Mainstay Medical Provides Company Update and Reports 2019 Half Year Financial Results

- *ReActiv8 Pre-Market Approval (PMA) application submitted to U.S. FDA in August 2019; acceptance for FDA review expected October 2019*
- *European commercial validation efforts continue to progress*
- *Successful completion of financing transactions providing approximately $28 million of cash runway extension*

Dublin – Ireland, 20 September 2019 – Mainstay Medical International plc ("Mainstay" or the "Company", Euronext Paris: MSTY.PA and Euronext Growth of Euronext Dublin: MSTY.IE), a medical device company focused on bringing to market ReActiv8®, an implantable neurostimulation system to treat disabling Chronic Low Back Pain, today provides a company update and reports its financial results for the half year ended 30 June 2019.

Jason Hannon, CEO of Mainstay, said: *"We continue to make significant progress on our key corporate objectives of pursuing regulatory approval in the U.S. and advancing the commercial validation effort in Germany and other select European markets. I am pleased to report that we submitted the pre-market approval (PMA) application for ReActiv8 to the U.S. Food and Drug Administration (FDA) in August. Pending the FDA's acceptance of the PMA for review, anticipated in October 2019, we expect a decision regarding approval around the end of 2020. We also continue to make progress working with key physician partners in Germany who are incorporating ReActiv8 into their practices in order to validate commercial adoption, refine patient selection strategies and follow ongoing patient progress."*

Business Update

- In August 2019, Mainstay submitted the PMA application to the FDA based upon the totality of its clinical data for ReActiv8. Pending acceptance of the submission by the FDA, anticipated in October 2019, a decision regarding approval is expected around the end of 2020. The pivotal clinical trial upon which the PMA submission was based is the 204-patient ReActiv8-B clinical study. A summary of the clinical trial results is as follows:
    - 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, with responders defined as having a 30% or greater improvement on this measure between baseline and 120 days after randomization, without any increase in pain medication and/or muscle relaxants taken in the two weeks prior to the primary endpoint assessment visit. In the treatment group the responder rate at 120 days was 57%, compared to 47% in the control group, resulting in a difference that is not statistically significant.
    - The protocol included a pre-specified analysis of the primary endpoint data examining the cumulative proportion of responders, which is a comparison of ranks and inherently preserves information over a dichotomized endpoint, thereby improving statistical power. In that analysis, a statistically significant difference between the treatment and control groups was demonstrated, with the treatment group showing a higher proportion of responders across all threshold levels.
    - The protocol also included a pre-specified analysis of the primary endpoint where Mainstay adjusted for patients who increased their pain medications for reasons unrelated to their back pain. In that analysis, the responder rate at 120 days in the treatment group was 61%, compared

to 47% in the control group, resulting in a difference that is statistically significant.

- Statistically significant differences on a number of key secondary endpoints and supplemental analyses were observed 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 of 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) and patient treatment satisfaction as measured by the treatment satisfaction questionnaire (TSQ).
- Improvements in the percentage of patients reporting pain reduction continued beyond the 120-day assessment through one year for both groups. The percentage of the 160 patients in the treatment and control groups that had completed the one-year assessment having a 30% or greater reduction in low back pain VAS at that assessment without a significant increase in pain medication was 66%. These data are subject to change as the remaining patients reach the one-year assessment.
- The protocol permitted patients to adjust their back pain medication usage after the 120-day assessment point. At one year, 49% of the 61 patients in both groups combined who were on opioids at baseline had discontinued or decreased their use of opioids. These results are subject to change as the remaining patients reach the one-year assessment.
- 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.

- In Germany, Mainstay's initial European market, the Company's re-focusing of its commercial validation efforts was undertaken throughout 2018. Mainstay is now solely dedicated to building a small number of reference sites where high volumes of patients are treated with ReActiv8, allowing the Company to gather associated clinical data, refine patient selection processes for commercial markets, and gain the learnings needed to accelerate commercial launch in future markets.

Financial Update

- Since the beginning of 2019, Mainstay has conducted financing activities that have resulted in approximately $28 million of cash runway extension:
  - On 29 July 2019, Mainstay completed financing transactions consisting 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 in additional debt from the Company's existing lender, IPF Partners, resulting in aggregate gross proceeds of €16.9 million (US$18.9 million).
  - On 18 April 2019, Mainstay and its subsidiary, Mainstay Medical Limited, entered into an amendment to their agreement with IPF Partners relating to the 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 Mainstay, which was drawn down by Mainstay on 29 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 will be 8% per annum, with interest accruing but capitalized prior to January 1, 2021. The interest rates previously applicable to the initial three tranches ranged from 10.5% to 12.5%.

- 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 Mainstay'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 Mainstay since 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 Mainstay 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.
- Mainstay 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.

- Revenue during the six-month period ended 30 June 2019 was $0.6 million ($0.36 million in 1H18).
- Operating expenses for the six-month period ended 30 June 2019 were $9.5 million ($15.8 million in 1H18). The decrease was driven primarily by reduced costs relating to activities for the ReActiv-8 B clinical trial following the completion of all implants, as well as a decrease in payroll related costs following a reduction in headcount within 2019.
- Cash on hand as at 30 June 2019 was $5.8 million (31 December 2018: $29.7 million). Cash on hand at 31 July 2019 was $23.5 million.

Details of ReActiv8-B Clinical Trial

The ReActiv8-B clinical trial is an international, multi-center, prospective, randomized, active sham-controlled, blinded trial with one-way cross-over, conducted under an IDE from the FDA. A total of 204 patients with chronic low back pain refractory to physical therapy were implanted with ReActiv8 at leading clinical sites in the U.S., Europe and Australia and randomized 1:1 to therapy or control. 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 to provide a low level of electrical stimulation. Following assessment of the primary endpoint at 120 days, patients in the control group crossed-over to receive levels of electrical stimulation similar to those in the treatment group. The FDA's review of the PMA may result in the FDA not agreeing with Mainstay's interpretation of its clinical data, including whether statistical significance was achieved for one or more endpoints.

Investor Conference Call

Jason Hannon, Chief Executive Officer, and Matthew Onaitis, Chief Financial Officer, will host a conference call and Q&A for analysts and investors at 13:00 BST (08:00 EDT, 14:00 CEST) on 20 September 2019. The call will be conducted in English and a replay will be available for 30 days. Dial-in details for the call are:

Europe: +44 333 300 0804
Ireland: +353 1 431 1252
France: +33 170750711
Germany: +49 6913803430
USA: +1 6319131422
Participant PIN: 34020721#

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This announcement contains inside information within the meaning of the EU Market Abuse Regulation 596/2014.

About Mainstay

Mainstay is a medical device company focused on commercializing an innovative implantable restorative neurostimulation system, ReActiv8®, for people with disabling Chronic Low Back Pain (CLBP). The Company is headquartered in Dublin, Ireland. It has subsidiaries operating in Ireland, the United States, Australia, Germany and the Netherlands, and is listed on regulated market of the Euronext Paris (MSTY.PA) and the Euronext Growth market of Euronext Dublin (MSTY.IE).

About Chronic Low Back Pain

One of the root causes of CLBP is impaired control by the nervous system of the muscles that dynamically stabilize the spine. ReActiv8 is designed to electrically stimulate the nerves responsible for contracting these muscles to improve dynamic spine stability, allowing the body to recover from CLBP.

People with CLBP usually have a greatly reduced quality of life and score significantly higher on scales for pain, disability, depression, anxiety and sleep disorders. Their pain and disability can persist despite the best available medical treatments, and only a small percentage of cases result from an identified pathological condition or anatomical defect that may be correctable with spine surgery. Their ability to work or be productive is seriously affected by the condition and the resulting days lost from work, disability benefits and health resource utilization put a significant burden on individuals, families, communities, industry and governments.

Further information can be found at www.mainstay-medical.com

CAUTION – in the United States, ReActiv8 is limited by federal law to investigational use only.

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Forward looking statements

This announcement 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 announcement 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 announcement. 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 announcement, 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 trial, the outcome of the Company's interactions with the FDA on the PMA application for ReActiv8, 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 announcement.

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

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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 p-value**
Endpoint	**N**	**Mean ± SD (Min, Max) or N (%)**	**N**	**Mean ± SD (Min, Max) or N (%)**	
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					NA p = 0.003
Much better	100	32 (32%)	101	18 (18%)	

	Treatment N=102		Control N=102		Difference p-value
Endpoint	**N**	**Mean ± SD (Min, Max) or N (%)**	**N**	**Mean ± SD (Min, Max) or N (%)**	
Better	100	22 (22%)	101	16 (16%)	
A little better	100	25 (25%)	101	29 (29%)	
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 p ≤ 0.001
Maybe	100	29 (29%)	101	37 (37%)	
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 p ≤ 0.001
About the Same	100	16 (16%)	100	42 (42%)	
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
Chairman

Jason Hannon
CEO

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

($'000)	**Half year ended 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

Authorized	**30 June 2019 €**	31 December 2018 €
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	**2019 $**	**2018 $**
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.