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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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

**Date of Report (Date of earliest event reported): February 15, 2019**

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**LivaNova PLC**

(Exact Name of Registrant as Specified in its Charter)

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

**001-37599**  
(Commission  
File Number)

**98-1268150**  
(IRS Employer  
Identification No.)

**20 Eastbourne Terrace  
London, W2 6LG  
United Kingdom**  
(Address of Principal Executive Offices)

**+44 20 33250660**  
(Registrant's Telephone Number, Including Area Code)

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

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Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- ☐ 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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**Item 8.01 Other Events**

On February 15, 2019, LivaNova PLC (the “Company”) issued a press release announcing that the Centers for Medicare & Medicaid Services issued a Final Decision Memo regarding its National Coverage Determination for the Company’s Vagus Nerve Stimulation Therapy® System for Treatment-Resistant Depression. A copy of the press release is filed as Exhibit 99.1 to this Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits.

Exhibit	Description
99.1	<a href="#"><u>Press Release Issued by LivaNova PLC dated February 15, 2019.</u></a>

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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: February 15, 2019

By: /s/ Catherine Moroz

Name: Catherine Moroz

Title: Company Secretary



NEWS RELEASE

**LivaNova Recognizes Final Decision from the  
U.S. Centers for Medicare & Medicaid Services Regarding  
National Coverage Determination for  
VNS Therapy for Treatment-Resistant Depression**

*Company plans to submit clinical study protocol for CMS consideration*

**London, February 15, 2019** – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology company, today recognized that the U.S. Centers for Medicare & Medicaid Services (CMS) finalized its National Coverage Determination (NCD) for the LivaNova Vagus Nerve Stimulation Therapy® (VNS Therapy) System for Treatment-Resistant Depression (TRD). Per its final decision, CMS has modified the NCD for VNS Therapy for TRD to include feedback received during the comment period in a manner that aligns the Coverage with Evidence Development (CED) framework with current indications and standard of practice for clinical study design in this disease state. This final decision initiates coverage for Medicare beneficiaries through CED when offered in a CMS-approved, double-blind, randomized, placebo-controlled trial with a follow-up duration of at least one year, as well as the coverage of VNS Therapy device replacement. The CED also includes the possibility to extend the study to a prospective longitudinal study.

“As part of our commitment to improving the lives of patients around the world, LivaNova requested that CMS formally reconsider coverage for VNS Therapy for Treatment-Resistant Depression,” said Damien McDonald, Chief Executive Officer of LivaNova. “We applaud CMS for taking this considerable step to provide increased access to treatment through Coverage with Evidence Development. We are pleased that CMS has expanded the potential beneficiaries of this therapy by including patients with bipolar disorder, an important and underserved patient population. Further, CMS expanded its research questions to include response to treatment, providing a much better gauge of benefit in this very ill patient population. Overall, this decision will help the large number of people who suffer from TRD receive access to an affordable, potentially life-altering treatment option.”

In October 2017, LivaNova submitted a letter to CMS requesting a formal reconsideration of the NCD for VNS Therapy for TRD. In May 2018, CMS accepted the request and published a tracking sheet to initiate a national coverage analysis and opened a public comment period, marking the first time CMS had opened the NCD in 10 years. In November 2018, CMS released a Proposed Decision Memo proposing to cover VNS devices that are approved by the U.S. Food and Drug Administration for TRD through CED. After another public comment period, CMS issued its Final Decision Memo today.

“Not only does the science support that VNS for TRD works, but we have seen first-hand the profound impact it has on the lives of patients,” said Dr. Charles R. Conway, Director of the Washington University Center for Advancement of Research in Resistant Mood and Affective Disorders. “We have implanted more than 80 TRD

patients with VNS devices, many of whom were on Medicare disability and completely incapacitated by their depressive illness, oftentimes for years or decades. With VNS treatment, we have seen them go on to lead productive lives, in most cases, the effects of the treatment are sustained—unlike most antidepressant treatments in TRD. This treatment is highly effective and significantly changes, and may even save, lives.”

LivaNova intends to submit a clinical study protocol to CMS for consideration and to be conducted in accordance with the agency’s NCD. Dr. Conway will serve as Principal Investigator for the study. Enrollment will likely begin in third quarter 2019, and could take as long as 18 months to enroll approximately 500 patients at a minimum of 40 sites.

“Medicare coverage for TRD patients is critical. Depression is the leading cause of disability in the U.S. Patients with TRD are often younger than the typical Medicare beneficiary and will likely become eligible for Medicare as a result of disability, not age,” said Edward Andrie, General Manager of Neuromodulation at LivaNova. “We believe that TRD is an area of high unmet medical need and an area where LivaNova can make a difference and improve the lives of patients.”

#### About LivaNova

LivaNova PLC is a global medical technology company built on nearly five decades of experience and a relentless commitment to improve the lives of patients around the world. LivaNova’s advanced technologies and breakthrough treatments provide meaningful solutions for the benefit of patients, healthcare professionals and healthcare systems. Headquartered in London, LivaNova has a presence in more than 100 countries worldwide. The Company currently employs approximately 4,000 employees. LivaNova operates as two businesses: Cardiovascular and Neuromodulation, with operating headquarters in Mirandola (Italy) and Houston (U.S.), respectively.

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

#### Safe Harbor Statement

This news release contains forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended, and Section 21E of the United States Securities Exchange Act of 1934, as amended. Forward-looking statements are not historical facts but are based on certain assumptions of management and describe LivaNova’s future plans, strategies and expectations. Forward-looking statements can generally be identified by the use of forward-looking terminology, including, but not limited to, “may,” “could,” “seek,” “guidance,” “predict,” “potential,” “likely,” “believe,” “will,” “expect,” “anticipate,” “estimate,” “plan,” “intend,” “forecast,” or variations of these terms and similar expressions, or the negative of these terms or similar expressions. Forward-looking statements contained in this news release are based on information presently available to LivaNova and assumptions that LivaNova believes to be reasonable, but are inherently uncertain. As a result, LivaNova’s actual results, performance or achievements may differ materially from those expressed or implied by these forward-looking statements, which are not guarantees of future performance or actions that may be taken by LivaNova and involve known and unknown risks, uncertainties and other factors

that are, in some cases, beyond LivaNova's control. You should carefully consider the risks and uncertainties that affect LivaNova, including those described in the "Risk Factors" section of LivaNova's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other documents filed from time to time with the United States Securities and Exchange Commission.

All information in this news release is as of the date of its release. LivaNova does not undertake or assume any obligation to update publicly any of the forward-looking statements in this news release to reflect actual results, new information or future events, changes in assumptions or changes in other factors affecting forward-looking statements, except to the extent required by applicable law. If we update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements. We caution you not to place undue reliance on any forward-looking statements, which are made only as of the date of this news release.

**LivaNova PLC Investor Relations and Media**

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