

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **January 28, 2016**



**LivaNova PLC**

(Exact Name of Registrant as Specified in its Charter)

**England and Wales**  
(State or Other Jurisdiction  
of Incorporation)

**333-203510**  
(Commission  
File Number)

**N/A**  
(IRS Employer  
Identification No.)

**5 Merchant Square  
North Wharf Road  
London, W2 1AY  
United Kingdom**

(Address of Principal Executive Offices)

**+44 20 37865275**  
(Registrant's Telephone Number, Including Area Code)

**N/A**  
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 8.01      Other Events.**

On January 28, 2016, LivaNova PLC (the "Company") announced the Company received approval of its new generation of full body MRI (Magnetic Resonance Imaging) conditional pacemakers by PMDA in Japan. KORA 250 SR and DR pacemakers allow patients to undergo MRI scans on any region of the body. The approval is effective immediately, and, in collaboration with the Company's established business partner, Japan Lifeline, will begin commercial distribution of the device in Japan over the coming quarter.

A copy of the Company's press release dated January 28, 2016 announcing PDMA approval of its new generation of full body MRI conditional pacemakers, KORA 250 SR and DR, is included in this filing as Exhibit 99.1.

**Item 9.01      Financial Statements and Exhibits.**

(d)      Exhibits.

Exhibit 99.1      Press Release issued by LivaNova PLC dated January 28, 2016

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## SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

LivaNova PLC

Date: January 28, 2016

By: /s/ Brian Sheridan  
Name: Brian Sheridan  
Title Company Secretary

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## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by LivaNova PLC dated January 28, 2016



PRESS RELEASE

## LIVANOVA RECEIVES REGULATORY APPROVAL IN JAPAN FOR KORA 250

### WORLD'S SMALLEST FULL BODY MRI CONDITIONAL PACING SYSTEM

WITH ITS UNIQUE COMBINATION OF SMALL SIZE, EXTENDED LONGEVITY, AND PROPRIETARY TECHNOLOGIES DESIGNED TO IMPROVE PATIENT OUTCOMES, KORA 250 ENABLES PATIENTS TO UNDERGO FULL BODY MRI SCANS

LONDON, January 28, 2016 – LivaNova, PLC (NASDAQ:LIVN; LSE:LIVN) (the "Company"), a leading global medical technology company, announced today the approval of its new generation of full body MRI (Magnetic Resonance Imaging) conditional pacemakers by PMDA in Japan. KORA 250 SR and DR pacemakers allow patients to undergo MRI scans on any region of the body.

KORA 250 also features the unique Automatic MRI Mode which makes MRI scans safe for pacemaker patients, automatically detecting the MRI scanner's magnetic field and ensuring appropriate pacemaker operation during the scan. After the scan, the device automatically returns to its initial configuration<sup>1</sup>. As a result, unlike other pacing systems, KORA 250 minimizes the amount of time that patients experience MRI mode.

Designed to proactively manage co-morbidities, KORA 250, at only 8cc, offers advanced therapeutic and diagnostic features including:

**SafeR**, the only algorithm proven to safely reduce unnecessary right ventricular pacing for patients with Atrio-Ventricular block as well as Sinus Node Disease<sup>2</sup>, while extending longevity by 2 years<sup>3</sup>. SafeR has also been shown to reduce the risk of heart failure and cardiac hospitalization by 51% and the risk of the first onset of atrial fibrillation by 23%<sup>4</sup>.

**Sleep Apnea Monitoring (SAM)**, a clinically validated tool to efficiently screen and monitor patients for severe sleep apnea<sup>5</sup>. Recent studies have highlighted the risks of sleep apnea, a significant co-morbidity associated with atrial fibrillation and heart failure<sup>6,7,8</sup>.

"In collaboration with our established business partner, Japan Lifeline, we are proud to launch our latest generation of full-body MRI conditional pacemakers in Japan where there is a strong demand for MRI compatible medical devices. KORA 250, with its combination of small size, extended longevity and therapeutic solutions, is an ideal solution for Japanese patients and physicians. With this latest launch, LivaNova is aiming to set a new standard in pacing technology in the Japanese market." said Stefano Di Lullo, President, CRM Business Unit.

<sup>1</sup> KORA 250 MRI solutions manual (U641 KORA 250) available at [www.sorinmanuals.com](http://www.sorinmanuals.com)

<sup>2</sup> Stockburger M et al. Longterm clinical effects of ventricular pacing reduction with a changeover mode to minimize ventricular pacing in general population (ANSWER study). Eur Heart J.2015; 36 (3): 151-157.

<sup>3</sup> Stockburger M et al. Safety and efficiency of ventricular pacing prevention with an A AI-DDD changeover mode in patients with sinus node disease or atrioventricular block: impact on battery longevity-a sub-study of the ANSWER trial. Europace, 2015.

<sup>4</sup> Boveda S et al. Minimized ventricular pacing to prevent the first onset of AF in pacemaker patients without atrial arrhythmia history: results from the ANSWER study, Europace Abstracts Supplement. ( 2015 ) 17 ( Supplement 3 ), iii24

<sup>5</sup> Defaye P et al. A pacemaker transthoracic impedance sensor with an advanced algorithm to identify severe sleep apnea: The DREAM European study. Heart Rhythm. 2014; 11: 842-8.

<sup>6</sup> Lee W et al. Epidemiology of Obstructive Sleep Apnea: a Population-based Perspective. Expert Rev Respir Med. 2008; 2(3): 349–364.

<sup>7</sup> Gottlieb DJ et al. Prospective study of obstructive sleep apnea and incident coronary heart disease and heart failure: the sleep heart health study. Circulation. 2010; 122(4): 352-60.

<sup>8</sup> Mehra R et al. Association of nocturnal arrhythmias with sleep-disordered breathing: The Sleep Heart Health Study. Am J Respir Crit Care Med. 2006; 173(8): 910-6.

## About LivaNova

LivaNova PLC, headquartered in London, UK, is a global medical technology company formed by the merger of Sorin S.p.A, a leader in the treatment of cardiovascular diseases, and Cyberonics Inc., a medical device company with core expertise in neuromodulation. LivaNova aims to transform medical innovation into meaningful solutions for the benefit of patients, healthcare professionals, and healthcare systems. The company employs approximately 4,500 employees worldwide. With a presence in more than 100 countries, LivaNova operates as three business units: Cardiac Rhythm Management, Cardiac Surgery, and Neuromodulation, with operating headquarters in Clamart (France), Mirandola (Italy) and Houston (U.S.A.), respectively.

LivaNova is listed on the NASDAQ stock exchange and London Stock Exchange (LSE), under the ticker symbol "LIVN."

## Safe harbor statement

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. These statements can be identified by the use of forward-looking terminology, including "may," "believe," "will," "expect," "anticipate," "estimate," "plan," "intend," "forecast," or other similar words. Statements contained in this press release are based on information presently available to LivaNova and assumptions that the parties believe to be reasonable. LivaNova is not assuming any duty to update this information if those facts change or if the assumptions are no longer believed to be reasonable. Investors are cautioned that all such statements involve risks and uncertainties, including without limitation, statements concerning developing novel opportunities in heart failure, sleep apnea and percutaneous mitral valve, creating new innovative solutions that benefit patients, healthcare professionals, and healthcare systems, and building significant shareholder value. Important factors that may cause actual results to differ include, but are not limited to: risks that the new businesses will not be integrated successfully or that the combined companies will not realize estimated cost savings, value of certain tax assets, synergies and growth, or that such benefits may take longer to realize than expected; the inability of LivaNova to meet expectations regarding the timing, completion and accounting and tax treatments; risks relating to unanticipated costs of integration, including operating costs, customer loss or business disruption being greater than expected; reductions in customer spending, a slowdown in customer payments and changes in customer demand for products and services; unanticipated changes relating to competitive factors in the industries in which the company operates; the ability to hire and retain key personnel; the ability to attract new customers and retain existing customers in the manner anticipated; reliance on and integration of information technology systems; changes in legislation or governmental regulations affecting the company; international, national or local economic, social or political conditions that could adversely affect the company or its customers; conditions in the credit markets; risks to the industries in which LivaNova operates that are described in the "Risk Factors" section of the Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and other documents filed from time to time with the SEC by Cyberonics, Inc. and LivaNova and the analogous section in annual reports and other documents filed from time to time by Sorin S.p.A. with the Italian financial market regulator (CONSOB); risks associated with assumptions made in connection with critical accounting estimates and legal proceedings; LivaNova's international operations, which are subject to the risks of currency fluctuations and foreign exchange controls; and the potential of international unrest, economic downturn or effects of currencies, tax assessments, tax adjustments, anticipated tax rates, raw material costs or availability, benefit or retirement plan costs, or other regulatory compliance costs. The foregoing list of factors is not exhaustive. You should carefully consider the foregoing factors and the other risks and uncertainties that affect the parties' businesses, including those described in Cyberonics' Annual Report on Form 10-K, as amended from time to time, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other documents filed from time to time with the SEC by Cyberonics and LivaNova and those described in Sorin's annual reports, registration documents and other documents filed from time to time with CONSOB by Sorin. LivaNova does not give any assurance (1) that LivaNova will achieve its expectations, or (2) concerning any result or the timing thereof, in each case, with respect to any regulatory action, administrative proceedings, government investigations, litigation, warning letters, consent decree, cost reductions, business strategies, earnings or revenue trends or future financial results.

For more information, please visit [www.livanova.com](http://www.livanova.com), or contact:

### Investor Relations:

**Vivid Sehgal**

Chief Financial Officer

e-mail: [investor.relations@livanova.com](mailto:investor.relations@livanova.com)

### Investor Relations and Media:

**Greg Browne**

Senior Vice President, Finance

Phone: +1 (281) 228-7262

Fax: +1 (281) 218-9332

e-mail: [corporate.communications@livanova.com](mailto:corporate.communications@livanova.com)

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