detailed above over half the required subjects have been implanted in this trial by physicians in centers in Australia, Europe and the US. The costs incurred include (without limitation) the cost of the device, direct hospital costs (for example operating theatre fees and costs related to the physicians and nurses time), clinical and legal consulting, training costs, clinical database fees, clinical monitoring fees and the payroll costs of our direct employees.

Our selling, general and administrative expenses were $5.1 million during the six-month period ended 30 June 2017, and $3.5 million during the same period in 2016. The increase of $1.6 million is primarily driven by commercialization and the related increase in our direct sales force during 2016 and 2017 (impacting recruitment fees, payroll, travel and training costs), as well as marketing, reimbursement consulting and market research costs.

Statement of financial position – Total assets of the Group at 30 June 2017 end were $27.9 million (31 December 2016: $39 million). Cash on hand at 30 June 2017 was $24.5 million (31 December 2016: $36.7 million). Cash used in operating activities was $11.4 million during the period (30 June 2016: $7.5 million), and is reflective of our increased operating expenses (excluding non-cash expenses, for example share based payments, and adjusted for outstanding payables at period end), and a build-up of inventory held for commercialization.

During the period ended 30 June 2017, we commenced repayment of our debt facility. As at 31 December 2016, the Group had drawn the full facility of $15 million, and during the period we made the first repayment of $0.75 million.

Principal risks and uncertainties

The principal risks and uncertainties faced by the Group and/or its industry for the remaining six months of 2017 remain substantially unchanged from the risks disclosed in the 2016 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 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 favorable to new investors, or to restrictions significantly limiting our access to additional capital
- Our future financial performance is substantially dependent on the commercial success of ReActiv8, our only product which at the date of this Half Year report is launched commercially in Germany and Ireland only
- 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
- The availability of coverage and adequate reimbursement for our product by government and private payers will be critical to market adoption for the existing and future products

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 2016 Annual Report, on pages 23 to 41, and should be considered carefully by Shareholders and prospective investors.

Outlook and future developments

We are pleased with the progress of the ReActiv8-B Trial. The Trial is advancing well, and in August 2017 we announced that over half the required number of implants in the Trial have been performed. We anticipate that enrollment will complete around the end of 2017, with results available in 2018. If successful, the ReActiv8-B Clinical Trial will yield level 1A Evidence of efficacy, which may be used to support applications for favorable reimbursement in the USA. Evidence from the ReActiv8-B Trial will also be used to support market development activities worldwide.

Our initial commercialization of ReActiv8 in Europe is underway. Our strategy is to work with key reference centers in Germany, 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 13.

Going concern

The Directors note the following relevant matters:

- The Group has an accumulated retained losses reserve of $108 million and a reorganization reserve of $44.6 million as at 30 June 2017 (31 December 2016: $94.7 million and $44.6 million respectively).
- The Group had operating cash out-flows of $11.4 million for the 6 months ended 30 June 2017 (year ended 31 December 2016: $16.7 million).
- The Group has funded operations to date through the proceeds of equity funding of approximately $85 million and as at 30 June 2017, debt with an outstanding principal of $14.25 million. The Group will require additional funding.
- The group expects to incur losses due to the ongoing investment in research and development, clinical and commercial activities.
- The Group has cash of $24.5 million as at 30 June 2017 ($36.7 million as at 31 December 2016).

The Directors have considered the conditions noted above and other factors, the potential of the Group to raise additional funding, and the potential to manage expenditure 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 14 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 04 September 2017,

Oern Stuge MD
Chairman

Peter Crosby
CEO

Mainstay Medical International plc
Condensed consolidated statement of profit or loss and other comprehensive income
for the half year ended 30 June 2017

($'000)	Notes	Half year ended 30 June 2017 Unaudited	Half year ended 30 June 2016 Audited
Revenue	4	250	-
Cost of sales		(136)	-
Gross profit		114	-
Operating expenses		(12,282)	(7,987)
Operating loss		(12,168)	(7,987)
Finance income		10	-
Finance expense		(986)	(784)
Net finance expense		(976)	(784)
Loss before income taxes		**(13,144)**	**(8,771)**
Income taxes	6	(131)	(71)
Loss for the half year		**(13,275)**	**(8,842)**
Net loss attributable to equity holders		**(13,275)**	**(8,842)**
Other Comprehensive Income			
Items that may be reclassified subsequently to the statement of profit or loss:			
Foreign currency translation differences of foreign operations		(50)	-
Total comprehensive loss for the half year		**(13,325)**	**(8,842)**
Total comprehensive loss attributable to equity holders		**(13,325)**	**(8,842)**
Basic and diluted loss per share (in $)	5	(2.01)	(1.98)

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

Mainstay Medical International plc
Condensed consolidated statement of financial position
at 30 June 2017

($'000)	Notes	30 June 2017	31 December 2016
		Unaudited	Audited
Non-current assets			
Property, plant and equipment		238	255
Current assets			
Inventory		2,070	1,123
Trade and other receivables	7	877	889
Income tax receivable		217	103
Cash and cash equivalents		24,499	36,670
Total current assets		27,663	38,785
Total assets		**27,901**	**39,040**
Equity			
Share capital	9	64	64
Share premium		106,364	106,360
Share based payment reserve		5,899	4,606
Other reserves		4,685	4,735
Retained loss		(107,979)	(94,707)
Surplus on shareholders' equity		**9,033**	**21,058**
Non-current liabilities			
Loans and borrowings	8	12,119	13,276
Total non-current liabilities		12,119	13,276
Current liabilities			
Loans and borrowings	8	3,006	2,268
Income tax payable		58	58
Trade and other payables		3,685	2,380
Total current liabilities		6,749	4,706
Total liabilities		**18,868**	**17,982**
Total equity and liabilities		**27,901**	**39,040**

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

Mainstay Medical International plc
Condensed consolidated statement of changes in shareholders' equity for the half year ended 30 June 2017

($'000)	Share capital	Share premium	Other reserves	Share based payment reserve	Retained loss	Total equity
Balance as at 1 January 2016	61	72,588	4,700	2,691	(74,816)	5,224
Loss for the half year	-	-	-	-	*(8,842)*	*(8,842)*
Other comprehensive income for the half year	-	-	-	-	-	-
Total comprehensive loss for the half year	-	-	-	-	(8,842)	(8,842)
Transactions with owners of the Company:						
Issue of shares	3	33,725	-	-	(1,053)	32,675
Share based payments	-	-	-	942	-	942
Issue of shares on exercise of share options or warrants	-	9	-	-	-	9
Balance at 30 June 2016 (Unaudited)	**64**	**106,322**	**4,700**	**3,633**	**(84,711)**	**30,008**
Loss for the year	-	-	-	-	*(9,916)*	*(9,916)*
Other comprehensive income	-	-	*35*	-	-	*35*
Total comprehensive loss for the half year	-	-	35	-	(9,916)	(9,881)
Transactions with owners of the Company:						
Issue of shares	-	-	-	-	(124)	(124)
Share based payments	-	-	-	1,017	-	1,017
Issue of shares on exercise of share options or warrants	-	38	-	(44)	44	38
Balance at 31 December 2016	**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**

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

Mainstay Medical International plc
Condensed consolidated statement of cash flows for the half year ended 30 June 2017

($'000)	Notes	Half year ended 30 June 2017	Half year ended 30 June 2016
		Unaudited	Unaudited
Cash flow from operating activities			
Net loss for the half year		(13,275)	(8,842)
Add/(less) non-cash items			
Depreciation		52	54
Finance income		(10)	-
Finance expense		986	784
Share-based compensation	11	1,296	942
Add/(less) changes in working capital			
Trade and other receivables		12	(273)
Inventory		(831)	-
Trade and other payables		1,274	293
Taxes paid		(238)	(114)
Interest paid		(656)	(389)
Net cash used in operations		**(11,390)**	**(7,545)**
Cash flow from investing activities			
Acquisition of property and equipment		(35)	(21)
Net cash used in investing activities		**(35)**	**(21)**
Cash flow from financing activities			
Gross proceeds from issue of shares		4	33,737
Transaction costs on issue of shares		-	(27)
Repayment of borrowings	8	(750)	-
Net cash (outflow)/inflow from financing activities		**(746)**	**33,710**
Net (decrease)/increase in cash and cash equivalents		**(12,171)**	**26,144**
Cash and cash equivalents at beginning of year		36,670	16,624
Cash and cash equivalents at 30 June 2017		**24,499**	**42,768**

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

Mainstay Medical International plc
Notes to the condensed consolidated Financial Statements

1 General information and reporting entity

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

The Half Year Report and condensed consolidated Financial Statements for the periods ended 30 June 2017 and 30 June 2016 comprise the results of the Company and of its subsidiaries (together the Group).

At 30 June 2017, the Group comprises the Company and its operating subsidiaries Mainstay Medical Limited, Mainstay Medical Distribution Limited, Mainstay Medical GmbH, MML US, Inc. and Mainstay Medical (Australia) Pty. Limited.

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

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

2 Basis of preparation

Statement of compliance

The condensed consolidated Financial Statements have been prepared in accordance with IAS 34 Interim Financial Reporting as adopted by the EU. They do not include all the information and disclosures necessary for a complete set of IFRS Financial Statements. However, selected explanatory notes are included to explain events and transactions that are significant to an understanding of the changes in the Group's financial position and performance since the last annual consolidated financial statements as at and for the year ended 31 December 2016.

The comparative information provided in the condensed consolidated Financial Statements relating to the periods ended 30 June 2016 and 31 December 2016 does not comprise the statutory financial statements of the Group. Those statutory financial statements for the year ended 31 December 2016 on which the auditors gave an unqualified audit opinion, have been delivered to the Companies Registry Office.

The half year ended 30 June 2017 is the first period in which the Group has recognized revenue, following CE Marking approval for the Group's product, ReActiv8, in May 2016. Therefore, except for revenue recognition, related warranties and trade and other receivables, (refer to significant accounting policies below), 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 2016.

The condensed consolidated Financial Statements were authorized for issue by the Board of Directors, on 04 September 2017.

Going concern

The Directors note the following relevant matters:

- The Group has an accumulated retained losses reserve of $108 million and a reorganization reserve of $44.6 million as at 30 June 2017 (31 December 2016: $94.7 million and $44.6 million respectively).
- The Group had operating cash out-flows of $11.4 million for the 6 months ended 30 June 2017 (year ended 31 December 2016: $16.7 million).
- The Group has funded operations to date through the proceeds of equity funding of approximately $85 million and as at 30 June 2017, debt with an outstanding debt principal of $14.25 million. The Group will require additional funding.
- The group expects to incur losses due to the ongoing investment in research and development, clinical and commercial activities.
- The Group has cash of $24.5 million as at 30 June 2017 ($36.7 million as at 31 December 2016).

The Directors have considered the conditions noted above and other factors, the potential of the Group to raise additional funding, and the potential to manage expenditure 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

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 2016 prepared in accordance with IFRS, as adopted by the EU and available on the Company's website (www.mainstay-medical.com). These accounting policies have been applied consistently for all periods presented. New accounting policies implemented during the half year ended 30 June 2017 are listed below:

a) Revenue recognition

Revenue is measured at the fair value of the consideration received/receivable for the sale of goods to external customers net of value added tax and discounts. The Group recognizes revenue when the amount of revenue can be reliably measured and when it is probable that future economic benefits of the transaction will flow to the Group. Revenue from the sale of goods is recognized when significant risks and rewards of ownership of the goods are transferred to the buyer. 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. Discounts are provided for based on agreements or contracts with customers, agreed promotional arrangements and accumulated experience. Discounts are recorded in the same period as the original revenue. 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.

b) Warranties

The Group offers a warranty on certain components of our product. The Group estimates the costs that may be incurred under its warranties and records a liability in the amount of such costs at the time the product is sold. The amount of the reserve recorded is equal to the net costs to repair or otherwise satisfy the obligation.

c) Financial instruments

Non-derivative financial assets

Financial assets are initially recognized on the date they are originated and when the Group obtains contractual rights to receive cash flows. The Group derecognizes financial assets when the contractual rights to cash flows expire or it transfers the right to receive cash flows in a transaction which transfers substantially all the risks and rewards of ownership of the asset.

Trade and other receivables

Trade and other receivables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method less provision for impairment.

d) Impairment of trade and other receivables

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. The amount of the impairment on doubtful receivables is measured individually and recorded as a specific allowance against the customer's receivable balance. The allowance is re-evaluated and adjusted periodically as additional information is received. The net movement in the provision for impairment of receivables is included within the income statement.

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

- Disclosure initiative (amendments to IAS 7) (effective 1 January 2017)
- IAS 12 (amended) – recognition of deferred tax assets for unrealized losses (effective 1 January 2017)

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

A number of new standards and amendments to standards are effective for future periods:

- IFRS 15 – Revenue from contracts with customers (effective 1 January 2018)
- IFRS 9 – Financial Instruments (effective 1 January 2018)
- IFRS 2 (amended) - Share Based Payments (effective 1 January 2018)
- IFRS 16 – Leases (effective 1 January 2019)

The above listed new standards and amendments to standards with an effective date after 1 January 2018 are not expected to have a material impact on the Group's 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 2017**	31 December 2016
Ireland	60	75
Germany	7	-
United States	171	180
Australia	-	-
Total non-current assets	**238**	**255**

4 Revenue

($'000)	**Half year ended 30 June 2017**	Half year ended 30 June 2016
Revenue arising from the sale of goods	242	-
Revenue arising from the sale of services	8	-
	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 2017	Half year ended 30 June 2016
Weighted average number of ordinary shares in issue	6,612,012	4,476,421
Loss per share	**2.01**	**1.98**

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 United States and Australia.

The Group has unrecognized potential deferred tax assets in relation to carryforward losses and other temporary differences. These potential assets are not recognized because future taxable profits against which they can be utilized are not sufficiently certain. The availability of these losses does not expire. Further information on these unrecognized potential deferred tax assets is available in the 2016 Annual Report.

($'000)	**Half year ended 30 June 2017**	Half year ended 30 June 2016
Income tax in Ireland	-	-
Income tax in other jurisdictions	131	71
Total income tax charge	**131**	**71**

7 Trade and other receivables

($'000)	**30 June 2017**	31 December 2016
Trade receivables, net	105	-
VAT and sales tax receivable	64	100
Prepaid expenses and other current assets	708	789
Total	**877**	**889**

8 Interest bearing loans and borrowings

IPF Debt Financing

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

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

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

A third tranche (Tranche C) of $4.5 million was received on 28 July 2016. The interest rate on Tranche C is 3-month Euribor plus a margin of 10.5%.

Other expenses directly associated with the facility of $466,000 were deferred and are amortized to profit or loss over the term of the loan on an effective interest rate basis.

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

The terms of the agreement include a requirement that Mainstay Medical Limited hold a minimum cash balance of $2 million, or achieve revenue targets within an agreed timeframe. It also includes monthly and quarterly reporting requirements. The Group is not in breach of any covenants at 30 June 2017 and has not been in breach at any reporting date.

($'000)	**30 June 2017**	31 December 2016
Loans and borrowings - current		
Term loan	2,775	2,025
Deferred finance cost	(91)	(91)
Accrued interest	322	334
Total current loans and borrowings	**3,006**	**2,268**
Loans and borrowings – non-current		
Term loan	11,475	12,975
Deferred finance cost	(25)	(142)
Accrued interest	669	443
Total non-current loans and borrowings	**12,119**	**13,276**
Total loans and borrowings	**15,125**	**15,544**

9 Called up share capital

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

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

Authorized and Issued Share Capital

Authorized	**30 June 2017 €**	31 December 2016 €
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**

Issued, called up and fully paid	**2017 $**	**2016 $**
6,612,452 (31 December 2016: 6,611,952) ordinary shares of €0.001 each	8,556	8,555
40,000 deferred shares of €1.00 each	55,268	55,268
	63,824	**63,823**
In $'000	**64**	**64**

During the half year ended 30 June 2017, 500 warrants over ordinary shares were exercised by the holders and the Company issued 500 ordinary shares. Proceeds of $3,850 were received on issue of the shares.

10 Financial instruments

Financial risk management

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

Risk management framework

Mainstay's Board of Directors has overall responsibility for the establishment and oversight of the Group's risk management framework. The Group's risk management policies are established to identify and 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. During January 2017, the Group made its first commercial sale of ReActiv8, and consequently the six-month period ended 30 June 2017 is the first period during which the group is exposed to credit risk arising on trade receivables. Further information is 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 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. The Group's objective is to manage 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 2017. 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 $24.5 million as at 30 June 2017.

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, taking into account their financial position, past experience and other factors. As at 30 June 2017 our trade and other receivables balances amounted to $105,000, and we have not recognized any impairment losses at this time. The total outstanding balance as at 30 June 2017 was received post period end.

The below table provides an analysis of aging of receivables as at 30 June 2017:

($'000)	**Current**	**1 - 30 Days**	**31 - 60 Days**	**61 – 90 Days**
Trade and other receivables	86	19	-	-

Liquidity risk

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

Since inception the Group has funded its operations primarily through (i) the issuance of equity securities and (ii) debt funding. The Group continues to explore funding strategies (e.g.: equity, debt, partnering)

to support its activities into the future. Adequate additional financing may not be available on acceptable terms, or at all. The Group's inability to raise capital as and when needed would have a negative impact on the Group's financial position and its ability to pursue its business strategy.

Foreign currency risk

The Group's reporting currency is the US Dollar. The Group's exposure to foreign currency risk arises through expenditure incurred in Euro and Australian Dollars.

The Group's Australian subsidiary has an Australian Dollar functional currency. Mainstay Medical Distribution Limited and Mainstay Medical GmbH have a Euro functional currency.

The Group did not have material asset or liability amounts in foreign currencies at 30 June 2017 other than trade payables and accruals (net of cash) of €540,000 and AU$36,000. A strengthening (or weakening) of the US Dollar against the Euro of 5% would have (decreased)/increased the loss for the period by $27,000 (June 2016: $84,000). Any reasonable or likely movement between the US Dollar and the Australian Dollar is considered not likely to have a material impact on the Group's statement of profit or loss and other comprehensive income.

Interest rate risk

The Group's cash balances are maintained in short term access accounts and carry a 0% rate of interest.

At 30 June 2017, the principal outstanding on MML's loan from IPF was $14,250,000. This loan carries a variable rate of 3-month Euribor plus a margin ranging from 10.5% to 12.5%. The terms of the debt agreement stipulate that if Euribor is less than zero, it is deemed to be zero. Any change in the Euribor rate above zero will directly affect the amount of interest repayable on this debt.

A 25-basis point increase in Euribor above zero would have increased the loss for the period by $35,189.

11 Share based payments

Share Options

The terms and conditions of the Group's share option plan are disclosed in the most recent, published, Annual Report. The charge of €1.3 million for the half year ended 30 June 2017 (30 June 2016: $0.9 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. 30,000 options were granted in the six months ended 30 June 2017 (30 June 2016: 47,500 options).

Warrants

On 2 December 2011, Silicon Valley Bank provided Mainstay Medical Limited (MML) with a loan of $2,000,000. This loan was repaid in full on 7 March 2014.

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

As at 30 June 2017 6,445 warrants were outstanding. During July 2017, all the remaining warrants were exercised by the holder.

12 Contingencies

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

13 Related party transactions

There were no balances due to or from related parties as at 30 June 2017 and 30 June 2016.

Key management compensation and Directors' remuneration

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

($'000)	**30 June 2017**	30 June 2016
Salaries	876	715
Non-executive directors' fees	111	108
Other remuneration	595	512
Payroll taxes	102	63
Share based payments	931	788
Pension	11	11
Total remuneration	**2,626**	**2,197**

14 Events subsequent to 30 June 2017

There were no events subsequent to the half year ended 30 June 2017 that would have a material impact on the condensed consolidated Financial Statements.