

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, 2017

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)

**20 Eastbourne Terrace
London, United Kingdom**

(Address of principal executive offices)

98-1268150

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

W2 6LG

(Zip Code)

(44) (0) 20 3325 0660

Registrant's telephone number, including area 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

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

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act

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 as of October 27, 2017

48,211,559

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 generator products: Model 102 (Pulse[®]), Model 102R (Pulse Duo[®]), Model 103 (Demipulse[®]), Model 104 (Demipulse Duo[®]), Model 105 (AspireHC[®]), Model 106 (AspireSR[®]) and Model 1000 (SenTiva[™]).
- Trademarks for our oxygenator 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 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.

NOTE ABOUT FORWARD LOOKING STATEMENTS

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, 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 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 products or procedures or enhances coverage for competitive products or 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 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, shareholder-related, environmental-related, income tax and other litigation, disputes, 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;

- failure of new acquisitions to further our strategic objectives or strengthen our existing businesses;
- 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, including volatility caused by the implementation of Brexit;
- changes in tax laws, including changes related 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
- failure of the market to adopt new therapies or to adopt new therapies quickly.
- 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2016 (“2016 Form 10-K”), (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 condensed consolidated financial statements and related notes included elsewhere in this report. Operating results for the three and nine months ended September 30, 2017 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 2016 Form 10-K.

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. Financial Statements

LIVANOVA PLC AND SUBSIDIARIES'
CONDENSED CONSOLIDATED STATEMENTS OF INCOME (LOSS)
(UNAUDITED)
(In thousands, except per share amounts)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|----------------------------------|-------------------|---------------------------------|--------------------|
| | 2017 | 2016 | 2017 | 2016 |
| Net sales | \$ 309,664 | \$ 295,268 | \$ 916,156 | \$ 903,284 |
| Cost of sales | 108,233 | 106,454 | 318,584 | 360,675 |
| Product remediation | 1,642 | 689 | 2,573 | 2,243 |
| Gross profit | <u>199,789</u> | <u>188,125</u> | <u>594,999</u> | <u>540,366</u> |
| Operating expenses: | | | | |
| Selling, general and administrative | 121,177 | 109,233 | 353,943 | 345,744 |
| Research and development | 31,393 | 32,175 | 104,051 | 94,076 |
| Merger and integration expenses | 2,013 | 7,576 | 7,743 | 20,537 |
| Restructuring expenses | 792 | 4,381 | 12,060 | 37,219 |
| Amortization of intangibles | 12,350 | 11,775 | 35,445 | 33,959 |
| Total operating expenses | <u>167,725</u> | <u>165,140</u> | <u>513,242</u> | <u>531,535</u> |
| Income from operations | 32,064 | 22,985 | 81,757 | 8,831 |
| Interest income | 199 | 585 | 724 | 1,119 |
| Interest expense | (1,421) | (3,495) | (5,314) | (6,665) |
| Gain on acquisition of Caisson Interventional, LLC | — | — | 39,428 | — |
| Foreign exchange and other gains (losses) | 491 | 1,216 | 957 | (2) |
| Income before income taxes | <u>31,333</u> | <u>21,291</u> | <u>117,552</u> | <u>3,283</u> |
| Income tax expense | 1,913 | 9,731 | 10,881 | 16,891 |
| Losses from equity method investments | <u>(1,590)</u> | <u>(13,129)</u> | <u>(20,072)</u> | <u>(19,382)</u> |
| Net income (loss) | <u>\$ 27,830</u> | <u>\$ (1,569)</u> | <u>\$ 86,599</u> | <u>\$ (32,990)</u> |
| Basic income (loss) per share | \$ 0.58 | \$ (0.03) | \$ 1.80 | \$ (0.67) |
| Diluted income (loss) per share | \$ 0.57 | \$ (0.03) | \$ 1.79 | \$ (0.67) |
| Shares used in computing basic income (loss) per share | 48,181 | 49,075 | 48,130 | 49,016 |
| Shares used in computing diluted income (loss) per share | 48,534 | 49,075 | 48,339 | 49,016 |

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, | | Nine Months Ended September 30, | |
|---|---|-------------------|--|-------------------|
| | 2017 | 2016 | 2017 | 2016 |
| Net income (loss) | \$ 27,830 | \$ (1,569) | \$ 86,599 | \$ (32,990) |
| Other comprehensive income (loss): | | | | |
| Net change in unrealized gain (loss) on derivatives | (1,980) | 2,042 | (5,923) | (5,224) |
| Tax effect | 473 | (673) | 1,756 | 1,513 |
| Net of tax | (1,507) | 1,369 | (4,167) | (3,711) |
| Foreign currency translation adjustment, net of tax | 39,106 | (1,805) | 111,123 | 32,598 |
| Total other comprehensive income (loss) | 37,599 | (436) | 106,956 | 28,887 |
| Total comprehensive income (loss) | <u>\$ 65,429</u> | <u>\$ (2,005)</u> | <u>\$ 193,555</u> | <u>\$ (4,103)</u> |

See accompanying notes to the condensed consolidated financial statements

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

| | <u>September 30, 2017</u> | <u>December 31, 2016</u> |
|--|---------------------------|--------------------------|
| | (Unaudited) | |
| ASSETS | | |
| <i>Current Assets:</i> | | |
| Cash and cash equivalents | \$ 65,158 | \$ 39,789 |
| Accounts receivable, net | 314,041 | 275,730 |
| Inventories | 214,593 | 183,489 |
| Prepaid and refundable taxes | 58,969 | 60,615 |
| Assets held for sale | 14,117 | 4,477 |
| Prepaid expenses and other current assets | 55,176 | 55,973 |
| Total Current Assets | 722,054 | 620,073 |
| Property, plant and equipment, net | 213,769 | 223,842 |
| Goodwill | 781,070 | 691,712 |
| Intangible assets, net | 717,646 | 609,197 |
| Investments | 46,380 | 61,092 |
| Deferred tax assets, net | 4,356 | 6,017 |
| Other assets | 117,855 | 130,698 |
| Total Assets | \$ 2,603,130 | \$ 2,342,631 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| <i>Current Liabilities:</i> | | |
| Current debt obligations | \$ 52,074 | \$ 47,650 |
| Accounts payable | 102,651 | 92,952 |
| Accrued liabilities and other | 92,212 | 75,567 |
| Taxes payable | 28,954 | 22,340 |
| Accrued employee compensation and related benefits | 80,466 | 78,302 |
| Total Current Liabilities | 356,357 | 316,811 |
| Long-term debt obligations | 71,853 | 75,215 |
| Deferred income taxes liability | 152,133 | 172,541 |
| Long-term employee compensation and related benefits | 33,957 | 31,668 |
| Other long-term liabilities | 74,404 | 39,487 |
| Total Liabilities | 688,704 | 635,722 |
| Commitments and contingencies (Note 9) | | |
| <i>Stockholders' Equity:</i> | | |
| Ordinary Shares, £1.00 par value: unlimited shares authorized; 48,250,361 shares issued and 48,200,257 shares outstanding at September 30, 2017; 48,156,690 shares issued and 48,028,413 shares outstanding at December 31, 2016 | 74,697 | 74,578 |
| Additional paid-in capital | 1,731,565 | 1,719,893 |
| Accumulated other comprehensive income (loss) | 38,469 | (68,487) |
| Retained earnings (deficit) | 72,024 | (14,575) |
| Treasury stock at cost, 50,104 shares at September 30, 2017 and 128,277 shares at December 31, 2016 | (2,329) | (4,500) |
| Total Stockholders' Equity | 1,914,426 | 1,706,909 |
| Total Liabilities and Stockholders' Equity | \$ 2,603,130 | \$ 2,342,631 |

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, | |
|---|--|------------------|
| | 2017 | 2016 |
| Operating Activities: | | |
| Net income (loss) | \$ 86,599 | \$ (32,990) |
| Non-cash items included in net income (loss): | | |
| Depreciation | 27,880 | 30,193 |
| Amortization | 35,445 | 33,959 |
| Stock-based compensation | 14,261 | 15,575 |
| Deferred income tax benefit | (27,270) | (10,224) |
| Losses from equity method investments | 20,072 | 19,382 |
| Gain on acquisition of Caisson Interventional, LLC | (39,428) | — |
| Impairment of property, plant and equipment | 4,581 | — |
| Amortization of income taxes payable on inter-company transfers of property | 23,831 | 17,114 |
| Other | 3,364 | 8,765 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (19,107) | (11,040) |
| Inventories | (11,006) | 20,607 |
| Other current and non-current assets | (17,846) | (25,845) |
| Restructuring reserve | (12,753) | 14,961 |
| Accounts payable and accrued current and non-current liabilities | (14,958) | (31,109) |
| Net cash provided by operating activities | 73,665 | 49,348 |
| Investing Activities: | | |
| Purchases of property, plant and equipment and other | (24,004) | (28,928) |
| Acquisition of Caisson Interventional, LLC, net of cash acquired | (14,194) | — |
| Proceeds from sale of cost method investment | 3,192 | — |
| Proceeds from asset sales | 5,346 | 222 |
| Purchases of cost and equity method investments | (5,209) | (8,059) |
| Loans to cost and equity method investees | (6,928) | (6,595) |
| Purchases of short-term investments | — | (7,054) |
| Maturities of short-term investments | — | 14,051 |
| Net cash used in investing activities | (41,797) | (36,363) |
| Financing Activities: | | |
| Change in short-term borrowing, net | (18,054) | (33,831) |
| Proceeds from short-term borrowing (maturities greater than 90 days) | 20,000 | — |
| Repayment of long-term debt obligations | (11,615) | (11,354) |
| Proceeds from exercise of stock options | 3,221 | 7,888 |
| Repayment of trade receivable advances | — | (23,848) |
| Proceeds from long-term debt obligations | — | 7,994 |
| Share repurchases | — | (11,053) |
| Other | (3,552) | 1,208 |
| Net cash used in financing activities | (10,000) | (62,996) |
| Effect of exchange rate changes on cash and cash equivalents | 3,501 | 1,030 |
| Net increase (decrease) in cash and cash equivalents | 25,369 | (48,981) |
| Cash and cash equivalents at beginning of period | 39,789 | 112,613 |
| Cash and cash equivalents at end of period | \$ 65,158 | \$ 63,632 |

See accompanying notes to the condensed consolidated financial statements

LIVANOVA PLC AND SUBSIDIARIES
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Note 1. Unaudited Condensed Consolidated Financial Statements

Basis of Presentation

The accompanying condensed consolidated financial statements of LivaNova as of, and for the three and nine months ended, September 30, 2017 and September 30, 2016, 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, 2016 has been derived from audited financial statements contained in our 2016 Form 10-K, but does 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, 2017, and are not necessarily indicative of the results that may be expected for the year ending December 31, 2017. The financial information presented herein should be read in conjunction with the audited consolidated financial statements and notes thereto accompanying our 2016 Form 10-K.

Description of the Mergers

On October 19, 2015 LivaNova became the holding company of the combined businesses of Cyberonics, Inc. ("Cyberonics") and Sorin S.p.A. ("Sorin") (the "Mergers"). Based on the structure of the Mergers, management determined that Cyberonics was considered to be the accounting acquirer and predecessor for accounting purposes.

Reclassification of Prior-Year Comparative Period Presentation

To conform the condensed consolidated statement of income (loss) for the three and nine months ended September 30, 2016, to the current period presentation, we reclassified \$0.7 million and \$2.2 million, respectively, of Litigation Related Expenses to the Product Remediation line, and \$1.7 million and \$2.5 million, respectively, of Litigation Related Expenses to Selling, General and Administrative Expenses.

To conform the condensed consolidated balance sheet as of December 31, 2016 to the current period presentation, we reclassified \$4.5 million of Assets Held for Sale, relating to our plan to exit the Costa Rica manufacturing operation, to a separate line item in the condensed consolidated balance sheet from Prepaid Expenses and Other Current Assets. We received \$4.9 million in proceeds from the sale of our Costa Rica manufacturing operation during the nine months ended September 30, 2017.

To conform the condensed consolidated statement of cash flows for the nine months ended September 30, 2016 to the current period presentation, certain amounts were reclassified within Operating Activities. Commencing with nine months ended September 30, 2017, Loans to Equity and Cost Method Investees of 6.9 million were presented as Investing Activities. To conform the condensed consolidated statement of cash flows for the nine months ended September 30, 2016 to the current period presentation, Loans to Equity and Cost Method Investees of \$6.6 million were reclassified from Financing Activities to Investing Activities.

Significant Accounting Policies

Our significant accounting policies are detailed in "Note 2: Basis of Presentation, Use of Accounting Estimates and Significant Accounting Policies" of our 2016 Form 10-K. A further explanation of our Foreign Currency accounting policy is discussed below:

Foreign Currency

Our functional currency is the U.S. dollar, however, a portion of the revenues earned and expenses incurred by certain of our subsidiaries are denominated in currencies other than the U.S. dollar. We determine the functional currency of our subsidiaries that exist and operate in different economic and currency environments based on the primary economic environment in which the subsidiary operates, that is, the currency of the environment in which an entity primarily generates and expends cash. Our significant foreign subsidiaries are located in Europe and the U.S. The functional currency of our significant European subsidiaries is the Euro and the functional currency of our significant U.S. subsidiaries is the U.S. dollar.

Assets and liabilities for subsidiaries whose functional currency is not the U.S. dollar are translated into U.S. dollars based on a combination of both current and historical exchange rates, while their revenues earned and expenses incurred are translated into U.S. dollars at average period exchange rates. Translation adjustments are included as ‘Accumulated other comprehensive income (loss)’ (“AOCI”) in the condensed consolidated balance sheets. Gains and losses arising from transactions denominated in a currency different from an entity’s functional currency are included in ‘Foreign exchange and other (losses) gains’ in our condensed consolidated statements of income (loss).

Note 2. Acquisitions

In support of our strategic growth initiatives, on May 2, 2017, we acquired the remaining 51% equity interests in Caisson Interventional, LLC (“Caisson”) for a purchase price of up to \$72.0 million, net of \$6.3 million of debt forgiveness, consisting of \$18.0 million paid at closing, \$14.4 million to be paid after 12 months, and contingent consideration of up to \$39.6 million to be paid on a schedule driven primarily by regulatory approvals and a sales-based earnout.

Caisson, a clinical-stage medical device company based in Maple Grove, Minnesota, is focused on the design, development and clinical evaluation of a novel transcatheter mitral valve replacement (“TMVR”) implant device with a fully transvenous delivery system.

The following table presents the acquisition date fair-value of the consideration transferred and the fair value of our interest in Caisson prior to the acquisition (in thousands):

| | | |
|--|----|---------|
| Cash ⁽¹⁾ | \$ | 15,660 |
| Debt forgiven ⁽²⁾ | | 6,309 |
| Deferred consideration ⁽¹⁾ | | 12,994 |
| Contingent consideration ⁽¹⁾ | | 29,303 |
| Fair value of consideration transferred | | 64,266 |
| Fair value of our interest prior to the acquisition ⁽²⁾ | | 52,505 |
| Fair value of total consideration | \$ | 116,771 |

- (1) Concurrent with the acquisition, we recognized \$5.8 million of post-combination compensation expense. Of this amount, \$2.4 million is reflected as a reduction of \$18.0 million in cash paid at closing of the acquisition, while \$3.4 million increased the deferred consideration and contingent consideration liabilities recognized at the date of the acquisition to a total of \$14.1 million and \$31.7 million, respectively.
- (2) On the acquisition date, we remeasured the notes receivable from Caisson and our existing investment in Caisson at fair value and recognized a pre-tax non-cash gain of \$1.3 million and \$38.1 million, respectively, which are included in ‘Gain on acquisition of Caisson Interventional, LLC’ in the condensed consolidated statements of income (loss).

The following table presents the preliminary purchase price allocation at fair value for the Caisson acquisition (in thousands):

| | | |
|--------------------------------------|----|---------|
| Cash and cash equivalents | \$ | 1,468 |
| In-process research and development | | 89,000 |
| Goodwill | | 42,417 |
| Other assets | | 918 |
| Current liabilities | | 1,023 |
| Deferred income tax liabilities, net | | 16,009 |
| Net assets acquired | \$ | 116,771 |

Acquired goodwill of \$9.6 million is expected to be deductible for tax purposes. Additionally, \$3.0 million of the initial cash payment was deposited in escrow for future claims indemnification. Of this amount, \$2.0 million is included in ‘Prepaid expenses and other current assets’ and the remaining \$1.0 million is included in ‘Other long-term assets’ on the condensed consolidated balance sheet as of September 30, 2017.

We recognized acquisition-related expenses of approximately \$1.0 million for legal and valuation expenses during the nine months ended September 30, 2017. These expenses are included within ‘Selling, general and administrative’ expenses in the condensed consolidated statements of income (loss). Additionally, the results of Caisson for the period of May 2, 2017 through September 30, 2017 added no revenue and \$16.9 million in expenses in our condensed consolidated statement of income (loss).

The contingent consideration arrangements are composed of potential cash payments upon the achievement of certain regulatory milestones and a sales-based earnout associated with sales of products covered by the purchase agreement. The sales-based earnout was valued using projected sales from our internal strategic plans. Both arrangements are Level 3 fair value measurements and include the following significant unobservable inputs (in thousands):

| Caisson Acquisition | Fair value at May 2, 2017 | Valuation Technique | Unobservable Input | Ranges |
|-------------------------------------|---------------------------|------------------------|--------------------------|-------------|
| Regulatory milestone-based payments | \$ 14,883 | Discounted cash flow | Discount rate | 2.6% - 3.4% |
| | | | Probability of payment | 90-95% |
| | | | Projected payment years | 2018-2023 |
| Sales-based earnout | 16,805 | Monte Carlo simulation | Discount rate | 11.5-12.7% |
| | | | Sales volatility | 36.9% |
| | | | Projected years of sales | 2019-2033 |
| | <u>\$ 31,688</u> | | | |

The following table provides a reconciliation of the beginning and ending balance of the contingent consideration liability, which consisted of arrangements that arose from the Caisson acquisition and other previous acquisitions that also included contingent consideration (in thousands):

| | |
|--|------------------|
| Balance at December 31, 2016 | \$ 3,890 |
| Purchase price - Caisson contingent consideration | 31,688 |
| Payments | (1,841) |
| Changes in fair value | 231 |
| Effect of changes in foreign currency exchange rates | 249 |
| Balance at September 30, 2017 ⁽¹⁾ | <u>\$ 34,217</u> |

- (1) The contingent consideration liability represents contingent payments related to three acquisitions: the first and second acquisitions, in September 2015, were Cellplex PTY Ltd. in Australia and 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. The third acquisition, Caisson, occurred in May 2017 and is discussed above. Refer to “Note 6. Fair Value Measurements.”

Note 3. Restructuring

Our 2015 and 2016 Reorganization Plans (the “Plans”) were initiated October 2015 and March 2016, respectively, in conjunction with the completion of the Mergers. We initiated these plans 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 our operating results in the condensed consolidated statements of income (loss). We estimate that the Plans will result in a net reduction of 326 personnel of which 292 have occurred as of September 30, 2017.

In March 2017, we committed to a plan to sell our Suzhou Industrial Park facility in Shanghai, China. As a result of this exit plan we recorded an impairment of the building and equipment of \$4.6 million and accrued \$0.5 million of additional costs, primarily related to employee severance, during the nine months ended September 30, 2017. In addition, the remaining carrying value of the land, building and equipment was reclassified to ‘Assets held for sale’ in March 2017, with a balance of \$14.1 million as of September 30, 2017, on the condensed consolidated balance sheet.

The following table presents restructuring expense accrual detail (in thousands):

| | Employee Severance and Other Termination Costs | | Other | Total |
|-------------------------------|--|----------|----------|-----------|
| Balance at December 31, 2016 | \$ | 21,092 | \$ 3,056 | \$ 24,148 |
| Charges | | 7,126 | 4,934 | 12,060 |
| Cash payments and adjustments | | (23,804) | (5,480) | (29,284) |
| Balance at September 30, 2017 | \$ | 4,414 | \$ 2,510 | \$ 6,924 |

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---------------------------|----------------------------------|----------|---------------------------------|-----------|
| | 2017 | 2016 | 2017 | 2016 |
| Cardiac Surgery | \$ 441 | \$ 916 | \$ 6,944 | \$ 5,878 |
| Cardiac Rhythm Management | (391) | 571 | (1,750) | 16,592 |
| Neuromodulation | 14 | 2,882 | 513 | 7,017 |
| Other | 728 | 12 | 6,353 | 7,732 |
| Total | \$ 792 | \$ 4,381 | \$ 12,060 | \$ 37,219 |

Note 4. Product Remediation Liability

At December 31, 2016, we recognized a liability for a product remediation plan related to our 3T Heater-Cooler device ("3T device"). The remediation plan we developed consists primarily of a modification of the 3T device design to include internal sealing and the addition of a vacuum system to new and existing devices. These changes are intended to address regulatory actions and to reduce further the risk of possible dispersion of aerosols from 3T devices in the operating room. The deployment of this solution for commercially distributed devices has been dependent upon final validation and verification of the design changes and approval or clearance by regulatory authorities worldwide, including FDA clearance in the U.S. In April 2017, we obtained CE Mark in Europe for the design change of the 3T device and in May 2017 we completed our first vacuum and sealing upgrade on a customer-owned device. We are currently implementing the vacuum and sealing upgrade program in as many countries as possible throughout the remainder of 2017. As part of the remediation plan, we also intend to perform a no-charge deep disinfection service for 3T device users who have reported confirmed *M. chimaera* mycobacterium contamination. Although the deep disinfection service is not yet available in the U.S., it is currently offered in many countries around the world and will be expanded to additional geographies as we receive the required regulatory approvals. Finally, we are continuing to offer the loaner program for 3T devices, initiated in the fourth quarter of 2016, to provide existing 3T device users with a new loaner 3T device at no charge pending regulatory approval and implementation of the vacuum system addition and deep disinfection service worldwide. This loaner program began in the U.S. and is being made available progressively on a global basis, prioritizing and allocating devices to 3T device users based on pre-established criteria.

Changes in the carrying amount of the product remediation liability are as follows (in thousands):

| | | |
|--|----|---------|
| Balance at December 31, 2016 | \$ | 33,487 |
| Adjustments | | (15) |
| Remediation activity | | (5,672) |
| Effect of changes in foreign currency exchange rates | | 2,446 |
| Balance at September 30, 2017 ⁽¹⁾ | \$ | 30,246 |

(1) At September 30, 2017, the product remediation liability balance is held within 'Accrued liabilities and other' and 'Other long-term liabilities' on the condensed consolidated balance sheet. Refer to "Note 15. Supplemental Financial Information."

It is reasonably possible that our estimate of the remediation liability could materially change in future periods due to the various significant assumptions involved, such as customer behavior, market reaction and the timing of approvals or clearance by regulatory authorities worldwide. We recognize changes in estimates on a prospective basis. At this stage, no liability has

been recognized with respect to any lawsuits involving us related to the 3T device, while related legal costs are expensed as incurred. For further information, please refer to “Note 9. Commitments and Contingencies - 3T Heater-Cooler Devices.”

Note 5. Investments

Cost-Method Investments

Our cost-method investments are included in ‘Investments’ in the condensed consolidated balance sheets and consist of our equity positions in the following privately-held companies (in thousands):

| | September 30, 2017 | December 31, 2016 |
|--------------------------------------|--------------------|-------------------|
| Respicardia Inc. ⁽¹⁾ | \$ 21,129 | \$ 17,518 |
| ImThera Medical, Inc. ⁽²⁾ | 12,000 | 12,000 |
| Rainbow Medical Ltd. ⁽³⁾ | 4,178 | 3,733 |
| MD Start II | 1,179 | 526 |
| Other ⁽⁴⁾ | 150 | — |
| | <u>\$ 38,636</u> | <u>\$ 33,777</u> |

- (1) Respicardia Inc. (“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. We have a loan outstanding to Respicardia with a carrying amount of \$1.5 million, as of September 30, 2017, which is included in ‘Prepaid expenses and other current assets’ on the condensed consolidated balance sheet.
- (2) ImThera Medical Inc. (“ImThera”) is a privately funded U.S. company developing a neurostimulation device system for the treatment of obstructive sleep apnea. We have a loan outstanding to ImThera as of September 30, 2017, with a carrying amount of \$1.0 million, which is included in ‘Other assets’ on the condensed consolidated balance sheet.
- (3) 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.
- (4) During the nine months ended September 30, 2017, we sold our investment in Istituto Europeo di Oncologia S.R.L. for a gain of \$3.2 million. This gain is included in ‘Foreign exchange and other gains (losses)’ in the condensed consolidated statement of income (loss).

Equity Method Investments

Our equity-method investments are included in ‘Investments’ in the condensed consolidated balance sheets and consist of our equity position in the following entities (in thousands, except for percent ownership):

| | % Ownership ⁽¹⁾ | September 30, 2017 | December 31, 2016 |
|--|----------------------------|--------------------|-------------------|
| MicroPort Sorin CRM (Shanghai) Co. Ltd. ⁽²⁾ | 49.0% | \$ 6,948 | \$ 4,867 |
| Highlife S.A.S. ⁽³⁾ | 38.0% | 779 | 6,009 |
| Caisson Interventional LLC ⁽⁴⁾ | | — | 16,423 |
| Other | | 17 | 16 |
| Total | | <u>\$ 7,744</u> | <u>\$ 27,315</u> |

- (1) Ownership percentages as of September 30, 2017.
- (2) During the three months ended September 30, 2017 we invested an additional \$4.5 million in MicroPort Sorin CRM (Shanghai) Co. Ltd.
- (3) Highlife S.A.S is a privately held clinical-stage medical device company located in France and is focused on the development of a unique transcatheter mitral valve replacement system to treat patients with mitral regurgitation. During the three months ended September 30, 2017, we recognized an impairment of our investment in, and notes receivable from, Highlife. See the paragraph below for further details.
- (4) On May 2, 2017, we acquired the 51% remaining equity interests in Caisson Interventional LLC (“Caisson”), and we began consolidating the results of Caisson as of the acquisition date. Refer to “Note 2. Acquisitions” and to “Note 6. Fair Value Measurements” for further information.

Highlife Impairment

We recognized an impairment of our equity-method investment in, and notes receivable from, Highlife S.A.S. (“Highlife”) during the nine months ended September 30, 2017. Certain factors, including a revision in our investment strategy, indicated that the carrying value of our aggregate investment might not be recoverable and that the decrease in value of our aggregate investment was other than temporary. We, therefore, estimated the fair value of our investment and notes receivable using the

market approach. The estimated fair value of our aggregate investment was below our carrying value by \$13.0 million. This aggregate impairment was included in 'Losses from equity method investments' in the condensed consolidated statements of income (loss). The updated carrying value of our notes receivable from Highlife at September 30, 2017 was \$0.8 million and is included in 'Other assets' on the condensed consolidated balance sheet.

Note 6. Fair Value Measurements

Assets and Liabilities 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, 2017 | Level 1 | Level 2 | Level 3 |
| Liabilities: | | | | |
| Derivative liabilities - designated as cash flow hedges (foreign currency exchange rate "FX") | \$ 724 | \$ — | \$ 724 | \$ — |
| Derivative liabilities - designated as cash flow hedges (interest rate swaps) | 1,807 | — | 1,807 | \$ — |
| Derivative liabilities - freestanding instruments (FX) | 1,456 | — | 1,456 | — |
| Contingent consideration | 34,217 | — | — | 34,217 |
| | <u>\$ 38,204</u> | <u>\$ —</u> | <u>\$ 3,987</u> | <u>\$ 34,217</u> |

| | Fair Value as of | Fair Value Measurements Using Inputs Considered as: | | |
|---|---------------------|--|-----------------|-------------|
| | December 31, 2016 | Level 1 | Level 2 | Level 3 |
| Assets: | | | | |
| Derivative assets - designated as cash flow hedges (FX) | \$ 4,911 | \$ — | \$ 4,911 | \$ — |
| Derivative assets - freestanding instruments (FX) | 3,358 | — | 3,358 | — |
| | <u>\$ 8,269</u> | <u>\$ —</u> | <u>\$ 8,269</u> | <u>\$ —</u> |

| | | | | |
|---|-----------------|-------------|-----------------|-----------------|
| Liabilities: | | | | |
| Derivative liabilities - designated as cash flow hedges (FX) | \$ 942 | \$ — | \$ 942 | \$ — |
| Derivative liabilities - designated as cash flow hedges (interest rate swaps) | 1,392 | — | 1,392 | — |
| Contingent consideration | 3,890 | — | — | 3,890 |
| | <u>\$ 6,224</u> | <u>\$ —</u> | <u>\$ 2,334</u> | <u>\$ 3,890</u> |

Our recurring fair value measurements, using significant unobservable inputs (level 3), relate solely to our contingent consideration liability. Refer to "Note 2. Acquisitions" for a discussion of the changes in the fair value of our contingent consideration liability.

Note 7. Financing Arrangements

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

| | September 30, 2017 | December 31, 2016 | Maturity | Interest Rate |
|---|--------------------|-------------------|-----------------------------------|---------------|
| European Investment Bank ⁽¹⁾ | \$ 78,590 | \$ 78,987 | June 2021 | 0.95% |
| Mediocredito Italiano ⁽³⁾ | 7,719 | 7,276 | December 2023 | 0.50% - 3.07% |
| Banca del Mezzogiorno ⁽²⁾ | 6,490 | 6,747 | December 2019 | 0.50% - 3.15% |
| Bpifrance (ex-Oséo) | 1,603 | 1,909 | October 2019 | 2.58% |
| Region Wallonne | 831 | 798 | December 2023 and June 2033 | 0.00% - 2.45% |
| Mediocredito Italiano - mortgages and other | 742 | 799 | September 2021 and September 2026 | 0.40% - 0.65% |
| Total debt | 95,975 | 96,516 | | |
| Less current portion of long-term debt | 24,122 | 21,301 | | |
| Total long-term debt | \$ 71,853 | \$ 75,215 | | |

- (1) The European Investment Bank (“EIB”) loan was obtained in July 2014 to support product development projects. The interest rate for the EIB loan is reset by the lender each quarter based on the Euribor. Interest payments are paid quarterly and principal payments are paid semi-annually.
- (2) The Banca del Mezzogiorno loan was obtained in January 2015 to support R&D projects as a part of the Large Strategic Project program of the Italian Ministry of Education.
- (3) We obtained the Mediocredito Italiano Bank loan in July 2016 as part of the Fondo Innovazione Teconologica program implemented by the Italian Ministry of Education.

Revolving Credit

The outstanding principal amount of our short-term unsecured revolving credit agreements and other agreements with various banks was \$28.0 million and \$26.4 million, at September 30, 2017 and December 31, 2016, respectively, with interest rates ranging from 0.2% to 10.5% and loan terms ranging from one day to 365 days.

European Investment Bank Financing Agreement

On June 29, 2017, we entered into a new finance contract (the “Finance Contract”) with the EIB to support financing of certain R&D projects. The Finance Contract has a borrowing base of €100 million (or approximately \$118 million USD equivalent) and can be drawn in up to two tranches, each in a minimum amount of €50 million (or approximately \$59 million USD equivalent). Drawdowns must occur by December 30, 2018, and the last repayment date of any tranche will be no earlier than four years and no later than eight years after the disbursement of the relevant tranche. Loans under the Finance Contract are subject to certain covenants and other terms and conditions. No loan drawdowns have occurred as of September 30, 2017.

Note 8. 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”) derivative contracts and interest rate swap contracts to reduce the impact of foreign currency rate and interest rate fluctuations on earnings 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 condensed consolidated balance sheets. We do not enter into derivative contracts for speculative purposes. At inception of the contract, the derivative is designated as either a freestanding derivative or a hedge. Derivatives that are not designated as hedging instruments are referred to as freestanding derivatives with changes in fair value included in earnings.

If the derivative qualifies for hedge accounting, depending on the nature of the hedge and hedge effectiveness, changes in the fair value of the derivative will either be recognized immediately in earnings or recorded in other AOCI until the hedged item is recognized in earnings upon settlement/termination. FX derivative gains and losses in AOCI are reclassified to the consolidated statement of income (loss) as shown in the tables below and interest rate swap gains and losses in AOCI are reclassified to interest expense in the consolidated statement of income (loss). We evaluate hedge effectiveness at inception and on an ongoing basis. If a derivative is no longer expected to be highly effective, hedge accounting is discontinued. Hedge ineffectiveness, if

any, is recorded in earnings. Cash flows from derivative contracts are reported as operating activities in the condensed consolidated statements of cash flows.

Freestanding Derivative FX Contracts

The gross notional amount of freestanding derivatives outstanding at September 30, 2017 and December 31, 2016 was \$239.0 million and \$489.1 million, respectively. These derivative contracts are designed to offset the FX effects in earnings of various intercompany loans, our EIB loan, and trade receivables. We recorded net losses for these freestanding derivatives of \$0.7 million and \$7.9 million for the three and nine months ended September 30, 2017, respectively, and net gains (losses) of \$(1.8) million and \$0.4 million for the three and nine months ended September 30, 2016, respectively. These gains and losses are included in 'Foreign exchange and other gains (losses)' in the condensed consolidated statements of income (loss).

Cash Flow Hedges

Notional amounts of open derivative contracts designated as cash flow hedges (in thousands):

| Description of Contract | September 30, 2017 | December 31, 2016 |
|--|--------------------|-------------------|
| FX derivative contracts to be exchanged for British Pounds | \$ 16,928 | \$ 6,663 |
| FX derivative contracts to be exchanged for Japanese Yen | 44,618 | 57,840 |
| FX derivative contracts to be exchanged for Canadian Dollars | 13,341 | — |
| Interest rate swap contracts | 62,917 | 63,246 |
| | <u>\$ 137,804</u> | <u>\$ 127,749</u> |

After-tax net loss associated with derivatives designated as cash flow hedges recorded in the ending balance of AOCI and the amount expected to be reclassified to earnings in the next 12 months (in thousands):

| Description of Contract | September 30, 2017 | Net Amount Expected to be Reclassified to Earnings in the Next 12 Months |
|------------------------------|--------------------|--|
| FX derivative contracts | \$ (287) | \$ (287) |
| Interest rate swap contracts | (261) | (69) |
| | <u>\$ (548)</u> | <u>\$ (356)</u> |

Pre-tax gains (losses) for derivative contracts designated as cash flow hedges recognized in Other Comprehensive Income (Loss) ("OCI") and the amount reclassified to earnings from AOCI (in thousands):

| Description of Contract | Location in Earnings of Reclassified Gain or Loss | Three Months Ended September 30, | | | |
|------------------------------|---|----------------------------------|---|----------------------------------|---|
| | | 2017 | | 2016 | |
| | | Losses Recognized in OCI | (Losses) Gains Reclassified from AOCI to Earnings | (Losses) Gains Recognized in OCI | Losses Reclassified from AOCI to Earnings |
| FX derivative contracts | Foreign exchange and other (losses) gains | \$ (2,537) | \$ (1,623) | \$ 2,535 | \$ 2,795 |
| FX derivative contracts | SG&A | — | 269 | — | (1,876) |
| Interest rate swap contracts | Interest expense | — | 797 | 263 | (163) |
| | | <u>\$ (2,537)</u> | <u>\$ (557)</u> | <u>\$ 2,798</u> | <u>\$ 756</u> |

Nine Months Ended September 30,

| Description of Contract | Location in Earnings of Reclassified Gain or Loss | 2017 | | 2016 | |
|------------------------------|---|--------------------------|---|--------------------------|---|
| | | Losses Recognized in OCI | (Losses) Gains Reclassified from AOCI to Earnings | Losses Recognized in OCI | Gains (Losses) Reclassified from AOCI to Earnings |
| FX derivative contracts | Foreign exchange and other (losses) gains | \$ (10,124) | \$ (6,833) | \$ (5,932) | \$ 2,943 |
| FX derivative contracts | SG&A | — | 1,623 | — | (3,437) |
| Interest rate swap contracts | Interest expense | — | 1,009 | (38) | (252) |
| | | <u>\$ (10,124)</u> | <u>\$ (4,201)</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 condensed consolidated balance sheets (in thousands):

| September 30, 2017 | | Liability Derivatives | |
|--|--|-------------------------------|-----------------------|
| Derivatives Designated as Hedging Instruments | | Balance Sheet Location | Fair Value (1) |
| Interest rate swap contracts | | Accrued liabilities | \$ 875 |
| Interest rate swap contracts | | Other long-term liabilities | 932 |
| FX derivative contracts | | Accrued liabilities | 724 |
| Total derivatives designated as hedging instruments | | | <u>2,531</u> |
| Derivatives Not Designated as Hedging Instruments | | | |
| FX derivative contracts | | Accrued liabilities | 1,456 |
| Total derivatives not designated as hedging instruments | | | <u>1,456</u> |
| | | | <u>\$ 3,987</u> |

| December 31, 2016 | | Asset Derivatives | | Liability Derivatives | |
|--|--|---|-----------------------|-------------------------------|-----------------------|
| Derivatives Designated as Hedging Instruments | | Balance Sheet Location | Fair Value (1) | Balance Sheet Location | Fair Value (1) |
| Interest rate swap contracts | | Prepaid expenses and other current assets | \$ — | Accrued liabilities | \$ 942 |
| Interest rate swap contracts | | Other assets | — | Other long-term liabilities | 1,392 |
| FX derivative contracts | | Prepaid expenses and other current assets | 4,911 | Accrued liabilities | — |
| Total derivatives designated as hedging instruments | | | <u>4,911</u> | | <u>2,334</u> |
| Derivatives Not Designated as Hedging Instruments | | | | | |
| FX derivative contracts | | Prepaid expenses and other current assets | 3,358 | Accrued liabilities | — |
| Total derivatives not designated as hedging instruments | | | <u>3,358</u> | | <u>—</u> |
| | | | <u>\$ 8,269</u> | | <u>\$ 2,334</u> |

(1) For the classification of input used to evaluate the fair value of our derivatives, refer to "Note 6. Fair Value Measurements."

Note 9. Commitments and Contingencies

3T Heater-Cooler Devices

FDA Warning Letter.

On December 29, 2015, the FDA issued LivaNova a Warning Letter (the “Warning Letter”) alleging certain violations of FDA regulations applicable to medical device manufacturers at our 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 devices and other devices we manufactured at our Munich facility are subject to refusal of admission into the U.S. 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 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 device, and manufacturing and shipment of all of our products other than the 3T device 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 devices to existing U.S. users pursuant to a certificate of medical necessity program.

Finally, 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, this restriction applies only to the Munich and Arvada facilities, which do not manufacture or design devices subject to Class III premarket approval.

We continue 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.

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 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 3T device 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 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 3T devices and provide guidance for providers and patients. The CDC notification states that the decision to use the 3T device 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 3T devices are critical medical devices and enable doctors to perform life-saving cardiac surgery procedures.

Also on October 13, 2016, we issued a Field Safety Notice Update for U.S. users of 3T devices to proactively and voluntarily contact facilities to aid in implementation of the CDC and FDA recommendations. In the fourth quarter of 2016, we initiated a program to provide existing 3T device users with a new loaner 3T device at no charge pending regulatory approval and implementation of additional risk mitigation strategies worldwide. This loaner program began in the U.S. and is being made available progressively on a global basis, prioritizing and allocating devices to 3T device users based on pre-established criteria. We anticipate that this program will continue until we are able to address customer needs through a broader solution that includes implementation of one or more of the risk mitigation strategies currently under review with regulatory agencies.

On December 31, 2016, we recognized a liability for our product remediation plan related to our 3T device. We concluded that it was probable that a liability had been incurred upon management’s approval of the plan and the commitments made by management to various regulatory authorities globally in November and December 2016, and furthermore, the cost associated with the plan was reasonably estimable. At September 30, 2017, the product remediation liability was \$30.2 million. Refer to “Note 4. Product Remediation Liability” for additional information.

Litigation

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 our 3T devices. The plaintiffs named in the complaint 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 our 3T devices; and (ii) we knew or should have known that design or manufacturing defects in 3T devices can lead to NTM bacterial colonization, regardless of the cleaning and disinfection procedures used (and recommended by us). The class of plaintiffs in the complaint consists 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 currently are asymptomatic for NTM infection.

On October 23, 2017, the U.S. District Court for the Middle District of Pennsylvania issued an order certifying a class with respect to the named plaintiffs. The class action, which is currently against Sorin Group Deutschland GmbH and Sorin Group USA, Inc. seeks: (i) declaratory relief finding the 3T devices are defective and unsafe for intended uses; (ii) medical monitoring; (iii) general damages; and (iv) attorneys’ fees. Other lawsuits related to surgeries in which a 3T device allegedly was used have been filed elsewhere in the U.S., as well as in Canada, and Europe, against various LivaNova entities.

We are defending each of these claims vigorously. Given the relatively early stage of these matters, we cannot give any assurances that additional legal proceedings making the same or similar allegations will not be filed against us or one of our subsidiaries, nor that the resolution of these complaints or other related litigation will not have a material adverse effect on our business, results of operations, financial condition or liquidity. We have not recognized an expense related to damages in connection with these matters because any potential loss is not currently probable or reasonably estimable. In addition we cannot reasonably estimate a range of potential loss, if any, that may result from these matters.

Other Litigation

SNIA Litigation

Sorin was created as a result of a spin-off (the “Sorin spin-off”) from SNIA S.p.A. (“SNIA”). The Sorin spin-off, which involved 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, for certain indebtedness or liabilities of the pre-spin-off company. We estimate that the value of the shareholders’ equity received by Sorin was approximately €573 million (approximately \$676 million).

We believe and have 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. 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 (approximately \$4.0 billion) for remediation costs relating to the environmental damage at the Caffaro Chemical Sites.

In September 2011, the Bankruptcy Court of Udine, and in July 2014, the Bankruptcy Court of Milan each held (in proceedings to which we are not parties) that the Italian Ministry of the Environment and other Italian government agencies (the “Public Administrations”) were not creditors of either SNIA Subsidiaries or SNIA in connection with their claims in the context of their Italian 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 joint liability of a parent and a spun-off company. SNIA’s civil action against Sorin also named the Public Administrations, the Italian Ministry of the Environment and other Italian government agencies, as defendants, in order to have them bound to the final ruling.

On April 1, 2016, the Court of Milan dismissed all legal actions of SNIA and of the Public Administrations against Sorin, further requiring the Public Administrations to pay Sorin €300,000 (or approximately \$353,910), as legal fees (of which SNIA is jointly liable for €50,000) (the “2016 Decision”).

On June 21, 2016, the Public Administrations appealed the 2016 Decision to the Court of Appeal of Milan. The first hearing of the appeal proceedings was held in December 2016, and the final hearing is now scheduled for November 22, 2017. After the hearing, the parties will file their final briefs, and the Court is expected to render its decision in mid-2018. SNIA did not file an appeal.

We (as successor to Sorin in the litigation) continue 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 alleged damages, related remediation costs, allocation and apportionment of any such responsibility, which party is responsible, and various time periods involving different parties, all remain issues in dispute and that no final decision on a remediation plan has been approved. As a result, we have not made any accrual in connection with the SNIA litigation.

Pursuant to European Union (“EU”), United Kingdom (“UK”) 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 us as successor to Sorin. Although we believe the claims against Sorin in connection with the SNIA litigation are without merit and continue to contest them vigorously, there can be no assurance as to the outcome. A finding during any appeal or novel proceedings that we are liable for environmental damage at the Caffaro Chemical Sites or its alleged cause(s) could have a material adverse effect on our results of operations, financial condition and/or liquidity.

Environmental Remediation Order

On July 28, 2015, Sorin and other direct and indirect shareholders of SNIA received an administrative order (the “Remediation Order”) from the Italian Ministry of the Environment (the “Ministry”), directing them to promptly commence environmental remediation efforts at the Caffaro Chemical Sites (as described above). We (as successor to Sorin) believe that we should not be liable for damages relating to the Caffaro Chemical Operations pursuant to the Italian statute on which the 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, we believe that Sorin should not be subject to the Remediation Order because Italian environmental regulations only permit such an order to be imposed on an “operator” of a remediation site, and Sorin never operated any activity at any of the industrial sites concerned and, further, was never identified in any legal proceeding as an operator at any of the Caffaro Chemical Sites and could not and in fact did not cause any environmental damage at any of the Caffaro Chemical Sites.

Accordingly, we (as successor to Sorin) alongside other parties, challenged the Remediation Order before the Administrative Court of Lazio in Rome (the “TAR”).

On March 21, 2016 the TAR annulled the Remediation Order based on the fact that (i) the Remediation Order lacks any detailed analysis of the causal link between the alleged damage and our activities, a pre-condition to imposition of the measures proposed in the 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 or evidence of a situation of contamination exists, and (iii) there was no proper legal basis for the Remediation Order, and in any event, the Ministry failed to verify the legal elements that could have led to a conclusion of legal responsibility of the recipients of the Remediation Order.

The TAR decisions described above have 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. We have not recognized an expense in connection with this matter because any potential loss is not currently probable or reasonably estimable. In addition, we cannot reasonably estimate a range of potential loss, if any, that may result from this matter.

Opposition to Merger Proceedings

On July 28, 2015, the Public Administrations filed an opposition proceeding to the proposed merger between Sorin and Cyberonics (the “Merger”), before the Commercial Courts of Milan, asking the Court to prohibit the execution of the Merger. In its initial decision on August 20, 2015, the Court authorized the Merger and the Public Administrations did not appeal this decision. The proceeding then continued as a civil case, with the Public Administration seeking damages against us. The Commercial Court of Milan delivered a decision in October 2016, fully rejecting the Public Administration’s request and awarding us €200,000 (approximately \$228,000) in damages for frivolous litigation, plus €200,000 (approximately \$228,000) in legal fees. The Public Administrations has appealed this decision to the Court of Appeal of Milan. The final hearing is scheduled on January 17, 2018. The Court of Appeal is likely to make a decision in mid-June 2018. We have not recognized an expense in connection with this matter because any potential loss is not currently probable or reasonably estimable. In addition, we cannot reasonably estimate a range of potential loss, if any, that may result from this matter.

Tax Litigation

In a tax audit report received in October 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 (approximately \$121.0 million), related to tax years 2002 through 2006) 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. We 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 denied at the first jurisdictional level. We appealed these decisions. The appeal submitted against the first-level decision for 2004 was successful. The Internal Revenue Office appealed this second-level decision to the Italian Supreme Court (Corte di Cassazione) in February 2017. The Italian Supreme Court’s decision is pending.

The appeals submitted against the first-level decisions for 2005 and 2006 were rejected. We appealed these adverse decisions to the Italian Supreme Court, where the matters are still pending.

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. In these matters the Internal Revenue Office claims 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 subsequently utilized in 2007 and 2008. We challenged both notices of assessment. The Provincial Tax Court of Milan has stayed its decision for years 2007 and 2008 pending resolution of the litigation regarding years 2004, 2005, and 2006. The total amount of losses in dispute is €62.6 million (approximately \$73.8 million). We have continuously reassessed our potential exposure in these matters, taking into account the recent, and generally adverse, trend to Italian taxpayers in this type of litigation. Although we believe that our defensive arguments are strong, noting the adverse trend in some of the court decisions, we have recognized a reserve for an uncertain tax position of €17.0 million (approximately \$20.0 million).

Other Matters

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 net income, financial position or liquidity.

Note 10. Stockholders' Equity

Comprehensive income

The table below presents the change in each component of AOCI, net of tax, and the reclassifications out of AOCI into net earnings for the nine months ended September 30, 2017 and September 30, 2016 (in thousands):

| | Change in Unrealized Gain (Loss) on Derivatives | Foreign Currency Translation Adjustments Gain (Loss) ⁽¹⁾ | Total |
|--|--|--|--------------------|
| As of December 31, 2016 | \$ 3,619 | \$ (72,106) | \$ (68,487) |
| Other comprehensive (loss) income before reclassifications, before tax | (10,124) | 111,123 | 100,999 |
| Tax benefit | 2,784 | — | 2,784 |
| Other comprehensive (loss) income before reclassifications, net of tax | (7,340) | 111,123 | 103,783 |
| Reclassification of loss from accumulated other comprehensive income, before tax | 4,201 | — | 4,201 |
| Tax benefit | (1,028) | — | (1,028) |
| Reclassification of loss from accumulated other comprehensive income, after tax | 3,173 | — | 3,173 |
| Net current-period other comprehensive (loss) income, net of tax | (4,167) | 111,123 | 106,956 |
| As of September 30, 2017 | \$ (548) | \$ 39,017 | \$ 38,469 |
| As of December 31, 2015 | \$ 888 | \$ (55,116) | \$ (54,228) |
| Other comprehensive (loss) income before reclassifications, before tax | (5,970) | 32,598 | 26,628 |
| Tax benefit | 1,792 | — | 1,792 |
| Other comprehensive (loss) income before reclassifications, net of tax | (4,178) | 32,598 | 28,420 |
| Reclassification of loss from accumulated other comprehensive income, before tax | 746 | — | 746 |
| Tax benefit | (279) | — | (279) |
| Reclassification of loss from accumulated other comprehensive income, after tax | 467 | — | 467 |
| Net current-period other comprehensive (loss) income, net of tax | (3,711) | 32,598 | 28,887 |
| As of September 30, 2016 | \$ (2,823) | \$ (22,518) | \$ (25,341) |

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

Note 11. Stock-Based Incentive Plans

Stock-based incentive plans compensation expense (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|----------------------------------|-----------------|---------------------------------|------------------|
| | 2017 | 2016 | 2017 | 2016 |
| Service-based stock appreciation rights ("SARs") | \$ 2,535 | \$ 1,983 | \$ 6,001 | \$ 6,567 |
| Service-based restricted stock units ("RSUs") | 2,225 | 2,517 | 6,718 | 8,419 |
| Market performance-based restricted stock units | 301 | 14 | 482 | 17 |
| Operating performance-based restricted stock units | 636 | 254 | 1,060 | 572 |
| Total stock-based compensation expense | \$ 5,697 | \$ 4,768 | \$ 14,261 | \$ 15,575 |

During the nine months ended September 30, 2017, we executed stock-based compensatory award agreements with contract terms agreed upon by us and the respective individuals, as approved by the Compensation Committee of our Board of

Directors. Awards with service conditions vest ratably over four years subject to forfeiture unless service conditions are met. Market performance-based awards vest ratably over four years subject to forfeiture unless certain future prices of our shares on the NASDAQ Stock Market exceed certain threshold prices in the first year following the grant date. And finally, operating performance-based awards vest ratably over four years subject to forfeiture unless certain thresholds of adjusted net sales and adjusted net income are met for fiscal year 2017. Compensation expense related to award agreements executed during 2017 for the three and nine months ended September 30, 2017 were \$2.0 million and \$3.2 million, respectively.

Stock-based compensation agreements executed during the nine months ended September 30, 2017, representing potential shares and their weighted average grant date fair values by type follows (shares in thousands, fair value in dollars):

| | Nine Months Ended September 30, 2017 | |
|----------------------------------|---|---|
| | Shares | Weighted Average Grant Date Fair Value |
| Service-based SARs | 639 | \$ 17.03 |
| Service-based RSUs | 108 | \$ 57.37 |
| Market performance-based RSUs | 158 | \$ 25.29 |
| Operating performance-based RSUs | 189 | \$ 56.18 |

Note 12. Income Taxes

During the three and nine months ended September 30, 2017, we recorded consolidated income tax expense of \$1.9 million and \$10.9 million, respectively, with consolidated effective income tax rates of 6.1% and 9.3%, respectively.

Our consolidated effective income tax rate for the three and nine months ended September 30, 2017 included the impact of various discrete tax items, including a net \$4.0 million deferred tax benefit due to the release of valuation allowances on tax losses upon the completion of a reorganization of our legal entities in the U.S. and a \$2.1 million tax benefit from the resolution of prior period tax matters. Discrete tax items for the nine months ended September 30, 2017 also included the acquisition of Caisson and the \$38.1 million non-taxable gain recognized to re-measure our existing equity investment in Caisson at fair value on the acquisition date, a \$3.9 million deferred tax benefit associated with certain temporary differences arising from the Mergers and the recognition of a \$3.0 million deferred tax asset related to a reserve for an uncertain tax position recognized in a prior year, in addition to various other discrete items.

During the three and nine months ended September 30, 2016, we recorded consolidated income tax expense of \$9.7 million and \$16.9 million, respectively, with consolidated effective income tax rates of 45.7% and 514.5%, respectively. The effective tax rate for the nine months ended September 30, 2016 was impacted by the recording of valuation allowances of \$23.9 million related to certain tax jurisdictions, including France and the UK, 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 jurisdictions, such as the U.S. and Germany, offset by tax savings from our inter-company financing as part of our 2015 tax restructuring.

Note 13. Net Income (Loss) Per Share

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|----------------------------------|------------|---------------------------------|-------------|
| | 2017 | 2016 | 2017 | 2016 |
| Numerator: | | | | |
| Net income (loss) | \$ 27,830 | \$ (1,569) | \$ 86,599 | \$ (32,990) |
| Denominator: | | | | |
| Basic weighted average shares outstanding | 48,181 | 49,075 | 48,130 | 49,016 |
| Add effects of share-based compensation instruments ⁽¹⁾ | 353 | — | 209 | — |
| Diluted weighted average shares outstanding | 48,534 | 49,075 | 48,339 | 49,016 |
| Basic income (loss) per share | \$ 0.58 | \$ (0.03) | \$ 1.80 | \$ (0.67) |
| Diluted income (loss) per share | \$ 0.57 | \$ (0.03) | \$ 1.79 | \$ (0.67) |

- (1) Excluded from the computation of diluted earnings per share for the three and nine months ended September 30, 2017 were 1.6 million stock options and SARs outstanding as of September 30, 2017, because to include them would have been anti-dilutive. Excluded from the computation of diluted earnings per share for the three and nine months ended September 30, 2016 were approximately 2.3 million stock options, SARs and restricted share units outstanding as of September 30, 2016, because to include them would have been anti-dilutive due to the net losses.

Note 14. 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. We have three reportable segments: Cardiac Surgery, Neuromodulation, and Cardiac Rhythm Management.

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 systems, mechanical heart valves and tissue heart valves.

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.

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, cardiac resynchronization therapy devices and low-voltage pacemakers.

“Other” includes Corporate shared services expenses for finance, legal, human resources and information technology and Corporate business development (“New Ventures”). New Ventures, which includes our recent Caisson acquisition, is focused on new growth platforms and identification of other opportunities for expansion.

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, and amortization of intangibles.

Net sales and income from operations by segment (in thousands):

| Net Sales: | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---------------------------|----------------------------------|-------------------|---------------------------------|-------------------|
| | 2017 | 2016 | 2017 | 2016 |
| Cardiac Surgery | \$ 159,822 | \$ 148,518 | \$ 457,612 | \$ 453,012 |
| Neuromodulation | 91,016 | 89,504 | 275,190 | 260,901 |
| Cardiac Rhythm Management | 58,411 | 56,768 | 182,235 | 188,057 |
| Other | 415 | 478 | 1,119 | 1,314 |
| | <u>\$ 309,664</u> | <u>\$ 295,268</u> | <u>\$ 916,156</u> | <u>\$ 903,284</u> |

| Income from Operations: | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|----------------------------------|------------------|---------------------------------|-----------------|
| | 2017 | 2016 | 2017 | 2016 |
| Cardiac Surgery | \$ 23,807 | \$ 17,791 | \$ 63,490 | \$ 29,197 |
| Neuromodulation | 45,932 | 47,049 | 139,357 | 134,871 |
| Cardiac Rhythm Management | 5,427 | (4,598) | 13,536 | (14,432) |
| Other | (27,947) | (13,525) | (79,378) | (49,090) |
| Total Reportable Segments' Income from Operations | 47,219 | 46,717 | 137,005 | 100,546 |
| Merger and integration expenses | 2,013 | 7,576 | 7,743 | 20,537 |
| Restructuring expenses | 792 | 4,381 | 12,060 | 37,219 |
| Amortization of intangibles | 12,350 | 11,775 | 35,445 | 33,959 |
| Income from operations | <u>\$ 32,064</u> | <u>\$ 22,985</u> | <u>\$ 81,757</u> | <u>\$ 8,831</u> |

The following tables present our assets and capital expenditures by segment (in thousands):

| Assets: | September 30, 2017 | December 31, 2016 |
|---------------------------|-----------------------|----------------------|
| Cardiac Surgery | \$ 1,414,260 | \$ 1,277,799 |
| Neuromodulation | 564,785 | 611,085 |
| Cardiac Rhythm Management | 351,390 | 341,998 |
| Other | 272,695 | 111,749 |
| | <u>\$ 2,603,130</u> | <u>\$ 2,342,631</u> |

| Capital expenditures: | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---------------------------|----------------------------------|------------------|---------------------------------|------------------|
| | 2017 | 2016 | 2017 | 2016 |
| Cardiac Surgery | \$ 5,541 | \$ 6,465 | \$ 13,292 | \$ 16,774 |
| Neuromodulation | 370 | 1,781 | 2,348 | 5,602 |
| Cardiac Rhythm Management | 1,537 | 1,591 | 4,343 | 2,786 |
| Other | 1,633 | 2,435 | 4,021 | 3,766 |
| | <u>\$ 9,081</u> | <u>\$ 12,272</u> | <u>\$ 24,004</u> | <u>\$ 28,928</u> |

The changes in the carrying amount of goodwill by reportable segment for the nine months ended September 30, 2017 were as follows (in thousands):

| | Neuromodulation | Cardiac Surgery | Cardiac Rhythm Management | Other | Total |
|---|-----------------|-----------------|---------------------------|-----------|------------|
| December 31, 2016 | \$ 315,943 | \$ 375,769 | \$ — | \$ — | \$ 691,712 |
| Goodwill as a result of acquisitions ⁽¹⁾ | — | — | — | 42,418 | 42,418 |
| Foreign currency adjustments | — | 46,940 | — | — | 46,940 |
| September 30, 2017 | \$ 315,943 | \$ 422,709 | \$ — | \$ 42,418 | \$ 781,070 |

(1) Goodwill recognized as a result of the Caisson acquisition. Refer to "Note 2. Acquisitions."

Geographic Information

We operate under three geographic regions: United States, Europe, and Rest of world. Net sales to external customers by geography are determined based on the country the products are shipped to and are as follows (in thousands):

| Net Sales | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---------------------------|----------------------------------|------------|---------------------------------|------------|
| | 2017 | 2016 | 2017 | 2016 |
| United States | \$ 122,208 | \$ 123,810 | \$ 366,115 | \$ 362,358 |
| Europe ^{(1) (2)} | 92,953 | 91,245 | 294,338 | 301,727 |
| Rest of world | 94,503 | 80,213 | 255,703 | 239,199 |
| Total ⁽³⁾ | \$ 309,664 | \$ 295,268 | \$ 916,156 | \$ 903,284 |

(1) Net sales to external customers in the UK include \$9.6 million and \$26.8 million for the three and nine months ended September 30, 2017, respectively and \$8.8 million and \$27.9 million for the three and nine months ended September 30, 2016, respectively.

(2) Includes those countries in Europe where we have 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 net sales exceeded 10% of our consolidated net sales. French sales were \$29.6 million and \$96.6 million for the three and nine months ended September 30, 2017, respectively, and \$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):

| PP&E | September 30, 2017 | December 31, 2016 |
|---------------|--------------------|-------------------|
| United States | \$ 62,630 | \$ 61,279 |
| Europe | 137,682 | 130,777 |
| Rest of world | 13,457 | 31,786 |
| Total | \$ 213,769 | \$ 223,842 |

Note 15. Supplemental Financial Information

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

| | September 30, 2017 | December 31, 2016 |
|--------------------------------------|--------------------|-------------------|
| Trade receivables from third parties | \$ 326,498 | \$ 285,336 |
| Allowance for bad debt | (12,457) | (9,606) |
| | \$ 314,041 | \$ 275,730 |

Inventories consisted of the following (in thousands):

| | September 30, 2017 | December 31, 2016 |
|-----------------|-----------------------|----------------------|
| Raw materials | \$ 51,628 | \$ 47,704 |
| Work-in-process | 39,873 | 32,316 |
| Finished goods | 123,092 | 103,469 |
| | <u>\$ 214,593</u> | <u>\$ 183,489</u> |

Inventories are reported net of the provision for obsolescence which totaled \$13.7 million and \$9.8 million at September 30, 2017 and December 31, 2016, respectively.

Prepaid expenses and other current assets consisted of the following (in thousands):

| | September 30, 2017 | December 31, 2016 |
|--|-----------------------|----------------------|
| Income taxes payable on inter-company transfers of property ⁽¹⁾ | \$ 19,445 | \$ 19,445 |
| Deposits and advances to suppliers | 7,298 | 5,417 |
| Earthquake grant receivable | 4,983 | 4,748 |
| Unbilled receivables | 4,363 | — |
| Escrow deposit - Caisson | 2,000 | — |
| Current loans and notes receivable | 1,553 | 7,093 |
| Derivative contract assets | — | 8,269 |
| Other prepaid expenses | 15,534 | 11,001 |
| | <u>\$ 55,176</u> | <u>\$ 55,973</u> |

- (1) The income taxes payable on intercompany transfers of property asset is the asset account created to defer the income tax effect of an intercompany intellectual property sale pursuant to ASC 810-10-45-8.

Other assets consisted of the following (in thousands):

| | September 30, 2017 | December 31, 2016 |
|--|-----------------------|----------------------|
| Income taxes payable on inter-company transfers of property ⁽¹⁾ | \$ 109,971 | \$ 124,551 |
| Investments ⁽²⁾ | 2,316 | 2,537 |
| Loans and notes receivable | 1,964 | 2,029 |
| Escrow deposit - Caisson | 1,000 | — |
| Guaranteed deposits | 777 | 940 |
| Other | 1,827 | 641 |
| | <u>\$ 117,855</u> | <u>\$ 130,698</u> |

- (1) The income taxes payable on intercompany transfers of property asset is the asset account created to defer the income tax effect of an intercompany intellectual property sale pursuant to ASC 810-10-45-8.
(2) Primarily cash surrender value of company owned life insurance policies.

Accrued liabilities and other consisted of the following (in thousands):

| | September 30, 2017 | December 31, 2016 |
|--|-----------------------|----------------------|
| Product remediation liability ⁽¹⁾ | \$ 20,060 | \$ 23,464 |
| Deferred compensation - Caisson acquisition | 14,137 | — |
| Legal and other administrative costs | 7,863 | 6,184 |
| Provisions for agents, returns and other | 8,505 | 7,271 |
| Restructuring related liabilities | 5,098 | 16,859 |
| Product warranty obligations | 1,747 | 2,736 |
| Royalty costs | 2,048 | 2,503 |
| Escrow indemnity liability - Caisson | 2,000 | — |
| Deferred income | 4,752 | — |
| Government grants | 1,275 | 1,708 |
| Derivative contract liabilities ⁽²⁾ | 3,055 | 942 |
| Research and development costs | 1,173 | 839 |
| Other | 20,499 | 13,061 |
| | <u>\$ 92,212</u> | <u>\$ 75,567</u> |

(1) Refer to “Note 4. Product Remediation Liability.”

(2) Refer to “Note 8. Derivatives and Risk Management.”

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

| | September 30, 2017 | December 31, 2016 |
|--|-----------------------|----------------------|
| Contingent consideration ⁽¹⁾ | \$ 34,217 | \$ 3,890 |
| Uncertain tax positions | 12,349 | 11,108 |
| Product remediation liability ⁽²⁾ | 10,186 | 10,023 |
| Government grants | 5,889 | 3,803 |
| Derivative contract liabilities ⁽³⁾ | 932 | 1,392 |
| Escrow indemnity liability - Caisson | 1,000 | — |
| Unfavorable operating leases ⁽⁴⁾ | 256 | 1,672 |
| Other | 9,575 | 7,599 |
| | <u>\$ 74,404</u> | <u>\$ 39,487</u> |

(1) The contingent consideration liability represents contingent payments related to three acquisitions: the first and second acquisitions, in September 2015, were Cellplex PTY Ltd. in Australia and 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 6. Fair Value Measurements.” The third acquisition, Caisson, occurred in May 2017. Refer to “Note 2. Acquisitions.”

(2) Refer to “Note 4. Product Remediation Liability.”

(3) Refer to “Note 8. Derivatives and Risk Management.”

(4) Unfavorable operating leases represent the adjustment to recognize future lease obligations at their estimated fair value in conjunction with the Mergers.

Note 16. New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued ASC Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers*. 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. The standard permits the use of either the retrospective or cumulative effect transition method. We will adopt the new standard under the cumulative effect transition method.

Based on the Company's evaluation performed to date, we believe the timing of revenue recognition for products and related revenue streams within our Neuromodulation and Cardiac Rhythm Management segments will not materially change. The Company continues to evaluate the impact of the new standard on the timing of when revenue will be recognized for equipment sales and certain services performed within our Cardiac Surgery segment specifically related to heart-lung machines and preventive maintenance contracts on cardiopulmonary equipment.

Upon adoption of the new standard, we expect to implement new internal controls related to our accounting policies and procedures, including review controls to ensure contractual terms and conditions that may require consideration under the standard are properly identified and analyzed. During the fourth quarter of 2017, we expect to finalize our impact assessment and redesign impacted processes, policies and controls.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments-Overall (Subtopic 825-10): *Recognition and Measurement of Financial Assets and Financial Liabilities*. Update 2016-01 requires 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 ASU No. 2016-02, *Leases*. 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 the current 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 ASU No. 2016-09, *Compensation—Stock Compensation: Improvements to Employee Share-Based Payment Accounting*. This simplified the accounting for certain aspects of share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. We adopted the amendments of ASU 2016-09 (each "an Amendment") effective January 1, 2017, using the following methods:

We adopted the Amendment that requires all of the tax effects related to the settlement of share based compensation awards to be recorded through the income statement on a prospective basis. The adoption of this Amendment did not have a material effect on income tax expense for the nine months ended September 30, 2017.

We adopted the Amendment related to cash flow presentation of tax-related cash flows resulting from share based payments on a prospective basis. The Amendment stipulates that all tax-related cash flows resulting from share based payments are to be reported as operating activities in the statement of cash flows, rather than, under past requirements, to present gross windfall tax benefits as an inflow from financing activities and an outflow from operating activities.

Under the Amendment related to forfeitures, entities are permitted to make a company-wide accounting policy election to either estimate forfeitures each period, as required prior to this Amendment's effective date, or to account for forfeitures as they occur. We elected to continue to account for forfeitures using the estimation method.

We adopted the Amendment related to the timing of when excess tax benefits are recognized, which requires that all windfalls and shortfalls be recognized when they arise. There were no unrecognized excess tax benefits prior to the adoption of the Amendment.

In August 2016, the FASB issued ASU No. 2016-15, *Classification of Certain Cash Receipts and Cash Payments (Topic 230 -Statement of Cash Flows)*. Update 2016-15 provides guidance on 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. The amendments should be applied using a retrospective transition method to each period presented. We are currently evaluating the effect this standard will have on our consolidated financial statements and related disclosures.

In October 2016, the FASB issued ASU 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 is effective for annual periods after December 15, 2017, including interim periods within those annual reporting periods. We currently estimate the cumulative-effect reduction to retained earnings to be approximately \$65.2 million upon adoption at January 1, 2018.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other - Simplifying the Test for Goodwill Impairment (Topic 350)*. This update removes step 2 of the goodwill impairment test that compares the implied fair value of goodwill with its carrying amount. Instead, an impairment test is performed by comparing the fair value of a reporting unit with its carrying amount. An impairment charge will be recorded by the amount a reporting unit’s carrying amount exceeds its fair value. The rule is effective for annual periods after December 15, 2019, including interim periods within those annual reporting periods. We are currently evaluating the impact of adopting this update on our consolidated financial statements.

In March 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805)—Clarifying the Definition of a Business*. This update clarifies when a set of assets and activities is a business. The amendments provide a screen to determine when a set is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, the amendments in this Update (1) require that to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. This update is effective for annual periods after December 15, 2017, including interim periods within those annual reporting periods. We are currently evaluating the impact of adopting this update on our consolidated financial statements.

In March 2017, the FASB issued ASU No. 2017-07, *Compensation—Retirement Benefits (Topic 715): Improving the Presentation of Net Periodic Pension Cost and Net Periodic Post Retirement Benefit Cost*. This update requires that an employer report the service cost component in the same line item or items as other compensation costs arising from services rendered by the pertinent employees during the period. The other components of net benefit cost are required to be presented in the income statement separately from the service cost component and outside a subtotal of income from operations, if one is presented. If a separate line item or items are used to present the other components of net benefit cost, that line item or items must be appropriately described. If a separate line item or items are not used, the line item or items used in the income statement to present the other components of net benefit cost must be disclosed. The amendments in this Update also allow only the service cost component to be eligible for capitalization when applicable. This Update is effective for annual periods after December 15, 2017, including interim periods within those annual reporting periods. We are currently evaluating the impact of adopting this update on our consolidated financial statements.

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 and with our Annual Report on Form 10-K for the year ended December 31, 2016 (“2016 Form 10-K”). Our discussion and analysis may contain forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth under “Risk Factors” in Item 1A of our 2016 Form 10-K and elsewhere in this quarterly report.

The capitalized terms used below have been defined in the notes to our condensed consolidated financial statements. In the following text, the terms “LivaNova,” “the Company,” “we,” “us” and “our” refer to LivaNova PLC and its consolidated subsidiaries.

Business Overview

We are a public limited company organized under the laws of England and Wales, headquartered in London, United Kingdom. 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 in the fields 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.

Business Franchises

We operate our business through three segments: Cardiac Surgery, Neuromodulation and Cardiac Rhythm Management. Our three reportable segments correspond to our Business Franchises and each Business Franchise corresponds to one of our three main therapeutic areas aligned to best serve our customers. Corporate activities include corporate business development ("New Ventures"). New Ventures is focused on new growth platforms and identification of other opportunities for expansion and investment.

For further information regarding 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.

Cardiac Surgery Update

On October 5, 2015, we announced the initiation of PERSIST-AVR, the first international, prospective post-market randomized multi-center clinical study evaluating the Perceval sutureless aortic valve compared to standard sutured bioprostheses in patients with aortic valve disease. The Perceval valve, the only sutureless biological aortic valve replacement ("AVR") on the market today, employs a unique self-anchoring frame that enables the surgeon to replace the diseased valve without suturing it into place. The study is expected to enroll 1,234 patients within a two-year enrollment period and patients will be followed until five years post procedure. In January 2017, the independent study, "Aortic Valve Replacement With Sutureless Perceval Bioprosthesis: Single-Center Experience With 617 Implants," was presented to The Society of Thoracic Surgeons. The study found AVR procedures conducted with the Perceval sutureless valve resulted in low mortality and excellent hemodynamic performance for patients.

In January 2016, we announced FDA approval of the Perceval sutureless valve. While we have been selling Perceval in other parts of the world for several years, we began commercial distribution of the device in the United States last year, with the first implant announced on March 8, 2016. The Perceval valve has been implanted in more than 25,000 patients in more than 310 hospitals in 34 countries across the world.

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

In March 2017, we committed to a plan to sell our Suzhou Industrial Park facility in Shanghai, China, an emerging market greenfield project for the local manufacture of Cardiopulmonary disposable products in Suzhou Industrial Park in China. As a result of this exit plan, we recorded an impairment of the building and equipment of \$4.6 million and accrued \$0.5 million of additional costs, primarily related to employee severance, during the nine months ended September 30, 2017, included in 'Restructuring expenses' in the condensed consolidated statement of income (loss). In addition, the land, building and equipment were recorded as 'Assets held for sale' on the condensed consolidated balance sheet, with a carrying value of \$14.1 million as of September 30, 2017.

In September 2017, we received FDA 510(k) clearance for the U.S. market launch of our Optiflow Arterial Cannulae Family. Optiflow aortic arch cannulae provide improved hydrodynamics with a novel dispersive tip design that improves blood flow characteristics resulting in reduced wall shear stress ("WSS") profiles. Optiflow Arterial cannulae feature a unique basket tip with large openings that allow a more physiologically compatible dispersive design. This design has been shown to significantly reduce WSS and turbulence, thereby improving hydrodynamics and potentially reducing ischemic complications from extracorporeal circulation during cardiac surgery.

3T Heater-Cooler Devices

FDA Warning Letter.

On December 29, 2015, the FDA issued LivaNova a Warning Letter (the "Warning Letter") alleging certain violations of FDA regulations applicable to medical device manufacturers at our 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 devices and other devices we manufactured at our Munich facility are subject to refusal of admission into the U.S. 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 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 device, and manufacturing and shipment of all of our products other than the 3T device 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 devices to existing U.S. users pursuant to a certificate of medical necessity program.

Finally, 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, this restriction applies only to the Munich and Arvada facilities, which do not manufacture or design devices subject to Class III premarket approval.

We continue 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.

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 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 3T device 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 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 3T devices and provide guidance for providers and patients. The CDC notification states that the decision to use the 3T device 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 3T devices are critical medical devices and enable doctors to perform life-saving cardiac surgery procedures.

Also on October 13, 2016, we issued a Field Safety Notice Update for U.S. users of 3T devices to proactively and voluntarily contact facilities to aid in implementation of the CDC and FDA recommendations. In the fourth quarter of 2016, we initiated a program to provide existing 3T device users with a new loaner 3T device at no charge pending regulatory approval and implementation of additional risk mitigation strategies worldwide. This loaner program began in the U.S. and is being made available progressively on a global basis, prioritizing and allocating devices to 3T device users based on pre-established criteria. We anticipate that this program will continue until we are able to address customer needs through a broader solution that includes implementation of one or more of the risk mitigation strategies currently under review with regulatory agencies.

On December 31, 2016, we recognized a liability for our product remediation plan related to our 3T device. We concluded that it was probable that a liability had been incurred upon management's approval of the plan and the commitments made by management to various regulatory authorities globally in November and December 2016, and furthermore, the cost associated with the plan was reasonably estimable. At September 30, 2017, the product remediation liability was \$30.2 million. Refer to "Note 4. Product Remediation Liability" for additional information.

Litigation

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 our 3T devices. The plaintiffs named in the complaint 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 our 3T devices; and (ii) we knew or should have known that design or manufacturing defects in 3T devices can lead to NTM bacterial colonization, regardless of the cleaning and disinfection procedures used (and recommended by us). The class of plaintiffs in the complaint consists 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 currently are asymptomatic for NTM infection.

On October 23, 2017, the U.S. District Court for the Middle District of Pennsylvania issued an order certifying a class with respect to the named plaintiffs. The class action, which is currently against Sorin Group Deutschland GmbH and Sorin Group USA, Inc. seeks: (i) declaratory relief finding the 3T devices are defective and unsafe for intended uses; (ii) medical monitoring; (iii) general damages; and (iv) attorneys’ fees. Other lawsuits related to surgeries in which a 3T device allegedly was used have been filed elsewhere in the U.S., as well as in Canada, and Europe, against various LivaNova entities.

We are defending each of these claims vigorously. Given the relatively early stage of these matters, we cannot give any assurances that additional legal proceedings making the same or similar allegations will not be filed against us or one of our subsidiaries, nor that the resolution of these complaints or other related litigation will not have a material adverse effect on our business, results of operations, financial condition or liquidity. We have not recognized an expense related to damages in connection with these matters because any potential loss is not currently probable or reasonably estimable. In addition we cannot reasonably estimate a range of potential loss, if any, that may result from these matters.

Neuromodulation Update

Epilepsy

Our product development efforts are directed toward improving the VNS Therapy System and developing new products that provide additional features and functionality. We are conducting ongoing product development activities to enhance the VNS Therapy System pulse generator, lead and programming software. We will be required to obtain appropriate U.S. and international regulatory approvals, and clinical studies may be a prerequisite to regulatory approvals for some products.

In June 2017, the FDA approved our VNS Therapy device for use in patients who are at least four years of age and have partial onset seizures that are refractory to antiepileptic medications. VNS Therapy is the first and only FDA-approved device for drug-resistant epilepsy in this pediatric population. Previously, VNS Therapy was approved by the FDA for patients 12 years or older.

In addition, in June 2017, we received FDA approval, and in August CE Mark approval, for our VNS Therapy device for expanded magnetic resonance imaging (“MRI”) labeling affirming VNS Therapy as the only epilepsy device approved by the FDA for MRI scans. Currently, SenTiva, AspireHC and AspireSR models of VNS Therapy technology provide for this expanded MRI access.

In October 2017, we obtained FDA approval to market our SenTiva VNS Therapy System, which consists of the SenTiva implantable generator and the next-generation VNS Therapy Programming System. SenTiva is the smallest and lightest responsive therapy for epilepsy. The new VNS Therapy Programming System features a wireless wand and new user interface on a small tablet. Together, the components offer patients with drug-resistant epilepsy a physician-directed customizable therapy with smart technology and proven results that reduce the number of seizures, lessen the duration of seizures and enable a faster recovery.

Depression

In March 2017, the American Journal of Psychiatry published the results of the longest and largest naturalistic study on effective treatments for patients experiencing chronic and severe depression. The findings showed that the addition of VNS Therapy to traditional treatment methods is effective in reducing symptoms in patients with treatment-resistant depression.

Cardiac Rhythm Management (“CRM”) Update

In September 2017, we announced that we had commenced a process to explore strategic options to realize the full value of our CRM Business Franchise. While our Board of Directors has approved examining strategic options, amongst which is the possibility of divestiture, no commitment to a plan of sale has been made. Accordingly, the CRM business franchise was not reported as an asset held for sale as of September 30, 2017.

Also in September 2017, we announced that the Company's Shanghai-based joint venture MicroPort Sorin Cardiac Rhythm Management Co. Ltd. obtained approval for its family of Rega™ pacemakers from the China Food and Drug Administration.

New Ventures Update

Heart failure

With respect to heart failure, New Ventures is focused on the development and clinical testing of the VITARIA® System for treating heart failure through vagus nerve stimulation.

We received CE Mark approval of the VITARIA System in February 2015 for patients who have moderate to severe heart failure (New York Heart Association Class II/III) with left ventricular dysfunction (ejection fraction < 40%) 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 - without the patient kit with magnets. We conducted a pilot study, ANTHEM-HF, outside the United States, which concluded in 2014. The study results support the safety and efficacy of ART delivered by the VITARIA System. We submitted the results to our European Notified Body, DEKRA, and on February 20, 2015, we received CE Mark approval. The VITARIA System is not approved in the U.S. During 2014, we 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.

Obstructive sleep apnea

ImThera Medical, Inc. ("ImThera") is a privately held, emerging-growth company developing an implantable neurostimulation device system for the treatment of obstructive sleep apnea. We have an investment of \$12.0 million in ImThera, and a \$1.0 million note receivable due from ImThera for a loan made during the nine months ended September 30, 2017 to fund operating expenses.

Mitral valve regurgitation

Mitral regurgitation ("MR") occurs when the heart's mitral valve does not close tightly, which allows blood to flow backwards in the heart. This reduces the amount of blood that flows to the rest of the body, making the patient feel tired or out of breath. Treatment depends on the nature and the severity of MR. In certain cases, heart surgery may be needed to repair or replace the valve. Left untreated, severe mitral valve regurgitation can cause heart failure or heart rhythm problems (arrhythmias).

On May 2, 2017, we agreed to pay up to \$72.0 million to acquire the remaining 51% equity interests in Caisson in support of our strategic growth initiatives. Caisson is developing a device for treating mitral regurgitation through replacement of the native mitral valve using a fully transvenous delivery system. As a result of our acquisition of Caisson, we began consolidating the results of Caisson as of May 2, 2017. In April 2016, we obtained FDA approval of an Investigational Device Exemption study using Caisson technology for treating mitral regurgitation heart failure with transcatheter mitral valve replacement and we are currently executing against a defined clinical data development plan designed to enable commercialization of the Caisson technology.

We are also invested in two mitral valve startups. Cardiosolutions Inc. and Highlife. Cardiosolutions, a startup headquartered in the U.S. in which we have held an interest since 2012, is developing an innovative spacer technology for treating mitral regurgitation. Highlife, headquartered in France, is focused on developing devices for treating mitral regurgitation through percutaneous replacement of the native mitral valve. We recognized an impairment of our equity method investment in, and notes receivable from, Highlife during the nine months ended September 30, 2017. The estimated fair value of our investment and notes receivable were below our carrying value by \$13.0 million.

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 2016 Form 10-K. The accompanying unaudited condensed consolidated financial statements of LivaNova and its consolidated subsidiaries have been prepared in accordance with U.S. GAAP on an interim basis.

New accounting pronouncements are disclosed in "Note 16. New Accounting Pronouncements" contained in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Other

On June 23, 2016, the UK held a referendum in which voters approved an exit from the EU, commonly referred to as “Brexit.” On March 29, 2017, the UK government gave formal notice of its intention to leave the EU, formally commencing the negotiations regarding the terms of withdrawal between the UK and the EU. The withdrawal must occur within two years, unless the deadline is extended. The negotiation process will determine the future terms of the UK’s relationship with the EU. The notification does not change the application of existing tax laws, and does not establish a clear framework for what the ultimate outcome of the negotiations and legislative process will be.

Various tax reliefs and exemptions that apply to transactions between EU Member States under existing tax laws may cease to apply to transactions between the UK and EU Member States when the UK ultimately withdraws from the EU. It is unclear at this stage if or when any new tax treaties between the UK and the EU or individual EU Member States will replace those reliefs and exemptions. It is also unclear at this stage what financial, trade and legal implications will ensue from Brexit and how Brexit may affect us, our customers, suppliers, vendors, or our industry.

Several of our wholly owned subsidiaries that are domiciled either in the UK, various EU Member States, or in the United States, and our parent company, LivaNova PLC, are party to intercompany transactions and agreements under which we receive various tax reliefs and exemptions in accordance with applicable international tax laws, treaties and regulations. If certain treaties applicable to our transactions and agreements are not renegotiated or replaced with new treaties containing terms, conditions and attributes similar to those of the existing treaties, Brexit may have a material adverse impact on our future financial results and results of operations. During the two-year negotiation period, we will monitor and assess the potential impact of this event and explore possible tax-planning strategies that may mitigate or eliminate any such potential adverse impact. We will not account for the impact of Brexit in our income tax provisions until changes in tax laws or treaties between the UK and the EU or individual EU Member States are enacted or the withdrawal becomes effective.

The Trump Administration has included as part of its agenda a potential reform of U.S. tax laws. On September 27, 2017, the White House released its “Unified Framework for Fixing Our Broken Tax Code” (the “Framework”), which was developed by the Trump Administration, the House Committee on Ways and Means, and the Senate Committee on Finance and which includes specific goals for lower business tax rates. The Framework calls for a 20% corporate tax rate and international reforms that include a territorial tax system and a one-time mandatory repatriation tax. The Framework proposes 100% expensing of new investments in depreciable assets for five years, effective after September 27, 2017, while partially limiting the tax deduction for net business interest expense. Additionally, the Framework would repeal the section 199 domestic manufacturing deduction and “numerous other special exclusions and deductions” but would retain the research tax credit. The content of any final legislation, the timing for enactment, and the reporting periods that would be impacted cannot be determined at this time.

Results of Operations

We are reporting, in this Quarterly Report on Form 10-Q, the results for LivaNova and its consolidated subsidiaries for the three and nine months ended September 30, 2017, as compared to the three and nine months ended September 30, 2016.

The following table summarizes our condensed consolidated results of operations (in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|----------------------------------|------------|---------------------------------|-------------|
| | 2017 | 2016 | 2017 | 2016 |
| Net sales | \$ 309,664 | \$ 295,268 | \$ 916,156 | \$ 903,284 |
| Cost of sales | 108,233 | 106,454 | 318,584 | 360,675 |
| Product remediation | 1,642 | 689 | 2,573 | 2,243 |
| Gross profit | 199,789 | 188,125 | 594,999 | 540,366 |
| Operating expenses: | | | | |
| Selling, general and administrative | 121,177 | 109,233 | 353,943 | 345,744 |
| Research and development | 31,393 | 32,175 | 104,051 | 94,076 |
| Merger and integration expenses | 2,013 | 7,576 | 7,743 | 20,537 |
| Restructuring expenses | 792 | 4,381 | 12,060 | 37,219 |
| Amortization of intangibles | 12,350 | 11,775 | 35,445 | 33,959 |
| Total operating expenses | 167,725 | 165,140 | 513,242 | 531,535 |
| Income from operations | 32,064 | 22,985 | 81,757 | 8,831 |
| Interest income | 199 | 585 | 724 | 1,119 |
| Interest expense | (1,421) | (3,495) | (5,314) | (6,665) |
| Gain on acquisition of Caisson Interventional, LLC | — | — | 39,428 | — |
| Foreign exchange and other gains (losses) | 491 | 1,216 | 957 | (2) |
| Income before income taxes | 31,333 | 21,291 | 117,552 | 3,283 |
| Income tax expense | 1,913 | 9,731 | 10,881 | 16,891 |
| Losses from equity method investments | (1,590) | (13,129) | (20,072) | (19,382) |
| Net income (loss) | \$ 27,830 | \$ (1,569) | \$ 86,599 | \$ (32,990) |

Net Sales

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

| | Three Months Ended September 30, | | % Change |
|--|----------------------------------|------------|----------|
| | 2017 | 2016 | |
| Cardiac Surgery | | | |
| United States | \$ 44,991 | \$ 46,768 | (3.8)% |
| Europe ⁽¹⁾ | 40,429 | 38,009 | 6.4% |
| Rest of world | 74,402 | 63,741 | 16.7% |
| | 159,822 | 148,518 | 7.6% |
| Neuromodulation | | | |
| United States | 76,286 | 74,864 | 1.9% |
| Europe ⁽¹⁾ | 8,057 | 8,489 | (5.1)% |
| Rest of world | 6,673 | 6,151 | 8.5% |
| | 91,016 | 89,504 | 1.7% |
| Cardiac Rhythm Management | | | |
| United States | 931 | 2,178 | (57.3)% |
| Europe ⁽¹⁾ | 44,468 | 44,747 | (0.6)% |
| Rest of world | 13,012 | 9,843 | 32.2% |
| | 58,411 | 56,768 | 2.9% |
| Other | 415 | 478 | (13.2)% |
| | \$ 309,664 | \$ 295,268 | 4.9% |
| Nine Months Ended September 30, | | | |
| | 2017 | 2016 | % Change |
| Cardiac Surgery | | | |
| United States | \$ 129,160 | \$ 133,995 | (3.6)% |
| Europe ⁽¹⁾ | 126,028 | 128,229 | (1.7)% |
| Rest of world | 202,424 | 190,788 | 6.1% |
| | 457,612 | 453,012 | 1.0% |
| Neuromodulation | | | |
| United States | 231,350 | 220,892 | 4.7% |
| Europe ⁽¹⁾ | 25,500 | 24,208 | 5.3% |
| Rest of world | 18,340 | 15,801 | 16.1% |
| | 275,190 | 260,901 | 5.5% |
| Cardiac Rhythm Management | | | |
| United States | 5,605 | 7,471 | (25.0)% |
| Europe ⁽¹⁾ | 142,811 | 149,141 | (4.2)% |
| Rest of world | 33,819 | 31,445 | 7.5% |
| | 182,235 | 188,057 | (3.1)% |
| Other | 1,119 | 1,314 | (14.8)% |
| | \$ 916,156 | \$ 903,284 | 1.4% |

(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'.

The table below illustrates segment income (loss) from operations (in thousands):

| | Three Months Ended September 30, | | % Change |
|---|---|------------------|-----------------|
| | 2017 | 2016 | |
| Cardiac Surgery | \$ 23,807 | \$ 17,791 | 33.8 % |
| Neuromodulation | 45,932 | 47,049 | (2.4)% |
| Cardiac Rhythm Management | 5,427 | (4,598) | 218.0 % |
| Other | (27,947) | (13,525) | (106.6)% |
| Total Reportable Segment's Income from Operations ⁽¹⁾ | \$ 47,219 | \$ 46,717 | 1.1 % |

| | Nine Months Ended September 30, | | % Change |
|---|--|-------------------|-----------------|
| | 2017 | 2016 | |
| Cardiac Surgery | \$ 63,490 | \$ 29,197 | 117.5 % |
| Neuromodulation | 139,357 | 134,871 | 3.3 % |
| Cardiac Rhythm Management | 13,536 | (14,432) | 193.8 % |
| Other | (79,378) | (49,090) | (61.7)% |
| Total Reportable Segment's Income from Operations ⁽¹⁾ | \$ 137,005 | \$ 100,546 | 36.3 % |

(1) For a reconciliation of segment operating income to consolidated operating income refer to "Note 14. Geographic and Segment Information" in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Cardiac Surgery net sales increased by 7.6% and 1.0% for the three and nine months ended September 30, 2017, as compared to the three and nine months ended September 30, 2016, respectively. Net sales increased \$11.3 million for the three months ended September 30, 2017, as compared to the prior-year period due to growth in both cardiopulmonary product revenue and heart valve revenue and favorable foreign currency exchange rate fluctuations. Cardiopulmonary sales increased 7.6%, or \$8.7 million, for the three months ended September 30, 2017, due to strength in heart-lung machines as a result of geographic sales expansion and continued progress towards upgrading customers from older machines to our current S5 device. Heart valve sales increased by 7.7%, or \$2.6 million, for the three months ended September 30, 2017, as compared to the prior-year period due primarily to increased demand for the Perceval sutureless tissue valve in the U.S. and quarter over quarter improvement in Europe, which more than offset declines in mechanical heart valve sales globally. Cardiac Surgery net sales increased \$4.6 million for the nine months ended September 30, 2017, as compared to the nine months ended September 30, 2016, due primarily to growth of \$5.3 million in cardiopulmonary product revenue, partially offset by a decline in heart valve revenues. Year-to-date cardiopulmonary product sales increased over the prior-year period due to heart-lung machine sales expansion outside of the U.S. and Europe. Cardiac Surgery operating income for the three months ended September 30, 2017 increased 33.8% over the prior-year period primarily due to increased operating leverage from the \$11.3 million increase in sales. The 117.5% increase in operating income for the nine months ended September 30, 2017 over the prior-year period was primarily driven by inventory fair value step-up amortization of \$25.2 million that was recognized during the nine months ended September 30, 2016. The inventory fair value step-up was fully amortized by September 30, 2016.

Neuromodulation net sales increased by 1.7% and 5.5% for the three and nine months ended September 30, 2017, as compared to the three and nine months ended September 30, 2016, respectively. The increase in net sales of \$1.5 million for the three months ended September 30, 2017, over the prior-year period was primarily due to increased average selling prices driven by continued AspireSR penetration of the U.S. market, partially offset by a decline in unit sales due to hurricane-related impacts in the U.S. and customer anticipation of the SenTiva system, our new generation VNS Therapy System, which launched in October 2017. The increase in net sales of \$14.3 million for the nine months ended September 30, 2017 over the prior-year period was primarily due to strong new patient sales and price premiums partially offset by hurricane-related impacts in the U.S. and customer anticipation of the SenTiva system. The decrease in Neuromodulation operating income for the three months ended September 30, 2017 as compared to the prior-year period was primarily due to increased selling, general and administrative costs driven by sales force expansion and marketing efforts in the U.S. The increase in Neuromodulation operating income for the nine months ended September 30, 2017 as compared to the prior-year period was primarily driven by increased operating leverage as a result of higher net sales, partially offset by the increased costs associated with sales force expansion and marketing efforts in the U.S.

Cardiac Rhythm Management net sales increased by 2.9% for the three months ended September 30, 2017, as compared to the prior-year period primarily due to favorable foreign currency exchange rate fluctuations. Additionally, growth of the

PLATINIUM Cardiac Resynchronization Therapy devices (CRT-Ds) in Europe and continued demand for KORA 250 pacemakers in Japan were mostly offset by a decrease in Implantable Cardiac Defibrillator (ICD) sales. Cardiac Rhythm Management net sales decreased by 3.1% for the nine months ended September 30, 2017, as compared to the prior-year period. This decline was primarily due to a decrease in ICD sales and reduced sales in the U.S. and Europe, both of which reflect a change in customer preferences. Cardiac Rhythm Management operating income increased \$10.0 million and \$28.0 million for the three and nine months ended September 30, 2017, respectively, as compared to the prior-year periods. The increase for the three months ended September 30, 2017 over the prior-year period was due to cost reductions resulting from prior restructuring actions, improvements in selling, general and administrative costs driven by reductions in the overall sales force and increased net sales. The increase for the nine months ended September 30, 2017 as compared to the prior-year period was driven by inventory fair value step-up amortization of \$10.0 million that was recognized during the nine months ended September 30, 2016, cost reductions resulting from prior restructuring actions and cost reductions associated with a reduction in the overall sales force partially offset by decreased sales during the nine months ended September 30, 2017.

‘Other’ comprises the results from our corporate and new ventures activity. Operating loss from Other increased \$14.4 million for the three months ended September 30, 2017, as compared to the prior-year period, primarily due to \$3.9 million of Caisson related expenses and \$12.9 million in increased Corporate costs. Operating loss from Other increased \$30.3 million for the nine months ended September 30, 2017, as compared to the prior-year period, primarily due to \$17.9 million of increased Caisson-related expenses and increased Corporate costs of \$20.3 million. Increased Corporate costs during the three and nine months ended September 30, 2017 includes \$2.8 million and \$8.3 million in legal costs, respectively, primarily associated with litigation related to our 3T devices and investments in building out global capabilities including international expansion, and project-related expenses.

Cost of Sales and Expenses

The table below illustrates our comparative cost of sales and major expenses as a percentage of sales:

| | Three Months Ended September 30, | | Change |
|-------------------------------------|----------------------------------|-------|--------|
| | 2017 | 2016 | |
| Cost of sales | 35.0% | 36.1% | (1.1)% |
| Product remediation | 0.5% | 0.2% | 0.3 % |
| Gross profit | 64.5% | 63.7% | 0.8 % |
| Operating expenses: | | | |
| Selling, general and administrative | 39.1% | 37.0% | 2.1 % |
| Research and development | 10.1% | 10.9% | (0.8)% |
| Merger and integration expenses | 0.7% | 2.6% | (1.9)% |
| Restructuring expenses | 0.3% | 1.5% | (1.2)% |
| Amortization of intangibles | 4.0% | 4.0% | — % |

| | Nine Months Ended September 30, | | Change |
|-------------------------------------|---------------------------------|-------|--------|
| | 2017 | 2016 | |
| Cost of sales | 34.8% | 39.9% | (5.1)% |
| Product remediation | 0.3% | 0.2% | 0.1 % |
| Gross profit | 64.9% | 59.8% | 5.1 % |
| Operating expenses: | | | |
| Selling, general and administrative | 38.6% | 38.3% | 0.3 % |
| Research and development | 11.4% | 10.4% | 1.0 % |
| Merger and integration expenses | 0.8% | 2.3% | (1.5)% |
| Restructuring expenses | 1.3% | 4.1% | (2.8)% |
| Amortization of intangibles | 3.9% | 3.8% | 0.1 % |

Cost of Sales

Cost of sales consisted primarily of direct labor, allocated manufacturing overhead, the acquisition cost of raw materials and components. Cost of sales as a percentage of net sales decreased by 1.1% to 35.0% and by 5.1% to 34.8% for the three and nine months ended September 30, 2017, respectively, as compared to the prior-year periods. The cost improvement for the three months ended September 30, 2017 reflects management's focus on cost efficiencies to improve gross margin. The cost improvement for the nine months ended September 30, 2017 was primarily due to inventory fair value step-up amortization in the prior year, which accounted for 3.9% of the decrease in our cost of sales as a percentage of net sales, as well as the previously mentioned cost efficiencies. The total amount recognized for amortization of the fair value step-up in inventory for the nine months ended September 30, 2016 was \$35.2 million. The fair value step-up in inventory basis was fully amortized by September 30, 2016.

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

SG&A expenses consisted of sales, marketing, general and administrative activities. SG&A expenses for the three months ended September 30, 2017 increased as a percentage of net sales, by 2.1% to 39.1%, as compared to the prior-year period, and was consistent at 38.6% for the nine months ended September 30, 2017, as compared to the prior-year period. The 2.1% increase was largely attributable to litigation related to our 3T devices and other legal matters.

Research and Development ("R&D") Expenses

R&D expenses consisted of product design and development efforts, clinical trial programs and regulatory activities. R&D expenses, as a percentage of net sales, was consistent for the three months ended September 30, 2017, as compared to the prior-year period, and increased by 1.0% to 11.4% for the nine months ended September 30, 2017, as compared to the prior-year period. The increase is due to the acquisition of Caisson, inclusive of \$5.8 million in post-combination compensation expense recognized concurrent with the acquisition of Caisson, and \$6.4 million in compensation expense associated with the retention of the employees of Caisson.

Merger and Integration Expenses

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.

Merger and integration expenses as a percentage of net sales decreased by 1.9% to 0.7% for the three months ended September 30, 2017 as compared to the prior-year period, and decreased by 1.5% to 0.8% for the nine months ended September 30, 2017 as compared to the prior-year period. These decreases were due to a continued decline in integration activities.

Restructuring Expenses

Restructuring expenses were primarily due to our efforts under our 2015 and 2016 Reorganization Plans and the Suzhou, China exit plan, to leverage economies of scale, eliminate duplicate corporate expenses and streamline distributions, logistics and office functions in order to reduce overall costs. Restructuring expenses as a percentage of net sales decreased by 1.2% to 0.3% and 2.8% to 1.3% for the three and nine months ended September 30, 2017, respectively, as compared to the prior-year periods due to a continued decline in restructuring activities.

Gain on Caisson Acquisition

On May 2, 2017, we acquired the remaining 51% equity interests in Caisson which we previously accounted for under the equity method. On the acquisition date, we remeasured our notes receivable due from Caisson and our existing investment in Caisson at fair value and recognized a pre-tax non-cash gain of \$1.3 million and \$38.1 million, respectively.

Foreign Exchange and Other Gains (Losses)

Foreign exchange and other gains were \$0.5 million and \$1.2 million for the three months ended September 30, 2017 and September 30, 2016, respectively. The gains were primarily due to net foreign currency gains associated with foreign currency commercial transactions, freestanding foreign currency forward contracts, intercompany debt, and third-party financial assets and liabilities. The gains of \$1.0 million for the nine months ended September 30, 2017 included a \$3.2 million gain on a sale of the cost-method investment, Istituto Europeo di Oncologia S.R.L., partially offset by net foreign currency exchange losses of \$2.2 million.

Income Taxes

LivaNova PLC is domiciled and resident in the UK. Our subsidiaries conduct operations and earn income in numerous countries and are subject to the laws of taxing jurisdictions within those countries, and the income tax rates imposed in the tax jurisdictions in which our subsidiaries conduct operations vary. As a result of the changes in the overall level of our income, the deployment of various tax strategies and the changes in tax laws, our consolidated effective income tax rate may vary from one reporting period to another.

During the three and nine months ended September 30, 2017, we recorded consolidated income tax expense of \$1.9 million and \$10.9 million, respectively, with consolidated effective income tax rates of 6.1% and 9.3%, respectively.

Our consolidated effective income tax rate for the three and nine months ended September 30, 2017 included the impact of various discrete tax items including a net \$4.0 million deferred tax benefit due to the release of valuation allowances on tax losses upon the completion of a reorganization of our legal entities in the U.S. and a \$2.1 million tax benefit from the resolution of prior period tax matters. Discrete tax items for the nine months ended September 30, 2017 also included the acquisition of Caisson and the \$38.1 million non-taxable gain recognized to re-measure our existing equity investment in Caisson at fair value on the acquisition date, a \$3.9 million deferred tax benefit associated with certain temporary differences arising from the Mergers and the recognition of a \$3.0 million deferred tax asset related to a reserve for an uncertain tax position recognized in a prior year, in addition to various other discrete items.

During the three and nine months ended September 30, 2016, we recorded consolidated income tax expense of \$9.7 million and \$16.9 million, respectively, with consolidated effective income tax rates of 45.7% and 514.5%, respectively. The effective tax rate for the nine months ended September 30, 2016 was impacted by the recording of valuation allowances of \$23.9 million related to certain tax jurisdictions, including France and the UK, 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 jurisdictions, such as the U.S. and Germany, offset by tax savings from our inter-company financing as part of our 2015 tax restructuring.

Losses from Equity Method Investments

Losses from equity method investments were \$1.6 million and \$20.1 million during the three and nine months ended September 30, 2017, respectively. Losses for the three months ended September 30, 2017 were due to our equity method investee losses, primarily from Highlife and MicroPort. Losses for the nine months ended September 30, 2017 included the impairment of our investment in, and notes receivable from, Highlife of \$13.0 million, which consisted of the investment impairment of \$4.7 million and the notes receivable impairment of \$8.3 million. We recognized losses of \$13.1 million and \$19.4 million during the three and nine months ended September 30, 2016, respectively, primarily due to a \$9.2 million impairment of our investment in Respicardia and losses from our equity method investees.

Liquidity and Capital Resources

Based on our current business plan, we believe that our existing cash and cash equivalents, future cash generated from operations, and available borrowing capacity under our credit facilities 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 7. Financing Arrangements” in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information regarding our debt. Our liquidity could be adversely affected by the factors affecting future operating results, including those referred to in “Part II - Item 1A. Risk Factors” in 2016 Form 10-K.

On June 29, 2017, we entered into a new Finance Contract with the EIB to support financing of certain of our R&D projects. The Finance Contract has a borrowing base of €100 million (or approximately \$118 million) and can be drawn in up to two tranches, each in a minimum amount of €50 million (or approximately \$59 million). Drawdowns must occur by December 30, 2018 and the last repayment date of any tranche will be no earlier than four years and no later than eight years after the disbursement of the relevant tranche. Loans under the Finance Contract are subject to certain covenants and other terms and conditions.

No provision has been made for income taxes on unremitted earnings of our foreign controlled subsidiaries (non-UK subsidiaries) as of September 30, 2017. 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, | |
|--|---------------------------------|-------------|
| | 2017 | 2016 |
| Operating activities | \$ 73,665 | \$ 49,348 |
| Investing activities | (41,797) | (36,363) |
| Financing activities | (10,000) | (62,996) |
| Effect of exchange rate changes on cash and cash equivalents | 3,501 | 1,030 |
| Net increase (decrease) | \$ 25,369 | \$ (48,981) |

Operating Activities

Cash provided by operating activities during the nine months ended September 30, 2017 increased \$24.3 million as compared to the same prior-year period. The increase was primarily the result of an increase in net income of \$119.6 million, offset by a \$43.2 million change in operating assets and liabilities, a \$39.4 million gain recognized in conjunction with the acquisition of Caisson and a \$17.0 million increase in deferred income tax benefit.

Investing Activities

Cash used in investing activities during the nine months ended September 30, 2017 increased \$5.4 million as compared to the same prior-year period. The increase was primarily the result of net cash paid for the acquisition of Caisson of \$14.2 million as well as \$14.1 million received from maturities of short-term investments in the prior-year period, offset by \$7.1 million in purchases of short-term investments in the prior-year period.

Financing Activities

Cash used in financing activities during the nine months ended September 30, 2017 decreased \$53.0 million as compared to the same prior-year period. The decrease was primarily the result of a decrease in net debt repayments of \$27.5 million, a decrease in share repurchases of \$11.1 million and the repayment of trade receivable advances of \$23.8 million in the prior-year period, offset by a reduction in proceeds from stock option exercises of \$4.7 million.

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 this Form 10-Q in "Part I, Note 8", "Part I, Item 2. Management's Discussion and Analysis of Financial Conditions and Results of Operations" and "Part II, Item 1A. Risk Factors", and in our 2016 Form 10-K in "Part II, Item 7A Management's Discussion and Analysis of Financial Condition and Results of Operations." and "Part I, Item 1A. Risk Factors". 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, 2017.

(b) Changes in Internal Control Over Financial Reporting

We deployed a new enterprise resource planning (ERP) software system, SAP, to our U.S. locations during the quarter ended September 30, 2017. In conjunction with the implementation of SAP, we reorganized certain U.S. legal entities were to align with our strategic and operational focus. Our internal controls have been updated to reflect these changes. There have been no other changes in our internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act) during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are 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 9. Commitments and Contingencies” in our condensed 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 Report on Form 10-Q, other Reports on Form 10-Qs 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 2016 Form 10-K and elsewhere as described in this Report on Form 10-Q.

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

On June 23, 2016, the UK held a referendum in which voters approved an exit from the EU, commonly referred to as “Brexit.” On March 29, 2017, the UK Government gave formal notice of its intention to leave the EU, formally commencing the negotiations regarding the terms of withdrawal between the UK and the EU. The withdrawal must occur within two years, unless the deadline is extended or a withdrawal agreement is negotiated sooner. The negotiation process will determine the future terms of the UK’s relationship with the EU. The notification does not change the application of existing tax laws, and does not establish a clear framework for what the ultimate outcome of the negotiations and legislative process will be.

Various tax reliefs and exemptions that apply to transactions between EU Member States under existing tax laws may cease to apply to transactions between the UK and EU Member States when the UK ultimately withdraws from the EU. It is unclear at this stage if or when any new tax treaties between the UK and the EU or individual EU Member States will replace those reliefs and exemptions. It is also unclear at this stage what financial, trade and legal implications the withdrawal of the UK from the EU will have and how Brexit may affect us, our customers, suppliers, vendors, or our industry.

Several of our wholly-owned subsidiaries that are domiciled either in the UK, various EU Member States, or in the United States, and our parent company, LivaNova PLC, are party to intercompany transactions and agreements under which we receive various tax reliefs and exemptions. If certain treaties applicable to our transactions and agreements are not renegotiated or replaced with new treaties containing terms, conditions and attributes similar to those of the existing treaties, the departure of the UK from the EU may have a material adverse impact on our future financial results and results of operations. During the two-year negotiation period, we will monitor and assess the potential impact of this event and explore possible tax-planning strategies that may mitigate or eliminate any such potential adverse impact. We will not account for the impact of Brexit in our income tax provisions until changes in tax laws or treaties between the UK and the EU or individual EU Member States are enacted or the withdrawal becomes effective.

Our acquisition of Caisson may fail to further our strategic objectives or strengthen our existing businesses.

Acquisitions of medical technology companies are inherently risky, and we cannot guarantee that such acquisitions will be successful or will not materially adversely affect our consolidated earnings, financial condition, and/or cash flows. Caisson is in the early stages of clinical development, and therefore, there are risks inherent in the outcome of the clinical studies or regulatory approvals that may impact Caisson’s success. Further, our integration of Caisson’s operations requires significant efforts, including the coordination of information technologies, research and development, operations and finance. These efforts result in additional expenses and significant supervision by management. Our failure to manage and coordinate the growth of Caisson successfully could have an adverse impact on our business. In addition, we cannot be certain that the acquisition will become profitable or remain so. These effects, individually or in the aggregate, could cause a deterioration of our credit rating and result in increased borrowing costs and interest expense.

Item 2. *Unregistered Sales of Equity Securities and Use of Proceeds*

None

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 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 |
|----------------|---|---|---------------------------------|-------------------|
| 3.2 | Articles of Association of LivaNova PLC (as amended), effective June 14, 2017 | LivaNova Plc Current Report on Form 8-K, filed on June 15, 2017 | 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 | | | |
| 101* | Interactive Data Files Pursuant to Rule 405 of Regulation S-T: (i) the Condensed Consolidated Statement of Income (Loss) for the three and nine months ended September 30, 2017 and September 30, 2016, (ii) the Condensed Consolidated Statement of Comprehensive Income for the three and nine months ended September 30, 2017 and September 30, 2016, (iii) the Condensed Consolidated Balance Sheet as of September 30, 2017 and December 31, 2016, (iv) the Condensed Consolidated Statement of Cash Flows for the nine months ended September 30, 2017 and September 30, 2016, and (vi) the Notes to the Condensed Consolidated Financial Statements. | | | |

SIGNATURE

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

LIVANOVA PLC

By: /s/ DAMIEN MCDONALD

Damien McDonald
Chief Executive Officer
(Principal Executive Officer)

LIVANOVA PLC

By: /s/ THAD HUSTON

Thad Huston
Chief Financial Officer
(Principal Financial Officer)

Date: November 2, 2017

CERTIFICATION

I, Damien McDonald, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended September 30, 2017, filed by LivaNova PLC and its consolidated subsidiaries;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2017

/s/ DAMIEN MCDONALD

Damien McDonald

Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION

I, Thad Huston, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended September 30, 2017, filed by LivaNova PLC and its consolidated subsidiaries;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2017

/s/ THAD HUSTON

Thad Huston

Chief Financial Officer

(Principal Financial Officer)

**CERTIFICATION OF THE
CHIEF EXECUTIVE OFFICER AND
CHIEF FINANCIAL OFFICER
OF LIVANOVA PLC
PURSUANT TO 18 U.S.C. SECTION 1350**

Each of Damien McDonald, Chief Executive Officer of LivaNova PLC (the “Company”), and Thad Huston, Chief Financial Officer of the Company, each hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(a) the Quarterly Report on Form 10-Q of the Company and its consolidated subsidiaries for the quarter ended September 30, 2017, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(b) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 2, 2017

/s/ DAMIEN MCDONALD

Damien McDonald
Chief Executive Officer
(Principal Executive Officer)

/s/ THAD HUSTON

Thad Huston
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as a part of this report or on a separate disclosure document.