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Press Release

This announcement contains inside information

Mainstay Medical Announces Completion of Financing Transactions

- **Funds to be used to support PMA process for ReActiv8® in US and to further European commercial validation efforts**
- **Gross proceeds, together with savings from previously-announced debt restructuring, provides approximately $28 million in cash runway extension**

Dublin, Ireland – 29 July 2019: Mainstay Medical International plc (**Mainstay** or the **Company**, Euronext Paris: MSTY.PA and Euronext Growth of Euronext Dublin: 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 completed financing transactions to raise gross proceeds of €16.9 million (US$18.9) million.

Jason Hannon, CEO of Mainstay, commented: "*Our objectives for the remainder of 2019 and 2020 are clear: file the pre-market approval (PMA) application for ReActiv8 with the U.S. Food and Drug Administration (FDA) this summer; advance the PMA review process with the FDA, with an approval decision expected in late 2020; and continue the commercial validation effort in Germany and other select European markets by working with key physician partners who identify appropriate ReActiv8 patients in their centres in order to validate commercial adoption, refine patient selection strategies and follow ongoing patient progress. We are pleased with the outcome of this financing, which was oversubscribed. These deals will provide the capital to expeditiously advance each of these goals and, together with our previously-announced debt restructuring, expands our expected cash runway into 2021*."

The total cash runway extension achieved by Mainstay amounts to approximately $28.0 million: approximately $18.9 million in gross proceeds from the financing transactions and approximately $9.1 million in savings that resulted from the Company's restructuring of its debt completed in April.

Specific information regarding the Financing

The financing transactions consist of the issuance of 4,649,775 new ordinary shares (**New Shares**) at a purchase price of €3.00 per New Share and the drawdown of €3.0 million in additional debt from the Company's existing lender. The investors in the equity financing are primarily existing shareholders in the Company (principally Sofinnova Partners, KCK Limited, Fountain Healthcare Partners and several individual investors).

The New Shares, when issued, will represent an increase of approximately 53.0% from the Company's existing issued ordinary share capital. Following issuance of the New Shares, the Company's issued share capital will consist of 13,421,504 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 13,421,504.

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 Euronext Growth market (**Euronext Growth**) of Euronext Dublin (**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 EU prospectus law. 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 Euronext Growth Markets Rule Book (**Euronext Growth Rules**)) will subscribe for 533,333, 654,000 and 1,333,333 New Shares, respectively. Their participation in the financing will constitute related party transactions under Rule 5.18 of the Euronext Growth Rules. The Directors, with the exception of Antoine Papiernik (with respect to Sofinnova Partners) and Nael Karim Kassar and Greg Garfield (with respect to KCK Limited), consider, having consulted with J&E Davy, the Company's Euronext Growth 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.

David Brabazon, who is a Director, will also participate in the financing, subscribing for 155,000 New Shares, so that following completion of the financing, he will hold 212,828 Ordinary Shares, representing 1.6% of the enlarged issued ordinary share capital of the Company.

This announcement contains inside information for the purposes of the Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (the "**Market Abuse Regulation**" or "**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 Matt Onaitis.

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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 Euronext Growth market of Euronext Dublin (MSTY.IE).

About Chronic Low Back Pain

One of the root causes of CLBP is impaired control by the nervous system of the muscles that dynamically stabilize the spine. ReActiv8 is designed to electrically stimulate the nerves responsible for contracting these muscles to 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 plans to file a PMA application with the FDA for ReActiv8, the timing of such filing and of the FDA's review of such application, the clinical data relating to ReActiv8, the potential for the FDA to approve ReActiv8 for marketing in the United States, the Company's expected cash runway and 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 and other commercial performance.

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, the development of its main product, and 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 final outcome of the Company's ReActiv8-B clinical study, the outcome of the Company's interactions with the FDA on a PMA application for ReActiv8, the successful launch and commercialization of ReActiv8, general economic and business conditions, 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, and 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 (e) of the Regulation (EU) 2017/1129 of 14 June 2017 (the "**Prospectus Regulation**") 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 (e) of the Prospectus Regulation, 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 Regulation**" means Regulation (EU) 2017/1129 of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market 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 Regulation or in other circumstances falling within Article 2(e) of the Prospectus Regulation 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, the Company 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.

The 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.