# **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): January 11, 2016 (January 8, 2016)



# LivaNova PLC

(Exact Name of Registrant as Specified in its Charter)

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

333-203510

(Commission File Number)

N/A (IRS Employer Identification No.)

**5 Merchant Square** North Wharf Road London, W2 1AY **United Kingdom** 

(Address of Principal Executive Offices)

+44 20 37865275

(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 filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 8.01 Other Events.

On January 11, 2016, LivaNova PLC (the "Company") announced that, on January 8, 2016, the Company received approval from the United States Food and Drug Administration ("FDA") for the Perceval Sutureless Heart Valve ("Perceval"). The approval is effective immediately, and the Company will begin commercial distribution of the device in the U.S. over the coming quarter.

A copy of the Company's press release dated January 11, 2016 announcing the FDA approval of the Perceval is included in this filing as Exhibit 99.1.

Item 9.01	Financial Statements and Exhibits.

(d) Exhibits.

Exhibit 99.1 Press Release issued by LivaNova PLC dated January 11, 2016

#### 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: January 11, 2016

By:	/s/ Brian Sheridan
Name:	Brian Sheridan

Title Company Secretary

<u>Exhibit No.</u>	Description
99.1	Press Release issued by LivaNova PLC dated January 11, 2016



PRESS RELEASE

### LivaNova PLC Announces Approval of Perceval

LONDON, January 11, 2016 -- LivaNova PLC (NASDAQ:LIVN) (LSE:LIVN) (the "Company") announced that, on January 8, 2016, the Company received approval from the United States Food and Drug Administration ("FDA") for the Perceval Sutureless Heart Valve ("Perceval"). The approval is effective immediately, and the Company will begin commercial distribution of the device in the U.S. over the coming quarter.

Perceval is a surgical aortic valve with a unique self-anchoring frame that enables the surgeon to replace the diseased valve without suturing it into place. The valve's functional component is made of bovine pericardium and is mounted on a super-elastic alloy frame. Clinical results in patients implanted with Perceval have shown a significant reduction in surgical procedural time for both isolated and complex aortic valve replacement with aortic cross-clamp times typically reduced by at least 50%.

"We are excited to bring this important product to the U.S. market, which will provide real value to patients and physicians," said André-Michel Ballester, Chief Executive Officer. "The rapid acceptance of Perceval in Europe, an increasing number of positive publications on the product, and the solid preparation of our U.S. sales team, all provide a strong base for the achievement of our short and long term plans," concluded Mr. Ballester.

Perceval is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves. The sale and distribution of the Perceval heart valve is limited to prescription use by specially-trained practitioners, and the Company has developed a nationwide training and proctoring program to help ensure the safety and effectiveness of the device.

#### About LivaNova

LivaNova PLC, headquartered in London, UK, is a global medical technology company formed by the merger of Sorin S.p.A, a leader in the treatment of cardiovascular diseases, and Cyberonics Inc., a medical device company with core expertise in neuromodulation. LivaNova transforms medical innovation into meaningful solutions for the benefit of patients, healthcare professionals, and healthcare systems. The company employs approximately 4,500 employees worldwide. With a presence in more than 100 countries, LivaNova operates as three business units: Cardiac Rhythm Management, Cardiac Surgery, and Neuromodulation, with operating headquarters in Clamart (France), Mirandola (Italy) and Houston (U.S.A.), respectively.

LivaNova is listed on NASDAQ and listed on the Official List of the UK's Financial Conduct Authority and traded on London Stock Exchange (LSE) under the ticker symbol "LIVN".

For more information, please visit <u>www.livanova.com</u>, or contact:

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