

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2016

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-37599

LivaNova

LivaNova PLC

(Exact name of registrant as specified in its charter)

England and Wales

*(State or other jurisdiction of
incorporation or organization)*

5 Merchant Square, North Wharf Road
London, United Kingdom

(Address of principal executive offices)

(44) 203 786 5275

Registrant's telephone number, including area code:

98-1268150

*(I.R.S. Employer
Identification No.)*

W2 1AY

(Zip Code)

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

Ordinary Shares — £1.00 par value per share

Title of Each Class of Stock

The NASDAQ Stock Market LLC and the London Stock Exchange

Name of Each Exchange on Which Registered

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company) Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

Class

Ordinary Shares - £1.00 par value per share

Outstanding at October 28, 2016

48,774,669

EXPLANATORY NOTE

LivaNova PLC, a public limited company organized under the laws of England and Wales (“LivaNova”) was formed on February 20, 2015, for the purpose of facilitating the business combination of Cyberonics, Inc., a Delaware corporation (“Cyberonics”), and Sorin S.p.A., a joint stock company organized under the laws of Italy (“Sorin”). On October 19, 2015, as further described herein, LivaNova became the holding company of the combined businesses of Cyberonics and Sorin, and LivaNova’s ordinary shares were listed for trading on the NASDAQ Global Market and admitted to listing on the standard segment of the United Kingdom Financial Conduct Authority’s Official List and to trading on the Main Market of the London Stock Exchange under the trading symbol “LIVN.” In this Quarterly Report on Form 10-Q, in accordance with generally accepted accounting principles in the United States, we are reporting the consolidated results of LivaNova for the quarterly period July 1, 2016 to September 30, 2016 and the year-to-date period January 1, 2016 to September 30, 2016. LivaNova, as the successor company to Cyberonics is utilizing as a comparative prior reporting period the historical results for Cyberonics and its consolidated subsidiaries for the transitional and final quarterly period July 25, 2015 to October 18, 2015 and for the transitional and final year-to-date period January 24, 2015 to October 18, 2015. These periods are equivalent to twelve weeks and thirty-eight weeks as compared to the normal Cyberonics’ thirteen and thirty-nine weeks and are considered transitional because on October 19, 2015 LivaNova became the successor organization to Cyberonics and has a fiscal year ending December 31. The period October 19, 2015 to December 31, 2015 represents post-Merger activity of Cyberonics and Sorin combined and the activity during this period was reported in the 10-KT for LivaNova for the period April 25, 2015 to December 31, 2015.

LIVANOVA PLC
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In this Quarterly Report on Form 10-Q, "LivaNova," "the Company," "we," "us" and "our" refer to LivaNova PLC and its consolidated subsidiaries.

This report may contain references to our proprietary intellectual property, including among others:

- Trademarks for our VNS therapy systems, the VNS Therapy® System, the VITARIA™ System and our proprietary Pulse generators products: Model 102 (Pulse™), Model 102R (Pulse Duo™), Model 103 (Demipulse®), Model 104 (Demipulse Duo®), Model 105 (AspireHC®) and the Model 106 (AspireSR®).
- Trademarks for our Oxygenators product systems: Inspire™, Heartlink™ and Connect™.
- Trademarks for our line of surgical tissue and mechanical valve replacements and repair products: Mitroflow™, Crown PRT™, Solo Smart™, Perceval™, Top Hat™, Reduced Series Aortic Valves™, Carbomedics Carbo-Seal™, Carbo-Seal Valsalva™, Carbomedics Standard™, Orbis™ and Optiform™, and Mitral valve repair products: Memo 3D™, Memo 3D ReChord™, AnnuloFlo™ and AnnuloFlex™.
- Trademarks for our implantable cardiac pacemakers and associated services: REPLY 200™, ESPRIT™, KORA 100™, KORA 250™, SafeR™, the REPLY CRT-P™, the **remedé**® System.
- Trademarks for our Implantable Cardioverter Defibrillators and associated technologies: the INTENSIA™, PLATINIUM™, and PARADYM™ product families.
- Trademarks for our cardiac resynchronization therapy devices, technologies services: SonR™, SonRtip™, SonR CRT™, the INTENSIA™, PARADYM RF™, PARADYM 2™ and PLATINIUM™ product families and the Respond CRT™ clinical trial.
- Trademarks for heart failure treatment product: Equilia™.
- Trademarks for our bradycardia leads: BEFLEX™ (active fixation) and XFINE™ (passive fixation).

These trademarks and tradenames are the property of LivaNova or the property of our consolidated subsidiaries and are protected under applicable intellectual property laws. Solely for convenience, our trademarks and tradenames referred to in this Quarterly Report on Form 10-Q may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames.

“Safe Harbor” Statement under the Private Securities Litigation Reform Act of 1995

Certain statements in this Quarterly Report on Form 10-Q, other than purely historical information, are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These statements include, but are not limited to, statements about the benefits of the business combination of Sorin and Cyberonics, LivaNova’s plans, objectives, strategies, financial performance and outlook, trends, the amount and timing of future cash distributions, prospects or future events and involve known and unknown risks that are difficult to predict. As a result, our actual financial results, performance, achievements or prospects may differ materially from those expressed or implied by these forward-looking statements. In some cases, you can identify forward-looking statements by the use of words such as “may,” “could,” “seek,” “guidance,” “predict,” “potential,” “likely,” “believe,” “will,” “should,” “expect,” “anticipate,” “estimate,” “plan,” “intend,” “forecast,” “foresee” or variations of these terms and similar expressions, or the negative of these terms or similar expressions. Such forward-looking statements are necessarily based on estimates and assumptions that, while considered reasonable by LivaNova and its management based on their knowledge and understanding of the business and industry, are inherently uncertain. These statements are not guarantees of future performance, and stockholders should not place undue reliance on forward-looking statements. There are a number of risks, uncertainties and other important factors, many of which are beyond our control, that could cause our actual results to differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q, and include but are not limited to the risks and uncertainties summarized below:

Risks related to the Mergers:

- failure to effectively integrate and/or manage newly acquired businesses, and the cost, time and effort required to integrate newly acquired businesses, all of which may be greater than anticipated;
- operating costs, customer loss or business disruption (including, without limitation, difficulties in maintaining relationships with employees, customers, distributors or suppliers) being greater than expected following the Mergers;
- failure to retain certain key legacy employees of the Cyberonics or Sorin businesses; and
- changes in tax laws or interpretations that could increase our consolidated tax liabilities following the Mergers, including the risk that we could be treated as a domestic corporation for United States federal tax purposes (for further information, refer to “Note 20. Income Tax” to the consolidated financial statements accompanying this Quarterly Report on Form 10-Q).

Risks related to our business:

- changes in our common stock price;
- changes in our profitability;
- regulatory activities and announcements, including the failure to obtain regulatory approvals for our new products;
- effectiveness of our internal controls over financial reporting;
- fluctuations in future quarterly operating results;
- failure to comply with, or changes in, laws, regulations or administrative practices affecting government regulation of our products, including, but not limited to, U.S. Food and Drug Administration (“FDA”) laws and regulations;
- failure to establish, expand or maintain market acceptance of our products for the treatment of our approved indications;
- any legislative or administrative reform to the healthcare system, including the U.S. Medicare or Medicaid systems or international reimbursement systems, that significantly reduces reimbursement for our products or procedures or denies coverage for such procedures, as well as adverse decisions by administrators of such systems on coverage or reimbursement issues relating to our products;
- failure to maintain the current regulatory approvals for our products’ approved indications;
- failure to obtain or maintain insurance coverage and reimbursement for our products’ approved indications;
- unfavorable results from clinical studies;
- variations in sales and operating expenses relative to estimates;
- our dependence on certain suppliers and manufacturers to provide certain materials, components and contract services necessary for the production of our products;

- product liability, intellectual property disputes, shareholder related matters, environmental proceedings, income tax disputes, and other related losses and costs;
- protection, expiration and validity of our intellectual property;
- changes in technology, including the development of superior or alternative technology or devices by competitors;
- failure to comply with applicable U.S. domestic laws and regulations, including federal and state privacy and security laws and regulations;
- failure to comply with non-U.S. law and regulations;
- non-U.S. operational and economic risks and concerns;
- failure to attract or retain key personnel;
- losses or costs from pending or future lawsuits and governmental investigations;
- changes in accounting rules that adversely affect the characterization of our consolidated financial position, results of operations or cash flows;
- changes in customer spending patterns;
- continued volatility in the global market and worldwide economic conditions, in particular the implementation of Brexit will likely cause increased economic volatility;
- changes in tax laws, including changes due to Brexit, or exposure to additional income tax liabilities;
- harsh weather or natural disasters that interrupt our business operations or the business operations of our hospital-customers; and
- the adoption of new therapies by the market requires significant time and expense and cannot be guaranteed.
- Other factors that could cause our actual results to differ from our projected results are described in (1) “Part II, Item 1A. Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q, (2) our 2015 Form 10-KT, (3) our reports and registration statements filed and furnished from time to time with the SEC and (4) other announcements we make from time to time.

Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date hereof. We undertake no obligation to update or revise any forward-looking statements after the date they are made, whether as a result of new information, future events or otherwise. You should read the following discussion and analysis in conjunction with our unaudited consolidated financial statements and related notes included elsewhere in this report. Operating results for the three and nine months ended September 30, 2016 are not necessarily indicative of future results, including the full fiscal year. You should also refer to our “Annual Consolidated Financial Statements,” “Notes” thereto, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Risk Factors” contained in our 2015 Form 10-KT.

Financial Information and Currency of Financial Statements

All of the financial information included in this quarterly report has been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The reporting currency of our consolidated financial statements is U.S. dollars.

PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

LIVANOVA PLC AND SUBSIDIARIES'
CONDENSED CONSOLIDATED STATEMENTS OF INCOME (LOSS)
(UNAUDITED)

(In thousands, except per share amounts)

	Three Months Ended September 30, 2016	Twelve Weeks Ended October 18, 2015	Nine Months Ended September 30, 2016	Thirty-Eight Weeks Ended October 18, 2015
Net sales	\$ 295,268	\$ 67,521	\$ 903,284	\$ 222,603
Cost of sales	106,454	9,536	360,675	26,564
Gross profit	188,814	57,985	542,609	196,039
Operating expenses:				
Selling, general and administrative	107,553	41,186	343,309	104,581
Research and development	32,175	14,739	94,076	35,233
Merger and Integration expenses	7,576	27,902	20,537	43,143
Restructuring expenses	4,381	—	37,219	—
Amortization of intangibles	11,775	510	33,959	1,452
Litigation related expenses	2,369	—	4,678	—
Total operating expenses	165,829	84,337	533,778	184,409
Income (loss) from operations	22,985	(26,352)	8,831	11,630
Interest income	(585)	(39)	(1,119)	(124)
Interest expense	3,495	125	6,665	154
Impairment of investment	—	—	—	2,064
Foreign exchange and other - (gain) loss	(1,216)	109	2	1
Income (loss) before income taxes	21,291	(26,547)	3,283	9,535
Income tax (benefit) expense	9,731	(1,456)	16,891	11,693
Losses from equity method investments	13,129	—	19,382	—
Net loss	\$ (1,569)	\$ (25,091)	\$ (32,990)	\$ (2,158)
Basic loss per share	\$ (0.03)	\$ (0.96)	\$ (0.67)	\$ (0.08)
Diluted loss per share	\$ (0.03)	\$ (0.96)	\$ (0.67)	\$ (0.08)
Shares used in computing basic loss per share	49,075	26,025	49,016	26,015
Shares used in computing diluted loss per share	49,075	26,025	49,016	26,015

See accompanying notes to the condensed consolidated financial statements

LIVANOVA PLC AND SUBSIDIARIES'
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(UNAUDITED)
(In thousands)

	Three Months Ended September 30, 2016	Twelve Weeks Ended October 18, 2015	Nine Months Ended September 30, 2016	Thirty-Eight Weeks Ended October 18, 2015
Net loss	\$ (1,569)	\$ (25,091)	\$ (32,990)	\$ (2,158)
Other comprehensive income (loss):				
Net change in unrealized loss on derivatives	2,042	—	(5,224)	—
Tax effect	(673)	—	1,513	—
Net of tax	1,369	—	(3,711)	—
Foreign currency translation adjustment, net of tax	(1,805)	569	32,598	256
Total other comprehensive income (loss)	(436)	569	28,887	256
Total comprehensive loss	<u>\$ (2,005)</u>	<u>\$ (24,522)</u>	<u>\$ (4,103)</u>	<u>\$ (1,902)</u>

See accompanying notes to the condensed consolidated financial statements

LIVANOVA PLC AND SUBSIDIARIES'
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share data)

	<u>September 30, 2016</u>	<u>December 31, 2015</u>
ASSETS		
<i>Current Assets:</i>		
Cash and cash equivalents	\$ 63,632	\$ 112,613
Short-term Investments	—	6,997
Accounts receivable, net	284,345	272,352
Inventories	197,649	212,448
Prepaid taxes	49,854	42,425
Prepaid expenses and other current assets	51,850	26,579
Total Current Assets	<u>647,330</u>	<u>673,414</u>
Property, plant and equipment, net	245,120	244,587
Goodwill	731,144	745,356
Intangible assets, net	650,366	658,942
Investments	67,435	77,486
Deferred tax assets, net	6,010	153,509
Other assets	149,555	5,445
Total Assets	<u>\$ 2,496,960</u>	<u>\$ 2,558,739</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
<i>Current Liabilities:</i>		
Current debt obligations	\$ 53,617	\$ 82,513
Accounts payable	104,549	109,588
Accrued liabilities	62,046	63,047
Income taxes payable	16,655	26,699
Accrued employee compensation and related benefits liability	80,028	77,274
Total Current Liabilities	<u>316,895</u>	<u>359,121</u>
Long-term debt obligations	90,938	91,791
Deferred income taxes liability	213,062	235,483
Long-term employee compensation and related benefits liability	32,008	31,139
Other long-term liabilities	27,170	29,743
Total Liabilities	<u>680,073</u>	<u>747,277</u>
Commitments and contingencies (Note 16)		
<i>Stockholders' Equity:</i>		
Ordinary Shares, £1.00 par value: unlimited shares authorized; 48,924,009 and 48,868,305 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	75,538	75,444
Additional paid-in capital	1,751,466	1,742,032
Accumulated other comprehensive loss	(25,341)	(54,228)
Retained earnings	15,224	48,214
Total Stockholders' Equity	<u>1,816,887</u>	<u>1,811,462</u>
Total Liabilities and Stockholders' Equity	<u>\$ 2,496,960</u>	<u>\$ 2,558,739</u>

See accompanying notes to the condensed consolidated financial statements

LIVANOVA PLC AND SUBSIDIARIES'
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(UNAUDITED)
(In thousands)

	Ordinary		Additional	Accumulated Other	Accumulated	Total
	Shares	Amount	Paid-In Capital	Comprehensive Income (Loss)	Earnings (Loss)	Stockholders' Equity
Balance at December 31, 2015	48,868	\$ 75,444	\$ 1,742,032	\$ (54,228)	\$ 48,214	\$ 1,811,462
Stock-based compensation plans	269	374	22,018	—	—	22,392
Shares repurchased	(213)	(280)	(12,584)	—	—	(12,864)
Net loss	—	—	—	—	(32,990)	(32,990)
Other comprehensive income	—	—	—	28,887	—	28,887
Balance at September 30, 2016	48,924	\$ 75,538	\$ 1,751,466	\$ (25,341)	\$ 15,224	\$ 1,816,887

See accompanying notes to the condensed consolidated financial statements

LIVANOVA PLC AND SUBSIDIARIES'
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)
(In thousands)

	Nine Months Ended September 30, 2016	Thirty-Eight Weeks Ended October 18, 2015
Cash Flows From Operating Activities:		
Net loss	\$ (32,990)	\$ (2,158)
Non-cash items included in net loss:		
Depreciation	30,193	4,570
Amortization	33,959	1,004
Stock-based compensation	15,575	21,281
Deferred income tax expense (benefit)	(10,224)	4,638
Loss from investments	19,382	2,064
Other	8,765	912
Changes in operating assets and liabilities:		
Accounts receivable	(11,040)	1,431
Inventories	20,607	(4,849)
Other current and non-current assets	(23,142)	(3,771)
Restructuring reserve	14,961	—
Accounts payable and accrued current and non-current liabilities	(16,698)	40,507
Net cash provided by operating activities	49,348	65,630
Cash Flow From Investing Activities:		
Purchase of short-term investments	(7,054)	(6,995)
Maturities of short-term investments	14,051	27,033
Purchase of property, plant and equipment and other	(26,772)	(4,272)
Intangible assets purchases	(1,934)	(1,000)
Purchases of equity and cost method investments	(8,059)	—
Net cash provided by (used in) investing activities	(29,768)	14,766
Cash Flows From Financing Activities:		
Short-term borrowing	6,060	—
Short-term repayments	(39,891)	—
Proceeds from long-term debt obligations	7,994	—
Repayment of long-term debt obligations	(11,354)	—
Repayment of trade receivable advances	(23,848)	—
Loans to equity method investees	(6,595)	—
Proceeds from exercise of options for common stock	7,888	5,305
Realized excess tax benefits - stock-based compensation	1,208	4,531
Purchase of ordinary stock	(11,053)	—
Purchase of treasury stock	—	(15,700)
Cash settlement of compensation-based stock units	—	(1,092)
Net cash used in financing activities	(69,591)	(6,956)
Effect of exchange rate changes on cash and cash equivalents	1,030	122
Net increase (decrease) in cash and cash equivalents	(48,981)	73,562
Cash and cash equivalents at beginning of period	112,613	116,215
Cash and cash equivalents at end of period	\$ 63,632	\$ 189,777
Supplementary Disclosures of Cash Flow Information:		
Cash paid for interest	\$ 5,442	\$ 19
Cash paid for income taxes	\$ 38,947	\$ 8,272
Supplementary Disclosure of a Non-Cash Operating Transaction:		
Decrease to APIC related to share-based compensation options cashed out	\$ —	\$ (4,814)
Increase to liabilities related to share-based compensation options cashed-out	\$ —	\$ 4,814
Supplementary Disclosure of a Non-Cash Financing Transaction:		
Decrease to Ordinary shares at par value and APIC related to shares repurchased and unsettled	\$ (1,811)	
Increase to Current debt obligations related to unsettled shares	\$ 1,811	

See accompanying notes to the condensed consolidated financial statements

LIVANOVA PLC AND SUBSIDIARIES

NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Nature of Operations

Background. LivaNova PLC and its subsidiaries (collectively, the “Company”, “LivaNova”, “we” or “our”) was organized under the laws of England and Wales on February 20, 2015 for the purpose of facilitating the business combination of Cyberonics, Inc., a Delaware corporation (“Cyberonics”) and Sorin S.p.A., a joint stock company organized under the laws of Italy (“Sorin”). As a result of the business combination, LivaNova became the holding company of the combined businesses of Cyberonics and Sorin. This business combination became effective on October 19, 2015, at which time LivaNova’s ordinary shares were listed for trading on the NASDAQ Global Market (“NASDAQ”) and on the London Stock Exchange (the “LSE”) as a standard listing under the trading symbol “LIVN.” LivaNova PLC is headquartered in London, United Kingdom (“U.K.”).

Description of the Business. We are a global medical device company focused on the development and delivery of important therapeutic solutions for the benefit of patients, healthcare professionals and healthcare systems throughout the world. Working closely with medical professionals throughout the world in the field of Cardiac Surgery, Neuromodulation and Cardiac Rhythm Management, we design, develop, manufacture and sell innovative therapeutic solutions that are consistent with our mission to improve our patients’ quality of life, increase the skills and capabilities of healthcare professionals and minimize healthcare costs.

Description of the Mergers. On October 19, 2015, pursuant to the terms of a definitive Transaction Agreement entered into by LivaNova, Cyberonics, Sorin and Cypher Merger Sub (the “Merger Sub”), dated March 23, 2015, (the “Merger Agreement”) Sorin merged with and into LivaNova, with LivaNova continuing as the surviving company, immediately followed by the merger of Merger Sub with and into Cyberonics, with Cyberonics continuing as the surviving company and as a wholly owned subsidiary of LivaNova (the “Mergers”). Upon the consummation of the Mergers, the historical financial statements of Cyberonics became the Company’s historical financial statements. Accordingly, the historical financial statements of Cyberonics are included in the comparative prior periods.

The issuance of LivaNova ordinary shares in connection with the Mergers was registered under the Securities Act of 1933, as amended (the “Securities Act”), pursuant to the Registration Statement on Form S-4 (File No. 333-203510), as amended, filed with the United States Securities and Exchange Commission (the “SEC”) by LivaNova and declared effective on August 19, 2015. Further, pursuant to Rule 12g-3(a) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), LivaNova is deemed to be a “successor” issuer to Cyberonics. As such, the ordinary shares of LivaNova are deemed to be registered under Section 12(b) of the Exchange Act, and LivaNova is subject to the informational requirements of the Exchange Act and the rules and regulations promulgated thereunder.

Note 2. Basis of Presentation, Use of Accounting Estimates and Significant Accounting Policies

The Mergers: On October 19, 2015, as further described herein, LivaNova became the holding company of the combined businesses of Cyberonics and Sorin, and LivaNova’s ordinary shares were listed for trading on the NASDAQ Global Market and admitted to listing on the standard segment of the United Kingdom Financial Conduct Authority’s Official List and to trading on the Main Market of the London Stock Exchange under the trading symbol “LIVN.” Based on the structure of the Mergers, management determined that Cyberonics is considered to be the accounting acquirer and predecessor for accounting purposes.

The purchase price allocation recorded and reported in the Transition Report on Form 10-KT for the fiscal period that began April 25, 2015 and ended December 31, 2015, as amended (the “2015 Form 10-KT”), was based on a preliminary acquisition valuation and includes the use of estimates based on information that was available to management at the time. The finalization of appraisals and estimates resulted in a change in the valuation of assets acquired, liabilities assumed, goodwill recognized and the related impact on deferred taxes and cumulative translation adjustments. During the quarters ended June 30, 2016 and September 30, 2016, we recorded adjustments to the estimated fair values of the assets acquired and liabilities assumed in the Mergers as a result of analysis of the facts and circumstances that existed at the time of the acquisition. Fair value estimates are based on a complex series of judgments about future events and uncertainties and rely heavily on estimates and assumptions. The judgments used to determine the estimated fair value assigned to each class of assets acquired and liabilities assumed can materially impact the results of operations. Refer to “Note 3. Business Combinations” for further information regarding the adjustments.

Basis of Presentation. The accompanying condensed consolidated financial statements of LivaNova have been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S.” and such principles, “U.S. GAAP”) for interim financial information and the instructions to Form 10-Q and Article 10 of regulation S-X. The accompanying condensed consolidated balance sheet of LivaNova at December 31, 2015 has been derived from audited financial statements contained in our transitional report on form 10-KT for the period ended December 31, 2015, but do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, the condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the operating results of LivaNova and its subsidiaries, for the three and nine months ended September 30, 2016, and are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2016. The financial information presented herein should be read in conjunction with the audited consolidated financial statements and notes thereto accompanying our Transition Report on Form 10-KT for the fiscal period that began April 25, 2015 and ended December 31, 2015, as amended.

Fiscal Year-End. Prior to the Mergers, Cyberonics, LivaNova’s predecessor, utilized a 52/53-week fiscal year that ended on the last Friday in April. After the Mergers that consummated on October 19, 2015, Cyberonics, as a subsidiary of LivaNova PLC, changed to a calendar year ending December 31st.

Reporting Periods. In this Quarterly Report on Form 10-Q, we are reporting the results of our operations for the three and nine months ended September 30, 2016, which consist of the combined results of operations of Cyberonics and Sorin. Since LivaNova is the successor company to Cyberonics, we are presenting the results of Cyberonics’ operations for the twelve and thirty-eight weeks ended October 18, 2015, as the prior year equivalent periods. The twelve and thirty-eight weeks ended October 18, 2015 were selected for comparative purposes as they were the closest periods to the three and nine months ended September 30, 2016 (with approximately a two week difference) as it was impracticable and cost prohibitive to recast Cyberonics’ prior year financial information in order to present the three and nine months ended September 30, 2016.

Foreign Currency Translation and Remeasurement. We translate the assets and liabilities of its non-U.S. dollar functional currency subsidiaries into U.S. dollars using exchange rates in effect at the end of each period. Revenue and expenses for these subsidiaries are translated using rates that approximate those in effect during the period. Gains and losses from these translations are recognized in foreign currency translation included in AOCI in shareholders’ equity. Our subsidiaries that use the U.S. dollars as their functional currency remeasure their assets and liabilities that are denominated in a currency other than the U.S. dollars, at exchange rates in effect at the end of each period, while their inventories, property and nonmonetary assets and liabilities denominated in a currency other than the U.S. dollars, at historical rates.

Consolidation. The accompanying condensed consolidated operating statements for the three and nine months ended September 30, 2016, include the operating results for LivaNova PLC and the LivaNova PLC Employee Benefit Trust (the “Trust”), which consist of the combined results of operations of Cyberonics and Sorin. The accompanying condensed consolidated operating results for the twelve and thirty-eight weeks ended October 18, 2015 include the results of operations for Cyberonics and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

Use of Estimates. The preparation of our condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in such financial statements and accompanying notes. These estimates are based on management’s best knowledge of current events and actions we may undertake in the future. Estimates are used in accounting for, among other items, valuation and amortization of intangible assets, goodwill, amortization of intangible assets, measurement of deferred tax assets and liabilities, uncertain income tax positions, stock-based compensation, obsolete and slow-moving inventories, allowance for doubtful accounts, and in general, allocations to provisions and the fair value of assets and liabilities recorded in a business combination. Actual results could differ materially from those estimates.

Merger, Integration and Restructuring Charges. As a result of the Mergers, we incurred merger, integration and restructuring charges and reported merger and integration expenses and restructuring expenses separately as operating expenses in the consolidated statements of income (loss).

Merger Expenses. Merger expenses consisted of expenses directly related to the Mergers, such as professional fees for legal services, accounting services, due diligence, a fairness opinion and the preparation of registration and regulatory filings in the United States and Europe, as well as investment banking fees.

Integration Expenses. Integration expenses consisted primarily of consultancy fees with regard to: our systems integration, organization structure integration, finance, synergy and tax planning, the transition to U.S. GAAP for Sorin activity, our LSE listing and certain re-branding efforts.

Restructuring Expenses. After the consummation of the Mergers between Cyberonics and Sorin in October 2015, we initiated several restructuring plans (the “Restructuring Plans”) to combine our business operations. We identify costs incurred and liabilities assumed for the Restructuring Plans. The Restructuring Plans are intended to leverage economies of scale, eliminate duplicate corporate expenses and streamline distributions, logistics and office functions in order to reduce overall costs.

Reclassifications. The following reclassifications have been made to conform the prior period consolidated financial statements to current year presentations:

Amortization Expense. Amortization expense of \$0.5 million and \$1.5 million for the twelve and thirty-eight weeks ended October 18, 2015 were reclassified and reported separately in the consolidated statement of income (loss) rather than included with Research and Development expense.

Accrued Employee Compensation and Related Benefits. In the consolidated balance sheet, accruals amounting to \$17.5 million in total were reclassified from Other Current Liabilities to Accrued Employee Compensation and Related Benefit Liability.

Cash and Cash Equivalents. We consider all highly liquid investments with an original maturity of three months or less, consisting of demand deposit accounts and money market mutual funds, to be cash equivalents and are carried in the balance sheet at cost, which approximated their fair value. We carried \$41.1 million in money market mutual funds at December 31, 2015 and none at September 30, 2016.

U.S. Medical Device Excise Tax (“MDET”). Section 4191 of the Internal Revenue Code enacted by the Health Care and Education Reconciliation Act of 2010, in conjunction with the Patient Protection and Affordable Care Act, established a 2.3% excise tax on medical devices sold domestically beginning on January 1, 2013, with this excise tax now suspended from January 1, 2016 through December 31, 2017. We included the cost of MDET in cost of sales on the consolidated statements of income for the applicable reporting periods. The MDET tax expense amounted to \$0.9 million and \$2.9 million for the twelve and thirty-eight weeks ended October 18, 2015.

Italian Medical Device Payback (“IMDP”). The Italian Parliament introduced new rules for entities that supply goods and services to the Italian National Healthcare System. The new healthcare law is expected to impact the business and financial reporting of companies operating in the medical technology sector that sell medical devices in Italy. A key provision of the law is a ‘payback’ measure, requiring companies selling medical devices in Italy to make payments to the Italian state if medical device expenditures exceed regional maximum ceilings. Companies are required to make payments equal to a percentage of expenditures exceeding maximum regional caps. There is considerable uncertainty about how the law will operate and what the exact timeline is for finalization. Our current assessment of the IMDP involves significant judgment regarding the expected scope and actual implementation terms of the measure as the latter have not been clarified to date by Italian authorities. We account for the estimated cost of the IMDP as a deduction from revenue. The estimated cost of the IMDP amounted to \$0.2 million and \$0.7 million for the three and nine months ended September 30, 2016, respectively.

Income Taxes. LivaNova, organized as a public limited company under the laws of England and Wales, operates through various subsidiaries in a number of countries throughout the world. Our provision for income taxes is based on the tax laws and rates applicable in the jurisdictions in which we operate and earn income. We use significant judgment and estimates in accounting for our income taxes. We recognize deferred tax assets and liabilities for the anticipated future tax effects of temporary differences between the financial statements basis and the tax basis of our assets and liabilities, which are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Income tax expense compared to pre-tax income yields an effective tax rate.

Segments. Prior to the Mergers, Cyberonics had one operating and reportable segment. Upon completion of the Mergers, we reorganized our reporting structure and aligned our segments and the underlying divisions and businesses. We currently function in three operating segments; the historical Cyberonics operations are included in the Neuromodulation segment while the historical Sorin businesses comprise the Cardiac Surgery (“CS”) and the Cardiac Rhythm Management (“CRM”) segments. Refer to “Note 22. Geographic and Segment Information” for additional information.

Note 3. Business Combination

On October 19, 2015, and pursuant to the terms of the Merger Agreement, Sorin merged with and into LivaNova, with LivaNova continuing as the surviving company, immediately followed by the merger of Merger Sub with and into Cyberonics, with Cyberonics continuing as the surviving company and as a wholly owned subsidiary of LivaNova. Following the completion of the Mergers, LivaNova became the holding company of the combined businesses of Cyberonics and Sorin, and LivaNova's ordinary shares were listed, under the ticker symbol "LIVN," on NASDAQ and admitted for listing on the standard segment of the U.K. Financial Authority's Official List and trading on the LSE.

The estimated fair value of the assets acquired and liabilities assumed in the Mergers, as adjusted in the table below, are based on information that became available during the measurement period. We recognized adjustments to the provisional amounts with a corresponding adjustment to goodwill in the reporting period in which the adjustments were determined.

The measurement period ended and the fair values of the Mergers were finalized by October 19, 2016.

Goodwill is calculated as the excess of the consideration transferred over the fair value of assets acquired and liabilities assumed. Goodwill represents growth opportunities and expected cost synergies of the combined company. We assigned goodwill arising from the Mergers to the Cardiac Surgery, Cardiac Rhythm Management and Neuromodulation reporting units. This assignment was made by taking into consideration market participant rates of return for each acquired reporting unit, Cardiac Surgery and Cardiac Rhythm Management, in order to assess their respective fair values. The remaining goodwill, allocated to Neuromodulation, which is the accounting acquirer's existing business unit, is supported by the synergies derived from the Mergers.

The following table summarizes the fair value of the assets acquired and liabilities assumed in the Mergers on October 19, 2015, including the measurement period adjustments recognized since the fair values were presented in our report on Form 10-K/T for the transitional period ended December 31, 2015 (in thousands):

	October 19, 2015	Adjustments	October 19, 2015 (as adjusted)
Total fair value of consideration transferred	\$ 1,589,083	\$ —	\$ 1,589,083
Estimated Fair Value of Assets Acquired and Liabilities Assumed:			
Cash and cash equivalents	12,495	—	12,495
Accounts receivable	224,466	—	224,466
Inventories	233,832	—	233,832
Other current assets	60,674	(84)	60,590
Property, plant and equipment	207,639	(1,121)	206,518
Intangible assets	688,729	—	688,729
Equity investments	67,059	(72)	66,987
Other assets	7,483	(1,328)	6,155
Deferred tax assets	135,370	(121,234)	14,136
Total assets acquired	1,637,747	(123,839)	1,513,908
Current portion of debt and other obligations	110,601	—	110,601
Other current liabilities	237,855	830	238,685
Long-term debt	128,458	—	128,458
Deferred tax liabilities	279,328	(148,640)	130,688
Other long-term liabilities	55,567	—	55,567
Total liabilities assumed	811,809	(147,810)	663,999
Goodwill	\$ 763,145	\$ (23,971)	\$ 739,174

The measurement period adjustments shown in the table above were recorded in the quarters ended June 30, 2016 and September 30, 2016, and reflect changes in the estimated fair values of certain assets and liabilities, primarily related to deferred income taxes as a result of new information on facts and circumstances that existed at the time of acquisition. Adjustments were made to deferred income taxes as a result of the allocation of fair value to the legal entities. In addition, deferred income taxes were aggregated and presented on a net basis by jurisdiction.

We recorded reductions or (increases) to the following expenses due to the measurement period adjustments that were recorded during the nine months ended September 30, 2016 (in thousands):

	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2016
Amortization of intangible assets	\$ 193	\$ 1,844
Depreciation	1,539	2,790
Other costs	—	(40)
Income tax	(3,232)	(3,756)
Net	<u>\$ (1,500)</u>	<u>\$ 838</u>

The valuation of the intangible assets acquired in the Mergers and related amortization periods are as follows (in thousands, except years):

	Valuation as of October 19, 2015	Amortization period in years
Customer relationships	\$ 464,019	16-18
Developed technology	211,091	9-15
Sorin trade-name	13,619	4
	<u>\$ 688,729</u>	

Proforma results of operations

The following pro forma information presents the results of LivaNova as if the Mergers were consummated on April 26, 2014 and had been included in our consolidated statement of income (loss) for the twelve and thirty-eight weeks ended October 18, 2015 (in thousands, except per share data):

	Twelve Weeks Ended October 18, 2015	Thirty-Eight Weeks Ended October 18, 2015
Net Sales	\$ 295,099	\$ 901,493
Net Loss	(51,984)	(81,433)
Basic and diluted net loss per share	\$ (1.07)	\$ (1.68)

The unaudited pro forma combined results of operations for the twelve and thirty-eight weeks ended October 18, 2015 have been prepared by adjusting the historical results of Cyberonics for these same periods to include the historical results of Sorin. The unaudited pro forma information included for Sorin for the twelve weeks ended October 18, 2015 is based on the accounts of Sorin for the three months ended September 30, 2015 and the information for the thirty-eight weeks ended October 18, 2015 includes the accounts of Sorin for the nine months ended September 30, 2015.

The unaudited pro forma information reflects the effect of purchase accounting adjustments and the elimination of merger-related transactions expenses, among other items. This supplemental pro forma information has been prepared for comparative purposes and does not purport to be indicative of what would have occurred had the acquisition been made on April 26, 2014, and it is not indicative of any future results.

Note 4. Reorganization Plans

Our 2015 and 2016 Reorganization Plans (the “Plans”) were initiated October 2015 and March 2016, respectively, in conjunction with the completion of the Mergers. These Plans are intended to leverage economies of scale, streamline distribution and logistics and strengthen operational and administrative effectiveness in order to reduce overall costs. Costs associated with these Plans were reported as restructuring expenses in the operating results of our consolidated statement of income (loss). We expect to complete these plans in the first half of fiscal year 2018. There were no restructuring expenses in the comparative prior year periods.

We estimate that the Plans will result in a net reduction of approximately 190 personnel of which 115 have occurred as of September 30, 2016. The Plans also include the closure of our R&D facility in Meylan, France and consolidation of its research and development (“R&D”) capabilities into our Clamart, France facility.

The Reorganization Plans' accrual detail is as follows (in thousands):

	Employee severance and other termination costs	Other	Total
Balance as of December 31, 2015	\$ 6,919	\$ —	\$ 6,919
Restructuring charges	34,288	2,931	37,219
Cash payments	(21,066)	(591)	(21,657)
Balance as of September 30, 2016	<u>\$ 20,141</u>	<u>\$ 2,340</u>	<u>\$ 22,481</u>

The following table presents restructuring expense by reportable segment (in thousands):

	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2016
Cardiac Surgery	\$ 916	\$ 5,878
Cardiac Rhythm Management	571	16,592
Neuromodulation	2,882	7,017
Other	12	7,732
Total	<u>\$ 4,381</u>	<u>\$ 37,219</u>

Note 5. Accounts Receivable and Allowance for Bad Debt

Accounts receivable, net, consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Trade receivables from third parties	\$ 291,620	\$ 274,005
Allowance for bad debt	(7,275)	(1,653)
	<u>\$ 284,345</u>	<u>\$ 272,352</u>

During the nine months ended September 30, 2016, we increased our allowance for bad debt primarily due to certain receivables in Greece whose probability of recoverability became doubtful during the quarter ended June 30, 2016.

Note 6. Inventories

Inventories consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Raw materials	\$ 52,658	\$ 52,482
Work-in-process	40,725	44,369
Finished goods	104,266	115,597
	<u>\$ 197,649</u>	<u>\$ 212,448</u>

The step-up in inventory basis of \$35.0 million that resulted from the Mergers was fully amortized as of June 30, 2016 and is recorded in cost of sales in the consolidated statement of net income (loss). Inventories are reported net of the provision for obsolescence, which totaled \$7.5 million and \$3.6 million at September 30, 2016 and December 31, 2015, respectively. The provision reflects normal obsolescence and inventory turnover while the comparatively lower provision as of December 31, 2015 was positively conditioned by Sorin inventories which were fair valued as of the acquisition date.

Note 7. Property, Plant and Equipment (“PP&E”)

PP&E consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Land	\$ 16,321	\$ 15,662
Building and building improvements	101,898	82,014
Machinery equipment, software, furniture and fixtures	175,000	140,364
Capital investment-in-process	21,668	42,210
Other	7,896	8,634
Total	322,783	288,884
Accumulated depreciation	(77,663)	(44,297)
	<u>\$ 245,120</u>	<u>\$ 244,587</u>

Depreciation expense for LivaNova was \$10.7 million and \$30.2 million for the three and nine months ended September 30, 2016, respectively, and \$1.6 million and \$4.6 million for legacy Cyberonics for the twelve and thirty-eight weeks ended October 18, 2015, respectively. During the nine months ended September 30, 2016, the increases in our investments in PP&E were primarily due to costs associated with manufacturing and office facilities, R&D equipment, in addition to general infrastructure and information technology system improvements.

Note 8. Goodwill and Intangible Assets

Detail of finite-lived and indefinite-lived intangible assets is as follows (in thousands):

	September 30, 2016	December 31, 2015
Finite-lived intangible assets:		
Developed technology	\$ 216,334	\$ 213,873
Customer relationships	461,966	444,472
Trademarks and trade names	13,393	13,030
Other intangible assets	2,104	11
Total	693,797	671,386
Accumulated amortization	(43,431)	(12,444)
Net	<u>\$ 650,366</u>	<u>\$ 658,942</u>
Indefinite-lived intangible assets:		
Goodwill	<u>\$ 731,144</u>	<u>\$ 745,356</u>

The amortization periods for our finite-lived intangible assets as of September 30, 2016:

	Minimum life in years	Maximum life in years
Developed technology	7	15
Customer relationships	16	18
Trademarks and trade names	4	4
Other intangible assets	5	10

The estimated future aggregate amortization of our finite-lived intangible assets remaining at September 30, 2016 is as follows (in thousands):

Year ending December 31,	
2016	\$ 11,845
2017	47,661
2018	47,665
2019	47,665
2020	47,664
Thereafter	447,866

Detail of goodwill movements by segment is as follows (in thousands):

	Neuromodulation	Cardiac Surgery	Cardiac Rhythm Management	Total Goodwill
Balance as of December 31, 2015	\$ 315,943	\$ 412,541	\$ 16,872	\$ 745,356
Measurement period adjustments, net	—	(25,728)	1,757	(23,971)
Effect of changes in currency exchange rates	—	10,040	(281)	9,759
Balance as of September 30, 2016	<u>\$ 315,943</u>	<u>\$ 396,853</u>	<u>\$ 18,348</u>	<u>\$ 731,144</u>

We assigned goodwill arising from the Mergers to the Cardiac Surgery, Cardiac Rhythm Management and Neuromodulation reporting units.

We test goodwill for impairment on an annual basis or when events or changes in circumstances indicate that a potential impairment exists. If our operating performance or our anticipated business outlook deteriorates, our reporting units' estimated fair value could decline below their carrying value, resulting in an impairment of goodwill. Likewise, if the market conditions or anticipated performance for our Cardiac Rhythm Management reporting unit deteriorates, it is possible that the estimated fair value of this reporting unit could be less than its carrying value when we perform our annual impairment analysis in our fourth quarter of 2016.

Factors that could have a negative impact on the fair value of our reporting units include, but are not limited to:

- Decreases in revenue as a result of the inability of our sales force to effectively market and promote our products;
- Increased competition, patent expirations or new technologies or treatments;
- Declines in anticipated growth rates;
- The outcome of litigation, legal proceedings, investigations or other claims resulting in significant cash outflows;
- Sustained decline in our stock price

Adverse changes in one or more of these factors could reduce the estimated fair value of our reporting unit below its carrying value in future periods.

Note 9. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Restructuring related expense	\$ 22,481	\$ 6,919
Derivatives	6,267	1,815
Provisions for agents, returns and other	7,490	7,199
Advances received on customer receivables	1,329	24,494
Product warranty obligations	2,124	2,119
Royalty costs	2,152	1,316
Clinical study costs	1,815	2,004
Insurance	114	2,566
Other	18,274	14,615
	<u>\$ 62,046</u>	<u>\$ 63,047</u>

Note 10. Product Warranties

We include warranty obligations with current accrued liabilities in the consolidated balance sheet. Changes in the carrying amount of our warranty obligation consisted of the following (in thousands):

As of December 31, 2015	\$ 2,119
Product warranty accrual	247
Settlements	(266)
Effect of changes in currency exchange rates	24
As of September 30, 2016	<u>\$ 2,124</u>

Note 11. Other Long-Term Liabilities

Other long-term liabilities consisted of the following (in thousands):

	September 30, 2016	December 31, 2015
Uncertain tax positions	\$ 13,358	\$ 13,048
Government grant deferred revenue	4,027	3,918
Earnout for contingent payments ⁽¹⁾	1,435	3,457
Unfavorable operating leases ⁽²⁾	1,932	2,513
Financial derivatives ⁽³⁾	1,929	1,793
Other	4,489	5,014
	<u>\$ 27,170</u>	<u>\$ 29,743</u>

- (1) The earnout for contingent payments represents contingent payments we assumed during the Mergers for two acquisitions completed by Sorin prior to the Mergers. The first acquisition, in September 2015, was of Cellplex PTY Ltd. in Australia; the second acquisition was of the commercial activities of a local distributor in Colombia. The contingent payments for the first acquisition are based on achievement of sales targets by the acquiree through June 30, 2018 and the contingent payments for the second acquisition are based on sales of cardiopulmonary disposable products and heart lung machines of the acquiree through December 2019. Refer to "Note 13. Fair Value Measurements."
- (2) The unfavorable operating leases represents the adjustment to recognize Sorin's future lease obligations at their estimated fair value in conjunction with the Mergers.
- (3) Financial derivatives represent forward interest rate swap contracts, which hedge our long-term European Investment Bank debt. Refer to "Note 15. Derivatives and Risk Management."

Note 12. Investments

Short-Term Investments. As of December 31, 2015 our short-term investment consisted of \$7.0 million held-to-maturity commercial paper with maturities over three months but less than twelve months which were carried at cost plus accrued interest. The commercial paper matured during the quarter ended September 30, 2016, and was not rolled over, as a result, we had no short-term investments at quarter end.

Cost-Method Investments. Our cost-method investments are shown in long-term assets in the consolidated balance sheets and consist of our equity positions in the following privately-held companies (in thousands):

	September 30, 2016	December 31, 2015
ImThera Medical, Inc. - convertible preferred shares and warrants ⁽¹⁾	\$ 12,000	\$ 12,000
Rainbow Medical Ltd. ⁽²⁾	3,950	3,847
MD Start II	560	—
Total	<u>\$ 16,510</u>	<u>\$ 15,847</u>

(1) ImThera Medical, Inc. is a private U.S. company developing a neurostimulation device system for the treatment of obstructive sleep apnea.

(2) Rainbow Medical Ltd. is a private Israeli venture capital company that seeds and grows companies developing medical devices in a diverse range of medical fields.

Equity Method Investments. Our equity-method investments are shown in long-term assets of our condensed consolidated balance sheets and consist of our equity position in the following entities (in thousands, except for percent ownership):

	% Ownership ⁽¹⁾	September 30, 2016	December 31, 2015
Caisson Interventional LLC ⁽²⁾	49.1%	\$ 17,629	\$ 13,712
Highlife S.A.S. ⁽²⁾	38.0%	7,002	8,363
MicroPort Sorin CRM (Shanghai) Co. Ltd.	49.0%	6,516	8,959
Respicardia, Inc. ⁽³⁾	19.6%	19,761	30,586
Other		17	19
Total ⁽⁴⁾		<u>\$ 50,925</u>	<u>\$ 61,639</u>

(1) Ownership percentages as of September 30, 2016.

(2) We have outstanding loans to Caisson Interventional LLC and to Highlife S.A.S that amount to \$9.1 million, which are included in Other Assets (long-term) on the consolidated balance sheet. We invested an additional \$7.5 million in Caisson Series B Preferred Units upon achievement of a previously agreed upon milestone.

(3) Respicardia is a privately funded U.S. company developing an implantable device designed to restore a more natural breathing pattern during sleep in patients with central sleep apnea ("CSA") by transvenously stimulating the phrenic nerve.

(4) The total difference between the carrying amount of the investments and the amount of underlying equity in the net assets of the investees was \$47.1 million at September 30, 2016.

Respicardia. During the quarter ended September 30, 2016, we declined to exercise or extend our option to purchase all of the issued and outstanding shares of Respicardia held by other investors as we preferred to continue as a minority investor instead of becoming a strategic acquirer as taken into consideration with our overall portfolio management program. Our analysis indicated that our carrying value in Respicardia might not be recoverable and the decrease in value of our investment was other than temporary. We estimated the fair value of our investment in Respicardia using information about past events, current conditions, and forecasts and an estimate of future cash flows. The estimated fair value was below our carrying cost and we impaired our investment in Respicardia by \$9.2 million, which essentially represents the purchase option's carrying value on the date we declined to exercise our option. This loss is included in Losses from Equity Method Investments in the consolidated statement of income (loss). In addition, during the quarter ended September 30, 2016, we started the process that will result in the cancellation of our distributor agreement with Respicardia in the fourth quarter ending December 31, 2016. The distributor agreement is a key component in the determination of whether our influence over Respicardia is significant. We accounted for Respicardia as an equity method investment through September 30, 2016 and will reevaluate our accounting method as of the date of the complete cancellation of the distributor agreement.

Caisson. In July 2016, we invested \$7.5 million in Caisson Series B Preferred Units upon their achievement of a previously agreed upon milestone. This investment raised our interest in Caisson by 5.4% to 49.1%. There were no other changes with respect of our interest in, and control of, Caisson, therefore we continue to account for this investment under the equity method of accounting.

We adjusted the carrying amount of our equity-method investments for our share of the investees' losses and amortization of basis differences in the amount of \$3.9 million and \$10.1 million during the three and nine months ended September 30, 2016, respectively. In addition, we adjusted the carrying amount of certain of our equity-method investments for foreign currency translation gains of \$0.3 million and \$1.4 million during the three and nine months ended September 30, 2016, respectively, which are reflected in the consolidated statements of other comprehensive income (loss). Our share of the investee losses, the amortization of basis differences and the impairment of Respicardia were reflected in "Losses from equity method investments" in the consolidated statements of income (loss).

Other Assets. "Other assets" in the long-term section of the consolidated balance sheet includes \$136.8 million in deferred tax expense related to the inter-company sale of intangible assets which is discussed further in "Note 20. Income Taxes". Other assets also include the cash surrender value of company-owned life insurance policies, which are based on the fair values in a mutual fund portfolio, amounting to \$1.8 million and \$1.8 million at September 30, 2016 and December 31, 2015, respectively.

Note 13. Fair Value Measurements

Fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The authoritative guidance for fair value measurements establishes a three-tier fair value hierarchy, categorizing the inputs used to measure fair value. The hierarchy can be described as follows:

Level 1. Observable inputs such as quoted prices in active markets.

Level 2. Inputs other than the quoted prices in active markets that are observable either directly or indirectly. To measure the fair value of its derivative transactions (transactions to hedge exchange risk and interest rate risk), we calculate the mark-to-market of each transaction using prices quoted in active markets (e.g., the spot exchange rate of a currency for forward exchange transactions) and observable market inputs processed for the measurement (e.g., the fair value of an interest rate swap using the interest rate curve), or the measurement of an exchange rate option (with the processing of listed prices and observable variables such as volatility). For all level 2 valuations, we use the information provided by a third-party as a source for obtaining quoted observable prices and to process market variables.

Level 3. Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions. When a determination is made to classify an asset or liability within Level 3, the determination is based upon the significance of the unobservable inputs to the overall fair value measurement. The fair value of assets using Level 3 input are based on our own judgments about the assumptions that market participants would use in pricing the asset and on observable market data, when available. We generally consider: (a) sale prices for similar assets, (b) discounted estimated future cash flows using an appropriate discount rate and/or (c) estimated replacement cost.

We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy. There were no transfers between Level 1, Level 2, or Level 3 during the nine months ended September 30, 2016 or the thirty-eight weeks ended October 18, 2015.

Assets and Liabilities That Are Measured at Fair Value on a Recurring Basis

The following table provides information by level for assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	Fair Value as of	Fair Value Measurements Using Inputs Considered as:		
	September 30, 2016	Level 1	Level 2	Level 3
Assets:				
Derivative Assets - freestanding hedges (FX)	\$ 1,249	\$ —	\$ 1,249	\$ —
Total assets	<u>\$ 1,249</u>	<u>\$ —</u>	<u>\$ 1,249</u>	<u>\$ —</u>
Liabilities:				
Derivative Liabilities - designated as cash flow hedges (FX)	\$ 3,943	\$ —	\$ 3,943	\$ —
Derivative Liabilities - designated as cash flow hedges (interest rate swaps)	2,994	—	2,994	—
Derivative Liabilities - freestanding hedges (FX)	1,259	—	1,259	—
Earnout for contingent payments ⁽¹⁾	1,435	—	—	1,435
Total Liabilities	<u>\$ 9,631</u>	<u>\$ —</u>	<u>\$ 8,196</u>	<u>\$ 1,435</u>

	Fair Value as of	Fair Value Measurements Using Inputs Considered as:		
	December 31, 2015	Level 1	Level 2	Level 3
Assets:				
Derivative Assets - designated as cash flow hedges (FX)	\$ 839	\$ —	\$ 839	\$ —
Total Assets	<u>\$ 839</u>	<u>\$ —</u>	<u>\$ 839</u>	<u>\$ —</u>
Liabilities:				
Derivative Liabilities - designated as cash flow hedges (interest rate swaps)	\$ 2,876	\$ —	\$ 2,876	\$ —
Derivative Liabilities - freestanding hedges (interest rate swaps)	24	—	24	—
Derivative Liabilities - freestanding hedges (FX)	1,547	—	1,547	—
Earnout for contingent payments ⁽¹⁾	3,457	—	—	3,457
Total Liabilities	<u>\$ 7,904</u>	<u>\$ —</u>	<u>\$ 4,447</u>	<u>\$ 3,457</u>

(1) This contingent payment arose as a result of acquisitions by Sorin, prior to the Mergers, see “Note 11. Other Long-Term Liabilities” for further information.

Assets and Liabilities that are Measured at Fair Value on a Nonrecurring Basis

Our investment in entities accounted for under the cost-method and the equity method have no quoted market prices. These investments and our non-financial assets such as: goodwill, intangible assets, and PP&E, are remeasured at fair value if there is an indication of impairment and recorded at fair value only when the impairment is recognized. We classify the measurement input for these assets as Level 3 inputs within the fair value hierarchy.

During the quarter ended September 30, 2016, we recorded a \$9.2 million impairment of our equity-method investment in Respicardia, Inc. Refer to “Note 12. Investments” for further information.

During the thirty-eight weeks ended October 18, 2015, we fully impaired certain finite-lived intangible assets and PP&E for a loss of \$0.4 million and \$0.6 million, respectively, which was primarily related to R&D projects that no longer factored into our future product plans.

Short-Term Financial Instruments Not Measured at Fair Value

The carrying values of our cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair values due to the short-term nature of these items. The balance of our investments in short-term securities consisted of commercial paper carried at cost plus accrued interest which approximates its fair value. Refer to “Note 12. Investments” for further information.

The carrying value of our long-term debt including the short-term portion, as of September 30, 2016, was \$113.0 million which we believe approximates fair value.

Note 14. Financing Arrangements

The outstanding principal amount of long-term debt consisted of the following (in thousands, except interest rates):

	September 30, 2016	December 31, 2015	Maturity	Interest Rate
European Investment Bank ⁽¹⁾	\$ 92,925	\$ 99,426	June 2021	0.98%
Banca del Mezzogiorno ⁽²⁾	8,170	8,851	December 2019	0.50%
Mediocredito Italiano	7,278	—	December 2023	0.50%
Bpifrance (ex-Oséo) ⁽³⁾	2,190	2,621	October 2019	2.58%
Novalia SA (Vallonie) ⁽⁴⁾	844	1,192	March 2020 - June 2033	0.00% - 3.42%
Mediocredito Italiano - mortgages ⁽⁵⁾	846	944	September 2021-2026	0.87% - 1.37%
Mediocredito Italiano - Intesa Sanpaolo	719	—	December 2023	0.50% - 3.07%
Total long-term facilities	112,972	113,034		
Less current portion of long-term debt	22,034	21,243		
Total long-term debt	<u>\$ 90,938</u>	<u>\$ 91,791</u>		

- (1) In July 2014, Sorin obtained a European Investment Bank (“EIB”) loan to support product development projects in Italy and France for the Cardiac Surgery (the “CS”) and Cardiac Rhythm Management (the “CRM”) Business Units, and in addition, for the support of New Ventures therapeutic solutions aimed at treating heart failure and mitral valve regurgitation. The interest rate for the EIB loan is reset by the lender each quarter based on the Euribor. Interest payments are quarterly and principal payments are at six months. The variable interest rate for this debt was hedged with interest rate swap agreements. Refer to “Note 15. Derivatives and Risk Management.”
- (2) In January 2015, Sorin obtained loans to support R&D projects as a part of the Large Strategic Project program of the Italian Ministry of Education, Universities and Research. One loan is subsidized by Cassa Depositi e Prestiti, at a fixed rate of 0.5%, and a second loan provided by GE Capital Interbanca, at a floating interest rate of the 6-month Euribor rate plus 3.3%.
- (3) In 2012, Sorin obtained a loan with Bpifrance, a French government entity that provides financial support for R&D.
- (4) In 2010, Sorin obtained loans, at various fixed interest rates, from Novalia SA, a finance company in the Wallonia Region in Belgium, to support several R&D projects.
- (5) In 2014, Sorin assumed real estate mortgage loans with the acquisition of the cannulae business. The loans are due to Mediocredito Italiano and are secured by a mortgage on our building located at our Cantù manufacturing site in Italy.

During the quarter, we entered into two term loans as part of the Fondo Innovazione Tecnologica program implemented by the Italian Ministry of Education, University and Research through Mediocredito Italiano Bank. The first loan, has a fixed interest rate of 0.50% per annum, with principal and interest payments due half yearly, starting December 31, 2016 and ending December 31, 2023. The second loan has a floating interest rate using the six month Euribor rate plus 3.30%, with principal and accumulated interest due half yearly starting June 30, 2021 and ending December 31, 2023.

The outstanding principal amount of short-term debt (revolving credit agreements) consisted of the following (in thousands, except interest rates):

	September 30, 2016	December 31, 2015	Interest Rate
Intesa San Paolo Bank	\$ 7,813	\$ 20,630	0.300%
BNL BNP Paribas	3,348	18,459	0.250%
Unicredit Banca	12,277	15,201	0.194%
BNP Paribas (Brazil)	3,164	2,225	14.13%
French Government	2,088	2,030	—
Banco de Bogota	802	—	2.95%
Other short-term facilities	2,091	2,725	
Total short-term facilities	31,583	61,270	
Current portion of long-term debt	22,034	21,243	
Total current debt	53,617	82,513	
Total debt	\$ 144,555	\$ 174,304	

Note 15. Derivatives and Risk Management

Due to the global nature of our operations, we are exposed to foreign currency exchange rate fluctuations. In addition, due to certain loans with floating interest rates, we are also subject to the impact of changes in interest rates on our interest payments. We enter into foreign currency exchange rate (“FX”) forward contracts and interest rate swap contracts to reduce the impact of foreign currency rate and interest rate fluctuations on net revenues and cash flow. We measure all outstanding derivatives each period end at fair value and report the fair value as either financial assets or liabilities in the consolidated balance sheets. We do not enter into derivative contracts for speculative purposes. Derivatives that are not designated as hedging instruments are referred to as freestanding derivatives with changes in fair value included in earnings. If a derivative is designated as a hedging instrument and qualifies for hedge accounting then, depending on hedge effectiveness, we account for changes in the fair value of the derivative either immediately in earnings, for the ineffective portion, or in other comprehensive income for the effective portion. Accumulated hedge gains and losses in other comprehensive income are transferred to earnings upon settlement, termination or cancellation of the hedge contract. We measure hedge effectiveness each quarter end and if a derivative that qualified for hedge accounting is later determined to be ineffective, in whole or in part, due to changes in the underlying hedged transaction, the fair value of the portion of the derivative determined to be ineffective will be recognized as a gain or loss in earnings for the applicable period.

Freestanding Derivative Foreign Currency Forward Contracts

The gross notional amount of derivative FX forward contracts, not designated as hedging instruments, outstanding at September 30, 2016 and December 31, 2015 was \$422.4 million and \$254.4 million, respectively. These contracts are FX forward contracts designed to offset the FX effects in earnings of intercompany loans denominated in a variety of foreign currencies versus the euro, which settle monthly or quarterly, and are renewed or not in accordance with the underlying outstanding intercompany loan amounts.

The amount and location of the net gains (losses) in the condensed consolidated statements of income (loss) related to open and settled freestanding FX contracts (in thousands):

Derivatives Not Designated as Hedging Instruments	Location of gains / (losses) in the statement of net income (loss)	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2016
FX forward contracts ⁽¹⁾	Foreign exchange and other	\$ (1,802)	\$ 428

(1) There were no derivative FX contracts opened or settled during the thirty-eight weeks ended October 18, 2015.

Cash Flow Hedges

Foreign Currency Risk

We utilize foreign currency exchange rate (“FX”) derivative contracts designed to hedge the variability of cash flows associated with our 12 month forecast of revenues denominated in British Pound and Japanese Yen. These contracts are settled when the earnings process has completed and the receivables collected. These contracts are designated as cash flow hedges.

There was no hedge ineffectiveness and there were no components of the FX derivative contracts excluded in the measurement of hedge effectiveness during the nine months ended September 30, 2016.

During the nine months ended September 30, 2016, we discontinued and settled certain of our FX derivative contracts due to changes in our foreign currency revenue forecast that resulted in a gain of \$0.2 million reclassified to earnings from accumulated other comprehensive income.

Interest Rate Risk

In July 2014, Sorin entered into a European Investment Bank (“EIB”) long-term loan agreement that matures in June 2021 with variable interest payments due quarterly based on the Euribor 3 month floating interest rate. To minimize the impact of changes in the interest rate we entered into an interest rate swap agreement program to swap the EIB floating-rate interest payments for fixed-rate interest payments. The interest rate swap contracts qualify for, and are designated as, cash flow hedges.

There was no interest rate swap hedge ineffectiveness or component of the swap contract excluded in the measurement of hedge effectiveness during the nine months ended September 30, 2016.

The notional amount of interest rate swap contracts designated as cash flow hedges is as follows (in thousands):

Notional amounts:	September 30, 2016	December 31, 2015
Foreign currency exchange rate contracts	\$ 90,087	\$ 66,900
Interest rate swap contracts	74,407	79,625
Total	\$ 164,494	\$ 146,525

After-tax net gain (loss) associated with open FX cash flow hedging contracts recorded in the ending balance of AOCI and the net amount expected to be reclassified to earnings in the next 12 months:

	September 30, 2016	Net amount expected to be reclassified to earnings in next 12 months
Foreign currency exchange rate contracts	\$ (3,003)	\$ (3,003)
Interest rate swap contracts	180	38
Total	\$ (2,823)	\$ (2,965)

There were no FX or interest rate swap derivative contracts outstanding for the thirty-eight weeks ended October 18, 2015.

Gains (losses) posted to other comprehensive income (“OCI”) and the amount reclassified to earnings for derivative contracts designated as cash flow hedges is as follows (in thousands):

Description of derivative contract	Location in earnings of reclassified gain or loss	Three Months Ended September 30, 2016		Nine Months Ended September 30, 2016	
		Gains (Losses) Recognized in OCI	Gains (Losses) Reclassified from OCI to Earnings:	Gains (Losses) Recognized in OCI	Gains (Losses) Reclassified from OCI to Earnings:
FX derivative contracts	Foreign Exchange and Other	\$ 2,535	\$ 2,795	\$ (5,932)	\$ 2,943
FX derivative contracts	SG&A	—	(1,876)	—	(3,437)
Interest rate swap contracts	Interest expense	263	(163)	(38)	(252)
Total		<u>\$ 2,798</u>	<u>\$ 756</u>	<u>\$ (5,970)</u>	<u>\$ (746)</u>

The following tables present the fair value on a gross basis, and the location of, derivative contracts reported in the consolidated balance sheet (in thousands):

September 30, 2016	Asset Derivatives		Liability Derivatives	
Derivatives designated as hedging instruments	Balance Sheet Location	Fair Value (1)	Balance Sheet Location	Fair Value (1)
Interest rate contracts	Prepaid expenses and other current assets	\$ —	Accrued liabilities	\$ 1,065
Interest rate contracts	Other assets (long term)	—	Other long-term liabilities	1,929
Foreign currency exchange rate contracts	Prepaid expenses and other current assets	—	Accrued liabilities	3,943
Total derivatives designated as hedging instruments		—		6,937
Derivatives not designated as hedging instruments				
Foreign currency exchange rate contracts	Prepaid expenses and other current assets	1,249	Accrued liabilities	1,259
Total derivatives not designated as hedging instruments		1,249		1,259
Total derivatives		\$ 1,249		\$ 8,196

December 31, 2015	Asset Derivatives		Liability Derivatives	
Derivatives designated as hedging instruments	Balance Sheet Location	Fair Value (1)	Balance Sheet Location	Fair Value (1)
Interest rate contracts	Prepaid expenses and other current assets	\$ —	Accrued liabilities	\$ 1,083
Interest rate contracts	Other assets (long term)	—	Other long-term liabilities	1,793
Foreign currency exchange rate contracts	Prepaid expenses and other current assets	839	Accrued liabilities	—
Total derivatives designated as hedging instruments		839		2,876
Derivatives not designated as hedging instruments				
Interest rate contracts	Prepaid expenses and other current assets	—	Accrued liabilities	24
Foreign currency exchange rate contracts	Prepaid expenses and other current assets	—	Accrued liabilities	1,547
Total derivatives not designated as hedging instruments		—		1,571
Total derivatives		\$ 839		\$ 4,447

(1) For the classification of input used to evaluate the fair value of our derivatives, refer to “Note 13. Fair Value Measurements.”

Note 16. Commitments and Contingencies

3T Heater Cooler

FDA Warning Letter. On December 31, 2015, LivaNova received a Warning Letter (the “Warning Letter”) dated December 29, 2015 from the U.S. Food and Drug Administration (“FDA”) alleging certain violations of FDA regulations applicable to medical device manufacturers at the Company’s Munich, Germany and Arvada, Colorado facilities.

The FDA inspected the Munich facility from August 24, 2015 to August 27, 2015 and the Arvada facility from August 24, 2015 to September 1, 2015. On August 27, 2015, the FDA issued a Form 483 identifying two observed non-conformities with certain regulatory requirements at the Munich facility. We did not receive a Form 483 in connection with the FDA’s inspection of the Arvada facility. Following the receipt of the Form 483, we provided written responses to the FDA describing corrective and preventive actions that were underway or to be taken to address the FDA’s observations at the Munich facility. The Warning Letter responded in part to our responses and identified other alleged violations not previously included in the Form 483.

The Warning Letter further stated that our 3T Heater Cooler devices and other devices we manufactured at our Munich facility are subject to refusal of admission into the United States until resolution of the issues set forth by the FDA in the Warning Letter. The FDA has informed us that the import alert is 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 manufacturing and shipment of all of our products other than the 3T Heater Cooler remain unaffected by the import limitation. To help clarify these issues for current customers, we issued an informational Customer Letter in January 2016, and that same month agreed with the FDA on a process for shipping 3T Heater Cooler devices to existing U.S. users pursuant to a certificate of medical necessity program.

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

We are continuing to work diligently to remediate the FDA’s inspectional observations for the Munich facility as well as the additional issues identified in the Warning Letter. We take these matters seriously and intend to respond timely and fully to the FDA’s requests.

The Warning Letter had no impact on our consolidated financial position, results of operations or cash flows in our fiscal year ended December 31, 2015, and the impact on our consolidated financial position, results of operations or cash flows for the nine months ended September 30, 2016 was not material. Although we have started to see an impact to sales outside the U.S., we continue to believe that the Warning Letter and the FDA's concerns will be resolved without a material impact on our consolidated financial position, results of operations or cash flows for our fiscal year 2016.

CDC and FDA Safety Communications and Company Field Safety Notice Update. On October 13, 2016 the Centers for Disease Control and Prevention ("CDC") and FDA separately released safety notifications regarding the 3T Heater-Cooler devices. The CDC's Morbidity and Mortality Weekly Report ("MMWR") and Health Advisory Notice ("HAN") reported that tests conducted by CDC and its affiliates indicate that there appears to be genetic similarity between both patient and heater-cooler strains of the non-tuberculous mycobacterium ("NTM") bacteria *M. chimaera* isolated in hospitals in Iowa and Pennsylvania. Citing the geographic separation between the two hospitals referenced in the investigation, the report asserts that 3T heater-cooler devices manufactured prior to August 18, 2014 could have been contaminated during the manufacturing process. The CDC's HAN and FDA's Safety Communication, issued contemporaneously with the MMWR report, each assess certain risks associated with heater-cooler devices and provide guidance for providers and patients. The CDC notification states that the decision to use the 3T Heater-Cooler during a surgical operation is to be taken by the surgeon based on a risk approach and on patient need. Both the CDC's and FDA's communications confirm that heater-cooler devices are critical medical devices and enable doctors to perform life-saving cardiac surgery procedures.

Also on October 13, 2016, the Company issued a Field Safety Notice Update for US users of 3T heater-cooler devices to proactively and voluntarily contact facilities to facilitate implementation of the CDC and FDA recommendations. Discussions regarding the execution of the Field Safety Notice Update continue with FDA. Pending the outcome of those discussions, the Company is currently unable to determine the outcome or impact of the CDC and FDA safety communications on its future revenues, results of operations, earnings, cash flows or financial condition.

Baker, Miller et al v. LivaNova PLC. On February 12, 2016, LivaNova was alerted that a class action complaint had been filed in the U.S. District Court for the Middle District of Pennsylvania with respect to the Company's 3T Heater Cooler devices, naming as evidence, in part, the Warning Letter issued by the FDA in December 2015. The named plaintiffs to the complaint are two individuals who underwent open heart surgeries at WellSpan York Hospital and Penn State Milton S. Hershey Medical Center in 2015, and the complaint alleges that: (i) patients were exposed to a harmful form of bacteria, known as nontuberculous mycobacterium ("NTM"), from LivaNova's 3T Heater Cooler devices; and (ii) LivaNova knew or should have known that design or manufacturing defects in 3T Heater Cooler devices can lead to NTM bacterial colonization, regardless of the cleaning and disinfection procedures used (and recommended by the Company). Named plaintiffs seek to certify a class of plaintiffs consisting of all Pennsylvania residents who underwent open heart surgery at WellSpan York Hospital and Penn State Milton S. Hershey Medical Center between 2011 and 2015 and who are currently asymptomatic for NTM infection (approximately 3,600 patients).

The putative class action, which has not been certified, seeks: (i) declaratory relief finding the 3T Heater Cooler devices are defective and unsafe for intended uses; (ii) medical monitoring; (iii) general damages; and (iv) attorneys' fees. On March 21, 2016, the plaintiffs filed a First Amended Complaint adding Sorin Group Deutschland GmbH and Sorin Group USA, Inc. as defendants. On September 29, 2016 the Court dismissed LivaNova PLC from the case, and on October 11, 2016, the Court denied the Company's motion to dismiss Sorin Group Deutschland GmbH and Sorin Group USA, Inc. from the lawsuit.

The Company has recently been served with additional similar lawsuits related to surgical cases in which a 3T Heater Cooler device was allegedly used. Six complaints have been filed in Pennsylvania State Court in York, PA (five against the Company and Wellspan York Hospital, and one solely against the Company, all related to surgical cases at York Hospital), one complaint has been filed in Pennsylvania State Court in Dauphin County, PA against the Company and Milton S. Hershey Medical Center related to a surgical case at Hershey Medical Center and one complaint has been filed in Pennsylvania State Court against the Company and University of Pennsylvania related to a surgical case at Penn Presbyterian Hospital. Nine complaints have been filed in the U.S. District Court for the District of South Carolina related to surgical cases at Greenville Health System Hospital in Greenville, SC. One additional case has been filed against the Company in the U.S. District Court for the Southern District of Iowa related to a surgical case at the University of Iowa Hospital. Finally, on October 30, 2016, the Company learned of a class action petition brought against the Montreal Heart Institute and LivaNova PLC in the Province of Quebec, Canada related to surgical cases at the Montreal Heart Institute. The Company has not yet been served with the complaint in this case.

At LivaNova, patient safety is of the utmost importance, and significant resources are dedicated to the delivery of safe, high-quality products. We intend to vigorously defend each of these claims. Given the early stage of this matters, we cannot, however, give any assurances that additional legal proceedings making the same or similar allegations will not be filed against LivaNova PLC or one of its subsidiaries, nor that the resolution of these complaints or other related litigation in connection therewith will not have a material adverse effect on our business, results of operations, financial condition and/or liquidity.

Other Matters

SNIA Litigation. Sorin S.p.A. was created as a result of a spin-off (the “Sorin spin-off”) from SNIA S.p.A. (“SNIA”). The Sorin spin-off, which spun off SNIA’s medical technology division, became effective on January 2, 2004. Pursuant to the Italian Civil Code, in a spin-off transaction, the parent and the spun-off company can be held jointly liable up to the actual value of the shareholders’ equity conveyed or received (we estimate that the value of the shareholders’ equity received was approximately €573 million) for certain indebtedness or liabilities of the pre-spin-off company:

- for “debt” (*debiti*) of the pre-spin-off company that existed at the time of the spin-off (this joint liability is secondary in nature and, consequently, arises only when such indebtedness is not satisfied by the company owing such indebtedness);
- for “liabilities” (*elementi del passivo*) whose allocation between the parties to the spin-off cannot be determined based on the spin-off plan.

Sorin believes and has argued before the relevant fora that Sorin is not jointly liable with SNIA for its alleged SNIA debts and liabilities. Specifically, between 1906 and 2010, SNIA’s subsidiaries Caffaro Chimica S.r.l. and Caffaro S.r.l. and their predecessors (the “SNIA Subsidiaries”), conducted certain chemical operations (the “Caffaro Chemical Operations”), at sites in Torviscosa, Brescia and Colleferro, Italy (the “Caffaro Chemical Sites”). These activities allegedly resulted in substantial and widely dispersed contamination of soil, water and ground water caused by a variety of hazardous substances released at the Caffaro Chemical Sites. In 2009 and 2010, SNIA and the SNIA Subsidiaries filed for insolvency. In connection with SNIA’s Italian insolvency proceedings, the Italian Ministry of the Environment and the Protection of Land and Sea (the “Italian Ministry of the Environment”), sought compensation from SNIA in an aggregate amount of €3.4 billion for remediation costs relating to the environmental damage at the Caffaro Chemical Sites allegedly caused by the Caffaro Chemical Operations. The amount was based on certain clean-up activities and precautionary measures set forth in three technical reports prepared by ISPRA, the technical agency of the Ministry of Environment. In addition to disputing liability, the Company also disputes the amount being claimed and the basis for its estimation by Italian authorities, and that issue also remains in dispute. No final remediation plan has been approved at any time by the Italian authorities.

In September 2011, the Bankruptcy Court of Udine, and in July 2014, the Bankruptcy Court of Milan each held (in proceedings to which our Company is not part) that the Italian Ministry of the Environment and other Italian government agencies (the “Public Administrations”) were not creditors of either SNIA or its SNIA Subsidiaries in connection with their claims in the context of their Italian insolvency proceedings. LivaNova (as the successor to Sorin in the litigation) believes these findings are and will be influential (although not formally binding) upon other Italian courts, including civil courts. Public Administrations have appealed both decisions in those insolvency proceedings: in January 2016 the Court of Udine rejected the appeal brought by the Italian Public Administrations. The Public Administrations have appealed that second loss in pending proceedings before the Italian Supreme Court. The appeal by the Public Administrations before the Court of Milan remains pending.

In January 2012, SNIA filed a civil action against Sorin in the Civil Court of Milan asserting provisions of the Italian Civil Code relating to potential joint liability of a parent and a spun-off company in the context of a spin-off, as described above. Those proceedings seek to determine Sorin’s joint liability with SNIA for damages allegedly related to the Caffaro Chemical Operations (as described below). SNIA’s civil action against Sorin also named the Public Administrations Italian Ministry of the Environment and other Italian government agencies, as defendants, in order to have them bound to the final ruling. The Public Administrations that had also sought compensation from SNIA for alleged environmental damage subsequently counterclaimed against Sorin, seeking to have Sorin declared jointly liable towards those Public Administrations alongside SNIA, and on the same legal basis. SNIA and the Public Administrations also requested the court to declare inapplicable to the Sorin spin-off the cap on potential joint liability of parties to a spin-off otherwise provided for by the Italian Civil Code. The cap, if applied, would limit any joint liability to the actual value of the shareholders’ equity received. The Public Administrations have argued before the court that the Sorin spin-off was planned prior to the date such caps were enacted under the Italian Civil Code (although executed after such caps were introduced into Italian law) and should therefore not be applied to the Sorin spin-off.

Sorin has vigorously contested all of SNIA's claims against Sorin as well as those claims brought by the Public Administrations. A favorable decision pertaining to the case was delivered in Judgment No. 4101/2016 on April 1, 2016 (the "Decision"). In its Decision, the Court of Milan dismissed all legal actions of SNIA and of the Public Administrations against Sorin (now LivaNova), further requiring the Public Administrations to pay Sorin €300,000, as legal fees (of which €50,000 jointly with SNIA).

On June 21, 2016, the Public Administrations filed an appeal against the above decision before the Court of Appeal of Milan. To date SNIA has not filed an appeal in this case. The first hearing of the appeal proceedings was scheduled for November 22, 2016; the Court of Appeals afterwards adjourned the first hearing to December 20, 2016.

LivaNova (as successor to Sorin in the litigation) continues to believe that the risk of material loss relating to the SNIA litigation is not probable as a result of the reasoning contained in, and legal conclusions reached in, the recent court decisions described above. We also believe that the amount of potential losses relating to the SNIA litigation is, in any event, not estimable given that the underlying damages, related remediation costs, allocation and apportionment of any such responsibility, which party is responsible for which time period, all remain issues in dispute and that no final decision on a remediation plan has been approved. As a result, LivaNova has not made any accrual in connection with the SNIA litigation.

Pursuant to European Union, United Kingdom and Italian cross-border merger regulations applicable to the Mergers, legacy Sorin liabilities, including any potential liabilities arising from the claims against Sorin relating to the SNIA litigation, are assumed by LivaNova as successor to Sorin. Although LivaNova believes the claims against Sorin in connection with the SNIA litigation are without merit and continues to contest them vigorously, there can be no assurance as to the outcome. A finding during any appeal or novel proceedings that Sorin or LivaNova is liable for relating to the environmental damage at the Caffaro Chemical Sites or its alleged cause(s) could have a material adverse effect on our consolidated financial position, results of operations or cash flows.

Environmental Remediation Order. On July 28, 2015, Sorin and other direct and indirect shareholders of SNIA received an administrative order from the Italian Ministry of the Environment (the "Environmental Remediation Order"), directing them to promptly commence environmental remediation efforts at the Caffaro Chemical Sites (as described above). LivaNova believes that the Environmental Remediation Order is without merit. LivaNova (as successor to Sorin) believes that it should not be liable for damages relating to the Caffaro Chemical Operations pursuant to the Italian statute on which the Environmental Remediation Order relies because, inter alia, the statute does not apply to activities occurring prior to 2006, the date on which the statute was enacted (Sorin was spun off from SNIA in 2004). Additionally, LivaNova believes that Sorin should not be subject to the Environmental Remediation Order because Italian environmental regulations only permit such an order to be imposed on an "operator" of a remediation site, and Sorin has never operated any activity of whatsoever nature at any of the industrial sites concerned and, further, has never been identified in any legal proceeding as an operator at any of these Caffaro Chemical Sites, and could not and in fact did not cause any environmental damage at any of the Caffaro Chemical Sites.

Accordingly, LivaNova (as successor to Sorin) alongside other parties, challenged the Environmental Remediation Order before the Administrative Court of Lazio in Rome (the "TAR"). A hearing was held on February 3, 2016.

On March 21, 2016 the TAR issued several judgments, annulling the Environmental Remediation Order, one for each of the addressees of the Environmental Remediation Order, including LivaNova. Those judgments were based on the fact that (i) the Environmental Remediation Order lacks any detailed analysis of the causal link between the alleged damage and the activities of the Company, which is a pre-condition to imposition of the measures proposed in the Environmental Remediation Order, (ii) the situation of the Caffaro site does not require urgent safety measures, because no new pollution events have occurred and no additional information/evidence of a situation of contamination exists and (iii) the Environmental Remediation Order was not enacted using the correct legal basis, and in any event the Ministry failed to verify the legal elements that could have led to a conclusion of legal responsibility of the addressees of the Environmental Remediation Order.

LivaNova has welcomed the decisions. The TAR decisions described above have nonetheless been appealed by the Ministry before the Council of State. No information on the timing of the first hearing of this appeal is presently available.

Andrew Hagerty v. Cyberonics, Inc. On December 5, 2013, the United States District Court for the District of Massachusetts (“District Court”) unsealed a qui tam action filed by former employee Andrew Hagerty against Cyberonics under the False Claims Act (the “False Claims Act”) and the false claims statutes of 28 different states and the District of Columbia (*United States of America et al ex rel. Andrew Hagerty v. Cyberonics, Inc.* Civil Action No. 1:13-cv-10214-FDS). The False Claims Act prohibits the submission of a false claim or the making of a false record or statement to secure reimbursement from, or limit reimbursement to, a government-sponsored program. A “qui tam” action is a lawsuit brought by a private individual, known as a relator, purporting to act on behalf of the government. The action is filed under seal, and the government, after reviewing and investigating the allegations, may elect to participate, or intervene, in the lawsuit. Typically, following the government’s election, the qui tam action is unsealed.

Previously, in August 2012, Mr. Hagerty filed a related lawsuit in the same court and then voluntarily dismissed that lawsuit immediately prior to filing this qui tam action. In addition to his claims for wrongful and retaliatory discharge stated in the first lawsuit, the qui tam lawsuit alleges that Cyberonics violated the False Claims Act and various state false claims statutes while marketing its VNS Therapy System, and seeks an unspecified amount consisting of treble damages, civil penalties, and attorneys’ fees and expenses.

In October 2013, the United States Department of Justice declined to intervene in the qui tam action, but reserved the right to do so in the future. In December 2013, the District Court unsealed the action. In April 2014, Cyberonics filed a motion to dismiss the qui tam complaint, alleging a number of deficiencies in the lawsuit. In May 2014, the relator filed a First Amended Complaint. Cyberonics filed another motion to dismiss in June 2014, and the parties completed their briefing on the motion in July 2014. On April 6, 2015, the District Court dismissed all claims filed by Andrew Hagerty under the False Claims Act, but did not dismiss the claims for wrongful and retaliatory discharge. On July 28, 2015, Cyberonics filed its answer to the surviving claims in Mr. Hagerty’s first Amended Complaint and asserted its demand for arbitration pursuant to Mr. Hagerty’s employment documents.

In August 2015, Mr. Hagerty filed a Motion Seeking Leave to file a Second Amended Complaint responding to certain deficiencies noted by the District Court when dismissing claims in his First Amended Complaint alleging that Cyberonics submitted, or caused the submission of false claims under the False Claims Act. On September 4, 2015, Cyberonics filed our Brief in Opposition to Hagerty’s Motion for Leave to file a Second Amended Complaint. Mr. Hagerty filed a Reply Brief in support of his Motion for Leave to file a Second Amended Complaint on September 11, 2015. On September 16, 2015, the District Court heard oral arguments on (a) Mr. Hagerty’s motion seeking to amend his complaint, and (b) Cyberonics’ pending motion demanding arbitration on the claims relating to wrongful and retaliatory discharge. On November 17, 2015, the District Court (1) denied Mr. Hagerty’s Motion for Leave to File a Second Amended Complaint (accordingly, the previously dismissed claims remain dismissed); (2) granted Cyberonics’ Motion to Compel Arbitration of the two remaining claims (for retaliatory discharge under the False Claims Act and for wrongful termination/retaliation under Massachusetts law); and (3) stayed the pending case (in order to consolidate all issues for appeal pending resolution of the arbitration). On or about February 22, 2016, Mr. Hagerty dismissed, without prejudice, his individual claims that were ordered to arbitration. Subsequently, on or about March 21, 2016, Mr. Hagerty filed an appeal of the previously dismissed FCA claims with the U.S. First Circuit Court of Appeals (“Appeals Court”). Both Mr. Hagerty and the Company filed written briefs with the Appeals Court and on September 30, 2016, the Company received notice that the Appeals Court scheduled oral arguments before it on November 8, 2016.

We believe that our commercial practices were and are in compliance with applicable legal standards, and we will continue to defend this case vigorously. We make no assurance as to the resources that will be needed to respond to these matters or the final outcome, and we cannot estimate a range of potential loss or damages.

Tax Litigation. In a tax audit report notified on October 30, 2009, the Regional Internal Revenue Office of Lombardy (the “Internal Revenue Office”) informed Sorin Group Italia S.r.l. that, among several issues, it was disallowing in part (for a total of €102.6 million) a tax-deductible write down of the investment in the U.S. company, Cobe Cardiovascular Inc., which Sorin Group Italia S.r.l. recognized in 2002 and deducted in five equal installments, beginning in 2002. In December 2009, the Internal Revenue Office issued notices of assessment for 2002, 2003 and 2004. The assessments for 2002 and 2003 were automatically voided for lack of merit. In December 2010 and October 2011, the Internal Revenue Office issued notices of assessment for 2005 and 2006 respectively. The Company challenged all three notices of assessment (for 2004, 2005 and 2006) before the relevant Provincial Tax Courts.

The preliminary challenges filed for 2004, 2005 and 2006 were heard and all denied at the first jurisdictional level, and subsequently, the Company filed an appeal against the decisions in the belief that all the decisions are incorrect in their reasoning and radically flawed. The appeal submitted against the first-level decision for 2005 was rejected. The second-level decision, relating to the 2005 notice of assessment, was appealed to the Italian Supreme Court (Corte di Cassazione) where we argued that the assessment should be deemed null and void and illegitimate because of a false application of regulations. The

Court's decision is pending. The appeal we submitted against the first-level negative decision for 2004 assessment was accepted by the Commissione Tributaria Regionale di Bologna in June 2016, allowing our tax deduction. We expect the Italian Revenue Agency will file an appeal against this decision to the Supreme Court

In November 2012, the Internal Revenue Office served a notice of assessment for 2007 and, in July 2013, served a notice of assessment for 2008, wherein the Internal Revenue Office claimed an increase in taxable income due to a reduction (similar to the previous notices of assessment for 2004, 2005 and 2006) of the losses reported by Sorin Group Italia S.r.l. for the 2002, 2003 and 2004 tax periods and utilized in 2007 and 2008. Both notices of assessment were challenged within the statutory deadline. The Provincial Tax Court of Milan suspended the decision for 2007 until the litigation regarding years 2004, 2005 and 2006 are defined.

The total amount of losses in dispute is €62.6 million or \$71.3 million. At the time of the Cyberonics-Sorin merger, LivaNova carefully reassessed its exposure on this complex tax litigation, taking into account the recent general adverse trend to taxpayers on litigations with Italian tax authorities. Although the Company's defensive arguments are strong, the negative Court trend experienced so far by Sorin (four consecutive negative judgments received and one positive judgment received to date) as well as the fact of the ultimate outcome being dependent on the last possible Court level, i.e. the Italian Supreme Court, which is entitled to resolve only on procedural and legal aspects of the case but not on its substance, led LivaNova to leave unchanged (in euro) the previously recognized risk provision of \$18.9 million.

Other Litigation. Additionally, we are the subject of various pending or threatened legal actions and proceedings that arise in the ordinary course of our business. These matters are subject to many uncertainties and outcomes that are not predictable and that may not be known for extended periods of time. Since the outcome of these matters cannot be predicted with certainty, the costs associated with them could have a material adverse effect on our consolidated financial position, results of operations or cash flows.

Note 17. Stockholders' Equity

Share repurchase plans.

On August 1, 2016, the Board of Directors ("BOD") authorized a share repurchase plan pursuant to an authority granted by shareholders at the 2016 annual general meeting held on June 15, 2016. The repurchase program authorized by the BOD is structured to enable us to buy back up to \$30 million of ordinary shares on NASDAQ in the period up to and including December 31, 2016 and an aggregate of \$150 million of ordinary shares (inclusive of the \$30 million of ordinary shares set out above) also on NASDAQ up to and including December 31, 2018. As of September 30, 2016, 212,860 shares had been repurchased under this plan totaling \$12.9 million at an average price per share of \$60.44. All the repurchased shares have been canceled and are no longer considered issued.

Comprehensive income.

The table below presents the change in each component of accumulated other comprehensive income (loss), net of tax and the reclassifications out of accumulated other comprehensive income into net earnings for the nine months ended September 30, 2016 and the thirty-eight weeks ended October 18, 2015 (in thousands):

	Change in Unrealized Gain (Loss) on Cash Flow Hedging Derivatives	Foreign Currency Translation Adjustments Gain (Loss) ⁽¹⁾	Total
As of December 31, 2015	\$ 888	\$ (55,116)	\$ (54,228)
Other comprehensive income (loss) before reclassifications, before tax	(5,970)	32,598	26,628
Tax benefit (expense)	1,792	—	1,792
Other comprehensive income (loss) before reclassifications, net of tax	(4,178)	32,598	28,420
Reclassification of (gain)/loss from accumulated other comprehensive income, before tax	746	—	746
Tax effect	(279)	—	(279)
Reclassification of (gain)/loss from accumulated other comprehensive income, after tax	467	—	467
Net current-period other comprehensive income (loss), net of tax	(3,711)	32,598	28,887
As of September 30, 2016	\$ (2,823)	\$ (22,518)	\$ (25,341)
As of January 23, 2015	\$ —	\$ (2,924)	\$ (2,924)
Other comprehensive income (loss) before reclassifications, before tax	—	256	256
As of October 18, 2015	\$ —	\$ (2,668)	\$ (2,668)

(1) Taxes are not provided for foreign currency translation adjustments as translation adjustment are related to earnings that are intended to be reinvested in the countries where earned.

Note 18. Stock-Based Incentive Plans

Stock-Based Incentive Plans

On October 16, 2015, the sole shareholder of LivaNova approved the adoption of the LivaNova 2015 Incentive Award Plan (the “2015 Plan”). The Plan became effective as of October 19, 2015. Incentive awards may be granted under the 2015 Plan in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, other stock- and cash-based awards and dividend equivalents. As of September 30, 2016, there were approximately 7,135,639 shares available for future grants under the 2015 Plan.

Stock-Based Compensation

Amounts of stock-based compensation recognized in the consolidated statement of income (loss), by expense category are as follows (in thousands):

	Three Months Ended September 30, 2016	Twelve Weeks Ended October 18, 2015	Nine Months Ended September 30, 2016	Thirty-Eight Weeks Ended October 18, 2015
Cost of goods sold	\$ 153	\$ 931	\$ 838	\$ 1,214
Selling, general and administrative	4,645	9,219	13,679	13,026
Research and development	223	5,531	782	7,041
Merger-related expense	(253)	—	276	—
Total stock-based compensation expense	\$ 4,768	\$ 15,680	\$ 15,575	\$ 21,281
Income tax benefit, related to awards, recognized in the consolidated statements of income	833	5,019	3,806	6,492
Total expense, net of income tax benefit	\$ 3,935	\$ 10,661	\$ 11,769	\$ 14,789

Amounts of stock-based compensation expense recognized in the consolidated statement of income (loss) by type of arrangement are as follows (in thousands):

	Three Months Ended September 30, 2016	Twelve Weeks Ended October 18, 2015	Nine Months Ended September 30, 2016	Thirty-Eight Weeks Ended October 18, 2015
Service-based stock option awards and SAR's	\$ 1,983	\$ 7,191	\$ 6,567	\$ 9,401
Service-based restricted and restricted stock unit awards	2,517	6,282	8,419	9,099
Performance-based restricted stock and restricted stock unit awards	268	2,207	589	2,781
Total stock-based compensation expense	\$ 4,768	\$ 15,680	\$ 15,575	\$ 21,281

Note 19. Employee Retirement Benefit Plans

We sponsor various retirement plans. Prior to the Mergers, we did not sponsor any defined benefit pension plans. As a result of the Mergers, we assumed several defined benefit pension plans covering certain employees in the U.S., Italy, Germany, Japan and France. In the U.S., we assumed a frozen cash balance retirement plan that is a contributory, defined benefit plan that describes the benefit in terms of a stated account balance, which is partially dependent on the employer's promised interest rate. In Italy and France, we assumed a severance pay defined benefit plan that obligates the employer to compensate employees with severance pay in case of resignation, dismissal or retirement. In other jurisdictions we assumed non-contributory, defined benefit plans designated to provide a guaranteed minimum retirement benefits to eligible employees. We carried forward Cyberonics' defined contribution plans after the Mergers, which consisted of the Cyberonics, Inc. Employee Retirement Savings Plan, that qualifies under Section 401(k) of the IRC, covering U.S. employees, the Cyberonics, Inc. Non-Qualified Deferred Compensation Plan (the "Deferred Compensation") covering certain U.S. middle and senior management and the Belgium Defined Contribution Pension Plan for Cyberonics' Belgium employees.

Defined Benefit Plan Net Periodic Benefit Cost

The net periodic benefit cost of the defined benefit pension plans includes the following components (in thousands):

	U.S. Pension Benefits		Non-U.S. Pension Benefits	
	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2016	Three Months Ended September 30, 2016	Nine Months Ended September 30, 2016
Service cost	\$ —	\$ —	\$ 199	\$ 587
Interest cost	105	287	140	419
Expected return on plan assets	(71)	(211)	(3)	(13)
Amortization of net actuarial loss	449	877	(5)	54
Net periodic benefit cost	<u>\$ 483</u>	<u>\$ 953</u>	<u>\$ 331</u>	<u>\$ 1,047</u>

Defined Contribution Plans

We incurred expenses for our defined contribution plans of \$2.3 million and \$7.0 million for the three and nine months ended September 30, 2016, respectively, and \$0.5 million and \$1.6 million, respectively for the twelve and thirty-eight weeks ended October 18, 2015.

Note 20. Income Taxes

Our effective tax rates were 45.7% and 514.5% for the three and nine months ended September 30, 2016, respectively. The effective tax rate for the nine months ended September 30, 2016, differed from the U.K. statutory rate of 20%, (which is the tax rate for the location of our worldwide headquarters), primarily due to the recording of valuation allowances of \$23.9 million related to certain tax jurisdictions, including France and the U.K., in which we did not record tax benefits generated by their operating losses, as well as the tax expense generated by profitable operations in higher tax jurisdiction, such as the U.S. and Germany, offset by tax savings from our inter-co financing as part of our 2015 tax restructuring.

A valuation allowance is established if it is more-likely-than-not that all or a portion of the deferred tax assets, such as net operating loss carryforwards, will not be realized. We have experienced significant operating losses in certain entities with sufficient uncertainty regarding future taxable income in these entities such that a valuation allowance is required to fully offset the NOL carryforwards.

In fiscal year 2016, we consolidated certain of our intangible assets into an entity organized under the laws of England and Wales. Because the intangible assets were sold and purchased inter-company, the tax expense on the inter-company gain is deferred, and as a result, in the quarter ended June 30, 2016, we recorded the deferred tax expense as an asset, in the amount of \$156.4 million, and we recorded a deferred tax liability of the same amount. The deferred expense is recorded in the consolidated balance sheet as Other Current Assets and Other Assets, Long-Term, in the amount of \$19.6 million and \$136.8 million, respectively. These assets are being amortized to current income tax expense in the consolidated statement of net income (loss) over an 8 year period, which represents the estimated useful life of the intangible assets that were consolidated into the U.K. entity. As taxes become payable on the intercompany gain the deferred tax credit will be offset against current tax liabilities.

The effective tax rate for the three months ended September 30, 2016 differed from the U.K. statutory rate of 20% primarily due to the recording of valuation allowances and the results of our profitable operations in higher tax jurisdiction, such as the U.S. and Germany.

Effective tax rates for the historical Cyberonics activity for the twelve and thirty-eight weeks ended October 18, 2015 were 5% and 123%, respectively. The effective tax rate for the twelve weeks ended October 18, 2015 was primarily comprised of the U.S. federal income tax rate of 35%, plus state and foreign (other than U.S.) income taxes and non-deductible transaction costs. The effective tax rate for the thirty-eight weeks ended October 18, 2015 was primarily comprised of the U.S. federal income tax rate of 35%, plus state and foreign (other than U.S.) income taxes and non-deductible transaction costs.

In April 2016, the Guardia di Finanza, the Italian enforcement agency, under the authority of the Minister of Economy and Finance, commenced an audit of Sorin Group Italia Srl for tax years 2012 through 2015. At this time we are unable to predict the results of the audit.

In April 2016, the U.S. Internal Revenue Service (“IRS”) and U.S. Treasury Department issued new rules that materially change the manner in which the determination is made as to whether the U.S. anti-inversion rules under Section 7874 will apply. The new rules have the effect of linking with the Mergers certain future acquisitions of U.S. businesses made in exchange for LivaNova equity, and such linkage may impact LivaNova’s ability to engage in particular acquisition strategies. For example, the new temporary regulations would impact certain acquisitions of U.S. companies in an exchange for stock in LivaNova during the 36 month period beginning October 19, 2015 by excluding from the Section 7874 calculations the portion of shares of LivaNova that are allocable to the legacy Cyberonics shareholders. This new rule would generally have the effect of increasing the otherwise applicable Section 7874 fraction with respect to future acquisitions of a U.S. business, thereby increasing the risk that such acquisition could cause LivaNova to be treated as a U.S. corporation for U.S. federal income tax purposes.

For further information relating to the impact of Section 7874 on LivaNova, refer to the section entitled “*The IRS may not agree with the conclusion that LivaNova should be treated as a foreign corporation for U.S. federal tax purposes, and LivaNova may be required to pay substantial U.S. federal income taxes*” and the subsequent related risk factors included in “Part I, Item 1A. Risk Factors” in the 2015 Form 10-KT.

On October 13, 2016, the U.S. IRS and U.S. Treasury Department released final regulations under Section 385. The regulation establishes extensive documentation requirements that must be satisfied for a debt instrument to constitute debt for U.S. federal tax purposes and re-characterizes a debt instrument as equity if the instrument is issued in one of a number of specified transactions. The final rules will not have a material impact on our current intercompany transactions or structure.

Note 21. Income Per Share

The following table sets forth the computation of basic and diluted net loss per share of common/ordinary stock, (in thousands, except per share data):

	Three Months Ended September 30, 2016	Twelve Weeks Ended October 18, 2015	Nine Months Ended September 30, 2016	Thirty-Eight Weeks Ended October 18, 2015
Numerator:				
Net loss	\$ (1,569)	\$ (25,091)	\$ (32,990)	\$ (2,158)
Denominator:				
Basic weighted average shares outstanding	49,075	26,025	49,016	26,015
Add effects of stock options ⁽¹⁾	—	—	—	—
Diluted weighted average shares outstanding	49,075	26,025	49,016	26,015
Basic loss per share	\$ (0.03)	\$ (0.96)	\$ (0.67)	\$ (0.08)
Diluted loss per share	\$ (0.03)	\$ (0.96)	\$ (0.67)	\$ (0.08)

- (1) Excluded from the computation of diluted earnings per share for the three months ended September 30, 2016 were average outstanding options and stock appreciation rights ("SARs") to purchase 198 thousand ordinary shares of LivaNova because to include them would be anti-dilutive due to the net loss during the period. Excluded from the computation of diluted earnings per share for the nine months ended September 30, 2016 were average outstanding restricted share units, options and SAR's to purchase 153 thousand ordinary shares of LivaNova because to include them would be anti-dilutive due to the net loss during the period. Excluded from the computation of diluted earnings per share for the twelve and thirty-eight weeks ended October 18, 2015 were outstanding options to purchase 179 thousand and 219 thousand of Cyberonics shares, respectively (traded previous to the Mergers under trading symbol "CYBX") because to include them would have been anti-dilutive due to the net loss during the periods.

Note 22. Geographic and Segment Information

Segment Information

We identify operating segments based on the way we manage, evaluate and internally report our business activities for purposes of allocating resources and assessing performance.

In July 2016, we announced a new organizational structure, the introduction of new talent into the executive leadership team, and the appointment of a Chief Operating Officer ("COO"), who started on October 3, 2016, and will be responsible for driving innovative product development, commercialization and geographic expansion across the global organization with a focus on margin expansion and profitable growth. We are transitioning the organization to a regional focus with regional leaders in the US, Europe, and the rest of world. Supporting the regions will be our three product franchises: Neuromodulation, Cardiac Surgery, and Cardiac Rhythm Management. The product franchise leaders will be responsible for product R&D and marketing on a global basis. We believe a regional focus will allow a number of tangible benefits, namely the ability to share resources, faster decision-making, improved market access capabilities, and greater focus on the needs of physicians, hospitals, and patients. Our new operating structure and the introduction of new talent into the leadership team will facilitate an evolution of our goals and decision making processes in the near to immediate term; accordingly, we will continue to monitor the way we manage, evaluate and internally report our business activities and the corresponding impact this could have on our segment reporting.

Upon completion of the Mergers, in October 2015, we reorganized our reporting structure and aligned our segments and the underlying divisions and businesses. The historical Cyberonics operations are included in the Neuromodulation segment, and the historical Sorin businesses are included in the Cardiac Surgery and the Cardiac Rhythm Management segments. This change had no impact on the reported historical Cyberonics results for the thirteen weeks ended July 24, 2015.

The Cardiac Surgery segment generates its revenue from the development, production and sale of cardiovascular surgery products. Cardiac Surgery products include oxygenators, heart-lung machines, autotransfusion, mechanical heart valves and tissue heart valves. The Cardiac Rhythm Management segment generates its revenue from the development, manufacturing

and marketing of products for the diagnosis, treatment, and management of heart rhythm disorders and heart failure. Cardiac Rhythm Management products include high-voltage defibrillators CRT-D and low-voltage pacemakers. The Neuromodulation segment generates its revenue from the design, development and marketing of neuromodulation therapy for the treatment of drug-resistant epilepsy and treatment resistant depression. Neuromodulation products include the VNS Therapy System, which consists of an implantable pulse generator, a lead that connects the generator to the vagus nerve, surgical equipment to assist with the implant procedure, equipment to enable the treating physician to set the pulse generator stimulation parameters for the patient, instruction manuals and magnets to suspend or induce stimulation manually.

Corporate expenses include shared services for finance, legal, human resources and information technology. Corporate business development (“New Ventures”) is focused on new growth platforms and identification of other opportunities for expansion. In the tables below, these organizations are reported together in “Other.”

Net sales of our reportable segments include end-customer revenues from the sale of products they each develop and manufacture or distribute. We define segment income as operating income before merger and integration, restructuring, amortization and litigation expenses.

Net sales and operating income (loss) by reportable segment are as follows (in thousands):

Net Sales:	Three Months Ended September 30, 2016	Twelve Weeks Ended October 18, 2015	Nine Months Ended September 30, 2016	Thirty-Eight Weeks Ended October 18, 2015
Cardiac Surgery	\$ 148,518	\$ —	\$ 453,012	\$ —
Cardiac Rhythm Management	56,768	—	188,057	—
Neuromodulation	89,504	67,521	260,901	222,603
Other	478	—	1,314	—
Total Net Sales	\$ 295,268	\$ 67,521	\$ 903,284	\$ 222,603

Segment Income (Loss) from Operations:	Three Months Ended September 30, 2016	Twelve Weeks Ended October 18, 2015	Nine Months Ended September 30, 2016	Thirty-Eight Weeks Ended October 18, 2015
Cardiac Surgery	\$ 18,383	\$ —	\$ 31,251	\$ —
Cardiac Rhythm Management	(4,299)	—	(14,133)	—
Neuromodulation	47,049	2,060	134,871	56,225
Other	(12,047)	—	(46,765)	—
Total Reportable Segments’ Income from Operations	49,086	2,060	105,224	56,225
Merger and Integration expenses	7,576	27,902	20,537	43,143
Restructuring expenses	4,381	—	37,219	—
Amortization of intangibles	11,775	510	33,959	1,452
Litigation related expenses	2,369	—	4,678	—
Operating Income (Loss)	\$ 22,985	\$ (26,352)	\$ 8,831	\$ 11,630

The following table presents our assets by reportable segment (in thousands):

Assets:	September 30, 2016	December 31, 2015
Cardiac Surgery	\$ 1,357,087	\$ 1,472,108
Cardiac Rhythm Management	386,005	432,758
Neuromodulation	643,061	539,698
Other	110,807	114,175
Total Assets	\$ 2,496,960	\$ 2,558,739

The following tables present the depreciation and amortization expense and capital expenditures by reportable segment (in thousands):

Depreciation and Amortization Expense: ⁽¹⁾	Three Months Ended September 30, 2016	Twelve Weeks Ended October 18, 2015	Nine Months Ended September 30, 2016	Thirty-Eight Weeks Ended October 18, 2015
Cardiac Surgery	\$ 15,781	\$ —	\$ 44,511	\$ —
Cardiac Rhythm Management	6,342	—	16,585	—
Neuromodulation	233	3,584	2,927	5,574
Other	128	—	128	—
Total	\$ 22,484	\$ 3,584	\$ 64,151	\$ 5,574

- (1) Amortization of intangibles, as disclosed separately in the consolidated statement of income (loss), is included in the amortization by Segment above.

Capital expenditures:	Three Months Ended September 30, 2016	Twelve Weeks Ended October 18, 2015	Nine Months Ended September 30, 2016	Thirty-Eight Weeks Ended October 18, 2015
Cardiac Surgery	\$ 6,465	\$ —	\$ 16,774	\$ —
Cardiac Rhythm Management	1,591	—	2,786	—
Neuromodulation	1,781	1,391	5,602	4,272
Other	2,435	—	3,766	—
Total	\$ 12,272	\$ 1,391	\$ 28,928	\$ 4,272

Geographic Information

We operate under three geographic regions: United States, Europe, and Rest of World. Accordingly, the geographic information for the prior years has been restated to present these regions.

Net sales to external customers by geography are determined based on the country the products are shipped to and are as follows (in thousands):

	Three Months Ended September 30, 2016	Twelve Weeks Ended October 18, 2015	Nine Months Ended September 30, 2016	Thirty-Eight Weeks Ended October 18, 2015
United States	\$ 123,810	\$ 58,353	\$ 362,358	\$ 185,454
Europe ⁽¹⁾⁽²⁾	91,245	5,772	301,727	22,958
Rest of World	80,213	3,396	239,199	14,191
Total ⁽³⁾	\$ 295,268	\$ 67,521	\$ 903,284	\$ 222,603

- (1) Net sales to external customers include \$8.8 million and \$27.9 million in the United Kingdom for the three and nine months ended September 30, 2016, respectively. Prior to the Mergers, we were domiciled in the United States.
- (2) Includes those countries in Europe where LivaNova has a direct sales presence. Countries where sales are made through distributors are included in Rest of World.
- (3) No single customer represented over 10% of our consolidated net sales. Except for the U.S. and France, no country's sales exceeded 10% of our consolidated net sales. French sales were \$28.9 million and \$95.9 million for the three and nine months ended September 30, 2016, respectively.

Property, plant and equipment, net by geography are as follows (in thousands):

	September 30, 2016	December 31, 2015
United States	\$ 61,261	\$ 57,806
Europe ⁽¹⁾	142,002	148,708
Rest of World	41,857	38,073
Total	<u>\$ 245,120</u>	<u>\$ 244,587</u>

(1) Property, plant and equipment, net includes \$3.0 million and \$2.4 million in the United Kingdom at September 30, 2016 and at December 31, 2015, respectively.

Note 23. New Accounting Pronouncements

In May 2014, the FASB issued ASC Update No. 2014-09, Revenue from Contracts with Customers (Topic 606): Update No. 2014-09 requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers and will replace most existing revenue recognition guidance when it becomes effective. This new standard is effective for annual reporting periods beginning after December 15, 2017, and interim periods within that reporting period. Early application is not permitted, and the standard permits the use of either the retrospective or cumulative effect transition method. We are evaluating the effect this standard will have on our financial statements and related disclosures. We have not yet selected a transition method, nor has it determined the effect of the standard on its ongoing financial reporting.

In September 2015, the FASB issued ASC Update No. 2015-16, Business Combination (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments. This accounting guidance requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period with a corresponding adjustment to goodwill in the reporting period in which the adjustment amounts are determined. The effect on earnings of changes in depreciation, amortization or other income effects, if any, as a result of the change to the provisional amounts will be recorded in the same period's financial statements, calculated as if the accounting had been completed at the acquisition date. This guidance should be applied prospectively to adjustments to provisional amounts that occur after the effective date. This guidance is effective for fiscal years beginning after December 15, 2015 and interim periods within those fiscal years. We adopted this guidance January 1, 2016 and as a result of the adoption we reduced goodwill by \$24.0 million for the nine months ended September 30, 2016.

In January 2016, the FASB issued ASC Update No. 2016-01, Financial Instruments-Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. Update 2016-01 requires entities to measure equity investments that do not result in consolidation and are not accounted for under the equity method to be measured at fair value with changes recognized in net income. However, an entity may elect to measure equity investments that do not have readily determinable fair values at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. The amendments, in addition, reduce complexity of the impairment assessment of equity investments without readily determinable fair values with regard to the other-than-temporary impairment guidance. The amendments also require separate presentation of financial assets and financial liabilities by measurement category and form of financial asset and liability. This guidance is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early application of certain provisions is permitted. We are currently evaluating the effect this standard will have on our consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASC Update No. 2016-02, Leases (new Topic 842, superseded Topic 840): This guidance requires lessees to recognize most leases on their balance sheets as lease liabilities with corresponding right-of-use assets. While many aspects of lessor accounting remain the same, the new standard makes some changes, such as eliminating today's real estate-specific guidance. The new standard requires lessees and lessors to classify most leases using a principle generally consistent with that of "IAS 17 - Leases," which is similar to U.S. GAAP but without the use of bright lines. The standard also changes what is considered initial direct costs. Entities are required to use a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. The standard is effective for annual periods beginning after December 15, 2018 and interim periods within that year. Early adoption is permitted. We are currently evaluating the effect this standard will have on our consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASC Update No. 2016-09, Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. This update simplifies the accounting for certain income tax aspects of share-based payment transactions, including: the recognition of excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement, the treatment of the tax effects of exercised or vested awards as discrete items in the reporting period in which they occur and the recognition of excess tax benefits regardless of whether the benefit reduces taxes payable in the current period. The amendments related to the timing of when excess tax benefits should be applied using a modified retrospective transition method by means of a cumulative-effect adjustment to equity as of the beginning of the period in which the guidance is adopted. In addition, simplification includes the classification of all excess tax benefits on the statement of cash flows as an operating activity; the entity may elect to apply this cash flow simplification using either a prospective or a retrospective transition method. The amendments in this Update are effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods; early adoption is permitted in any interim or annual period. We are currently evaluating the effect this standard will have on our consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASC Update No. 2016-13, Financial Instruments—Credit Losses (Topic 326): The amendments in this update require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The measurement of expected credit losses is based on relevant information about past events, including historical experience, current conditions, and reasonable and supportable forecasts that affect the collectibility of the reported amount. An entity must use judgment in determining the relevant information and estimation methods that are appropriate in its circumstances. The initial allowance for credit losses is added to the purchase price rather than being reported as a credit loss expense. Only subsequent changes in the allowance for credit losses are recorded as a credit loss expense for these assets. In addition, credit losses relating to available-for-sale debt securities should be recorded through an allowance for credit losses. The amendments limit the amount of the allowance for credit losses to the amount by which fair value is below amortized cost, require that credit losses be presented as an allowance rather than as a write-down and will allow an entity to record reversals of credit losses in current period earnings in situations in which the estimate of credit losses declines in current period. Current GAAP prohibits reflecting those improvements in current period earnings. The amendments in this update are effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted as of the fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The modified-retrospective approach is generally applicable through a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. We are currently evaluating the effect this standard will have on our consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASC Update No. 2016-15, Classification of Certain Cash Receipts and Cash Payments (Topic 230 -Statement of Cash Flows): The amendments provide guidance in the presentation and classification of certain cash receipts and cash payments in the statement of cash flows including debt prepayment or debt extinguishment costs, settlement of zero-coupon debt instruments, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies, and distributions received from equity method investees. The amendments are effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years with early adoption permitted. The amendments should be applied using a retrospective transition method to each period presented. We are currently evaluating the impact of adopting these provisions on its consolidated financial statements.

In October 2016, the FASB issued ASC Update No. 2016-16, Income Taxes - Intra-Entity Transfers of Assets Other Than Inventory (Topic 740): This update simplifies the accounting for the income tax consequences of transfers of assets from one unit of a corporation to another unit or subsidiary by eliminating an accounting exception that prevents the recognition of current and deferred income tax consequences for such “intra-entity transfers” until the assets have been sold to an outside party. The amendment should be applied using a modified retrospective transition method by means of a cumulative-effect adjustment directly to retained earnings as of the beginning of the period in which the guidance is adopted. The rule takes effect for annual periods after Dec. 15, 2017, including interim periods within those annual reporting periods; early adoption is permitted. We are currently evaluating the effect this standard will have on our consolidated financial statements and related disclosures.

Note 24. Subsequent Events

Financing arrangement. In October 2016, we entered into a \$40.0 million revolving credit facility for two years with Barclays Bank PLC for general corporate purposes. The maximum interest for this facility is the Libor rate plus 0.95%.

Departure of Chief Executive Officer. On November 2, 2016, the Company announced the November 1, 2016 resignation of André-Michel Ballester as Chief Executive Officer and as a member of the Board of Directors of LivaNova Plc effective on December 31, 2016. Mr. Ballester will receive a payment in lieu of notice as described in his service agreement filed with the Securities and Exchange Commission as Exhibit 10.7 to the Form 8-K filed on October 19, 2015. He will also be eligible to receive a bonus for fiscal year 2016 consistent with the Company's Annual Executive Bonus Program. In addition, Mr. Ballester and the Company have agreed that Mr Ballester will provide consulting services to assist the Company until the end of 2020. Mr Ballester will forfeit all equity awards that have not vested by the end of 2017. None of the costs associated with these severance arrangements have been accounted for in the quarter ended September 30, 2016.

Appointment of New Chief Executive Officer. On November 2, 2016, the Company also announced that its Chief Operating Officer, Damien McDonald, had been appointed Chief Executive Officer and a member of the Board of Directors of the Company effective January 1, 2017.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our condensed consolidated financial statements and related notes which appear elsewhere in this document. This discussion and analysis is intended to assist in providing an understanding of our financial condition, changes in financial condition and results of operations and is organized as follows:

- **Business Overview.** This section provides a general description of our business and recent events.
- **Results of Operations.** This section provides an analysis of the results of our operations for the three and nine months ended September 30, 2016.
- **Liquidity and Capital Resources.** This section provides an analysis of our liquidity, capital resources, cash flows and contractual commitments.

The capitalized terms used below have been defined in the notes to our condensed consolidated financial statements. In the following text, the terms "we," "our," "our company" and "us" may refer, as the context requires, to LivaNova PLC or collectively to LivaNova PLC and its subsidiaries.

Business Overview

LivaNova (formerly known as Sand Holdco PLC and Sand Holdco Limited) is a public limited company organized under the laws of England and Wales. Headquartered in London, United Kingdom ("U.K."), LivaNova, is a global medical device company focused on the development and delivery of important therapeutic solutions for the benefit of patients, healthcare professionals and healthcare systems throughout the world. Working closely with medical professionals in the fields of Cardiac Surgery, Cardiac Rhythm Management and Neuromodulation, we design, develop, manufacture and sell innovative therapeutic solutions that are consistent with our mission to improve our patients' quality of life, increase the skills and capabilities of healthcare professionals and minimize healthcare costs.

We operate our business through three segments, which we call Business Units: Neuromodulation, Cardiac Surgery and Cardiac Rhythm Management. Each Business Unit corresponds to one of our three main therapeutic areas resulting from the strategic combination of Cyberonics and Sorin and aligned to best serve our customers and capitalize upon the benefits of the Mergers. The historical Cyberonics operations are included under the Neuromodulation Business Unit, and the historical Sorin businesses are included in our Cardiac Surgery and Cardiac Rhythm Management Business Units.

Corporate activities include corporate business development, which we refer to as the New Ventures Organization or New Ventures. New Ventures is focused on new growth platforms and identification of other opportunities for expansion and investment.

For further information regarding the Mergers our business segments, historical financial information and our methodology for the presentation of financial results, please refer to the condensed consolidated financial statements and accompanying notes of this Quarterly Report on Form 10-Q as well as to our 2015 annual report on Form 10-KT.

Cardiac Surgery Business Unit

LivaNova's Cardiac Surgery ("CS") Business Unit is engaged in the development, production and sale of cardiovascular surgery products, including oxygenators, heart-lung machines, perfusion tubing systems, cannulae and accessories and systems for autotransfusion and autologous blood washing, as well as implantable prostheses for the replacement or repair of heart valves. Cardiac Surgery consists of two sub-categories, Cardiopulmonary and Heart Valves. Cardiopulmonary products include oxygenators, heart-lung machines, perfusion tubing systems, cannulae and accessories and systems for autotransfusion and autologous blood washing. Heart Valve products include a comprehensive line of surgical tissue and mechanical valve replacements and repair products for damaged or diseased heart valves.

Cardiopulmonary Recent Developments

In December 2015, we received an FDA Warning Letter (the "Warning Letter") alleging certain violations of FDA regulations applicable to our Munich, Germany and Arvada, Colorado manufacturing facilities. On October 13, 2016 the Centers for Disease Control and Prevention ("CDC") and FDA separately released safety notifications regarding the 3T heater-cooler devices and the Company issued a Field Safety Notice Update for US users of 3T heater-cooler devices to proactively and voluntarily contact facilities to facilitate implementation of the CDC and FDA recommendations. Furthermore, we have received additional lawsuits related to the 3T heater-cooler device during the third quarter ended September 30, 2016. For further information, please refer to "Note 16. Commitments and Contingencies" in our consolidated financial statements included in this Quarterly Report on Form 10-Q.

Heart Valve Recent Developments

In January 2016, we announced FDA approval of our Perceval valve. Perceval is the only sutureless biological aortic replacement valve on the market today with a unique self-anchoring frame that enables the surgeon to replace the diseased valve without suturing it into place. While we have been selling Perceval in other parts of the world, we began commercial distribution of the device in the United States with the first implant announced on March 8, 2016. To date, the Perceval valve has been implanted in more than 15,000 patients in over 310 hospitals worldwide.

In addition, in early February 2016, we announced that we had received FDA approval of CROWN PRT valve for the treatment of aortic valve disease. The CROWN PRT is a stented aortic bioprosthesis technology and features a surgeon-friendly design, with optimized hemodynamics with patented PRT, designed to enhance valve durability. We anticipate launching CROWN PRT in the U.S. later this year.

Cardiac Rhythm Management Business Unit

The Cardiac Rhythm Management ("CRM") Business Unit develops, manufactures and markets products for the diagnosis, treatment, and management of heart rhythm disorders and heart failure. These products include implantable devices, leads and delivery systems and information systems for the management of patients with CRM devices.

CRM Recent Developments

The 2015 and the 2016 Reorganization Plans (the "Plans") were initiated October 2015 and March 2016, respectively, and were initiated in conjunction with the Mergers. These Plans are intended to leverage economies of scale, streamline distribution and logistics and strengthen operational and administrative effectiveness in order to reduce overall costs. Costs associated with these Plans were reported as restructuring expense in the operating results of our consolidated statement of income (loss). As part of these Plans, certain activities previously undertaken within the New Ventures organization will be integrated into and combined with the CRM Business Unit. We estimate that these Plans will result in a net reduction in the workforce at our manufacturing and R&D facility located in Clamart, France. This plan also includes the closure of our R&D facility in Meylan, France and consolidation of the R&D capabilities into the Clamart facility.

In November 2015, we launched the PLATINIUM implantable cardiac defibrillator ("ICD") in Europe. In September 2016, we announced the launch in the U.S. During 2015, we continued the development of our IS4 PLATINIUM CRTD with SonR dedicated to the use of quadripolar left ventricular catheters with IS-4 compatibilities. The development of new ranges of leads for defibrillation and left ventricular stimulation also enjoyed significant progress with the completion of the pre-qualification phase.

In June 2015, we announced the European launch of a full body MRI conditional pacemaker, the KORA 250. The KORA 250 is equipped with our proprietary Automatic MRI mode. In addition, the device is designed to proactively manage comorbidities, including a pacing mode that manages all types of atrioventricular block ("AV"), referred to as "SafeR", and the ability to monitor patients for severe sleep apnea using Sleep Apnea Monitoring ("SAM"). In the first quarter of 2016, the KORA 250 was approved and launched in Japan.

In June 2013, following FDA approval to initiate a clinical trial under an Investigational Device Exemption (“IDE”), the first patients were enrolled in the United States in the Respond CRT clinical trial (cardiac resynchronization therapy). The purpose of this trial is to assess the safety and effectiveness of the SonR CRT™ system in patients affected by advanced heart failure. In October 2014, Sorin announced having completed enrollment in the Respond CRT™ clinical trial, enrolling 1,039 patients in the study. In May 2016 we announced results from the Respond CRT™ clinical trial, showing that a 35% risk reduction in heart failure hospitalization was associated with SonR. In August 2016, we announced the results from the 18-month follow-up period that confirm significant long term risk reduction in heart failure hospitalization.

Neuromodulation Business Unit

Our Neuromodulation Business Unit designs, develops and markets neuromodulation-based medical devices for the treatment of epilepsy and depression. Through this Business Unit, we market our proprietary implantable VNS Therapy Systems that deliver vagus nerve stimulation therapy for the treatment of epilepsy and depression. In July 2005, the FDA approved our VNS Therapy System for the adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who have not had an adequate response to multiple anti-depressant treatments. Regulatory bodies in the European Economic Authority (“EEA”), Canada, Brazil, Mexico, Australia, Israel and certain other international markets have approved our VNS Therapy products for the treatment of chronic or recurrent depression in patients who are in a treatment-resistant or treatment-intolerant depressive episode. Reimbursement for the use of VNS Therapy to treat TRD is significantly limited in most countries in which it is available.

Neuromodulation Recent Developments

In June 2015, the FDA approved AspireSR® for commercialization in the United States. Growth of VNS Therapy products has been strong during the period following this approval. Acceptance of the new product, as evidenced by the proportion of generators sold, has been high, and pricing obtained for the product has been at a premium due to the unique nature of the device.

New Ventures

The New Ventures group was created to invest in significant, new growth opportunities. The three significant unmet clinical needs the New Ventures group is seeking to address are: heart failure, sleep apnea and mitral valve regurgitation.

New Ventures Recent Developments

Heart failure. In the heart failure area, New Ventures is currently managing three internal neurostimulation projects, being Equilia, VITARIA and Intense, each aimed at treating heart failure through vagus nerve stimulation. Equilia is a first-generation device that benefited from the legacy Sorin business’ acquisition of the Belgian company, Neurotech SA in 2012, which enhanced Sorin’s technical expertise and intellectual property in the field of neurostimulation. The successful implantation of the first Equilia neurostimulation system device occurred in February 2015 as part of the Vanguard (Vagal Nerve Stimulation Safeguarding Heart Failure) clinical trial. The aim of the system is to treat heart failure through stimulation of the vagus nerve.

In February 2015, the legacy Cyberonics business received CE Mark approval of the VITARIA System for patients who have moderate to severe heart failure (New York Heart Association Class II/III) with left ventricular dysfunction (ejection fraction < 40 per cent.) and who remain symptomatic despite stable, optimal heart failure drug therapy. The VITARIA System provides a specific method of VNS called autonomic regulation therapy (“ART”), and it includes the same elements as the VNS Therapy System - pulse generator, lead, programming wand and software, programming computer, tunneling tool and accessory pack, but without the patient kit with magnets. Cyberonics conducted a pilot study, ANTHEM-HF, outside the United States, which concluded during the quarter ended 24 October 2014. The study results support the safety of ART delivered by the VITARIA System. Cyberonics submitted the results to its European Notified Body, DEKRA, and on 20 February 2015, it received CE Mark approval. Cyberonics also initiated a second pilot study, ANTHEM-HfpEF, to study ART in patients experiencing symptomatic heart failure with preserved ejection fraction. This pilot study is currently underway outside the United States.

The other principal New Ventures heart failure initiative, Intense, is a broader project that is partially subsidized by the French government through Banque Publique d’Investissement.

With the completion of the Mergers, the New Ventures group is continuing to evaluate the appropriate course of action for each project, which could include future development efforts such as additional clinical trials or re-evaluation of certain projects.

Sleep Apnea. In October 2014, Sorin invested \$20 million in Respicardia, a U.S.-based developer of implantable therapies designed to improve Respiratory Rhythm Management and cardiovascular health. Respicardia’s remedé System is an

implantable device system designed to restore a more natural breathing pattern during sleep in patients with central sleep apnea (CSA) by transvenously stimulating the phrenic nerve. The remedé System received CE Mark certification in 2010 and is currently available in certain countries in Europe. Results from a randomized, controlled pivotal trial were reported at the European Society of Cardiology - Heart Failure meeting in May 2016. Investigators reported that patients in the treatment group were significantly more likely to have a reduction in AHI of $\geq 50\%$ between baseline and 6 months ($p < 0.001$) compared to patients in the control group. This result was matched by significant improvements in other apnea-related parameters and quality of life measures. The device was well-tolerated, with 91% of patients free from serious adverse events associated with implantation. In September 2016, Respicardia applied for U.S. FDA market approval. In September 2016 we elected not to exercise our option to purchase the outstanding shares of Respicardia as the investment no longer met our objective for substantial ongoing involvement taken into consideration with our overall portfolio management program. As a result, we recorded an impairment of \$9.2 million equal to the amount of the carrying value of the option. Also in September 2016, we started the process to terminate our exclusive distribution agreement with Respicardia.

Cyberonics completed an investment of \$12.0 million in ImThera Medical, Inc. (“ImThera”) by December 2013. ImThera is a privately held company developing an implantable neurostimulation device system for the treatment of obstructive sleep apnea (OSA). The aura6000[®] System stimulates the hypoglossal nerve to treat OSA. In November 2014, ImThera announced that the U.S. FDA approved an IDE for their pivotal clinical study and patient enrollment has commenced. In May 2015 the first subjects were implanted in the pivotal study.

Mitral valve regurgitation. Sorin invested in three mitral valve startups: (i) Cardiosolutions Inc., a startup headquartered in the United States developing an innovative Spacer technology for treating mitral regurgitation, (ii) Highlife S.A.S. (“Highlife”), headquartered in France, and (iii) Caisson Interventional LLC (“Caisson”), headquartered in the United States. Highlife and Caisson are companies focused on developing devices for treating mitral regurgitation through percutaneous replacement of the native mitral valve. Although both ventures are focused on mitral valve replacement, their devices differ significantly in both the delivery system (transapical versus transfemoral) and the anchoring system. In the quarter ended September 30, 2016, we invested an additional \$7.5 million in Caisson. In the quarter ended March 31, 2016 we loaned an additional \$2.8 million to Highlife and in the quarter ended June 30, 2016 we loaned an additional \$1.0 million to Caisson.

Significant Accounting Policies and Critical Accounting Estimates

There have been no material changes to our critical accounting policies from the information provided in “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our 2015 Form 10-KT. The accompanying unaudited condensed consolidated financial statements of historical Cyberonics and its consolidated subsidiaries have been prepared in accordance with U.S. GAAP on an interim basis.

New accounting pronouncements are disclosed in “Note 23. New Accounting Pronouncements” in the consolidated financial statements.

Other

On June 23, 2016, the United Kingdom held a referendum in which voters approved an exit from the European Union, commonly referred to as “Brexit,” which has caused and may continue to cause significant volatility in capital and currency markets worldwide. Asset valuations, currency exchange rates and credit ratings may be especially subject to increased market volatility. The full impact of Brexit remains uncertain. A process of negotiation, which is likely to take two years or longer, will determine the future terms of the U.K.’s relationship with the European Union. It is unclear at this stage what financial, trade and legal implications the withdrawal of the U.K. from the European Union would have and how such withdrawal would affect us. Management will continue to monitor and assess the potential impact of this event on an ongoing basis.

Results of Operations

The merger of Cyberonics and Sorin on October 19, 2015 was considered a business combination with Cyberonics considered the acquirer of Sorin using the acquisition method of accounting. As a result, Sorin's assets and liabilities were combined at their estimated fair values. In addition, LivaNova became the holding company of the combined businesses of Cyberonics and Sorin and the "successor" company to Cyberonics for accounting and Exchange Act reporting purposes. LivaNova is reporting, in this Quarterly Report on Form 10-Q, the results for LivaNova and its consolidated subsidiaries for the period January 1, 2016 to September 30, 2016, which is the first, second and third quarters of the fiscal year ended December 31, 2016. In addition, LivaNova reported the historical results of Cyberonics and its consolidated subsidiaries for the thirteen and thirty-eight weeks ended October 18, 2015 as the comparative prior fiscal year periods, which consisted of the thirteen weeks ended April 24, 2015, or the fourth quarter of Cyberonics' fiscal year ended April 24, 2015 and the twenty-five weeks ended October 18, 2015, or the first and second quarter of the transitional fiscal year that ended December 31, 2015.

Upon completion of the Mergers we reorganized our reporting structure and aligned our segments and the underlying divisions and businesses. The Cyberonics operations and historical data are now included in the Neuromodulation segment, and the Sorin operations are included in the Cardiac Surgery and the CRM segments. Refer to "Note 22. Geographic and Segment Information" to the consolidated financial statements included in this Quarterly Report on Form 10-Q for additional discussion related to our segment reporting.

Net Sales

The table below illustrates net sales by operating segment (in thousands, except for percentages):

	Three Months Ended September 30, 2016	Twelve Weeks Ended October 18, 2015 ⁽¹⁾	\$ Increase	% Change
Cardiac Surgery	\$ 148,518	\$ —	\$ 148,518	—%
Cardiac Rhythm Management	56,768	—	56,768	—%
Neuromodulation	89,504	67,521	21,983	32.6%
Corporate and New Ventures	478	—	478	—%
Total	<u>\$ 295,268</u>	<u>\$ 67,521</u>	<u>\$ 227,747</u>	

	Nine Months Ended September 30, 2016	Thirty-Eight Weeks Ended October 18, 2015 ⁽¹⁾	\$ Increase	% Change
Cardiac Surgery	\$ 453,012	\$ —	\$ 453,012	—%
Cardiac Rhythm Management	188,057	—	188,057	—%
Neuromodulation	260,901	222,603	38,298	17.2%
Corporate and New Ventures	1,314	—	1,314	—%
Total	<u>\$ 903,284</u>	<u>\$ 222,603</u>	<u>\$ 680,681</u>	

(1) The equivalent prior period data uses unaudited historical Cyberonics' data.

The Cardiac Surgery and CRM segment sales occurred from January 1, 2016 to September 30, 2016, as a result of the Mergers on October 19, 2015.

Neuromodulation net sales for the three months ended September 30, 2016 increased \$22.0 million, or 32.6%, as compared to the twelve weeks ended October 18, 2015, with a generator unit sales volume increase of 22.8%. The revenue growth was due to an increase in revenue of 28.3% in the U.S. market and a 59.7% increase in revenue in non-U.S. markets. These increases were partially due to an extra week this year as compared to the previous year and partially due to increased demand.

Neuromodulation net sales for the nine months ended September 30, 2016 increased by \$38.3 million or 17.2%, as compared to the thirty-eight weeks ended October 18, 2015, with a generator unit sales volume increase of 5.5%. The revenue growth was due to an increase in revenue of 19.1% in the U.S. market and a 7.7% increase in revenue in non-U.S. markets. These increases were partially due to an extra week this year as compared to the previous year and partially due to increased demand. The decrease in international unit volume was primarily due to the drop-off of sales activity in Venezuela.

The table below illustrates net sales by market geography (in thousands):

	Three Months Ended September 30, 2016				Twelve Weeks Ended October 18, 2015
	Neuromodulation	Cardiac Surgery	Cardiac Rhythm Management	New Ventures and Corporate	Neuromodulation
United States	\$ 74,864	\$ 46,768	\$ 2,178	\$ —	\$ 58,353
Europe ⁽¹⁾	8,489	38,009	44,747	—	5,772
Rest of World	6,151	63,741	9,843	478	3,396
Total	<u>\$ 89,504</u>	<u>\$ 148,518</u>	<u>\$ 56,768</u>	<u>\$ 478</u>	<u>\$ 67,521</u>

	Nine Months Ended September 30, 2016				Thirty-Eight Weeks Ended October 18, 2015
	Neuromodulation	Cardiac Surgery	Cardiac Rhythm Management	New Ventures and Corporate	Neuromodulation
United States	\$ 220,892	133,995	7,471	\$ —	\$ 185,454
Europe ⁽¹⁾	24,208	128,229	149,141	149	22,958
Rest of World	15,801	190,788	31,445	1,165	14,191
Total	<u>\$ 260,901</u>	<u>\$ 453,012</u>	<u>\$ 188,057</u>	<u>\$ 1,314</u>	<u>\$ 222,603</u>

- (1) Includes those countries in Europe where LivaNova has a direct sales presence. Countries where sales are made through distributors are included in Rest of World.

Cost of Sales and Expenses

The table below illustrates our cost of sales and major expenses as a percentage of sales for the three and nine months ended September 30, 2016 as compared to the twelve and thirty-eight weeks ended October 18, 2015. We developed the equivalent prior period data using unaudited historical Cyberonics' data:

	Three Months Ended September 30, 2016	Twelve Weeks Ended October 18, 2015	% Change
Cost of sales	36.1%	14.1%	22.0 %
Selling, general and administrative	36.4%	61.0%	(24.6)%
Research and development	10.9%	21.8%	(10.9)%
Merger and integration expenses	2.6%	41.3%	(38.7)%
Restructuring expenses	1.5%	—%	1.5 %
Amortization of intangibles	4.0%	0.8%	3.2 %
Litigation related expenses	0.8%	—%	0.8 %

	Nine Months Ended September 30, 2016	Thirty-Eight Weeks Ended October 18, 2015	% Change
Cost of sales	39.9%	11.9%	28.0 %
Selling, general and administrative	38.0%	47.0%	(9.0)%
Research and development	10.4%	15.8%	(5.4)%
Merger and integration expenses	2.3%	19.4%	(17.1)%
Restructuring expenses	4.1%	—%	4.1 %
Amortization of intangibles	3.8%	0.7%	3.1 %
Litigation related expenses	0.5%	—%	0.5 %

Cost of Sales

Cost of sales consisted primarily of direct labor, allocated manufacturing overhead, the acquisition cost of raw materials and components. Amortization of the inventory step-up in basis recorded at the Mergers is included in cost of sales.

Our cost of sales as a percentage of net sales increased to 36.1% and 39.9% for the three and nine months ended September 30, 2016, respectively, as compared to 14.1% and 11.9% reported for Cyberonics' historical data for the twelve and thirty-eight weeks ended October 18, 2015, respectively. The year over year increases were primarily due to the inclusion of Sorin's business activities after the Mergers. We recorded no amortization of the inventory step-up in basis for the three months ended September 30, 2016, while the inventory step-up amortization accounted for 3.9% of our cost of sales as a percent of net sales for the nine months ended September 30, 2016.

Selling, General and Administrative ("SG&A") Expenses

SG&A expenses are comprised of sales, marketing, general and administrative activities. SG&A expenses exclude expenses incurred in connection with the merger between Cyberonics and Sorin, integration costs after the Mergers and restructuring costs under the 2015 and 2016 Restructuring Plans initiated after the Mergers. Also excluded from SG&A expense is amortization of intangible assets.

SG&A expenses as a percentage of net sales were 36.4% and 38.0%, for the three and nine months ended September 30, 2016, respectively, as compared to 61.0% and 47.0% for the twelve and thirty-eight weeks ended October 18, 2015, respectively. These reductions in costs as a percent of net sales was due to our integration and re-organization efforts that have capitalized on synergies between Cyberonics and Sorin. In addition, in May 2016 we received a grant of \$4.7 million from the Italian government, the Regione Emilia Romagna, as a reimbursement and offset to the costs Sorin incurred as a consequence of the earthquake of May 2012 in Italy, which we recorded as a reduction to SG&A expenses for the quarter ended June 30, 2016.

Research and Development (“R&D”) Expenses

R&D expenses consist of product design and development efforts, clinical trial programs and regulatory activities. R&D expenses as a percentage of net sales were 10.9% and 10.4% for the three and nine months ended September 30, 2016, respectively and were 21.8% and 15.8% for the twelve and thirty-eight weeks ended October 18, 2015, respectively. These decreases were due to the completion of certain R&D projects and the reduction of R&D work as a result of our ongoing review of projects and priorities in conjunction with the 2015 and 2016 Reorganization Plans.

Merger and Integration Expenses

Our merger and integration expenses consisted primarily of consulting costs associated with: computer systems integration efforts, organization structure integration, synergy and tax planning, as well as the integration of internal controls for the two legacy organizations. In addition, integration expenses include retention bonuses, branding and renaming efforts and lease cancellation penalties in Milan and Brussels.

During the three and nine months ended September 30, 2016, we incurred \$7.6 million and \$20.5 million, respectively, in merger and integration expenses, which we reported as a separate operating expense in our consolidated statement of income (loss). For the twelve and thirty-eight weeks ended October 18, 2015 our merger and integration expenses were \$27.9 million and \$43.1 million, respectively.

Restructuring Expenses

Restructuring expenses were primarily due to our efforts under our 2015 and 2016 Reorganization Plans to leverage economies of scale, eliminate duplicate corporate expenses and streamline distributions, logistics and office functions in order to reduce overall costs, which we reported as a separate operating expense in our consolidated statement of income (loss). We incurred restructuring expenses of \$4.4 million and \$37.2 million in the three and nine months ended September 30, 2016, respectively.

Amortization of intangible assets

We incurred amortization expense of \$11.8 million and \$34.0 million for the three and nine months ended September 30, 2016, respectively, and \$0.5 million and \$1.5 million for the twelve and thirty-eight weeks ended October 18, 2015, respectively. The fiscal year 2016 amounts represent amortization expense of intangible property, primarily intellectual property and customer relationships acquired at fair value in the Mergers. Amortization is reported as a separate item in the consolidated statement of income (loss) and does not include amortization of the step-up in the fair value of inventory that resulted from the Mergers, which is included in cost of sales in the consolidated statement of income (loss).

Goodwill Impairment

We test goodwill for impairment on an annual basis or when events or changes in circumstances indicate that a potential impairment exists. If our operating performance or our anticipated business outlook deteriorates, our reporting units' estimated fair value could decline below their carrying value, resulting in an impairment of goodwill. Likewise, if the market conditions or anticipated performance for our Cardiac Rhythm Management reporting unit deteriorates, it is possible that the estimated fair value of this reporting unit could be less than its carrying value when we perform our annual impairment analysis in our fourth quarter of 2016.

Factors that could have a negative impact on the fair value of our reporting units include, but are not limited to:

- Decreases in revenue as a result of the inability of our sales force to effectively market and promote our products;
- Increased competition, patent expirations or new technologies or treatments;
- Declines in anticipated growth rates;
- The outcome of litigation, legal proceedings, investigations or other claims resulting in significant cash outflows;
- Sustained decline in our stock price

Adverse changes in one or more of these factors could reduce the estimated fair value of our reporting unit below its carrying value in future periods.

Litigation Related Expenses

We segregate and report separately certain litigation expenses in the consolidated statements of net income (loss). For the three and nine months ended September 30, 2016, we reported \$2.4 million and \$4.7 million, respectively, of litigation expenses related to the FDA Warning Letter regarding our 3T Heater Cooler devices we manufactured at our Munich facility, the SNIA S.p.A litigation regarding potential liabilities arising from claims for environmental damage and the termination of two agents.

Interest Expense, net of interest income

We incurred interest expense, net of interest income, of \$2.9 million and \$5.5 million for the three and nine months ended September 30, 2016, respectively and interest income, net of interest expense of \$86 thousand and \$30 thousand for the twelve and thirty-eight weeks ended October 18, 2015, respectively. Interest expense for the three and nine months ended September 30, 2016, was primarily due to interest on taxes payable related to our inter-company sale of intellectual property undertaken during the second quarter ended June 30, 2016 and interest expense related to the debt acquired in the Mergers.

Foreign Exchange and Other, Net

Our FX gains and losses are primarily due to inter-company debt and third party financial assets and liabilities, partially hedged by FX derivative contracts. For the nine months ended September 30, 2016 and the thirty-eight weeks ended October 18, 2015 there were no material net foreign exchange gains or losses.

Income Taxes

Our effective tax rates were 46% and 514% for the three and nine months ended September 30, 2016, respectively. The effective tax rate for the nine months ended September 30, 2016 differed from the U.K. statutory rate of 20%, which is the tax rate for the location of our worldwide headquarters, primarily due to the recording of valuation allowances of \$23.9 million related to certain tax jurisdictions, including France and the U.K., in which we did not record tax benefits generated by their operating losses, as well as the tax expense generated by profitable operations in higher tax jurisdiction, such as the U.S. and Germany, offset by tax savings from our inter-co financing entered as part of our 2015 tax restructuring.

A valuation allowance is established if it is more-likely-than-not that all or a portion of the deferred tax assets, such as net operating loss carryforwards, will not be realized. We have experienced significant operating losses in certain entities with sufficient uncertainty regarding future taxable income in these entities such that a valuation allowance is required to fully offset the NOL carryforwards.

In fiscal year 2016 we consolidated certain of our intangible assets into an entity organized under the laws of England and Wales. Because the intangible assets were sold and purchased inter-company, the tax expense on the inter-company gain is deferred and as a result, in the quarter ended June 30, 2016, we recorded the deferred tax expense as an asset, in the amount of \$156.4 million, and we recorded a deferred tax liability of the same amount. The deferred expense is recorded in the consolidated balance sheet as Other Current Assets and Other Assets, Long-Term, in the amount of \$19.6 million and \$136.8 million, respectively. These assets are being amortized to current income tax expense in the consolidated statement of net income (loss) over an 8 year period, which represents the estimated useful life of the intangible assets that were consolidated into the U.K. entity. As taxes become payable on the intercompany gain the deferred tax credit will be offset against current tax liabilities.

The effective tax rate for the three months ended September 30, 2016 differed from the U.K. statutory rate of 20% primarily due to the recording of valuation allowances and the results of our profitable operations in higher tax jurisdiction, such as the U.S. and Germany.

Effective tax rates for historical Cyberonics activity for the twelve and thirty-eight weeks ended October 18, 2015 were 5% and 123%, respectively. The effective tax rates were primarily comprised of the U.S. federal income tax rate of 35%, plus state and foreign income taxes and non-deductible transaction costs.

In April 2016, the Guardia di Finanza, the Italian enforcement agency, under the authority of the Minister of Economy and Finance, commenced an audit of Sorin Group Italia Srl for tax years 2012 through 2015. At this time we are unable to predict the results of the audit.

In April 2016, the U.S. Internal Revenue Service (“IRS”) and U.S. Treasury Department issued new rules that materially change the manner in which the determination is made as to whether the U.S. anti-inversion rules under Section 7874 will apply. The new rules have the effect of linking with the Mergers certain future acquisitions of U.S. businesses made in exchange for LivaNova equity, and such linkage may impact LivaNova’s ability to engage in particular acquisition strategies. For example, the new temporary regulations would impact certain acquisitions of U.S. companies in an exchange for stock in LivaNova during the 36 month period beginning October 19, 2015 by excluding from the Section 7874 calculations the portion of shares of LivaNova that are allocable to the legacy Cyberonics shareholders. This new rule would generally have the effect of increasing the otherwise applicable Section 7874 fraction with respect to future acquisitions of a U.S. business, thereby increasing the risk that such acquisition could cause LivaNova to be treated as a U.S. corporation for U.S. federal income tax purposes.

For further information relating to the impact of Section 7874 on LivaNova, refer to the section entitled “*The IRS may not agree with the conclusion that LivaNova should be treated as a foreign corporation for U.S. federal tax purposes, and LivaNova may be required to pay substantial U.S. federal income taxes*” and the subsequent related risk factors included in “Part I, Item 1A. Risk Factors” in the 2015 Form 10-KT.

On October 13, 2016, the U.S. IRS and U.S. Treasury Department released final regulations under Section 385. The regulation establishes extensive documentation requirements that must be satisfied for a debt instrument to constitute debt for U.S. federal tax purposes and re-characterizes a debt instrument as equity if the instrument is issued in one of a number of specified transactions. The final rules will not have a material impact on our intercompany transactions or structure.

Losses from Equity Method Investments

We recognized losses of \$13.1 million and \$19.4 million during the three and nine months ended September 30, 2016, primarily for the impairment of Respicardia and our share of investee losses at Highlife, Caisson, Respicardia and MicroPort SorinCRM.

During the quarter ended September 30, 2016, we declined to exercise or extend our option to purchase all of the issued and outstanding shares of Respicardia held by other investors as we preferred to continue as a minority investor instead of becoming a strategic acquirer as taken into consideration with our overall portfolio management program. Our analysis indicated that our carrying value in Respicardia might not be recoverable and the decrease in value of our investment was other than temporary. We estimated the fair value of our investment in Respicardia using information about past events, current conditions, and forecasts and an estimate of future cash flows. The estimated fair value was below our carrying cost and we impaired our investment in Respicardia by \$9.2 million, which essentially is representative of the purchase option’s carrying value on the date we declined to exercise our option. This loss is included in Losses from Equity Method Investments in the consolidated statement of income (loss). In addition, during the quarter ended September 30, 2016, we started the process that will result in the cancellation of our distributor agreement with Respicardia in the fourth quarter ending December 31, 2016. The distributor agreement is a key component in the determination of whether our influence over Respicardia is significant. We accounted for Respicardia as an equity method investment through September 30, 2016 and will reevaluate our accounting method as of the date of the formal cancellation of the distributor agreement.

Liquidity and Capital Resources

Based on our current business plan, we believe that our existing cash, investments and future cash generated from operations will be sufficient to fund our expected operating needs, working capital requirements, R&D opportunities, capital expenditures and debt service requirements over the next 12 months. We regularly review our capital needs and consider various investing and financing alternatives to support our requirements. Refer to “Note 14. Financing Arrangements” in the consolidated financial statements in this Quarterly Report on Form 10-Q for additional information regarding our debt. Our liquidity could be adversely affected by factors affecting future operating results, including those referred to in “Item 1A. Risk Factors” above.

No provision has been made for income taxes on unremitted earnings of our foreign controlled subsidiaries (non-U.K. locations) as of September 30, 2016. In the event of the distribution of those earnings in the form of dividends, a sale of the subsidiaries or certain other transactions, we may be liable for income taxes. However, the tax liability on future distributions should not be significant as most jurisdictions with unremitted earnings have various participation exemptions or no withholding tax.

Cash Flows

Net cash and cash equivalents provided by (used in) operating, investing and financing activities and the net increase (decrease) in the balance of cash and cash equivalents were as follows (in thousands):

	Nine Months Ended September 30, 2016	Thirty-Eight Weeks Ended October 18, 2015
Operating activities	\$ 49,348	\$ 65,630
Investing activities	(29,768)	14,766
Financing activities	(69,591)	(6,956)
Effect of exchange rate changes on cash and cash equivalents	1,030	122
Net increase (decrease)	<u>\$ (48,981)</u>	<u>\$ 73,562</u>

Operating Activities

Cash provided by our consolidated operating activities during the nine months ended September 30, 2016 was \$49.3 million. During the nine months ended September 30, 2016, we incurred a net loss of \$33.0 million, which included the non-cash expenses amounting to \$97.6 million offset by the utilization of \$15.3 million in cash for our operating assets and liabilities. Accounts receivables increased by \$11.0 million, before FX affects, due to increased revenues. Inventories decreased \$20.6 million, before FX affects, due to the amortization of the inventory step-up recognized for the Mergers of \$35.0 million, offset by the inventory build-up for the Platinum range of implantable cardiac defibrillators and cardiac resynchronization therapy devices in the CRM Business Unit, which was launched in November 2015 in Europe and Japan, and by the inventory build-up in preparation for the CS Business Unit launch in the U.S. of the Perceval sutureless heart valve, which followed FDA approval in January 2016. An increase in other current and non-current assets of \$23.1 million, before FX affects, was primarily due to an increase in our VAT tax receivables and to the recording of the \$4.7 million grant receivable related to the May 2012 Italian earthquake. For the cash flow presentation, we netted the equal and opposite cash flow effects of the tax consequences of the intercompany sale of intangible assets to our subsidiary in the U.K., which resulted in an increase in our current and non-current assets and an increase in deferred tax liabilities of \$156.4 million. Accounts payable and accrued current and non-current liabilities has increased by \$16.7 million primarily due to increased activity driving trade payables.

During the thirty-eight weeks ended October 18, 2015, cash flow provided by historical Cyberonics operations, the Neuromodulation Business Unit, was \$65.6 million, due to net loss of \$2.2 million offset by non-cash operating expenses of \$34.5 million and a contribution of \$33.3 million due to operating assets and liabilities. Accounts payable and accrued liabilities increased by \$40.5 million primarily due to professional fees related to the Mergers. Inventories increased by \$4.8 million due to a build-up of inventory to ensure an adequate supply of products and to increase our Costa Rica manufacturing facility inventory.

Investing Activities

Cash used in investing activities of \$29.8 million during the nine months ended September 30, 2016 was primarily for purchases of property, plant and equipment for manufacturing and R&D initiatives to support operational excellence initiatives and new product development as well as administrative integration initiatives. We invested \$7.5 million in the preferred shares of a private medical start-up company, Caisson Interventional, LLC. Caisson's purpose is the development and commercialization of a percutaneous mitral valve replacement system.

Cash received during the thirty-eight weeks ended October 18, 2015 of \$14.8 million, for investing activities, was primarily a result of the transfer of \$27.0 million cash equivalents from short-term investments. The increase in cash was partly offset by \$7.0 million for the purchase of commercial paper. In addition we invested \$4.3 million in the purchase of manufacturing equipment and infrastructure improvements.

Financing Activities

We utilized cash of \$69.6 million for financing activities during the nine months ended September 30, 2016, primarily as a result of repayment of debt of \$51.2 million, repayment of our trade accounts receivable factoring (advances) of \$23.8 million and share repurchases of \$11.1 million, offset by borrowing of \$14.1 million.

On August 1, 2016, the Board of Directors (“BOD”) authorized a share repurchase plan pursuant to an authority granted by shareholders at the 2016 annual general meeting held on June 15, 2016. The repurchase program authorized by the BOD is structured to enable the Company to approve the buyback of up to \$30 million of ordinary shares on NASDAQ in the period up to and including December 31, 2016 and an aggregate of \$150 million of ordinary shares (inclusive of the \$30 million of Ordinary Shares set out above) also on NASDAQ up to and including December 31, 2018. As of September 30, 2016, 212,860 shares have been repurchased under this plan at an average price per share of \$60.44. Included in the total shares repurchased were 30,000 shares for which the settlement process was completed in November and were recorded as an accrued liability at September 30, 2016.

Cash utilized for financing activities during the thirty-eight weeks ended October 18, 2015 was \$7.0 million, primarily the result of our purchase of treasury shares for \$15.7 million offset by the collection of \$5.3 million from stock option exercises.

Debt and Capital

As of September 30, 2016 our total debt of \$144.6 million was 8.0% of total equity of \$1.8 billion.

Debt Acquired in the Mergers. At the consummation of the Mergers on October 19, 2015, LivaNova acquired all of the outstanding debt of Sorin in the aggregate principal amount of \$203.0 million payable to various financial and non-financial institutions. Prior to the Mergers, Cyberonics had no debt.

Factoring. We included an obligation, under Accrued Liabilities in the consolidated balance sheet, for the amount of our outstanding advance on customer receivables of \$1.3 million and \$24.5 million as of September 30, 2016 and December 31, 2015, respectively.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to certain market risks as part of our ongoing business operations, including risks from foreign currency exchange rates, interest rate risks and concentration of procurement suppliers that could adversely affect our consolidated financial position, results of operations or cash flows. We manage these risks through regular operating and financing activities and, at certain times, derivative financial instruments. Quantitative and qualitative disclosures about these risks are included in our 2015 Form 10-KT in “Part II, Item 7A Management’s Discussion and Analysis of Financial Condition and Results of Operations.” There have been no material changes from the information provided therein.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. This information is also accumulated and communicated to management, including our Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), as appropriate, to allow timely decisions regarding required disclosure. Our management, under the supervision and with the participation of our CEO and CFO, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the most recent fiscal quarter reported herein. Based on that evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of September 30, 2016.

(b) Changes in Internal Control Over Financial Reporting

On October 19, 2015, the Mergers were consummated between Cyberonics and Sorin. The Company has incorporated internal controls over significant processes to the extent that it believes appropriate and necessary considering the level of integration during the period since the Mergers. As a result of the Mergers, the internal control over financial reporting utilized by Cyberonics prior to the Mergers became the internal control over financial reporting of our company, and we are currently in the process of evaluating and integrating Sorin’s historical internal controls over financial reporting.

Except for the paragraph above, no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-5(f) under the Exchange Act) occurred during the quarter ended September 30, 2016, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

For a description of our material pending legal and regulatory proceedings and settlements, refer to “Note 16. Commitments and Contingencies – *Litigation and Regulatory Proceedings*” in our consolidated financial statements included in this Report on Form 10-Q.

ITEM 1A. RISK FACTORS

Our business faces many risks. Any of the risks referenced below or elsewhere in this Quarterly Report on Form 10-Q or our other SEC filings could have a material impact on our business and consolidated financial position or results of operations. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also impair our business operations.

For additional detailed discussion of risk factors that should be understood by any investor contemplating investment in our stock, please refer to “Part I. Item 1A. Risk Factors” in our 2015 Form 10-KT and elsewhere as described in this Quarterly Report on Form 10-Q.

The results of the United Kingdom’s referendum on withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business, which could reduce the price of our ordinary shares.

We are a multinational company headquartered in London with worldwide operations, including significant business operations in Europe. In June 2016, a majority of voters in the United Kingdom elected to withdraw from the European Union in a national referendum. The referendum was advisory, and the terms of any withdrawal are subject to a negotiation period that could last at least two years after the government of the United Kingdom formally initiates a withdrawal process. Nevertheless, the referendum has created significant uncertainty about the future relationship between the United Kingdom and the European Union, and has given rise to calls for certain regions within the United Kingdom to preserve their place in the European Union by separating from the United Kingdom as well as for the governments of other European Union member states to consider withdrawal.

These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Asset valuations, currency exchange rates and credit ratings may be especially subject to increased market volatility. Lack of clarity about future United Kingdom laws and regulations as the United Kingdom determines which European Union laws to replace or replicate in the event of a withdrawal, including financial laws and regulations, tax and free trade agreements, intellectual property rights, supply chain logistics, environmental, health and safety laws and regulations, immigration laws and employment laws, could increase costs, depress economic activity and restrict our access to capital. If the United Kingdom and the European Union are unable to negotiate acceptable withdrawal terms or if other European Union member states pursue withdrawal, barrier-free access between the United Kingdom and other European Union member states or among the European economic area overall could be diminished or eliminated. Any of these factors could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our ordinary shares.

The adoption of new therapies by the market requires significant time and expense in therapy education efforts, and such adoption may be delayed by a variety of factors and cannot be guaranteed.

LivaNova, as a result of internal research and development or investments in technologies, will introduce new products or new therapies to the market over time. Introducing a new product to the market requires significant expense and resources in order to support the adoption of the new product or treatment option in the market, as a significant amount of effort needs to be undertaken to train and educate health care professionals, patients, and payors on the disease to be treated, the benefits of the new product or therapy, and the clinical data in support of the therapy. In such situations, LivaNova will need to create therapy awareness programs, train and educate health care professionals on the clinical need and benefits of the new therapy, and conduct additional market access activities in order to obtain reimbursement approvals and medical codes for the new product or therapy. There are various factors that could delay the adoption of the new therapy, including the need to create new clinical pathways to identify potential patients, screen potential patients, and provide therapy to the new patients, as well as resource constraints or reimbursement constraints at the medical hospitals or institutions to support new infrastructure for the adoption

of the new therapy. We cannot guarantee the adoption of new therapies, or the timing of adoption, by the market or that it will not materially adversely affect our sales projections, consolidated earnings, financial condition, operations, and/or cash flows.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Period	Total Number of Shares Purchased ⁽¹⁾	Average Price Paid per Share ⁽²⁾	Total number of Shares Purchased as Part of Publicly Announced Plans or Programs ⁽³⁾	Approximate dollar value of Shares that may yet be Purchased under the Plans or Programs ⁽³⁾
September 1 - September 30, 2016	212,860	60.435	212,860	\$ 137,132,000

(1) Total number of shares purchased includes shares purchased as part of a publicly announced plan.

(2) Shares are purchased at market price.

(3) In August 2016, the Board of Directors authorized a share repurchase program of up to \$150.0 million of our ordinary stock. As of September 30, 2016, we had repurchased 212,860 shares under this plan.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The exhibits marked with the asterisk symbol (*) are filed or furnished (in the case of Exhibit 32.1) with this Quarterly Report on Form 10-Q. The exhibits marked with the cross symbol (†) are management contracts or compensatory plans or arrangements filed pursuant to Item 601(b)(10)(iii) of Regulation S-K.

Exhibit Number	Document Description	Report or Registration Statement	SEC File or Registration Number	Exhibit Reference
2.1	Transaction Agreement, dated March 23, 2015, by and among LivaNova PLC (f/k/a Sand Holdco Limited), Cyberonics, Inc., Sorin S.p.A. and Cypher Merger Sub, Inc.	LivaNova PLC Registration Statement on Form S-4, filed on April 20, 2015, as amended	333-203510	2.1
3.1	Articles of Association of LivaNova PLC	LivaNova PLC Current Report on Form 8-K, filed on October 19, 2015	001-37599	3.1
31.1*	Certification of the Chief Executive Officer of LivaNova PLC pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
31.2*	Certification of the Chief Financial Officer of LivaNova PLC pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
32.1*	Certification of the Chief Executive Officer and Chief Financial Officer of LivaNova PLC pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
10.48*	Letter Agreement dated July 1, 2016 between Mr Douglas Manko and Cyberonics Inc, a wholly owned subsidiary of LivaNova Plc			
10.49*	Amendment Agreement between Mr Jacques Gutedel, dated July 6, 2016 and LivaNova Switzerland S.A., a subsidiary of LivaNova (the "2016 Amendment Agreement") to amend Mr Gutedel's existing employment agreement dated March, 1, 2009.			
10.50	Service Agreement dated October 3, 2016 between Mr Damien McDonald and LivaNova Plc	LivaNova Plc Current Report on Form 8-K filed on August 1, 2016	001-37599	10.1
10.51	Side Letter effective October 3, 2016 between Mr Damien McDonald and LivaNova Plc	LivaNova Plc Current Report on Form 8-K filed on August 1, 2016	001-37599	10.2
10.52	Termination and Settlement Agreement dated August 3, 2016 between Mr Michel Darnaud and LivaNova France SAS	LivaNova Plc Current Report on Form 8-K filed on August 5, 2016	001-37599	10.1
10.53	Consulting Agreement effective August 4, 2016 between LivaNova France SAS and Mr Michel Darnaud	LivaNova Plc Current Report on Form 8-K filed on August 5, 2016	001-37599	10.2
10.54	Form of Share Repurchase Contract approved by shareholders at the 2016 Annual Meeting of Shareholders	LivaNova Plc Proxy Statement on Schedule 14A filed on May 16, 2016	001-37599	Annex A
10.55	Form of Rule 10b5-1 Repurchase Plan approved by shareholders at the 2016 Annual Meeting of Shareholders	LivaNova Plc Proxy Statement on Schedule 14A filed on May 16, 2016	001-37599	Annex B

10.56 Board approval of Share Repurchase Program on August 2, 2016 LivaNova Plc Current Report on Form 8-K filed on August 2, 2016 001-37599

10.57* \$40m Revolving Facility Agreement between LivaNova Plc and Barclays Bank Plc

21.1* List of Subsidiaries of LivaNova PLC

24.1* Power of Attorney (included on the Signature Page to this Quarterly Report on Form 10-Q)

101* Interactive Data Files Pursuant to Rule 405 of Regulation S-T: (i) the Condensed Consolidated Statement of Income for the three and nine months ended September 30, 2016 and the twelve and thirty-eight weeks ended October 18, 2015, (ii) the Condensed Consolidated Statement of Comprehensive Income for the three and nine months ended September 30, 2016 and the twelve and thirty-eight weeks ended October 18, 2015, (iii) the Condensed Consolidated Balance Sheet as of September 30, 2016 and December 31, 2015, (iv) the Condensed Consolidated Statement of Stockholders' Equity for the nine months ended September 30, 2016, (v) the Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2016 and the thirty-eight weeks ended October 18, 2015, and (vi) the Notes to the Condensed Consolidated Financial Statements.

SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

LIVANOVA PLC

By: /s/ VIVID SEHGAL
Vivid Sehgal
Chief Financial Officer
(Principal Financial Officer)

LIVANOVA PLC

By: /s/ DOUGLAS J MANKO
Douglas J Manko
Chief Accounting Officer
(Principal Accounting Officer)

Date: November 2, 2016

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24.1*	Power of Attorney (included on the Signature Page to this Quarterly Report on Form 10-Q)			
101*				

Interactive Data Files Pursuant to Rule 405 of Regulation S-T: (i) the Condensed Consolidated Statement of Income for the three and nine months ended September 30, 2016 and the twelve and thirty-eight weeks ended October 18, 2015, (ii) the Condensed Consolidated Statement of Comprehensive Income for the three and nine months ended September 30, 2016 and the twelve and thirty-eight weeks ended October 18, 2015, (iii) the Condensed Consolidated Balance Sheet as of September 30, 2016 and December 31, 2015, (iv) the Condensed Consolidated Statement of Stockholders' Equity for the nine months ended September 30, 2016, (v) the Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2016 and the thirty-eight weeks ended October 18, 2015, and (vi) the Notes to the Condensed Consolidated Financial Statements.