

Mainstay Medical – Interim Management Statement

DUBLIN--([BUSINESS WIRE](#))-- Regulatory News:

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 January 2015 to today's date.

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

Business Update

The ReActiv8-A clinical trial is at an advanced stage in Australia and Europe. Over 40 subjects have been implanted in the trial and the Company is pleased with this progress. Mainstay believes that data from these subjects may be sufficient to apply for a CE Mark. The Company plans to announce data from the ReActiv8-A clinical trial after the outcome data from all implanted subjects are available, audited and adjudicated.

In January 2015, the Company submitted an application to the US Food and Drug Administration ("FDA") for approval to start a clinical trial of ReActiv8 under an Investigational Device Exemption (an "IDE"). The Company is interacting with the FDA to develop a clinical trial that meets the needs of the Company, the FDA and the people who could potentially benefit from ReActiv8.

Financial Update

There have been no significant changes in the financial position of the Company since publication of the Annual Report for the year ended 31 December 2014. The Company had \$15.0 million cash on hand as at 31 March 2015.

Outlook

Mainstay looks forward to continuing progress with the ReActiv8-A clinical trial as it works towards obtaining CE Mark, commencing commercialisation of ReActiv8 in Europe and advancing its interactions with the FDA on its IDE application.

Mainstay will host its first Annual General Meeting on 18 June, 2015 in Dublin.

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About Mainstay

Mainstay is a medical device company which is developing an innovative implantable neurostimulation system, ReActiv8[®], for people with disabling Chronic Low Back Pain (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 the ReActiv8-A Trial

The ReActiv8-A clinical trial, is a prospective single arm clinical trial with up to 96 subjects at sites in Australia and Europe. Outcome measures for the ReActiv8-A clinical trial are assessed at a three month endpoint after activation of stimulation and compared to baseline prior to implant. Further details can be obtained at

<https://clinicaltrials.gov/show/NCT01985230>.

About Chronic Low Back Pain

One of the recognised root causes of CLBP is impaired control by the nervous system of the muscles that dynamically stabilise 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 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 utilisation put a significant burden on economies.

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

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 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 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.

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