

## Mainstay Medical – Interim Management Statement

**Dublin, Ireland – 9 November 2015:** Mainstay Medical International plc (**Mainstay** or the **Company**, Euronext Paris: MSTY.PA and ESM of the Irish Stock Exchange: MSTY.IE), a medical device company focused on bringing to market ReActiv8<sup>®</sup>, an implantable neurostimulation system to treat disabling Chronic Low Back Pain, today issues this Interim Management Statement covering the period from 1 July 2015 to today's date.

### Business Update

On 2 November 2015, the Company announced it had submitted an application for a CE Mark for ReActiv8. The submission represents a further key step towards commercialisation of ReActiv8 in Europe. Mainstay's application for CE Mark includes the results of the ReActiv8-A Clinical Trial, which were announced by the Company on 31 August 2015.

The results of the ReActiv8-A Clinical Trial showed clinically important, statistically significant, and lasting improvement in pain, disability, and quality of life for people with Chronic Low Back Pain and limited treatment options. The Clinical Results announcement is available on the Company's website at [http://www.mainstay-medical.com/news/press\\_releases](http://www.mainstay-medical.com/news/press_releases).

On 24 August 2015, Mainstay announced the closing of debt financing for up to \$15 million. The secured debt facility is non-dilutive to existing shareholders, and is provided by IPF Partners, a leading financing provider focused on the European healthcare sector. The announcement and details of the financing are available on the Company's website at [http://www.mainstay-medical.com/news/press\\_releases](http://www.mainstay-medical.com/news/press_releases).

In July and August 2015, Mainstay announced the issuance of three new U.S. Patents.

### Financial Update

There have been no significant changes in the financial position of the Company since publication of the Half Year Report for the period ended 30 June 2015. The Company had \$14.0 million cash on hand at 30 September 2015.

### Outlook

Mainstay looks forward to continuing to work towards obtaining CE Mark for ReActiv8, commencing commercialisation in Europe, and to progressing the US clinical trial, ReActiv8-B, a summary of which can be found at <https://clinicaltrials.gov/show/NCT02577354>.

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### **About Mainstay**

Mainstay is a medical device company which is developing an innovative implantable neurostimulation system, ReActiv8<sup>®</sup>, 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 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 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 individuals, families, communities, industry and governments.

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

*ReActiv8 is an investigational device and is not approved for commercialization anywhere in the world.*

*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” 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 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 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, 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 announcement.