

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, 2018

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)

(44) (0) 20 3325 0660

Registrant's telephone number, including area code:

98-1268150

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

W2 6LG

(Zip Code)

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 every Interactive Data File required to be submitted 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 such files). Yes No

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

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 at October 25, 2018
48,685,079

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 perfusion systems and products: Inspire[®], Heartlink[®], Connect[™], XTRA[®], S5[®] and Revolution[®]
- 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[®], MEMO 3D[®], MEMO 3D[®] ReChord[™], MEMO 4D[®], MEMO 4D[®] ReChord[™], AnnuloFlo[®], AnnuloFlex[®], Bicarbon Slimline[™], Bicarbon Filtrine[™] and Bicarbon Overline[®].

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

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 of 1933 (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:

- 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;
- competition from providers of alternative medical therapies, such as pharmaceutical companies and providers of cannabis;
- failure to comply with applicable U.S. laws and regulations, including federal and state privacy and security laws and regulations;
- failure to comply with applicable non-U.S. laws 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 and/or changes to existing trade agreements and relationships between the U.S. and other countries;
- 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, 2017 (“2017 Form 10-K”), (3) our reports and registration statements filed and furnished from time to time with the Securities and Exchange Commission (“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, 2018 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 2017 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 generally accepted accounting principles in the United States of America (“U.S.” and such principles, “U.S. GAAP”). The reporting currency of our condensed consolidated financial statements is U.S. dollars.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net sales	\$ 272,082	\$ 251,253	\$ 809,978	\$ 733,921
Cost of sales	94,300	87,752	270,891	251,743
Product remediation	3,434	1,642	8,691	2,573
Gross profit	<u>174,348</u>	<u>161,859</u>	<u>530,396</u>	<u>479,605</u>
Operating expenses:				
Selling, general and administrative	115,136	97,201	342,736	278,805
Research and development	42,417	22,903	108,384	77,122
Merger and integration expenses	12,659	2,010	20,028	7,708
Restructuring expenses	436	1,183	2,793	13,810
Amortization of intangibles	9,457	8,540	28,075	24,616
Total operating expenses	<u>180,105</u>	<u>131,837</u>	<u>502,016</u>	<u>402,061</u>
Operating (loss) income from continuing operations	(5,757)	30,022	28,380	77,544
Interest income	184	199	863	724
Interest expense	(2,633)	(1,421)	(7,750)	(5,314)
Gain on acquisitions	—	—	11,484	39,428
Foreign exchange and other (losses) gains	(727)	527	(1,070)	863
(Loss) income from continuing operations before tax	<u>(8,933)</u>	<u>29,327</u>	<u>31,907</u>	<u>113,245</u>
Income tax (benefit) expense	(2,660)	1,905	203	10,819
Losses from equity method investments	—	(407)	(627)	(16,505)
Net (loss) income from continuing operations	(6,273)	27,015	31,077	85,921
Net (loss) income from discontinued operations	(904)	815	(9,915)	678
Net (loss) income	<u>\$ (7,177)</u>	<u>\$ 27,830</u>	<u>\$ 21,162</u>	<u>\$ 86,599</u>
Basic (loss) income per share:				
Continuing operations	\$ (0.13)	\$ 0.56	\$ 0.64	\$ 1.79
Discontinued operations	(0.02)	0.02	(0.20)	0.01
	<u>\$ (0.15)</u>	<u>\$ 0.58</u>	<u>\$ 0.44</u>	<u>\$ 1.80</u>
Diluted (loss) income per share:				
Continuing operations	\$ (0.13)	\$ 0.56	\$ 0.63	\$ 1.78
Discontinued operations	(0.02)	0.01	(0.20)	0.01
	<u>\$ (0.15)</u>	<u>\$ 0.57</u>	<u>\$ 0.43</u>	<u>\$ 1.79</u>
Shares used in computing basic (loss) income per share	48,637	48,181	48,484	48,130
Shares used in computing diluted (loss) income per share	48,637	48,534	49,427	48,339

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,	
	2018	2017	2018	2017
Net (loss) income	\$ (7,177)	\$ 27,830	\$ 21,162	\$ 86,599
Other comprehensive income (loss):				
Net change in unrealized gains (losses) on derivatives	693	(1,980)	237	(5,923)
Tax effect	(168)	473	(57)	1,756
Net of tax	525	(1,507)	180	(4,167)
Foreign currency translation adjustment, net of tax	1,863	39,106	(45,738)	111,123
Total other comprehensive income (loss)	2,388	37,599	(45,558)	106,956
Total comprehensive (loss) income	<u>\$ (4,789)</u>	<u>\$ 65,429</u>	<u>\$ (24,396)</u>	<u>\$ 193,555</u>

See accompanying notes to the condensed consolidated financial statements

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

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
ASSETS		
<i>Current Assets:</i>		
Cash and cash equivalents	\$ 79,948	\$ 93,615
Accounts receivable, net of allowance of \$9,464 at September 30, 2018 and \$9,418 at December 31, 2017	252,304	282,145
Inventories	153,056	144,470
Prepaid and refundable taxes	50,264	46,274
Assets held for sale	—	13,628
Assets of discontinued operations	—	250,689
Prepaid expenses and other current assets	37,666	39,037
Total Current Assets	<u>573,238</u>	<u>869,858</u>
Property, plant and equipment, net	188,460	192,359
Goodwill	969,277	784,242
Intangible assets, net	784,264	535,397
Investments	24,113	34,492
Deferred tax assets, net	65,808	11,559
Other assets	5,520	75,984
Total Assets	<u>\$ 2,610,680</u>	<u>\$ 2,503,891</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
<i>Current Liabilities:</i>		
Current debt obligations	\$ 48,983	\$ 84,034
Accounts payable	88,883	85,915
Accrued liabilities and other	118,733	78,942
Taxes payable	18,883	12,826
Accrued employee compensation and related benefits	71,585	66,224
Liabilities of discontinued operations	—	78,075
Total Current Liabilities	<u>347,067</u>	<u>406,016</u>
Long-term debt obligations	108,090	61,958
Contingent consideration	164,610	33,973
Deferred income taxes liability	150,142	123,342
Long-term employee compensation and related benefits	30,315	28,177
Other long-term liabilities	25,464	35,111
Total liabilities	<u>825,688</u>	<u>688,577</u>
Commitments and contingencies (Note 11)		
<i>Stockholders' Equity:</i>		
Ordinary Shares, £1.00 par value: unlimited shares authorized; 48,693,535 shares issued and 48,680,054 shares outstanding at September 30, 2018; 48,290,276 shares issued and 48,287,346 shares outstanding at December 31, 2017	75,311	74,750
Additional paid-in capital	1,750,886	1,735,048
Accumulated other comprehensive (loss) income	(245)	45,313
Accumulated deficit	(40,932)	(39,664)
Treasury stock at cost, 13,481 shares at September 30, 2018 and 2,930 shares at December 31, 2017	(28)	(133)
Total Stockholders' Equity	<u>1,784,992</u>	<u>1,815,314</u>
Total Liabilities and Stockholders' Equity	<u>\$ 2,610,680</u>	<u>\$ 2,503,891</u>

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,	
	2018	2017
Operating Activities:		
Net income	\$ 21,162	\$ 86,599
Non-cash items included in net income:		
Depreciation	24,979	27,880
Amortization	28,052	35,445
Stock-based compensation	21,387	14,252
Deferred income tax benefit	(13,488)	(27,270)
Losses from equity method investments	1,838	20,072
Gain on acquisitions	(11,484)	(39,428)
Impairment of property, plant and equipment	517	4,581
Amortization of income taxes payable on inter-company transfers of property	4,155	23,831
Other	(1,902)	3,373
Changes in operating assets and liabilities:		
Accounts receivable, net	30,506	(19,107)
Inventories	(7,622)	(11,006)
Other current and non-current assets	(16,757)	(17,846)
Accounts payable and accrued current and non-current liabilities	17,888	(14,958)
Restructuring reserve	368	(12,753)
Net cash provided by operating activities	99,599	73,665
Investing Activities:		
Acquisitions, net of cash acquired	(279,863)	(14,194)
Purchases of property, plant and equipment and other	(25,099)	(24,004)
Proceeds from the sale of CRM business franchise	186,682	—
Proceeds from asset sales	13,872	5,346
Proceeds from sale of investment	—	3,192
Loans to investees	—	(6,928)
Purchases of investments	(3,000)	(5,209)
Net cash used in investing activities	(107,408)	(41,797)
Financing Activities:		
Change in short-term borrowing, net	(31,281)	(18,054)
Proceeds from short-term borrowing (maturities greater than 90 days)	240,000	20,000
Repayment of short-term borrowing (maturities greater than 90 days)	(240,000)	—
Proceeds from long-term debt obligations	60,000	—
Repayment of long-term debt obligations	(12,290)	(11,615)
Proceeds from exercise of stock options	4,177	3,221
Payment of deferred consideration - acquisition of Caisson Interventional, LLC	(14,073)	—
Shares repurchased from employees for minimum tax withholding	(8,559)	(2,391)
Other	(884)	(1,161)
Net cash used in financing activities	(2,910)	(10,000)
Effect of exchange rate changes on cash and cash equivalents	(2,948)	3,501
Net (decrease) increase in cash and cash equivalents	(13,667)	25,369
Cash and cash equivalents at beginning of period	93,615	39,789
Cash and cash equivalents at end of period	\$ 79,948	\$ 65,158

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, 2018 and September 30, 2017, have been prepared in accordance with 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, 2017 has been derived from audited financial statements contained in our 2017 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 only normal recurring adjustments) considered necessary for a fair statement of the operating results of LivaNova and its subsidiaries, for the three and nine months ended September 30, 2018 and are not necessarily indicative of the results that may be expected for the year ending December 31, 2018. The financial information presented herein should be read in conjunction with the audited consolidated financial statements and notes thereto accompanying our 2017 Form 10-K.

Sale of our Cardiac Rhythm Management Business Franchise

We completed the sale of our Cardiac Rhythm Management (“CRM”) business franchise to MicroPort Cardiac Rhythm B.V. and MicroPort Scientific Corporation (the “CRM Sale”) on April 30, 2018 for total cash proceeds of \$195.9 million, less cash transferred of \$9.2 million, subject to a closing working capital adjustment. In conjunction with the CRM Sale, we entered into transition services agreements to provide certain support services for generally up to twelve months from the closing date of the sale. We previously concluded that the sale of CRM represents a strategic shift in our business that will have a major effect on future operations and financial results. Accordingly, the operating results of CRM are classified as discontinued operations in our condensed consolidated statements of income. The assets and liabilities of CRM are presented as assets or liabilities of discontinued operations in the condensed consolidated balance sheet at December 31, 2017.

Reclassification of Prior-Period Comparative Presentation

We have reclassified certain prior period amounts for comparative purposes. These reclassifications did not have a material effect on our financial condition, results of operations or cash flows.

We reclassified \$34.0 million to contingent consideration from other long-term liabilities at December 31, 2017 to conform to the presentation on the condensed consolidated balance sheet at September 30, 2018.

We have reclassified certain amounts reported in “Note 4. Discontinued Operations” for the nine months ended September 30, 2018. These corrections had no net impact to our previously reported net loss from discontinued operations for the three and six months ended June 30, 2018.

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 2017 Form 10-K.

On January 1, 2018, we adopted ASC Update (“ASU”) No 2014-09, Revenue from Contracts with Customers. Refer to “Note 2. Revenue Recognition.” We elected the cumulative effect transition method; however, we recognized no cumulative effect to the opening balance of retained earnings because the impact on the timing of when revenue is recognized within our Cardiovascular segment (formerly Cardiac Surgery), specifically related to heart-lung machines and preventative maintenance contracts on cardiopulmonary equipment, was insignificant. The timing of revenue recognition for products and related revenue streams within our Neuromodulation segment and discontinued operations did not change.

Note 2. Revenue Recognition

We generate our revenue through contracts with customers that primarily consist of hospitals, healthcare institutions, distributors and other organizations. Revenue is measured based on consideration specified in a contract with a customer, and excludes amounts collected on behalf of third parties. We measure the consideration based upon the estimated amount to be received. The amount of consideration we ultimately receive varies depending upon the return terms, sales rebates, discounts, and other incentives that we may offer, which are accounted for as variable consideration when estimating the amount of revenue to recognize. The estimate of variable consideration requires significant judgment.

We have historically experienced a low rate of product returns and the total dollar value of product returns has not been significant to our financial statements.

We recognize revenue when a performance obligation is satisfied by transferring the control of a product or providing service to a customer. Some of our contracts include the purchase of multiple products and/or services. In such cases, we allocate the transaction price based upon the relative estimated stand-alone price of each product and/or service sold. We record state and local sales taxes net; that is, we exclude sales tax from revenue. Typically, our contracts do not have a significant financing component.

We incur incremental commission fees paid to the sales force associated with the sale of products. We apply the practical expedient within ASC 606-10-50-22 and have elected to recognize the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset the entity would otherwise recognize is one year or less. As a result, no commissions are capitalized as contract costs at September 30, 2018.

The following is a description of the principal activities (separated by reportable segments) from which we generate our revenue. For more detailed information about our reportable segments including disaggregated revenue results by major product line and primary geographic markets, see "Note 16. Geographic and Segment Information."

Cardiovascular Products and Services

The Cardiovascular ("CV") segment has three primary product lines: cardiopulmonary products, heart valves and advanced circulatory support.

Cardiopulmonary products include oxygenators, heart-lung machines, autotransfusion systems, perfusion tubing systems, cannulae and other related accessories. Heart valves include mechanical heart valves, tissue heart valves and related repair products. Advanced circulatory support, which represents our recently acquired TandemLife business, includes temporary life support product kits that can include a combination of pumps, oxygenators, and cannulae.

Cardiopulmonary products may include performance obligations associated with assembly and installation of equipment. Accordingly, we allocate a portion of the sales prices to installation obligations and recognize that revenue when the service is provided. We recognize revenue for equipment and accessory product sales when control of the equipment or product passes to the customer.

Heart valve revenue is recognized when control passes to the customer, usually at the point of surgery.

Advanced circulatory support revenue is recognized when control passes to the customer, usually at the point of shipment.

Technical services include installation, repair and maintenance of cardiopulmonary equipment under service contracts or upon customer request. Technical service agreements generally provide for upfront payments in advance of rendering services or periodic billing over the contract term. Amounts billed in advance are deferred and recognized as revenue when the performance obligation is satisfied. Technical services are not a significant component of CV revenue and have been presented with the related equipment and accessories revenue.

Neuromodulation Products

The Neuromodulation ("NM") segment generates its revenue from the sale of neuromodulation therapy systems for the treatment of drug-resistant epilepsy, treatment-resistant depression and obstructive sleep apnea. The NM product line includes the VNS Therapy System, which consists of an implantable pulse generator, a lead that connects the generator to the vagus nerve, and other accessories. The NM product line also includes an implantable device for the treatment of obstructive sleep apnea that stimulates multiple tongue muscles via the hypoglossal nerve, which opens the airway while a patient is sleeping. We recognize revenue for NM product sales when control passes to the customer.

Contract Balances

Due to the nature of our products and services, revenue producing activities may result in contract assets and contract liabilities which are insignificant to our financial position and results of operations. These activities relate primarily to CV technical services contracts for short-term and multi-year service agreements. Contract assets are primarily comprised of unbilled revenues, which occur when a performance obligation has been completed, but not billed to the customer. Contract liabilities are made up of deferred revenue, which occurs when a customer pays for a service, before a performance obligation has been completed. Contract assets are included within "Prepaid expenses and other current assets" in the condensed consolidated balance sheets and were insignificant at September 30, 2018 and December 31, 2017. As of September 30, 2018 and December 31, 2017, contract liabilities of \$5.2 million and \$3.8 million, respectively, are included within "Accrued liabilities and other" and "Other long-term liabilities" in the condensed consolidated balance sheets.

Note 3. Business Combinations

Caisson Interventional, LLC

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 paid during the second quarter of 2018, 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 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 for the treatment of mitral valve regurgitation. The purchase price allocation was finalized during the second quarter of 2018 and there were no adjustments to the preliminary purchase price allocation during the measurement period.

We performed a quantitative impairment assessment, as of April 1, 2018, for the goodwill and in-process research and development assets arising from the Caisson acquisition. Based upon the assessment performed, we determined that the goodwill and the in-process research and development assets were not impaired. The quantitative impairment assessment was performed using management’s current estimate of future cash flows which are based on the expected timing of future regulatory approvals. A delay in the anticipated timing of these regulatory approvals or a change in management’s estimates could result in a fair value of the in-process research and development that is below its carrying amount. We will continue to monitor any changes in circumstances for indicators of impairment.

ImThera Medical, Inc.

On January 16, 2018, we acquired the remaining 86% outstanding interest in ImThera Medical, Inc. (“ImThera”) for cash consideration of up to \$225 million. Cash in the amount of \$78.3 million was paid at closing with the balance to be paid based on achievement of a certain regulatory milestone and a sales-based earnout.

ImThera manufactures an implantable device for the treatment of obstructive sleep apnea that stimulates multiple tongue muscles via the hypoglossal nerve, which opens the airway while a patient is sleeping. ImThera has a commercial presence in the European market, and an FDA pivotal study is ongoing in the U.S.

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

Cash	\$	78,332
Contingent consideration		112,744
Fair value of our interest in ImThera prior to the acquisition ⁽¹⁾		25,580
Fair value of consideration transferred	\$	<u>216,656</u>

- (1) The fair value of our previously-held interest in ImThera was determined based on the fair value of total consideration transferred and application of a discount for lack of control. As a result, we recognized a gain of \$11.5 million for the fair value in excess of our carrying value of \$14.1 million. The gain is reflected as “Gain on acquisitions” on our condensed consolidated statement of income for the nine months ended September 30, 2018.

The following table presents the purchase price allocation at fair value for the ImThera acquisition including certain measurement period adjustments (in thousands):

	Initial Purchase Price Allocation	Measurement Period Adjustments ⁽¹⁾	Adjusted Purchase Price Allocation
In-process research and development ⁽²⁾	\$ 151,605	\$ 10,677	\$ 162,282
Developed technology	5,661	(5,661)	—
Goodwill	87,063	(4,467)	82,596
Deferred income tax liabilities, net ⁽³⁾	(27,980)	(1,278)	(29,258)
Other assets and liabilities, net	836	200	1,036
Net assets acquired	<u>\$ 217,185</u>	<u>\$ (529)</u>	<u>\$ 216,656</u>

- (1) During the second quarter of 2018, measurement period adjustments were recorded based upon new information obtained about facts and circumstances that existed as of the acquisition date.
- (2) The fair value of in-process research and development ("IPR&D") was determined using the income approach, which is a valuation technique that provides a fair value estimate based on the market participant expectations of cash flows the asset would generate. The cash flows were discounted commensurate with the level of risk associated with the asset. The discount rates were developed after assigning a probability of success to achieving the projected cash flows based on the current stage of development, inherent uncertainty in reaching certain regulatory milestones and risks associated with commercialization of the product. The IPR&D amount is included in "Intangible assets, net" in the condensed consolidated balance sheet at September 30, 2018.
- (3) The amounts are presented net of deferred tax assets acquired.

Goodwill arising from the ImThera acquisition, which is not deductible for tax purposes, primarily represents the synergies anticipated between ImThera and our existing neuromodulation business. The assets acquired, including goodwill, are recognized in our Neuromodulation segment.

During the second quarter of 2018, we determined that developments in the ImThera clinical trial will result in a minimum 12-month delay of regulatory approval. This delay constituted a triggering event that required evaluation of the in-process research and development asset for impairment. Based on the quantitative impairment evaluation, the in-process research and development asset was not impaired; however, a further delay or a change in management's estimates could result in a fair value that is below the carrying amount for such an asset. We will continue to monitor any changes in circumstances for indicators of impairment.

The results of the ImThera acquisition added \$0.1 million and \$0.3 million in revenue and \$2.9 million and \$6.5 million in operating losses during the three and nine months ended September 30, 2018, respectively. Additionally, we recognized ImThera acquisition-related expenses of approximately \$0.1 million and \$0.4 million for legal and valuation expenses during the three and nine months ended September 30, 2018, respectively. These expenses are included within "Selling, general and administrative" expenses in the condensed consolidated statements of income. Pro forma financial information assuming the ImThera acquisition had occurred as of the beginning of the calendar year prior to the year of acquisition was not material for disclosure purposes.

The ImThera business combination involved contingent consideration arrangements composed of potential cash payments upon the achievement of a certain regulatory milestone 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 plan. Both arrangements are Level 3 fair value measurements and include the following significant unobservable inputs (in thousands):

ImThera Acquisition	Fair value at January 16, 2018	Valuation Technique	Unobservable Input	Ranges
Regulatory milestone-based payment	\$ 50,429	Discounted cash flow	Discount rate	4.3% - 4.7%
			Probability of payment	85% - 95%
			Projected payment years	2020 - 2021
Sales-based earnout	62,315	Monte Carlo simulation	Risk-adjusted discount rate	11.5%
			Credit risk discount rate	4.7% - 5.8%
			Revenue volatility	29.3%
			Probability of payment	85% - 95%
			Projected years of earnout	2020 - 2025
	<u>\$ 112,744</u>			

TandemLife

On April 4, 2018, we acquired CardiacAssist, Inc., doing business as TandemLife ("TandemLife") for cash consideration of up to \$254 million. Cash of \$204 million was paid at closing with up to \$50 million in contingent consideration based on achieving regulatory milestones. TandemLife, headquartered in Pittsburgh, Pennsylvania, is focused on the delivery of leading-edge temporary life support systems, including cardiopulmonary and respiratory support solutions. TandemLife complements our Cardiovascular portfolio, and expands our existing line of cardiopulmonary products.

The following table presents the acquisition date fair value of the consideration transferred (in thousands):

Cash	\$ 203,671
Contingent consideration	40,190
Fair value of consideration transferred	<u>\$ 243,861</u>

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

	Initial Purchase Price Allocation	Measurement Period Adjustments ⁽¹⁾	Adjusted Purchase Price Allocation
In-process research and development ⁽²⁾⁽³⁾	\$ 110,977	\$ (3,474)	\$ 107,503
Trade names ⁽²⁾	11,539		11,539
Developed technology ⁽²⁾	6,387		6,387
Goodwill	118,917	2,771	121,688
Inventory	10,296	(140)	10,156
Other assets and liabilities, net	3,632		3,632
Deferred income tax liabilities, net ⁽⁴⁾	(17,887)	843	(17,044)
Net assets acquired	<u>\$ 243,861</u>	<u>\$ —</u>	<u>\$ 243,861</u>

- (1) During the third quarter of 2018, measurement period adjustments were recorded based upon new information regarding future estimates of R&D expenses that existed as of the acquisition date.
- (2) The amounts are included in "Intangible assets, net" in the condensed consolidated balance sheet at September 30, 2018. Trade names and developed technology are amortized over remaining useful lives of 15 and 2 years, respectively.
- (3) The fair value of in-process research and development ("IPR&D") was determined using the income approach, which is a valuation technique that provides a fair value estimate based on the market participant expectations of cash flows the asset would generate. The cash flows were discounted commensurate with the level of risk associated with the asset. The discount rates were developed after assigning a probability of success to achieving the projected cash flows based on the current

stage of development, inherent uncertainty in reaching certain regulatory milestones and risks associated with commercialization of the product.

(4) The amounts include a provisional estimate for deferred tax assets acquired.

Goodwill arising from the TandemLife acquisition, which is not deductible for tax purposes, primarily represents the synergies anticipated between TandemLife and our existing cardiovascular business. The assets acquired, including goodwill, are recognized in our Cardiovascular segment.

The results of the TandemLife acquisition added \$6.1 million and \$12.1 million in revenue and \$6.0 million and \$12.1 million in operating losses during the three and nine months ended September 30, 2018, respectively. Additionally, we recognized TandemLife acquisition-related expenses of approximately \$0.4 million and \$2.2 million for legal and valuation expenses during the three and nine months ended September 30, 2018, respectively. These expenses are included within "Selling, general and administrative" expenses in the condensed consolidated statements of income. Pro forma financial information assuming the TandemLife acquisition had occurred as of the beginning of the calendar year prior to the year of acquisition was not material for disclosure purposes.

The TandemLife business combination involved a contingent consideration arrangement composed of potential cash payments upon the achievement of certain regulatory milestones. The arrangement is a Level 3 fair value measurement and includes the following significant unobservable inputs (in thousands):

TandemLife Acquisition	Fair value at April 4, 2018	Valuation Technique	Unobservable Input	Ranges
Regulatory milestone-based payments	\$ 40,190	Discounted cash flow	Discount rate	4.2% - 4.8%
			Probability of payments	75% - 95%
			Projected payment years	2019 - 2020

Note 4. Discontinued Operations

In November 2017, we concluded that the sale of CRM represented a strategic shift in our business that would have a major effect on future operations and financial results. Accordingly, the operating results of CRM are classified as discontinued operations in our condensed consolidated statements of income for all the periods presented in this Quarterly Report on Form 10-Q. The assets and liabilities of CRM are presented as assets or liabilities of discontinued operations in the condensed consolidated balance sheets at December 31, 2017.

We completed the CRM Sale on April 30, 2018 for total cash proceeds of \$195.9 million, less cash transferred of \$9.2 million, subject to a closing working capital adjustment. In conjunction with the sale, we entered into transition services agreements to provide certain support services for generally up to twelve months from the closing date of the sale. The services include, among others, accounting, information technology, human resources, quality assurance, regulatory affairs, supply chain, clinical affairs and customer support. During the three and nine months ended September 30, 2018, we recognized income of \$1.1 million and \$2.0 million, respectively, for providing these services. Income recognized related to the transition services agreements is recorded as a reduction to the related expenses in the associated expense line items in the condensed consolidated statements of income.

The following table represents assets and liabilities of CRM presented as assets and liabilities of discontinued operations in the condensed consolidated balance sheet:

	December 31, 2017
Accounts receivable, net	\$ 64,684
Inventories	54,097
Prepaid taxes	14,725
Prepaid and other assets	3,498
Property, plant and equipment, net	12,104
Deferred tax assets, net	2,517
Investments	6,098
Intangible assets, net	92,966
Assets of discontinued operations	<u>\$ 250,689</u>
Accounts payable	26,501
Accrued liabilities and other	7,669
Taxes payable	5,084
Accrued employee compensation and benefits	30,753
Deferred income taxes liability	8,068
Liabilities of discontinued operations	<u>\$ 78,075</u>

The following table represents the financial results of CRM presented as net (loss) income from discontinued operations in the condensed consolidated statements of income:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018 ⁽¹⁾	2017
Revenues	\$ —	\$ 58,411	\$ 77,366	\$ 182,235
Cost of sales	—	20,493	27,306	66,778
Gross profit	—	37,918	50,060	115,457
Selling, general and administrative expenses	543	24,000	43,441	74,997
Research and development	—	8,502	16,577	26,879
Merger and integration expenses	—	3	—	35
Restructuring expenses	—	(391)	651	(1,750)
Amortization of intangibles	—	3,810	—	10,829
Revaluation gain on assets and liabilities held for sale	—	—	(1,213)	—
Loss on sale of CRM	—	—	214	—
Total operating expenses	543	35,924	59,670	110,990
Operating (loss) income from discontinued operations	(543)	1,994	(9,610)	4,467
Foreign exchange and other gains (losses)	—	12	102	(160)
(Loss) income from discontinued operations, before tax	(543)	2,006	(9,508)	4,307
Income tax expense (benefit)	361	8	(804)	62
Losses from equity method investments	—	(1,183)	(1,211)	(3,567)
Net (loss) income from discontinued operations	<u>\$ (904)</u>	<u>\$ 815</u>	<u>\$ (9,915)</u>	<u>\$ 678</u>

(1) CRM financial results for the nine months ended September 30, 2018 include operating activities through the close of the sale on April 30, 2018.

Cash flows attributable to our discontinued operations are included in our condensed consolidated statements of cash flows. For the nine months ended September 30, 2018 and 2017, CRM capital expenditures were \$0.9 million and \$4.3 million, respectively and stock-based compensation expense was \$2.1 million and \$0.6 million, respectively. For the nine months ended September 30, 2017 CRM depreciation and amortization was \$15.4 million.

Note 5. Restructuring

Our 2015 and 2016 Reorganization Plans (the “Plans”) were initiated October 2015 and March 2016, respectively, in conjunction with the completion of the merger of Cyberonics, Inc. and Sorin S.p.A. in October 2015. 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 are reported as ‘Restructuring expenses’ in our operating results in the condensed consolidated statements of income.

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. The land, building and equipment were recorded as Assets held for sale on the condensed consolidated balance sheet as of December 31, 2017. We completed the sale of the Suzhou facility in April 2018 and received cash proceeds from the sale of \$13.3 million.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cardiovascular ⁽¹⁾	\$ 354	\$ 441	\$ 2,093	\$ 6,944
Neuromodulation	17	(32)	34	407
Other	65	774	666	6,459
Restructuring expense from continuing operations	\$ 436	\$ 1,183	\$ 2,793	\$ 13,810

(1) Cardiovascular restructuring expense for the nine months ended September 30, 2017 included building and equipment impairment and additional costs of \$5.1 million related to the Suzhou, China facility exit plan.

Note 6. Product Remediation Liability

On December 29, 2015, we received an FDA Warning Letter (the “Warning Letter”) alleging certain violations of FDA regulations applicable to medical device manufacturing at our Munich, Germany and Arvada, Colorado facilities. On October 13, 2016, the Centers for Disease Control and Prevention (“CDC”) and FDA separately released safety notifications regarding 3T Heater-Cooler devices in response to which we issued a Field Safety Notice Update for U.S. users of our 3T Heater-Cooler devices to proactively and voluntarily contact facilities to facilitate implementation of the CDC and FDA recommendations.

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. 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. 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. 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.

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 canister and internal sealing upgrade on a customer-owned device. We are currently implementing the vacuum canister and internal sealing upgrade program in as many countries as possible until all devices are upgraded. On October 11, 2018, after review of information provided by LivaNova, the FDA concluded that LivaNova could commence the vacuum canister and internal sealing upgrade program in the U.S.

As part of the remediation plan, we continue to offer a no-charge deep disinfection service (deep cleaning service) for 3T device users as we receive the required regulatory approvals. On April 12, 2018, the FDA agreed to allow us to move forward

with the deep cleaning service in the U.S., adding to the growing list of countries around the world in which we offer this service. 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, 2017	\$	27,546
Remediation activity		(9,442)
Effect of changes in foreign currency exchange rates		(157)
Balance at September 30, 2018 ⁽¹⁾	\$	<u>17,947</u>

- (1) At September 30, 2018, the product remediation liability balance is included within 'Accrued liabilities and other' and 'Other long-term liabilities' in the condensed consolidated balance sheet.

We recognized product remediation expenses during the three and nine months ended September 30, 2018, of \$3.4 million and \$8.7 million, respectively, and \$1.6 million and \$2.6 million during the three and nine months ended September 30, 2017, respectively. Product remediation expenses include internal labor costs, costs to remediate certain inspectional observations made by the FDA at our Munich facility and costs associated with the incorporation of the modification of the 3T device design into the next generation 3T device. These costs are expensed as incurred and are not included within the product remediation liability presented above.

For further information, please refer to "Note 11. Commitments and Contingencies." At this stage, we have recognized no liability with respect to any claims related to the 3T device and our related legal costs are expensed as incurred.

Note 7. Investments

The following table details the carrying value of our investment in equity securities of non-consolidated affiliates without readily determinable fair values and are reported at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. These equity positions in privately-held companies are included in "Investments" in the condensed consolidated balance sheets (in thousands):

	September 30, 2018	December 31, 2017
Respicardia Inc. ⁽¹⁾	\$ 17,706	\$ 17,422
Ceribell, Inc. ⁽²⁾	3,000	—
ImThera Medical, Inc. ⁽³⁾	—	12,900
Rainbow Medical Ltd. ⁽⁴⁾	1,134	1,172
MD Start II ⁽⁵⁾	1,158	1,199
Highlife S.A.S. ⁽⁶⁾	1,098	—
Other	17	17
	<u>\$ 24,113</u>	<u>\$ 32,710</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 by transvenously stimulating the phrenic nerve. We have a loan outstanding to Respicardia with a carrying amount of \$0.6 million, as of September 30, 2018, which is included in "Prepaid expenses and other current assets" in the condensed consolidated balance sheet.
- (2) On September 7, 2018, we acquired 1,007,319 shares of Series B Preferred Stock of Ceribell, Inc. ("Ceribell"). Ceribell is focused on utilizing electroencephalography to improve the diagnosis and treatment of patients at risk for seizures.
- (3) On January 16, 2018, we acquired the remaining outstanding interests in ImThera. Refer to "Note 3. Business Combinations."
- (4) 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.
- (5) MD Start II is a private venture capital collaboration for the development of medical device technology in Europe.
- (6) Due to an additional investment by a third party during the nine months ended September 30, 2018, our equity interest in Highlife S.A.S. ("Highlife") decreased to 17.5% from 24.6%. We determined that we no longer had significant influence over Highlife and, as a result, we began to measure Highlife at cost minus impairment, if any, plus or minus changes resulting from observable price

changes in orderly transactions for the identical or similar investment of the same issuer. At December 31, 2017, we accounted for Highlife under the equity method and the carrying value was \$1.8 million.

Note 8. Fair Value Measurements

We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy. There were no transfers between Level 1, Level 2, or Level 3 during the nine months ended September 30, 2018.

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 September 30, 2018	Fair Value Measurements Using Inputs Considered as:		
		Level 1	Level 2	Level 3
Assets:				
Derivative assets - freestanding instruments (foreign currency exchange rate "FX")	\$ 3,309	\$ —	\$ 3,309	\$ —
	<u>\$ 3,309</u>	<u>\$ —</u>	<u>\$ 3,309</u>	<u>\$ —</u>
Liabilities:				
Derivative liabilities - designated as cash flow hedges FX	\$ 1,084	\$ —	\$ 1,084	\$ —
Derivative liabilities - designated as cash flow hedges (interest rate swaps)	996	—	996	—
Derivative liabilities - freestanding instruments FX	224	—	224	—
Contingent consideration ⁽¹⁾	183,012	—	—	183,012
	<u>\$ 185,316</u>	<u>\$ —</u>	<u>\$ 2,304</u>	<u>\$ 183,012</u>

	Fair Value as of December 31, 2017	Fair Value Measurements Using Inputs Considered as:		
		Level 1	Level 2	Level 3
Assets:				
Derivative assets - freestanding instruments (FX)	\$ 519	\$ —	\$ 519	\$ —
	<u>\$ 519</u>	<u>\$ —</u>	<u>\$ 519</u>	<u>\$ —</u>
Liabilities:				
Derivative liabilities - designated as cash flow hedges (FX)	\$ 460	\$ —	\$ 460	\$ —
Derivative liabilities - designated as cash flow hedges (interest rate swaps)	1,585	—	1,585	—
Contingent consideration ⁽¹⁾	33,973	—	—	33,973
	<u>\$ 36,018</u>	<u>\$ —</u>	<u>\$ 2,045</u>	<u>\$ 33,973</u>

(1) The contingent consideration liability represents contingent payments related to five completed acquisitions: Cellplex PTY Ltd., Inversiones Drilltex SAS, Caisson, ImThera and TandemLife. See the table below for additional information.

Our recurring fair value measurements, using significant unobservable inputs (Level 3), relate solely to our contingent consideration liability. The following table provides a reconciliation of the beginning and ending balance of the contingent consideration liability (in thousands):

Total contingent consideration liability at December 31, 2017	\$	33,973
Purchase price - ImThera contingent consideration		112,744
Purchase price - TandemLife contingent consideration		40,190
Payments		(2,661)
Changes in fair value ⁽¹⁾		(1,258)
Effect of changes in foreign currency exchange rates		24
Total contingent consideration liability at September 30, 2018		183,012
Less current portion of contingent consideration liability at September 30, 2018		18,402
Long-term portion of contingent consideration liability at September 30, 2018	\$	164,610

- (1) Includes a decrease of \$3.8 million and \$2.3 million recorded to cost of sales and R&D expenses, respectively, recognized during the second quarter of 2018 due to the delay in the timing of anticipated regulatory approval for ImThera. See “Note 3. Business Combinations” for additional discussion.

Note 9. Financing Arrangements

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

	September 30, 2018	December 31, 2017	Maturity	Interest Rate
2017 European Investment Bank ⁽¹⁾	\$ 60,000	\$ —	June 2026	3.35%
2014 European Investment Bank ⁽²⁾	57,903	69,893	June 2021	0.97%
Mediocredito Italiano ⁽³⁾	8,383	9,118	December 2023	0.50% - 3.10%
Banca del Mezzogiorno ⁽⁴⁾	4,118	5,499	December 2019	0.50% - 3.15%
Region Wallonne	752	845	December 2023 and June 2033	0.00% - 2.45%
Mediocredito Italiano - mortgages and other	512	997	September 2021 and September 2026	0.80% - 1.30%
Bpifrance (ex-Oséo)	—	1,450	—	2.58%
Total long-term facilities	131,668	87,802		
Less current portion of long-term debt	23,578	25,844		
Total long-term debt	\$ 108,090	\$ 61,958		

- (1) The 2017 European Investment Bank (“2017 EIB”) loan was obtained to support certain product development projects. The interest rate for the 2017 EIB loan is reset by the lender each principal payment date based on LIBOR. Interest payments are paid quarterly and principal payments are paid semi-annually. On July 30, 2018, we borrowed \$60.0 million under the 2017 EIB loan.
- (2) The 2014 European Investment Bank (“2014 EIB”) loan was obtained in July 2014 to support certain product development projects. The interest rate for the 2014 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.
- (3) We obtained the Mediocredito Italiano Bank loan in July 2016 as part of the Fondo Innovazione Tecnologica program implemented by the Italian Ministry of Education.
- (4) 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.

Revolving Credit

The outstanding principal amount of our short-term unsecured revolving credit agreements and other agreements with various banks was \$25.4 million and \$58.2 million, at September 30, 2018 and December 31, 2017, respectively, with interest rates ranging from 0.5% to 9.3% and loan terms ranging from 30 days to 180 days.

On April 10, 2018, we entered into an amendment and restatement agreement with Barclays Bank PLC amending the revolving facility agreement originally dated October 21, 2016 (the “Amendment”). The Amendment increases the borrowing capacity under the facility from \$40.0 million to \$70.0 million and extends the term of the facility one year, terminating October 20, 2019. Borrowings under the facility bear interest at a rate of LIBOR plus 0.85%.

In connection with the CRM sale, on May 1, 2018, the borrowing capacity of the 2017 EIB loan decreased from €100.0 million (approximately \$115.8 million as of September 30, 2018) to €90.0 million (approximately \$104.2 million as of September 30, 2018).

Bridge Facility Agreement

In connection with the April 2018 acquisition of TandemLife, LivaNova entered into a bridge facility agreement (the “Bridge Facility Agreement”) providing a term loan facility with the aggregate principal amount of \$190.0 million. On April 3, 2018, we borrowed \$190.0 million under the Bridge Facility Agreement to facilitate the initial payment for our acquisition of TandemLife. We used the proceeds from the sale of the CRM business franchise to repay the borrowings under the Bridge Facility Agreement in full during the second quarter of 2018.

Note 10. 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 accumulated other comprehensive income (“AOCI”) until the hedged item is recognized in earnings upon settlement/termination. FX derivative gains and losses in AOCI are reclassified to the condensed consolidated statements of income as shown in the tables below and interest rate swap gains and losses in AOCI are reclassified to interest expense in the condensed consolidated statements of income. 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 FX derivative contracts, not designated as hedging instruments, outstanding at September 30, 2018 and December 31, 2017 was \$229.3 million and \$231.9 million, respectively. These derivative contracts are designed to offset the FX effects in earnings of various intercompany loans, our 2014 EIB loan, and trade receivables. We recorded net gains for these freestanding derivatives of \$5.6 million for the three months ended September 30, 2018, a loss of \$0.7 million for the three months ended September 30, 2017 and net losses of \$6.0 million and \$7.9 million for the nine months ended September 30, 2018 and September 30, 2017, respectively. The net gains and losses are included in “Foreign exchange and other (losses) gains” in the condensed consolidated statements of income.

Cash Flow Hedges

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

Description of Derivative Contract	September 30, 2018	December 31, 2017
FX derivative contracts to be exchanged for British Pounds	\$ 8,256	\$ 16,847
FX derivative contracts to be exchanged for Japanese Yen	13,712	32,302
FX derivative contracts to be exchanged for Canadian Dollars	14,053	16,494
FX derivative contracts to be exchanged for Euros	28,657	—
Interest rate swap contracts	46,322	55,965
	<u>\$ 111,000</u>	<u>\$ 121,608</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 twelve months (in thousands):

Description of Derivative Contract	After-tax net loss in AOCI as of September 30, 2018	Amount Expected to be Reclassified to Earnings in Next 12 Months
FX derivative contracts	\$ (601)	\$ (601)
Interest rate swap contracts	(139)	(51)
	<u>\$ (740)</u>	<u>\$ (652)</u>

During the nine months ended September 30, 2018, we discontinued and settled certain of our FX derivative contracts due to changes in our foreign currency revenue forecast that resulted in a loss of \$0.6 million reclassified to earnings from accumulated other comprehensive income (loss).

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):

		Three Months Ended September 30,			
		2018		2017	
Description of Derivative Contract	Location in Earnings of Reclassified Gain or Loss	Gains Recognized in OCI	Gains (Losses) Reclassified from AOCI to Earnings	Losses Recognized in OCI	(Losses) Gains Reclassified from AOCI to Earnings
FX derivative contracts	Foreign exchange and other gains (losses)	\$ 125	\$ 2,511	\$ (2,537)	\$ (1,623)
FX derivative contracts	SG&A	—	(3,007)	—	269
Interest rate swap contracts	Interest expense	—	(72)	—	797
		<u>\$ 125</u>	<u>\$ (568)</u>	<u>\$ (2,537)</u>	<u>\$ (557)</u>

		Nine Months Ended September 30,			
		2018		2017	
Description of Derivative Contract	Location in Earnings of Reclassified Gain or Loss	Gains Recognized in OCI	Gains (Losses) Reclassified from AOCI to Earnings	Losses Recognized in OCI	(Losses) Gains Reclassified from AOCI to Earnings
FX derivative contracts	Foreign exchange and other gains (losses)	\$ 314	\$ 1,999	\$ (10,124)	\$ (6,833)
FX derivative contracts	SG&A	—	(1,833)	—	1,623
Interest rate swap contracts	Interest expense	—	(89)	—	1,009
		<u>\$ 314</u>	<u>\$ 77</u>	<u>\$ (10,124)</u>	<u>\$ (4,201)</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, 2018		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	\$ 487	
Interest rate swap contracts	Other assets	—	Other long-term liabilities	509	
FX derivative contracts	Prepaid expenses and other current assets	—	Accrued liabilities	1,084	
Total derivatives designated as hedging instruments		—		2,080	
Derivatives Not Designated as Hedging Instruments					
FX derivative contracts	Prepaid expenses and other current assets	3,309	Accrued liabilities	224	
Total derivatives not designated as hedging instruments		3,309		224	
Total derivatives		\$ 3,309		\$ 2,304	
December 31, 2017					
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	\$ 834	
Interest rate swap contracts	Other assets	—	Other long-term liabilities	751	
FX derivative contracts	Prepaid expenses and other current assets	—	Accrued liabilities	460	
Total derivatives designated as hedging instruments		—		2,045	
Derivatives Not Designated as Hedging Instruments					
FX derivative contracts	Prepaid expenses and other current assets	519	Accrued liabilities	—	
Total derivatives not designated as hedging instruments		519		—	
Total derivatives		\$ 519		\$ 2,045	

(1) For the classification of inputs used to evaluate the fair value of our derivatives, refer to "Note 8. Fair Value Measurements."

Note 11. Commitments and Contingencies

FDA Warning Letter

On December 29, 2015, the FDA issued a Warning Letter alleging certain violations of FDA regulations applicable to medical device manufacturers at our Munich, Germany and Arvada, Colorado facilities.

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 related to the manufacture of our 3T device that were 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 CDC and the 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, in response to the Warning Letter and CDC's HAN and FDA's Safety Communication, 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, including a vacuum canister and internal sealing upgrade program and a deep disinfection service. 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 the risk mitigation strategies described above. We are currently implementing the vacuum and sealing upgrade program in as many countries as possible until all devices are upgraded. On October 11, 2018, after review of information provided by LivaNova, the FDA concluded that LivaNova could commence the vacuum and sealing upgrade program in the U.S. Furthermore, we continue to offer a no-charge deep disinfection service (deep cleaning service) for 3T device users as we receive the required regulatory approvals. On April 12, 2018, the FDA agreed to allow us to move forward with the deep cleaning service in the U.S. adding to the growing list of countries around the world in which we offer this service.

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, 2018, the product remediation liability was \$17.9 million. Refer to "Note 6. Product Remediation Liability" for additional information.

Litigation

Product Liability

The Company is currently involved in litigation involving our 3T device. The litigation includes a class action complaint in the U.S. District Court for the Middle District of Pennsylvania, federal multi-district litigation in the U.S. District Court for the Middle District of Pennsylvania, various U.S. state court cases and cases in jurisdictions outside the U.S. As of October 31, 2018, we are involved in approximately 150 claims worldwide, with the majority of the claims in various federal or state courts throughout the United States. The complaints generally seek damages and other relief based on theories of strict liability, negligence, breach of express and implied warranties, failure to warn, design and manufacturing defect, fraudulent and negligent misrepresentation/concealment, unjust enrichment, and violations of various state consumer protection statutes. The class action, filed in February 2016, 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. Members of the class seek declaratory relief that the 3T devices are defective and unsafe for intended uses, medical monitoring, damages, and attorneys' fees. The class action and cases in federal court have been stayed as a result of the federal multi-district litigation. However, cases in state courts in the U.S. and in jurisdictions outside the U.S. continue to progress. 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.

Civil Investigative Demand

On May 31, 2017, the Company received a Civil Investigative Demand ("CID") from the US Attorney's Office for the Northern District of Georgia. The CID requested, and we have provided, certain documents relating to the sales and marketing of VNS devices and related products in the State of Georgia. On October 25, 2018, without an admission of guilt, we entered into a settlement agreement with the US Department of Justice, the State of Georgia, and a former Company employee, and agreed to pay approximately \$1.9 million. Accordingly, during the three months ended September 30, 2018 we recognized \$1.9 million in selling, general and administrative expenses reflecting settlement of this matter.

Environmental Liability

SNIA Litigation

Our subsidiary, Sorin S.p.A. ("Sorin") was created as a result of a spin-off (the "Sorin spin-off") from SNIA S.p.A. ("SNIA") in January, 2004. SNIA subsequently became insolvent and 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 approximately \$4 billion for remediation costs relating to the environmental damage at chemical sites previously operated by SNIA's other subsidiaries.

In September 2011 and July 2014, the Bankruptcy Court of Udine and the Bankruptcy Court of Milan 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 or its subsidiaries in connection with their claims in the Italian insolvency proceedings. The Public Administrations appealed and in January 2016, the Court of Udine rejected the appeal. The Public Administrations have also appealed that decision.

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. On April 1, 2016, the Court of Milan dismissed all legal actions of SNIA and of the Public Administrations further requiring the Public Administrations to pay Sorin approximately \$338,000 for legal fees. The Public Administrations appealed the 2016 Decision to the Court of Appeal of Milan and a final decision is pending.

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.

Environmental Remediation Order

On July 28, 2015, Sorin received an administrative order (the "Remediation Order") from the Italian Ministry of the Environment directing prompt commencement of environmental remediation at the chemical sites previously operated by SNIA's other subsidiaries. We challenged the Remediation Order before the Administrative Court of Lazio in Rome (the "TAR"), and the TAR annulled the Remediation Order. The Italian Ministry of the Environment appealed to the Administrative Court of Appeal. On August 22, 2018, the Court of Appeals confirmed the decision and ordered the Public Administrations to bear court expenses of approximately \$5,000. The Public Administrations have six months to determine whether they will

attempt an appeal to the Supreme Court. 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 merger between Sorin and Cyberonics, Inc. (the “Merger”), before the Commercial Courts of Milan. 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 Administrations seeking damages. The Commercial Court of Milan delivered a decision in October 2016, fully rejecting the Public Administrations’ request and awarding us approximately \$480,000 in damages for frivolous litigation and legal fees. The Public Administrations appealed to the Court of Appeal of Milan. On May 15, 2018, the Court of Appeal of Milan confirmed its decision authorizing the Merger, but reduced the penalty of \$480,000 in damages for frivolous litigation and legal fees to \$58,000 for legal fees. The Public Administrations subsequently filed an appeal with the Supreme Court against the decision of the Court of Appeal of Milan. 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.

Patent Litigation

On May 11, 2018, Neuro and Cardiac Technologies LLC (“NCT”), a non-practicing entity, filed a complaint in the United States District Court for the Southern District of Texas asserting that the VNS Therapy System, when used with the SenTiva Model 1000 generator, infringes the claims of U.S. Patent No. 7,076,307 owned by NCT. The complaint requests damages that include a royalty, costs, interest, and attorneys’ fees. On September 13, 2018, we petitioned the Patent Trial and Appeal Board of the U. S. Patent and Trademark Office for an *inter partes review* (“IPR”) of the validity of the ‘307 patent. The Court has stayed the litigation pending the outcome of the IPR proceeding. 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 October 30, 2009, the Regional Internal Revenue Office of Lombardy (the “Internal Revenue Office”) informed Sorin Group Italia S.r.l. that, among several issues, it was disallowing in part (for a total of €102.6 million (approximately \$118.8 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) on February 3, 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 \$72.5 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 \$19.6 million as of September 30, 2018).

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 12. Stockholders' Equity

The table below presents the change in each component of AOCI, net of tax, and the reclassifications out of AOCI into net income for the nine months ended September 30, 2018 and September 30, 2017 (in thousands):

	Change in Unrealized Gain (Loss) on Derivatives	Foreign Currency Translation Adjustments Gain (Loss) ⁽¹⁾	Total
As of December 31, 2017	\$ (919)	\$ 46,232	\$ 45,313
Other comprehensive income (loss) before reclassifications, before tax	314	(36,727)	(36,413)
Tax expense	(75)	—	(75)
Other comprehensive income (loss) before reclassifications, net of tax	239	(36,727)	(36,488)
Reclassification of gain from accumulated other comprehensive income, before tax	(77)	(9,011) ⁽²⁾	(9,088)
Reclassification of tax expense	18	—	18
Reclassification of gain from accumulated other comprehensive income, after tax	(59)	(9,011)	(9,070)
Net current-period other comprehensive income (loss), net of tax	180	(45,738)	(45,558)
As of September 30, 2018	\$ (739)	\$ 494	\$ (245)
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
Reclassification of 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

- (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.
- (2) Cumulative foreign currency translation adjustments eliminated upon the sale of CRM.

Note 13. Stock-Based Incentive Plans

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Service-based stock appreciation rights ("SARs")	\$ 2,491	\$ 2,433	\$ 6,514	\$ 5,764
Service-based restricted stock units ("RSUs")	3,368	2,135	8,158	6,453
Market performance-based restricted stock units	509	289	1,814	463
Operating performance-based restricted stock units	909	611	2,941	1,018
Total stock-based compensation expense	\$ 7,277	\$ 5,468	\$ 19,427	\$ 13,698

During the nine months ended September 30, 2018, we issued stock-based compensatory awards with contract terms agreed upon by us and the respective individuals, as approved by the Compensation Committee of our Board of Directors. The awards with service conditions generally vest ratably over four years, subject to forfeiture unless service conditions are met. Market performance-based awards cliff vest after three years subject to the rank of our total shareholder return for the three-year period ending December 31, 2020 relative to the total shareholder returns for a peer group of companies. Operating performance-based awards cliff vest after three years subject to the achievement of certain thresholds of cumulative adjusted free cash flow for the three year period ending December 31, 2020. Compensation expense related to awards granted during 2018 for the three and nine months ended September 30, 2018 was \$3.4 million and \$7.3 million, respectively.

Stock-based compensation agreements issued during the nine months ended September 30, 2018, 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, 2018	
	Shares	Weighted Average Grant Date Fair Value
Service-based SARs	648	\$ 28.13
Service-based RSUs	255	\$ 95.61
Market performance-based RSUs	43	\$ 101.50
Operating performance-based RSUs	43	\$ 89.74

Note 14. Income Taxes

Our effective income tax rate from continuing operations for the three months ended September 30, 2018 was 29.8% compared with 6.5% for the three months ended September 30, 2017. For the nine months ended September 30, 2018, the effective income tax rate from continuing operations was 0.6% compared with 9.6% for the nine months ended September 30, 2017. Our effective income tax rate fluctuates based on, among other factors, changes in pretax income in countries with varying statutory tax rates, changes in valuation allowances, changes in tax credits and incentives, and changes in unrecognized tax benefits associated with uncertain tax positions.

Compared with the three months ended September 30, 2017, the increase in the effective tax rate for the three months ended September 30, 2018 was primarily attributable to the impact of several discrete tax benefits recorded during the three months ended September 30, 2017, 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 deferred tax benefit from the resolution of prior period tax matters.

Compared with the nine months ended September 30, 2017, the decrease in the effective tax rate for the nine months ended September 30, 2018 was primarily attributable to the impact of the reduction to the U.S. federal statutory tax rate as a result of the U.S. "Tax Cuts and Jobs Act" (the "Tax Act"), the benefit of foreign derived intangible income partially offset by the repeal of the U.S. domestic production activity deduction, certain tax law changes in the UK that occurred during the three months ended December 31, 2017 and the impact of discrete tax items.

During the second quarter of 2018, we entered into an audit settlement impacting one of our uncertain tax positions in Italy. This audit settlement resulted in the recognition of an additional \$1.7 million in income tax expense.

Further regulations and notices and state conformity could be issued as a result of U.S. tax reform covering various issues that may affect our tax position including, but not limited to, an increase in the corporate state tax rate and elimination of the interest deduction. The content of any future legislation, the timing for regulations, notices, and state conformity, and the reporting periods that would be impacted cannot be determined at this time. During the nine months ended September 30, 2018, the Company did not record material adjustments to the \$27.5 million provisional non-cash net charge recorded in the fourth quarter of 2017 related to the Tax Act.

Note 15. Net Income (Loss) Per Share

Reconciliation of the shares used in the basic and diluted earnings per share computations for the three and nine months ended September 30, 2018 and September 30, 2017 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Basic weighted average shares outstanding	48,637	48,181	48,484	48,130
Add effects of share-based compensation instruments ⁽¹⁾	—	353	943	209
Diluted weighted average shares outstanding	48,637	48,534	49,427	48,339

- (1) Excluded from the computation of diluted earnings per share for the three months ended September 30, 2018 were stock options, SARs and restricted share units totaling 2.8 million, because to include them would be anti-dilutive under the treasury stock method due to the net loss. Excluded from the computation of diluted earnings per share for the nine months ended September 30, 2018 were stock options, SARs and restricted share units totaling 0.5 million because to include them would be anti-dilutive under the treasury stock method. Excluded from the computation of diluted earnings per share for the three and nine months ended September 30, 2017 were stock options, SARs and restricted share units totaling 1.6 million, because to include them would have been anti-dilutive under the treasury stock method.

Note 16. Geographic and 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 two reportable segments: Cardiovascular and Neuromodulation.

The Cardiovascular segment generates its revenue from the development, production and sale of cardiopulmonary products, heart valves and advanced circulatory support. Cardiopulmonary products include oxygenators, heart-lung machines, autotransfusion systems, perfusion tubing systems, cannulae and other related accessories. Heart valves include mechanical heart valves, tissue heart valves and related repair products. Advanced circulatory support, which represents our recently acquired TandemLife business, includes temporary life support product kits that can include a combination of pumps, oxygenators, and cannulae.

The Neuromodulation segment generates its revenue from the design, development and marketing of neuromodulation therapy systems 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, and other accessories. On January 16, 2018, we acquired the remaining 86% outstanding interest in ImThera which is also included in our Neuromodulation segment. ImThera manufactures an implantable device for the treatment of obstructive sleep apnea that stimulates multiple tongue muscles via the hypoglossal nerve, which opens the airway while a patient is sleeping.

“Other” includes corporate shared service expenses for finance, legal, human resources and information technology and corporate business development (“New Ventures”). New Ventures is focused on new growth platforms and identification of other opportunities for expansion.

Effective January 1, 2018, we began to include the results of heart failure within the Neuromodulation segment for internal reporting purposes in order to manage and evaluate business activities for purposes of allocating resources and assessing performance. Previously, the results of heart failure were reported within “Other”. Segment results for the three and nine months ended September 30, 2017 have been recast to conform to the current period presentation.

Net sales of our reportable segments include 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.

We operate under three geographic regions: United States, Europe, and Rest of world. The table below presents net sales by operating segment and geographic region (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cardiopulmonary				
United States	\$ 40,396	\$ 38,379	\$ 120,980	\$ 110,274
Europe	32,186	30,520	104,972	95,088
Rest of world	55,358	54,665	163,757	149,645
	<u>127,940</u>	<u>123,564</u>	<u>389,709</u>	<u>355,007</u>
Heart Valves				
United States	6,145	6,612	18,828	18,886
Europe	9,421	9,909	33,400	30,940
Rest of world	16,980	19,737	45,162	52,779
	<u>32,546</u>	<u>36,258</u>	<u>97,390</u>	<u>102,605</u>
Advanced Circulatory Support				
United States	5,947	—	11,415	—
Europe	38	—	391	—
Rest of world	90	—	284	—
	<u>6,075</u>	<u>—</u>	<u>12,090</u>	<u>—</u>
Cardiovascular				
United States	52,488	44,991	151,223	129,160
Europe	41,645	40,429	138,763	126,028
Rest of world	72,428	74,402	209,203	202,424
	<u>166,561</u>	<u>159,822</u>	<u>499,189</u>	<u>457,612</u>
Neuromodulation				
United States	87,194	76,286	254,581	231,350
Europe	9,497	8,057	31,731	25,500
Rest of world	8,252	6,673	23,128	18,340
	<u>104,943</u>	<u>91,016</u>	<u>309,440</u>	<u>275,190</u>
Other				
	<u>578</u>	<u>415</u>	<u>1,349</u>	<u>1,119</u>
Totals				
United States	139,682	121,277	405,804	360,510
Europe ⁽¹⁾	51,142	48,486	170,494	151,528
Rest of world	81,258	81,490	233,680	221,883
Total ⁽²⁾	<u>\$ 272,082</u>	<u>\$ 251,253</u>	<u>\$ 809,978</u>	<u>\$ 733,921</u>

(1) Europe sales include those countries in which we have a direct sales presence, whereas European countries in which we sell through distributors are included in Rest of world.

(2) No single customer represented over 10% of our consolidated net sales. No country's net sales exceeded 10% of our consolidated sales except for the U.S.

Operating income by segment is as follows (in thousands):

Operating Income from Continuing Operations	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cardiovascular	\$ 9,783	\$ 23,788	\$ 36,378	\$ 63,594
Neuromodulation	36,432	46,524	132,377	138,544
Other	(29,420)	(28,557)	(89,479)	(78,460)
Total reportable segment income from continuing operations	16,795	41,755	79,276	123,678
Merger and integration expenses	12,659	2,010	20,028	7,708
Restructuring expenses	436	1,183	2,793	13,810
Amortization of intangibles	9,457	8,540	28,075	24,616
Operating (loss) income from continuing operations	\$ (5,757)	\$ 30,022	\$ 28,380	\$ 77,544

Assets by reportable segment (in thousands):

Assets	September 30, 2018	December 31, 2017
Cardiovascular	\$ 1,548,866	\$ 1,386,032
Neuromodulation	762,375	532,894
Other	299,439	334,276
Discontinued operations	—	250,689
Total assets	\$ 2,610,680	\$ 2,503,891

Capital expenditures by segment (in thousands):

Capital expenditures	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cardiovascular	\$ 8,032	\$ 5,541	\$ 15,757	\$ 13,292
Neuromodulation	512	370	1,359	2,348
Other	4,359	1,633	7,058	4,021
Discontinued operations	—	1,537	925	4,343
Total	\$ 12,903	\$ 9,081	\$ 25,099	\$ 24,004

The changes in the carrying amount of goodwill by reportable segment for the nine months ended September 30, 2018 were as follows (in thousands):

	Neuromodulation	Cardiovascular	Other	Total
December 31, 2017	\$ 315,943	\$ 425,882	\$ 42,417	\$ 784,242
Goodwill as a result of acquisitions ⁽¹⁾	82,596	121,688	—	204,284
Foreign currency adjustments	—	(19,249)	—	(19,249)
September 30, 2018	\$ 398,539	\$ 528,321	\$ 42,417	\$ 969,277

(1) Goodwill recognized as a result of the ImThera and TandemLife acquisitions. Refer to "Note 3. Business Combinations."

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

PP&E	September 30, 2018	December 31, 2017
United States	\$ 65,776	\$ 62,154
Europe	112,092	119,133
Rest of world	10,592	11,072
Total	\$ 188,460	\$ 192,359

Note 17. Supplemental Financial Information

Inventories consisted of the following (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	\$ 37,839	\$ 39,810
Work-in-process	20,321	18,206
Finished goods	94,896	86,454
	\$ 153,056	\$ 144,470

Inventories are reported net of the provision for obsolescence. This provision, which reflects normal obsolescence and includes components that are phased out or expired, totaled \$11.5 million and \$10.5 million at September 30, 2018 and December 31, 2017, respectively.

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

	September 30, 2018	December 31, 2017
Contingent consideration ⁽¹⁾	\$ 18,402	\$ —
Product remediation ⁽²⁾	15,509	16,811
CRM purchase price adjustment payable to MicroPort Scientific Corporation	14,891	—
Legal and administrative costs	13,041	6,082
Other amounts payable to MicroPort Scientific Corporation	11,419	—
Deferred consideration - Caisson	—	14,300
Other accrued expenses	45,471	41,749
	\$ 118,733	\$ 78,942

(1) Refer to "Note 8. Fair Value Measurements"

(2) Refer to "Note 6. Product Remediation Liability"

Note 18. New Accounting Pronouncements

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 an identical or a similar investment of the same issuer. We made this election beginning January 1, 2018, resulting in no material impact to our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* and later issued subsequent amendments to the initial guidance: ASU 2017-13, ASU 2018-10 and ASU 2018-11 (collectively, Topic 842). This guidance requires lessees to recognize most leases on the balance sheet as lease liabilities with corresponding right-of-use assets and to provide enhanced disclosures. We currently expect the majority of our operating lease commitments will be subject to the new standard, which we expect will increase the total assets and total liabilities that we report for these lease commitments by a material amount. The guidance provides certain practical expedients including an option to apply transition provisions of the new standard, including its disclosure requirements, at its adoption date instead of at the beginning of the earliest comparative period presented. We are in

the process of assessing available practical expedients, including the transition provision that we have elected to apply, implementing lease accounting software and evaluating the effect this standard will have on our consolidated financial statements and related disclosures. The standard will be effective for us on January 1, 2019.

In June 2016, the FASB issued ASU Update No. 2016-13, *Financial Instruments—Credit Losses* (Topic 326): The amendments in this update require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The amendments in this update are effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted as of the fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The modified-retrospective approach is generally applicable through a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is effective. We are currently evaluating the effect this standard will have on our consolidated financial statements and related disclosures.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows* (Topic 230): *Classification of Certain Cash Receipts and Cash Payments*. Update 2016-15 provides guidance on the presentation and classification of certain cash receipts and cash payments in the statement of cash flows. We adopted this update on January 1, 2018 resulting in no material impact to our consolidated statements of cash flows.

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes* (Topic 740): *Intra-Entity Transfers of Assets Other Than Inventory*. 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.

We adopted this update on January 1, 2018 and recognized the following balance sheet adjustments (in thousands):

	Balance at December 31, 2017		Adjustment due to ASU No. 2016-16		Balance at January 1, 2018
Assets					
Prepaid expenses and other current assets	\$ 39,037	\$	(12,604)	\$	26,433
Deferred tax assets, net	11,559		58,301		69,860
Other assets	75,984		(68,127)		7,857
Equity					
Accumulated deficit	\$ (39,664)	\$	(22,430)	\$	(62,094)

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles-Goodwill and Other* (Topic 350): *Simplifying the Test for Goodwill Impairment*. 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 update is effective for annual periods after December 15, 2019, including interim periods within those annual reporting periods with early adoption permitted.

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. We adopted this update on January 1, 2018. The ImThera and TandemLife acquisitions were considered acquisitions of a business. Refer to “Note 3. Business Combinations” for a discussion of our acquisitions of ImThera and TandemLife.

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. We adopted this update on January 1, 2018, resulting in an immaterial impact to our consolidated financial statements. The condensed consolidated statements of income for the three and nine months ended September 30, 2017 have been recast for the adoption of this update.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation* (Topic 718): *Improvements to Nonemployee Share-Based Payment Accounting*. This update simplifies the accounting for non-employee share-based payment transactions. The amendment specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor’s own operations by issuing share-based payment awards. The update is effective for annual periods after December 15, 2018, including interim periods within those annual reporting periods

with early adoption permitted. We do not expect the adoption of this update to have a material effect on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): *Changes to the Disclosure Requirements for Fair Value Measurement*. This update removes, modifies and adds certain disclosure requirements related to fair value measurements. The update is effective for annual periods after December 15, 2019, including interim periods within those annual reporting periods with early adoption permitted. We do not expect the adoption of this update to have a material effect on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-14, Compensation—Retirement Benefits—Defined Benefit Plans—General (Subtopic 715-20): *Changes to the Disclosure Requirements for Defined Benefit Plans*. This update adds and removes certain disclosure requirements related to defined benefit plans. The update is effective for annual periods after December 15, 2020, on a retrospective basis for all periods presented with early adoption permitted. We do not expect the adoption of this update to have a material effect on our consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. This update clarifies and aligns the accounting for implementation costs for hosting arrangements with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. This update is effective for annual periods after December 15, 2019, including interim periods within those annual reporting periods with early adoption permitted and should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. We do not expect the adoption of this update to have a material effect 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 2017 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 2017 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 Cardiovascular and Neuromodulation, we design, develop, manufacture and sell innovative therapeutic solutions that are consistent with our mission to improve our patients' quality of life, increase the skills and capabilities of healthcare professionals and minimize healthcare costs.

Sale of the CRM Business Franchise

We completed the CRM Sale on April 30, 2018 for total cash proceeds of \$195.9 million, less cash transferred of \$9.2 million, subject to a closing working capital adjustment. In conjunction with the sale, we entered into transition services agreements to provide certain support services for generally up to twelve months from the closing date of the sale. The services include, among others, accounting, information technology, human resources, quality assurance, regulatory affairs, supply chain, clinical affairs and customer support.

The results of operations of CRM are reflected as discontinued operations for all periods presented in this Quarterly Report on Form 10-Q. Discontinued operations for the nine months ended September 30, 2018 include operating activities through the close of the sale on April 30, 2018. The assets and liabilities of CRM are presented as assets or liabilities of discontinued operations in the condensed consolidated balance sheets at December 31, 2017. Refer to "Note 4. Discontinued Operations" to the Financial Statements in this Quarterly Report on Form 10-Q.

Business Franchises

LivaNova is comprised of two Business Franchises: Cardiovascular (formerly Cardiac Surgery) and Neuromodulation, corresponding to our main therapeutic areas. Corporate activities include corporate business development (“New Ventures”). New Ventures is focused on new growth platforms and identification of other opportunities for expansion.

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.

Cardiovascular Update

The Cardiovascular segment is engaged in the development, production and sale of cardiopulmonary products, heart valves and advanced circulatory support. Cardiopulmonary products include oxygenators, heart-lung machines, autotransfusion systems, perfusion tubing systems, cannulae and other related accessories. Heart valves include mechanical heart valves, tissue heart valves and related repair products. Advanced circulatory support, which represents our recently acquired TandemLife business, includes temporary life support product kits that can include a combination of pumps, oxygenators, and cannulae.

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. The sale of the Suzhou facility was completed in April 2018.

In April 2018, we acquired TandemLife, headquartered in Pittsburgh, Pennsylvania. TandemLife is focused on the delivery of leading-edge temporary life support products, including cardiopulmonary and respiratory support solutions.

Product Remediation Plan

In response to an FDA Warning Letter, the CDC’s Health Alert Network and the FDA’s Safety Communication, 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, including a vacuum and sealing program and a deep disinfection service. 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 the risk mitigation strategies described above. We are currently implementing a vacuum canister and internal sealing upgrade program in as many countries as possible until all devices are upgraded. On October 11, 2018, after review of information provided by LivaNova, the FDA concluded that LivaNova could commence the vacuum and sealing upgrade program in the U.S. Furthermore, we continue to offer a no-charge deep disinfection service (deep cleaning service) for 3T device users as we receive the required regulatory approvals. On April 12, 2018, the FDA agreed to allow us to move forward with the deep cleaning service in the U.S., adding to the growing list of countries around the world in which we offer the service.

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, 2018, the product remediation liability was \$17.9 million. For further information, please refer to “Note 6. Product Remediation Liability” in our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Heart Valves

In January 2018, we announced that we had started enrollment in our BELIEVE study. This study focuses on the overall incidence of reduced leaflet motion identified by CT imaging in patients receiving a LivaNova aortic heart valve. We are planning to enroll approximately 230 patients at 15 sites in the U.S. and Canada.

In March 2018, we announced that we had started enrollment in PERFECT, a Perceval valve clinical study in China. The study is being conducted to demonstrate the safety and effectiveness of Perceval in the Chinese population. We plan to enroll approximately 160 patients at 8 investigational sites.

In June 2018, we announced that Japan’s Ministry of Health, Labour and Welfare approved our Perceval sutureless aortic heart valve to treat aortic valve disease, which will enable us to provide patients and clinicians in Japan with a new option for aortic heart valve replacement. We are currently working to obtain reimbursement in Japan.

In June 2018, we announced FDA 510(k) clearance of the MEMO 4D semi-rigid mitral annuloplasty ring and confirmed the first implantation of the device. In October 2018, we received CE mark approval for Memo 4D. This next-generation of the MEMO device family offers several innovations, such as broader range of ring sizes, a new ring design and true semi-rigid stability and flexibility that allows us to reach a larger patient population with mitral regurgitation (“MR”) for treatment with the potential to improve patient outcomes.

Neuromodulation Update

The Neuromodulation segment designs, develops and markets neuromodulation therapy for the treatment of drug-resistant epilepsy, treatment-resistant depression, obstructive sleep apnea and heart failure. Through this segment, we market our proprietary implantable VNS Therapy Systems that deliver vagus nerve stimulation therapy for the treatment of epilepsy and depression.

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, and we support studies for our product development efforts and to build clinical evidence for the VNS Therapy System.

Epilepsy

In March 2018, we announced the launch and enrollment of the first patient in a clinical study to examine the use of our VNS Therapy System using Microburst technology. This feasibility study will determine the initial safety and effectiveness of delivering VNS Therapy using high frequency bursts of stimulation in patients who have drug-resistant epilepsy. The study consists of two cohorts, enrolling up to 40 patients at approximately 15 sites in the U.S. and Europe.

In April 2018, we obtained CE Mark for our SenTiva VNS Therapy System, which followed FDA approval in the U.S. in October 2017. The SenTiva VNS Therapy System consists of the SenTiva implantable generator and the next-generation VNS Therapy Programming System. SenTiva is our 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, these components offer patients with drug-resistant epilepsy a physician-directed, customizable therapy with smart technology that reduces the number of seizures, lessens the duration of seizures and enables a faster recovery.

In August 2018, we announced a new cost analysis that found our VNS Therapy System results in lower resource utilization and lower cost for drug-resistant epilepsy patients when compared to continued treatment with anti-epileptic drugs. The analysis showed initial costs for the VNS Therapy device, including placement and programming, were estimated to be offset 1.7 years post-implant and equated to an estimated net cost savings of \$77,480 per patient over five years. The net cost savings are due primarily to a reduction in seizure-related hospitalizations, resulting in a 21.5% decrease in costs compared to treatment with anti-epileptic drugs alone.

Depression

In January 2018, we announced the launch and enrollment of the first patient in our Global RESTORE-LIFE study, which evaluates the use of our VNS Therapy System in patients who have treatment-resistant depression and failed to achieve an adequate response to standard psychiatric management. We expect to enroll up to 500 patients at approximately 80 sites outside of the U.S. We are currently enrolling patients in Germany and will expand to other countries during the remainder of the year.

In May 2018, the U.S. Centers for Medicare and Medicaid Services (“CMS”) published a tracking sheet to reconsider its National Coverage Determination (“NCD”) of our VNS Therapy System for treatment-resistant depression. The tracking sheet was in response to a letter that we submitted to CMS requesting a formal reconsideration of the NCD. We requested this review after a significant body of new evidence emerged about treatment-resistant depression and the role of VNS Therapy in its treatment. The 30-day public comment period on the NCD closed on June 29, 2018. The release of a Proposed Decision Memorandum is expected during the fourth quarter of fiscal year 2018. Once that occurs, CMS will have another 30-day public comment period. By the end of February 2019, we expect that the agency will render a final decision.

Heart Failure

We are 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. 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. 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. The VITARIA System is not approved in the U.S.

In September 2018, we announced the first successful implantation of the VITARIA System in a patient enrolled in the ANTHEM-HFrEF pivotal study. ANTHEM-HFrEF is an international, multi-center, randomized trial to evaluate the VITARIA System for the treatment of advanced heart failure.

Obstructive Sleep Apnea

We have invested in ImThera, a privately held emerging-growth company developing an implantable neurostimulation device system for the treatment of obstructive sleep apnea (“OSA”) since 2011. On January 16, 2018, we acquired the remaining 86% outstanding interests in ImThera. ImThera manufactures an implantable device that stimulates multiple tongue muscles via the hypoglossal nerve, which opens the airway while a patient is sleeping. ImThera has a commercial presence in the European market and an FDA pivotal study is ongoing in the U.S.

During the second quarter of 2018, we determined that developments in the ImThera clinical trial will result in a minimum 12-month delay of regulatory approval. This delay constituted a triggering event that required evaluation of the in-process research and development asset for impairment. Based on the quantitative impairment evaluation, the in-process research and development asset was not impaired; however, a further delay or a change in management’s estimates could result in a fair value that is below the carrying amount for such an asset. We will continue to monitor any changes in circumstances for indicators of impairment.

Corporate Activities and New Ventures

Corporate activities include shared services for finance, legal, human resources and information technology and New Ventures. New Ventures is focused on new growth platforms and identification of other opportunities for expansion.

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).

In May 2017, we acquired the remaining 51% outstanding equity interest in Caisson. Caisson 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 for the treatment of mitral valve regurgitation. In April 2016, Caisson obtained FDA approval of an Investigational Device Exemption study using its 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.

In August 2018, we announced the conclusion of the PRELUDE feasibility study of the TMVR system. The PRELUDE first-inhuman study evaluated the TMVR system to treat moderate to severe MR using a transseptal approach. This is a less invasive approach using a tube (catheter) through an incision in the groin, instead of an opening in the chest, to replace a patient’s mitral valve. Following the positive patient outcomes from the PRELUDE study, we will now focus on enrolling patients in the INTERLUDE CE Mark trial and finalize the protocol for the U.S. pivotal trial, ENSEMBLE, with the FDA.

We performed a quantitative impairment assessment, as of April 1, 2018, for the goodwill and in-process research and development assets arising from the Caisson acquisition. Based upon the assessment performed, we determined that the goodwill and the in-process research and development assets were not impaired. The quantitative impairment assessment was performed using management’s current estimate of future cash flows which are based on the expected timing of future regulatory approvals. A delay in the anticipated timing of these regulatory approvals or management’s estimates could result in a fair value of the in-process research and development asset that is below its carrying amount.

We are also invested in two mitral valve startups, Cardiosolutions Inc. (“Cardiosolutions”) and Highlife S.A.S. (“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.

Significant Accounting Policies and Critical Accounting Estimates

In addition to our critical accounting policies provided in “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our 2017 Form 10-K, refer to “Note 2. Revenue Recognition” included in this Quarterly Report on Form 10-Q.

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 18. New Accounting Pronouncements” contained in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Other

U.S. Tax Reform

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act (the “Tax Act”). The Tax Act, which is also commonly referred to as “U.S. tax reform”, significantly changed U.S. corporate income tax laws by, among other things, reducing the U.S. corporate income tax rate to 21%, which commenced in 2018. In addition, the Tax Act created a one-time mandatory tax, a toll charge, on previously deferred foreign earnings of non-U.S. subsidiaries controlled by a U.S. corporation, or, in our case, a non-U.S. subsidiary controlled by one of our U.S. subsidiaries.

The Tax Act also established various other new U.S. corporate income tax laws that came into effect in 2018, including, but not limited to, (1) elimination of the corporate alternative minimum tax (AMT); (2) the creation of the base erosion anti-abuse tax (BEAT), a new minimum tax; (3) a new provision designed to tax global intangible low-taxed income (GILTI); (4) a new limitation on deductible interest expense; (5) the repeal of the domestic production activity deduction; (6) limitations on the deductibility of certain executive compensation; and (7) limitations on net operating losses (NOLs) generated after December 31, 2017, to 80 percent of taxable income. The extent to which these and other provisions of the Tax Act, or future legislation or regulations, could impact our consolidated effective income tax rate in future periods depends on many factors including, but not limited to, the amount of profit generated by our subsidiaries operating in the U.S., the impact of the Company’s current or contemplated tax planning strategies, the impact of new or amended tax laws or regulations by the U.S. and by countries outside the U.S., and other factors beyond our control.

Further regulations and notices and state conformity could be issued as a result of U.S. tax reform covering various issues that may affect our tax position including, but not limited to, an increase in the corporate state tax rate and elimination of the interest deduction. The content of any future legislation, the timing for regulations, notices, and state conformity, and the reporting periods that would be impacted cannot be determined at this time. During the nine months ended September 30, 2018, the Company did not record material adjustments to the \$27.5 million provisional non-cash net charge recorded in the fourth quarter of 2017 related to the Tax Cuts and Jobs Act. to account for the impact of law changes, or enactments.

Brexit

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, and on March 19, 2018, the UK and the EU released a draft withdrawal agreement highlighting the progress made between the two parties on the terms of a transition period that will usher the UK out of the EU. Negotiations between the UK and the EU continue about provisions of the withdrawal agreement. Unless the deadline is extended, the UK will leave the EU on March 29, 2019. Although the long-term effects of Brexit will depend on any agreements the UK makes to retain access to the EU markets, Brexit has created additional uncertainties that may ultimately result in new regulatory costs and challenges for medical device companies and increased restrictions on imports and exports throughout Europe. This could adversely affect our ability to conduct and expand our operations in Europe and may have an adverse effect on our business, financial condition and results of operations.

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.

We and several of our wholly owned subsidiaries that are domiciled either in the UK, various EU Member States, or in the United States, 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 with the UK and/or the U.S. are enacted or the withdrawal becomes effective.

European Union State Aid Challenge

On October 26, 2017, the European Commission (“EC”) announced that an investigation will be opened with respect to the UK’s controlled foreign company (“CFC”) rules. The CFC rules under investigation provide certain tax exceptions to entities controlled by UK parent companies that are subject to lower tax rates if the activities being undertaken by the CFC relate to financing. The EC is investigating whether the exemption is a breach of EU State Aid rules. The investigation is estimated to be completed by December 31, 2018 with an appeal process likely to follow. It is unclear as to whether the UK will be part of the EU once a decision has been finalized due to Brexit and what impact, if any, Brexit will have on the outcome of the investigation or the enforceability of a decision. Due to the many uncertainties related to this matter, including the state of the investigation, the pending Brexit negotiations and political environment and the unknown outcome of the investigation and resulting appeals, no uncertain tax position reserve has been recognized related to this matter and we are unable to reasonably estimate the potential liability.

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, 2018, as compared to the three and nine months ended September 30, 2017.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net sales	\$ 272,082	\$ 251,253	\$ 809,978	\$ 733,921
Cost of sales	94,300	87,752	270,891	251,743
Product remediation	3,434	1,642	8,691	2,573
Gross profit	174,348	161,859	530,396	479,605
Operating expenses:				
Selling, general and administrative	115,136	97,201	342,736	278,805
Research and development	42,417	22,903	108,384	77,122
Merger and integration expenses	12,659	2,010	20,028	7,708
Restructuring expenses	436	1,183	2,793	13,810
Amortization of intangibles	9,457	8,540	28,075	24,616
Total operating expenses	180,105	131,837	502,016	402,061
Operating (loss) income from continuing operations	(5,757)	30,022	28,380	77,544
Interest income	184	199	863	724
Interest expense	(2,633)	(1,421)	(7,750)	(5,314)
Gain on acquisitions	—	—	11,484	39,428
Foreign exchange and other (losses) gains	(727)	527	(1,070)	863
(Loss) income from continuing operations before tax	(8,933)	29,327	31,907	113,245
Income tax (benefit) expense	(2,660)	1,905	203	10,819
Losses from equity method investments	—	(407)	(627)	(16,505)
Net (loss) income from continuing operations	(6,273)	27,015	31,077	85,921
Net (loss) income from discontinued operations	(904)	815	(9,915)	678
Net (loss) income	\$ (7,177)	\$ 27,830	\$ 21,162	\$ 86,599

Net Sales

The tables below present net sales by operating segment and geographic region (in thousands, except for percentages):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Increase (Decrease)	2018	2017	% Increase (Decrease)
Cardiopulmonary						
United States	\$ 40,396	\$ 38,379	5.3 %	\$ 120,980	\$ 110,274	9.7 %
Europe	32,186	30,520	5.5 %	104,972	95,088	10.4 %
Rest of world	55,358	54,665	1.3 %	163,757	149,645	9.4 %
	<u>127,940</u>	<u>123,564</u>	3.5 %	<u>389,709</u>	<u>355,007</u>	9.8 %
Heart Valves						
United States	6,145	6,612	(7.1)%	18,828	18,886	(0.3)%
Europe	9,421	9,909	(4.9)%	33,400	30,940	8.0 %
Rest of world	16,980	19,737	(14.0)%	45,162	52,779	(14.4)%
	<u>32,546</u>	<u>36,258</u>	(10.2)%	<u>97,390</u>	<u>102,605</u>	(5.1)%
Advanced Circulatory Support						
United States	5,947	—	— %	11,415	—	— %
Europe	38	—	— %	391	—	— %
Rest of world	90	—	— %	284	—	— %
	<u>6,075</u>	<u>—</u>	— %	<u>12,090</u>	<u>—</u>	— %
Cardiovascular						
United States	52,488	44,991	16.7 %	151,223	129,160	17.1 %
Europe	41,645	40,429	3.0 %	138,763	126,028	10.1 %
Rest of world	72,428	74,402	(2.7)%	209,203	202,424	3.3 %
	<u>166,561</u>	<u>159,822</u>	4.2 %	<u>499,189</u>	<u>457,612</u>	9.1 %
Neuromodulation						
United States	87,194	76,286	14.3 %	254,581	231,350	10.0 %
Europe	9,497	8,057	17.9 %	31,731	25,500	24.4 %
Rest of world	8,252	6,673	23.7 %	23,128	18,340	26.1 %
	<u>104,943</u>	<u>91,016</u>	15.3 %	<u>309,440</u>	<u>275,190</u>	12.4 %
Other						
	<u>578</u>	<u>415</u>	39.3 %	<u>1,349</u>	<u>1,119</u>	20.6 %
Totals						
United States	139,682	121,277	15.2 %	405,804	360,510	12.6 %
Europe ⁽¹⁾	51,142	48,486	5.5 %	170,494	151,528	12.5 %
Rest of world	81,258	81,490	(0.3)%	233,680	221,883	5.3 %
Total	<u>\$ 272,082</u>	<u>\$ 251,253</u>	8.3 %	<u>\$ 809,978</u>	<u>\$ 733,921</u>	10.4 %

(1) Europe sales include those countries in which we have a direct sales presence, whereas European countries in which we sell through distributors are included in "Rest of world."

The tables below present segment income from operations (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	% Change	2018	2017	% Change
Cardiovascular	\$ 9,783	\$ 23,788	(58.9)%	\$ 36,378	\$ 63,594	(42.8)%
Neuromodulation	36,432	46,524	(21.7)%	132,377	138,544	(4.5)%
Other	(29,420)	(28,557)	(3.0)%	(89,479)	(78,460)	(14.0)%
Total reportable segment income from continuing operations ⁽¹⁾	\$ 16,795	\$ 41,755	(59.8)%	\$ 79,276	\$ 123,678	(35.9)%

(1) For a reconciliation of segment operating income to consolidated operating income refer to "Note 16. Geographic and Segment Information" in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Cardiovascular

Cardiovascular net sales increased for the three and nine months ended September 30, 2018 compared to the three and nine months ended September 30, 2017 primarily due to strong heart-lung machine sales as customers continue to upgrade from legacy S3 to current S5 devices and increased oxygenator and autotransfusion sales. Additionally, net sales were positively impacted by \$6.1 million and \$12.1 million, for the three and nine months ended September 30, 2018, respectively, from the acquisition of TandemLife on April 4, 2018. With respect to heart valves, increased sales of our Perceval sutureless aortic heart valves and traditional tissue valves were more than offset by a non-recurring sales return reserve of \$3.4 million recorded during the three months ended September 30, 2018, and continued declines in mechanical heart valve sales. Additionally, the expected termination of a manufacturing contract resulted in a decrease in heart valve net sales of \$4.8 million for the nine months ended September 30, 2018, as compared to the same prior year period. Finally, overall Cardiovascular net sales during the three months ended September 30, 2018 were negatively impacted by foreign currency fluctuations of approximately \$4.6 million, while the nine months ended September 30, 2018 were positively impacted by approximately \$10.3 million, as compared to the same prior year period.

Cardiovascular operating income decreased for the three and nine months ended September 30, 2018 compared to the three and nine months ended September 30, 2017 as the positive impact to operating income associated with the increases in net sales was more than offset by increased sales and marketing expenses related to our efforts to expand market share in international markets, increased R&D investments in support of the next generation heart-lung machine and increased legal costs associated with our 3T litigation. Additionally, the inclusion of the operating results of TandemLife resulted in a \$5.0 million and \$10.1 million decrease in operating income for the three and nine months ended September 30, 2018, respectively, as compared to the same prior year periods.

Neuromodulation

Effective January 1, 2018, we began to include the results of heart failure within the Neuromodulation segment for internal reporting purposes in order to manage and evaluate business activities for purposes of allocating resources and assessing performance. Segment results for the three and nine months ended September 30, 2017 have been recast to conform to the current period presentation.

Neuromodulation net sales increased for the three and nine months ended September 30, 2018 compared to the three and nine months ended September 30, 2017 primarily due to strong adoption of the SenTiva VNS Therapy System in the U.S. Net sales for the three and nine months ended September 30, 2018 also benefited from increased sales in Europe following the approval and launch of Sentiva in April 2018, the early success of a business model change in Japan and favorable reimbursement decisions in five additional countries in the Rest of World region.

Neuromodulation operating income decreased for the three and nine months ended September 30, 2018 compared to the three and nine months ended September 30, 2017. The positive impact to operating income associated with increases in sales was more than offset by increased sales and marketing expenses related to efforts to market direct to consumer, increased R&D expenses for new projects surrounding our Sentiva VNS Therapy System and heart failure and the inclusion of the operating results of ImThera.

Cost of Sales and Expenses

The table below presents our comparative cost of sales and significant expenses as a percentage of sales:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2018	2017	Change	2018	2017	Change
Cost of sales	34.7%	34.9%	(0.2)%	33.4%	34.3%	(0.9)%
Product remediation	1.3%	0.7%	0.6 %	1.1%	0.4%	0.7 %
Gross profit	64.1%	64.4%	(0.3)%	65.5%	65.3%	0.2 %
Operating expenses:						
Selling, general and administrative	42.3%	38.7%	3.6 %	42.3%	38.0%	4.3 %
Research and development	15.6%	9.1%	6.5 %	13.4%	10.5%	2.9 %
Merger and integration expenses	4.7%	0.8%	3.9 %	2.5%	1.1%	1.4 %
Restructuring expenses	0.2%	0.5%	(0.3)%	0.3%	1.9%	(1.6)%
Amortization of intangibles	3.5%	3.4%	0.1 %	3.5%	3.4%	0.1 %

Sales, General and Administrative (“SG&A”) Expenses

SG&A expenses consisted of sales, marketing, general and administrative activities. SG&A expenses as a percentage of net sales increased for the three and nine months ended September 30, 2018 compared to the three and nine months ended September 30, 2017, primarily due to key growth driver investments in the U.S., including efforts to market direct to consumer within our Neuromodulation business, acquisition costs and the operational impacts of TandemLife and ImThera. Increased sales and marketing expenses internationally for general market expansion, increased litigation expenses related to our 3T devices and the overall strengthening of our organizational capabilities to support growth also contributed to the increase in SG&A expenses as a percentage of net sales.

Research and Development (“R&D”) Expenses

R&D expenses consist of product design and development efforts, clinical study programs and regulatory activities, which are essential to our strategic portfolio initiatives, including TMVR, Treatment-Resistant Depression (“TRD”), Obstructive Sleep Apnea and Heart Failure. R&D expenses as a percentage of net sales increased during the three and nine months ended September 30, 2018 as compared to the three and nine months ended September 30, 2017, primarily due additional R&D expenses for our development of next generation products, including heart-lung machines, SenTiva, and TandemLife and clinical trials and investments in TRD, TMVR, sleep apnea and heart failure.

Merger and Integration (“M&I”) Expenses

M&I expenses consist primarily of costs associated with computer systems integration efforts, organization structure integration, synergy and tax planning. M&I expenses as a percentage of net sales increased for the three and nine months ended September 30, 2018 compared to the three and nine months ended September 30, 2017 due to costs associated with efforts to improve and standardize product pricing and procurement strategies.

Restructuring Expenses

Restructuring expenses were primarily related to our efforts under our 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 decreased as a percentage of net sales the three and nine months ended September 30, 2018, as compared to the three and nine months ended September 30, 2017, as our restructuring activities continue to decline.

Gain on Acquisitions

On January 16, 2018, we acquired the remaining outstanding interest of ImThera for cash consideration of up to \$225 million. On the acquisition date, we remeasured our existing investment in ImThera at fair value and recognized a pre-tax non-cash gain of \$11.5 million.

On May 2, 2017, we acquired the remaining 51% equity interest in Caisson. 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.

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 substantially from one reporting period to another.

Our effective income tax rate from continuing operations for the three months ended September 30, 2018 was 29.8% compared with 6.5% for the three months ended September 30, 2017. For the nine months ended September 30, 2018, the effective income tax rate from continuing operations was 0.6% compared with 9.6% for the nine months ended September 30, 2017. Our effective income tax rate fluctuates based on, among other factors, changes in pretax income in countries with varying statutory tax rates, changes in valuation allowances, changes in tax credits and incentives, and changes in unrecognized tax benefits associated with uncertain tax positions.

Compared with the three months ended September 30, 2017, the increase in the effective tax rate for the three months ended September 30, 2018 was primarily attributable to the impact of several discrete tax benefits recorded during the three months ended September 30, 2017, 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 deferred tax benefit from the resolution of prior period tax matters.

Compared with the nine months ended September 30, 2017, the decrease in the effective tax rate for the nine months ended September 30, 2018 was primarily attributable to the impact of the reduction to the U.S. federal statutory tax rate as a result of the U.S. "Tax Cuts and Jobs Act" (the "Tax Act"), the benefit of foreign derived intangible income partially offset by the repeal of the U.S. domestic production activity deduction, certain tax law changes in the UK that occurred during the three months ended December 31, 2017 and the impact of discrete tax items.

During the second quarter of 2018, we entered into an audit settlement impacting one of our uncertain tax positions in Italy. This audit settlement resulted in the recognition of an additional \$1.7 million in income tax expense.

Losses from Equity Method Investments

Due to an additional investment by a third party during the nine months ended September 30, 2018, our equity interest in Highlife decreased to 17.5% from 24.6%. We determined that we no longer had significant influence over Highlife and, as a result, we began to measure Highlife at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. Losses from equity method investments were \$0.6 million for the nine months ended September 30, 2018, which was attributable to Highlife, and \$0.4 million and \$16.5 million for the three and nine months ended September 30, 2017, respectively. The loss of \$16.5 million for the nine months ended September 30, 2017 was primarily due to the impairment of our investment in, and notes receivable from, Highlife of \$13.0 million during the second quarter of 2017.

Liquidity and Capital Resources

Based on our current business plan, we believe that our existing cash and cash equivalents, future cash generated from continuing 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 9. 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 the 2017 Form 10-K.

In connection with the TandemLife acquisition, we entered into a Bridge Facility Agreement providing a term loan facility with the aggregate principal amount of \$190.0 million. On April 3, 2018, we borrowed \$190.0 million under the Bridge Facility Agreement to facilitate the initial payment for our acquisition of TandemLife. We used the proceeds from the sale of the CRM business franchise to repay the borrowings under the Bridge Facility Agreement in full during the second quarter of 2018.

On July 30, 2018, we borrowed \$60.0 million under the 2017 European Investment Bank loan, obtained in June 2017, to support certain product development projects.

No provision has been made for income taxes on unremitted earnings of our foreign controlled subsidiaries (non-UK subsidiaries) as of September 30, 2018. 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 (decrease) increase in the balance of cash and cash equivalents were as follows (in thousands):

	Nine Months Ended September 30,	
	2018	2017
Operating activities	\$ 99,599	\$ 73,665
Investing activities	(107,408)	(41,797)
Financing activities	(2,910)	(10,000)
Effect of exchange rate changes on cash and cash equivalents	(2,948)	3,501
Net (decrease) increase	<u>\$ (13,667)</u>	<u>\$ 25,369</u>

Operating Activities

Cash provided by operating activities during the nine months ended September 30, 2018 increased \$25.9 million as compared to the same prior-year period. The increase is primarily due to a \$100.1 million increase in cash from changes in net operating assets and liabilities, partially offset by a decrease in net income adjusted for non-cash items of \$74.1 million.

Investing Activities

Cash used in investing activities during the nine months ended September 30, 2018 increased \$65.6 million as compared to the same prior-year period. The increase primarily resulted from an increase in cash paid for acquisitions of \$265.7 million, partially offset by cash received from the sale of CRM of \$186.7 million and an \$8.5 million increase due to cash received from the sale of assets.

Financing Activities

Cash used in financing activities during the nine months ended September 30, 2018 decreased \$7.1 million as compared to the same prior-year period. Changes in net borrowings resulting in an increase in cash of \$26.1 million were partially offset by the current year payment of deferred consideration related to an acquisition of \$14.1 million and a \$5.2 million decrease associated with share-based compensation arrangements.

Contractual Obligations

We had no material changes in our contractual commitments and obligations from amounts listed under “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations - Liquidity and Capital Resources” in our Annual Report on Form 10-K for the year ended December 31, 2017.

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 10. Derivatives and Risk Management”, “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 2017 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, 2018.

(b) Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-5(f) under the Exchange Act) occurred during the quarter ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. *Legal Proceedings*

For a description of our material pending legal and regulatory proceedings and settlements, refer to “Note 11. Commitments and Contingencies” in our condensed consolidated financial statements included in this Report on Form 10-Q.

Item 1A. *Risk Factors*

There were no material changes to the description of the risk factors associated with our business as previously disclosed in Part I, Item 1A “Risk Factors” of our 2017 Form 10-K.

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

Exhibit Number	Document Description	Report or Registration Statement	SEC File or Registration Number	Exhibit Reference
2.1	Stock and Asset Purchase Agreement, dated as of March 8, 2018, by and among LivaNova PLC, MicroPort Cardiac Rhythm B.V. and MicroPort Scientific Corporation	LivaNova PLC Current Report on Form 8-K, filed on March 8, 2018	001-37599	2.1
3.1	Amended Articles of Association of LivaNova PLC, effective as from 14 June 2017	LivaNova PLC Current Report on Form 8-K, filed on June 15, 2017	001-37599	3.1
10.1†	Form of Letter of Appointment as Non-Executive Director, dated 18 July 2018	LivaNova PLC Quarterly Report on Form 10-Q, filed on August 2, 2018	001-37599	10.5
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 Statements of Income for the three and nine months ended September 30, 2018 and September 30, 2017, (ii) the Condensed Consolidated Statements of Comprehensive Income for the three and nine months ended September 30, 2018 and September 30, 2017, (iii) the Condensed Consolidated Balance Sheet as of September 30, 2018 and December 31, 2017, (iv) the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2018 and September 30, 2017, 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: October 31, 2018

CERTIFICATION

I, Damien McDonald, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the quarterly period ended September 30, 2018, 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: October 31, 2018

/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, 2018, 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: October 31, 2018

/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, 2018, 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: October 31, 2018

/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.

