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Press Release



Mainstay Medical Announces €30 million Fundraising

New Capital to Support European Commercialisation and US PMA Clinical Trial

Dublin, Ireland – 17 June 2016: 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®, an implantable neurostimulation system to treat disabling Chronic Low Back Pain, announces today that it has raised gross proceeds of €30 million through a placement of 2,307,694 new ordinary shares with a nominal value of €0.001 each in the Company (the “**Placing Shares**”) with new and existing shareholders (the “**Placing**”).

The Placing Shares will be issued to selected institutional investors in Europe and in North America and a small number of individual investors in Europe (together, the “**Placees**”), at a price of €13.00 per share. KCK Ltd. (“**KCK**”) is participating as cornerstone investor in the Placing, subscribing for 1,153,846 Placing Shares, representing approximately 50% of the total number of Placing Shares, for an amount of approximately €15 million. KCK is a family investment fund that invests in a diverse set of industries, including medical technologies.

Mainstay plans to use the net proceeds from the Placing:

- to support European commercialization;
- to conduct clinical trials including the ReActiv8-B Clinical Trial to gather data in support of an application for pre-market approval (PMA) in the United States; and
- for general corporate purposes.

Peter Crosby, CEO of Mainstay, commented: *“This fundraising will allow us to further progress towards our objectives of commercialisation of ReActiv8 in Europe and the United States, and help improve the lives of millions of people who suffer from chronic low back pain. We thank our existing investors for their continuing support, and we are proud to welcome KCK as the cornerstone investor for this fundraising, as well as several other new investors in Mainstay.”*

Mainstay received CE Marking for ReActiv8 on 24 May 2016, which enables commercialization of ReActiv8 in Europe. Mainstay will initially focus its sales and marketing efforts in Germany, where the Company has a direct sales force, supported by its team of experienced field clinical specialists and is working toward first commercial implant of ReActiv8. With new capital available, the Company will ramp up the ReActiv8-B Clinical Trial, an international prospective randomized sham controlled one-

way crossover FDA approved clinical trial, which, if successful, will lead to a PMA application that will be filed with the FDA, a key step towards commercialization of ReActiv8 in the USA.

In addition to the funds raised in this Placing, the Company had \$10.4 million cash on hand at 31 May 2016.

Additional information regarding the Placing

The Placing Shares will be issued immediately following the publication of this announcement. In addition to KCK, the Company's existing long-term investors, Sofinnova Partners, Fountain Healthcare Partners and Capricorn Venture Partners, together with IPF Partners (which provided a debt facility to the Group in 2015) and several individual investors, are also participating in the Placing.

The Company has agreed with KCK that it will have the right to nominate two additional non-executive directors of the Company ("**Directors**") immediately following completion of the Placing, bringing the total number of Directors to nine. Accordingly, Mr. Nael Karim Kassar and Mr. Greg Garfield will be appointed as Directors today immediately following completion of the Placing.

The Placing Shares, when issued, will represent an increase of approximately 54% from the Company's existing issued ordinary share capital. Following issuance of the Placing Shares, the Company's issued share capital will consist of 6,607,000 ordinary shares of €0.001 each ("**Ordinary Shares**") (which carry voting rights) and 40,000 deferred shares with a nominal value of €1.00 each (which do not carry voting rights). Therefore, the figure that should be used by shareholders as the denominator for the calculations by which they will determine if they are required to notify their holdings of voting rights, or a change to their holdings of voting rights, over the Ordinary Shares of the Company under the Transparency (Directive 2004/109/EC) Regulations 2007 of Ireland, as amended and the Transparency Rules of the Central Bank of Ireland is 6,607,000.

The Placing Shares, when issued, will be fully paid and rank *pari passu* in all respects with the existing issued Ordinary Shares, except that the Placing Shares will not be admitted to trading on Euronext Paris or the Enterprise Securities Market ("**ESM**") of the Irish Stock Exchange plc ("**Admission**") until the Company has published a prospectus that is required to effect the admission to trading of the Placing Shares on Euronext Paris in accordance with Directive 2003/71/EC, as amended. The Company expects to publish that prospectus (which requires approval by the Central Bank of Ireland and which will be "passported" into France), and that Admission will occur, by 15 September 2016. Under the terms of the subscription agreements with relevant Placees, the Company has agreed that if Admission does not occur by 120 days after the issuance of the Placing Shares, then for all or part of one or more of the consecutive 30 day periods following that date during which Admission does not occur, Placees shall have the right to subscribe at par (i.e. at €0.001 per share) for 1% of the number of Placing Shares issued to them (rounded down to the nearest whole

number) for each such consecutive 30 day period (or part thereof). The number of additional Ordinary Shares that may be issued to each Placee is capped at 10% of the number of Placing Shares issued to that Placee (rounded down to the nearest whole number) under the Placing.

Sofinnova Partners and Fountain Healthcare Partners (who are considered substantial shareholders under the Enterprise Securities Market Rules for Companies (the “**ESM Rules**”)) will subscribe for 389,984 and 230,769 of the Placing Shares respectively. Their participation in the Placing will constitute related party transactions under Rule 13 of the ESM Rules. The Directors (with the exception of Antoine Papiernik and Manus Rogan), consider, having consulted with Davy Corporate Finance, the Company’s ESM Adviser, that the terms of their participation in the Placing are fair and reasonable insofar as Mainstay shareholders are concerned.

David Brabazon, who is a Director, will also participate in the Placing, subscribing for 23,100 Placing Shares, so that following completion of the Placing, he will hold 27,828 Ordinary Shares, representing 0.42% of the enlarged issued ordinary share capital of the Company.

Kempen & Co (Amsterdam) acted as financial adviser and coordinating placement agent, J&E Davy (Dublin) acted as financial adviser and placement agent and Merrion Capital (Dublin) acted as placement agent.

Conference call

The Company will host a live conference call (in English) for analysts and investors on Friday, 17 June 2016 at 10am Dublin time (11am Paris time).

Dial in details for this call are:

Ireland Toll Free Number: 1800 936 842

France Toll Free Number: 0805 101 988

Finland Toll Free Number: 0800 523 133

Germany Toll Free Number: 0800 589 3001

Netherlands Toll Free Number: 0800 265 8619

International Non Toll Free Number: +44 203 139 4830

Passcode: 62363666#

Appendix - Additional Information regarding the New Directors

The following information is required to be disclosed pursuant to Rule 17 and paragraph (g) of Schedule 2 of the ESM Rules:

Mr Greg Garfield

Mr. Greg Garfield will be appointed as a Director (having been nominated by KCK) immediately following completion of the Placing, which is expected to occur today. Greg Shaw Garfield, aged 53, is an experienced medical technology executive. Greg does not currently have any interest in Ordinary Shares, save for the interest to be acquired by KCK under the Placing.

Greg was a non-executive director of Sonitus Medical Inc. until January 2015, when the company entered into a voluntary liquidation. The liquidation was completed in January 2016. Greg has confirmed that there are no other items requiring disclosure in accordance with Schedule 2(g)(iii) to (viii) of the ESM Rules.

Current directorships:

- C2 Therapeutics Inc.
- Aerin Medical, Inc.
- Rodo Medical, Inc.
- Cogent Therapeutics LLC
- Revent Medical Inc.
- Semler Scientific Inc.
- BioInspire Technologies Inc.
- Applaud Medical Inc.
- RefleXion Medical Inc.
- Sonitus Technologies Inc.

Previous directorships within the past five years:

- Sonitus Medical Inc.

Mr. Nael Karim Kassar

Mr. Nael Karim Kassar will be appointed as a Director (having been nominated by KCK) immediately following completion of the Placing, which is expected to occur today. Nael Karim Kassar, aged 37, is a director of KCK. Nael does not currently have any interest in Ordinary Shares save for the interest to be acquired by KCK under the Placing. Nael has a beneficial interest of 10% in the issued share capital of KCK.

Nael has confirmed that there are no other items requiring disclosure in accordance with Schedule 2(g)(iii) to (viii) of the ESM Rules.

Current directorships:

- KCK Ltd
- KCK Properties Ltd
- Future Finance Loan Corporation Limited
- Timeshare Finance Investments Limited
- Specialty Finance ICAV Limited
- Judgment Acquisition Corporation Limited
- High Sealed and Coupled "HSC" FZCO
- Sentient Energy, Inc.
- OnePhone Holding AB;
- Citizens Parking Inc.
- Affirmed Networks, Inc.
- GFL Environmental Holdings Inc.
- SiGNa Chemistry, Inc.
- Murosa Development S.a r.l.
- Hibernia NGS Limited
- HPS Del Mar Holdings LLC
- BioInspire Technologies, Inc.
- Aerin Medical Inc.
- QM Power Inc.
- Sonitus Technologies, Inc.
- RefleXion Medical Inc.

Previous directorships within the past five years:

- Tunnel Capital City Partners Inc

- End -

About Mainstay

Mainstay is a medical device company focused on bringing to market an innovative implantable 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 and Germany, 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 low 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

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

PR and IR Enquiries:

Consilium Strategic Communications (international strategic communications - business and trade media)

Chris Gardner, Mary-Jane Elliott, Jessica Hodgson, Hendrik Thys,

Tel: +44 203 709 5700 / +44 7921 697 654

Email: mainstaymedical@consilium-comms.com

FTI Consulting (for Ireland):

Jonathan Neilan

Tel: +353 1 663 3686

Email: jonathan.neilan@fticonsulting.com

FTI Consulting (for France):

Astrid Villette

Tel: +33 1 47 03 69 51

Email: Astrid.Villette@fticonsulting.com

Investor Relations:

The Trout Group LLC

Jillian Connell

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

Email: jconnell@troutgroup.com

ESM Advisers:

Davy

Fergal Meegan or Barry Murphy

Tel: +353 1 679 6363

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”, “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 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 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 successful launch and commercialisation of ReActiv8, the initiation and success of the ReActiv8-B Clinical Trial, 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.

Disclaimers

This announcement and the information it contains does not constitute and shall not be considered as constituting a public offer, an offer to subscribe or an intention to solicit the interest of the public for a public offering of Mainstay’s securities in Ireland, France, the United Kingdom, the United States or any other jurisdiction.

In Ireland, the offer of Placing Shares described above is being made solely to persons who are “qualified investors” within the meaning of article 2(1)(e) of the Directive 2003/71/EC (the “Prospectus Directive”) and “professional clients” as defined in schedule 2 of the European Communities Markets in Financial Instruments Regulations 2007 (as amended) and, to a small number of other individual investors in accordance with other applicable exemptions under Irish prospectus law.

In France, the offer of Placing Shares described above is being made solely as a private placement, in accordance with Article L. 411-2 of the Code monétaire et financier and applicable regulations. The offering does not constitute a public offering in France, as defined in Article L. 411-1 of the Code monétaire et financier and no prospectus reviewed or approved by the Autorité des marchés financiers will be published. A listing prospectus will be prepared for approval by the Central Bank of Ireland, passported into France and published as part of the application for listing of the Placing Shares.

This announcement does not constitute an offer of the Placing Shares to the public in the United Kingdom, nor is it intended to be an inducement to engage in investment activity for the purpose of section 21 of the Financial Services and Markets Act 2000 (as amended) of the United Kingdom. Consequently, this announcement is only directed at (i) persons who are outside the United Kingdom; (ii) investment professionals within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 as amended (the “Order”); (iii) persons falling within Article 49(2)(a)-(d) of the Order; or (iv) other persons to whom it may be lawfully be communicated, together being referred to as “relevant persons”. The Placing Shares are only available to, and any invitation, offer or agreement to purchase or otherwise acquire the Placing Shares will be engaged in only with relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

With respect to Member States of the European Economic Area, no action has been taken or will be taken to permit a public offering of the securities referred to in this announcement which would require the publication of a prospectus in any Member State. There will be no offer to the public of the Placing Shares in any Member State

of the European Economic Area and no prospectus or other offering document has been or will be prepared in connection with the sale of the Placing Shares by Mainstay. In Member States of the European Economic Area other than Ireland, France or the United Kingdom, the Placing Shares are only being offered and sold to “qualified investors” as defined in the Prospectus Directive or in other circumstances falling within Article 3(2) of the Prospectus Directive.

This announcement does not constitute or form part of any offer or solicitation to purchase or subscribe for, nor does it constitute an offer to sell, or the solicitation of an offer to buy Placing Shares in the United States or in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to its registration or qualification under the laws of such jurisdiction. The Placing Shares mentioned herein have not been, and will not be, registered under the U.S. Securities Act of 1933 (the “**Securities Act**”). The Placing Shares may not be offered or sold in the United States except pursuant to an effective registration statement under, or an exemption from the registration requirements of, the Securities Act. There will be no public offer of securities in the United States.

This distribution of this announcement may be subject to legal or regulatory restrictions in certain jurisdictions. Any person who comes into possession of this announcement must inform him or herself of and comply with any such restrictions.

J&E Davy, trading as Davy, which is authorised and regulated in Ireland by the Central Bank of Ireland, is acting exclusively for the Company and no one else in connection with Placing and will not be responsible to anyone other than the Company for providing the protections afforded to its clients or for providing any advice in relation to the Placing or any matter referred to herein.