

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): May 30, 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 May 30, 2018, the Centers for Medicare & Medicaid Services (“CMS”) published a tracking sheet to reconsider the National Coverage Determination (“NCD”) for LivaNova PLC’s (“LivaNova” or the “Company”) Vagus Nerve Stimulation Therapy® (“VNS Therapy”) System for Treatment-Resistant Depression (“TRD”).

This decision by CMS follows LivaNova’s submission of a letter to CMS requesting a formal reconsideration of the NCD for VNS Therapy, NCD 160.18, specifically for TRD. 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.

The posting of the National Coverage Analysis (“NCA”) tracking sheet has opened the 30-day public comment period [\[insert hyperlink\]](#). Interested parties may comment on the NCA tracking sheet by [X p.m.](#) on [\[insert date\]](#) as CMS brings greater attention to this important public health issue.

Following the 30-day comment period and up to six months later, CMS will release a Proposed Decision Memorandum. The proposed decision could result in any of the following possibilities or variations thereof:

1. CMS may confirm its NCD
2. CMS may reverse its NCD
3. CMS may remove the national non-coverage language from its NCD and allow its local Medicare Administrative Contractors (“MACs”) to make coverage decisions
4. CMS may use a coverage with evidence development (“CED”) framework to expand coverage for patients with TRD while additional evidence is being collected

Once the Proposed Decision Memorandum is released, CMS will open another 30-day public comment period, after which, the agency will render a final decision on the NCD for VNS Therapy for TRD.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release issued by LivaNova PLC dated May 30, 2018

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by LivaNova PLC dated May 30, 2018

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: May 30, 2018

By: /s/ Catherine Moroz

Name: Catherine Moroz

Title: Company Secretary



Health innovation that matters

NEWS RELEASE

LivaNova Comments on the U.S. Centers for Medicare & Medicaid Services' Reconsideration of its National Coverage Determination for VNS Therapy for Treatment-Resistant Depression

London, May 30, 2018 – LivaNova PLC (NASDAQ:LIVN) (“LivaNova” or the “Company”), a market-leading medical technology company, today issued a statement in regard to the U.S. Centers for Medicare & Medicaid Services’ (“CMS”) publication of a tracking sheet to reconsider its National Coverage Determination (“NCD”) for the Company’s Vagus Nerve Stimulation Therapy[®] (“VNS Therapy”) System for Treatment-Resistant Depression (“TRD”):

LivaNova has been engaged with CMS on this important issue and submitted a letter to CMS requesting a formal reconsideration of the NCD for VNS Therapy for patients with TRD. The Company is encouraged that CMS has taken this initial step, which may provide access to this important therapy for TRD that has been a Medicare non-covered indication for more than a decade. A change in the Medicare coverage status of VNS Therapy for TRD that ensures adequate patient access to this important therapy would be a positive outcome for patients and physicians. The posting of the [National Coverage Analysis \(“NCA”\) tracking sheet](https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=292&TimeFrame=7&DocType=All&bc=AAAAIAAAQAAA&), <https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=292&TimeFrame=7&DocType=All&bc=AAAAIAAAQAAA&>, has opened the 30-day public comment period. Interested parties may comment on the NCA tracking sheet until June 29 as CMS brings greater attention to this important public health issue. 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. We look forward to working with CMS as they consider a change in Medicare coverage.

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 more than 3,500 employees. LivaNova operates as two business franchises: Cardiac Surgery and Neuromodulation, with operating headquarters in Mirandola (Italy) and Houston (U.S.A.), 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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