

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): November 19, 2018



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)

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 November 19, 2018, the Centers for Medicare & Medicaid Services (“CMS”) issued a Proposed Decision Memo regarding its National Coverage Determination (“NCD”) for LivaNova PLC (“LivaNova” or the “Company”) Vagus Nerve Stimulation Therapy® (“VNS Therapy”) System for Treatment-Resistant Depression (“TRD”). In the Proposed Decision Memo, CMS proposes to change the NCD for TRD to expand United States Medicare coverage. CMS proposes to cover the VNS device for TRD through Coverage with Evidence Development when offered in a CMS-approved, double-blind, randomized, placebo-controlled trial with a follow-up duration of at least one year with the possibility of extending the study to a prospective longitudinal study when the trial has completed enrollment, and there are positive interim primary endpoint findings.

Previously, on May 30, 2018, the CMS had published a tracking sheet to reconsider the NCD for LivaNova’s VNS Therapy System for TRD following LivaNova’s submission of a letter to CMS requesting a formal reconsideration of the NCD for VNS Therapy in NCD Manual Section 160.18, specifically for TRD. CMS had earlier established coverage in 1999 for VNS for patients with medically refractory partial onset seizures for whom surgery is not recommended or for whom surgery has failed, and in 2007, CMS reconsidered the NCD and determined that, at that time, there was insufficient evidence to conclude that VNS was reasonable and necessary for TRD, and VNS for TRD was therefore not covered. However, over the last decade, a significant body of new evidence has emerged showing that the addition of VNS Therapy is effective in reducing symptoms in patients with TRD.

With the release of its Proposed Decision Memo, CMS opened a 30-day public comment period. Interested parties must comment on the proposed decision memo by December 19, 2018 to be considered by CMS. All relevant information related to this process is available on the CMS website (www.cms.gov).

Following the 30-day comment period, CMS will release a final decision by February 17, 2019. The final decision will result in one of the following outcomes:

- a. CMS grants the request for NCD and assigns a temporary or permanent code (whether existing or unclassified) and implements the coding change
- b. CMS denies the request for NCD

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

<u>Exhibit</u>	<u>Description</u>
99.1	<u>Press Release issued by LivaNova PLC dated November 20, 2018</u>

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: November 20, 2018

By: /s/ Catherine Moroz

Name: Catherine Moroz

Title: Company Secretary



NEWS RELEASE

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

Final decision to be rendered by CMS in 90 days

London, November 20, 2018 – LivaNova PLC (NASDAQ:LIVN), a market-leading medical technology company, today commented on the U.S. Centers for Medicare & Medicaid Services (CMS) Proposed Decision Memo regarding its National Coverage Determination (NCD) for the LivaNova Vagus Nerve Stimulation Therapy[®] (VNS Therapy) System for Treatment-Resistant Depression (TRD).

Within the Proposed Decision Memo, CMS proposes to change the NCD for VNS Therapy for TRD to expand Medicare coverage. CMS could initiate coverage for Medicare beneficiaries through Coverage with Evidence Development (CED) when offered in a CMS-approved, double-blind, randomized, placebo-controlled trial with a follow-up duration of at least one year, with the possibility of extending the study to a prospective longitudinal study.

LivaNova intends to commence a clinical study that meets these requirements, once the NCD decision is finalized by CMS on or before Feb. 17, 2019.

LivaNova remains committed to providing additional treatment options for patients with depression and finds the Proposed Decision Memo from CMS to be a positive step toward increased access to important therapies for these patients. Over the last decade, a significant body of new evidence has emerged showing that the addition of VNS Therapy is effective in reducing symptoms in patients with chronic or recurrent depression.

With the release of its Proposed Decision Memo, CMS opened a 30-day public comment period. LivaNova encourages interested parties to comment on the proposed decision memo by Dec. 19, 2018 to be considered by CMS. All relevant information related to this process is available on the CMS website.

LivaNova looks forward to the final decision from CMS regarding Medicare coverage of VNS Therapy for TRD. This would be a positive outcome for patients and physicians.

Conference Call Instructions

The Company will host a conference call for interested parties commencing at 2 p.m. London time (9 a.m. Eastern Standard Time) on Tuesday, Nov. 20, 2018. To listen to the conference call, dial (844) 601-5111 (if dialing from within the U.S.) or (647) 253-8650 (if dialing from outside the U.S.). The conference ID is 7786437.

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.

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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