

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): December 12, 2022



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 8.01 Other Events

Close-Out of FDA Warning Letter

As previously disclosed, including on our Form 10-Q for the quarter ended September 30, 2022 (the “Form 10-Q”), on December 29, 2015, the Food and Drug Administration (the “FDA”) issued a Warning Letter alleging certain violations of FDA regulations applicable to medical device manufacturers at our Munich, Germany and Arvada, Colorado facilities. We took actions to remediate the alleged violations and related inspectional observations. On December 12, 2022, the Company received a communication from the FDA, dated November 28, 2022, indicating that the FDA considers the Warning Letter closed. See “Note 10. Commitments and Contingencies” in the Notes to the Condensed Consolidated Financial Statements and Item 1A. “Risk Factors” in the Form 10-Q for additional information.

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: December 13, 2022

By: /s/ Michael Hutchinson

Name: Michael Hutchinson

Title: Senior Vice President & Chief Legal Officer