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**Press Release**

**This announcement contains inside information**

# Mainstay Medical Announces €30 million Financing

## New Capital to Complete US Pivotal ReActiv8-B Clinical Study and Advance European Commercialization

**Dublin, Ireland – 15 February 2018**: 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 €30.1 million through the issue of 2,151,332 new ordinary shares (**New Shares**) to new and existing shareholders.

The funds raised in this financing will be used to significantly advance Mainstay's business. In particular, the net proceeds will be used:

- to complete the U.S. Pivotal ReActiv8-B Clinical Study in support of an application for pre-market approval (PMA) from the US Food and Drug Administration (FDA)
- to advance the initial commercialization of ReActiv8 in Germany and additional markets
- to invest in early commercial activities in preparation for launch in the United States
- for general corporate purposes.

Jason Hannon, CEO of Mainstay, commented: "*Our goals for the next two years are clear: complete the ReActiv8-B clinical study, file the PMA for ReActiv8 with the FDA, and build our commercial presence in 2018 for more meaningful commercial expansion starting in 2019. A key focus in 2018 will be building market awareness in Germany and developing reference sites who care for chronic back pain patients and believe in ReActiv8. Over the next year we are targeting to have 10 or more physician partners who have performed multiple implants, with whom we will work to expand market awareness and adoption, refine patient selection strategies and follow ongoing patient progress. This financing provides the capital to drive forward on all these goals.*"

**Business Update**

- In December 2017, we announced the positive outcome of the Interim Analysis of the ReActiv8-B Study. The Independent Data Monitoring Committee recommended the continuation of the

Study with a definitive size of 168 evaluable patients. The DMC also reported that they had no safety concerns in the Study.

- The ReActiv8-B Study is expected to be fully enrolled by the end of the second quarter of 2018, with a full data readout expected towards the end of 2018. The ultimate number of patients in the Study will be higher than 168 due to the nature of the enrollment process.
- Mainstay has continued to advance the initial commercialization of ReActiv8 in Europe. Our European commercial activities are initially focused on Germany, where we are working to drive adoption in a select number of high volume spine care centers to develop reference sites.
- To date, 5 centers in Germany and Ireland have implanted patients with ReActiv8, and several additional sites have been trained.
- We were recently issued a new US Patent, U.S. Patent No. 9,861,811 "Electrical Stimulator for Treatment of Back Pain and Methods of Use", bringing the total current number of US issued patents in the Mainstay portfolio to nine.

**Investors in the Financing**

The investors in this pivotal financing are primarily institutions in Europe and North America, at a price of €14 per New Share. The Ireland Strategic Investment Fund) (**ISIF**) is participating in the financing, subscribing for 714,285 New Shares, representing approximately 33.2% of the total number of New Shares, for an amount of approximately €10 million. ISIF is an Irish sovereign development fund with a statutory mandate to invest on a commercial basis in a manner designed to support economic activity and employment in Ireland. ISIF played a key role in this transaction.

Mainstay is implementing plans to bring additional elements of its operations to Ireland following the ISIF investment. Mainstay will build on its Irish footprint and benefit from the strong local talent base. These elements of operational infrastructure will take shape as the Company's business scales commercially. These investments will, the Directors believe, support the Company's growth over time and allow it to reach more customers, while simultaneously adding investment and job creation to the Irish market.

**Specific information regarding the Financing**

The New Shares will be issued immediately following the publication of this announcement. In addition to ISIF, the Company's existing long-term investors, Sofinnova Partners, Fountain Healthcare Partners and KCK Limited and several individual investors, are also participating in the financing.

The New Shares, when issued, will represent an increase of approximately 32.5% from the Company's existing issued ordinary share capital. Following issuance of the New Shares, the Company's issued share capital will consist of 8,770,229 Ordinary Shares of €0.001 each (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 8,770,229.

The New Shares, when issued, will be fully paid and rank *pari passu* in all respects with the existing issued Ordinary Shares, except that the New 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 New 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 May 2018. Under the terms of the subscription agreements for the New Shares, the Company has agreed that if Admission does not occur by 120 days after the issuance of the New Shares, then for all or part of one or more of the consecutive 30 day periods following that date (a **Relevant Period**) during which Admission does not occur the Company shall separately pay to each investor, as liquidated damages, a cash payment of 0.5% of the total subscription price paid by the relevant investor for each Relevant Period (or partial Relevant Period) during which Admission has still not occurred; provided, however that in no event shall the Company be required to pay to any investor an aggregate amount that exceeds 5% of the total subscription price paid by that investor. Any such payment(s) shall be made within five Business Days of the end of each such Relevant Period.

Sofinnova Partners, KCK Limited and Fountain Healthcare Partners (who are considered substantial shareholders under the Enterprise Securities Market Rules for Companies (**ESM Rules**)) will subscribe for 250,000, 428,572 and 138,280 New Shares respectively. Their participation in the financing will constitute related party transactions under Rule 13 of the ESM Rules. The Directors, with the exception of Antoine Papiernik (with respect to Sofinnova Partners), Nael Karim Kassar and Greg Garfield (with respect to KCK Limited) and Manus Rogan (with respect to Fountain Healthcare Partners), consider, having consulted with J&E Davy, the Company's ESM Adviser, that the terms of the participation of Sofinnova Partners, KCK Limited and Fountain Healthcare Partners in the financing are fair and reasonable insofar as Mainstay shareholders are concerned.

Jason Hannon, who is a Director, will also participate in the financing, subscribing for 30,000 New Shares, so that following completion of the financing, he will hold 30,000 Ordinary Shares, representing 0.3% of the enlarged issued ordinary share capital of the Company.

David Brabazon, who is also a Director, will also participate in the financing, subscribing for 30,000 New Shares, so that following completion of the financing, he will hold 57,828 Ordinary Shares, representing 0.7% of the enlarged issued ordinary share capital of the Company.

Greg Garfield, who is also a Director, will also participate in the financing, subscribing for 2,912 New Shares, so that following completion of the financing, he will hold 2,912 Ordinary Shares, representing 0.03% of the enlarged issued ordinary share capital of the Company.

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

This Announcement contains inside information for the purposes of the Market Abuse Regulation (EU) No 596/2014 (**MAR**). Market soundings, as defined in MAR, were taken in respect of the Financing, with the result that certain persons became aware of inside information, as permitted by MAR. That inside information is set out in this Announcement. Therefore, those persons that received inside information in a market sounding are no longer in possession of inside information relating to the Company and its securities.

The person responsible for arranging release of this Announcement on behalf of Mainstay is Tom Maher.

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**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, Germany and the Netherlands, and is listed on regulated market of the Euronext Paris (MSTY.PA) and the ESM of the Irish Stock Exchange (MSTY.IE).

**About Chronic Low Back Pain**

One of the recognized root causes of CLBP is impaired control by the nervous system of the muscles that dynamically stabilize 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 utilization 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.*

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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”, “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 commercialization of ReActiv8, the progress 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 New 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, or “eligible counterparties” as defined in Regulation 38, of the European Union (markets in financial instruments) Regulations 2017 and, to a small number of other individual investors in accordance with other applicable exemptions under Irish prospectus law.

In France, the offer of New 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 New Shares.

This announcement does not constitute an offer to the public in the United Kingdom. No prospectus has been or will be approved in the United Kingdom in respect of the New Shares. Consequently, this announcement is only directed at persons who (i) are located outside the United Kingdom, or (ii) are in the United Kingdom and are "qualified investors" as defined in section 86(7) of FSMA, being persons falling within the meaning of Article 2(1)(e) of the Prospectus Directive, and (a) who have professional experience in matters relating to investments and who falls within the definition of "investment professionals" in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended) (the "**Order**"), (b) fall within Article 49(2)(a) to (d) of the Order, or (c) are persons to whom it may lawfully be communicated under an exemption contained in the Order, (all such persons together being referred to as "**Relevant Persons**"). Any investment or investment activity to which this announcement relates is available only to Relevant Persons and will be engaged in only with such persons. Any person in the United Kingdom who is not a Relevant Person should not act or rely on this document or any of its contents. For the purpose of this paragraph, the expression "**Prospectus Directive**" means Directive 2003/71/EC as amended and implemented in the United Kingdom.

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 Ordinary 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 New Shares by Mainstay. In Member States of the European Economic Area other than Ireland or the United Kingdom, the New Shares are only being offered and sold to "qualified investors" as defined in the Prospectus Directive or in other circumstances falling within Article 2(1)(e) of the Prospectus Directive and to "professional clients" or "eligible counterparties" within the meaning of Directive 2014/65/EU on markets in financial instruments, as amended ("**MiFID II**").

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 Ordinary 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 New Shares mentioned herein have not been, and will not be, registered under the U.S. Securities Act of 1933 (the "**Securities Act**"). The New 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.

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 the Financing 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 Financing or any matter referred to herein.

**Information to distributors**

Solely for the purposes of the product governance requirements contained within: (a) MiFID II; (b) Articles 9 and 10 of Commission Delegated Directive (EU) 2017/593 supplementing MiFID II; and (c) local implementing measures (together, the "**MiFID II Product Governance Requirements**"), and disclaiming all and any liability, whether arising in tort, contract or otherwise, which any "manufacturer" (for the purposes of the MiFID II Product Governance Requirements) may otherwise have with respect thereto, the New Shares have been subject to a product approval process, which has determined that such New Shares are: (i) compatible with an end target market of retail investors and investors who meet the criteria of professional clients and eligible counterparties, each as defined in MiFID II; and (ii) eligible for distribution through all distribution channels as are permitted by MiFID II (the "**Target Market Assessment**"). Notwithstanding the Target Market Assessment, distributors should note that: the price of the New Shares may decline and investors could lose all or part of their investment; the New Shares offer no guaranteed income and no capital protection; and an investment in the New Shares is compatible only with investors who do not need a guaranteed income or capital protection, who (either alone or in conjunction with an appropriate financial or other adviser) are capable of evaluating the merits and risks of such an investment and who have sufficient resources to be able to bear any losses that may result therefrom. The Target Market Assessment is without prejudice to the requirements of any contractual, legal or regulatory selling restrictions in relation to the offer of the New Shares. Furthermore, it is noted that, notwithstanding the Target Market Assessment, Kempen & Co N.V. will only procure investors who meet the criteria of professional clients and eligible counterparties. For the avoidance of doubt, the Target Market Assessment does not constitute: (a) an assessment of suitability or appropriateness for the purposes of MiFID II; or (b) a recommendation to any investor or group of investors to invest in, or purchase, or take any other action whatsoever with respect to the New Shares. Each distributor is responsible for undertaking its own target market assessment in respect of the New Shares and determining appropriate distribution channels.

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.