

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): February 17, 2023



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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name on each exchange on which registered
Ordinary Shares - £1.00 par value per share	LIVN	NASDAQ Global Market

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.

☐

Item 7.01. Regulation FD Disclosure

On February 17, 2023, LivaNova PLC (the “Company”) learned that the independent Statistical Analysis Committee advised that trial enrollment in the Company’s RECOVER difficult-to-treat depression trial should continue on from 450 to 475 unipolar patients, in line with the protocol. As has been previously discussed, the study was designed with frequent interim analyses, which occur every 25 patients. The interim analysis assesses if predictive probability of success has been reached for the unipolar cohort of the study, at which point the randomized controlled trial enrollment will cease and future patients will be enrolled into the prospective open label longitudinal study for that cohort. After the last patient enrolled into the RCT has completed 12 months of follow-up, a final analysis will be conducted on the complete dataset for that respective cohort. The trial, if successful, will be used to support a peer-reviewed article and reconsideration of reimbursement for VNS Therapy™ by the U.S. Centers for Medicare & Medicaid Services for the treatment of depression that is difficult to treat.

The information furnished pursuant to this Current Report on Form 8-K shall not be considered “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be incorporated by reference into any filing by the Company under the Securities Act of 1933, as amended, or under the Securities Exchange Act of 1934, as amended, unless the Company expressly sets forth by specific reference in such filing that such information is to be considered “filed” or incorporated by reference therein.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

<u>Exhibit</u>	<u>Description</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

LivaNova PLC

Date: February 17, 2023

By: /s/ Michael Hutchinson

Name: Michael Hutchinson

Title: Senior Vice President & Chief Legal Officer