Statement Regarding a Warning Letter Received from the FDA

January 5, 2016 2:21 PM ET

London, January 5, 2016 - On December 31, 2015, LivaNova PLC (NASDAQ, LSE: LIVN, "LivaNova" or the "Company") received a Warning Letter dated December 29, 2015, from the United States Food and Drug Administration ("FDA") alleging certain violations of FDA regulations applicable to medical device manufacturers at its Munich, Germany and Arvada, Colorado facilities.

The Company currently believes that less than 1 percent of 2016 consolidated sales could be impacted by this Warning Letter, and that FDA's concerns can be resolved without a material impact on the Company's financial results. Further meetings are planned with FDA in order to clarify certain aspects of the Warning Letter.

FDA inspected the Company's Munich facility from August 24, 2015, to August 27, 2015, and its Arvada facility from August 24, 2015, to September 1, 2015. On August 27, 2015, FDA issued a Form 483 identifying two observed non-conformities with certain regulatory requirements at the Munich facility. The Company did not receive a Form 483 in connection with FDA's inspection of the Arvada facility.

Following the receipt of the Form 483, the Company provided written responses to FDA describing corrective and preventive actions that were underway or to be taken to address FDA's observations at the Munich facility. The Warning Letter responded in part to the Company's responses and identified other alleged violations not previously included in the Form 483. The Company will continue to work diligently to remediate FDA's inspectional observations for the Munich facility as well as the additional issues identified in the Warning Letter. The Company takes these matters seriously and intends to respond timely and fully to FDA's requests.

The Warning Letter states that the 3T Heater Cooler devices, and other devices manufactured by the Company's Munich facility, are subject to refusal of admission into the United States until resolution of the issues set forth in the Warning Letter. FDA has informed the Company that the import alert is, at the present time, limited to the 3T Heater Cooler devices but that the agency reserves the right to expand the scope of the import alert if future circumstances warrant such action. The Warning Letter did not request that existing users cease using the 3T Heater Cooler device, and to help clarify the Warning Letter, the Company has issued an informational Customer Letter. The Company is working constructively with FDA to reduce the impact of this decision on existing U. S. customers of 3T Heater Cooler devices, and the Company will promptly communicate to its customers and users of the 3T Heater Cooler any updates agreed upon with FDA in this regard. Manufacturing and shipment of all of the Company's products other than the 3T Heater Cooler are unaffected by this limitation at the present time and will continue as normal.

Lastly, while the Warning Letter states that premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected, the Company notes that this Warning Letter only specifically names the Munich and Arvada facilities, which do not manufacture or design devices subject to premarket approval.

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”.

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