

## Mainstay Medical - Interim Management Statement

*Continued progress towards commercialisation of ReActiv8®*

**Dublin – Ireland, 6 November 2014** – Mainstay Medical International plc (“Mainstay” or the “Company” listed on Euronext Paris: MSTY.PA and ESM of the Irish Stock Exchange: MSTY.IE) is issuing this Interim Management Statement covering the period from 1 July 2014 to today’s date.

Mainstay is an Irish medical device company with operations in Ireland, Australia and the United States. The Company is focused on the development and commercialisation of ReActiv8, an innovative implantable neurostimulation device designed to treat people with Chronic Low Back Pain (CLBP) by helping to restore control to the muscles that stabilise the lumbar spine.

### **Business Update**

We continue to make progress in the ReActiv8-A clinical trial, with subjects being recruited the UK, Belgium, and Australia, (see <http://clinicaltrials.gov/show/NCT01985230>). The ReActiv8-A clinical trial is a prospective single arm clinical trial with up to 96 subjects at sites in Australia and Europe. The Company currently expects that data from 40 subjects could be sufficient to apply for a CE Mark. We are pleased to report that over 25 subjects have been implanted as part of the ReActiv8-A clinical trial to date.

In July 2014, the Company submitted an information package about ReActiv8 and the proposed US clinical trial to the US Food and Drug Administration (‘FDA’) under an Investigational Device Exemption (‘IDE’). We met with the FDA in September 2014 and obtained feedback and guidance. We currently anticipate making a submission to start the proposed US clinical trial under an IDE to the FDA in the first quarter of 2015.

### **Financial Update**

There have been no significant changes in the financial position of the group since publication of the Half Year Results for the period ended 30 June 2014. Expenditure relating to clinical trial activities, ongoing research and development and general and administrative expenses is in line with expectations. The Company had \$21.4 million cash on hand as at 30 September 2014.

### **Outlook**

Mainstay looks forward to continuing progress with the ReActiv8-A clinical trial as it works towards obtaining CE Mark and commencing the commercialisation of ReActiv8.

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## About Mainstay

Mainstay is a medical device company which is developing an innovative implantable neurostimulation medical device, ReActiv8, for people with debilitating CLBP. Low Back Pain is a leading cause of activity limitation and work absence throughout much of the developed world, imposing a high economic burden on individuals, families, communities, industry, and governments.

The Company is headquartered in Dublin, Ireland. It has subsidiaries operating in Ireland, the United States and Australia, and is listed on Euronext Paris (MSTY.PA) and the ESM of the Irish Stock Exchange (MSTY.IE).

## About Chronic Low Back Pain

One of the recognised root causes of CLBP is impaired control by the nervous system of the muscles that stabilize the spine in the lower back, and an unstable spine can lead to back pain. ReActiv8 is designed to electrically stimulate the nerves responsible for contracting these muscles and thereby help to restore muscle control and improve spine stability, allowing the body to recover from CLBP.

People with debilitating 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 spinal 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 utilisation put a significant burden on economies.

Further information can be found at [www.mainstay-medical.com](http://www.mainstay-medical.com)

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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” or “will”, 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 Company’s results of operations, financial position, prospects, financing strategies, expectations for product design and development, regulatory 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 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 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, 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, currency fluctuations, changes in its business strategy, political and economic uncertainty. The forward-looking statements herein speak only at the date of this announcement.

The Company disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this document to reflect any change in its expectations or any change in events, conditions or circumstances on which such statements are based unless required to do so by applicable law or regulations.