

Mainstay Medical Announces Two Additional US Patents Issued

Dublin – Ireland, 15 July 2015 – Mainstay Medical International plc (“Mainstay” or the “Company” listed on Euronext Paris: MSTY.PA and ESM of the Irish Stock Exchange: MSTY.IE), a medical device company focused on the development and commercialization of a novel neurostimulation therapy for people suffering from debilitating Chronic Low Back Pain (CLBP), today announced the issuance of two new U.S. Patents:

- U.S. Patent No. 9,072,897 entitled “Systems and Methods for Restoring Muscle Function to the Lumbar Spine”
- U.S. Patent No. 9,079,019 entitled “Apparatus and Methods for Anchoring Electrode Leads for Use with Implantable Neuromuscular Electrical Stimulator”.

Corresponding applications have been made in other countries. Mainstay continues to add to its portfolio of issued patents and pending applications.

Most people with CLBP have exhausted conventional treatments, are not candidates for surgery or spinal cord stimulation, and in the prime of their lives face a future of continuing pain and disability. For many of these people the root cause of their CLBP is a disruption in the control of the muscles that stabilize the lumbar spine. ReActiv8’s unique approach is to use electrical stimulation to elicit repetitive contractions of the key stabilising muscles of the lumbar spine to reactivate the body’s control over these muscles allowing recovery from CLBP.

Peter Crosby, Mainstay’s Chief Executive Officer, commented: *“Our approach to the treatment of CLBP in this challenging population is unique. We are proud of our intellectual property portfolio, and look forward to continued development of the portfolio in the coming years.”*

Clinical trials with ReActiv8 are ongoing in Europe and Australia, and the Company recently announced FDA approval to start a clinical trial of ReActiv8 under an Investigational Device Exemption (IDE).

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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 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 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

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

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

Media queries:

Jonathan Neilan, FTI Consulting

Tel: +353 1 663 3686

Email: jonathan.neilan@fticonsulting.com

Astrid Villette, FTI Consulting (French language enquiries)

Tel: +33 1 47 03 69 51

Email: Astrid.Villette@fticonsulting.com

Investor relations:

Jillian Connell, The Trout Group LLC

Tel: +1 646 378 2956 / +1 617 309 8349

Email: jconnell@troutgroup.com

ESM Advisers:

Fergal Meegan or Barry Murphy, Davy

Tel: +353 1 6796363

Email: fergal.meegan@davy.ie or barry.murphy2@davy.ie

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, the time required to commence and complete clinical trials, currency fluctuations, changes in its business strategy, political and economic uncertainty. The forward-looking statements herein speak only at the date of this announcement.