SUMMARY

1. Introduction and Warnings

1.1 Introduction

This summary dated 25 October 2019 (the "**Summary**") is derived from the full text of the registration document dated 25 October 2019 (the "**Registration Document**") and the securities note dated 25 October 2019 (the "**Securities Note**") relating to Mainstay Medical International plc (the "**Company**"), which together with this Summary, constitute a prospectus (the "**Prospectus**"), for the purposes of Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 ("**Prospectus Regulation**"). The Prospectus was approved by the Central Bank of Ireland (the "**Central Bank**"), as competent authority under the Prospectus Regulation, on 25 October 2019. Contact information relating to the Central Bank can be found at https://www.centralbank.ie/contact-us.

The Prospectus has been prepared in connection with the proposed admission to trading on Euronext Paris SA and Euronext Growth of Euronext Dublin ("**Admission**") of 4,649,775 new ordinary shares of €0.001 each in the capital of the Company (the "**New Ordinary Shares**") which will be registered with International Securities Identification Number ("**ISIN**") IE00BJYS1G50. The Company's LEI code is 635400IUPSOZ26H56Y03, its registered office is located at 77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, Dublin 2, D02 T804 and the telephone number is +353 (1) 553 0217.

1.2 Warnings

THIS SUMMARY SHOULD BE READ AS AN INTRODUCTION TO THE PROSPECTUS. ANY DECISION TO INVEST IN THE ORDINARY SHARES OF THE COMPANY SHOULD BE BASED ON CONSIDERATION OF THE PROSPECTUS AND ANY DOCUMENTS INCORPORATED BY REFERENCE AS A WHOLE BY THE INVESTOR, INCLUDING IN PARTICULAR THE RISK FACTORS. THE INVESTOR COULD LOSE ALL OR PART OF THEIR INVESTED CAPITAL.

Where a claim relating to the information contained in the Prospectus is brought before a court, the plaintiff investor might, under the national legislation of the member states of the European Union, have to bear the costs of translating this Prospectus before the legal proceedings are initiated.

Civil liability attaches only to those persons who have tabled the Summary, including any translation thereof, but only if the Summary is misleading, inaccurate or inconsistent when read together with the other parts of the Prospectus or it does not provide, when read together with other parts of the Prospectus, key information in order to aid investors when considering whether to invest in such securities.

2. Key Information on the Issuer

2.1 Who is the issuer of the securities?

(a) The Company is incorporated in Ireland with registered number 539688 and is a public limited company registered under the Companies Act 2014 of Ireland. The Company's registered office is located at 77 Sir John Rogerson's Quay, Block C, Grand Canal Docklands, Dublin 2, D02 VK60. The Company's LEI code is 635400IUPSOZ26H56Y03.

(b) **Principal Activities -** We are focused on the development and commercialisation of our only product, ReActiv8, an active implantable medical device ("**AIMD**") designed to treat people with Chronic Low Back Pain ("**CLBP**"). Low Back Pain is the number one cause of years lived with disability worldwide and is a leading cause of activity limitation and work absence throughout much of the world, imposing a high

economic burden on individuals, families, communities, industry, and governments. In approximately 7% of all cases of Low Back Pain, the pain persists for more than three months thus meeting the definition of chronic.

The term "Chronic Low Back Pain" embraces a constellation of conditions and a range of severity from mild to disabling. We estimate that approximately 1-6% of the population has disabling CLBP. Of those, only approximately 15% have a form of CLBP that is suitable for surgical correction.[1]

We are focused on clinical development, regulatory approval and commercialisation. We have defined the pathway from ReActiv8 product development to revenue growth with four key elements as discussed below.

(i) Obtain regulatory approval in order to allow commercialisation

CE Marking was obtained in May 2016 allowing the start of commercialisation in the EU. Our European commercial activities for ReActiv8 are initially focused on commercial validation 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.

Approval to enter the U.S. market is via a Pre-Market Approval ("**PMA**") from the US Food and Drug Administration ("**FDA**"). We conducted the U.S. Pivotal ReActiv8-B Clinical Trial under an Investigational Device Exemption ("**IDE**") from the FDA to gather information for the PMA application. The Company held a pre-PMA meeting with the FDA on 25 June 2019 and submitted the final module of the PMA application to the FDA relating to ReActiv8 in August 2019.

(ii) Leverage existing reimbursement and expand coverage

To our knowledge, hospitals in Germany are today using existing stationary (inpatient) reimbursement codes and associated tariffs for reimbursement payments related to ReActiv8. In addition, based on our review of the reimbursement climate (both internally and with external consultants), we believe hospitals in Switzerland and Austria can also use similar existing inpatient reimbursement codes for ReActiv8. We intend to gather data on cost effectiveness of ReActiv8 to support reimbursement in other target markets.

(iii) Drive adoption of ReActiv8 in routine clinical practice

We continue to support the presentation of ReActiv8 and the results from past, present and future Clinical Trials of ReActiv8 by clinicians at scientific meetings. We also continue to support the publication of results of Clinical Trials of ReActiv8 in peer reviewed journals, and the growing body of evidence will help to drive adoption of ReActiv8 in routine clinical practice. In addition, we may support or sponsor regional or local meetings to drive awareness of ReActiv8 in the physician groups who see people with CLBP, with the objective of driving referrals to physicians who offer ReActiv8.

(iv) Drive broader awareness of ReActiv8

[1] Deyo, R. A. & Weinstein, J. N. Low Back Pain. NEJM 344, 363–370 (2001).

We continue to seek and take advantage of opportunities to tell the ReActiv8 story in popular press, and other media (within the regulatory constraints of a medical device or an investigational device). Our objective is to drive awareness and education around the causes of CLBP, the role of the multifidus in spine stability, and the identification of patients who are likely to benefit from ReActiv8 amongst physicians and the broader healthcare community. We intend to target markets we deem most important first, determined by market size and availability of reimbursement.

(c) **Major shareholders –** As of 23 October 2019 (the "**Latest Practicable Date**"), the Company is not aware of any other person, who, directly or indirectly, jointly or severally, exercises or could exercise control over the Company nor is it aware of any arrangements the operation of which may at a subsequent date result in a change in control over the Company. In so far as is known to the Company, the following persons had an interest which represented three per cent. or more of the issued ordinary share capital of the Company:

	Immediately prior to the 2019 Placing		*As at the Latest Practicable Date*	
Name	*Number of issued Ordinary Shares*	*Percentage of issued ordinary share capital*	*Number of issued Ordinary Shares* (2)	*Percentage of issued ordinary share capital*
Sofinnova Capital VI FCPR	2,415,813	27.5%	2,949,146	22.0%
KCK Limited	1,582,418	18.0%	2,236,418	16.7%
Fountain Healthcare Partners (1)	935,220	10.7%	2,268,333	16.9%
ISIF	714,285	8.1%	714,285	5.3%
Dan Sachs, MD	515,000	5.9%	515,000	3.8%
Seamus Mulligan (3)	372,039	4.2%	772,039	5.8%
RICA Universal, S.A.	64,935	0.7%	1,064,935	7.9%

Notes:

(1) Fountain Healthcare Partners Fund 1, L.P holds 935,000 Ordinary Shares and Fountain Healthcare Partners Fund 3, L.P. holds 1,333,333 Ordinary Shares. Fountain Healthcare Partners Fund 1, L.P. also holds 40,000 Deferred Shares.

(2) Numbers include the following numbers of New Ordinary Shares subscribed for under the 2019 Placing: (i) Sofinnova Capital VI FCPR: 533,333 New Ordinary Shares (ii) KCK Limited: 654,000 New Ordinary Shares (iii) Fountain Healthcare Partners Fund 3, L.P: 1,333,333 New Ordinary Shares and (iv) Nerano Capital Limited (a company controlled by Seamus Mulligan): 400,000 New Ordinary Shares.

(3) Includes Ordinary Shares held by Barrymore Investments Limited and Nerano Capital Limited (both companies controlled by Seamus Mulligan).

(d) The board of directors of the Company comprises: Oern Stuge MD (Chairman), Jason Hannon (Chief Executive Officer), David Brabazon, Greg Garfield, Antoine Papiernik, James Reinstein and Dan Sachs MD.

(e) The statutory auditors of the Company are KPMG. The nominated representative from KPMG is Sean O'Keefe.

2.2 What is the key financial information regarding the issuer?

The summary historical financial information presented below as at and for the years ended 31 December 2018, 2017 and 2016 has been extracted without material adjustment from the Group's Historical Financial Information, set out in the Group's summary financial information for the years ended 31 December 2018, 2017 and 2016 and has been audited by KPMG. The summary historical financial information presented below as at and for the half years ended 30 June 2019 and 2018 has been extracted without material adjustment from the Group's unaudited condensed consolidated financial statements for the half years ended 30 June 2019 and 2018.

Income statement for the Group:

($'000)	**Year ended 31 December 2018**	**Year ended 31 December 2017**	**Year ended 31 December 2016**	**Half year ended 30 June 2019**	**Half year ended 30 June 2018**
Revenue	663	348	-	552	358
Operating loss	(29,285)	(27,719)	(16,828)	(8,323)	(15,661)
Net Loss for the year	**(31,077)**	**(29,835)**	**(18,758)**	**(11,146)**	**(16,523)**

Balance Sheet for the Group:

($'000)	**31 December 2018**	**31 December 2017**	**31 December 2016**	**30 June 2019**	**30 June 2018**
Total assets	19,381	13,347	39,040	9,745	33,582
Total equity	3,284	(5,821)	21,058	(3,851)	15,610

Cash flow statement for the Group:

($'000)	**Year ended 31 December 2018**	**Year ended 31 December 2017**	**Year ended 31 December 2016**	**30 June 2019**	**30 June 2018**
Net cash from operating activities, investing activities and financing activities	15,545	9,975	36,670	5,806	29,711

KPMG's report in respect of the Historical Financial Information was unqualified. In forming its opinion KPMG considered the fact that the Group intended to seek additional equity and debt finance in 2019 to fund its future operations. That the receipt of such funding could not be certain as of the date of approval of the financial statements for the year ended 31 December 2018 represented a material uncertainty that could cast doubt on the Group's ability to continue as a going concern. However, on 29 July 2019 the Company completed the 2019 Placing, raising gross proceeds of €13.9 million and announced the drawdown of €3 million in additional debt from the new tranche of the existing debt facility. As a result the Company believes that the material uncertainty around receipt of future funding at the time of approval of the financial statements no longer exists and that there is no doubt regarding the Group's ability to continue as a going concern.

2.3 What are the key risks that are specific to the issuer?

The key risks specific to the Company include the following:

(a) We have incurred significant operating losses and may not be able to achieve or subsequently maintain profitability.

(b) We expect to require additional funds in the future in order to meet our capital and expenditure needs and further financing may not be available when required or, if available, could require us to agree to terms which are specifically favourable to new investors, or to restrictions significantly limiting our access to additional capital.

(c) Our future financial performance is entirely dependent on the commercial success of ReActiv8, our only product as of the date of this document, obtaining adequate reimbursement for ReActiv8, and rates of product adoption and market penetration.

(d) Failure to comply with debt covenants or failure to make repayments on our debt facility could have a material adverse effect.

(e) We operate in a highly regulated environment and regulatory approval is required before we can market or sell ReActiv8 in any market.

(f) Seeking and obtaining regulatory approval for medical devices can be a long and uncertain process. Strict or changing regulatory regimes, government policies and legislation in any of our target markets may delay, prohibit or reduce potential sales.

(g) We are required to conduct Clinical Trials for regulatory approvals and other purposes. Clinical Trials carry substantial risks and are costly and time consuming, with uncertain result.

(h) Any inability to fully protect and exploit our intellectual property may adversely impact our financial condition, business, prospects and results of operations.

3. Key Information on the Securities

3.1 What are the main features of the securities?

(a) **The New Ordinary Shares -** The Company issued 4,649,775 Ordinary Shares pursuant to the 2019 Placing. As at the Latest Practicable Date there are in issue 13,421,504 Ordinary Shares **of** €0.001 each and 40,000 Deferred Shares of €1.00 each, all of which are fully paid.

When admitted to trading, the New Ordinary Shares will be registered with ISIN number IE00BJYS1G50, SEDOL number BJYS1G5 and will trade under the symbol MSTY. The New Ordinary Shares are denominated in Euro and have a nominal value of €0.001 each.

(b) **Rights attaching to the New Ordinary Shares -** The New Ordinary Shares, were issued fully paid and rank pari passu in all respects with the existing issued Ordinary Shares, except that the New Ordinary Shares will not be listed or traded on Euronext Paris and Euronext Growth until Admission occurs, which is expected to occur on 31 October 2019.

The Ordinary Shares have the following rights:

(i) the right to attend, speak and vote at any general meeting of the Company;

(ii) the right to participate pro rata in all dividends declared by the Company; and

(iii) the right, in the event of winding up, to participate pro rata in the total assets of the Company, subject to the rights of the holders of any Deferred Shares, as described in the following sub-paragraph.

(c) **The relative seniority of the New Ordinary Shares in the Company's capital structure in the event of insolvency**

On a return of assets on a winding up of the Company, the holders of the Deferred Shares shall only be entitled to repayment of the amounts paid up on those shares after the holders of the Ordinary Shares have received the sum of €1,000,000 for each Ordinary Share held by them and shall not be entitled to any further participation in the assets and profits of the Company. Subject to the preceding sentence, if the Company shall be wound up and the assets available for distribution among the members as such shall be insufficient to repay the whole of the paid up share capital, such assets shall be distributed so that, as nearly as may be, the losses shall be borne by the members in proportion to the capital paid up at the commencement of the winding up on the shares held by them respectively; and if in a winding up the assets available for distribution among the members shall be more than sufficient to repay the whole of the share capital paid up at the commencement of the winding up, the excess shall be distributed among the members in proportion to the capital at the commencement of the winding up paid up on the shares held by them respectively.

(d) **Restrictions on the free transferability of the New Ordinary Shares -** The New Ordinary Shares are freely transferable, other than selling and transfer restrictions applicable under the relevant laws of certain jurisdictions applicable to the transferor or transferee, including in the United States.

(e) **Dividend policy -** The Company has never declared or paid any cash dividends on its Ordinary Shares and does not currently intend to do so for the foreseeable future. The Company currently intends to invest its future earnings, if any, to fund its growth.

3.2 Where will the securities be traded?

Applications have been made to Euronext Paris SA and Euronext Dublin for Admission of the New Ordinary Shares. Dealings in the New Ordinary Shares are expected to commence on Euronext Paris and Euronext Growth at 8.00 a.m. Irish Standard Time (9.00 a.m. CET) on 31 October 2019. No application has been, or is currently intended to be, made for the New Ordinary Shares to be admitted to listing or trading on any other stock exchange.

3.3 What are the key risks that are specific to the securities?

The risks relating to the Ordinary Shares (including the New Ordinary Shares) include the following:

- Future issuances of Ordinary Shares or exercise of warrants or options over Ordinary Shares may affect the market price of the Ordinary Shares and could dilute the interests of existing Shareholders
- We may be a passive foreign investment company for 2019 or subsequent years, which could result in adverse U.S. federal income tax consequences to U.S. investors.
- Our Ordinary Share ownership is concentrated in the hands of our principal shareholders, who may be able to exercise a direct or indirect controlling influence on us.
- We do not currently intend to pay dividends, and, consequently, the ability to achieve a return on investment will depend on appreciation in the price of the Ordinary Shares.

4. Key Information on the Admission to Trading on a Regulated Market

4.1 Under which conditions and timetable can I invest in this security?

This document does not constitute an offer or invitation to any person to subscribe for or purchase any shares in the Company.

The Company issued 4,649,775 New Ordinary Shares pursuant to the 2019 Placing. Dealings in the New Ordinary Shares are expected to commence on Euronext Paris and Euronext Growth at 8.00 a.m. Irish Standard Time (9.00 a.m. CET) on 31 October 2019.

The New Ordinary Shares represented an increase of approximately 53.0% from the Company's issued ordinary share capital immediately prior to the 2019 Placing.

There were total expenses and fees of €0.45 million relating to the 2019 Placing and Admission. Investors in the 2019 Placing were not charged any fees or commissions.

4.2 Why is this prospectus being produced?

The Prospectus has been prepared to effect Admission of the New Ordinary Shares.

(a) **The use and estimated net amount of the proceeds**

The Company has used, and intends to continue to use, the net proceeds from the 2019 Placing to:

- to further its application for pre-market approval from the US Food and Drug Administration ("**FDA**") in the United States;
- to continue to advance the initial commercial validation of ReActiv8 in Germany and additional markets; and
- for general corporate purposes,

The gross proceeds of the 2019 Placing were approximately €13.9 million and the net proceeds of the 2019 Placing, after deduction of fees and expenses of €0.45 million relating to the 2019 Placing and Admission, were approximately €13.45 million.

(b) **Conflicts of interest**

Under the 2019 Placing, Sofinnova Partners, Fountain Healthcare Partners and KCK (who are considered substantial shareholders of the Company under the Euronext Growth Rules) subscribed for 533,333, 1,333,333 and 654,000 of the New Ordinary Shares respectively. Their participation in the 2019 Placing constituted related party transactions under Rule 5.18 of the Euronext Growth Rules. The Directors (with the exception of Antoine Papiernik, Nael Karim Kassar and Greg Garfield), considered, having consulted with Davy, the Company's Euronext Growth Adviser, that the terms of their participation in the 2019 Placing were fair and reasonable insofar as the Company's shareholders were concerned.

David Brabazon, a Director, also participated in the 2019 Placing, subscribing for 155,000 New Ordinary Shares. As at the Latest Practicable Date, David Brabazon holds 212,828 Ordinary Shares, representing 1.6% of the issued ordinary share capital of the Company.