

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, 2019

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 98-1268150  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification No.)

20 Eastbourne Terrace, London, United Kingdom, W2 6LG  
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (44) (0) 203 325-0660

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares - £1.00 par value per share	LIVN	NASDAQ Global Market

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	Outstanding at October 28, 2019
Ordinary Shares - £1.00 par value per share	48,400,468

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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 Cardiopulmonary product systems: S5® heart-lung machine, S3® heart-lung machine, Inspire™, Heartlink™, XTRA® Autotransfusion System, 3T Heater-Cooler®, Connect™ and Revolution®.
- Trademarks for our line of surgical tissue and mechanical valve replacements and repair products: Mitroflow®, Crown PRT®, Solo Smart™, Perceval®, Miami Instruments™, 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 Filtline™ and Bicarbon Overline®.
- Trademarks for our advanced circulatory support systems: TandemLife®, TandemHeart®, TandemLung®, ProtekDuo®, and LifeSPARC™.
- Trademarks for our obstructive sleep apnea system: ImThera® and Aura6000®.

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 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;
- cyber-attacks or other disruptions to our information technology systems;
- 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, 2018 (“2018 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, 2019 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 2018 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 (LOSS)**  
**(UNAUDITED)**  
(In thousands, except per share amounts)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
Net sales	\$ 268,610	\$ 272,082	\$ 796,580	\$ 809,978
Costs and expenses:				
Cost of sales - exclusive of amortization	86,128	94,300	245,324	270,891
Product remediation	3,076	3,434	11,136	8,691
Selling, general and administrative	123,015	115,136	375,932	342,736
Research and development	45,904	42,417	124,023	108,384
Merger and integration expenses	6,716	12,659	14,345	20,028
Restructuring expenses	698	436	4,563	2,793
Impairment of intangible assets	—	—	50,295	—
Amortization of intangibles	11,146	9,457	29,690	28,075
Insurance recovery	(33,834)	—	(33,834)	—
Operating income (loss) from continuing operations	25,761	(5,757)	(24,894)	28,380
Interest income	151	184	624	863
Interest expense	(4,774)	(2,633)	(10,490)	(7,750)
Gain on acquisition	—	—	—	11,484
Foreign exchange and other gains (losses)	327	(727)	(795)	(1,070)
Income (loss) from continuing operations before tax	21,465	(8,933)	(35,555)	31,907
Income tax (benefit) expense	(10,653)	(2,660)	(23,431)	203
Losses from equity method investments	—	—	—	(627)
Net income (loss) from continuing operations	32,118	(6,273)	(12,124)	31,077
Net (loss) income from discontinued operations, net of tax	—	(904)	178	(9,915)
Net income (loss)	\$ 32,118	\$ (7,177)	\$ (11,946)	\$ 21,162
Basic income (loss) per share:				
Continuing operations	\$ 0.66	\$ (0.13)	\$ (0.25)	\$ 0.64
Discontinued operations	—	(0.02)	—	(0.20)
	\$ 0.66	\$ (0.15)	\$ (0.25)	\$ 0.44
Diluted income (loss) per share:				
Continuing operations	\$ 0.66	\$ (0.13)	\$ (0.25)	\$ 0.63
Discontinued operations	—	(0.02)	—	(0.20)
	\$ 0.66	\$ (0.15)	\$ (0.25)	\$ 0.43
Shares used in computing basic income (loss) per share	48,395	48,637	48,329	48,484
Shares used in computing diluted income (loss) per share	48,820	48,637	48,329	49,427

See accompanying notes to the condensed consolidated financial statements

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2019</b>	<b>2018</b>	<b>2019</b>	<b>2018</b>
Net income (loss)	\$ 32,118	\$ (7,177)	\$ (11,946)	\$ 21,162
Other comprehensive (loss) income:				
Net change in unrealized (loss) gain on derivatives	(870)	693	(665)	237
Tax effect	209	(168)	159	(57)
Net of tax	(661)	525	(506)	180
Foreign currency translation adjustment	(27,775)	1,863	(16,628)	(45,738)
Total other comprehensive (loss) income	(28,436)	2,388	(17,134)	(45,558)
Total comprehensive income (loss)	\$ 3,682	\$ (4,789)	\$ (29,080)	\$ (24,396)

See accompanying notes to the condensed consolidated financial statements

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

	September 30, 2019	December 31, 2018
<b>ASSETS</b>		
<i>Current Assets:</i>		
Cash and cash equivalents	\$ 75,313	\$ 47,204
Accounts receivable, net of allowance of \$12,247 at September 30, 2019 and \$11,598 at December 31, 2018	243,179	256,135
Inventories	167,756	153,535
Prepaid and refundable taxes	38,093	46,852
Prepaid expenses and other current assets	22,505	29,571
Total Current Assets	546,846	533,297
Property, plant and equipment, net	179,507	191,400
Goodwill	945,544	956,815
Intangible assets, net	699,493	770,439
Operating lease assets (Note 11)	54,283	—
Investments	24,942	24,823
Deferred tax assets	53,577	68,146
Other assets	5,749	4,781
Total Assets	\$ 2,509,941	\$ 2,549,701
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<i>Current Liabilities:</i>		
Current debt obligations	\$ 68,777	\$ 28,794
Accounts payable	75,522	76,735
Accrued liabilities and other	128,456	124,285
Current litigation provision liability	121,468	161,851
Taxes payable	10,128	22,530
Accrued employee compensation and related benefits	64,840	82,551
Total Current Liabilities	469,191	496,746
Long-term debt obligations	272,887	139,538
Contingent consideration	140,472	161,381
Litigation provision liability	31,500	132,210
Deferred tax liabilities	16,126	68,189
Long-term operating lease liabilities (Note 11)	44,724	—
Long-term employee compensation and related benefits	25,838	25,264
Other long-term liabilities	13,921	22,635
Total Liabilities	1,014,659	1,045,963
<i>Commitments and contingencies (Note 12)</i>		
<i>Stockholders' Equity:</i>		
Ordinary Shares, £1.00 par value: unlimited shares authorized; 49,380,570 shares issued and 48,399,097 shares outstanding at September 30, 2019; 49,323,418 shares issued and 48,205,783 shares outstanding at December 31, 2018	76,217	76,144
Additional paid-in capital	1,725,482	1,705,111
Accumulated other comprehensive loss	(41,610)	(24,476)
Accumulated deficit	(263,525)	(251,579)
Treasury stock at cost, 981,473 ordinary shares at September 30, 2019; 1,117,635 ordinary shares at December 31, 2018	(1,282)	(1,462)
Total Stockholders' Equity	1,495,282	1,503,738
Total Liabilities and Stockholders' Equity	\$ 2,509,941	\$ 2,549,701

See accompanying notes to the condensed consolidated financial statements

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

	<b>Nine Months Ended September 30,</b>	
	<b>2019</b>	<b>2018</b>
<b>Operating Activities:</b>		
Net (loss) income	\$ (11,946)	\$ 21,162
Non-cash items included in net (loss) income:		
Impairment of intangible assets	50,295	—
Amortization	29,690	28,052
Deferred tax benefit	(26,422)	(13,488)
Stock-based compensation	24,127	21,387
Depreciation	23,115	24,979
Amortization of operating lease assets	8,961	—
Amortization of income taxes payable on intercompany transfers of property	3,261	4,155
Gain on acquisition	—	(11,484)
Other	1,952	453
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable, net	5,433	30,506
Inventories	(18,181)	(7,622)
Other current and non-current assets	6,627	(16,757)
Accounts payable and accrued current and non-current liabilities	(28,964)	12,895
Taxes payable	(14,367)	4,993
Litigation provision liability	(140,823)	—
Restructuring reserve	(6,766)	368
<b>Net cash (used in) provided by operating activities</b>	<b>(94,008)</b>	<b>99,599</b>
<b>Investing Activities:</b>		
Purchases of property, plant and equipment	(16,801)	(24,318)
Acquisitions, net of cash acquired	(10,750)	(279,863)
Purchases of intangible assets	(3,186)	(781)
Proceeds from asset sales	505	13,872
Purchase of investment	(287)	(3,000)
Proceeds from the sale of CRM business franchise, net of cash disposed	—	186,682
<b>Net cash used in investing activities</b>	<b>(30,519)</b>	<b>(107,408)</b>
<b>Financing Activities:</b>		
Proceeds from long-term debt obligations	193,490	60,000
Payment of contingent consideration	(17,989)	(651)
Repayment of long-term debt obligations	(12,330)	(12,290)
Shares repurchased from employees for minimum tax withholding	(6,183)	(8,559)
Debt issuance costs	(3,795)	—
Proceeds from share issuances under ESPP	2,574	—
Change in short-term borrowing, net	(2,173)	(31,281)
Proceeds from exercise of stock options	331	4,177
Proceeds from short-term borrowing (maturities greater than 90 days)	—	240,000
Repayment of short-term borrowing (maturities greater than 90 days)	—	(240,000)
Payment of deferred consideration - acquisition of Caisson Interventional, LLC	—	(14,073)
Other	(184)	(233)
<b>Net cash provided by (used in) financing activities</b>	<b>153,741</b>	<b>(2,910)</b>
Effect of exchange rate changes on cash and cash equivalents	(1,105)	(2,948)
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>28,109</b>	<b>(13,667)</b>
Cash and cash equivalents at beginning of period	47,204	93,615
<b>Cash and cash equivalents at end of period</b>	<b>\$ 75,313</b>	<b>\$ 79,948</b>

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, 2019 and 2018, 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, 2018 has been derived from audited financial statements contained in our 2018 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, 2019, and are not necessarily indicative of the results that may be expected for the year ending December 31, 2019. The financial information presented herein should be read in conjunction with the audited consolidated financial statements and notes thereto accompanying our 2018 Form 10-K.

**Reclassifications**

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.

Gross profit, as previously presented for the nine months ended September 30, 2018, excluded amortization of certain intangible assets. For the nine months ended September 30, 2018, \$10.7 million of such amortization expense should have been included in cost of sales. The Company has determined that this misclassification error was not material to any prior annual or interim periods. For comparability among periods, the Company no longer presents gross profit within its condensed consolidated statements of income (loss).

**Significant Accounting Policies**

Our significant accounting policies are detailed in “Note 2. Basis of Presentation, Use of Accounting Estimates and Significant Accounting Policies” and “Note 3. Revenue Recognition” of our 2018 Form 10-K. Changes to our accounting policies as a result of adopting the new lease accounting standard are discussed below.

On January 1, 2019, we adopted ASC Update (“ASU”) No 2016-02, *Leases*, including subsequent related accounting updates (collectively referred to as “Topic 842”), which supersedes the previous accounting model for leases. We adopted the standard using the modified retrospective approach with an effective date as of January 1, 2019. Prior year financial statements were not recast under the new standard. In addition, we elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed us to carry forward our historical assessment of whether contracts are or contain leases and lease classification. We also elected the practical expedient to account for lease and non-lease components together as a single combined lease component, which is applicable to all asset classes. We did not, however, elect the practical expedient related to using hindsight in determining the lease term as this was not relevant following our election of the modified retrospective approach.

In addition, we elect certain practical expedients on an ongoing basis, including the practical expedient for short-term leases pursuant to which a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize a lease liability and operating lease asset for leases with a term of 12 months or less and that do not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise. We have applied this accounting policy to all asset classes in our portfolio and will recognize the lease payments for such short-term leases within profit and loss on a straight-line basis over the lease term.

Furthermore, from a lessor perspective, certain of our agreements that allow the customer to use, rather than purchase, our medical devices will meet the criteria of being a lease in accordance with the new standard. While the amount of revenue and expenses recognized over the contract term will not be impacted, the timing of revenue and expense recognition will be impacted depending upon lease classification. We enacted appropriate changes to our business processes, systems and internal controls to support identification, recognition and disclosure of leases under the new standard.

We determine if an arrangement is or contains a lease at inception. Operating lease assets and operating lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at the latter of our lease standard effective date for adoption or the lease commencement date. Variable lease payments, such as common area rent

maintenance charges and rent escalations not known upon lease commencement, are not included in determination of the minimum lease payments and will be expensed in the period in which the obligation for those payments is incurred. As most of our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement in determining the present value of future payments. The incremental borrowing rate represents an estimate of the interest rate we would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease within a particular currency environment. We used the incremental borrowing rate available nearest to our adoption date for leases that commenced prior to that date. The operating lease asset also includes any lease payments made in advance and excludes lease incentives. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

For additional information refer to “Note 11. Leases.”

## **Note 2. Business Combinations**

### **Miami Instruments**

On June 12, 2019, we acquired the minimally invasive cardiac surgery instruments business from Miami Instruments, LLC (“Miami Instruments”) for cash consideration of up to \$17.0 million. The related operations have been integrated into our Cardiovascular business franchise as part of our Heart Valves portfolio. Cash of \$10.8 million was paid at closing with up to \$6.0 million in contingent consideration based on achieving certain milestones. In connection with this acquisition, we recognized \$14.7 million in developed technology and in-process research and development (“IPR&D”) intangible assets and \$1.5 million in goodwill.

## **Note 3. Discontinued Operations**

In November 2017, we concluded that the sale of our Cardiac Rhythm Management (“CRM”) business franchise 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 on our condensed consolidated statements of income (loss) for all the periods presented in this Quarterly Report on Form 10-Q.

We completed the CRM Sale on April 30, 2018 to MicroPort Cardiac Rhythm B.V. and MicroPort Scientific Corporation 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 generally for 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. For providing these services, during three and nine months ended September 30, 2019, we recognized income of \$0.1 million and \$0.9 million, respectively, and during the three and nine months ended September 30, 2018, we recognized income of \$1.1 million and \$2.0 million, respectively. 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 (loss).

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net sales	\$ —	\$ —	\$ —	\$ 77,366
Costs and expenses:				
Cost of sales	—	—	(43)	27,306
Selling, general and administrative expenses	—	543	26	43,441
Research and development	—	—	(161)	16,577
Restructuring expenses	—	—	—	651
Revaluation gain on assets and liabilities held for sale	—	—	—	(1,213)
Loss on sale of CRM	—	—	—	214
Operating (loss) income from discontinued operations	—	(543)	178	(9,610)
Foreign exchange and other gains	—	—	—	102
(Loss) income from discontinued operations, before tax	—	(543)	178	(9,508)
Income tax expense (benefit)	—	361	—	(804)
Losses from equity method investments	—	—	—	(1,211)
Net (loss) income from discontinued operations	\$ —	\$ (904)	\$ 178	\$ (9,915)

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, CRM's capital expenditures were \$0.9 million and stock-based compensation expense was \$2.1 million.

#### Note 4. Restructuring

We initiate restructuring plans to leverage economies of scale, streamline distribution and logistics and strengthen operational and administrative effectiveness in order to reduce overall costs. Costs associated with these plans were reported as restructuring expenses in the operating results of our condensed consolidated statements of income (loss).

Our 2015 and 2016 Reorganization Plans (the "Prior 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. The Prior Plans include the closure of the R&D facility in Meylan, France and consolidation of its R&D capabilities into the Clamart, France facility. We completed the Prior Plans during 2018.

In December 2018, we initiated a reorganization plan (the "2018 Plan") in order to reduce manufacturing and operational costs associated with our Cardiovascular facilities in Saluggia and Mirandola, Italy and Arvada, Colorado. We estimate that the 2018 Plan will result in a net reduction of approximately 75 personnel and is expected to be completed by the end of 2019.

The following table presents the accruals, inventory obsolescence and other reserves, recorded in connection with our reorganization plans (in thousands):

	Employee Severance and Other Termination Costs	Other	Total
Balance at December 31, 2018	\$ 10,195	\$ 3,069	\$ 13,264
Charges	4,488	75	4,563
Cash payments and other	(13,147)	(2,059)	(15,206)
Balance at September 30, 2019 <sup>(1)</sup>	\$ 1,536	\$ 1,085	\$ 2,621

(1) Cumulatively, we have recognized a total of \$103.8 million in restructuring expense inclusive of discontinued operations under the Prior Plans and the 2018 Plan.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Cardiovascular	\$ 783	\$ 354	\$ 1,521	\$ 2,093
Neuromodulation	(171)	17	314	34
Other	86	65	2,728	666
Total	\$ 698	\$ 436	\$ 4,563	\$ 2,793

## Note 5. 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 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 us, the FDA concluded that we 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. The deep disinfection service was rolled out in Europe in the second half of 2015, and on April 12, 2018, the FDA agreed to allow us to move forward with the deep cleaning service in the U.S., thereby adding to the growing list of countries around the world in which we offer this service. Also, 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., was rolled out in Europe shortly thereafter, 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, 2018	\$ 14,745
Adjustments	2,567
Remediation activity	(9,341)
Effect of changes in foreign currency exchange rates	(527)
Balance at September 30, 2019 <sup>(1)</sup>	\$ 7,444

(1) At September 30, 2019, the product remediation liability balance is included within accrued liabilities and other on the condensed consolidated balance sheet.

We recognized product remediation expenses during the three and nine months ended September 30, 2019, of \$3.1 million and \$11.1 million, respectively, and \$3.4 million and \$8.7 million, respectively, during the three and nine months ended

September 30, 2018. 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 and related legal costs are expensed as incurred and are not included within the product remediation liability presented above. At September 30, 2019, our balance sheet includes a \$153.0 million provision related to litigation involving our 3T device. For further information, please refer to “Note 12. Commitments and Contingencies.”

## Note 6. Intangible Assets

### Intangible Asset Impairment

During the second quarter of 2019, we determined that there would be a delay in the estimated commercialization date of the Company’s obstructive sleep apnea product currently under development. This delay constituted a triggering event that required evaluation of the IPR&D asset arising from the ImThera Medical Inc. (“ImThera”) acquisition for impairment. Based on the assessment performed, we determined that the IPR&D asset was impaired and as a result, recorded an impairment of \$50.3 million, which is included in our Neuromodulation segment. The carrying value of the IPR&D asset as of September 30, 2019 is \$112.0 million. The estimated fair value of IPR&D was determined using the income approach. Future delays in commercialization or changes in management estimates could result in further impairment.

### Intangible Asset Reclassification

During the third quarter of 2019, upon receiving FDA approval of the LifeSPARC system, we reclassified IPR&D assets of \$107.5 million from the acquisition of CardiacAssist, Inc., doing business as TandemLife (“TandemLife”) to finite-lived developed technology intangible assets and began amortizing the intangible asset over a useful life of 15 years.

## Note 7. Investments

The following table details the carrying value of our investments in equity securities of non-consolidated affiliates without readily determinable fair values for which we do not exert significant influence over the investee. These equity investments 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 investments are included in investments on the condensed consolidated balance sheets (in thousands):

Equity Investments Without Readily Determinable Fair Values	September 30, 2019	December 31, 2018
Respicardia Inc. <sup>(1)</sup>	\$ 17,706	\$ 17,706
Ceribell, Inc.	3,000	3,000
Rainbow Medical Ltd.	1,067	1,119
MD Start II	1,090	1,144
Highlife S.A.S.	1,034	1,084
Other	770	770
	24,667	24,823
Equity method investments <sup>(2)</sup>	275	—
	\$ 24,942	\$ 24,823

- (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, 2019 and December 31, 2018, which is included in prepaid expenses and other current assets in the condensed consolidated balance sheet.
- (2) During the second quarter of 2019, we invested in equity securities that we account for under the equity method of accounting due to our deemed ability to exercise significant influence. We initially invested \$0.3 million and are required to fund up to a total of approximately €5.0 million (approximately \$5.5 million as of September 30, 2019) based on cash calls.

## 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, 2019 and 2018.

## Assets and Liabilities Measured at Fair Value on a Recurring Basis

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

		Fair Value Measurements Using Inputs Considered as:		
	Fair Value as of September 30, 2019	Level 1	Level 2	Level 3
Assets:				
Derivative assets - freestanding instruments (FX)	\$ 1,213	\$ —	\$ 1,213	\$ —
	<u>\$ 1,213</u>	<u>\$ —</u>	<u>\$ 1,213</u>	<u>\$ —</u>
Liabilities:				
Derivative liabilities - designated as cash flow hedges (FX)	\$ 1,458	\$ —	\$ 1,458	\$ —
Derivative liabilities - designated as cash flow hedges (interest rate swaps)	519	—	519	—
Derivative liabilities - freestanding instruments (FX)	1,869	—	1,869	—
Contingent consideration <sup>(1)</sup>	165,274	—	—	165,274
	<u>\$ 169,120</u>	<u>\$ —</u>	<u>\$ 3,846</u>	<u>\$ 165,274</u>
		Fair Value Measurements Using Inputs Considered as:		
	Fair Value as of December 31, 2018	Level 1	Level 2	Level 3
Assets:				
Derivative assets - freestanding instruments (FX)	\$ 236	\$ —	\$ 236	\$ —
	<u>\$ 236</u>	<u>\$ —</u>	<u>\$ 236</u>	<u>\$ —</u>
Liabilities:				
Derivative liabilities - designated as cash flow hedges (FX)	\$ 1,354	\$ —	\$ 1,354	\$ —
Derivative liabilities - designated as cash flow hedges (interest rate swaps)	865	—	865	—
Derivative liabilities - freestanding instruments (FX)	3,173	—	3,173	—
Contingent consideration <sup>(1)</sup>	179,911	—	—	179,911
	<u>\$ 185,303</u>	<u>\$ —</u>	<u>\$ 5,392</u>	<u>\$ 179,911</u>

(1) The contingent consideration liability represents contingent payments primarily related to five completed acquisitions, including: Inversiones Driltex SAS (“Driltex”), Caisson, ImThera, TandemLife and Miami Instruments. 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, 2018	\$	179,911
Additions <sup>(1)</sup>		7,184
Payments <sup>(2)</sup>		(19,234)
Changes in fair value <sup>(3) (4)</sup>		(2,425)
Effect of changes in foreign currency exchange rates		(162)
Total contingent consideration liability at September 30, 2019		165,274
Less current portion of contingent consideration liability at September 30, 2019		24,802
Long-term portion of contingent consideration liability at September 30, 2019	\$	140,472

(1) See “Note 2. Business Combinations” for additional discussion.

(2) In July 2019, we achieved a regulatory milestone upon receiving FDA approval of the LifeSPARC system, triggering the payment of \$19.0 million during the third quarter of 2019 to settle the related contingent consideration liability in connection with our TandemLife acquisition. The probability of additional payments and projected years of payment for the remaining regulatory milestones, as outlined in our TandemLife acquisition, remain unchanged.

(3) The change in fair value includes a decrease of \$17.8 million that was recognized during the second quarter of 2019 primarily due to the delay in timing of anticipated regulatory approval and commercialization for ImThera. While the probability of payment remains unchanged from the time of acquisition, the projected years of payment for the regulatory milestone-based payment and the sales-based earnout have been updated to occur between 2023-2024 and 2024-2028, respectively. See “Note 6. Intangible Assets” for additional discussion. This decrease was largely offset by impacts from the change in interest rates and the passage of time subsequent to December 31, 2018.

(4) During the nine months ended September 30, 2019, the change in fair value resulted in a decrease of \$0.9 million and \$1.5 million recorded to cost of sales - exclusive of amortization and research and development, respectively.

## Note 9. Financing Arrangements

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

	September 30, 2019	December 31, 2018	Maturity	Interest Rate
2019 Debt Facility <sup>(1)</sup>	\$ 182,434	\$ —	March 2022	1.40% - 3.72%
2017 European Investment Bank <sup>(2)</sup>	103,570	103,570	June 2026	3.47% - 3.53%
2014 European Investment Bank <sup>(3)</sup>	36,317	47,606	June 2021	0.98%
Mediocredito Italiano	6,674	7,623	December 2023	0.50% - 2.86%
Bank of America Merrill Lynch Banco Múltiplo S.A.	4,898	—	July 2021	8.47%
Bank of America, U.S.	1,999	—	January 2021	4.51%
Banca del Mezzogiorno	1,304	2,718	December 2019	0.50% - 2.91%
Other	1,375	1,324		
Total long-term facilities	338,571	162,841		
Less current portion of long-term debt	65,684	23,303		
Total long-term debt	\$ 272,887	\$ 139,538		

(1) The facility agreement with Bank of America Merrill Lynch International DAC, Barclays Bank PLC, BNP Paribas (London Branch) and Intesa Sanpaolo S.P.A. provides a multicurrency term loan facility in an aggregate amount of \$350 million and terminates on March 26, 2022 (the “2019 Debt Facility”). Principal repayments of 20% of the outstanding borrowings under the 2019 Debt Facility are due in September 2020, March 2021 and September 2021, with the remainder of the outstanding borrowings due in March 2022.

(2) 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.

(3) 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.

On March 26, 2019, we entered into the 2019 Debt Facility. Borrowings under the facility bear interest at a rate of LIBOR plus 1.6% for borrowings in U.S. dollars and EURIBOR plus 1.4% for Euro-denominated borrowings. Proceeds from the facility are used for general corporate and working capital purposes, excluding acquisitions, dividends and share buybacks. Available borrowings under the 2019 Debt Facility commenced on March 26, 2019 and extend through March 26, 2020. Principal repayments of 20% of the outstanding borrowings under the 2019 Debt Facility are due in September 2020, March 2021 and September 2021, with the remainder of the outstanding borrowings due in March 2022. The 2019 Debt Facility contains financial covenants that require LivaNova to maintain a maximum consolidated net debt to EBITDA ratio, a minimum interest coverage ratio and a maximum consolidated net debt to net worth ratio. LivaNova must also maintain a minimum amount of consolidated net worth. The 2019 Debt Facility also contains customary representations and warranties, covenants, and events of default. At September 30, 2019, LivaNova was in compliance with all covenants.

On July 25, 2019, we entered into a €40.0 million (approximately \$43.6 million as of September 30, 2019) credit facility agreement with Banca Nazionale del Lavoro SpA (“2019 Revolving Credit Facility”) for working capital needs. The 2019 Revolving Credit Facility has a term of two years and borrowings bear interest at Euribor plus 0.8%. Borrowings under the 2019 Revolving Credit Facility were zero at September 30, 2019.

#### Revolving Credit

The outstanding principal amount of our short-term unsecured revolving credit agreements and other agreements with various banks was \$3.1 million and \$5.5 million, at September 30, 2019 and December 31, 2018, respectively, with interest rates ranging from 8.50% to 8.69% and loan terms ranging from ten days to 210 days, as of September 30, 2019.

#### 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 exchange 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 on 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, changes in the fair value of the derivative will be 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 our condensed consolidated statements of income (loss) as shown in the tables below and interest rate swap gains and losses in AOCI are reclassified to interest expense on our condensed consolidated statements of income (loss). We evaluate hedge effectiveness at inception and on an ongoing basis. If a derivative is no longer expected to be highly effective, hedge accounting is discontinued and the gains or losses are reclassified into earnings. Cash flows from derivative contracts are reported as operating activities on our condensed consolidated statements of cash flows.

#### Freestanding FX Derivative Contracts

The gross notional amount of FX derivative contracts, not designated as hedging instruments, outstanding at September 30, 2019 and December 31, 2018 was \$273.1 million and \$320.2 million, respectively. These derivative contracts are designed to offset the FX effects in earnings of various intercompany loans, our 2014 EIB loan, the Euro-denominated borrowings under the 2019 Debt Facility and trade receivables. We recorded net gains for these freestanding derivatives of \$3.1 million and \$5.6 million for the three months ended September 30, 2019 and 2018, respectively, and net gains (losses) of \$6.8 million and \$(6.0) million for the nine months ended September 30, 2019 and 2018, respectively. These gains and (losses) are included in foreign exchange and other gains (losses) on our condensed consolidated statements of income (loss).



## Cash Flow Hedges

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

Description of Derivative Contract	September 30, 2019	December 31, 2018
FX derivative contracts to be exchanged for British Pounds	\$ 8,185	\$ 9,629
FX derivative contracts to be exchanged for Japanese Yen	26,462	23,985
FX derivative contracts to be exchanged for Canadian Dollars	1,532	7,637
FX derivative contracts to be exchanged for Euros	29,563	29,768
Interest rate swap contracts	29,072	38,115
	<u>\$ 94,814</u>	<u>\$ 109,134</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, 2019	Amount Expected to be Reclassified to Earnings in Next 12 Months
FX derivative contracts	\$ (1,313)	\$ (1,313)
Interest rate swap contracts	(137)	(78)
	<u>\$ (1,450)</u>	<u>\$ (1,391)</u>

Pre-tax gains (losses) for derivative contracts designated as cash flow hedges recognized in other comprehensive income (loss) ("OCI") and the amount reclassified to earnings from AOCI (in thousands):

		Three Months Ended September 30,			
		2019		2018	
Description of Derivative Contract	Location in Earnings of Reclassified Gain or Loss	Losses Recognized in OCI	Gains (Losses) Reclassified from AOCI to Earnings	Gains Recognized in OCI	Gains (Losses) Reclassified from AOCI to Earnings
FX derivative contracts	Foreign exchange and other (losses) gains	\$ (689)	\$ 963	\$ 125	\$ 2,511
FX derivative contracts	SG&A	—	(742)	—	(3,007)
Interest rate swap contracts	Interest expense	—	(40)	—	(72)
		<u>\$ (689)</u>	<u>\$ 181</u>	<u>\$ 125</u>	<u>\$ (568)</u>

  

		Nine Months Ended September 30,			
		2019		2018	
Description of Derivative Contract	Location in Earnings of Reclassified Gain or Loss	Gains Recognized in OCI	Gains (Losses) Reclassified from AOCI to Earnings	Gains Recognized in OCI	Gains (Losses) Reclassified from AOCI to Earnings
FX derivative contracts	Foreign exchange and other gains (losses)	\$ 933	\$ 3,094	\$ 314	\$ 1,999
FX derivative contracts	SG&A	—	(1,470)	—	(1,833)
Interest rate swap contracts	Interest expense	—	(26)	—	(89)
		<u>\$ 933</u>	<u>\$ 1,598</u>	<u>\$ 314</u>	<u>\$ 77</u>

We offset fair value amounts associated with our derivative instruments on our condensed consolidated balance sheets that are executed with the same counterparty under master netting arrangements. Our netting arrangements include a right to set off or net together purchases and sales of similar products in the settlement process.

The following tables present the fair value and the location of derivative contracts reported in the condensed consolidated balance sheets (in thousands):

<b>September 30, 2019</b>		<b>Asset Derivatives</b>		<b>Liability Derivatives</b>	
<b>Derivatives Designated as Hedging Instruments</b>		<b>Balance Sheet Location</b>	<b>Fair Value <sup>(1)</sup></b>	<b>Balance Sheet Location</b>	<b>Fair Value <sup>(1)</sup></b>
Interest rate swap contracts				Accrued liabilities	\$ 385
Interest rate swap contracts				Other long-term liabilities	134
FX derivative contracts				Accrued liabilities	1,201
FX derivative contracts				Prepaid expenses and other current assets	257
Total derivatives designated as hedging instruments					1,977
<b>Derivatives Not Designated as Hedging Instruments</b>					
FX derivative contracts	Prepaid expenses and other current assets		\$ 1,213	Accrued liabilities	1,869
Total derivatives not designated as hedging instruments			1,213		1,869
Total derivatives			<u>\$ 1,213</u>		<u>\$ 3,846</u>
<b>December 31, 2018</b>					
<b>Derivatives Designated as Hedging Instruments</b>		<b>Balance Sheet Location</b>	<b>Fair Value <sup>(1)</sup></b>	<b>Balance Sheet Location</b>	<b>Fair Value <sup>(1)</sup></b>
Interest rate swap contracts				Accrued liabilities	\$ 536
Interest rate swap contracts				Other long-term liabilities	329
FX derivative contracts				Accrued liabilities	1,354
Total derivatives designated as hedging instruments					2,219
<b>Derivatives Not Designated as Hedging Instruments</b>					
FX derivative contracts	Prepaid expenses and other current assets		\$ 236	Accrued liabilities	3,173
Total derivatives not designated as hedging instruments			236		3,173
Total derivatives			<u>\$ 236</u>		<u>\$ 5,392</u>

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

**Note 11. Leases**

We have operating leases primarily for (i) office space, (ii) manufacturing, warehouse and research and development facilities and (iii) vehicles. Our leases have remaining lease terms up to 12 years, some of which include options to extend the leases, and some of which include options to terminate the leases at our sole discretion. The components of operating lease assets, liabilities and costs are as follows (in thousands):

<b>Operating Lease Assets and Liabilities</b>	<b>September 30, 2019</b>
<b>Assets</b>	
Operating lease right-of-use assets	\$ 54,283
<b>Liabilities</b>	
Accrued liabilities and other	\$ 10,565
Long-term operating lease liabilities	44,724
<b>Total lease liabilities</b>	<b>\$ 55,289</b>

<b>Operating Lease Cost</b>	<b>Three Months Ended September 30, 2019</b>	<b>Nine Months Ended September 30, 2019</b>
Operating lease cost	\$ 3,391	\$ 10,600
Variable lease cost	225	651
Short-term lease cost	258	538
<b>Total lease cost</b>	<b>\$ 3,874</b>	<b>\$ 11,789</b>

Contractual maturities of our lease liabilities as of September 30, 2019, are as follows (in thousands):

Remaining 2019	\$ 2,728
2020	11,309
2021	9,411
2022	8,263
2023	6,913
Thereafter	21,866
Total lease payments	60,490
Less: Amount representing interest	5,201
<b>Present value of lease liabilities</b>	<b>\$ 55,289</b>

<b>Lease Term and Discount Rate</b>	<b>September 30, 2019</b>
Weighted Average Remaining Lease Term (in years)	7.3
Weighted Average Discount Rate	2.3%

<b>Other Information</b> (in thousands)	<b>Nine Months Ended September 30, 2019</b>
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows for operating leases	\$ 10,111
Operating lease assets obtained in exchange for lease liabilities	\$ 5,403

## Disclosures Related to Periods Prior to Adoption of Topic 842

On January 1, 2019, we adopted Topic 842 using the modified retrospective adoption approach, as noted in “Note 1. Unaudited Condensed Consolidated Financial Statements.” As required and as previously disclosed in our 2018 Form 10-K, the following table summarizes our future minimum operating lease payments as of December 31, 2018 (in thousands):

Less than one year	\$	11,986
One to three years		21,031
Three to five years		14,998
Thereafter		20,943
Total	\$	68,958

## Note 12. 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 Heater-Cooler 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

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 the 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, concurrent with the 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., was rolled out in Europe shortly thereafter, 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 us, the FDA concluded that we 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. The deep disinfection service was rolled out in Europe in the second half of 2015, and on April 12, 2018, the FDA agreed to allow us to move forward with the deep cleaning service in the U.S. thereby 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, 2019, the product remediation liability was \$7.4 million. Refer to "Note 5. 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. 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.

On March 29, 2019, we announced a settlement framework that provides for a comprehensive resolution of the personal injury cases pending in the multi-district litigation in U.S. federal court, the related class action pending in federal court, as well as certain cases in state courts across the United States. The agreement, which makes no admission of liability, is subject to certain conditions, including acceptance of the settlement by individual claimants and provides for a total payment of up to \$225 million to resolve the claims covered by the settlement. Per the agreed-upon terms, the first payment of \$135 million was paid into a qualified settlement fund in July 2019, and the remainder will be paid in January 2020. Cases covered by the settlement will be dismissed as amounts are disbursed to individual plaintiffs from the qualified settlement fund.

Cases in state courts in the U.S. and in jurisdictions outside the U.S. continue to progress. As of October 29, 2019, including the cases encompassed in the settlement framework described above that have not yet been dismissed, we are aware of approximately 100 filed and unfiled 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 or concealment, unjust enrichment, and violations of various state consumer protection statutes.

In the fourth quarter of 2018, we recognized a \$294.1 million provision, which represented our best estimate of the Company's liability for these matters. At September 30, 2019, the provision was \$153.0 million. While the amount accrued represents our best estimate, the actual liability for resolution of these matters remains uncertain and may vary from our estimate.

The changes in the litigation provision liability for the nine months ended September 30, 2019 were as follows (in thousands):

	<b>Litigation Provision Liability</b>
Total litigation provision liability at December 31, 2018	\$ 294,061
Payments	(140,823)
FX and other	(270)
Total litigation provision liability at September 30, 2019	152,968
Less current portion of litigation provision liability at September 30, 2019	121,468
Long-term portion of litigation provision liability at September 30, 2019	\$ 31,500

In July 2019, we entered into agreements with our insurance carriers to recover \$33.8 million under our product liability insurance policies related to the litigation involving our 3T device. The insurance recovery was received and recognized as insurance recovery on the condensed consolidated statements of income (loss) during the three and nine months ended September 30, 2019.

### *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 to the Supreme Court. In addition, the Bankruptcy Court of Milan’s decision has been appealed.

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 \$318,000 for legal fees. The Public Administrations appealed the 2016 Decision to the Court of Appeal of Milan. On March 5, 2019, the Court of Appeal issued a partial decision on the merits declaring Sorin/LivaNova jointly liable with SNIA for SNIA’s environmental liabilities in an amount up to the fair value of the net worth received by Sorin as a result of the Sorin spin-off. Additionally the Court issued a separate order, staying the proceeding until a panel of three experts can assess the environmental damages, the cost of clean-up, and the costs that the Public Administrations has already borne for the clean-up of the sites to allow the Court to decide on the second claim of the Public Administrations against LivaNova, (i.e., to refund the Public Administrations for the SNIA environmental liabilities). In the interim, we are appealing the decision to the Italian Supreme Court (Corte di Cassazione).

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 before the Commercial Division of the Court of Milan to the merger of Sorin and Cyberonics, Inc., the predecessor companies to LivaNova. The Court authorized the merger and the Public Administrations did not appeal that 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 €400,000 (approximately \$436,000 as of September 30, 2019) 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 annulled the penalty for frivolous litigation and reduced the overall contribution to legal fees to €84,000 (approximately \$92,000 as of September 30,

2019) for legal fees. The Public Administrations subsequently filed an appeal with the Supreme Court against the decision of the Court of Appeal of Milan. The proceedings before the Supreme Court are presently pending, and no decision is expected in 2019. 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 November 12, 2018, we petitioned the Patent Trial and Appeal Board of the U.S. Patent and Trademark Office (the “Patent Office”) for an *inter partes* review (“IPR”) of the validity of the ‘307 patent. The Patent Office instituted an IPR of all the challenged claims. 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 on October 30, 2009, the Regional Internal Revenue Office of Lombardy (the “Internal Revenue Office”) informed Sorin Group Italia S.r.l. that, among several issues, it was disallowing in part (for a total of €102.6 million (approximately \$111.9 million as of September 30, 2019), 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 2004. 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. On November 16, 2018, the Supreme Court returned the decisions for years 2005 and 2006 to the previous-level Court (Regional Tax Court) due to lack of substance of the motivation given in the 2<sup>nd</sup> level judgments that were appealed.

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 \$68.2 million as of September 30, 2019). 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 for the full amount of the potential liability. On May 31, 2019, we filed an application to settle the litigation according to law N. 136/2018 and paid the required settlement balance of €1.9 million. As per law N. 136/2018, the Italian Revenue Agency will review the settlement and decide to accept or reject the application by July 31, 2020. Until the settlement is accepted by the Italian Revenue Agency, we will continue to reserve for the full amount of the potential liability, by recognizing a €15.4 million reserve for uncertain tax position (\$16.8 million as of September 30, 2019), net of the settlement payment.

### **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 13. Stockholders' Equity

The tables below present the condensed consolidated statement of stockholders' equity as of and for the three and nine months ended September 30, 2019 and 2018 (in thousands):

	Ordinary Shares	Ordinary Shares - Amount	Additional Paid- In Capital	Treasury Stock	Accumulated Other Comprehensive (Loss) Income	Retained Deficit	Total Stockholders' Equity
June 30, 2019	49,380	\$ 76,217	\$ 1,717,220	\$ (1,292)	\$ (13,174)	\$ (295,643)	\$ 1,483,328
Stock-based compensation plans	1	—	8,262	10	—	—	8,272
Net income	—	—	—	—	—	32,118	32,118
Other comprehensive loss	—	—	—	—	(28,436)	—	(28,436)
September 30, 2019	49,381	\$ 76,217	\$ 1,725,482	\$ (1,282)	\$ (41,610)	\$ (263,525)	\$ 1,495,282

  

June 30, 2018	48,661	\$ 75,269	\$ 1,744,262	\$ (109)	\$ (2,633)	\$ (33,755)	\$ 1,783,034
Stock-based compensation plans	33	42	6,624	81	—	—	6,747
Net loss	—	—	—	—	—	(7,177)	(7,177)
Other comprehensive income	—	—	—	—	2,388	—	2,388
September 30, 2018	48,694	\$ 75,311	\$ 1,750,886	\$ (28)	\$ (245)	\$ (40,932)	\$ 1,784,992

  

	Ordinary Shares	Ordinary Shares - Amount	Additional Paid- In Capital	Treasury Stock	Accumulated Other Comprehensive (Loss) Income	Retained Deficit	Total Stockholders' Equity
December 31, 2018	49,323	\$ 76,144	\$ 1,705,111	\$ (1,462)	\$ (24,476)	\$ (251,579)	\$ 1,503,738
Stock-based compensation plans	58	73	20,371	180	—	—	20,624
Net loss	—	—	—	—	—	(11,946)	(11,946)
Other comprehensive loss	—	—	—	—	(17,134)	—	(17,134)
September 30, 2019	49,381	\$ 76,217	\$ 1,725,482	\$ (1,282)	\$ (41,610)	\$ (263,525)	\$ 1,495,282

  

December 31, 2017	48,290	\$ 74,750	\$ 1,735,048	\$ (133)	\$ 45,313	\$ (39,664)	\$ 1,815,314
Adoption of ASU No. 2016-16	—	—	—	—	—	(22,430)	(22,430)
Share issuances	300	422	—	(422)	—	—	—
Stock-based compensation plans	104	139	15,838	527	—	—	16,504
Net income	—	—	—	—	—	21,162	21,162
Other comprehensive loss	—	—	—	—	(45,558)	—	(45,558)
September 30, 2018	48,694	\$ 75,311	\$ 1,750,886	\$ (28)	\$ (245)	\$ (40,932)	\$ 1,784,992



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, 2019 and 2018 (in thousands):

	Change in Unrealized Gain (Loss) on Derivatives	Foreign Currency Translation Adjustments Gain (Loss) <sup>(1)</sup>	Total
<b>As of December 31, 2018</b>	<b>\$ (944)</b>	<b>\$ (23,532)</b>	<b>\$ (24,476)</b>
Other comprehensive income (loss) before reclassifications, before tax	933	(16,628)	(15,695)
Tax expense	(224)	—	(224)
Other comprehensive income (loss) before reclassifications, net of tax	709	(16,628)	(15,919)
Reclassification of gain from accumulated other comprehensive income (loss), before tax	(1,598)	—	(1,598)
Reclassification of tax expense	383	—	383
Reclassification of gain from accumulated other comprehensive income (loss), after tax	(1,215)	—	(1,215)
Net current-period other comprehensive loss, net of tax	(506)	(16,628)	(17,134)
<b>As of September 30, 2019</b>	<b>\$ (1,450)</b>	<b>\$ (40,160)</b>	<b>\$ (41,610)</b>
<b>As of December 31, 2017</b>	<b>\$ (919)</b>	<b>\$ 46,232</b>	<b>\$ 45,313</b>
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 (loss), before tax	(77)	(9,011) <sup>(2)</sup>	(9,088)
Reclassification of tax expense	18	—	18
Reclassification of gain from accumulated other comprehensive income (loss), after tax	(59)	(9,011)	(9,070)
Net current-period other comprehensive income (loss), net of tax	180	(45,738)	(45,558)
<b>As of September 30, 2018</b>	<b>\$ (739)</b>	<b>\$ 494</b>	<b>\$ (245)</b>

(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 14. Stock-Based Incentive Plans

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Service-based restricted stock units (“RSUs”)	\$ 3,583	\$ 3,368	\$ 10,428	\$ 8,158
Service-based stock appreciation rights (“SARs”)	2,896	2,491	7,804	6,514
Market performance-based restricted stock units	757	509	2,146	1,814
Operating performance-based restricted stock units	983	909	2,752	2,941
Employee stock purchase plan	312	—	997	—
Total stock-based compensation expense	\$ 8,531	\$ 7,277	\$ 24,127	\$ 19,427

During the nine months ended September 30, 2019, we issued stock-based compensatory awards with terms 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, 2021 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, 2021.

Compensation expense related to awards granted during 2019 for the three and nine months ended September 30, 2019 was \$3.6 million and \$6.8 million, respectively.

On January 1, 2019, we initiated the LivaNova Global Employee Share Purchase Plan (“ESPP”). Compensation expense related to the ESPP for the three and nine months ended September 30, 2019 was \$0.3 million and \$1.0 million, respectively.

Stock-based compensation agreements issued during the nine months ended September 30, 2019, 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, 2019	
	Shares	Weighted Average Grant Date Fair Value
Service-based SARs	592	\$ 31.22
Service-based RSUs	286	\$ 93.03
Market performance-based RSUs	44	\$ 100.41
Operating performance-based RSUs	44	\$ 96.59

## Note 15. Income Taxes

Our effective income tax rate from continuing operations for the three and nine months ended September 30, 2019 was (49.6)% and 65.9%, respectively, compared with 29.8% and 0.6% the three and nine months ended September 30, 2018, respectively. 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 and nine months ended September 30, 2018, the change in the effective tax rate for the three and nine months ended September 30, 2019 was primarily attributable to a release of uncertain tax positions and a U.S. federal tax benefit from a return to provision adjustment, partly offset by the establishment of a valuation allowance for a portion of the U.S. state net operating losses and attributes.

We operate in multiple jurisdictions throughout the world, and our tax returns are periodically audited or subjected to review by tax authorities. As a result, there is an uncertainty in income taxes recognized in our financial statements. Tax benefits totaling \$16.6 million and \$22.9 million were unrecognized as of September 30, 2019 and December 31, 2018, respectively. It is reasonably possible that, within the next twelve months, due to the settlement of uncertain tax positions with various tax authorities and the expiration of statutes of limitations, unrecognized tax benefits could decrease by up to approximately \$1.3 million.

We monitor income tax developments in countries where we conduct business. In 2017, the U.S. enacted the “Tax Cuts and Jobs Act” (the “Tax Act”). To determine the full effects of the Tax Act, we are awaiting the finalization of several proposed U.S. Treasury regulations that were issued during 2018, as well as additional regulations to be proposed and finalized pursuant to the U.S. Treasury’s expanded regulatory authority under the Tax Act. It is also possible that technical correction legislation concerning the Tax Act could retroactively affect tax liabilities for 2018. In addition, state legislative changes addressing conformity to the Tax Act are still pending.

## Note 16. Net Income 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, 2019 and 2018 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Basic weighted average shares outstanding	48,395	48,637	48,329	48,484
Add effects of share-based compensation instruments <sup>(1)</sup>	425	—	—	943
Diluted weighted average shares outstanding	48,820	48,637	48,329	49,427

- (1) Excluded from the computation of diluted earnings per share were stock options, SARs and restricted share units totaling 1.4 million and 2.8 million for the three months ended September 30, 2019 and 2018, respectively, and 3.1 million and 0.5 million for the nine months ended September 30, 2019 and 2018, respectively, because to include them would have been anti-dilutive under the treasury stock method.

## Note 17. 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, developing and executing our strategy, 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 includes temporary life support product kits that can include a combination of pumps, oxygenators, and cannulae. On June 12, 2019, we acquired the minimally invasive cardiac surgery instruments business from Miami Instruments, which are integrated into our Cardiovascular business franchise as part of our Heart Valves portfolio.

Our 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 (“TRD”). 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. Our Neuromodulation segment 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.

“Other” includes corporate shared service expenses for finance, legal, human resources and information technology and corporate business development and New Ventures.

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: U.S., 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,	
	2019	2018	2019	2018
<b>Cardiopulmonary</b>				
United States	\$ 39,054	\$ 40,396	\$ 119,580	\$ 120,980
Europe	30,052	32,186	99,933	104,972
Rest of world	50,908	55,358	152,650	163,757
	120,014	127,940	372,163	389,709
<b>Heart Valves</b>				
United States	4,626	6,145	13,660	18,828
Europe	9,572	9,421	30,757	33,400
Rest of world	14,679	16,980	43,484	45,162
	28,877	32,546	87,901	97,390
<b>Advanced Circulatory Support</b>				
United States	6,313	5,947	22,290	11,415
Europe	186	38	497	391
Rest of world	36	90	310	284
	6,535	6,075	23,097	12,090
<b>Cardiovascular</b>				
United States	49,993	52,488	155,530	151,223
Europe	39,810	41,645	131,187	138,763
Rest of world	65,623	72,428	196,444	209,203
	155,426	166,561	483,161	499,189
<b>Neuromodulation</b>				
United States	88,433	87,194	245,870	254,581
Europe	10,425	9,497	34,080	31,731
Rest of world	13,685	8,252	31,511	23,128
	112,543	104,943	311,461	309,440
<b>Other</b>				
	641	578	1,958	1,349
<b>Totals</b>				
United States	138,426	139,682	401,400	405,804
Europe <sup>(1)</sup>	50,235	51,142	165,267	170,494
Rest of world	79,949	81,258	229,913	233,680
Total <sup>(2)</sup>	\$ 268,610	\$ 272,082	\$ 796,580	\$ 809,978

(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.

The table below presents a reconciliation of segment income from continuing operations to consolidated income from continuing operations before tax (in thousands):

Operating Income (Loss) from Continuing Operations	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Cardiovascular <sup>(1)</sup>	\$ 36,180	\$ 9,783	\$ 47,289	\$ 36,378
Neuromodulation <sup>(2)</sup>	30,010	36,432	52,260	132,377
Other	(21,869)	(29,420)	(75,845)	(89,479)
<b>Total reportable segment income from continuing operations</b>	<b>44,321</b>	<b>16,795</b>	<b>23,704</b>	<b>79,276</b>
Merger and integration expenses	6,716	12,659	14,345	20,028
Restructuring expenses	698	436	4,563	2,793
Amortization of intangibles	11,146	9,457	29,690	28,075
Operating income (loss) from continuing operations	25,761	(5,757)	(24,894)	28,380
Interest income	151	184	624	863
Interest expense	(4,774)	(2,633)	(10,490)	(7,750)
Gain on acquisition	—	—	—	11,484
Foreign exchange and other gains (losses)	327	(727)	(795)	(1,070)
<b>Income (loss) from continuing operations before tax</b>	<b>\$ 21,465</b>	<b>\$ (8,933)</b>	<b>\$ (35,555)</b>	<b>\$ 31,907</b>

- (1) Results for the three and nine months ended September 30, 2019 include an insurance recovery of \$33.8 million. Refer to “Note 12. Commitments and Contingencies” for additional information.
- (2) Results for the nine months ended September 30, 2019 include the impairment of intangible assets of \$50.3 million.

Assets by reportable segment are as follows (in thousands):

Assets	September 30, 2019	December 31, 2018
Cardiovascular	\$ 1,511,639	\$ 1,532,825
Neuromodulation	696,666	731,840
Other	301,636	285,036
<b>Total assets</b>	<b>\$ 2,509,941</b>	<b>\$ 2,549,701</b>

Capital expenditures by segment are as follows (in thousands):

Capital expenditures	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Cardiovascular	\$ 5,178	\$ 8,032	\$ 13,564	\$ 15,757
Neuromodulation	136	512	666	1,359
Other	691	4,359	2,571	7,058
Discontinued operations	—	—	—	925
<b>Total</b>	<b>\$ 6,005</b>	<b>\$ 12,903</b>	<b>\$ 16,801</b>	<b>\$ 25,099</b>

The changes in the carrying amount of goodwill by reportable segment for the nine months ended September 30, 2019 were as follows (in thousands):

	Neuromodulation	Cardiovascular	Other	Total
December 31, 2018	\$ 398,539	\$ 515,859	\$ 42,417	\$ 956,815
Goodwill as a result of acquisitions	—	1,550	—	1,550
Measurement period adjustments	—	(3,326)	—	(3,326)
Foreign currency adjustments	215	(9,710)	—	(9,495)
<b>September 30, 2019</b>	<b>\$ 398,754</b>	<b>\$ 504,373</b>	<b>\$ 42,417</b>	<b>\$ 945,544</b>

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

<b>PP&amp;E</b>	<b>September 30, 2019</b>	<b>December 31, 2018</b>
United States	\$ 63,473	\$ 68,862
Europe	106,066	112,376
Rest of world	9,968	10,162
Total	<u>\$ 179,507</u>	<u>\$ 191,400</u>

#### **Note 18. Supplemental Financial Information**

Inventories consisted of the following (in thousands):

	<b>September 30, 2019</b>	<b>December 31, 2018</b>
Raw materials	\$ 45,239	\$ 40,387
Work-in-process	18,245	15,999
Finished goods	104,272	97,149
	<u>\$ 167,756</u>	<u>\$ 153,535</u>

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 \$10.9 million and \$11.6 million at September 30, 2019 and December 31, 2018, respectively.

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

	<b>September 30, 2019</b>	<b>December 31, 2018</b>
Contingent consideration <sup>(1)</sup>	\$ 24,802	\$ 18,530
CRM purchase price adjustment payable to MicroPort Scientific Corporation	14,891	14,891
Legal and administrative costs	13,200	9,189
Operating lease liabilities <sup>(2)</sup>	10,565	—
Product remediation <sup>(3)</sup>	7,444	13,945
Contract liabilities	5,628	3,304
Research and development costs	5,109	1,841
Provisions for agents, returns and other	4,038	4,934
Restructuring related liabilities <sup>(4)</sup>	2,621	9,393
Derivative contract liabilities <sup>(5)</sup>	3,455	5,063
Other amounts payable to MicroPort Scientific Corporation	852	9,319
Other accrued expenses	35,851	33,876
	<u>\$ 128,456</u>	<u>\$ 124,285</u>

(1) Refer to “Note 8. Fair Value Measurements”

(2) Refer to “Note 11. Leases”

(3) Refer to “Note 5. Product Remediation Liability”

(4) Refer to “Note 4. Restructuring”

(5) Refer to “Note 10. Derivatives and Risk Management”

As of September 30, 2019 and December 31, 2018, contract liabilities of \$7.1 million and \$4.8 million, respectively, are included within accrued liabilities and other long-term liabilities on the condensed consolidated balance sheets.

## Note 19. New Accounting Pronouncements

### Adoption of New Accounting Pronouncements

The following table provides a description of our adoption of new Accounting Standards Updates (“ASUs”) issued by the FASB and the impact of the adoption on our condensed financial statements:

Issue Date & Standard	Description	Date of Adoption	Effect on Financial Statements or Other Significant Matters
<u>February 2016</u> ASU No. 2016-02, Leases (Topic 842) and subsequent amendments	The standard requires lessees to recognize most leases on the balance sheet as lease liabilities with corresponding right-of-use (“ROU”) assets and to provide enhanced disclosures. Furthermore, from a lessor perspective, certain of our agreements that allow the customer to use, rather than purchase, our medical devices met the criteria of being a lease in accordance with the new standard.	January 1, 2019	Adoption of the new standard resulted in the recognition of ROU assets and lease liabilities of approximately \$60 million as of January 1, 2019. Refer to “Note 11. Leases.”
<u>June 2018</u> ASU No. 2018-07, Compensation—Stock Compensation (Topic 718): <i>Improvements to Nonemployee Share-Based Payment Accounting</i>	This update simplifies the accounting for non-employee share-based payment transactions.	January 1, 2019	There was no material impact to our condensed consolidated financial statements as a result of adopting this ASU.

## Future Adoption of New Accounting Pronouncements

The following table provides a description of future adoptions of new accounting standards that may have an impact on our financial statements when adopted:

Issue Date & Standard	Description	Projected Date of Adoption	Effect on Financial Statements or Other Significant Matters
<u>June 2016</u> ASU No. 2016-13, <i>Financial Instruments—Credit Losses</i> (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 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. Early adoption is permitted.	January 1, 2020	We are currently evaluating the effect this standard will have on our condensed consolidated financial statements and related disclosures.
<u>January 2017</u> ASU No. 2017-04, <i>Intangibles-Goodwill and Other</i> (Topic 350): <i>Simplifying the Test for Goodwill Impairment</i>	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. Early adoption is permitted.	January 1, 2020	We are currently evaluating the effect this standard will have on our condensed consolidated financial statements and related disclosures.
<u>August 2018</u> ASU No. 2018-13, <i>Fair Value Measurement</i> (Topic 820): <i>Changes to the Disclosure Requirements for Fair Value Measurement</i>	This update removes, modifies and adds certain disclosure requirements related to fair value measurements. Early adoption is permitted.	January 1, 2020	We do not expect the adoption of this update to have a material effect on our condensed consolidated financial statement disclosures.
<u>August 2018</u> ASU No. 2018-14, <i>Compensation—Retirement Benefits—Defined Benefit Plans—General</i> (Subtopic 715-20): <i>Changes to the Disclosure Requirements for Defined Benefit Plans</i>	This update adds and removes certain disclosure requirements related to defined benefit plans. This ASU is to be implemented on a retrospective basis for all periods presented with early adoption permitted.	January 1, 2021	We do not expect the adoption of this update to have a material effect on our condensed consolidated financial statement disclosures.
<u>August 2018</u> ASU No. 2018-15, <i>Intangibles—Goodwill and Other—Internal-Use Software</i> (Subtopic 350-40): <i>Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract</i>	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 ASU is to be applied either retrospectively or prospectively with early adoption permitted.	January 1, 2020	We do not expect the adoption of this update to have a material effect on our condensed 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 2018 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 2018 Form 10-K and elsewhere in this Quarterly Report on Form 10-Q.

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, England. 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.

### **Acquisition**

On June 12, 2019, we acquired the minimally invasive cardiac surgery instruments business from Miami Instruments for cash consideration of up to \$17.0 million. The related operations have been integrated into our Cardiovascular business franchise as part of our Heart Valves portfolio. Cash of \$10.8 million was paid at closing with up to \$6.0 million in contingent consideration based on achieving certain milestones. In connection with this acquisition, we recognized \$14.7 million in developed technology and IPR&D intangible assets and \$1.5 million in goodwill.

### **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. The results of operations of CRM are reflected as discontinued operations for all periods presented in this Quarterly Report on Form 10-Q. Refer to "Note 3. Discontinued Operations" to the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

### **Business Franchises**

LivaNova is comprised of two principal business franchises, which are also our reportable segments: Cardiovascular and Neuromodulation, corresponding to our primary therapeutic areas. Other corporate activities include corporate shared service expenses for finance, legal, human resources, information technology and New Ventures.

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**

Our Cardiovascular business franchise is engaged in the development, production and sale of cardiopulmonary products, heart valves and advanced circulatory support products. 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 includes temporary life support product kits that can include a combination of pumps, oxygenators, and cannulae.

#### *Product Remediation Plan*

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 and issued inspectional observations on FDA's Form-483 applicable to our Munich, Germany facility.

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. For further information, please refer to "Note 5. Product Remediation Liability" in our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

#### *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. 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.

On March 29, 2019, we announced a settlement framework that provides for a comprehensive resolution of the personal injury cases pending in the multi-district litigation in U.S. federal court, the related class action pending in federal court, as well as certain cases in state courts across the United States. The agreement, which makes no admission of liability, is subject to certain conditions, including acceptance of the settlement by individual claimants and provides for a total payment of up to \$225 million to resolve the claims covered by the settlement. Per the agreed-upon terms, the first payment of \$135 million was paid into a qualified settlement fund in July 2019, and the remainder will be paid in January 2020. Cases covered by the settlement will be dismissed as amounts are disbursed to individual plaintiffs from the qualified settlement fund.

Cases in state courts in the U.S. and in jurisdictions outside the U.S. continue to progress. As of October 29, 2019, including the cases encompassed in the settlement framework described above that have not yet been dismissed, we are aware of approximately 100 filed and unfiled 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 or concealment, unjust enrichment, and violations of various state consumer protection statutes.

In the fourth quarter of 2018, we recognized a \$294.1 million provision, which represented our best estimate of the Company's liability for these matters. At September 30, 2019, the provision was \$153.0 million. For further information refer to "Note 12. Commitments and Contingencies."

In July 2019, we entered into agreements with our insurance carriers to recover \$33.8 million under our product liability insurance policies related to the litigation involving our 3T device. The insurance recovery was received and recognized as insurance recovery on the condensed consolidated statements of income (loss) during the three and nine months ended September 30, 2019.

#### *Heart Valves*

In February 2019, Japan's Ministry of Health, Labour and Welfare granted national reimbursement for the Perceval sutureless aortic heart valve to treat aortic valve disease.

#### *Advanced Circulatory Support*

In July 2019, the FDA approved our LifeSPARC system, a new generation of the Advanced Circulatory Support pump and controller. We expect a limited commercial release in the U.S. by the end of 2019.

#### *Cardiopulmonary*

In July 2019, we launched Bi-Flow, our innovative arterial femoral cannula. Bi-Flow received CE Mark approval earlier in the year and is the only bidirectional arterial cannula designed to prevent leg ischemia during cardiac surgery procedures requiring femoral artery cannulation.

## Neuromodulation Update

Our Neuromodulation business franchise designs, develops and markets neuromodulation therapy for the treatment of drug-resistant epilepsy, TRD and obstructive sleep apnea. We are also focused on the development and clinical testing of the VITARIA System for treating heart failure through vagus nerve stimulation.

### *Depression*

In February 2019, the U.S. Centers for Medicare & Medicaid Services (“CMS”) finalized its National Coverage Determination (“NCD”) for the LivaNova Vagus Nerve Stimulation Therapy (“VNS Therapy”) System for TRD. This final decision initiates coverage for Medicare beneficiaries through Coverage with Evidence Development (“CED”) when offered in a CMS-approved, double-blind, randomized, placebo-controlled trial with a follow-up duration of at least one year, as well as the coverage of VNS Therapy device replacement. The CED also includes the possibility to extend the study to a prospective longitudinal study.

In September 2019, CMS accepted the protocol for our RECOVER clinical study, evaluating VNS Therapy for treatment-resistant depression. RECOVER is a double-blind randomized, placebo-controlled study with a follow-up duration of at least one year. The CED framework also includes the possibility to extend the study to a prospective registry. RECOVER will include up to 500 unipolar and up to 500 bipolar patients at a maximum of 100 sites in the United States. On September 27, 2019, the first patient was enrolled in the RECOVER study. Separate from the study, CMS is also covering device replacement for patients with a VNS Therapy device for TRD.

## 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 2018 Form 10-K, refer to “Significant Accounting Policies” within “Note 1. Unaudited Condensed Consolidated Financial Statements” 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 19. New Accounting Pronouncements” contained in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

## Other

### *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 and began the process of negotiating the future terms of the UK’s relationship with the EU. Brexit could adversely affect UK, regional (including European) and worldwide economic and market conditions and could contribute to instability in global financial and foreign exchange markets, including volatility in the value of the British Pound and Euro. We have foreign exchange exposure management programs designed to help minimize the impact from foreign currency exchange rate movements. For the three months ended September 30, 2019 and 2018, net sales generated from our European operations constituted approximately 18.7% and 18.8%, respectively, of total net sales. For the nine months ended September 30, 2019 and 2018, net sales generated from our European operations constituted approximately 20.7% and 21.0%, respectively.

Negotiations between the UK and the EU continue about provisions of the withdrawal agreement. Unless the deadline is further extended, the UK will leave the EU on January 31, 2020. 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 overall business, financial condition and results of operations. For additional information on how Brexit could affect our business, see “Part I, Item 1A Risk Factors - *The UK’s vote in favor of withdrawing from the EU could lead to increased market volatility and make it more difficult for us to do business in Europe or have other adverse effects on our business*” of our 2018 Form 10-K.

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 ultimately 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 U.S., 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 change materially, Brexit may have a material adverse impact on our future financial results and results of operations. We continue to monitor and assess the potential impact of this event.

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 group finance exemptions (“GFE”) 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. On April 2, 2019, the EC concluded that “when financing income from a foreign group company, channeled through an offshore subsidiary, is financed with UK connected capital and there are no UK activities involved in generating the finance profits, the group finance exemption is justified and does not constitute State aid under EU rules.” However, in relation to Significant People Functions, “when financing income from a foreign group company, channeled through an offshore subsidiary, derives from UK activities, the group finance exemption is not justified and constitutes State aid under EU rules.” Her Majesty’s Revenue and Customs (“HMRC”) has stated that they do not consider the timing and form of the UK’s exit from the EU will have a practical impact on the requirement to recover the alleged aid. On June 14, 2019, the UK filed an appeal to the Commission’s decision. HMRC will still proceed to identify Chapter 9 claims and collect the alleged state aid during the appeal process. Based upon our assessment of the issue and the limited level of UK activities involved in our financing, no uncertain tax position reserve has been recognized related to this matter.

## 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, 2019, as compared to the three and nine months ended September 30, 2018.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net sales	\$ 268,610	\$ 272,082	\$ 796,580	\$ 809,978
Costs and expenses:				
Cost of sales - exclusive of amortization	86,128	94,300	245,324	270,891
Product remediation	3,076	3,434	11,136	8,691
Selling, general and administrative	123,015	115,136	375,932	342,736
Research and development	45,904	42,417	124,023	108,384
Merger and integration expenses	6,716	12,659	14,345	20,028
Restructuring expenses	698	436	4,563	2,793
Impairment of intangible assets	—	—	50,295	—
Amortization of intangibles	11,146	9,457	29,690	28,075
Insurance recovery	(33,834)	—	(33,834)	—
Operating income (loss) from continuing operations	25,761	(5,757)	(24,894)	28,380
Interest income	151	184	624	863
Interest expense	(4,774)	(2,633)	(10,490)	(7,750)
Gain on acquisition	—	—	—	11,484
Foreign exchange and other gains (losses)	327	(727)	(795)	(1,070)
Income (loss) from continuing operations before tax	21,465	(8,933)	(35,555)	31,907
Income tax (benefit) expense	(10,653)	(2,660)	(23,431)	203
Losses from equity method investments	—	—	—	(627)
Net income (loss) from continuing operations	32,118	(6,273)	(12,124)	31,077
Net (loss) income from discontinued operations, net of tax	—	(904)	178	(9,915)
Net income (loss)	\$ 32,118	\$ (7,177)	\$ (11,946)	\$ 21,162

## Net Sales

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	% Increase (Decrease)	2019	2018	% Increase (Decrease)
<b>Cardiopulmonary</b>						
United States	\$ 39,054	\$ 40,396	(3.3)%	\$ 119,580	\$ 120,980	(1.2)%
Europe	30,052	32,186	(6.6)%	99,933	104,972	(4.8)%
Rest of world	50,908	55,358	(8.0)%	152,650	163,757	(6.8)%
	120,014	127,940	(6.2)%	372,163	389,709	(4.5)%
<b>Heart Valves</b>						
United States	4,626	6,145	(24.7)%	13,660	18,828	(27.4)%
Europe	9,572	9,421	1.6 %	30,757	33,400	(7.9)%
Rest of world	14,679	16,980	(13.6)%	43,484	45,162	(3.7)%
	28,877	32,546	(11.3)%	87,901	97,390	(9.7)%
<b>Advanced Circulatory Support</b>						
United States	6,313	5,947	6.2 %	22,290	11,415	95.3 %
Europe	186	38	389.5 %	497	391	27.1 %
Rest of world	36	90	(60.0)%	310	284	9.2 %
	6,535	6,075	7.6 %	23,097	12,090	91.0 %
<b>Cardiovascular</b>						
United States	49,993	52,488	(4.8)%	155,530	151,223	2.8 %
Europe	39,810	41,645	(4.4)%	131,187	138,763	(5.5)%
Rest of world	65,623	72,428	(9.4)%	196,444	209,203	(6.1)%
	155,426	166,561	(6.7)%	483,161	499,189	(3.2)%
<b>Neuromodulation</b>						
United States	88,433	87,194	1.4 %	245,870	254,581	(3.4)%
Europe	10,425	9,497	9.8 %	34,080	31,731	7.4 %
Rest of world	13,685	8,252	65.8 %	31,511	23,128	36.2 %
	112,543	104,943	7.2 %	311,461	309,440	0.7 %
<b>Other</b>						
	641	578	10.9 %	1,958	1,349	45.1 %
<b>Totals</b>						
United States	138,426	139,682	(0.9)%	401,400	405,804	(1.1)%
Europe <sup>(1)</sup>	50,235	51,142	(1.8)%	165,267	170,494	(3.1)%
Rest of world	79,949	81,258	(1.6)%	229,913	233,680	(1.6)%
Total	\$ 268,610	\$ 272,082	(1.3)%	\$ 796,580	\$ 809,978	(1.7)%

(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 table below presents segment income from continuing operations (in thousands, except for percentages):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2019	2018	% Change	2019	2018	% Change
Cardiovascular	\$ 36,180	\$ 9,783	269.8 %	\$ 47,289	\$ 36,378	30.0 %
Neuromodulation	30,010	36,432	(17.6)%	52,260	132,377	(60.5)%
Other	(21,869)	(29,420)	(25.7)%	(75,845)	(89,479)	(15.2)%
Total reportable segment income from continuing operations <sup>(1)</sup>	\$ 44,321	\$ 16,795	163.9 %	\$ 23,704	\$ 79,276	(70.1)%

(1) For a reconciliation of segment income from continuing operations to income (loss) from continuing operations before tax refer to “Note 17. Geographic and Segment Information” in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

### Cardiovascular

Cardiovascular net sales for the three and nine months ended September 30, 2019 compared to the three and nine months ended September 30, 2018 decreased 6.7% and 3.2%, respectively. The decline in net sales for the three month period was due to declines in Cardiopulmonary and Heart Valves sales of 6.2% and 11.3%, respectively. Cardiopulmonary sales of \$120.0 million were negatively impacted as a result of exiting a Canadian distribution agreement on January 1, 2019 that accounted for \$8.0 million in sales during the three months ended September 30, 2018. Growth in oxygenator and cannula sales was offset by a decline in heart-lung machine sales and the impacts of foreign currency. Heart Valves sales declined primarily as a result of softness in the U.S. and the impacts of foreign currency. The decline in Cardiovascular net sales for the nine month period was due to declines in Cardiopulmonary and Heart Valves sales of 4.5% and 9.7%, respectively, partially offset by a \$11.0 million increase in Advanced Circulatory Support sales due to strong growth in the first half of 2019 and the inclusion of the operating results of TandemLife starting from the acquisition date in April 2018. Cardiopulmonary sales of \$372.2 million were negatively impacted as a result of exiting a Canadian distribution agreement on January 1, 2019 that accounted for \$24.4 million in sales during the nine months ended September 30, 2018 offset by growth in oxygenator sales in the Rest of world region. Heart Valves sales were negatively impacted by declines tissue valve sales and the impacts of foreign currency.

Cardiovascular operating income for the three and nine months ended September 30, 2019 compared to the three and nine months ended September 30, 2018 increased primarily due to receipt of insurance recovery proceeds related to the litigation involving our 3T device of \$33.8 million and the amortization of inventory step up value associated with the acquisition of TandemLife of \$4.0 million and \$8.0 million for the three and nine months ended September 30, 2018, respectively, partially offset by increased litigation expenses associated with our 3T device and a decrease in net sales. Operating income for the nine months ended September 30, 2019 was also negatively impacted by expenses associated with the expiration of a contract with one of our distributors.

### Neuromodulation

Neuromodulation net sales for the three and nine months ended September 30, 2019 compared to the three and nine months ended September 30, 2018 increased 7.2% and 0.7%, respectively. The increase in net sales for the three month period was due to strong growth in the Europe and Rest of world regions. The growth in Europe was attributable to the continued adoption of Sentiva and a strong performance in the UK, France, Germany and Spain, while the sales growth in the Rest of world region was driven by a strong performance in the Middle East, China, Eastern Europe, and Brazil from our commercial expansion and go to market strategies. Additionally, U.S sales grew 1.4% as the competitive dynamics and sales force turnover experienced during the first quarter of 2019 continue to moderate. The increase in sales for the nine month period was due to strong growth in the Europe and Rest of world regions partially offset by weakness in the U.S. market principally due to competitive dynamics and sales force turnover during the first half of 2019.

Neuromodulation operating income for the three months ended September 30, 2019 compared to the three months ended September 30, 2018 decreased due to increased costs associated with changes in the fair value of contingent consideration, increased selling costs in the U.S. and increased R&D expenses associated with TRD and heart failure, partially offset by an increase in net sales. Neuromodulation operating income for the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018 decreased primarily due to a \$50.3 million impairment of an IPR&D asset associated with obstructive sleep apnea, increased selling costs in the U.S. and increased R&D expenses associated with TRD and heart failure.

## 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,		
	2019	2018	Change	2019	2018	Change
Cost of sales - exclusive of amortization	32.1 %	34.7%	(2.6)%	30.8 %	33.4%	(2.6)%
Product remediation	1.1 %	1.3%	(0.2)%	1.4 %	1.1%	0.3 %
Selling, general and administrative	45.8 %	42.3%	3.5 %	47.2 %	42.3%	4.9 %
Research and development	17.1 %	15.6%	1.5 %	15.6 %	13.4%	2.2 %
Merger and integration expenses	2.5 %	4.7%	(2.2)%	1.8 %	2.5%	(0.7)%
Restructuring expenses	0.3 %	0.2%	0.1 %	0.6 %	0.3%	0.3 %
Impairment of intangible assets	— %	—%	— %	6.3 %	—%	6.3 %
Amortization of intangibles	4.1 %	3.5%	0.6 %	3.7 %	3.5%	0.2 %
Insurance recovery	(12.6)%	—%	(12.6)%	(4.2)%	—%	(4.2)%

## Cost of Sales - Exclusive of Amortization

Cost of sales consisted primarily of direct labor, allocated manufacturing overhead and the acquisition cost of raw materials and components. Cost of sales as a percentage of net sales for the three and nine months ended September 30, 2019 compared to the three and nine months ended September 30, 2018 decreased primarily due to the amortization of inventory step up value associated with the acquisition of TandemLife of \$4.0 million and \$8.0 million for the three and nine months ended September 30, 2018, respectively, reduced expense associated with changes in the fair value of sales-based contingent consideration arrangements, favorable product mix and pricing and the impacts of foreign currency.

## 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 for the three and nine months ended September 30, 2019 compared to the three and nine months ended September 30, 2018 increased primarily due to additional litigation expenses related to our 3T devices, the full impact of expanding Advanced Circulatory Support commercial capabilities, increased investment in Neuromodulation, strengthening our commercial organization in international markets and costs associated with material weakness remediation. SG&A expenses for the nine months ended September 30, 2019 were also negatively affected by expenses associated with the expiration of a contract with one of our distributors and overall lower 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, TRD, obstructive sleep apnea and heart failure. R&D expenses as a percentage of net sales for the three months ended September 30, 2019 compared to the three months ended September 30, 2018 increased primarily due to additional R&D expenses associated with TRD and heart failure. R&D expenses as a percentage of net sales for the nine months ended September 30, 2019 compared to the nine months ended September 30, 2018 increased primarily due to additional R&D expenses associated with advanced circulatory support, heart failure and TRD.

## Merger and Integration (“M&I”) Expenses

M&I expenses consist primarily of costs associated with systems integration efforts, organizational structure integration, synergy and tax planning. M&I expenses as a percentage of net sales for the three months ended September 30, 2019 compared to the three months ended September 30, 2018 decreased primarily due to efforts undertaken in 2018 to improve and standardize product pricing and procurement strategies.

## Impairment of Intangible Assets

During the second quarter of 2019, we determined that there would be a delay in the estimated commercialization date of the Company’s obstructive sleep apnea product currently under development. This delay constituted a triggering event that required evaluation of the IPR&D asset arising from the ImThera acquisition for impairment. Based on the assessment performed, we determined that the IPR&D asset was impaired and as a result, recorded an impairment of \$50.3 million, which is included in our Neuromodulation segment. The estimated fair value of IPR&D was determined using the income approach. Future delays in commercialization or changes in management estimates could result in further impairment.



## Insurance Recovery

In July 2019, we entered into agreements with our insurance carriers to recover \$33.8 million under our product liability insurance policies related to the litigation involving our 3T device. The insurance recovery was received and recognized during the third quarter of 2019.

## Gain on Acquisition

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.

## 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 earnings mix in various jurisdictions 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 and nine months ended September 30, 2019 was (49.6)% and 65.9%, respectively, compared with 29.8% and 0.6% the three and nine months ended September 30, 2018, respectively. 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 and nine months ended September 30, 2018, the change in the effective tax rate for the three and nine months ended September 30, 2019 was primarily attributable to a release of uncertain tax positions and a U.S. federal tax benefit from a return to provision adjustment, partly offset by the establishment of a valuation allowance for a portion of the U.S. state net operating losses and attributes.

## 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 from the issuance of these condensed consolidated financial statements. 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 2018 Form 10-K.

No provision has been made for income taxes on unremitted earnings of our foreign controlled subsidiaries (non-UK subsidiaries) as of September 30, 2019. 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 in the balance of cash and cash equivalents were as follows (in thousands):

	Nine Months Ended September 30,	
	2019	2018
Operating activities	\$ (94,008)	\$ 99,599
Investing activities	(30,519)	(107,408)
Financing activities	153,741	(2,910)
Effect of exchange rate changes on cash and cash equivalents	(1,105)	(2,948)
Net increase (decrease)	\$ 28,109	\$ (13,667)

## Operating Activities

Cash used in operating activities during the nine months ended September 30, 2019 increased by \$193.6 million as compared to the same prior-year period. The increase is primarily due to increases in working capital, of which \$140.8 million is due to cash outflows associated with the litigation provision liability, partially offset by an increase in net income adjusted for non-cash items.

## Investing Activities

Cash used in investing activities during the nine months ended September 30, 2019 decreased \$76.9 million as compared to the same prior-year period. The decrease is primarily due to the 2018 acquisitions of ImThera and TandemLife, net of cash acquired, which were partially offset by the 2018 sale of the CRM business franchise, net of cash disposed.

## Financing Activities

Cash provided by financing activities during the nine months ended September 30, 2019 increased \$156.7 million as compared to the same prior-year period. The increase is primarily due to an increase in long-term borrowing proceeds and a decrease in short-term borrowing repayments.

## Off-Balance Sheet Arrangements

As of September 30, 2019, we did not have any off-balance sheet arrangements.

## Contractual Obligations

Except for the borrowings associated with our 2019 Debt Facility, refer to “Note 9. Financing Arrangements,” 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 2018 Form 10-K.

## 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 Quarterly Report on 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 2018 Form 10-K in “Part II, Item 7. 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*

Management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of the design and effectiveness of our disclosure controls and procedures as of September 30, 2019. Based on that evaluation, the Chief Executive Officer (CEO) and the Chief Financial Officer (CFO) have concluded the disclosure controls and procedures were not effective as of that date due to the material weaknesses in internal control over financial reporting that were disclosed in our 2018 Form 10-K.

#### *(b) Changes in Internal Control Over Financial Reporting*

On January 1, 2019, we implemented a new software system, as well as new internal controls, to support adoption of the new Lease Accounting standard, ASC 842. The operating effectiveness of these controls will be evaluated as part of our annual assessment of the effectiveness of internal controls over financial reporting for the fiscal year ended December 31, 2019. No other changes over internal controls 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, 2019.

### Remediation

Efforts have been ongoing throughout the quarter to remediate the material weaknesses reported in our 2018 10-K filing. We have implemented a new tool, SAP’s Governance, Risk, and Compliance module, that will help us better manage IT and

business user access in our Enterprise Resource Planning system. In addition, we have designed and implemented new controls and formalized existing controls around price and quantity in our revenue process. The weaknesses will not be considered remediated, until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. We expect that the remediation of the material weaknesses will be completed prior to the end of fiscal year 2019.

## **PART II. OTHER INFORMATION**

### **Item 1. *Legal Proceedings***

For a description of our material pending legal and regulatory proceedings and settlements, refer to “Note 12. Commitments and Contingencies” in our condensed consolidated financial statements included in this Quarterly 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 2018 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***

#### **Disclosure Pursuant to Section 13(r) of the Exchange Act of 1934**

Section 13(r) of the Exchange Act requires issuers to disclose in their quarterly reports certain types of dealings with Iran, including transactions or dealing with government-owned entities, even when those activities are lawful and do not involve U.S. persons. Two of our non-U.S. subsidiaries currently sell medical devices, including cardiac surgery and cardiopulmonary products, to privately held distributors in Iran.

We have limited visibility into the identity of these distributors’ customers in Iran. It is possible that their customers include entities, such as government-owned hospitals or sub-distributors, that are owned or controlled directly or indirectly by the Iranian government. To the best of our knowledge at this time, we do not have any contracts or commercial arrangements with the Iranian government.

Our gross revenues and net profits attributable to the above-mentioned Iranian activities were \$3.2 million and \$1.2 million for the three months ended September 30, 2019, respectively, and \$8.7 million and \$3.1 million for the nine months ended September 30, 2019, respectively.

We believe our activities are consistent with applicable law, including U.S., EU, and other applicable sanctions laws, though such laws are complex and continue to evolve rapidly. We intend to continue our business in Iran.

## 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
<a href="#">3.1</a>	Amended Articles of Association, incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K, filed on June 15, 2017
<a href="#">31.1*</a>	Certification of the Chief Executive Officer of LivaNova PLC pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
<a href="#">31.2*</a>	Certification of the Chief Financial Officer of LivaNova PLC pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
<a href="#">32.1*</a>	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 formatted in Inline XBRL: (i) the Condensed Consolidated Statements of Income (Loss) for the three and nine months ended September 30, 2019 and September 30, 2018, (ii) the Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and nine months ended September 30, 2019 and September 30, 2018, (iii) the Condensed Consolidated Balance Sheet as of September 30, 2019 and December 31, 2018, (iv) the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2019 and September 30, 2018, and (vi) the Notes to the Condensed Consolidated Financial Statements
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

**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

Date: October 30, 2019    By:    /s/ DAMIEN MCDONALD  
Damien McDonald  
Chief Executive Officer  
*(Principal Executive Officer)*

LIVANOVA PLC

Date: October 30, 2019    By:    /s/ THAD HUSTON  
Thad Huston  
Chief Financial Officer  
*(Principal Financial Officer)*

## CERTIFICATION

I, Damien McDonald, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2019 of 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; and

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 30, 2019

/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, 2019 of 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; and

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 30, 2019

/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, 2019, 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 30, 2019

/s/ DAMIEN MCDONALD

Damien McDonald

Chief Executive Officer

*(Principal Executive Officer)*

Date: October 30, 2019

/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.