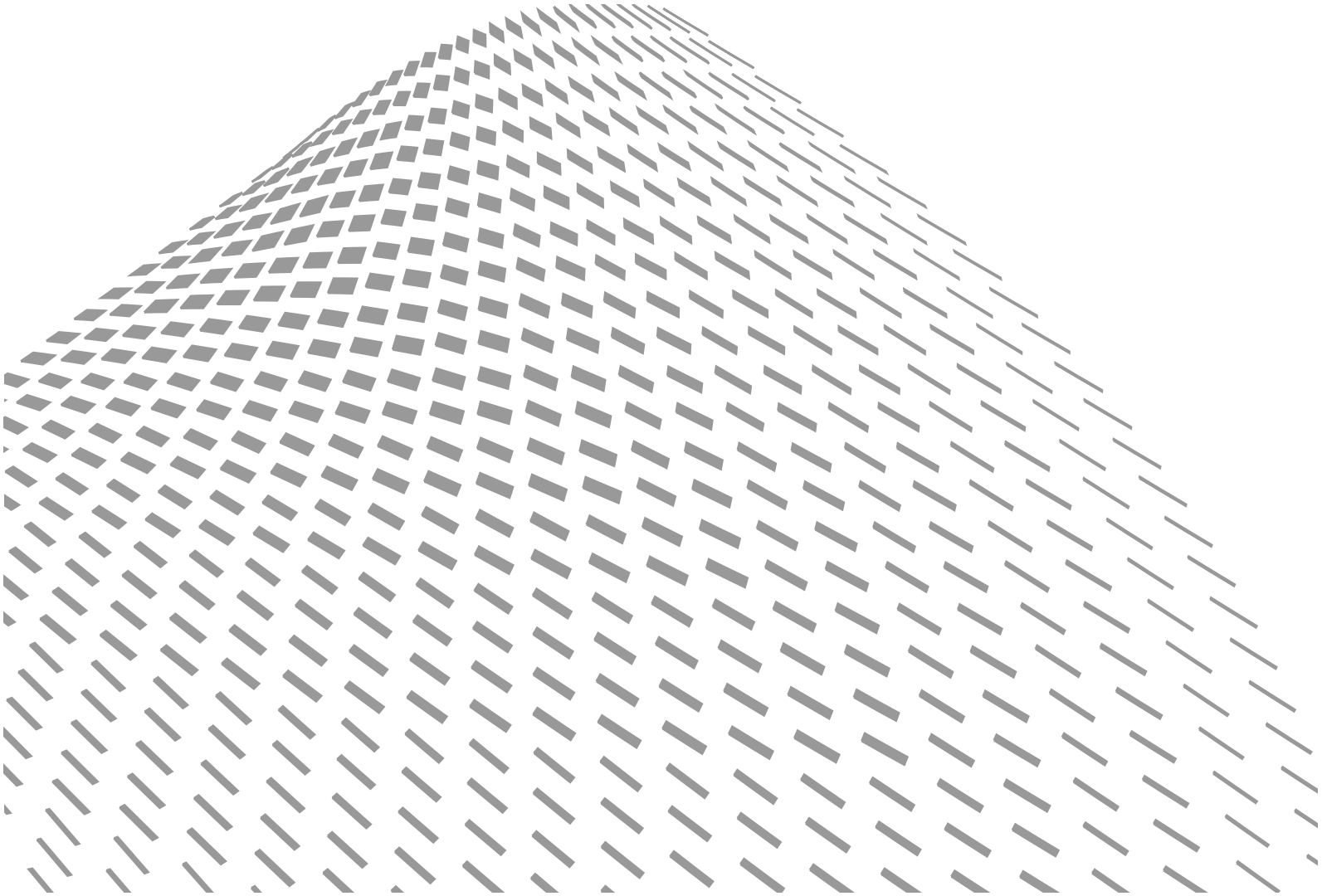
2019 Form 10-K

LivaNova

Health innovation that matters



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

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2019

or

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

Commission file number: 001-37599

LivaNova PLC

(Exact name of registrant as specified in its charter)

England and Wales	**98-1268150**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer 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

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2019, the last business day of the most recently completed second fiscal quarter, based upon the last sales price reported for such dates on the NASDAQ Global Market was approximately $3.5 billion. For purposes of this disclosure, ordinary shares held by persons who hold more than 5% of the outstanding ordinary shares and shares held by executive officers and directors of the registrant have been excluded as such persons may be deemed to be affiliates.

As of February 27, 2020, 48,445,251 ordinary shares were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement of LivaNova PLC for the 2020 Annual General Meeting of Shareholders, which will be filed within 120 days of December 31, 2019, are incorporated by reference into Part III of this Annual Report on Form 10-K.

LIVANOVA PLC

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In this Annual Report on Form 10-K, "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 Annual Report on Form 10-K 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.

CAUTIONARY STATEMENT ABOUT FORWARD-LOOKING STATEMENTS

Certain statements in this Annual Report on Form 10-K, 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, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements include, but are not limited, to LivaNova's plans, objectives, strategies, financial performance and outlook, trends, 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 Annual Report on Form 10-K. Such risks, uncertainties and other important factors include, among others: the risks, uncertainties and factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, previous or future Quarterly Reports on Form 10-Q and Annual or Transitional Reports on Form 10-K as well as other documents that we have filed or will file with the SEC.

The afore-referenced risks and uncertainties are not necessarily all the important factors that could cause our actual financial results, performance, achievements or prospects to differ materially from those expressed in or implied by any of our forward-looking statements. Other unknown or unpredictable factors also could harm our results. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements set forth above. Forward-looking statements speak only as of the date they are made, and we do not undertake or assume any obligation to update publicly any of these forward-looking statements to reflect actual results, new information or future events, changes in assumptions or changes in other factors affecting forward-looking statements, except to the extent required by applicable laws. If we update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

The following discussion and analysis should be read in conjunction with and are qualified in their entirety by reference to the discussions included in "Item 1A. Risk Factors," "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Annual Report on Form 10-K.

PART I

Item 1. *Business*

Description of the Business and Background

LivaNova PLC, headquartered in London, (collectively with its subsidiaries, the "Company," "LivaNova," "we" or "our"), is a global medical device company focused on the development and delivery of important therapeutic solutions for the benefit of patients, healthcare professionals and healthcare systems throughout the world. Working closely with a global team of medical professionals in the fields of cardiovascular disease and neuromodulation, we design, develop, manufacture and sell innovative therapeutic solutions that are consistent with our mission to improve our patients' quality of life, increase the skills and capabilities of healthcare professionals and minimize healthcare costs.

We were organized under the laws of England and Wales on February 20, 2015 for the purpose of facilitating the business combination of Cyberonics, Inc., a Delaware corporation, and Sorin S.p.A., a joint stock company organized under the laws of Italy. The business combination became effective in October 2015. LivaNova's ordinary shares are listed for trading on the NASDAQ Global Market under the symbol "LIVN."

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. New Ventures is focused on new growth platforms and identification of other opportunities for expansion.

For further information regarding our business segments, historical financial information and our methodology for the presentation of financial results, please refer to "Item 15. Exhibits, Financial Statement Schedules" of this Annual Report on Form 10-K.

Cardiovascular

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, related repair products and minimally invasive surgical instruments. Advanced circulatory support includes temporary life support product kits that can include a combination of pumps, oxygenators and cannulae.

Cardiopulmonary Products

During conventional coronary artery bypass graft procedures and heart valve surgery, the patient's heart is temporarily stopped, or arrested. The patient is placed on an extracorporeal circulatory support system that temporarily functions as the patient's heart and lungs and provides blood flow to the body. Our products include systems to enable cardiopulmonary bypass, including heart-lung machines, oxygenators, perfusion tubing sets, cannulae and accessories, as well as related equipment and disposables for autotransfusion and autologous blood washing for neonatal, pediatric and adult patients. Our primary cardiopulmonary products include:

Heart-lung machines. The heart-lung machine product group includes heart-lung machines, heater coolers, related cardiac surgery equipment and maintenance services.

Oxygenators and perfusion tubing systems. The oxygenators product group, which includes oxygenators and other disposable devices for extracorporeal circulation, includes the Inspire systems. The Inspire range of products, comprised of 12 models, provides perfusionists with a customizable approach for the benefit of patients.

Autotransfusion systems. One of the key elements for a complete blood management strategy is autologous blood transfusion, which involves the collection, processing and reinfusion of the patient's own blood lost at the surgical site during the perioperative period.

Cannulae. Our cannulae product family, part of the oxygenator product group, is used to connect the extracorporeal circulation to the heart of the patient during cardiac surgery.

Connect. Connect is our perfusion charting system. Focused on real time and retrospective calculations and trending tools, Connect assists perfusionists with data management during and after cardiopulmonary bypass.

Heart Valves and Repair Products

We offer a comprehensive line of products to treat a variety of heart valve disorders, including a complete line of surgical tissue and mechanical valve replacements and repair products for damaged or diseased heart valves. Our heart valves and repair product offerings include:

Self-anchoring tissue heart valves. Perceval is our sutureless bioprosthetic device designed to replace a diseased native valve or a malfunctioning prosthetic aortic valve using either traditional or minimally invasive heart surgery techniques. Perceval incorporates a unique technology that allows 100% sutureless positioning and anchoring at the implantation site. This, in turn, offers the potential to reduce the time the patient spends in cardiopulmonary bypass.

Other tissue heart valves. Other tissue valves include the Mitroflow aortic pericardial tissue valve with phospholipid reduction treatment ("PRT"), which is designed to mitigate valve calcification, and the Crown PRT and Solo Smart aortic pericardial tissue valves. Our Solo Smart aortic pericardial tissue valve is an innovative, completely biological aortic heart valve with no synthetic material and a removable stent. Solo Smart provides the ease of implantation of a stented valve with the hemodynamic performance of a stentless valve.

Mechanical heart valves. Our wide range of mechanical valve offerings includes the Carbomedics Standard, Top Hat and Reduced Series Aortic Valves, as well as the Carbomedics Carbo-Seal and Carbo-Seal Valsalva aortic prostheses. We also offer the Carbomedics Standard, Orbis and Optiform mechanical mitral valves and Bicarbon Slimline, Bicarbon Fitline and Bicarbon Overline aortic and mitral valves.

Heart valve repair products. Mitral valve repair is a well-established solution for patients suffering from a leaky mitral valve, or mitral valve regurgitation ("MR"). We offer a wide range of mitral valve repair products, including the Memo 3D and Memo 3D ReChord, AnnuloFlo and AnnuloFlex.

Minimally invasive surgical instruments. Through the acquisition of the minimally invasive cardiac surgery business from Miami Instruments in June 2019, we offer minimally invasive cardiac surgery instruments that support the implantation of our heart valve products during surgery.

Advanced Circulatory Support Products

In 2018, we acquired the TandemLife business, which simplifies temporary extracorporeal cardiopulmonary life support solutions for critically ill patients. Built around a common compact console and pump, LifeSPARC provides temporary support for emergent rescue patients in a variety of settings. Designed for ease of use, the system offers power and versatility for multi-disciplinary programs to support more patients. The system is accompanied by four specialized and ready-to-deploy kits, each designed to support diverse cannulation strategies.

Neuromodulation

Our Neuromodulation business franchise designs, develops and markets neuromodulation-based medical devices for the treatment of epilepsy, depression and obstructive sleep apnea. We are also developing and conducting clinical testing of the VITARIA System for treating heart failure through vagus nerve stimulation ("VNS").

Our seminal Neuromodulation product, the LivaNova Vagus Nerve Stimulation Therapy ("VNS Therapy") System, is an implantable device authorized for the treatment of drug-resistant epilepsy and difficult-to-treat depression ("DTD"). The VNS Therapy System consists of an implantable pulse generator and connective lead that stimulate the vagus nerve; surgical equipment to assist with the implant procedure; equipment and instruction manuals enabling a treating physician to set parameters for a patient's pulse generator; and for epilepsy, magnets to manually suspend or induce nerve stimulation. The pulse generator and lead are surgically implanted in a subcutaneous pocket in the upper left chest area, generally during an out-patient procedure; the lead, which does not need to be removed to replace a generator with a depleted battery, is connected to the pulse generator and tunneled under the skin to the vagus nerve in the lower left side of the patient's neck.

Epilepsy

Globally, there are several broad types of treatment available to patients with epilepsy: multiple seizure medications; various forms of the ketogenic diet; VNS; resective brain surgery; trigeminal nerve stimulation; responsive intracranial neurostimulation; and deep brain stimulation. Seizure medications typically serve as a first-line treatment and are prescribed for virtually all patients diagnosed with epilepsy. After two seizure medications fail to deliver seizure control, the epilepsy is characterized as drug-resistant, at which point, adjunctive non-drug options are considered, including VNS therapy, brain surgery and a ketogenic diet.

Our VNS Therapy System was the first medical device treatment approved by the U.S. Food and Drug Administration ("FDA") in 1997 for refractory, drug-resistant epilepsy in adults and adolescents over 12 years of age and is indicated for use as an adjunctive therapy in reducing the frequency of seizures. In June 2017, the FDA approved our VNS Therapy device for use in patients who are at least four years of age and have partial onset seizures that are refractory to antiepileptic medications. At the same time, our VNS Therapy device received FDA approval for expanded magnetic resonance imaging ("MRI"), affirming VNS Therapy as the only epilepsy device FDA-approved for MRI scans. CE Mark approval followed shortly thereafter, in August 2017. Currently, SenTiva, AspireHC and AspireSR models of VNS Therapy technology provide for this expanded MRI access. Other worldwide regulatory bodies have also approved the VNS Therapy System for the treatment of epilepsy, many without age restrictions or seizure-type limitations.

We sell a number of VNS Therapy System product models for the treatment of epilepsy, including our Model 102 (Pulse), Model 102R (Pulse Duo), Model 103 (Demipulse), Model 104 (Demipulse Duo), Model 105 (AspireHC), Model 106 (AspireSR) and Model 1000 (SenTiva) pulse generators. Our AspireSR and SenTiva generators provide the benefits of VNS Therapy, with an additional feature: automatic stimulation in response to detection of changes in heart rate potentially indicative of a seizure. The SenTiva generator is the smallest and lightest device capable of delivering responsive therapy for epilepsy.

Depression

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

In January 2018, we announced the launch and enrollment of the first patient in our Global RESTORE-LIFE study, which evaluates the use of our VNS Therapy System in patients who have DTD and failed to achieve an adequate response to standard psychiatric management. We expect to enroll up to 500 patients at approximately 80 sites outside of the U.S. We are currently enrolling patients in Germany, Belgium, and the United Kingdom (the "UK").

In July 2005, the FDA approved the VNS Therapy System for the adjunctive treatment of chronic or recurrent depression for patients 18 years or older who are experiencing a major depressive episode and have not had an adequate response to four or more antidepressant treatments. In May 2007, the United States ("U.S.") Centers for Medicare and Medicaid Services ("CMS") issued a national determination of non-coverage within the U.S. with respect to reimbursement of the VNS Therapy System for patients with DTD, significantly limiting access to this therapeutic option for most patients. However, in May 2018, CMS published a tracking sheet to reconsider its National Coverage Determination ("NCD") of our VNS Therapy System for DTD in response to a letter that we submitted to CMS requesting a formal reconsideration of the NCD. We requested this review after a significant body of new evidence emerged about DTD and the role of VNS Therapy in its treatment.

In February 2019, CMS finalized its National Coverage Determination ("NCD") for the VNS Therapy System for DTD. 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 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 and the first patient was enrolled. RECOVER will include up to 500 unipolar and up to 500 bipolar patients at a maximum of 100 sites in the United States.

Obstructive Sleep Apnea

In January 2018, we acquired ImThera Medical, Inc. ("ImThera"), a privately held emerging-growth company developing an implantable neurostimulation device system for the treatment of obstructive sleep apnea. The Neuromodulation product line now includes ImThera's implantable device, which stimulates multiple tongue muscles via the hypoglossal nerve to open the airway while a patient is sleeping. ImThera has a commercial presence in the European market, and an FDA pivotal study is ongoing in the U.S.

Corporate Activities and New Ventures

Corporate activities include shared services for finance, legal, human resources and information technology and New Ventures. The New Ventures group evaluates growth opportunities and new potential areas of investment to expand our product portfolio to meet emerging patient needs.

Discontinued Operations

We completed the sale of our Cardiac Rhythm Management ("CRM") business franchise to MicroPort Cardiac Rhythm B.V. and MicroPort Scientific Corporation (the "CRM Sale") on April 30, 2018. We previously concluded that the sale of CRM represented a strategic shift in our business that has a major effect on future operations and financial results. Accordingly, the results of operations of the CRM business franchise are reflected as discontinued operations for all periods presented in this Annual Report on Form 10-K. For further information, refer to "Note 5. Discontinued Operations" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

Research and Development ("R&D")

The markets in which we participate are subject to rapid technological advances. Product improvement and innovation are necessary to maintain market leadership. We direct our R&D efforts toward maintaining or achieving technological leadership in each of the markets we serve to help ensure that patients using our devices and therapies receive the most advanced and effective treatment possible. We remain committed to developing technological enhancements and new uses for existing products and less invasive and new technologies for new and emerging markets to address unmet patient needs. We initiate and participate in many clinical trials each year as the demand for clinical and economic evidence remains high. We also expect our development activities to help reduce patient care costs and the length of hospital stays in the future.

Approximately 16% of our employees work in R&D improving existing products and therapies, expanding their uses and applications and developing new products. We continue to focus on optimizing innovation and assessing the ability of our R&D programs to deliver economic value to the customer. More specifically, our current 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 DTD and heart failure.

Acquisitions and Investments

Our strategy of providing a broad range of therapies requires a wide variety of technologies, products and capabilities. The rapid pace of technological development in the medical industry and the specialized expertise required in different areas of medicine make it difficult for one company alone to develop a broad portfolio of technological solutions. In addition to internally generated growth through R&D efforts, we have historically relied, and expect to continue to rely, on acquisitions, investments and alliances to provide access to new technologies in both new and existing markets.

We expect to further our strategic objectives and strengthen our existing businesses by making future acquisitions or investments in areas where we believe we can acquire or stimulate the development of new technologies and products. Mergers and acquisitions of medical technology companies are inherently risky, and no assurance can be given that any of our previous or future acquisitions will be successful or will not materially adversely affect our consolidated operations, financial condition and/or cash flows.

Caisson Interventional, LLC ("Caisson")

In May 2017, we acquired the remaining 51% equity interest in Caisson, a clinical-stage medical device company focused on the design, development and clinical evaluation of a novel transcatheter mitral valve replacement ("TMVR") implant device. The device is designed for treating mitral valve regurgitation ("MR") through replacement of the native mitral valve using a fully transvenous delivery system. As announced in November 2019, we ended our Caisson TMVR program effective December 31, 2019.

ImThera

In January 2018, we acquired the remaining 86% outstanding interest in ImThera; we previously held 14% of ImThera's outstanding equity. ImThera is focused on neurostimulation for the treatment of obstructive sleep apnea. ImThera manufactures an implantable device that stimulates multiple tongue muscles via the hypoglossal nerve, which opens the airway while a patient is sleeping. The financial results of ImThera are included within Neuromodulation.

TandemLife

In April 2018, we acquired CardiacAssist, Inc., doing business as TandemLife. TandemLife is focused on the delivery of leading-edge temporary life support systems, including cardiopulmonary and respiratory support solutions. The financial results of TandemLife are included within Cardiovascular.

Miami Instruments

On June 12, 2019, we acquired Miami Instruments, LLC's minimally invasive cardiac surgery instruments business and the related operations are integrated into Cardiovascular as part of our Heart Valves portfolio.

Patents and Licenses

We rely on a combination of patents, trademarks, copyrights, trade secrets, and non-disclosure and non-competition agreements to protect our intellectual property. We generally file patent applications in the U.S. and countries where patent protection for our technology is appropriate and available. As of December 31, 2019, we held more than 1,000 issued patents worldwide, with approximately 300 pending patent applications that cover various aspects of our technology. Patents typically have a 20-year term from the application filing date. In addition, we hold exclusive and non-exclusive licenses to a variety of third-party technologies covered by patents and pending patent applications. There can be no assurance that pending patent applications will result in the issuance of patents, that patents issued to or licensed by us will not be challenged or circumvented by competitors, or that these patents will be found to be valid or sufficiently broad to protect our technology or to provide us with a competitive advantage. We have also obtained certain trademarks and trade names for our products and maintain certain details about our processes, products and strategies as trade secrets. In the aggregate, we consider these intellectual property assets to be of material importance to our business segments and operations. We regularly review third-party patents and patent applications in an effort to protect our intellectual property and avoid disputes over proprietary rights.

We rely on non-disclosure and non-competition agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets and proprietary knowledge.

For additional information, please refer to "Item 1A. Risk Factors" of this Annual Report on Form 10-K, under the section entitled "*We are substantially dependent on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to our rights or the rights of others may result in our payment of significant monetary damages and/or royalty payments, negatively impact our ability to sell current or future products, or prohibit us from enforcing our patent and other proprietary rights against others.*"

Markets and Distribution Methods

The three largest markets for our medical devices are the U.S., Europe and Japan, though emerging markets are an area of increasing focus and opportunity for us. We sell most of our medical devices through direct sales representatives in the U.S. and a combination of direct sales representatives and independent distributors in markets outside the U.S.

Our marketing and sales strategy is focused on rapid, cost-effective delivery of high-quality products to a diverse group of customers worldwide, including perfusionists, neurologists, neurosurgeons and other physicians, hospitals and other medical institutions and healthcare providers. To achieve this objective, we maintain a highly knowledgeable and dedicated sales staff that is able to foster strong relationships with our broad range of customers. We maintain excellent working relationships with professionals in the medical industry, which provide us with a detailed understanding of therapeutic and diagnostic developments, trends and emerging opportunities, and which therefore enable us to respond quickly to the changing needs of providers and patients. We actively participate in medical meetings and conduct comprehensive training and educational activities to enhance our presence in the medical communities we serve, and we believe that these activities also contribute to advancing healthcare professionals' expertise.

Due to the emphasis on cost-effectiveness in healthcare delivery, the current trend among hospitals and other medical device customers is to consolidate into larger purchasing groups to enhance purchasing power. As a result, customer transactions have become increasingly complex. Enhanced purchasing power may also lead to pressure on pricing and an increase in the use of preferred vendors. Our customer base continues to evolve to reflect such economic changes across the geographic markets we serve.

Competition and Industry

We compete in the medical device market in more than 5,000 hospitals and in more than 100 countries. Technological advances and scientific discoveries cause rapid change in this market. Our competitors across our product portfolio range from large manufacturers with multiple business lines to small manufacturers offering a limited selection of specialized products. In addition, we face competition from providers of alternative medical therapies, such as pharmaceutical companies and providers of cannabis derived products, among others.

Product problems, physician advisories, safety alerts and publications about our products can cause major shifts in industry market share, reflecting the importance of product quality, product efficacy and quality systems in the medical device industry. In addition, because of developments in managed care, economically motivated customers, consolidation among healthcare providers, increased competition and declining reimbursement rates, we may be increasingly required to compete on the basis of price. In order to continue to compete effectively, we must continue to create or acquire advanced technology, incorporate this technology into proprietary products, obtain regulatory approvals in a timely manner, maintain high-quality manufacturing processes and successfully market these products.

Our primary medical device competitors in the Cardiovascular and Neuromodulation product groups are Terumo Medical Corporation, Maquet Medical Systems, Medtronic plc, Haemonetics Corporation, Edwards Lifesciences Corp., NeuroPace, Inc., Abiomed, Inc. and Abbott Laboratories, Inc. (formerly St. Jude Medical, Inc.), although not all competitors are present in all product lines.

Production, Quality Systems and Raw Materials

We manufacture a majority of our products at 11 manufacturing facilities located in Italy, Germany, the U.S., Canada, Brazil and Australia. We purchase raw materials and many of the components used in our manufacturing facilities from numerous suppliers in various countries. For quality assurance, sole source availability or cost effectiveness purposes, we may procure certain components and raw materials from a sole supplier. We work closely with our suppliers to ensure continuity of supply while maintaining high quality and reliability. We use quality systems in the design, production, warehousing and distribution of our products to ensure our products are safe and effective. In addition, we utilize environmental management systems and safety programs to protect the environment and our employees. For additional information related to our manufacturing facilities, refer to “Item 2. Properties” in this Annual Report on Form 10-K.

Government Regulation and Other Considerations

Our medical devices are subject to regulation by numerous government agencies, including the FDA and counterpart agencies outside the U.S. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the research, development, testing, manufacturing, labeling, pre-market clearance or approval, marketing, distribution, advertising, promotion, record keeping, reporting, tracking, and importing and exporting of our products. Our business is also affected by patient privacy and security laws, cost containment initiatives, and environmental health and safety laws and regulations worldwide.

The laws applicable to us are subject to changing and evolving interpretations. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe civil and criminal penalties, including substantial fines and damages, and exclusion from participation as a supplier of products to beneficiaries covered by government programs, among other potential enforcement actions.

Product Approval and Monitoring

Many countries where we sell our products subject such medical devices and technologies to their own approval and other regulatory requirements regarding performance, safety and quality. The following provides a brief overview of the oversight and requirements to which we are subject for the commercial distribution of our products in the U.S., Europe and Japan, the largest markets for our medical devices.

Each medical device we seek to distribute commercially in the U.S. must receive 510(k) clearance or pre-market approval (“PMA”) from the FDA, unless specifically exempted by the agency. The former, known as pre-market notification or the 510(k) process, requires us to demonstrate that our new medical device is substantially equivalent to a legally marketed medical device. The latter, the more costly and rigorous PMA process, requires us to demonstrate independently that a medical device is safe and effective for its intended use. One or more clinical studies may be required to support a 510(k) application and are almost always required to support a PMA application.

The European Union (“EU”), established a single regulatory approval process, according to which a “*Conformité Européenne*” (French for “European Conformity”) or CE Mark certifies conformity with all of the legal requirements of the regulatory process. To obtain a CE Mark, defined products must meet minimum standards of performance, safety and quality (i.e., the essential requirements), and then, according to their classification, comply with one or more of a selection of conformity assessment routes. To demonstrate compliance with the essential requirements, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based on, among other things, the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. The competent authorities of the EU countries separately regulate the clinical research for medical devices

and the market surveillance of products placed on the market, and manufacturers with CE marked devices are subject to regular inspections to monitor compliance with the applicable directives and essential requirements. The EU published its Medical Device Regulation ("Reg MDR") in 2017 that will impose significant additional premarket and post-market requirements for our medical devices. Reg MDR has a three-year implementation period, at the end of which, national competent authorities and manufacturers must implement and ensure compliance with the regulation. Among other things, Reg MDR imposes additional reporting requirements on manufacturers of high-risk medical devices and provides additional clinical evidence requirements. We have initiated activities and anticipate compliance with Reg MDR within the applicable timeframe.

To be sold in Japan, our medical devices must undergo thorough safety examinations and demonstrate medical efficacy before they are granted approval. The Japanese government, through the Ministry of Health, Labour and Welfare, regulates medical devices under the Pharmaceutical Affairs Law ("PAL"). Penalties for a company's noncompliance with the PAL can be severe, including revocation or suspension of a company's business license and criminal sanctions. Japanese regulatory bodies also assess the quality management systems of the manufacturer and product conformity to the requirements of the PAL. We are subject to compliance investigations by these agencies.

Many countries in which we sell our products (outside of the U.S., the EU and Japan) have their own regulatory requirements for medical devices. Most of these countries require that product approvals be recertified on a regular basis, generally every four to five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and, where needed, conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries.

The global regulatory environment is increasingly stringent and unpredictable. Several countries that did not have regulatory requirements for medical devices have established such requirements in recent years, and other countries have expanded, or plan to expand, their existing regulations. While some regulatory bodies have pursued harmonization of global regulations, requirements continue to differ significantly among countries. We expect this global regulatory environment will continue to evolve, which could impact the cost, the time needed to approve, and ultimately, our ability to maintain existing approvals or obtain future approvals for our products.

Product and Promotional Restrictions

Both before and after we release a product for commercial distribution, we have ongoing responsibilities under various laws and regulations governing medical devices. Regulations of the FDA and other regulatory agencies in and outside the U.S. impose extensive compliance and monitoring obligations on our business. These agencies review our design and manufacturing practices, labeling, record keeping, and required reports of adverse experiences and other information to identify potential problems with marketed medical devices. We are also subject to periodic inspections for compliance with applicable quality system regulations, which govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging and servicing of finished medical devices intended for human use. In addition, the FDA and other U.S. regulatory bodies monitor the manner in which we promote and advertise our products. Although physicians are permitted to use their medical judgment to prescribe medical devices for indications other than those cleared or approved by the FDA, we are prohibited from promoting products for such "off-label" uses and can only market our products for cleared or approved uses.

Any adverse regulatory action, depending on its magnitude, may limit our ability to market and sell our products effectively, limit our ability to obtain future premarket approvals or result in a substantial modification to our business practices and operations. For additional information, see "Item 1A. Risk Factors" of this Annual Report on Form 10-K, under the section entitled "*Our products are subject to costly and complex laws and governmental regulations, and failure to obtain product approvals or clearance may materially adversely affect our financial condition and business operations.*"

Governmental Trade Regulations

The sale and shipment of our products and services across international borders, as well as the purchase of components and products from international sources, subject us to extensive governmental trade regulations. A variety of laws and regulations apply to the sale, shipment and provision of goods, services and technology across international borders. Many countries control the export and re-export of goods, technology and services for public health, national security, regional stability, antiterrorism and other reasons. Some governments may also impose economic sanctions against certain countries, persons or entities. In certain circumstances, governmental authorities may require that we obtain an approval before we export or re-export goods, technology or services to certain destinations, to certain end-users and for certain end-uses. Because we are subject to extensive regulations in the countries in which we operate, we are subject to the risk that laws and regulations could change in a way that would expose us to additional costs, penalties or liabilities.

We also sell and provide goods, technology and services to agents, representatives and distributors who may export such items to customers and end-users, and if these third parties violate applicable export control or economic sanctions laws or

regulations when engaging in transactions involving our products, we may be subject to varying degrees of liability depending on the extent of our participation in the transaction. The activities of these third parties may cause disruption or delays in the distribution and sale of our products or result in restrictions being placed on our international distribution and sales of products, which may materially impact our business activities.

Patient Privacy and Security Laws

We are subject to various laws worldwide that protect the security and confidentiality of certain patient health information, including patient medical records, and that restrict the use and disclosure of patient health information. Privacy standards in Europe and Asia are becoming increasingly strict; enforcement actions and financial penalties related to privacy issues in the EU are growing; and new laws and restrictions are being passed in other countries including the U.S. The management of cross-border transfers of information among and outside of EU member countries is becoming more complex, which may complicate our clinical research activities, as well as product offerings that involve transmission or use of clinical data. We will continue our efforts to comply with those requirements and to adapt our business processes to those standards.

In the U.S., the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology and Clinical Health Act ("HITECH") and their respective implementing regulations impose specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. We may be deemed to operate as a business associate to covered entities in certain instances. In those cases, the patient data that we receive may include protected health information, as defined under HIPAA. Enforcement actions can be costly and interrupt regular operations of our business. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance and data protection efforts. For example, the California Consumer Privacy Act ("CCPA"), a bill to enhance privacy rights and consumer protection for residents of California went into effect January 1, 2020. For additional information, see "Item 1A. Risk Factors" of this Annual Report on Form 10-K, under the section entitled "*Cyber-attacks or other disruptions to our information technology systems could lead to reduced revenue, increased costs, liability claims, fines, harm to our competitive position and loss of reputation.*"

In the EU, Regulation 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data ("General Data Protection Regulation" or "GDPR") came into effect in May 2018. The GDPR replaces Directive 95/46/EC ("Data Protection Directive"). While many of the principles of the GDPR reflect those of the Data Protection Directive, for example in relation to the requirements relating to the privacy, security and transmission of individually identifiable health information, there are a number of changes. In particular: (1) proactive compliance measures are introduced, such as the requirement to carry out a Privacy Impact Assessment and to appoint a Data Protection Officer where health data is processed on a "large scale." Although "large scale" is not defined, it is likely that clinical trials involving substantial numbers of patients (or healthy volunteers if applicable) would mean that such requirements apply to us; and (2) the administrative fines that can be levied are significantly increased, the maximum being the higher of €20 million (approximately $22.4 million), or 4% of our total worldwide revenue in the previous financial year.

Cost Containment Initiatives

Government and private sector initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, bidding and tender mechanics, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements are continuing in many countries where we do business. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective medical devices and therapies. Government programs, private healthcare insurance and managed-care plans have attempted to control costs by limiting the extent of coverage or amount of reimbursement available for particular procedures or treatments, tying reimbursement to outcomes, shifting to population health management, and other mechanisms designed to constrain utilization and contain costs. Hospitals, which purchase implants, are also seeking to reduce costs through a variety of mechanisms, including, for example, creating centralized purchasing functions that set pricing and, in some cases, limit the number of vendors that can participate in the purchasing program. Hospitals are also aligning their interests with those of physicians through employment and other arrangements, such as gainsharing, whereby a hospital agrees with physicians to share certain realized cost savings resulting from the physicians' collective change in practice patterns, such as standardization of devices where medically appropriate, and participation in affordable care organizations. Such alignment has created increasing levels of price sensitivity among customers for our products.

Some third-party payers must also approve coverage and set reimbursement levels for new or innovative devices or therapies before they will reimburse healthcare providers who use the medical devices or therapies. Even though a new medical device

may be cleared for commercial distribution, we may find limited demand for the device until coverage and sufficient reimbursement levels have been obtained from governmental and private third-party payers. In addition, some private third-party payers require that certain procedures or the use of certain products be authorized in advance as a condition of coverage.

As a result of our manufacturing efficiencies, cost controls and other cost-savings initiatives, we believe we are well-positioned to respond to changes resulting from this worldwide trend toward cost containment; however, uncertainty remains as to the nature of any future legislation or other reforms, making it difficult for us to predict the potential impact of cost-containment trends on future operating results.

Applicability of Anti-Corruption Laws and Regulations

Our worldwide business is subject to the U.S. Foreign Corrupt Practices Act of 1977 (the "FCPA"), the UK Bribery Act of 2010 (the "UK Bribery Act") and other anti-corruption laws and regulations applicable in the jurisdictions where we operate. The FCPA can be used to prosecute companies in the U.S. for arrangements with physicians or other parties outside the U.S. if the physician or party is a government official of another country and prohibited payments are made to obtain or retain business. The UK Bribery Act prohibits both domestic and international bribery, as well as bribery across both public and private sectors. There are similar laws and regulations applicable to us outside the U.S. and the UK, all of which are subject to evolving interpretations. For additional information, please refer to "Item 1A. Risk Factors" of this Annual Report on Form 10-K, under the section entitled "*The failure to comply with anti-bribery laws could materially adversely affect our business and result in civil and/or criminal sanctions.*"

Environmental Regulation and Management

We are subject to various environmental laws, directives and regulations both in the U.S. and abroad. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe that sound environmental, health and safety performance contribute to our competitive strength while benefiting our customers, stockholders and employees. We are focused on continuous improvement in these areas by reducing pollution, depletion of natural resources and our overall environmental footprint. Specifically, we are working to optimize energy and resource usage, ultimately reducing greenhouse gas emissions and waste. We have implemented trigeneration in our plant in Mirandola, Italy which is designed to reduce CO2, reduce energy consumption, generate energy savings, and reduce costs, and we have moved from using oil to methane, reducing considerably the air pollution from our plant in Saluggia, Italy. We replaced fluorescent light in our plants in Arvada, Colorado and Mirandola with LED to reduce overall energy consumption, and we are continually working to improve the efficiency of our machinery, e.g., by replacing HVAC units with more efficient equivalents. Finally, our Saluggia plant was awarded ISO 14001 certification in 2018, becoming our second ISO-certified plant alongside Munich, Germany.

Health Care Fraud and Abuse Laws

We are also subject to U.S. federal and state government healthcare regulation and enforcement and government regulations and enforcement in other countries in which we conduct our business. The federal healthcare Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully offering or paying remuneration, directly or indirectly, to a person to induce the purchase, order, lease, or recommendation of a good or service for which payment may be made in whole or part under a federal healthcare program such as Medicare or Medicaid, unless the arrangement fits within one of several statutory exemptions or regulatory "safe harbors." Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation, plus up to three times the remuneration involved. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment for up to 10 years. Finally, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid.

In addition to the Anti-Kickback Statute, many states have their own anti-kickback laws. Often, these laws closely follow the language of the federal law, although they do not always have the same exceptions or safe harbors. In some states, these anti-kickback laws apply with respect to all payers, including commercial health insurance companies.

Additionally, violations of the U.S. False Claims Act (the "False Claims Act") can result in significant monetary penalties and treble damages. The U.S. federal government is using the False Claims Act, and the accompanying threat of significant financial liability, in its investigation and prosecution of device and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The U.S. government has obtained multi-million and multi-billion-dollar settlements under the False Claims Act, in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, we anticipate that the U.S. government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

HIPAA includes federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors; knowingly and willfully embezzling or stealing from a healthcare benefit program; willfully obstructing a criminal investigation of a healthcare offense; and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. We are subject, for example, to the Physician Payments Sunshine Act, which requires us to annually report annually certain payments and other transfers of value we make to U.S. licensed physicians or U.S. teaching hospitals. Any failure to comply with such laws and regulations hold the potential for criminal and civil financial penalties.

The shifting commercial compliance environment and the need to build and maintain robust systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, and exclusion from participation in federal and state healthcare programs, any of which could adversely affect our ability to operate our business and our financial results.

Environmental Health and Safety Laws

We are also subject to various environmental health and safety laws and regulations worldwide. Like other medical device companies, our manufacturing and other operations involve the use, storage and transportation of substances regulated under environmental health and safety laws, including those related to the transportation of hazardous materials. To the best of our knowledge at this time, we do not expect that compliance with environmental protection laws will have a material impact on our consolidated results of operations, financial position or cash flows.

Working Capital Practices

Our goal is to carry sufficient levels of inventory to ensure adequate supply of raw materials from suppliers and meet the product delivery needs of our customers. To meet the operational demands of our customers, we also provide payment terms to customers in the normal course of business and rights to return product under warranty.

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 annual 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 $1.6 million and $0.5 million for the three months ended December 31, 2019, respectively, and $10.3 million and $3.6 million for the twelve months ended December 31, 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.

Employees

As of December 31, 2019, we employed approximately 4,000 employees worldwide. Our employees are vital to our success, and we are engaged in an ongoing effort to identify, hire, manage and maintain the talent necessary to meet our business objectives. We believe that we have been successful in attracting and retaining qualified personnel in a highly competitive labor market due, in large part, to our competitive compensation and benefits and our rewarding work environment, fostering employee professional training and development and providing employees with opportunities to contribute to our continued growth and success.

Seasonality

For both of our segments, the number of medical procedures incorporating our products is generally lower during the summer months, particularly in European countries, due to summer vacation schedules.

Available Information

Our executive headquarters are located at 20 Eastbourne Terrace, London, UK W2 6LG. Our website address is *www.livanova.com.* We make available free of charge on or through our website our Proxy Statements on Schedule 14A, Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, and reports relating to beneficial ownership of our securities filed or furnished pursuant to Section 16 of the Exchange Act, as soon as reasonably practicable after electronically filing such material with the SEC. Our website also contains the charters for each standing committee of our Board of Directors.

We may from time to time provide important disclosures to investors by posting them in the Investor Relations section of our website, as allowed by SEC rules. Information on our website is not incorporated into this Annual Report on Form 10-K.

The SEC also maintains a website at www.sec.gov that contains reports, proxy statements and other information about SEC registrants, including LivaNova.

Item 1A. *Risk Factors*

Our business and assets are subject to varying degrees of risk and uncertainty. An investor should carefully consider the risks described below, as well as other information contained in this Annual Report on Form 10-K and in our other filings with the SEC. Based on the information currently known to us, we believe the following information identifies the most significant risks affecting us, but the risks and uncertainties included below are not the only ones related to our businesses. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.

Risks Relating to the Company

The global medical device industry is highly competitive and we may be unable to compete effectively.

We are in highly competitive markets characterized by increasingly complex products that are expensive to develop and manufacture with significant price competition. In the product lines in which we compete, we face a mixture of competitors ranging from large manufacturers with multiple business lines to small manufacturers that offer a limited selection of specialized products. Development by other companies of new or improved products, processes, or technologies, as discussed above, may make our products or proposed products less competitive. In addition, we face competition from providers of alternative medical therapies such as pharmaceutical companies. Competitive factors include:

- product quality, reliability and performance;
- product technology;
- breadth of product lines and product services;
- ability to identify new market trends;
- customer support;
- price;
- capacity to recruit engineers, scientists and other qualified employees; and
- reimbursement approval from governmental payors and private healthcare insurance providers.

Shifts in industry market share can occur as a result of product issues, physician advisories, safety alerts, and publications about our products. The importance of product quality, product efficacy, and quality systems in the medical device industry cannot be overstated. In the current environment of managed care, consolidation among healthcare providers, increased competition, and declining reimbursement rates, we are increasingly required to compete on the basis of price. In order to continue to compete effectively, we must continue to create, invest in, or acquire advanced technology, incorporate this technology into our proprietary products, obtain regulatory approvals in a timely manner, and manufacture and successfully market our products. Additionally, we may experience design, manufacturing, marketing or other difficulties that could delay or prevent our development, introduction or marketing of new products or new versions of our existing products. As a result of such difficulties and delays, our development expenses may increase and, as a consequence, our results of operations could suffer.

Risks related to the reduction or interruption in supply and an inability to develop alternative sources for supply may adversely affect our manufacturing operations and related product sales.

We maintain manufacturing operations in six countries located throughout the world and purchase many of the components and raw materials used in manufacturing these products from numerous suppliers in various countries. Any problem affecting a supplier (whether due to external or internal causes) could have a negative impact on us.

In a few limited cases, specific components and raw materials are purchased from primary or main suppliers (or in some cases, a single supplier) for reasons related to quality assurance, cost-effectiveness ratio and availability. While we work closely with our suppliers to ensure supply continuity, we cannot guarantee that our efforts will always be successful. Moreover, due to strict standards and regulations governing the manufacture and marketing of our products, we may not be able to locate new supply sources quickly in response to a supply reduction or interruption, with negative effects on our ability to manufacture our products effectively and in a timely fashion.

Our products are subject to costly and complex laws and governmental regulations, and failure to obtain product approvals or clearance may materially adversely affect our financial condition and business operations.

Our medical devices and technologies, as well as our business activities, are subject to a complex set of regulations and rigorous enforcement, including by the FDA, U.S. Department of Justice, Health and Human Services - Office of the Inspector General, and numerous other federal, state, and non-U.S. governmental authorities. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of our products. As a part of the regulatory process of obtaining marketing clearance or approval for new products and new indications for existing products, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations, and trial endpoints. Unfavorable or inconsistent clinical data from existing or future clinical trials or the market's or FDA's perception of this clinical data, may adversely impact our ability to obtain product approvals, our position in, and share of, the markets in which we participate, and our business, financial condition, results of operations and cash flows. Success in pre-clinical testing and early clinical studies does not always ensure that later clinical studies will be successful, and we cannot be sure that later studies will replicate the results of prior studies. Clinical studies must also be conducted in compliance with Good Clinical Practice requirements administered by the FDA and other non-U.S. regulatory authorities, and global regulatory bodies may undertake enforcement action against us based on a failure to adhere to these requirements. Any delay or termination of our clinical studies will delay the filing of product submissions and, ultimately, our ability to commercialize new products or product modifications. It is also possible that patients enrolled in clinical studies will experience adverse side effects that are not currently part of the product's profile, which could inhibit further marketing and development of such products.

We cannot guarantee that we will be able to obtain or maintain marketing clearance for our new products or enhancements or modifications to existing products, and the failure to maintain approvals or obtain approval or clearance could have a material adverse effect on our business, results of operations, financial condition and cash flows. Even if we are able to obtain approval or clearance, it may take a significant amount of time; require the expenditure of substantial resources; involve stringent clinical and pre-clinical testing, as well as increased post-market surveillance; and involve modifications, repairs or replacements of our products, or limit the proposed uses of our products.

Modifications to our marketed products may require new clearances or approvals and may require us to cease marketing or recall the modified products until required clearances or approvals are obtained.

An element of our strategy is to continue to upgrade our products, add new features and expand clearance or approval of our current products to new indications. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. No assurance can be given that regulators will agree with any of our decisions not to seek clearance or approval.

If regulators require us to cease marketing and to recall a modified device until we obtain a new clearance or approval, our business, financial condition, operating results and future growth prospects could be materially adversely affected. Any recall requirement that we seek additional clearances or approvals could result in significant delays, fines, increased costs associated with modification of a product, loss of revenue, reputational damage and potential operating restrictions imposed by regulators.

Failure to comply with product-related government regulations may materially adversely affect our financial condition and business operations.

Both before and after a product is commercially released, we have ongoing responsibilities under FDA and other applicable non-U.S. government agency regulations. For instance, many of our facilities and procedures and those of our suppliers are also subject to periodic inspections by the FDA to determine compliance with applicable regulations. The results of these inspections can include inspectional observations on FDA's Form-483, warning letters, or other forms of enforcement. If the

FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical products are ineffective or pose an unreasonable health risk, the FDA could ban such medical products, detain or seize adulterated or misbranded medical products, order a recall, repair, replacement, or refund of such products, refuse to grant pending PMA applications or require certificates of non-U.S. governments for exports, and/or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA and other non-U.S. government agencies may also assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis. The FDA may also recommend prosecution to the U.S. Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future pre-market clearances or PMAs, and could result in a substantial modification to our business practices and operations. These potential consequences, as well as any adverse outcome from government investigations, could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

In addition, in the U.S., device manufacturers are prohibited from promoting their products other than for the uses and indications set forth in the approved product labeling, and any failure to comply could subject us to significant civil or criminal exposure, administrative obligations and costs, and/or other potential penalties from, and/or agreements with, the federal government.

Governmental regulations outside the U.S. have, and may continue to, become increasingly stringent and common. In the EU, for example, Reg MDR, when it enters into full force in 2020, will include significant additional premarket and post-market requirements. Penalties for regulatory non-compliance could be severe, including fines and revocation or suspension of a company's business license, mandatory price reductions and criminal sanctions. Future laws and regulations may also have a material adverse effect on us.

If our marketed medical devices are defective or otherwise pose safety risks, the FDA and similar non-U.S. governmental authorities could require their recall or initiate an enforcement action, or we may initiate a recall of our products voluntarily.

The FDA and similar non-U.S. governmental authorities may require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers, on their own initiative, may recall a product with a material deficiency. We have initiated voluntary product recalls in the past. A future recall announcement could harm our reputation with customers and negatively affect our revenue.

A government-mandated recall or voluntary recall by us or one of our sales agencies could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies or issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and operating results. Any recall could impair our ability to produce our products in a cost-effective and timely manner. We also may be required to bear other costs or take other actions that may have a negative impact on our future revenue and our ability to generate profits. In the future, we may initiate voluntary withdrawal, removal or repair actions that we determine do not require notification as a recall. If the regulating authority disagrees with our determinations, it could require us to report those actions as recalls. In addition, if we conduct a recall but fail to report it, we could be subject to enforcement action.

In addition, depending on the corrective action we take to redress a device's deficiencies or defects, the regulators may require, or we may decide, that we need to obtain new approvals or clearances for the device before we market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Any corrective action, whether voluntary or involuntary, or litigation, will require the dedication of our time and capital, distract management from operating the business, and may harm our reputation and financial results. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines.

As a manufacturer of medical devices, we will continue to be exposed to product liability claims that could adversely affect our consolidated financial condition and tarnish our reputation.

Our business exposes us to potential product liability risks that are inherent in the design, manufacture and marketing of medical devices. In addition, many of the medical devices we manufacture and sell are designed to be implanted in the human body for long periods of time. Component failures, manufacturing defects, design flaws or inadequate disclosure of product-related risks or product-related information with respect to these or other products we manufacture or sell could result in an unsafe condition or injury to, or death of, a patient. The occurrence of such an event could result in product liability claims or a recall of, or safety alert relating to, one or more of our products. We have elected to self-insure with respect to a significant portion of our product liability risks and also hold global insurance policies to cover a portion of future potential losses. Product

liability claims or product recalls in the future, regardless of their ultimate outcome, could have a material adverse effect on our business and reputation and on our ability to attract and retain customers for our products, and losses from product liability claims in the future could exceed our product liability insurance coverage and lead to a material adverse effect on our financial condition. In addition, future unanticipated large liability claims may raise substantial doubt about our ability to continue as a going concern.

We are currently involved in litigation that could adversely affect our business and financial results, divert management's attention from our business, and subject us to significant liabilities.

As described under "Note 14. Commitments and Contingencies" in our consolidated financial statements included in this Annual Report on Form 10-K, we are involved in various litigation matters that may adversely affect our financial condition and may require us to devote significant resources to our defense of these claims.

Such litigation includes a federal multi-district litigation in the U.S. District Court for the Middle District of Pennsylvania and cases in various state courts and jurisdictions outside the U.S. relating to our 3T Heater-Cooler product. As of March 2, 2020, we are aware of approximately 95 filed and unfiled claims worldwide, with the majority of the claims filed in various federal or state courts throughout the U.S. The number includes cases that have settled but have not yet been dismissed. The complaints generally seek damages and other relief based on theories of strict liability, negligence, breach of express and implied warranties, failure to warn, design and manufacturing defect, fraudulent and negligent misrepresentation/concealment, unjust enrichment and violations of various state consumer protection statutes. In the fourth quarter of the year ended December 31, 2018, we recognized a $294.1 million litigation provision and in the fourth quarter of the year ended December 31, 2019 we recognized an additional $33.2 million litigation provision related to these claims. Although we are defending these matters vigorously, we cannot predict the outcome or effect of any claim or other litigation matter.

Global healthcare policy changes and tightening of reimbursement for products may have a material adverse effect on us.

In response to increases in healthcare costs, there have been and continue to be proposals by governments, regulators and third-party payors to control these costs. These proposals have resulted in efforts to enact healthcare system reforms that may lead to pricing restrictions, limits on the amounts of reimbursement available for our products and could limit the acceptance and use of our products. The adoption of some or all of these proposals could have a material adverse effect on our financial position and results of operations.

Our ability to commercialize our products is dependent, in large part, on whether third-party payors, including private healthcare insurers, managed care plans, governmental programs and others agree to cover the costs and services associated with our products and related procedures in the U.S. and internationally.

Our products are purchased principally by healthcare providers that typically bill various third-party payors, such as governmental programs (e.g., Medicare and Medicaid in the U.S.) and private insurance plans for the healthcare services provided to their patients. The availability of adequate reimbursement affects the decision as to which procedures are performed, which products are purchased and what prices customers are willing to pay. After we develop a promising new product, we may find limited demand for the product if reimbursement approval is not obtained from private and governmental third-party payors. In addition, periodic changes to reimbursement methodologies could have an adverse impact on our business.

Our failure to comply with rules relating to reimbursement of healthcare goods and services, healthcare fraud and abuse, false claims and other applicable laws or regulations may subject us to penalties and adversely impact our reputation and business operations.

Our devices and therapies are subject to regulation by various governmental agencies worldwide responsible for coverage, reimbursement and regulation of healthcare goods and services, including laws and regulations related to kickbacks, false claims, self-referrals and health care fraud. Any failure to comply with these laws and regulations could subject us or our officers and employees to criminal and civil financial penalties.

The risk of being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including our relationships with surgeons and other healthcare providers, some of whom recommend, purchase and/or prescribe our devices, group purchasing organizations and our independent sales agents and distributors, could be subject to challenge under one or more of such laws.

Patient confidentiality and federal and state privacy and security laws and regulations may adversely impact our financial position and reputation.

HIPAA establishes federal rules protecting the privacy and security of personal health information in the U.S. In addition to HIPAA, virtually every U.S. state has enacted laws to safeguard privacy, and these laws vary significantly from state to state and change frequently. The privacy and security rules address the use and disclosure of individual healthcare information and the rights of patients to understand and control how such information is used and disclosed. The operation of our business involves the collection and use of substantial amounts of "protected health information." If we fail to comply with the applicable regulations, we could suffer civil penalties up to or exceeding $50,000 per violation, with a maximum of $1.5 million for multiple violations of an identical requirement during a calendar year and criminal penalties with fines up to $250,000 and potential imprisonment.

Similarly, the EU's GDPR protects the privacy and security of "personally identifiable information" and personal health information relating to individuals within the EU and, like HIPAA, GDPR addresses the use and disclosure of individual healthcare information and the rights of patients to understand and control how such information is used and disclosed. It subjects us to a rigorous proactive compliance scheme, and if we fail to comply with the GDPR, we could be sued for compensation by individuals who have suffered material or non-material damage and could suffer administrative fines up to the higher of €20.0 million (approximately $22.4 million), or 4% of the total worldwide annual revenue of the group in the previous financial year. We may also be subject to criminal sanctions.

Cyber-attacks or other disruptions to our information technology systems could lead to reduced revenue, increased costs, liability claims, fines, harm to our competitive position and loss of reputation.

We are increasingly dependent on our own sophisticated information technology systems and those of third parties to operate our business, and certain products of ours include integrated software and information technology. We rely on information technology systems to collect and process customer orders, manage product manufacturing and shipping and support regulatory compliance, and we routinely process, store and transmit large amounts of data, including sensitive personal information, protected health information and confidential business information. Many of our products incorporate software and information technology that allow patients and physicians to be connected and collect data regarding a patient and the therapy he or she is receiving, or that otherwise allow the products or services to operate as intended. The secure processing, maintenance and transmission of this information is critical to our operations but the size and complexity of our products and the information technology systems on which we rely make them vulnerable to cyber-attacks, breakdown, interruptions, destruction, loss or compromise of data, obsolescence or incompatibility among systems or other significant disruptions. Unauthorized persons routinely attempt to access our products or systems in order to disrupt, disable or degrade such products or services, to obtain proprietary or confidential information, or to remotely disrupt or access the systems of large health care providers by exploiting our products or systems. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. The negative publicity resulting from such disruptions could significantly impact our reputation and stock price.

In addition, we continue to grow, in part, through new business acquisitions. As a result of acquisitions, we may face risks due to implementation, modification, or remediation of controls, procedures and policies relating to data privacy and cybersecurity at the acquired company. We continue to consolidate and over time integrate the number of systems we operate, and to upgrade and expand our information system capabilities for stable and secure business operations. There can be no assurance that our process of consolidating, protecting, upgrading and expanding our systems and capabilities, continuing to build security into the design of our products, and developing new systems to keep pace with continuing changes in information processing technology will be successful or that additional systems issues will not arise in the future. Any significant breakdown, intrusion, interruption, corruption or destruction of these systems, as well as any data breaches, could have a material adverse effect on our business.

If we are unable to maintain secure, reliable information technology systems and prevent disruptions, outages, or data breaches, we may suffer legal and regulatory consequences in addition to business consequences. Our worldwide operations mean that we are subject to laws and regulations, including data protection and cyber-security laws and regulations, in many jurisdictions. For example, if we are in breach of the GDPR's or CCPA's requirement that we ensure a level of security, both in terms of technology and other organizational measures, appropriate to the risk that the confidentiality, integrity or availability of personally identifiable data is compromised, we could be subject to fines and enforcement actions. Despite programs to comply with such laws and regulations, there is no guarantee that we will avoid enforcement actions by governmental bodies. Enforcement actions may be costly and interrupt regular operations of our business. In addition, there is a trend of civil lawsuits and class actions relating to breaches of consumer data or other cyber-attacks pursuant to laws such as CCPA. While we have

not been named in any such lawsuits, if a breach or loss of data occurs, we could become a target of civil litigation or government enforcement actions.

Quality problems with our processes, goods, and services could harm our reputation for producing high-quality products and erode our competitive advantage, sales, and market share.

Quality is extremely important to us and our customers due to the serious and costly consequences of product failure. Our quality certifications are critical to the marketing success of our goods and services. If we fail to meet these standards, our reputation could be damaged, we could lose customers, and our revenue and results of operations could decline. Aside from specific customer standards, our success depends generally on our ability to manufacture precision-engineered components, sub-assemblies, and finished products to exact tolerances and from multiple materials. If our components fail to meet these standards or fail to adapt to evolving standards, our reputation as a manufacturer of high-quality components will be harmed, our competitive advantage could be damaged, and we could lose customers and market share.

Our R&D efforts rely on investments and investment collaborations, and we cannot guarantee that any previous or future investments or investment collaborations will be successful.

Our strategy to provide a broad range of therapies to restore patients to fuller, healthier lives requires a wide variety of technologies, products and capabilities. The rapid pace of technological development in the medical industry and the specialized expertise required in different areas of medicine make it difficult for one company alone to develop a broad portfolio of technological solutions. As a result, we also rely on investments and investment collaborations to provide us access to new technologies both in areas served by our existing or legacy businesses as well as in new areas.

We expect to make future investments where we believe that we can stimulate the development of, or acquire new technologies and products to further our strategic objectives and strengthen our existing businesses. Investments and investment collaborations in and with medical technology companies are inherently risky, and we cannot guarantee that any of our previous or future investments or investment collaborations will be successful or will not materially adversely affect our consolidated earnings, financial condition or cash flows.

We are substantially dependent on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to our rights or the rights of others may result in our payment of significant monetary damages and/or royalty payments, negatively impact our ability to sell current or future products, or prohibit us from enforcing our patent and other proprietary rights against others.

We rely on a combination of patents, trade secrets, and non-disclosure and non-competition agreements to protect our proprietary intellectual property, and we will continue to do so. Physician customers have historically moved quickly to new products and new technologies, and intellectual property rights, particularly patents and trade secrets, play a significant role in product development and differentiation. We operate in an industry characterized by extensive patent litigation, and intellectual property litigation is inherently complex and unpredictable. Patent litigation can result in significant damage awards and injunctions that could prevent our manufacture and sale of affected products or require us to pay significant royalties in order to continue to manufacture or sell affected products. While we intend to defend against any threats to our intellectual property, these patents, trade secrets, or other agreements may not adequately protect our intellectual property.

Further, pending patent applications may not result in patents being issued to us. Patents issued to or licensed by us in the past or in the future may be challenged or circumvented by competitors and such patents may be found invalid, unenforceable or insufficiently broad to protect our technology and may limit our competitive advantage. Third parties could obtain patents that may require us to negotiate licenses to conduct our business, and the required licenses may not be available on reasonable terms or at all. We also rely on non-disclosure and non-competition agreements with certain employees, consultants and other parties to protect, in part, trade secrets and other proprietary rights. We cannot be certain that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information, or that third parties will not otherwise gain access to our trade secrets or proprietary knowledge.

The laws and intellectual property systems of certain countries in which we market some of our products do not protect our intellectual property rights to the same extent as in the U.S., which may impact our market position in those countries. If we are unable to protect our intellectual property in those countries, it could have a material adverse effect on our business, financial condition, cash flows and reputation.

We may experience volatility in the trading price of our shares due to fluctuations in our quarterly operating results or other factors.

We experienced volatility in the trading price of our shares during 2019, including following the pre-release of our earnings for the first quarter thereof. In the future, our operating results may vary significantly from quarter to quarter due to many factors, including factors beyond our control, which may cause further volatility in the trading price of our shares. A number of other factors may also cause future volatility in our stock price, including the items discussed in this Item 1A. *Risk Factors*.

We are subject to environmental laws and regulations and the risk of environmental liabilities, violations and litigation in multiple jurisdictions.

Our operations involve the use of substances regulated under environmental laws, primarily those used in manufacturing and sterilization processes in the various jurisdictions where we operate. Certain environmental laws assess liability on current, prior and/or related owners or operators of real property for the costs or investigation, removal or remediation of hazardous substance at their properties or at properties on which they have disposed of hazardous substances. In addition, a governmental authority may seek to hold us liable for successor liability violations committed by any companies in which we invest or that we acquire. In addition to cleanup actions brought by governmental authorities, private parties could bring personal injury or other claims due to the presence of, or exposure to, hazardous substances. The ultimate cost of site cleanup and timing or future cash outflows is difficult to predict, given the uncertainties regarding the extent of the required cleanup and the interpretation of applicable laws and regulations. The costs of complying with current or future environmental protection and health and safety laws and regulations, or liabilities arising from past or future releases of, or exposures to, hazardous substances, may exceed our estimates, or have a material adverse effect on our business, results of operations, financial condition and cash flows.

We are subject to the risks of conducting business internationally.

We develop, manufacture, distribute and sell our products globally and we intend to continue to pursue growth opportunities worldwide. Our international operations are subject to risks that are inherent in conducting business overseas and under non-U.S. laws, regulations and customs. These risks include possible nationalization, negative consequences associated with Brexit, expropriation, importation limitations, pricing restrictions and violations of laws. Our profitability and operations are, and will continue to be, subject to a number of risks and potential costs, including:

- local product preferences and product requirements;
- longer-term receivables than are typical in the EU or the U.S.;
- difficulty enforcing agreements;
- creditworthiness of customers;
- trade protection measures and import and export licensing requirements;
- different labor regulations and workforce instability;
- higher danger of terrorist activity, war or civil unrest;
- selling our products through distributors and agents;
- political and economic instability; and
- the risks further described above in the section entitled "*The failure to comply with anti-bribery laws could materially adversely affect our business and result in civil and/or criminal sanctions.*"

We transact business in numerous countries around the world and expect that a significant portion of our business will continue to take place in international markets. Consolidated financial statements are prepared in our functional currency, while the financial statements of each of our subsidiaries are prepared in the functional currency of that entity. Accordingly, fluctuations in the exchange rate of the functional currencies of our foreign currency entities against our functional currency will impact our results of operations and financial condition. Although we may elect to hedge certain foreign currency exposure, we cannot be certain that the hedging activity will eliminate our currency risk.

In addition, in many of the countries where we operate, employees are covered by various laws and/or collective bargaining agreements that endow them, through their local or national representatives, with the right to be consulted in relation to specific issues, including the downsizing or closing of departments and staff reductions. The laws and/or collective bargaining agreements that are applicable to these agreements could have an impact on our flexibility, as they apply to programs to redefine and/or strategically reposition our activities. Our ability to implement staff downsizing programs or even temporary interruptions of employment relationships is predicated on the approval of government entities and the consent of labor unions. A negative response from a works council or union-organized work stoppages by employees could have a negative impact on our business.

We have significant global sales and operations and face risks related to health epidemics that could impact our sales and operating results.

Our business could be adversely affected by the effects of a widespread outbreak of contagious disease, including the recent outbreak of respiratory illness caused by a novel coronavirus first identified in China. Any outbreak of contagious diseases, and other adverse public health developments, could have a material adverse effect on our business operations. These could include disruptions or restrictions on our ability to travel or to distribute our products, as well as temporary closures of our facilities or the facilities of our suppliers or customers, the deferral of procedures in impacted countries or the temporary suspension of operations by us or our suppliers or customers. At the end of February 2020, for example, we temporarily closed a small administrative office in Milan, Italy and we continue to monitor the rapidly evolving situation. While we have not closed our two manufacturing plants in Italy as they are not in the impacted regions, there can be no assurance that they will not need to shut down. Any disruption of our operations, or those of our suppliers or customers, could impact our sales and operating results. In addition, a significant outbreak of contagious diseases in the human population could result in a widespread health crisis that could adversely affect the economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our products and likely impact our operating results.

The failure to comply with anti-bribery laws could materially adversely affect our business and result in civil and/or criminal sanctions.

Our operations are subject to anti-corruption laws, including the UK Bribery Act, FCPA and other anti-corruption laws that apply in countries where we do business. The UK Bribery Act, FCPA and these other laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Because of the predominance of government-administered healthcare systems in many parts of the world outside the U.S., many of our customer relationships are potentially subject to such laws.

We are, therefore, exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, independent sales agents and distributors may engage in fraudulent or other illegal activity in violation of these laws and our Code of Conduct. It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

Global enforcement of anti-corruption laws has increased substantially in recent years, with more frequent voluntary self-disclosures by companies, aggressive investigations and enforcement proceedings by governmental agencies, and assessment of significant fines and penalties against companies and individuals. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. Any alleged or actual violations of these regulations may subject us to government scrutiny, severe criminal or civil sanctions and other liabilities, including exclusion from government contracting or government healthcare programs, and could negatively affect our business, reputation, operating results and financial condition.

Our debt instruments require us to comply with affirmative covenants and specified financial covenants and ratios.

Certain restrictions and covenants in our debt instruments could affect our ability to operate and may limit our ability to react to market conditions or to take advantage of potential business opportunities as they arise. For example, such restrictions could adversely affect our ability to finance our operations, make strategic acquisitions, investments or alliances, restructure our organization or finance capital needs. Additionally, our ability to comply with these covenants and restrictions may be affected by events beyond our control, such as prevailing economic, financial, regulatory and industry conditions. If any of these restrictions or covenants is breached, we could be in default under one or more of our debt instruments, which, if not cured or waived, could result in acceleration of the indebtedness under such agreements and cross defaults under our other debt instruments. Any such actions could result in the enforcement of our lenders' security interests and/or force us into bankruptcy or liquidation, which could have a material adverse effect on our financial condition and results of operations.

Our inability to integrate recently acquired businesses or to successfully complete and integrate future acquisitions could limit our future growth or otherwise be disruptive to our ongoing business.

From time to time, we acquire businesses and expect to pursue acquisitions in support of our strategic goals. There can be no assurance that acquisition opportunities will be available on acceptable terms or at all, or that we will be able to obtain necessary financing or regulatory approvals to complete potential acquisitions. The success of any acquisition, investment or alliance may be affected by a number of factors, including our ability to properly assess and value the potential business opportunity or to successfully integrate any businesses we may acquire into our existing business. The integration of the

operations of acquired businesses requires significant efforts, including the coordination of information technologies, human resources, R&D, sales and marketing, operations, manufacturing, legal, compliance and finance. These efforts result in additional expenses and involve significant amounts of management's time that cannot then be dedicated to other projects. Failure to manage and coordinate the growth of the combined company successfully could also have an adverse impact on our business. In addition, we cannot be certain that our investments, alliances and acquired businesses will become profitable or remain so. If our investments, alliances or acquisitions are not successful, we may record unexpected impairment charges.

We may incur impairments of intangible assets and goodwill, primarily acquired in acquisitions, including the merger between Sorin and Cyberonics, that adversely affect our financial results.

As of December 31, 2019, the carrying value of our net intangible assets and goodwill totaled $1.5 billion, which represents 63.2% of our total assets. As of December 31, 2018, the carrying value of our net intangible assets and goodwill totaled $1.7 billion, which represented 67.7% of our total assets. During the year ended December 31, 2019, we determined that the In Process Research and Development ("IPR&D") asset relating to ImThera was impaired and as a result, recorded an impairment of $50.3 million, and we also fully impaired the goodwill and the IPR&D asset associated with the discontinuation of the Caisson business by recording a $42.4 million impairment to goodwill and a $89.0 million impairment to the IPR&D asset.

We review, when circumstances warrant, the carrying amounts of our intangible assets to determine whether those carrying amounts continue to be recoverable in accordance with U.S. generally accepted accounting principles. Significant negative industry or economic trends, disruptions to our businesses, significant unexpected or planned changes in the use of assets, divestitures and market capitalization declines, among other events, may result in impairments to goodwill and other intangible assets. Current impairments have significantly affected our financial results and future impairments could significantly affect reported financial results.

Consolidation in the healthcare industry could have an adverse effect on our revenue and results of operations.

Many healthcare industry companies, including medical device companies, are consolidating to create new companies with greater market power. As the healthcare industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions for medical devices that incorporate components we produce. Increasing pricing pressures as a result of industry consolidation could have an adverse effect on our revenue, results of operations, financial position and cash flows.

The success and continuing development of our products depend on maintaining strong relationships with physicians and healthcare professionals.

If we fail to maintain our working relationships with physicians and other healthcare professionals, our products may not be developed and marketed in line with the needs and expectations of the professionals who use and support our products. Physicians assist us as researchers, marketing consultants, product consultants, inventors and public speakers, and we rely on these professionals to provide us with considerable knowledge and experience. If we are unable to maintain these strong relationships, the development and marketing of our products could suffer, which could have a material adverse effect on our consolidated financial condition and results of operations.

Inadequate funding for U.S. federal government agencies and government shutdowns could negatively affect our business, results of operations and financial condition.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, government shutdowns and statutory, regulatory and policy changes. Disruptions at the FDA and in other U.S. federal agencies may increase the time necessary for new medical devices to be reviewed and/or approved which would adversely affect our business.

In addition, a portion of our revenue is dependent on U.S. federal government healthcare program reimbursement. Any disruption in U.S. federal government operations, including government shutdowns, could have a material adverse effect on our business, results of operations and financial condition.

Risks from Tax, Residency and Jurisdiction of Incorporation

Changes in tax laws or exposure to additional income tax liabilities could have a material impact on our financial condition and results of operations.

We are subject to income taxes as well as non-income based taxes, in the U.S., the UK, the EU and various other jurisdictions. No assurances can be given as to what our worldwide effective corporate tax rate will be because of, among other things, uncertainty regarding the tax regulations and laws, enactment and enforceability thereof and policies of the jurisdictions where we operate. Our actual effective tax rate may vary from our expectations or from historical trends and that variance may

be material. Our effective tax rates could be affected by changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities or changes in tax laws or their interpretation. We are also subject to ongoing tax audits in various non-U.S. jurisdictions. Tax authorities may disagree with certain positions we have taken and assess additional taxes. We believe that our accruals reflect the probable outcome of known contingencies. However, there can be no assurance that we will accurately predict the outcomes of ongoing audits, and the actual outcomes of these audits could have a material impact on our consolidated statements of income (loss) or financial condition.

The IRS may not agree with the conclusion that we should be treated as a foreign corporation for U.S. federal tax purposes, and we may be required to pay substantial U.S. federal income taxes.

Based on our management and organizational structure, we believe that we should be regarded as a resident exclusively in the UK for tax purposes and that we are appropriately treated as a foreign corporation for U.S. federal tax purposes. Although we are incorporated in the UK, the U.S. Internal Revenue Service (the "IRS") may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal tax purposes. If we were to be treated as a U.S. corporation for U.S. federal income tax purposes, we could be subject to substantially greater U.S. tax liability than currently contemplated as a non-U.S. corporation.

The IRS may limit Cyberonics' and its U.S. affiliates' ability to utilize their U.S. tax attributes and impose an excise tax on gains recognized by certain individuals as a result of the merger of Cyberonics and Sorin.

The merger of Cyberonics and Sorin is considered an inversion for tax purposes. The U.S. Internal Revenue Code ("IRC") and regulations under the IRC impose a minimum level of tax on any "inversion gain" of a U.S. corporation (and any U.S. person related to the U.S. corporation) depending on the resulting percentage ownership by U.S. persons of the merged company. The effect of this provision in the IRC is to deny the use of certain U.S. tax attributes (including net operating losses and certain tax credits) to offset U.S. tax liability, if any, attributable to such inversion gain. In addition, an excise tax may be imposed on certain individuals. In our case, we believe that the former stockholders of Cyberonics own less than the IRC's stated percentage of the Company. However, the final regulations relating to calculating the ownership percentage are new and subject to interpretation, and thus it cannot be assured that the IRS will agree with our position.

The UK's withdrawal from the EU, commonly referred to as "Brexit," 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.

On January 31, 2020, the UK departed from the EU and has entered a transition period that is scheduled to end on December 31, 2020, unless extended. Brexit could adversely affect UK, 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. For the three months and full year ended December 31, 2019, net sales generated from our European operations constituted approximately 20% and 21%, respectively, of total net sales. Although the long-term effects of Brexit will depend on any agreements the UK makes to retain access to the EU markets during the transition period, 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. In addition, 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 parties to intercompany transactions and agreements under which we receive various tax reliefs and exemptions in accordance with applicable international tax laws, treaties and regulations that could be materially changed by Brexit. Any of the foregoing could adversely affect our ability to conduct and expand our operations in Europe and may have an adverse effect on our business, financial condition and results of operations.

As an English public limited company, certain capital structure decisions will require shareholder approval, which may limit our flexibility to manage our capital structure.

We are a public limited company incorporated under the laws of England and Wales. Under English law, our board of directors may only allot shares with the prior authorization of shareholders. Our articles of association currently authorize the allotment of additional shares for a period of five years up to an aggregate of approximately 9.8 million shares. English law also generally provides shareholders with preemptive rights when new shares are issued for cash; which rights may be excluded by shareholders. Our articles currently exclude preemptive rights in relation to the allotment of shares for cash. In addition, English law also generally prohibits a public company from repurchasing its own shares without the prior approval of shareholders. The approval of the allotment of additional shares, the exemption of statutory preemptive rights and the restriction on repurchase of shares must all be renewed by shareholders at least every five years. We cannot provide any assurance that these authorizations will always be approved, which could limit our ability to issue equity and thereby adversely affect the holders of our securities.

Transfers of our shares, other than ones effected by means of the transfer of book-entry interests in the Depository Trust Company ("DTC"), may be subject to UK stamp duty or UK stamp duty reserve tax ("SDRT").

Transfers of our shares effected by means of the transfer of book-entry interests in DTC are not subject to UK stamp duty or SDRT. However, if a shareholder holds our shares directly rather than through DTC, any transfer of shares could be subject to UK stamp duty on SDRT at a rate of 0.5% of the consideration paid for the transfer and certain issues or transfers of shares to depositories or into clearance services are charged at a rate of 1.5% of the consideration paid for the transfer. The transferee generally pays the UK stamp duty or SDRT. The potential for UK stamp duty or SDRT could adversely affect the trading price of our shares.

The facilities of DTC are a widely used mechanism that allow for rapid electronic transfers of securities between the participants in the DTC system, which include many large banks and brokerage firms. Our shares are at present, subject to certain conditions, generally eligible for deposit and clearing within the DTC system. However, DTC generally has discretion to cease to act as a depository and clearing agency for our shares. If DTC determines at any time that our shares are not eligible for continued deposit and clearance within its facilities, then we believe that our shares would not be eligible for continued listing on a U.S. securities exchange and trading in our shares would be disrupted. While we would pursue alternative arrangements to preserve the listing and maintain trading, any such disruption could have a material adverse effect on the trading price of our shares.

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

Our principal executive office is located in the UK and is leased by us. Our business franchises, corresponding to our main therapeutic areas, Neuromodulation and Cardiovascular, have headquarters located in U.S. and Italy, respectively. The locations in the U.S. and Italy are owned by us. Manufacturing and research facilities are located in Brazil, Canada, Germany, Italy, Australia and the U.S. Manufacturing and research facilities are approximately 1.3 million square feet. Approximately 34% of our manufacturing and research facilities by square feet are located within the U.S. Approximately 66% of our manufacturing and research facilities by square feet are owned by us and the balance is leased.

We also maintain 23 primary administrative offices in 18 countries. Most of these locations are leased. We are using substantially all of our currently available productive space to develop, manufacture and market our products. Our facilities are in good operating condition, suitable for their respective uses and adequate for current needs.

Item 3. *Legal Proceedings*

Discussion of our material pending legal and regulatory proceedings and settlements is incorporated herein by reference to "Note 14. Commitments and Contingencies" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K and should be considered an integral part of "Item 3 of Part I" of this Annual Report on Form 10-K.

Item 4. *Mine Safety Disclosures*

Not applicable.

PART II

Item 5. *Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*

Our ordinary shares are quoted on the NASDAQ Global Market under the symbol "LIVN."

As of February 27, 2020, according to data provided by our transfer agent, there were 23 stockholders of record. However, we believe that the actual number of beneficial holders of our shares may be substantially greater than the stated number of holders of record because a substantial portion of the shares are held in street name.

Recent Sales of Unregistered Securities

During the past fiscal year, we did not issue any securities that were not registered under the Securities Act.

Dividend Policy

As a company organized under the laws of England and Wales, we must have "distributable reserves" to make share repurchases or pay dividends to shareholders. Distributable reserves may be created through the earnings of the UK parent company and, amongst other methods, through a reduction in share capital approved by the English Companies Court. Distributable reserves are not linked to a U.S. GAAP reported amount. In addition to having sufficient distributable reserves, English law requires a public company's net worth to be at least equal to the amount of its capital. Accordingly, a public company can only make a distribution: (a) if, at the time that the distribution is made, the amount of its net assets (that is, the total excess of assets over liabilities) is not less than the total of its called-up share capital and undistributable reserves; and (b) if, and to the extent that, the distribution itself, at the time that it is made, does not reduce the amount of the net assets to less than that total.

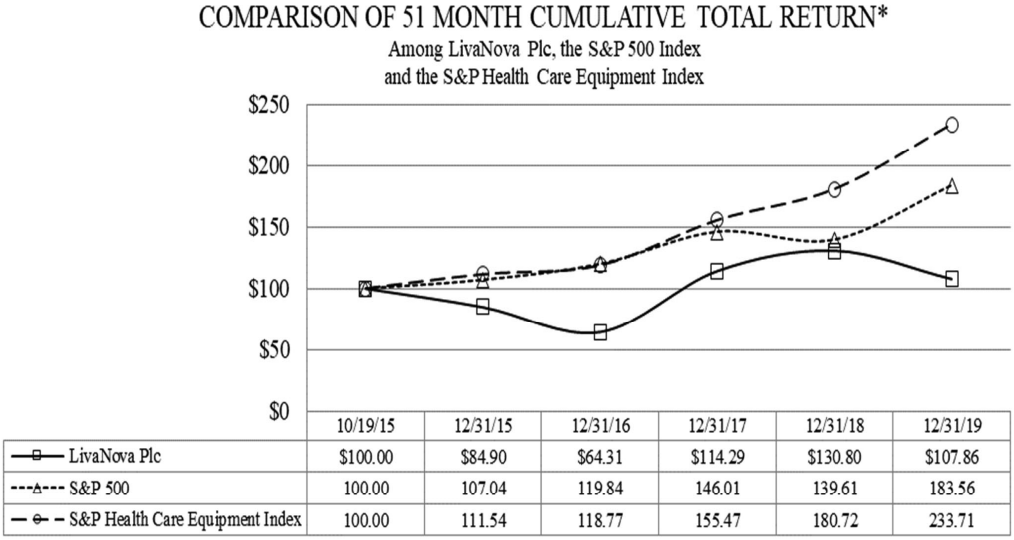
We currently have no intention to declare and pay dividends.

Issuer Purchases of Securities

On August 1, 2016, the Board of Directors of LivaNova approved the authorization of a share repurchase plan (the "Share Repurchase Program") pursuant to an authority granted by shareholders at the 2016 annual general meeting held on June 15, 2016. The authority granted by the shareholders has a five-year expiration. The Share Repurchase Program was structured to enable us to buy back up to $150.0 million of our shares on NASDAQ between September 1, 2016 through December 31, 2016. On November 15, 2016, the Board of Directors approved an amendment (the "Amended Share Repurchase Program") to the Share Repurchase Program authorizing the Company to repurchase up to $150.0 million of our shares between September 1, 2016 and December 31, 2018. No shares were repurchased under the Share Repurchase Program or the Amended Share Repurchase Program after December 31, 2018.

Stock Performance Graph

The following graph illustrates our 51-month cumulative total return compared with the S&P 500 Index and the S&P Health Care Equipment Index over the same period.



	10/19/15	12/31/15	12/31/16	12/31/17	12/31/18	12/31/19
LivaNova Plc	$100.00	$84.90	$64.31	$114.29	$130.80	$107.86
S&P 500	100.00	107.04	119.84	146.01	139.61	183.56
S&P Health Care Equipment Index	100.00	111.54	118.77	155.47	180.72	233.71

*$100 invested on 10/19/15 in stock or 9/30/15 in index, including reinvestment of dividends.
Fiscal year ending December 31.

The information under the caption “Stock Performance Graph” above is not deemed to be “filed” as part of the Annual Report on Form 10-K and is not subject to the liability provisions of Section 18 of the Exchange Act. Such information will not be deemed incorporated by reference into any filing we make under the Securities Act unless we explicitly incorporate it into such filing at such time.

Item 6. *Selected Financial Data*

The following table summarizes certain selected financial data and is qualified by reference to, and should be read in conjunction with, the consolidated financial statements and related notes under the section entitled "Item 15. Exhibits, Financial Statement Schedules" included in this Annual Report on Form 10-K. The selected financial data and the related notes for the years ended December 31, 2019, December 31, 2018, December 31, 2017 and December 31, 2016 are derived from audited consolidated financial statements that are included in this Annual Report on Form 10-K. The selected financial data and the related notes for the transitional period April 25, 2015 to December 31, 2015, and for the fiscal year ended April 24, 2015 are derived from audited consolidated financial statements that are included in the Annual Report on Form 10-KT for the transitional period ended December 31, 2015.

Consolidated Statements of Operations Data (In thousands, except per share data)	**Year Ended December 31, 2019**	**Year Ended December 31, 2018**	**Year Ended December 31, 2017**	**Year Ended December 31, 2016**	**Transitional Period April 25, 2015 to December 31, 2015**	**Fiscal Year Ended April 24, 2015**
Net sales	$ 1,084,170	$ 1,106,961	$ 1,012,277	$ 964,858	$ 363,237	$ 291,558
Costs and expenses:						
Cost of sales - exclusive of amortization	323,635	361,812	353,192	367,845	113,404	27,311
Product remediation	15,777	10,680	7,254	37,534	—	—
Selling, general and administrative	506,542	464,967	380,100	355,164	147,025	123,619
Research and development	149,889	146,024	109,516	82,078	41,916	42,245
Merger and integration expenses	23,457	24,420	15,528	20,377	55,776	8,692
Restructuring expenses	12,254	15,915	17,056	37,377	10,494	—
Impairment of goodwill	42,417	—	—	—	—	—
Impairment of intangible assets	139,295	—	—	—	—	—
Amortization of intangibles	40,375	37,194	33,144	31,035	7,030	1,039
Litigation provision, net	(601)	294,021	—	—	—	—
Operating (loss) income from continuing operations	(168,870)	(248,072)	96,487	33,448	(12,408)	88,652
Interest (expense) income, net	(14,288)	(8,978)	(6,479)	(8,918)	(1,117)	163
Gain on acquisitions	—	11,484	39,428	—	—	—
Impairment of investments	—	—	(8,565)	—	(5,062)	—
Foreign exchange and other (losses) gains	(2,536)	(1,881)	267	1,136	(7,411)	479
(Loss) income from continuing operations before tax	(185,694)	(247,447)	121,138	25,666	(25,998)	89,294
Income tax (benefit) expense	(30,153)	(69,629)	49,954	5,113	(13,501)	31,446
Losses from equity method investments	—	(644)	(16,719)	(18,679)	(2,223)	—
Net (loss) income from continuing operations	(155,541)	(178,462)	54,465	1,874	(14,720)	57,848
Discontinued Operations:						
Income (loss) from discontinued operations, net of tax	365	(10,937)	(1,271)	(64,663)	(14,893)	—
Impairment of discontinued operations, net of tax	—	—	(78,283)	—	—	—
Net income (loss) from discontinued operations, net of tax	365	(10,937)	(79,554)	(64,663)	(14,893)	—
Net (loss) income	$ (155,176)	$ (189,399)	$ (25,089)	$ (62,789)	$ (29,613)	$ 57,848

Consolidated Statements of Operations Data (In thousands, except per share data)	**Year Ended December 31, 2019**	**Year Ended December 31, 2018**	**Year Ended December 31, 2017**	**Year Ended December 31, 2016**	**Transitional Period April 25, 2015 to December 31, 2015**	**Fiscal Year Ended April 24, 2015**
Basic (loss) income per share:						
Continuing operations	$ (3.22)	$ (3.68)	$ 1.13	$ 0.04	$ (0.45)	$ 2.19
Discontinued operations	0.01	(0.23)	(1.65)	(1.33)	(0.45)	—
	$ (3.21)	$ (3.91)	$ (0.52)	$ (1.29)	$ (0.90)	$ 2.19
Diluted (loss) income per share:						
Continuing operations	$ (3.22)	$ (3.68)	$ 1.12	$ 0.04	$ (0.45)	$ 2.17
Discontinued operations	0.01	(0.23)	(1.64)	(1.32)	(0.45)	—
	$ (3.21)	$ (3.91)	$ (0.52)	$ (1.28)	$ (0.90)	$ 2.17
Shares used in computing basic (loss) income per share	48,349	48,497	48,157	48,860	32,741	26,391
Shares used in computing diluted (loss) income per share	48,349	48,497	48,501	49,014	32,741	26,626

Consolidated Balance Sheet Data (In thousands)	**December 31, 2019**	**December 31, 2018**	**December 31, 2017**	**December 31, 2016**	**December 31, 2015**	**April 24, 2015**
Cash, cash equivalent and short-term investments	$ 61,137	$ 47,204	$ 93,615	$ 39,789	$ 119,610	$ 151,207
Working capital	36,890	36,551	463,842	462,800	314,293	209,272
Total assets [(1)]	2,411,797	2,549,701	2,503,891	2,342,631	2,558,739	315,944
Long-term debt, net of current portion	260,330	139,538	61,958	75,215	91,791	—
Accumulated (deficit) earnings	(406,755)	(251,579)	(39,664)	(14,575)	48,214	77,827
Stockholders' equity	1,383,717	1,503,738	1,815,314	1,706,909	1,811,462	276,574

(1) The selected financial data for fiscal year 2019 reflects the adoption of ASU 2016-02. Leases (Topic 842). For additional information refer to "Note 2. Basis of Presentation, Use of Accounting Estimates and Significant Accounting Policies." The selected financial data for the periods prior to 2019 do not reflect the adoption of ASU 2016-02.

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

You should read the following discussion and analysis together with the sections entitled "Business" and "Risk Factors" in Part I of this Annual Report on Form 10-K, the matters set forth in "Cautionary Statement About Forward-Looking Statements" and our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K as of and for the years ended December 31, 2019, December 31, 2018 ("2018") and December 31, 2017 ("2017").

We have elected to omit certain discussions on the earliest of the three years covered in this Annual Report on Form 10-K. Refer to Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations located in our Form 10-K for the year ended December 31, 2018, filed on March 18, 2019, for reference to discussion of the fiscal year ended December 31, 2017, the earliest of the three fiscal years presented.

Description of the Business

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.

Background

We were organized under the laws of England and Wales on February 20, 2015 for the purpose of facilitating the business combination of Cyberonics, Inc., a Delaware corporation, and Sorin S.p.A., a joint stock company organized under the laws of Italy. The business combination became effective in October 2015. LivaNova's ordinary shares are listed for trading on the NASDAQ Global Market under the symbol "LIVN."

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.

Cardiovascular

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, related repair products and minimally invasive surgical instruments. Advanced circulatory support includes temporary life support product kits that can include a combination of pumps, oxygenators and cannulae.

Cardiopulmonary

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

Product Remediation

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

The Warning Letter further stated that our 3T Heater-Cooler devices (the "3T devices") and other devices we manufactured at our Munich facility were 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 informed us that the import alert was limited to the 3T devices, but that the agency reserved the right to expand the scope of the import alert if future circumstances warranted such action. The Warning Letter did not request that existing users cease using the 3T device, and manufacturing and shipment of all our products other than the 3T device were 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 were reasonably related would not be approved until the violations had been corrected; however, this restriction applied only to the Munich and Arvada facilities, which do not manufacture or design devices subject to Class III premarket approval.

On February 25, 2020, LivaNova received clearance for K191402, a 510(k) for the 3T devices that addressed issues contained in the 2015 Warning Letter along with design changes that further mitigate the potential risk of aerosolization. Concurrent with this clearance, (1) 3T devices manufactured in accordance with K191402 will not be subjected to the import alert and (2) LivaNova initiated a correction to distribute the updated Operating Instructions cleared under K191402.

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 refer to "Note 14. Commitments and Contingencies" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

Centers for Disease Control and Prevention ("CDC") and FDA Safety Communications, Company Field Safety Notice Update and Product Remediation Plan

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 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. 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 April 12, 2018, the FDA agreed to allow us to move forward with the deep cleaning service in the U.S. adding to the growing list of countries around the world in which we offer this service. On 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., and on February 25, 2020, LivaNova received clearance for K191402, a 510(k) for the 3T devices that addressed issues contained in the 2015 Warning Letter along with design changes that further mitigate the potential risk of aerosolization. Furthermore, we continue to offer a no-charge deep disinfection service (deep cleaning service) for 3T device users as we receive the required regulatory approvals.

On 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 December 31, 2019, the product remediation liability was $3.3 million. For further information, refer to "Note 7. Product Remediation Liability" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

Heart Valves

In January 2018, we announced that we had started enrollment in our BELIEVE study. This study focuses on the overall incidence of reduced leaflet motion identified by CT imaging in patients receiving our aortic heart valve. We are planning to enroll a minimum of 75 patients at 11 sites in the U.S. and Canada.

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

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

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

In June 2019, we acquired Miami Instruments, LLC's minimally invasive cardiac surgery instruments business for cash consideration of up to $17.0 million. The related operations are integrated into our Cardiovascular business franchise as part of our Heart Valves portfolio.

Advanced Circulatory Support

In April 2018, we acquired TandemLife, which is focused on the delivery of leading-edge temporary life support products, including cardiopulmonary and respiratory support solutions. For further information, refer to "Note 4. Business Combinations" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

In July 2019, the FDA approved our LifeSPARC system, a new generation of the Advanced Circulatory Support pump and controller. In the fourth quarter of 2019, we began a limited commercial release in the U.S. and expect a full commercial launch in the second half of 2020.

Neuromodulation

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

Epilepsy

Our product development efforts are directed toward improving the VNS Therapy System and developing new products that provide additional features and functionality. We are conducting ongoing product development activities to enhance the VNS Therapy System pulse generator, lead and programming software, and we support studies for our product development efforts and to build clinical evidence for the VNS Therapy System.

In October 2017, we obtained FDA approval and in April 2018, we received CE mark approval for our SenTiva VNS Therapy System, which consists of the SenTiva implantable generator and the next-generation VNS Therapy Programming System. SenTiva is the smallest and lightest responsive therapy for epilepsy. The new VNS Therapy Programming System features a wireless wand and new user interface on a small tablet. Together, these components offer patients with drug-resistant epilepsy a physician-directed, customizable therapy with smart technology that reduces the number of seizures, lessens the duration of seizures and enables a faster recovery.

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

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

Depression

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

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

In July 2005, the FDA approved the VNS Therapy System for the adjunctive treatment of chronic or recurrent depression for patients 18 years or older who are experiencing a major depressive episode and have not had an adequate response to four or more antidepressant treatments. In May 2007, CMS issued a national determination of non-coverage within the U.S. with respect to reimbursement of the VNS Therapy System for patients with DTD, significantly limiting access to this therapeutic option for most patients. In May 2018, CMS published a tracking sheet to reconsider its National Coverage Determination ("NCD") of our VNS Therapy System for DTD in response to a letter that we submitted to CMS requesting a formal reconsideration of the NCD. We requested this review after a significant body of new evidence emerged about DTD and the role of VNS Therapy in its treatment.

In February 2019, CMS finalized its NCD for the VNS Therapy System for DTD. 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 coverage for 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 DTD. 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 DTD.

Obstructive Sleep Apnea

We have invested in ImThera, a privately held, emerging-growth company developing an implantable neurostimulation device system for the treatment of obstructive sleep apnea, since 2011. On January 16, 2018, we acquired the remaining 86% outstanding equity interests in ImThera for up to approximately $225 million. Up-front costs were approximately $78 million with the balance paid on a schedule driven by regulatory and sales milestones. ImThera manufactures an implantable device that stimulates multiple tongue muscles via the hypoglossal nerve, which opens the airway while a patient is sleeping. ImThera has a commercial presence in the European market, and an FDA pivotal study is ongoing in the U.S.

Heart Failure

We are focused on the development and clinical testing of the VITARIA System for treating heart failure through vagus nerve stimulation.

The VITARIA System provides a specific method of VNS called autonomic regulation therapy ("ART"), and it includes the same elements as the VNS Therapy System. We conducted a pilot study, ANTHEM-HF, outside the U.S., which concluded in 2014. The study results support the safety and efficacy of ART delivered by the VITARIA System. During 2014, we also initiated a second pilot study, ANTHEM-HFPEF, to study ART in patients experiencing symptomatic heart failure with preserved ejection fraction. This pilot study is currently underway outside the U.S. The VITARIA System is not approved in the U.S.

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

Discontinued Operations

We completed the sale of our CRM business franchise to MicroPort Cardiac Rhythm B.V. and MicroPort Scientific Corporation (the "CRM Sale") on April 30, 2018 for total cash proceeds of $195.9 million, less cash transferred of $9.2 million, subject to a closing working capital adjustment. In conjunction with the CRM Sale, we entered into transition services agreements to provide certain support services generally for up to twelve months from the closing date of the sale. We

previously concluded that the sale of CRM represented a strategic shift in our business that has a major effect on future operations and financial results. Accordingly, the results of operations of the CRM business franchise are reflected as discontinued operations for all periods presented in this Annual Report on Form 10-K. For further information, refer to "Note 5. Discontinued Operations" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

Corporate Activities and New Ventures Update

Corporate activities include shared services for finance, legal, human resources and information technology, corporate business development and New Ventures.

Mitral Valve Regurgitation

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

In May 2017, we acquired the remaining 51% outstanding equity interests in Caisson, a clinical-stage medical device company focused on the design, development and clinical evaluation of a novel TMVR implant device with a fully transvenous delivery system for the treatment of MR for a purchase price of up to $72.0 million. As a result of our acquisition of Caisson, we began consolidating the results of Caisson as of May 2, 2017.

As we announced in November 2019, we ended our Caisson TMVR program effective December 31, 2019, and as a result, we fully impaired the IPR&D asset and goodwill of $89.0 million and $42.4 million, respectively. Patients who participated in clinical trials related to TMVR will continue to be followed within the parameters of the trial.

We are also invested in two mitral valve startups, Cardiosolutions, Inc. ("Cardiosolutions") and Highlife S.A.S. ("Highlife"). Cardiosolutions, a startup headquartered in the U.S. in which we have held an interest since 2012, is developing an innovative spacer technology for treating MR. Highlife, headquartered in France, is focused on developing devices for treating MR through percutaneous replacement of the native mitral valve. We recognized an impairment of our equity method investment in, and notes receivable from, Highlife during the year ended December 31, 2017, due to certain factors including a revision in our investment strategy indicating that the carrying value of our aggregate investment might not be recoverable and that the decrease in value of our aggregate investment was other than temporary. We, therefore, estimated the fair value of our investment and notes receivable using the market approach and recorded an aggregate impairment of $13.0 million. For further information regarding Highlife, refer to "Note 9. Investments" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

Central Sleep Apnea

We are invested in Respicardia Inc. ("Respicardia"), a U.S.-based developer of implantable therapies designed to improve Respiratory Rhythm Management and cardiovascular health. Respicardia's remedē System is an implantable device system designed to restore a more natural breathing pattern during sleep in patients with central sleep apnea by transvenously stimulating the phrenic nerve. The remedē System received CE Mark certification in 2010 and in October 2017, Respicardia received U.S. FDA market approval. In December 2017, certain factors, including an additional round of external financing with a new investor, indicated that the carrying value of our investment might not be recoverable and the decrease in value of our investment was other than temporary. Our estimate of the fair value of our investment using the income approach was below our carrying value and as a result, we recorded an impairment of $5.5 million. This impairment was recorded in impairment of investments in our consolidated statement of income (loss) for our fiscal year 2017.

Results of Operations

The following table summarizes our consolidated results for the years ended December 31, 2019, 2018 and 2017 (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Net sales	$ 1,084,170	$ 1,106,961	$ 1,012,277
Costs and expenses:			
Cost of sales - exclusive of amortization	323,635	361,812	353,192
Product remediation	15,777	10,680	7,254
Selling, general and administrative	506,542	464,967	380,100
Research and development	149,889	146,024	109,516
Merger and integration expenses	23,457	24,420	15,528
Restructuring expenses	12,254	15,915	17,056
Impairment of goodwill	42,417	—	—
Impairment of intangible assets	139,295	—	—
Amortization of intangibles	40,375	37,194	33,144
Litigation provision, net	(601)	294,021	—
Operating (loss) income from continuing operations	(168,870)	(248,072)	96,487
Interest income	803	847	1,318
Interest expense	(15,091)	(9,825)	(7,797)
Gain on acquisitions	—	11,484	39,428
Impairment of investments	—	—	(8,565)
Foreign exchange and other (losses) gains	(2,536)	(1,881)	267
(Loss) income from continuing operations before tax	(185,694)	(247,447)	121,138
Income tax (benefit) expense	(30,153)	(69,629)	49,954
Losses from equity method investments	—	(644)	(16,719)
Net (loss) income from continuing operations	(155,541)	(178,462)	54,465
Discontinued Operations:			
Income (loss) from discontinued operations, net of tax	365	(10,937)	(1,271)
Impairment of discontinued operations, net of tax	—	—	(78,283)
Net income (loss) from discontinued operations, net of tax	365	(10,937)	(79,554)
Net loss	$ (155,176)	$ (189,399)	$ (25,089)

Net Sales by segments and geographic area:

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

	Year Ended December 31,			% Change	% Change
	2019	2018	2017	2019 vs 2018	2018 vs 2017
Cardiopulmonary					
United States	$ 161,471	$ 161,134	$ 152,828	0.2 %	5.4 %
Europe	135,632	141,720	133,585	(4.3)%	6.1 %
Rest of World	207,613	233,554	210,911	(11.1)%	10.7 %
	504,716	536,408	497,324	(5.9)%	7.9 %
Heart Valves					
United States	18,900	24,709	24,977	(23.5)%	(1.1)%
Europe	40,548	44,258	42,120	(8.4)%	5.1 %
Rest of World	60,559	56,989	71,096	6.3 %	(19.8)%
	120,007	125,956	138,193	(4.7)%	(8.9)%
Advanced Circulatory Support					
United States	30,781	18,588	—	65.6 %	—
Europe	741	580	—	27.8 %	—
Rest of World	401	293	—	36.9 %	—
	31,923	19,461	—	64.0 %	—
Cardiovascular					
United States	211,152	204,431	177,805	3.3 %	15.0 %
Europe	176,921	186,558	175,705	(5.2)%	6.2 %
Rest of World	268,573	290,836	282,007	(7.7)%	3.1 %
	656,646	681,825	635,517	(3.7)%	7.3 %
Neuromodulation					
United States	335,332	348,980	316,916	(3.9)%	10.1 %
Europe	46,262	42,443	34,765	9.0 %	22.1 %
Rest of World	42,953	31,567	23,295	36.1 %	35.5 %
	424,547	422,990	374,976	0.4 %	12.8 %
Other	2,977	2,146	1,784	38.7 %	20.3 %
Totals					
United States	546,484	553,411	494,721	(1.3)%	11.9 %
Europe [1]	223,183	229,001	210,470	(2.5)%	8.8 %
Rest of World	314,503	324,549	307,086	(3.1)%	5.7 %
Total	$ 1,084,170	$ 1,106,961	$ 1,012,277	(2.1)%	9.4 %

(1) Includes those countries in Europe where we have a direct sales presence. Countries where sales are made through distributors are included in ‘Rest of World’.

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

	Year Ended December 31,			% Change	% Change
	2019	2018	2017	2019 vs 2018	2018 vs 2017
Cardiovascular	$ 28,460	$ (258,493)	$ 81,412	(111.0)%	(417.5)%
Neuromodulation	83,483	184,674	183,228	(54.8)%	0.8 %
Other	(204,727)	(96,724)	(102,425)	111.7 %	5.6 %
Total reportable segment (loss) income from continuing operations [1]	$ (92,784)	$ (170,543)	$ 162,215	(45.6)%	(205.1)%

(1) For a reconciliation of segment (loss) income from continuing operations to our consolidated (loss) income from continuing operations before tax, refer to "Note 20. Geographic and Segment Information" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

Cardiovascular

Cardiovascular net sales for the year ended December 31, 2019 compared to the year ended December 31, 2018 decreased 3.7%. The decline in net sales for the year ended December 31, 2019 was due to declines in Cardiopulmonary and Heart Valves sales of 5.9% and 4.7%, respectively, partially offset by a $12.5 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 $504.7 million were negatively impacted as a result of exiting a Canadian distribution agreement on January 1, 2019 that accounted for $32.9 million in sales during the year ended December 31, 2018. Growth in sales of oxygenators, autotransfusion systems and heart-lung machines were mostly offset by the impacts of foreign currency. Growth in oxygenator sales was impacted by an unexpected component supplier issue that occurred during the fourth quarter of 2019. Heart Valves sales declined as Rest of World growth was more than offset by softness in the U.S. and the impacts of foreign currency.

Cardiovascular segment operating income increased for the year ended December 31, 2019 as compared to the year ended December 31, 2018, primarily due to the recording of a $294.1 million litigation provision liability related to our 3T device during 2018.

Cardiovascular segment net sales increased $46.3 million, or 7.3% for the year ended December 31, 2018, as compared to the year ended December 31, 2017, primarily due to growth of $39.1 million in cardiopulmonary product revenue and $19.5 million from the acquisition of TandemLife on April 4, 2018, partially offset by a $12.2 million decline in heart valve net sales. Cardiopulmonary product sales increased year-over-year primarily due to strong heart-lung machine sales as customers continued in 2018 to upgrade from our legacy S3 device to our current S5 device and as well as strong sales of the Inspire oxygenator. With respect to heart valves, the expected termination of a manufacturing contract resulted in a decrease in heart valve net sales of $8.4 million for the year ended December 31, 2018 as compared to 2017. Additionally, increased sales of our Perceval sutureless aortic heart valves were more than offset by a non-recurring sales return reserve of $3.4 million recorded during 2018 and continuing global declines in traditional tissue heart valve and mechanical heart valve sales.

Cardiovascular segment operating income decreased for the year ended December 31, 2018 as compared to 2017, primarily due to the $294.1 million litigation provision related to our 3T device that was recorded during 2018. Additionally, positive impacts to operating income associated with the increases in net sales were more than offset by increased sales and marketing expenses related to our efforts to expand market share in international markets, increased R&D investments in support of the next generation heart-lung machine and increased legal costs associated with our 3T litigation. The inclusion of the operating results of TandemLife also resulted in a $10.8 million decrease in operating income for the year ended December 31, 2018 as compared to 2017.

Neuromodulation

Neuromodulation net sales for the year ended December 31, 2019 compared to the year ended December 31, 2018 increased 0.4%. The increase in net sales for the year ended December 31, 2019 was due to adoption of the Sentiva VNS Therapy System and strong growth in Europe and Rest of World, offset by a decline in U.S. sales principally due to competitive dynamics and sales force turnover during the first half of 2019.

Neuromodulation segment operating income decreased for the year ended December 31, 2019 compared to the year ended December 31, 2018 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 DTD, heart failure and obstructive sleep apnea.

Neuromodulation segment net sales increased $48.0 million or 12.8% for the year ended December 31, 2018 compared to 2017 primarily due to strong adoption of the SenTiva VNS Therapy System in the U.S. Net sales in 2018 also benefited from increased sales in Europe following the approval and launch of the SenTiva VNS Therapy System in April 2018, and strong growth in the Rest of World region despite the short-term impact of business model changes.

Neuromodulation segment operating income slightly increased for the year ended December 31, 2018 compared to 2017 primarily due to increased sales, partially offset by increased marketing expenses related to efforts to market direct to consumer, increased R&D expenses for new projects surrounding our SenTiva VNS Therapy System, DTD and heart failure and the inclusion of the operating results of ImThera in 2018 which represented a loss of $8.8 million.

Costs and Expenses

The table below illustrates our costs and expenses as a percentage of net sales:

	Year Ended December 31,		
	2019	2018	2017
Cost of sales - exclusive of amortization	29.9 %	32.7%	34.9%
Product remediation	1.5 %	1.0%	0.7%
Selling, general and administrative	46.7 %	42.0%	37.5%
Research and development	13.8 %	13.2%	10.8%
Merger and integration expenses	2.2 %	2.2%	1.5%
Restructuring expenses	1.1 %	1.4%	1.7%
Impairment of goodwill	3.9 %	—%	—%
Impairment of intangible assets	12.8 %	—%	—%
Amortization of intangibles	3.7 %	3.4%	3.3%
Litigation provision, net	(0.1)%	26.6%	—%

Cost of Sales

Cost of sales consisted primarily of direct labor, allocated manufacturing overhead, the acquisition cost of raw materials and components.

Cost of sales as a percentage of net sales was 29.9% for the year ended December 31, 2019, a decrease of 2.8% as compared to 2018. This decrease was primarily due to the amortization of inventory step-up value associated with the acquisition of TandemLife of $8.0 million for the twelve months ended December 31, 2018, reduced expense associated with the change in the fair value of sales-based contingent consideration arrangements, favorable product mix and the impacts of foreign currency.

Cost of sales as a percentage of net sales was 32.7% for the year ended December 31, 2018, a decrease of 2.2% as compared to 2017. This decrease was primarily due to favorable product mix, pricing discipline and our focus on cost efficiencies.

Product Remediation

Product remediation as a percentage of net sales was 1.5%, 1.0% and 0.7% for the years ended December 31, 2019, 2018 and 2017, respectively. Product remediation expenses include internal labor costs, costs to remediate certain inspectional observations made by the FDA at our Munich facility and costs associated with the incorporation of the modification of the 3T device design into the next generation heater cooler device.

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

SG&A expenses are comprised of sales, marketing, general and administrative activities. SG&A expenses exclude integration costs incurred following the merger between Cyberonics and Sorin and restructuring costs under the restructuring plans.

SG&A expenses as a percentage of net sales increased for the year ended December 31, 2019 as compared to 2018 primarily due to increased 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, costs associated with material weakness remediation, expenses associated with the expiration of a contract with one of our distributors and overall lower sales.

SG&A expenses as a percentage of net sales increased for the year ended December 31, 2018 as compared to 2017 primarily due to key growth driver investments in the U.S., including efforts to market directly to consumers within our Neuromodulation

business, acquisition costs and additional SG&A costs from the acquisitions of TandemLife and ImThera. Increased sales and marketing expenses internationally for general market expansion, increased litigation expenses primarily related to our 3T devices and the overall strengthening of our organizational capabilities to support growth also contributed to the increase in SG&A expenses as a percentage of net sales.

Research and Development 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 DTD, obstructive sleep apnea and heart failure.

R&D expenses as a percentage of net sales increased for the year ended December 31, 2019 as compared to 2018 primarily due to additional R&D expenses associated with obstructive sleep apnea, heart failure and DTD, offset by reductions in fair value of milestone-based contingent consideration arrangements.

R&D expenses as a percentage of net sales increased for the year ended December 31, 2018 as compared to 2017 primarily due to additional R&D expenses for our development of next generation products, including heart-lung machines, the SenTiva VNS Therapy System and TandemLife and clinical trials and investments in DTD, TMVR, obstructive sleep apnea and heart failure.

Merger and Integration ("M&I") Expenses

M&I expenses consist primarily of costs associated with computer systems integration efforts, organizational structure integration, synergy and tax planning.

M&I expenses as a percentage of net sales for the year ended December 31, 2019 was consistent with the year ended December 31, 2018.

M&I expenses as a percentage of net sales increased 0.7% to 2.2% for the year ended December 31, 2018 as compared to 2017, primarily due to efforts to improve and standardize product pricing and procurement strategies.

Restructuring Expenses

Our restructuring plans leverage economies of scale, eliminate duplicate corporate expenses and streamline distributions, logistics and office functions in order to reduce overall costs. Restructuring expenses are detailed in "Note 6. Restructuring" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K. Our 2015 and 2016 Reorganization Plans (the "Prior Plans") were initiated in October 2015 and March 2016, respectively, in conjunction with the completion of the merger of Sorin and Cyberonics. The Prior Plans included the Costa Rica manufacturing operation exit plan, initiated in December 2016 and completed during 2017, and the Suzhou, China exit plan, initiated in March 2017 and completed 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. The 2018 Plan resulted in a net reduction of approximately 75 personnel and was completed at the end of 2019.

In November 2019, we initiated a reorganization plan (the "2019 Plan") to streamline our organizational structure in order to address new regulatory requirements, create efficiencies, improve profitability and ensure business continuity. As a result, we incurred restructuring expenses of $4.4 million during the year ended December 31, 2019, primarily associated with severance costs for approximately 35 impacted employees.

Also in November 2019, we announced that we would be ending our Caisson TMVR program effective December 31, 2019 after determining that it was no longer viable to continue to invest in the program. As a result, we recognized restructuring expenses of $3.5 million during the year ended December 31, 2019, primarily associated with severance costs for approximately 50 impacted employees.

Impairment of Goodwill and Intangibles

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.

Our announcement that we would be ending our Caisson TMVR program effective December 31, 2019, triggered an evaluation of finite and indefinite lived assets for impairment. As a result, we fully impaired the goodwill and IPR&D asset of $42.4 million and $89.0 million, respectively.

Amortization of Intangibles

Amortization of intangible assets for the years ended December 31, 2019, 2018 and 2017, consisted primarily of the amortization of finite-lived intangible assets, primarily intellectual property and customer relationships.

Amortization of intangibles increased for the year ended December 31, 2019 to $40.4 million as compared to $37.2 million for the year ended December 31, 2018 primarily due to amortization of developed technology associated with the acquisition of TandemLife. The developed technology of $107.5 million was initially recorded to IPR&D assets upon acquisition in April 2018 but was reclassified to developed technology during the third quarter of 2019 upon receiving FDA approval of the LifeSPARC system.

Amortization for the year ended December 31, 2018 increased by $4.1 million as compared to 2017 due primarily to the amortization of intangible assets recognized as part of the acquisition of TandemLife in April 2018.

Litigation Provision, Net

During 2018, we recognized a $294.1 million litigation provision involving our 3T device. During 2019, we entered into agreements with our insurance carriers to recover $33.8 million under our product liability insurance policies. The insurance recovery was received and recognized in 2019. We recorded an additional liability of $33.2 million due to additional information obtained in the fourth quarter of 2019, including but not limited to: the nature and quality of filed and unfiled claims; certain settlement discussions with plaintiffs' counsel; and the current stage of litigation in our remaining filed and unfiled claims. For further information, refer to "Note 14. Commitments and Contingencies" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

Interest Expense

We incurred interest expense of $15.1 million for the year ended December 31, 2019, as compared to $9.8 million and $7.8 million for 2018 and 2017, respectively. The increase for the year ended December 31, 2019 as compared to 2018 was primarily due to increased debt borrowings in 2019 mostly associated with 3T litigation settlements. The increase for the year ended December 31, 2018 as compared to 2017 was also primarily due to increased debt borrowings in 2018.

Gain on Acquisitions

On January 16, 2018, we acquired the remaining outstanding interest of ImThera. 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 year ended December 31, 2019 was 16.2% compared with 28.1% for 2018. 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.

Our effective income tax rate from continuing operations for the year ended December 31, 2018 was 28.1% compared with 41.2% for 2017. Our effective income tax rate fluctuates based on, among other factors, changes in pretax income in countries with varying statutory tax rates, changes in valuation allowances, changes in tax credits and incentives and changes in unrecognized tax benefits associated with uncertain tax positions.

Compared with the year ended December 31, 2018, the decrease in the effective tax rate for 2019 was primarily attributable to the impact of a full valuation allowance for the U.S. losses, release of uncertain tax positions, change in our UK group filing exemption and other discrete items.

Compared with the year ended December 31, 2017, the decrease in the effective tax rate for 2018 was primarily attributable to the impact of the reduction to the U.S. federal statutory tax rate as a result of the Tax Act enacted on December 22, 2017, the

repeal of the U.S. domestic production activity deduction, certain tax law changes in the UK that occurred during the three months ended December 31, 2017, the 2018 acquisitions of ImThera Medical Inc. and CardiacAssist, Inc., the sale of CRM, audit settlements in Italy and Germany and the impact of other discrete tax items.

U.S. Tax Reform

The Tax Act, which is also commonly referred to as "U.S. tax reform," significantly changed U.S. corporate income tax laws by, among other things, reducing the U.S. corporate income tax rate to 21%, which commenced in 2018.

During the fourth quarter of 2018, we finalized our accounting under Staff Accounting Bulletin No. 118 for the remeasurement of the deferred tax assets and liabilities and impairment of foreign tax credits related to the Tax Act. Our accounting for the remeasurement is complete with a final non-cash net charge of $21.0 million.

The Tax Act also established various other new U.S. corporate income tax laws that came into effect in 2018 along with proposed regulations issued in 2018 and final regulations issued in 2019. The extent to which these and other provisions of the Tax Act, or future legislation or additional final regulations clarifying the Tax Act, could impact our consolidated effective income tax rate in future periods depends on many factors including, but not limited to, the amount of profit generated by our subsidiaries operating in the U.S., the impact of the Company's current or contemplated tax planning strategies, the impact of new or amended tax laws or regulations by the U.S. and by countries outside the U.S., and other factors beyond our control.

Brexit

On January 31, 2020, the UK departed from the EU (in a move commonly referred to as "Brexit"), and the UK will now enter a transition period that is scheduled to end on December 31, 2020, unless requested to be extended before July 1, 2020. During the transition period, the UK will cease to be an EU member but the trading relationship will remain the same under the EU's rules. Although the long-term effects of Brexit will depend on any agreements the UK makes to retain access to the EU markets, Brexit has created additional uncertainties that may ultimately result in new regulatory costs and challenges for medical device companies and increased restrictions on imports and exports throughout Europe. This could adversely affect our ability to conduct and expand our operations in Europe and may have an adverse effect on our business, financial condition and results of operations.

Passage of the withdrawal bill does not change the application of existing tax laws and does not establish a clear framework for what the ultimate outcome of the transition period 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 transition period is over. 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 and explore possible tax-planning strategies that may mitigate or eliminate potential adverse impacts.

We will not account for the impact of Brexit in our income tax provisions until there are material changes in tax laws or treaties between the UK and other countries.

European Union State Aid Challenge

On October 26, 2017, the European Commission ("EC") announced that an investigation would be opened with respect to the UK's controlled foreign company ("CFC") rules for the period January 1, 2013 through December 31, 2018. Under the CFC rules, financing profits of entities controlled by UK parent companies are taxed when the funding originates in the UK, or Significant People Functions relating to the financing are located in the UK. The provisions under investigation provide group finance exemptions related to the profits of entities involved in financing of the non-UK group activities. 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. On July 5, 2019, HMRC began the first step in the recovery process to identify beneficiaries and sent letters asking for information. Based upon our assessment of the technical arguments as to whether the exemption is State aid, together with no UK activities involved in our financing, no uncertain tax position reserve has been recognized related to this matter. Furthermore, in December 2019, we amended our 2017 tax return filing to avail ourselves of different rules to determine UK taxation, which are not subject to the EU decision. We filed our 2018 tax return similarly, and therefore, we do not believe that the EU state aid decision will result in a material liability.

Losses from Equity Method Investments

Due to an additional investment by a third party during the year ended December 31, 2018, our equity interest in Highlife decreased to 7.8% from 24.6%. We determined that we no longer had significant influence over Highlife and, as a result, we began to measure Highlife at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. Losses from equity method investments were $0.6 million for the year ended December 31, 2018, which was attributable to Highlife.

Results of Discontinued Operations

The table below illustrates the results of discontinued operations (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Income (loss) from discontinued operations, net of tax	$ 365	$ (10,937)	$ (1,271)
Impairment of discontinued operations, net of tax	—	—	(78,283)
Net income (loss) from discontinued operations, net of tax	$ 365	$ (10,937)	$ (79,554)

In November 2017, we concluded that the sale of CRM represented a strategic shift in our business that would have a major effect on future operations and financial results. Accordingly, the operating results of CRM are classified as discontinued operations in our consolidated statements of income (loss) for all the periods presented in this Annual Report on Form 10-K. Additionally, we tested the long-lived assets of CRM for impairment and recognized an impairment to tangible and intangible assets of $78.3 million, net of a $15.3 million tax benefit during the year ended December 31, 2017.

We completed the CRM Sale on April 30, 2018, for total cash proceeds of $195.9 million, less cash transferred of $9.2 million, subject to a closing working capital adjustment. In conjunction with the sale, we entered into transition services agreements to provide certain support services 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 the year ended December 31, 2019 and December 31, 2018, we recognized income of $0.9 million and $2.8 million, respectively, for providing these services. Income recognized related to the transition services agreements is recorded as a reduction to the related expenses in the associated expense line items in our consolidated statement of income (loss).

Significant Accounting Policies and Critical Accounting Estimates

We have adopted various accounting policies to prepare the consolidated financial statements in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP"). Our most significant accounting policies are disclosed in "Note 2. Basis of Presentation, Use of Accounting Estimates and Significant Accounting Policies" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K. New accounting pronouncements are disclosed in "Note 23. New Accounting Pronouncements" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

To prepare our consolidated financial statements in conformity with U.S. GAAP, management makes estimates and assumptions that may affect the reported amounts of our assets and liabilities, the disclosure of contingent liabilities as of the date of our consolidated financial statements and the reported amounts of our revenue and expenses during the reporting period. Our actual results may differ from these estimates. We consider estimates to be critical if we are required to make assumptions about material matters that are uncertain at the time of estimation, or if materially different estimates could have been made or it is reasonably likely that the accounting estimate will change from period to period. The following are areas requiring management's judgment that we consider critical:

Leases

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 13. Leases" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

Business Combinations and Goodwill

We allocate the amounts we pay for an acquisition to the assets we acquire and liabilities we assume based on their fair values at the date of acquisition, including property, plant and equipment, inventories, accounts receivable, long-term debt, and identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. We base the fair value of identifiable intangible assets acquired in a business combination, including IPR&D, on valuations that use information and assumptions provided by management, which consider management's best estimates of inputs and assumptions that a market participant would use. We allocate any excess purchase price over the fair value of the net tangible and identifiable intangible assets acquired to goodwill. Transaction costs associated with these acquisitions are expensed as incurred and are reported in selling, general and administrative on the consolidated statements of income (loss). We recognize adjustments to the provisional amounts identified during the measurement period with a corresponding adjustment to goodwill in the reporting period in which the adjustment amounts are determined. The effect on earnings of changes in depreciation, amortization or other income effects, if any, as a result of the change to the provisional amounts are recorded in the same period's consolidated financial statements, calculated as if the accounting had been completed at the acquisition date.

Intangible Assets, Other than Goodwill

Intangible assets shown on the consolidated balance sheets consist of finite-lived and indefinite-lived assets expected to generate future economic benefits and are recorded at their respective fair values as of their acquisition date. Finite-lived

intangible assets consist primarily of developed technology and technical capabilities, including patents, related know-how and licensed patent rights, trade names and customer relationships. Customer relationships consist of relationships with hospitals and surgeons in the countries where we operate. Indefinite-lived intangible assets other than goodwill are composed of IPR&D assets acquired in acquisitions. We estimate the useful lives of our intangible assets, which requires significant management judgment. We amortize our finite-lived intangible assets over their useful lives using the straight-line method.

Amortization expense is disclosed separately on our consolidated statements of income (loss). We evaluate our intangible assets each reporting period to determine whether events and circumstances indicate either a different useful life or impairment. If we change our estimate of the useful life of an asset, we amortize the carrying amount over the revised remaining useful life.

Impairment of Long-Lived Assets and Goodwill

We review, when circumstances warrant, the carrying amounts of our property and equipment and our intangible assets to determine whether such carrying amounts continue to be recoverable. Such changes in circumstance may include, among other items, an expectation of a sale or disposal of a long-lived asset or asset group, adverse changes in market or competitive conditions, an adverse change in legal factors or business climate in the markets in which we operate and operating or cash flow losses. For purposes of impairment testing, long-lived assets are grouped at the lowest level for which cash flows are largely independent of other assets and liabilities, generally at or below the reporting unit level. If the carrying amount of the asset or asset group is greater than the expected undiscounted cash flows to be generated by such asset or asset group, an impairment adjustment is recognized. Such adjustment is measured by the amount that the carrying value of such asset or asset group exceeds its fair value. We generally measure fair value by considering sale prices for similar assets, discounted estimated future cash flows using an appropriate discount rate and/or estimated replacement cost. Assets to be disposed of are carried at the lower of their financial statement carrying amount or fair value less costs to sell.

We evaluate the goodwill and indefinite-lived intangible assets for impairment at least annually on October 1st and whenever other facts and circumstances indicate that the carrying amounts of goodwill and other indefinite-lived intangible assets may not be recoverable. In the case of goodwill, if it is more-likely-than-not that a reporting unit's fair value is less than its carrying value, we then compare the fair value of the reporting unit to its respective carrying amount. A reporting unit is an operating segment or one level below an operating segment (referred to as a "component"). Our operating segments are deemed to be our reporting units. If the carrying value of a reporting unit were to exceed its fair value, we would then compare the implied fair value of the reporting unit's goodwill to its carrying amount, and any excess of the carrying amount over the fair value would be charged to operations as an impairment loss. Estimating the fair value requires various assumptions, including revenue and gross margin growth rates and discount rates. With respect to indefinite-lived intangible assets, if it is more-likely-than-not that the fair value of an indefinite-lived intangible asset is less than its carrying value, we then estimate its fair value and any excess of the carrying value over the fair value of the indefinite-lived intangible asset is also charged to operations as an impairment loss. Estimating the fair value of indefinite-lived intangible assets requires various assumptions, including revenue growth rates, timing and probability of commercialization, and discount rates.

Revenue

For the years presented in our consolidated statements of income (loss) prior to December 31, 2018, we recognized revenue under the Financial Accounting Standards Board (the "FASB") Accounting Standards Codification Topic 605, *Revenue Recognition.* We recognized revenue when persuasive evidence of a sales arrangement existed, title to the goods and risk of loss transferred to the customer or to an independent distributor, the selling price was fixed or determinable and collectability was reasonably assured. We estimated expected sales returns based on historical data and recorded a reduction of sales with a return reserve. We recorded state and local sales taxes net; that is, we excluded sales tax from revenue. Service-related revenue was recognized on the basis of progress of the services, when services were rendered, when collectability was reasonably assured and when the amount was fixed and determinable.

In May 2014, the FASB issued ASC Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* (Topic 606). Update No. 2014-09 requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers and replaces most existing revenue recognition guidance. We adopted the new revenue guidance on January 1, 2018. We elected the cumulative effect transition method; however, we recognized no cumulative effect to the opening balance of retained earnings because the impact on the timing of when revenue is recognized was insignificant.

We generate our revenue through contracts with customers. Our customers are primarily hospitals, healthcare institutions, distributors and other organizations. Revenue is measured based on consideration specified in a contract with a customer, and excludes amounts collected on behalf of third parties, such as sales tax. We measure the consideration based upon the estimated amount to be received. The amount of consideration we ultimately receive varies depending upon the return terms, sales

rebates, discounts, and other incentives that we may offer, which are accounted for as variable consideration when estimating the amount of revenue to recognize. The estimate of variable consideration requires significant judgment.

We recognize revenue when a performance obligation is satisfied by transferring the control of a product, or providing service, to a customer. Some of our contracts include the purchase of multiple products and/or services. In such cases, we allocate the transaction price based upon the relative estimated stand-alone price of each product and/or service sold. Typically, our contracts do not have a significant financing component. We have historically experienced a low rate of product returns and the total dollar value of product returns has not been significant to our consolidated financial statements.

We incur incremental commission fees paid to the sales force associated with the sale of products. We elected the practical expedient within ASC 606-10-50-22 and recognize the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset the entity would otherwise recognize is one year or less. As a result, no commissions are capitalized as contract costs at December 31, 2019.

Income Taxes

We are a UK corporation, and we operate through our various subsidiaries in a number of countries throughout the world. Our provision for income taxes is based on the tax laws and rates applicable in the jurisdictions in which we operate and earn income. We use significant judgment and estimates in accounting for our income taxes. We recognize deferred tax assets and liabilities for the anticipated future tax effects of temporary differences between the financial statements basis and the tax basis of our assets and liabilities, which are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

We file federal and local tax returns in many jurisdictions throughout the world and are subject to income tax examinations for our fiscal year 2001 and subsequent years, with certain exceptions. While we believe that our tax return positions are fully supported, tax authorities may disagree with certain positions we have taken and assess additional taxes and as a result, we may establish reserves for uncertain tax positions, which require a significant degree of management judgment. We regularly assess the likely outcomes of our tax positions in order to determine the appropriateness of our reserves; however, the actual outcome of an audit can be significantly different than our expectations, which could have a material impact on our tax provision. The total amount of unrecognized tax benefit, as of December 31, 2019, if recognized, would reduce our income tax expense by approximately $12.9 million. Our tax positions are evaluated for recognition using a more-likely-than-not threshold. Uncertain tax positions requiring recognition are measured as the largest amount of tax benefit that has a greater than 50% likelihood of being realized upon effective settlement with a taxing authority that has full knowledge of all relevant information. Some of the reasons a reserve for an uncertain tax position may be reversed are: completion of a tax audit; a change in applicable tax law including a tax case or legislative guidance; or an expiration of the statute of limitations. We recognize interest and penalties associated with unrecognized tax benefits and record interest in interest expense, and penalties in selling, general and administrative expense, in our consolidated statements of income (loss).

We periodically assess the recoverability of our deferred tax assets by considering whether it is more-likely-than-not that some or all of the actual benefit of those assets will be realized. To the extent that realization does not meet the “more-likely-than-not” criterion, we establish a valuation allowance. We periodically review the adequacy and necessity of the valuation allowance by considering significant positive and negative evidence relative to our ability to recover deferred tax assets and to determine the timing and amount of valuation allowance that should be released. This evidence includes: profitability in the most recent quarters; internal forecasts for the current and next two future years; size of deferred tax asset relative to estimated profitability; the potential effects on future profitability from increasing competition, healthcare reforms and overall economic conditions; limitations and potential limitations on the use of our net operating losses due to ownership changes, pursuant to IRC Section 382; and the implementation of prudent and feasible tax planning strategies, if any.

The Tax Act also established various other new U.S. corporate income tax laws that came into effect in 2018 along with proposed regulations issued in 2018 and final regulations issued in 2019. The extent to which these and other provisions of the Tax Act, or future legislation or additional final regulations clarifying the Tax Act, could impact our consolidated effective income tax rate in future periods depends on many factors including, but not limited to, the amount of profit generated by our subsidiaries operating in the U.S., the impact of the Company’s current or contemplated tax planning strategies, the impact of new or amended tax laws or regulations by the U.S. and by countries outside the U.S., and other factors beyond our control. During the fourth quarter of 2018, we finalized our accounting under SAB 118 for the remeasurement of the deferred tax assets and liabilities and impairment of foreign tax credits related to the Tax Act. Our accounting for the remeasurement is complete with a final non-cash net charge of $21.0 million.

New Accounting Pronouncements

For a discussion of new accounting standards and disclosure requirements, please refer to "Note 23. New Accounting Pronouncements" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

Liquidity and Capital Resources

Based on our current business plan, we believe that our existing cash and cash equivalents, future cash generated from operations and borrowings under our existing credit facilities will be sufficient to fund our expected operating needs, working capital requirements, R&D opportunities, capital expenditures, obligations associated with the litigation involving our 3T device and debt service requirements over the 12-month period beginning from the issuance date of these financial statements. We regularly review our capital needs and consider various investing and financing alternatives to support our requirements. Refer to "Note 11. Financing Arrangements" in the consolidated financial statements in this Annual Report on Form 10-K for additional information regarding our debt. Our liquidity could be adversely affected by the factors affecting future operating results, including those referred to in "Item 1A. Risk Factors" above.

Cash Flows

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

	Year Ended December 31,		
	2019	2018	2017
Operating activities	$ (91,142)	$ 120,489	$ 91,339
Investing activities	(41,290)	(120,556)	(52,855)
Financing activities	146,581	(42,348)	11,294
Effect of exchange rate changes on cash and cash equivalents	(216)	(3,996)	4,048
Net increase (decrease)	$ 13,933	$ (46,411)	$ 53,826

Operating Activities

Cash used in operating activities for the year ended December 31, 2019 increased $211.6 million as compared to 2018, primarily due to $156.9 million in 3T litigation settlement payments made during 2019 and the change in operating assets and liabilities.

Cash provided by operating activities for the year ended December 31, 2018 increased $29.2 million as compared to 2017, primarily due to improved working capital management offset by a decrease in net income adjusted for non-cash items.

Investing Activities

Cash used in investing activities during the year ended December 31, 2019 decreased $79.3 million as compared to 2018. The decrease primarily resulted from a decrease in cash paid for acquisitions of $268.9 million, partially offset by cash received from the sale of CRM in 2018 of $186.7 million.

Cash used in investing activities during the year ended December 31, 2018 increased $67.7 million as compared to 2017. The increase primarily resulted from an increase in cash paid for acquisitions of $265.5 million, partially offset by cash received from the sale of CRM of $186.7 million and an increase in proceeds from asset sales of $8.3 million.

Financing Activities

Cash provided by financing activities during the year ended December 31, 2019 increased $188.9 million as compared to 2018, primarily due to an increase in net borrowings of $139.0 million and cash used in 2018 of $50.0 million to repurchase shares under a publicly announced repurchase plan.

Cash used in financing activities during the year ended December 31, 2018 increased $53.6 million as compared to 2017, primarily due to $50.0 million in cash used to repurchase shares in 2018 under a publicly announced repurchase plan and a $13.0 million payment for deferred consideration related to an acquisition, partially offset by an increase in net borrowings of $17.3 million.

Debt and Capital

Our capital structure consists of debt and equity. As of December 31, 2019, our total debt of $337.7 million was 24.4% of total equity of $1.4 billion. As of December 31, 2018, our total debt of $168.3 million was 11.2% of total equity of $1.5 billion.

During the year ended December 31, 2019, we borrowed $197.2 million in long-term debt, incurred $3.8 million in debt issuance costs, and repaid $24.2 million in long-term debt. Additionally, we reduced our short-term unsecured revolving credit agreements and other agreements with various banks by $1.2 million.

During the year ended December 31, 2018, we reduced our outstanding revolving credit facilities by $50.7 million, repaid $23.8 million of long-term debt obligations and borrowed $103.6 million in additional long-term debt.

Off-Balance Sheet Arrangements

As of December 31, 2019, we did not have any off-balance sheet arrangements.

Contractual Obligations

We have various contractual commitments that we expect to fund from existing cash, future operating cash flows and borrowings under our credit facilities. The following table summarizes our significant contractual obligations as of December 31, 2019 and the periods in which such obligations are due (in thousands):

	Less Than One Year	One to Three Years	Three to Five Years	Thereafter	Total Contractual Obligations
Principal payments on debt obligations	$ 77,710	$ 203,300	$ 33,610	$ 24,261	$ 338,881
Interest payments on long-term debt	8,623	9,991	2,943	798	22,355
3T litigation settlements	90,000	—	—	—	90,000
Operating leases	12,399	19,626	13,499	16,907	62,431
Inventory supply contract obligations	21,538	1,343	—	—	22,881
Derivative instruments	3,619	61	—	—	3,680
Contingent consideration [1]	22,953	893	113,503	—	137,349
Other commitments	489	50	50	113	702
Total contractual obligations [2]	$ 237,331	$ 235,264	$ 163,605	$ 42,079	$ 678,279

(1) Includes the fair value of our current and non-current positions of contingent consideration. While it is not certain if and/or when payments will be made, the maturity dates and amounts included in this table reflect our best estimates.

(2) Contractual obligations above do not include $4.3 million of unrecognized tax benefits, inclusive of interest and penalties, included on our consolidated balance sheet as of December 31, 2019, because we are unable to specify with certainty the future periods in which we may be obligated to settle such amounts.

Guarantees and Other Commitments

We have other commitments that we are contractually obligated to fulfill with cash under certain circumstances. Obligations under these guarantees are not normally called, as we typically comply with underlying performance requirements. As of December 31, 2019, no liability has been recorded in the consolidated financial statements associated with these obligations.

The following table summarizes our guarantees as of December 31, 2019 (in thousands):

	Less Than One Year	One to Three Years	Three to Five Years	Thereafter	Total Guarantees
Guarantees on government bids [1]	$ 6,479	$ 10,148	$ 1,141	$ 1,275	$ 19,043
Guarantees - commercial [2]	814	1,361	—	1,028	3,203
Guarantees to tax authorities [3]	976	4,015	—	12,710	17,701
Guarantees to third-parties	2	14	1	483	500
Total guarantees	$ 8,271	$ 15,538	$ 1,142	$ 15,496	$ 40,447

(1) Government bid guarantees include such items as unconditional bank guarantees, irrevocable letters of credit and bid bonds.
(2) Commercial guarantees include our lease and tenancy guarantees.
(3) Guarantees to tax authorities consist of guarantees issued to the Italian Revenue Agency.

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.

Foreign Currency Exchange Rate Risk

Due to the global nature of our operations, we are exposed to foreign currency exchange rate fluctuations. We maintain a foreign currency exchange rate risk management strategy that utilizes derivatives to reduce our exposure to unanticipated fluctuations in forecast revenue and costs and fair values of debt, inter-company debt and accounts receivable caused by changes in foreign currency exchange rates.

We mitigate our credit risk relating to counter-parties of our derivatives through a variety of techniques, including transacting with multiple, high-quality financial institutions, thereby limiting our exposure to individual counter-parties and by entering into International Swaps and Derivatives Association, Inc. ("ISDA") Master Agreements, which include provisions for a legally enforceable master netting agreement, with almost all of our derivative counter-parties. The terms of the ISDA agreements may also include credit support requirements, cross default provisions, termination events, and set-off provisions. Legally enforceable master netting agreements reduce credit risk by providing protection in bankruptcy in certain circumstances and generally permitting the closeout and netting of transactions with the same counter-party upon the occurrence of certain events.

Interest Rate Risk

We are subject to interest rate risk on our investments and debt. We manage a portion of our interest rate risk with contracts that swap floating-rate interest payments for fixed rate interest payments. If interest rates were to increase or decrease by 0.5%, the effects on our consolidated statement of income (loss) would not be material.

Concentration of Credit Risk

Our trade accounts receivable represent potential concentrations of credit risk. This risk is limited due to the large number of customers and their dispersion across a number of geographic areas, as well as our efforts to control our exposure to credit risk by monitoring our receivables and the use of credit approvals and credit limits. In addition, we have historically had strong collections and minimal write-offs. While we believe that our reserves for credit losses are adequate, essentially all of our trade receivables are concentrated in the hospital and healthcare sectors worldwide, and accordingly, we are exposed to their respective business, economic and country-specific variables. Although we do not currently foresee a concentrated credit risk associated with these receivables, repayment is dependent on the financial stability of these industry sectors and the respective countries' national economies and healthcare systems.

Factors Affecting Future Operating Results and Share Price

The material factors affecting our future operating results and share prices are disclosed in "Item 1A. Risk Factors" of this Annual Report on Form 10-K.

Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

The information required under 7A. has been incorporated by reference to the information contained in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report on Form 10-K under the section entitled "*Market Risk."*

Item 8. *Financial Statements and Supplementary Data*

Our audited consolidated financial statements and notes thereto included in "Item 15. Exhibits, Financial Statement Schedules" of this Annual Report on Form 10-K, beginning on page F-1 of this Annual Report on Form 10-K, are incorporated herein by reference.

Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

None.

Item 9A. *Controls and Procedures*

Disclosure Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information is accumulated and communicated to management, including our Chief Executive Officer ("CEO") and Chief Financial Officer ("CFO"), as appropriate, to allow timely decisions regarding required disclosure. Our management, under the supervision and with the participation of our CEO and CFO, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of December 31, 2019.

(b) Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019 using the criteria set forth in the *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, we concluded that the Company's internal control over financial reporting was effective as of December 31, 2019.

The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm. Their report is included after "Item 16. Form 10-K Summary" in this Annual Report on Form 10-K.

(c) Changes in Internal Control Over Financial Reporting

During the fourth quarter of 2019, there were no changes to our internal control over financial reporting (as defined in Rules 13a-15(f) under the Exchange Act) that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

(d) Remediation of the Material Weaknesses

As of December 31, 2019, we determined that we remediated the previously disclosed material weaknesses related to:

1. A deficiency in the design and maintenance of our controls related to access to our primary financial system by certain members of our Information Technology (IT) group and end-users. Specifically, we did not design and maintain user access controls that adequately restrict end-user and privileged access to, and ensure segregation of duties within, our primary financial system and data, and

2. A deficiency in the design and maintenance of our controls, related to the accounting for revenue and related accounts, to ensure accuracy in price and quantity during the billing and revenue processes. This deficiency was impacted by the deficiency related to the design and maintenance of our user access controls.

Item 9B. *Other Information*

None.

PART III

Item 10. *Directors, Executive Officers and Corporate Governance*

The information required for this Item 10 is incorporated by reference to the information set forth under the headings "Election of Directors," "Executive Compensation," "Corporate Governance," and "Share Ownership Information" in our Definitive Proxy Statement for the 2020 Annual General Meeting of Shareholders.

We have adopted a Code of Business Conduct and Ethics (the "Code of Conduct") that applies to all employees, officers and directors of the Company. A copy of the Code of Conduct is publicly available on our website, *www.livanova.com.* We intend to post any amendments to the Code of Conduct or any grant of a waiver from a provision of the Code of Conduct requiring disclosure under applicable SEC rules on the Investor Relations section of our website.

Item 11. *Executive Compensation*

The information required for this Item 11 is incorporated by reference to the information set forth under the heading "Executive Compensation" in our Definitive Proxy Statement for the 2020 Annual General Meeting of Shareholders.

Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*

The information required for this Item 12 is incorporated by reference to the information set forth under the headings "Executive Compensation" and "Share Ownership Information" in our Definitive Proxy Statement for the 2020 Annual General Meeting of Shareholders.

Item 13. *Certain Relationships and Related Transactions, and Director Independence*

The information required for this Item 13 is incorporated by reference to the information set forth under the heading "Corporate Governance" in our Definitive Proxy Statement for the 2020 Annual General Meeting of Shareholders.

Item 14. *Principal Accounting Fees and Services*

The information required for this Item 14 is incorporated by reference to the information set forth under the heading "Audit Matters" in our Definitive Proxy Statement for the 2020 Annual General Meeting of Shareholders.

PART IV

Item 15. *Exhibits, Financial Statement Schedules*

(1) Financial Statements

The Consolidated Financial Statements of LivaNova PLC and its subsidiaries and the Report of Independent Registered Public Accounting Firms are included in this Annual Report on Form 10-K beginning on page F-1:

(2) Financial Statement Schedules

All schedules required by Regulation S-X have been omitted as not applicable or not required, or the information required has been included in the notes to the consolidated financial statements.

(3) Index to Exhibits

The exhibits marked with the asterisk symbol (*) are filed or furnished (in the case of Exhibit 32.1) with this Form 10-K. 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
2.1	Transaction Agreement, dated March 23, 2015, by and among the Company (f/k/a Sand Holdco Limited), Cyberonics, Inc., Sorin S.p.A. and Cypher Merger Sub, Inc., incorporated by reference to Annex A-1 of the Company's Registration Statement on Form S-4, filed on April 20, 2015, as amended
2.2	Letter of Intent, dated as of November 20, 2017, by and among the Company, MicroPort Cardiac Rhythm B.V. and MicroPort Scientific Corporation (including the form of Stock and Asset Purchase Agreement attached as Exhibit A thereto), incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K, filed on November 20, 2017
2.3	Stock and Asset Purchase Agreement, dated as of March 8, 2018, by and among the Company, MicroPort Cardiac Rhythm B.V. and MicroPort Scientific Corporation (excluding schedules and exhibits, which the Company agrees to furnish supplementally to the Securities and Exchange Commission upon request), incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K, filed on March 8, 2018
3.1	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
4.1*	Description of Securities Registered Under Section 12 of the Exchange Act
10.1	Amendment and Restatement Agreement, dated October 2, 2015, by and among the Company, Sorin S.p.A., Sorin CRM S.A.S., Sorin Group Italia S.r.l. and the European Investment Bank, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed on October 19, 2015
10.2†	Form of Deed of Indemnification (Directors), each effective October 19, 2015, incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, filed on October 19, 2015
10.3†	Form of Deed of Indemnification (Officers), each effective October 19, 2015, incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K, filed on October 19, 2015

10.4†	2015 Incentive Award Plan and related Sub-Plan for U.K. Participants, adopted on October 16, 2015, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed on October 19, 2015
10.5†	Form of Stock Appreciation Right Grant Notice and Stock Appreciation Right Agreement under the Company's 2015 Incentive Award Sub-Plan (Non-U.S. Form), incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K12B, filed on October 19, 2015
10.6†	Form of Stock Appreciation Right Grant Notice and Stock Appreciation Right Agreement under the Company's 2015 Incentive Award Plan (U.S. Form), incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K12B, filed on October 19, 2015
10.7†	Director Appointment Letters for Non-Employee Directors, dated the dates indicated therein, incorporated by reference to Exhibit 10.5 of the Company's Current Report on Form 8-K12B, filed on October 19, 2015
10.8†	Form of Director Restricted Stock Unit Award Grant Notice and Director Restricted Stock Unit Award Agreement under the Company's 2015 Incentive Award Plan (Non-Employee Directors), incorporated by reference to Exhibit 10.6 of the Company's Current Report on Form 8-K12B, filed on October 19, 2015
10.9†	Cyberonics, Inc. 2009 Stock Plan, as amended, incorporated by reference to Appendix A to Cyberonics, Inc.'s Proxy Statement on Schedule 14A, filed on August 2, 2012
10.10†	Amended and Restated Cyberonics, Inc. New Employee Equity Inducement Plan, as amended, incorporated by reference to Exhibit 10.3 of Cyberonics, Inc.'s Quarterly Report on Form 10-Q for the fiscal quarter ended October 24, 2008
10.11†	Letter Agreement dated July 1, 2016 between Douglas Manko and Cyberonics Inc., a wholly owned subsidiary of the Company, incorporated by reference to Exhibit 10.48 of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016
10.12	Form of Share Repurchase Contract, incorporated by reference to Appendix A of the Company's Proxy Statement on Schedule 14A, filed on May 16, 2016
10.13	Form of Rule 10b5-1 Repurchase Plan, incorporated by reference to Appendix B of the Company's Proxy Statement on Schedule 14A, filed on May 16, 2016
10.14	Board approval of Share Repurchase Programme on August 2, 2016, incorporated by reference to the Company's Current Report on Form 8-K, filed on August 2, 2016
10.15†	Settlement Agreement between Andre-Michel Ballester and the Company dated December 21, 2016, incorporated by reference to Exhibit 10.58 of the Company's Annual Report on Form 10-K for the year ended December 31, 2016
10.16†	Consultancy Agreement between Andre-Michel Ballester and the Company dated December 26, 2016, incorporated by reference to Exhibit 10.59 of the Company's Annual Report on Form 10-K for the year ended December 31, 2016
10.17†	Form of the Company's 2017 Service-Based RSU Agreement, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed on May 11, 2017
10.18†	Form of the Company's 2017 Performance-Based RSU Agreement, incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed on May 11, 2017
10.19†	CEO Employment Agreement effective January 1, 2017 between the Company and Damien McDonald, incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed on February 28, 2017
10.20†	Side Letter dated January 1, 2017 between the Company and Damien McDonald, incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, filed on February 28, 2017
10.21†	Service Agreement, by and between the Company and Thad Huston, dated April 27, 2017, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed on May 16, 2017
10.22†	Side Letter dated April 27, 2017 from the Company to Thad Huston, incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed on May 16, 2017
10.23†	Service Agreement effective May 24, 2017, between the Company and Keyna Skeffington, incorporated by reference to Exhibit 10.6 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017
10.24†	Non-Employee Director Compensation Policy, adopted December 2017, incorporated by reference to Exhibit 10.74 of the Company's Annual Report on Form 10-K for the year ended December 31. 2017
10.25	Form of Share Repurchase Contract, incorporated by reference to Appendix A of the Company's Proxy Statement on Schedule 14A, filed on May 16, 2017
10.26	Form of Rule 10b5-1 Repurchase Plan, incorporated by reference to Appendix B of the Company's Proxy Statement on Schedule 14A, filed on May 16, 2017
10.27†	Description of 2018 Long Term Incentive Plan, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed on March 16, 2018

10.28†	Form of 2018 Long Term Incentive Plan RSU Award Agreement, incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed on March 16, 2018
10.29†	Form of 2018 Long Term Incentive Plan SAR Award Agreement, incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, filed on March 16, 2018
10.30†	Form of 2018 Long Term Incentive Plan PSU Award Agreement (rTSR condition), incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K, filed on March 16, 2018
10.31†	Form of 2018 Long Term Incentive Plan PSU Award Agreement (FCF condition), incorporated by reference to Exhibit 10.5 of the Company's Current Report on Form 8-K, filed on March 16, 2018
10.32†	2018 Director RSU Agreement, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed on June 15, 2018
10.33†	General Provisions of the Company's Global Employee Share Purchase Plan dated 12 June 2018, incorporated by reference to Exhibit 10.4 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018
10.34†	Form of Letter of Appointment as Non-Executive Director, dated 18 July 2018, incorporated by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018
10.35†	2019 LivaNova Short-Term Incentive Plan approved February 20, 2019, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K/A, filed on March 6, 2019
10.36	US$350 million multicurrency term facilities agreement dated March 26, 2019, by and among LivaNova PLC, the lenders, arrangers and bookrunners, documentation agent and co-ordinator parties thereto and Barclays Bank PLC as agent, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed March 29, 2019
10.37†	Description of 2019 Long Term Incentive Plan approved March 29, 2019, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed on April 1, 2019
10.38†	Form of the Company's 2019 Long Term Incentive Plan RSU Award Agreement, incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K, filed on April 1, 2019
10.39†	Form of the Company's 2019 Long Term Incentive Plan SAR Award Agreement, incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K, filed on April 1, 2019
10.40†	Form of the Company's 2019 Long Term Incentive Plan PSU Award Agreement (rTSR condition), incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K, filed on April 1, 2019
10.41†	Form of the Company's 2019 Long Term Incentive Plan PSU Award Agreement (FCF condition), incorporated by reference to Exhibit 10.5 of the Company's Current Report on Form 8-K, filed on April 1, 2019
10.42†	Service Agreement, dated February 28, 2017, between Alistair Simpson and LivaNova PLC, incorporated by reference to Exhibit 10.9 of the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019
10.43†	Service Agreement, dated January 2, 2019, between Trui Hebbelinck and LivaNova PLC, incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019
10.44	Amendment and Restatement Agreement, dated June 6, 2019, in relation to the Finance Contract originally dated May 6, 2014, between the European Investment Bank, Sorin Group Italia S.r.l., and LivaNova PLC, incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019
10.45	Amendment and Restatement Agreement, dated June 6, 2019, in relation to the Finance Contract originally dated June 29, 2017, between the European Investment Bank, Sorin Group Italia S.r.l., and LivaNova PLC, incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019
10.46*†	Separation and Settlement Agreement, dated November 2019, between Alistair Simpson and LivaNova PLC
10.47*†	Separation Agreement, dated December 2019, between Edward S. Andrle and LivaNova USA, Inc.
16.1	Letter from PricewaterhouseCoopers SpA to the Securities and Exchange Commission, dated March 26, 2018, incorporated by reference to Exhibit 16.1 of the Company's Current Report on Form 8-K, filed on March 26, 2018
21.1*	List of Subsidiaries of LivaNova PLC
23.1*	Consent of PricewaterhouseCoopers LLP
23.2*	Consent of PricewaterhouseCoopers SpA
31.1*	Certification of the Chief Executive Officer of LivaNova PLC pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Chief Financial Officer of LivaNova PLC pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of the Chief Executive Officer and of the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted 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 Consolidated Statements of Income (Loss) for the years ended December 31, 2019, December 31, 2018 and December 31, 2017, (ii) the Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2019, December 31, 2018 and December 31, 2017, (iii) the Consolidated Balance Sheets as of December 31, 2019 and December 31, 2018, (iv) the Consolidated Statements of Stockholders' Equity for the years ended December 31, 2019, December 31, 2018 and December 31, 2017, (v) the Consolidated Statements of Cash Flows for the years ended December 31, 2019, December 31, 2018 and December 31, 2017, and (vi) the Notes to the Consolidated Financial Statements.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURES

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

LIVANOVA PLC

By: /s/ DAMIEN MCDONALD

Damien McDonald
Chief Executive Officer
(Principal Executive Officer)

LIVANOVA PLC

By: /s/ THAD HUSTON

Thad Huston
Chief Financial Officer
(Principal Financial Officer)

Date: March 2, 2020

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ DANIEL J. MOORE Daniel J. Moore	Chairman of the Board of Directors	March 2, 2020
/s/ DAMIEN MCDONALD Damien McDonald	Director, Chief Executive Officer *(Principal Executive Officer)*	March 2, 2020
/s/ THAD HUSTON Thad Huston	Chief Financial Officer *(Principal Financial Officer)*	March 2, 2020
/s/ DOUG MANKO Doug Manko	Chief Accounting Officer *(Principal Accounting Officer)*	March 2, 2020
/s/ FRANCESCO BIANCHI Francesco Bianchi	Director	March 2, 2020
/s/ WILLIAM A. KOZY William A. Kozy	Director	March 2, 2020
/s/ HUGH M. MORRISON Hugh M. Morrison	Director	March 2, 2020
/s/ ALFRED J. NOVAK Alfred J. Novak	Director	March 2, 2020
/s/ SHARON O'KANE Sharon O'Kane, Ph.D.	Director	March 2, 2020
/s/ ARTHUR L. ROSENTHAL Arthur L. Rosenthal, Ph.D.	Director	March 2, 2020
/s/ ANDREA L. SAIA Andrea L. Saia	Director	March 2, 2020
/s/ STACY ENXING SENG Stacy Enxing Seng	Director	March 2, 2020

Item 16. Form 10-K Summary

None.

CONSOLIDATED FINANCIAL STATEMENTS

For the years ended December 31, 2019, December 31, 2018 and December 31, 2017

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of LivaNova PLC

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of LivaNova PLC and its subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of income (loss), of comprehensive income (loss), of stockholders' equity and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Changes in Accounting Principles

As discussed in Notes 2 and 23 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019 and the manner in which it accounts for the income tax effects of intra-entity transfers of assets other than inventory in 2018, respectively.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the

company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Goodwill Impairment Assessment - Cardiovascular Reporting Unit

As described in Notes 2 and 8 to the consolidated financial statements, the Company's consolidated goodwill balance was $915.8 million as of December 31, 2019, and the amount of goodwill associated with the Cardiovascular reporting unit was $517.0 million. Management conducts impairment testing of goodwill on October 1 each year. Management tests goodwill for impairment between annual tests if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of a reporting unit below its carrying amount. Fair value refers to the price that would be received if management were to sell the unit as a whole in an orderly transaction. An impairment loss is recognized when the carrying amount of the reporting unit's net assets exceeds the estimated fair value of the reporting unit, up to and including the carrying amount of the goodwill. Fair value is estimated by management using a discounted cash flow model. Estimating the fair value requires various assumptions, including revenue and gross margin growth rates and discount rates.

The principal considerations for our determination that performing procedures relating to the goodwill impairment assessment of the Cardiovascular reporting unit is a critical audit matter are there was significant judgment by management when developing the estimated fair value of the reporting unit. This led to a high degree of auditor judgment, subjectivity, and effort in performing procedures relating to management's projected financial information and significant assumptions, including the revenue and gross margin growth rates and discount rates. In addition, the audit effort involved the use of professionals with specialized skill and knowledge in performing these procedures and evaluating the audit evidence obtained.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's goodwill impairment assessment, including controls over the valuation of the Company's reporting units. These procedures also included, among others, testing management's process for developing the fair value of the Cardiovascular reporting unit. Testing management's process included evaluating the appropriateness of the discounted cash flow model and the reasonableness of management's projected financial information and significant assumptions, including the revenue and gross margin growth rates and discount rates. Evaluating the reasonableness of the revenue and gross margin growth rates involved considering the current and past performance of the reporting unit, consistency with third-party industry data, and whether the assumptions were consistent with evidence obtained in other areas of the audit. Professionals with specialized skill and knowledge were used to assist in the evaluation of the discounted cash flow model and the reasonableness of certain significant assumptions, including the discount rates.

Long-Lived Intangible Asset Impairment Assessment - ImThera IPR&D

As described in Notes 2 and 8 to the consolidated financial statements, the Company's consolidated In-Progress Research & Development (IPR&D) indefinite-lived intangible asset balance was $115.8 million as of December 31, 2019. Management conducts impairment testing of indefinite-lived intangible assets on October 1 each year. Management tests indefinite-lived intangible assets for impairment between annual tests if an event occurs or circumstances change that would indicate the carrying amount may be impaired. An impairment loss is recognized when the asset's carrying value exceeds its fair value. During the second quarter of 2019, management 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, management determined that the IPR&D asset was impaired and as a result, recorded an impairment of $50.3 million, which was included in the Neuromodulation segment. The estimated fair value of IPR&D was determined using the multi-period excess earnings income approach. Estimating the fair value of the ImThera IPR&D asset requires various assumptions, including revenue growth rates, timing and probability of commercialization, and the discount rate.

The principal considerations for our determination that performing procedures relating to the long-lived intangible asset impairment assessment - ImThera IPR&D is a critical audit matter are there was significant judgment by management when developing the estimated fair value of the IPR&D. This in turn led to a high degree of auditor judgment, subjectivity, and effort in performing procedures relating to management's significant assumptions, including the revenue growth rates, timing and probability of commercialization, and the discount rate. In addition, the audit effort involved the use of professionals with specialized skill and knowledge in performing these procedures and evaluating the audit evidence obtained.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's long-lived intangible asset impairment assessment, including controls over the valuation of the Company's IPR&D assets. These procedures also included, among others, testing management's process for estimating the fair value of IPR&D. Testing management's process included evaluating the reasonableness of significant assumptions, including the revenue growth rates, timing and probability of commercialization, and the discount rate. Evaluating the reasonableness of the revenue growth rate and timing and probability of commercialization involved considering the historical results of peer companies, consistency with third-party industry data, and whether the assumptions were consistent with evidence obtained in other areas of the audit. Professionals with specialized skill and knowledge were used to assist in evaluating the appropriateness of the multi-period excess earnings income approach and the reasonableness of certain significant assumptions, including the discount rate.

Litigation Provision Liability - 3T Heater-Cooler Device

As described in Notes 2 and 14 to the consolidated financial statements, the Company recognizes product liability accruals for the resolution of pending litigation when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Accruals for product liability claims are adjusted periodically as additional information becomes available. The Company is currently involved in litigation involving the 3T Heater-Cooler device. On March 29, 2019, the Company 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. Cases covered by the settlement are being dismissed as amounts are disbursed to individual plaintiffs from the qualified settlement fund. In the fourth quarter of 2019, the Company recorded an additional liability of $33.2 million due to additional information obtained, including but not limited to: the nature and quantity of filed and unfiled claims; certain settlement discussions with plaintiffs' counsel; and the current stage of litigation in the remaining filed and unfiled claims. As of December 31, 2019, the litigation provision liability was $170.4 million.

The principal considerations for our determination that performing procedures relating to the 3T Heater-Cooler device litigation provision liability is a critical audit matter are there was significant judgment by management when assessing the likelihood of a loss being incurred and when determining a reasonable estimate of the loss for each claim. This in turn led to a high degree of auditor judgment, subjectivity and effort in evaluating management's assessment of the loss contingencies associated with this litigation.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's evaluation of the 3T Heater-Cooler device litigation and estimation of the provision for losses, including controls over determining whether a loss is probable and whether the amount of loss can be reasonably estimated. These procedures also included, among others, gaining an understanding of the Company's process around the accounting and reporting for the 3T Heater-Cooler device litigation, obtaining and evaluating the letters of audit inquiry with internal and external legal counsel, assessing the completeness of the population of claims, evaluating the reasonableness of management's assessment regarding whether an unfavorable outcome is reasonably possible or probable and reasonably estimable, and evaluating the sufficiency of the Company's litigation contingency disclosures.

/s/ PricewaterhouseCoopers LLP
Houston, Texas
March 2, 2020

We have served as the Company's auditor since 2018.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of LivaNova PLC

Opinion on the Financial Statements

We have audited the consolidated statements of income (loss), comprehensive income (loss), stockholders' equity and cash flows of LivaNova PLC and its subsidiaries (the "Company") for the year ended December 31, 2017, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the results of operations and cash flows of the Company for the year ended December 31, 2017 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers SpA
Milan, Italy
February 28, 2018

PricewaterhouseCoopers SpA served as the Company's auditor from 2015 to 2018.

LIVANOVA PLC AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF INCOME (LOSS)

(In thousands, except per share amounts)

	Year Ended December 31,		
	2019	**2018**	**2017**
Net sales	$ 1,084,170	$ 1,106,961	$ 1,012,277
Costs and expenses:			
Cost of sales - exclusive of amortization	323,635	361,812	353,192
Product remediation	15,777	10,680	7,254
Selling, general and administrative	506,542	464,967	380,100
Research and development	149,889	146,024	109,516
Merger and integration expenses	23,457	24,420	15,528
Restructuring expenses	12,254	15,915	17,056
Impairment of goodwill	42,417	—	—
Impairment of intangible assets	139,295	—	—
Amortization of intangibles	40,375	37,194	33,144
Litigation provision, net	(601)	294,021	—
Operating (loss) income from continuing operations	(168,870)	(248,072)	96,487
Interest income	803	847	1,318
Interest expense	(15,091)	(9,825)	(7,797)
Gain on acquisitions	—	11,484	39,428
Impairment of investments	—	—	(8,565)
Foreign exchange and other (losses) gains	(2,536)	(1,881)	267
(Loss) income from continuing operations before tax	(185,694)	(247,447)	121,138
Income tax (benefit) expense	(30,153)	(69,629)	49,954
Losses from equity method investments	—	(644)	(16,719)
Net (loss) income from continuing operations	(155,541)	(178,462)	54,465
Discontinued Operations:			
Income (loss) from discontinued operations, net of tax	365	(10,937)	(1,271)
Impairment of discontinued operations, net of tax	—	—	(78,283)
Net income (loss) from discontinued operations, net of tax	365	(10,937)	(79,554)
Net loss	$ (155,176)	$ (189,399)	$ (25,089)
Basic (loss) income per share:			
Continuing operations	$ (3.22)	$ (3.68)	$ 1.13
Discontinued operations	0.01	(0.23)	(1.65)
	$ (3.21)	$ (3.91)	$ (0.52)
Diluted (loss) income per share:			
Continuing operations	$ (3.22)	$ (3.68)	$ 1.12
Discontinued operations	0.01	(0.23)	(1.64)
	$ (3.21)	$ (3.91)	$ (0.52)
Shares used in computing basic (loss) income per share	48,349	48,497	48,157
Shares used in computing diluted (loss) income per share	48,349	48,497	48,501

See accompanying notes to the consolidated financial statements

LIVANOVA PLC AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(In thousands)

	Year Ended December 31,		
	2019	**2018**	**2017**
Net loss	$ (155,176)	$ (189,399)	$ (25,089)
Other comprehensive (loss) income:			
Net change in unrealized gain (loss) on derivatives	1,917	(33)	(6,413)
Tax effect	(460)	8	1,875
Net of tax	1,457	(25)	(4,538)
Foreign currency translation adjustment, net of tax	3,627	(69,764)	118,338
Total other comprehensive income (loss)	5,084	(69,789)	113,800
Total comprehensive (loss) income	$ (150,092)	$ (259,188)	$ 88,711

See accompanying notes to the consolidated financial statements

LIVANOVA PLC AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2019 and 2018
(In thousands, except share data)

ASSETS	**2019**	**2018**
Current Assets:		
Cash and cash equivalents	$ 61,137	$ 47,204
Accounts receivable, net of allowance of $13,105 at December 31, 2019 and $11,598 at December 31, 2018	257,769	256,135
Inventories, net	164,154	153,535
Prepaid and refundable taxes	37,779	46,852
Prepaid expenses and other current assets	28,604	29,571
Total Current Assets	549,443	533,297
Property, plant and equipment, net	181,354	191,400
Goodwill	915,794	956,815
Intangible assets, net	607,546	770,439
Operating lease assets (Note 13)	54,372	—
Investments	27,256	24,823
Deferred tax assets	68,676	68,146
Other assets	7,356	4,781
Total Assets	$ 2,411,797	$ 2,549,701
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Current debt obligations	$ 77,396	$ 28,794
Accounts payable	85,892	76,735
Accrued liabilities and other	120,100	124,285
Current litigation provision liability	146,026	161,851
Taxes payable	12,719	22,530
Accrued employee compensation and related benefits	70,420	82,551
Total Current Liabilities	512,553	496,746
Long-term debt obligations	260,330	139,538
Contingent consideration	114,396	161,381
Litigation provision liability	24,378	132,210
Deferred tax liabilities	32,219	68,189
Long-term operating lease liabilities (Note 13)	46,027	—
Long-term employee compensation and related benefits	22,797	25,264
Other long-term liabilities	15,380	22,635
Total Liabilities	1,028,080	1,045,963
Commitments and contingencies (Note 14)		
Stockholders' Equity:		
Ordinary Shares, £1.00 par value: unlimited shares authorized; 49,411,016 shares issued and 48,443,830 shares outstanding at December 31, 2019; 49,323,418 shares issued and 48,205,783 shares outstanding at December 31, 2018	76,257	76,144
Additional paid-in capital	1,734,870	1,705,111
Accumulated other comprehensive loss	(19,392)	(24,476)
Accumulated deficit	(406,755)	(251,579)
Treasury stock at cost, 967,186 and 1,117,635 shares at December 31, 2019 and 2018	(1,263)	(1,462)
Total Stockholders' Equity	1,383,717	1,503,738
Total Liabilities and Stockholders' Equity	$ 2,411,797	$ 2,549,701

See accompanying notes to the consolidated financial statements

LIVANOVA PLC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Ordinary Shares	Ordinary Shares - Amount	Additional Paid-In Capital	Treasury Stock	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
December 31, 2016	48,157	$ 74,578	$ 1,719,893	$ (4,500)	$ (68,487)	$ (14,575)	$ 1,706,909
Stock-based compensation plans	133	172	15,155	4,367	—	—	19,694
Net loss	—	—	—	—	—	(25,089)	(25,089)
Other comprehensive income	—	—	—	—	113,800	—	113,800
December 31, 2017	48,290	74,750	1,735,048	(133)	45,313	(39,664)	1,815,314
Adoption of ASU No. 2016-16	—	—	—	—	—	(22,516)	(22,516)
Share issuances	1,423	1,887	—	(1,887)	—	—	—
Share repurchases	(500)	(640)	(49,360)	—	—	—	(50,000)
Stock-based compensation plans	110	147	19,423	558	—	—	20,128
Net loss	—	—	—	—	—	(189,399)	(189,399)
Other comprehensive loss	—	—	—	—	(69,789)	—	(69,789)
December 31, 2018	49,323	76,144	1,705,111	(1,462)	(24,476)	(251,579)	1,503,738
Stock-based compensation plans	88	113	29,759	199	—	—	30,071
Net loss	—	—	—	—	—	(155,176)	(155,176)
Other comprehensive income	—	—	—	—	5,084	—	5,084
December 31, 2019	49,411	$ 76,257	$ 1,734,870	$ (1,263)	$ (19,392)	$ (406,755)	$ 1,383,717

See accompanying notes to the consolidated financial statements

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

	Year Ended December 31,		
Operating Activities:	**2019**	**2018**	**2017**
Net loss	$ (155,176)	$ (189,399)	$ (25,089)
Non-cash items included in net loss:			
Impairment of intangible assets	139,295	—	—
Impairment of goodwill	42,417	—	—
Amortization	40,375	37,194	45,881
Stock-based compensation	32,553	26,923	19,062
Depreciation	30,317	32,746	37,054
Remeasurement of contingent consideration to fair value	(29,406)	(4,311)	56
Deferred tax benefit	(26,277)	(95,050)	(9,272)
Amortization of operating lease assets	12,297	—	—
Impairment of property, plant and equipment	3,222	567	5,979
Amortization of income taxes payable on inter-company transfers of property	2,575	13,370	31,784
Losses from equity method investments	—	1,855	21,606
Gain on acquisitions	—	(11,484)	(39,428)
Impairment of discontinued operations	—	—	93,574
Impairment of investments	—	—	8,565
Other	5,412	2,791	5,240
Changes in operating assets and liabilities:			
Accounts receivable, net	(5,321)	21,181	(48,934)
Inventories, net	(10,608)	(10,647)	7,187
Other current and non-current assets	(2,103)	(12,989)	(6,180)
Accounts payable and accrued current and non-current liabilities	(31,830)	4,526	7,522
Taxes payable	(8,442)	2,651	(48,711)
Litigation provision liability, net	(123,695)	294,061	—
Restructuring reserve	(6,747)	6,504	(14,557)
Net cash (used in) provided by operating activities	**(91,142)**	**120,489**	**91,339**
Investing Activities:			
Purchases of property, plant and equipment	(24,691)	(37,188)	(32,933)
Acquisitions, net of cash acquired	(10,750)	(279,691)	(14,194)
Purchases of intangible assets	(3,289)	(809)	(1,174)
Purchases of investments	(2,500)	(3,770)	(6,255)
Proceeds from asset sales	1,261	14,220	5,935
Proceeds from the sale of CRM business franchise, net of cash disposed	—	186,682	—
Proceeds from sale of investment	—	—	3,192
Loans to investees	—	—	(7,426)
Other	(1,321)	—	—
Net cash used in investing activities	**(41,290)**	**(120,556)**	**(52,855)**
Financing Activities:			
Proceeds from long-term debt obligations	197,160	103,570	2,048
Repayment of long-term debt obligations	(24,210)	(23,827)	(22,755)
Payment of contingent consideration	(18,955)	(651)	(1,097)
Shares repurchased from employees for minimum tax withholding	(7,064)	(11,611)	(4,083)
Proceeds from share issuances under ESPP	4,468	—	—
Debt issuance costs	(3,795)	—	—
Change in short-term borrowing, net	(1,188)	(30,745)	12,396
Proceeds from exercise of stock options	372	4,178	4,973
Proceeds from short-term borrowing (maturities greater than 90 days)	—	240,000	20,000
Repayment of short-term borrowing (maturities greater than 90 days)	—	(260,000)	—
Share repurchases under share repurchase program	—	(50,000)	—
Payment of deferred consideration - acquisition of Caisson Interventional, LLC	—	(12,994)	—
Other	(207)	(268)	(188)
Net cash provided by (used in) financing activities	**146,581**	**(42,348)**	**11,294**
Effect of exchange rate changes on cash and cash equivalents	(216)	(3,996)	4,048
Net increase (decrease) in cash and cash equivalents	**13,933**	**(46,411)**	**53,826**
Cash and cash equivalents at beginning of period	47,204	93,615	39,789
Cash and cash equivalents at end of period	**$ 61,137**	**$ 47,204**	**$ 93,615**

See accompanying notes to the consolidated financial statements

Supplementary Disclosures of Cash Flow Information:	Year Ended December 31, 2019	2018	2017
Cash paid for interest	$ 15,828	$ 9,278	$ 7,510
Cash paid for income taxes	2,011	26,393	38,974

See accompanying notes to the consolidated financial statements

Note 1. Nature of Operations

Description of the Business

LivaNova PLC, headquartered in London, (collectively with its subsidiaries, the "Company," "LivaNova," "we" or "our") is a global medical device company focused on the development and delivery of important therapeutic solutions for the benefit of patients, healthcare professionals and healthcare systems throughout the world. Working closely with medical professionals in the fields of cardiovascular disease and neuromodulation, we design, develop, manufacture and sell innovative therapeutic solutions that are consistent with our mission to improve our patients' quality of life, increase the skills and capabilities of healthcare professionals and minimize healthcare costs. We are a public limited company organized under the laws of England and Wales, and headquartered in London, England.

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.

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

Basis of Presentation

The accompanying consolidated financial statements of LivaNova have been prepared in accordance with generally accepted accounting principles in the United States ("U.S." and such principles, "U.S. GAAP") and the instructions to Form 10-K and Article 3 and Article 5 of Regulation S-X.

Consolidation

The accompanying consolidated financial statements for LivaNova include LivaNova's wholly owned subsidiaries and the LivaNova PLC Employee Benefit Trust ("the Trust"). All intercompany accounts and transactions have been eliminated.

Use of Estimates

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

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.

Cash and Cash Equivalents

We consider all highly liquid investments with an original maturity of three months or less, consisting of demand deposit accounts and money market mutual funds, to be cash equivalents. Cash equivalents are carried on the consolidated balance sheet at cost, which approximated their fair value.

Accounts Receivable

Our accounts receivable consisted of trade receivables from direct customers and distributors. We maintain an allowance for doubtful accounts for potential credit losses based on our estimates of the ability of customers to make required payments, historical credit experience, existing economic conditions and expected future trends. We write off uncollectible accounts against the allowance when all reasonable collection efforts have been exhausted.

Inventories

We state our inventories at the lower of cost, using the first-in first-out ("FIFO") method, or net realizable value. Our calculation of cost includes the acquisition cost of raw materials and components, direct labor and overhead, including depreciation of manufacturing related assets. We reduce the carrying value of inventories for those items that are potentially excess, obsolete or slow moving based on changes in customer demand, technology developments or other economic factors.

Property, Plant and Equipment ("PP&E")

Assets held and used

PP&E is carried at cost, less accumulated depreciation. Maintenance, repairs and minor replacements are charged to expense as incurred, while significant renewals and improvements are capitalized. We compute depreciation using the straight-line method over estimated useful lives. Leasehold improvements are depreciated over the shorter of the following terms: the useful life of the asset or a term that includes required lease periods and renewals that are deemed to be reasonably assured at the date the leasehold improvements are purchased. Capital improvements to the building are added as building components and depreciated over the useful life of the improvement or the building, whichever is less.

Assets held for sale

We classify long-lived assets as held for sale in the period in which we commit to a plan to sell the asset, the asset is available for immediate sale, the asset is being actively marketed for sale at a price that is reasonable in relation to its current fair value and the sale of the asset is probable within the next twelve months and when actions required to complete the plan indicate that it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn. A long-lived asset classified as held for sale is measured at the lower of its carrying amount or fair value less cost to sell and depreciation is discontinued. We recognize an impairment for any excess of carrying value over the fair value less cost to sell.

Goodwill

We allocate the amounts we pay for an acquisition to the assets we acquire and liabilities we assume based on their fair values at the date of acquisition, including property, plant and equipment, inventories, accounts receivable, long-term debt, and identifiable intangible assets which either arise from a contractual or legal right or are separable from goodwill. We base the fair value of identifiable intangible assets acquired in a business combination, including IPR&D, on valuations that use information and assumptions provided by management, which consider management's best estimates of inputs and assumptions that a market participant would use. We allocate any excess purchase price over the fair value of the net tangible and identifiable intangible assets acquired to goodwill. Transaction costs associated with these acquisitions are expensed as incurred and are reported in selling, general and administrative on the consolidated statements of income (loss). We recognize adjustments to the provisional amounts identified during the measurement period with a corresponding adjustment to goodwill in the reporting period in which the adjustment amounts are determined. The effect on earnings of changes in depreciation, amortization or other income effects, if any, as a result of the change to the provisional amounts are recorded in the same period's consolidated financial statements, calculated as if the accounting had been completed at the acquisition date.

Intangible Assets, Other than Goodwill

Intangible assets shown on the consolidated balance sheets consist of finite-lived and indefinite-lived assets expected to generate future economic benefits and are recorded at their respective fair values as of their acquisition date. Finite-lived intangible assets consist primarily of developed technology and technical capabilities, including patents, related know-how and licensed patent rights, trade names and customer relationships. Customer relationships consist of relationships with hospitals and surgeons in the countries where we operate. Indefinite-lived intangible assets other than goodwill are composed of IPR&D assets acquired in acquisitions. We estimate the useful lives of our intangible assets, which requires significant management judgment. We amortize our finite-lived intangible assets over their useful lives using the straight-line method.

Amortization expense is disclosed separately on our consolidated statements of income (loss). We evaluate our intangible assets each reporting period to determine whether events and circumstances indicate either a different useful life or impairment. If we change our estimate of the useful life of an asset, we amortize the carrying amount over the revised remaining useful life.

Impairments of Long-Lived Assets and Goodwill

Long-lived Assets Impairment

We evaluate the carrying value of our long-lived assets and investments for impairment when events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Such changes in circumstance may include, among other items, (i) an expectation of a sale or disposal of a long-lived asset or asset group, (ii) adverse changes in

market or competitive conditions, (iii) an adverse change in legal factors or business climate in the markets in which we operate and (iv) operating or cash flow losses.

For PP&E and intangible assets used in our operations, recoverability generally is determined by comparing the carrying value of an asset, or group of assets to their expected undiscounted future cash flows. If the carrying value of an asset (asset group) is not recoverable, the amount of impairment loss is measured as the difference between the carrying value of the asset (asset group) and its estimated fair value. The asset grouping as well as the determination of expected undiscounted cash flow amounts requires significant judgments, estimates, and assumptions, including cash flows generated upon disposition. We measure fair value as the price that would be received if we were to sell the assets in an orderly transaction. Assets to be disposed of are carried at the lower of their financial statement carrying amount or fair value less costs to sell.

We conduct impairment testing of our indefinite-lived intangible assets on October 1st each year. We test indefinite-lived intangible assets for impairment between annual tests if an event occurs or circumstances change that would indicate the carrying amount may be impaired. An impairment loss is recognized when the asset's carrying value exceeds its fair value.

Goodwill Impairment

We conduct impairment testing of our goodwill on October 1st each year. We test goodwill for impairment between annual tests if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of a reporting unit below its carrying amount. Testing is performed at the reporting unit level, which is defined as an operating segment or a component of an operating segment that constitutes a business for which financial information is available and is regularly viewed by management. Our operating segments are deemed to be our reporting units for purposes of goodwill impairment testing.

If we determine that goodwill is more-likely-than-not impaired, we perform the first step of a two-step goodwill impairment test. We first identify potential impairment by comparing the fair value of the reporting unit to its carrying amount, including goodwill. Fair value refers to the price that would be received if we were to sell the unit as a whole in an orderly transaction. If the carrying amount of our reporting unit is greater than zero and its fair value exceeds its carrying amount, goodwill of the reporting unit is considered not impaired and the second step of the impairment test is unnecessary. If the carrying value of the reporting unit exceeds its fair value, we perform step 2 of the goodwill impairment test. An impairment loss is recognized when the carrying amount of the reporting unit's net assets exceeds the estimated fair value of the reporting unit, up to and including the carrying amount of the goodwill. Fair value is estimated using a discounted cash flow model. Estimating fair value requires various assumptions, including revenue and gross margin growth rates and discount rates.

If the aggregate fair value of our reporting units exceeds our market capitalization, we evaluate the reasonableness of the implied control premium which includes a comparison to implied control premiums from recent market transactions within our industry or other relevant benchmark data.

Goodwill impairment evaluations are highly subjective. In most instances, they involve expectations of future cash flows that reflect our judgments and assumptions regarding future industry conditions and operations. The estimates, judgments and assumptions used in the application of our goodwill impairment policies reflect both historical experience and an assessment of current operational, industry, market, economic and political environments. The use of different estimates, judgments, assumptions and expectations regarding future industry and market conditions and operations would likely result in materially different asset carrying values and operating results.

Quantitative factors used to determine the fair value of the reporting units reflect our best estimates, and we believe they are reasonable. Future declines in the reporting units' operating performance or our anticipated business outlook may reduce the estimated fair value of our reporting units and result in an impairment. Factors that could have a negative impact on the fair value of the reporting units include, but are not limited to:

- decreases in revenue as a result of the inability of our sales force to effectively market and promote our products;
- increased competition, patent expirations or new technologies or treatments;
- declines in anticipated growth rates;
- the outcome of litigation, legal proceedings, investigations or other claims resulting in significant cash outflows; and
- increases in the market-participant risk-adjusted Weighted Average Cost of Capital ("WACC").

Derivatives and Risk Management

U.S. GAAP requires companies to recognize all derivatives as assets and liabilities on the balance sheet and to measure the instruments at fair value through earnings unless the derivative qualifies for hedge accounting. If the derivative qualifies for hedge accounting, depending on the nature of the hedge and hedge effectiveness, changes in the fair value of the derivative will either be recognized immediately in earnings or recorded in other comprehensive income ("OCI") until the hedged item is recognized in earnings. The changes in the fair value of the derivative are intended to offset the change in fair value of the

hedged asset, liability or probable commitment. We evaluate hedge effectiveness at inception. Cash flows from derivative contracts are reported as operating activities on the consolidated statements of cash flows.

We use currency exchange rate derivative contracts and interest rate derivative instruments to manage the impact of currency exchange and interest rate changes on earnings and cash flows. Forward currency exchange rate contracts are designed to hedge anticipated foreign currency transactions and changes in the value of specific assets and liabilities. At inception of the forward contract, the derivative is designated as either a freestanding derivative or a cash flow hedge. We do not enter into derivative contracts for speculative purposes. All derivative instruments are recorded at fair value on the consolidated balance sheets, as assets or liabilities (current or non-current) depending upon the gain or loss position of the contract and contract maturity date.

Forward contracts designated as cash flow hedges are designed to hedge the variability of cash flows associated with forecasted transactions denominated in a foreign currency that will take place in the future. For derivative instruments that are designated and qualify as a cash flow hedge, the gain or loss on the derivative instrument is reported as a component of accumulated other comprehensive income ("AOCI") and reclassified into earnings to offset exchange differences originated by the hedged item or the current earnings effect of the hedged item. We use freestanding derivative forward contracts to offset exposure to the variability of the value associated with assets and liabilities denominated in a foreign currency. These derivatives are not designated as hedges, and therefore changes in the value of these forward contracts are recognized in earnings, thereby offsetting the current earnings effect of the related change in value of foreign currency denominated assets and liabilities.

We use interest rate derivative instruments designated as cash flow hedges to manage the exposure to interest rate movements and to reduce the risk of increased borrowing costs by converting floating-rate debt into fixed-rate debt. Under these agreements, we agree to exchange, at specified intervals, the difference between fixed and floating interest amounts calculated by reference to agreed-upon notional principal amounts. The interest rate swaps are structured to mirror the payment terms of the underlying loan. The fair value of the interest rate swaps is reported on the consolidated balance sheets as assets or liabilities (current or non-current) depending upon the gain or loss position of the contract and the maturity of the future cash flows of each contract. The gain or loss on these derivatives is reported as a component of AOCI.

Fair Value Measurements

We follow the authoritative guidance on fair value measurements and disclosures with respect to assets and liabilities that are measured at fair value on both a recurring and nonrecurring basis. Under this guidance, fair value is defined as the exit price, or the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants as of the measurement date. The authoritative guidance also establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs market participants would use in valuing the asset or liability, based on market data obtained from sources independent of us. Unobservable inputs are inputs that reflect our assumptions about the factors market participants would use in valuing the asset or liability developed based upon the best information available in the circumstances. The categorization of financial assets and financial liabilities within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement. The hierarchy is broken down into three levels defined as follows:

- Level 1 - Inputs are quoted prices in active markets for identical assets or liabilities;
- Level 2 - Inputs include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, and inputs (other than quoted prices) that are observable for the asset or liability, either directly or indirectly; and
- Level 3 - Inputs are unobservable for the asset or liability.

Financial assets and liabilities that are classified as Level 2 include derivative instruments, primarily forward and option currency contracts and interest rate swaps contracts, which are valued using standard calculations and models that use readily observable market data as their basis.

Financial liabilities that are classified as Level 3 include contingent consideration arrangements resulting from acquisitions that involve potential future payment of consideration that is contingent upon the achievement of performance milestones and sales-based earn-outs. Contingent consideration is recognized at fair value at the date of acquisition based on the consideration expected to be transferred and estimated as the probability of future cash flows, discounted to present value in accordance with accepted valuation methodologies. The discount rate used is determined at the time of measurement. Contingent consideration is remeasured each reporting period with the change in fair value, including accretion for the passage of time, recorded in earnings. The change in fair value of contingent consideration based on the achievement of regulatory milestones is recorded as research and development expense while the change in fair value of sales-based earnout contingent consideration is recorded as cost of sales. Contingent consideration payments made soon after the acquisition date are classified as an investing activity. Contingent consideration

payments that are not made soon after the acquisition date are classified as a financing activity up to the amount of the contingent consideration liability recognized at the acquisition date, with any excess classified as an operating activity.

Investments in Equity Securities

Our investments in equity securities, and related loans, are investments in affiliates that are in varied stages of development and not publicly traded. Our equity investments are reported in investments, and related loans in other assets, on the consolidated balance sheets.

We elect to measure investments that do not have readily determinable fair values, at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for an identical or a similar investment of the same issuer.

Our investments in affiliates in which we have significant influence but not control are accounted for using the equity method. Our share of net income or loss is reflected as one line item on our consolidated statements of income (loss) under losses from losses from equity-method investments and will increase or decrease, as applicable, the carrying value of our equity method investments reported under investments on the consolidated balance sheets. We regularly review our investments for changes in circumstance or the occurrence of events that suggest our investment may not be recoverable, and if an impairment is considered to be other-than-temporary, the loss is recognized on the consolidated statements of income (loss) in the period the determination is made and reported as losses from equity-method investments.

Warranty Obligation

We offer a warranty on various products. We estimate the costs that may be incurred under warranties and record a liability in the amount of such costs at the time the product is sold. The amount of the reserve recorded is equal to the net costs to repair or otherwise satisfy the claim. We include the warranty obligation in accrued liabilities and other on the consolidated balance sheets. Warranty expense is recorded to cost of goods sold on our consolidated statements of income (loss).

Retirement Benefit Plan Assumptions

We sponsor various retirement benefit plans, including defined benefit pension plans (pension benefits), defined contribution savings plans and termination indemnity plans, covering substantially all U.S. employees and employees outside the U.S. Pension benefit costs include assumptions for the discount rate, retirement age, compensation rate increases and the expected return on plan assets.

Product Liability Accruals

Accruals for product liability claims are recorded when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information. Accruals for product liability claims are adjusted periodically as additional information becomes available.

Revenue Recognition

Refer to “Note 3. Revenue Recognition.”

Research and Development

All R&D costs are expensed as incurred. R&D includes costs of basic research activities as well as engineering and technical effort required to develop a new product or make significant improvements to an existing product or manufacturing process. R&D costs also include regulatory and clinical study expenses, including post-market clinical studies.

Leases

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 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 13. Leases.”

Prior to the adoption of ASU No. 2016-02, *Leases* (Topic 842) and subsequent amendments on January 1, 2019, we accounted for leases that transfer substantially all benefits and risks incidental to the ownership of property as an acquisition of an asset and the incurrence of an obligation, and we accounted for all other leases as operating leases. Certain of our leases provide for tenant improvement allowances that were recorded as deferred rent and amortized using the straight-line method over the life of the lease as a reduction to rent expense. In addition, scheduled rent increases and rent holidays were recognized on a straight-line basis over the term of the lease.

Stock-Based Compensation

Stock-Based Incentive Awards

We may grant stock-based incentive awards to directors, officers, key employees and consultants. We measure the cost of employee services received in exchange for an award of equity instruments based on the grant date fair market value of the award. We recognize equity-based compensation expense ratably over the period that an employee is required to provide service in exchange for the entire award (all vesting periods). We issue new shares upon stock option exercises, otherwise issuance of stock for vesting of restricted stock units or exercises of stock appreciation rights are issued from treasury shares. We have the right to elect to pay the cash value of vested restricted stock units in lieu of the issuance of new shares.

Stock Appreciation Rights (“SARs”)

A SAR confers upon an employee the contractual right to receive an amount of cash, stock, or a combination of both that equals the appreciation in the company’s stock from an award’s grant date to the exercise date. SARs may be exercised at the employee’s discretion during the exercise period and do not give the employee an ownership right in the underlying stock. SARs do not involve payment of an exercise price. We use the Black-Scholes option pricing methodology to calculate the grant date fair market value of SARs and compensation is expensed ratably over the service period. We determine the expected volatility of the awards based on historical volatility. Calculation of compensation for stock awards requires estimation of volatility, employee turnover and forfeiture rates.

Restricted Stock Units (“RSUs”)

We may grant RSUs at no purchase cost to the grantee. The grantees of unvested RSUs have no voting rights or rights to dividends. Sale or transfer of the stock and stock units is restricted until they are vested. The fair market value of service-based

RSUs is determined using the market closing price on the grant date, and compensation is expensed ratably over the service period. Calculation of compensation for stock awards requires estimation of employee turnover and forfeiture rates.

Income Taxes

We are a UK corporation, and we operate through our various subsidiaries in a number of countries throughout the world. Our provision for income taxes is based on the tax laws and rates applicable in the jurisdictions in which we operate and earn income. We use significant judgment and estimates in accounting for our income taxes. We recognize deferred tax assets and liabilities for the anticipated future tax effects of temporary differences between the financial statements basis and the tax basis of our assets and liabilities, which are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled.

We periodically assess the recoverability of our deferred tax assets by considering whether it is more-likely-than-not that some or all of the actual benefit of those assets will be realized. To the extent that realization does not meet the "more-likely-than-not" criterion, we establish a valuation allowance. We periodically review the adequacy and necessity of the valuation allowance by considering significant positive and negative evidence relative to our ability to recover deferred tax assets and to determine the timing and amount of valuation allowance that should be released. This evidence includes: profitability in the most recent quarters; internal forecasts for the current and next two future years; size of deferred tax asset relative to estimated profitability; the potential effects on future profitability from increasing competition, healthcare reforms and overall economic conditions; limitations and potential limitations on the use of our net operating losses due to ownership changes, pursuant to IRC Section 382; and the implementation of prudent and feasible tax planning strategies, if any.

We file federal and local tax returns in many jurisdictions throughout the world and are subject to income tax examinations for our fiscal year 2001 and subsequent years, with certain exceptions. While we believe that our tax return positions are fully supported, tax authorities may disagree with certain positions we have taken and assess additional taxes and as a result, we may establish reserves for uncertain tax positions, which require a significant degree of management judgment. We regularly assess the likely outcomes of our tax positions in order to determine the appropriateness of our reserves; however, the actual outcome of an audit can be significantly different than our expectations, which could have a material impact on our tax provision. Our tax positions are evaluated for recognition using a more-likely-than-not threshold. Uncertain tax positions requiring recognition are measured as the largest amount of tax benefit that has a greater than 50% likelihood of being realized upon effective settlement with a taxing authority that has full knowledge of all relevant information. Some of the reasons a reserve for an uncertain tax benefit may be reversed are: completion of a tax audit; a change in applicable tax law including a tax case or legislative guidance; or an expiration of the statute of limitations. We recognize interest and penalties associated with unrecognized tax benefits and record interest in interest expense, and penalties in selling, general and administrative expense, on our consolidated statements of income (loss).

Foreign Currency

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

Assets and liabilities of subsidiaries whose functional currency is not the U.S. dollar are translated into U.S. dollars based on a combination of both current and historical exchange rates, while their revenues earned and expenses incurred are translated into U.S. dollars at average period exchange rates. Translation adjustments are included as AOCI on the consolidated balance sheets. Gains and losses arising from transactions denominated in a currency different from an entity's functional currency are included in foreign exchange and other (losses) gains on our consolidated statements of income (loss). Taxes are not provided on cumulative translation adjustments, as substantially all translation adjustments are related to earnings which are intended to be indefinitely reinvested in the countries where earned.

Contingencies

We are subject to product liability claims, government investigations and other legal proceedings in the ordinary course of business. Legal fees and other expenses related to litigation are expensed as incurred and included in selling, general and administrative expenses on our consolidated statements of income (loss). Contingent liabilities are recorded when we determine that a loss is both probable and reasonably estimable. Due to the fact that legal proceedings and other contingencies are inherently unpredictable, our assessments involve significant judgment regarding future events.

Note 3. Revenue Recognition

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

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

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

We incur incremental commission fees paid to the sales force associated with the sale of products. We apply the practical expedient within ASC 606-10-50-22 and have elected to recognize the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset the entity would otherwise recognize is one year or less. As a result, no commissions have been capitalized as contract costs since adoption of ASC 606. The following is a description of the principal activities (separated by reportable segments) from which we generate our revenue. For more detailed information about our reportable segments including disaggregated revenue results by major product line and primary geographic markets, see “Note 20. Geographic and Segment Information.”

Cardiovascular Products and Services

Our Cardiovascular segment has three primary product lines: cardiopulmonary products, heart valves and advanced circulatory support.

Cardiopulmonary products include oxygenators, heart-lung machines, autotransfusion systems, perfusion tubing systems, cannulae and other related accessories. Heart valves include mechanical heart valves, tissue heart valves, related repair products and minimally invasive surgical instruments. Advanced circulatory support includes temporary life support product kits that can include a combination of pumps, oxygenators, and cannulae.

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

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

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

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

Neuromodulation Products

Neuromodulation segment products are comprised of Neuromodulation therapy systems for the treatment of drug-resistant epilepsy, DTD and obstructive sleep apnea. Our Neuromodulation product line includes the VNS Therapy System, which consists of an implantable pulse generator, a lead that connects the generator to the vagus nerve, and other accessories. Our Neuromodulation product line also includes an implantable device for the treatment of obstructive sleep apnea that stimulates multiple tongue muscles via the hypoglossal nerve, which opens the airway while a patient is sleeping. We recognize revenue for Neuromodulation product sales when control passes to the customer.

Contract Balances

Due to the nature of our products and services, revenue producing activities may result in contract assets and contract liabilities which are insignificant to our financial position and results of operations. These activities relate primarily to Cardiovascular technical services contracts for short-term and multi-year service agreements. Contract assets are primarily

comprised of unbilled revenues, which occur when a performance obligation has been completed, but not billed to the customer. Contract liabilities are made up of deferred revenue, which occurs when a customer pays for a service, before a performance obligation has been completed. Contract assets are included within prepaid expenses and other current assets on the consolidated balance sheets and were insignificant at December 31, 2019 and 2018. As of December 31, 2019 and December 31, 2018, contract liabilities of $8.6 million and $4.8 million, respectively, were included within accrued liabilities and other and other long-term liabilities on the consolidated balance sheets.

Note 4. Business Combinations

ImThera

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

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

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

Cash	$	78,332
Contingent consideration		112,744
Fair value of our interest in ImThera prior to the acquisition [1]		25,580
Fair value of consideration transferred	$	216,656

(1) The fair value of our previously held interest in ImThera was determined based on the fair value of total consideration transferred and application of a discount for lack of control. As a result, we recognized a gain of $11.5 million for the fair value in excess of our carrying value of $14.1 million. The gain is included in Gain on acquisitions on our consolidated statement of income (loss) for the year ended December 31, 2018.

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

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

(1) During the second quarter of 2018, measurement period adjustments were recorded based upon new information obtained about facts and circumstances that existed as of the acquisition date.

(2) The fair value of IPR&D was determined using the income approach, which is a valuation technique that provides a fair value estimate based on the market participant expectations of cash flows the asset would generate. The cash flows were discounted commensurate with the level of risk associated with the asset. The discount rates were developed after assigning a probability of success to achieving the projected cash flows based on the current stage of development, inherent uncertainty in reaching certain regulatory milestones and risks associated with commercialization of the product. The IPR&D amount is included in intangible assets, net on the consolidated balance sheets as of December 31, 2019 and 2018.

(3) The amounts are presented net of deferred tax assets acquired.

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

The results of the ImThera acquisition added $0.3 million in revenue and $8.8 million in operating losses during the year ended December 31, 2018. Additionally, we recognized ImThera acquisition-related expenses of approximately $0.7 million for legal and valuation expenses during the year ended December 31, 2018. These expenses are included within “Selling, general

and administrative" expenses on our consolidated statement of income (loss). Pro forma financial information, assuming the ImThera acquisition had occurred as of the beginning of the calendar year prior to the year of acquisition, was not material for disclosure purposes.

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

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

For a reconciliation of the beginning and ending balance of contingent consideration liabilities refer to "Note 10. Fair Value Measurements."

TandemLife

TandemLife is focused on the delivery of leading-edge temporary life support systems, including cardiopulmonary and respiratory support solutions. TandemLife complements our Cardiovascular segment portfolio and expands our existing product line of cardiopulmonary products.

On April 4, 2018, we acquired CardiacAssist, Inc., doing business as TandemLife for cash consideration of up to $254 million. Cash of $204 million was paid at closing with up to $50 million in contingent consideration based on the achievement of regulatory milestones.

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

Cash	$	203,671
Contingent consideration		40,190
Fair value of consideration transferred	$	243,861

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

	Initial Purchase Price Allocation	Measurement Period Adjustments [1]	Adjusted Purchase Price Allocation
In-process research and development [2] [3]	$ 110,977	$ (3,474)	$ 107,503
Trade names [2]	11,539	—	11,539
Developed technology [2]	6,387	—	6,387
Goodwill	118,917	(797)	118,120
Inventory	10,296	(140)	10,156
Other assets and liabilities, net	3,632	242	3,874
Deferred income tax liabilities, net [4]	(17,887)	4,169	(13,718)
Net assets acquired	$ 243,861	$ —	$ 243,861

(1) During the third quarter of 2018, measurement period adjustments were recorded based upon new information regarding future estimates of R&D expenses that existed as of the acquisition date. In addition, during the first quarter of 2019, measurement period adjustments related to finalizing our tax attributes were recorded, which resulted in an increase of $3.3 million in deferred tax assets and a commensurate decrease to goodwill.

(2) The amounts are included in intangible assets, net on the consolidated balance sheets as of December 31, 2019 and 2018. Trade names and developed technology are amortized over remaining useful lives of 15 and 2 years, respectively.

(3) The fair value of IPR&D was determined using the income approach, which is a valuation technique that provides a fair value estimate based on the market participant expectations of cash flows the asset would generate. The cash flows were discounted commensurate with the level of risk associated with the asset. The discount rates were developed after assigning a probability of success to achieving the projected cash flows based on the current stage of development, inherent uncertainty in reaching certain regulatory milestones and risks associated with commercialization of the product.

(4) The amounts are presented net of deferred tax assets and include deferred tax assets acquired.

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

The results of the TandemLife acquisition added $19.5 million in revenue and $14.0 million in operating losses during the year ended December 31, 2018. Additionally, we recognized TandemLife acquisition-related expenses of approximately $2.1 million for legal and valuation expenses during the year ended December 31, 2018. These expenses are included within selling, general and administrative expenses on our consolidated statement of income (loss). Pro forma financial information, assuming the TandemLife acquisition had occurred as of the beginning of the calendar year prior to the year of acquisition, was not material for disclosure purposes.

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

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

For a reconciliation of the beginning and ending balance of contingent consideration liabilities refer to “Note 10. Fair Value Measurements.”

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 IPR&D intangible assets and $1.5 million in goodwill.

Note 5. Discontinued Operations

In November 2017, we concluded that the sale of CRM represented a strategic shift in our business that would have a major effect on future operations and financial results. Accordingly, the operating results of CRM are classified as discontinued operations on our consolidated statements of income (loss) for all the periods presented in this Annual Report on Form 10-K.

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 that could result in a negative adjustment of up to $10.0 million in addition to $14.9 million recorded within accrued liabilities and other at December 31, 2019. 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. During the year ended December 31, 2019 and December 31, 2018 we recognized income of $0.9 million and $2.8 million, respectively, for providing these services. Income recognized related to the transition services agreements is recorded as a reduction to the related expenses in the associated expense line items on our consolidated statements of income (loss).

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

	Year Ended December 31,		
	2019	2018	2017
Revenues	$ —	$ 77,366	$ 245,171
Costs and expenses:			
Cost of sales	(43)	28,028	92,609
Selling, general and administrative expenses	(161)	43,382	105,831
Research and development	(161)	16,592	37,936
Merger and integration expenses	—	—	22
Restructuring expenses	—	651	(1,617)
Amortization of intangibles	—	—	12,737
Impairment of tangible and intangible assets	—	—	93,574
Revaluation gain on assets and liabilities held for sale	—	(1,213)	—
Loss on sale of CRM	—	214	—
Operating income (loss) from discontinued operations	365	(10,288)	(95,921)
Foreign exchange and other gains (losses)	—	102	(381)
Income (loss) from discontinued operations, before tax	365	(10,186)	(96,302)
Income tax benefit	—	(460)	(21,635)
Losses from equity method investments	—	(1,211)	(4,887)
Net income (loss) from discontinued operations	$ 365	$ (10,937)	$ (79,554)

Cash flows attributable to our discontinued operations are included on our consolidated statements of cash flows. For the years ended December 31, 2018 and December 31, 2017, CRM's capital expenditures were $1.0 million and $6.1 million, respectively, and stock-based compensation expense was $2.0 million and $1.4 million, respectively. For the year ended December 31, 2017, CRM's depreciation and amortization was $18.3 million. Income tax benefit for the year ended December 31, 2017 includes a $15.3 million tax benefit recognized on the impairment of CRM.

Note 6. 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 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. In addition, during the year ended December 31, 2016, we initiated a plan to exit the Costa Rica manufacturing operation and

transfer its operations to Houston, Texas. We completed the exit of the Costa Rica manufacturing operation in the first half of 2017 and substantially completed the Prior Plans during 2018.

Included in Prior Plans was our commitment to sell our Suzhou Industrial Park facility in Shanghai, China, which we announced in March 2017. As a result of this exit plan we recorded an impairment of the building and equipment of $5.4 million and accrued $0.5 million of additional costs, primarily related to employee severance, during the year ended December 31, 2017. We completed the sale of the Suzhou facility in April 2018 and received cash proceeds from the sale of $13.3 million.

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. The 2018 Plan resulted in a net reduction of approximately 75 personnel and was completed prior to the end of 2019.

In November 2019, we initiated a reorganization plan (the "2019 Plan") to streamline our organizational structure in order to address new regulatory requirements, create efficiencies, improve profitability and ensure business continuity. As a result, we incurred restructuring expenses of $4.4 million during the year ended December 31, 2019, primarily associated with severance costs for approximately 35 impacted employees.

Additionally, we ended our Caisson TMVR program effective December 31, 2019 after determining that it was no longer viable to continue to invest in the program. As a result, we recognized restructuring expenses of $3.5 million during the year ended December 31, 2019, primarily associated with severance costs for approximately 50 impacted employees.

We expect our restructuring actions will result in an incremental benefit to operating (loss) income from continuing operations, primarily through reductions to cost of sales - exclusive of amortization, selling, general and administrative and research and development from the 2019 Plan and to research and development from the Caisson TMVR restructuring plan.

The following table presents the accruals, inventory obsolescence and other reserves, recorded in connection with our reorganization plans including the balances and activity related to the CRM business franchise (in thousands):

	Employee Severance and Other Termination Costs	Other	Total
Balance at December 31, 2016	$ 21,092	$ 3,056	$ 24,148
Charges	10,076	5,363	15,439
Cash payments / write-downs	(27,279)	(5,794)	(33,073)
Balance at December 31, 2017	3,889	2,625	6,514
Charges	15,641	925	16,566
Cash payments	(9,335)	(481)	(9,816)
Balance at December 31, 2018	10,195	3,069	13,264
Charges	11,472	782	12,254
Cash payments	(17,570)	(2,451)	(20,021)
Balance at December 31, 2019 [1]	$ 4,097	$ 1,400	$ 5,497

(1) Cumulatively, we have recognized a total of $111.5 million in restructuring expense, inclusive of discontinued operations.

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

	Year Ended December 31,		
	2019	2018	2017
Cardiovascular [1]	$ 3,592	$ 11,497	$ 8,819
Neuromodulation	1,082	1,595	561
Other [2]	7,580	2,823	7,676
Restructuring expense from continuing operations	12,254	15,915	17,056
Discontinued operations	—	651	(1,617)
Total	$ 12,254	$ 16,566	$ 15,439

(1) Cardiovascular restructuring expense for the year ended December 31, 2018 included $6.5 million of 2018 Plan expenses. Cardiovascular restructuring expense for the year ended December 31, 2017 included building and equipment impairment of $5.4 million related to the Suzhou, China facility exit plan.

(2) Other restructuring expense for the year ended December 31, 2019 included $3.5 million of Caisson restructuring expenses.

Note 7. 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. In October 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., and on February 25, 2020, LivaNova received clearance for K191402, a 510(k) for the 3T devices that addressed issues contained in the 2015 Warning Letter along with design changes that further mitigate the potential risk of aerosolization. Concurrent with this clearance, (1) 3T devices manufactured in accordance with K191402 will not be subjected to the import alert and (2) LivaNova initiated a correction to distribute the updated Operating Instructions cleared under K191402.

As a second 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 in April 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. Finally, we are continuing to offer the loaner program for 3T devices, initiated in the fourth quarter of 2016, to provide existing 3T device users with a new loaner 3T device at no charge pending regulatory approval and implementation of the vacuum system addition and deep disinfection service worldwide. This loaner program, which 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, 2016	$	33,487
Adjustments		2,452
Remediation activity		(11,283)
Effect of changes in foreign currency exchange rates		2,890
Balance at December 31, 2017		27,546
Adjustments		(200)
Remediation activity		(12,212)
Effect of changes in foreign currency exchange rates		(389)
Balance at December 31, 2018		14,745
Adjustments		3,663
Remediation activity		(14,909)
Effect of changes in foreign currency exchange rates		(248)
Balance at December 31, 2019	$	3,251

We recognized product remediation expenses during the years ended December 31, 2019, 2018 and 2017 of $15.8 million, $10.7 million and $7.3 million, respectively. Product remediation expenses include internal labor costs, costs to remediate certain inspectional observations made by the FDA at our Munich facility and costs associated with the incorporation of the modification of the 3T device design into the next generation 3T device. These costs and related legal costs are expensed as incurred and are not included within the product remediation liability presented above. During the fourth quarter of 2018, we recognized a $294.1 million liability related to the litigation involving the 3T device. As of December 31, 2019, the liability was $170.4 million. Our related legal costs are expensed as incurred. For further information, please refer to “Note 14. Commitments and Contingencies.”

Note 8. Goodwill and Intangible Assets

Our finite-lived and indefinite-lived intangible assets as of December 31, 2019 and 2018 consisted of the following (in thousands):

	2019	2018
Finite-lived intangible assets:		
Customer relationships	$ 320,023	$ 317,292
Developed technology	293,785	176,476
Trade names	25,004	25,260
Other intangible assets	975	897
Total gross finite-lived intangible assets	639,787	519,925
Accumulated amortization - Customer relationships	75,156	57,350
Accumulated amortization - Developed technology	57,362	39,144
Accumulated amortization - Trade names	14,811	11,440
Accumulated amortization - Other intangible assets	712	337
Total accumulated amortization	148,041	108,271
Net finite-lived intangible assets	$ 491,746	$ 411,654
Indefinite-lived intangible assets:		
IPR&D	$ 115,800	$ 358,785
Goodwill	915,794	956,815
Total indefinite-lived intangible assets	$ 1,031,594	$ 1,315,600

During the year ended December 31, 2019, we recognized $14.7 million of developed technology and in-process R&D and $1.5 million in goodwill related to the acquisition of Miami Instruments.

The amortization periods for our finite-lived intangible assets as of December 31, 2019, are as follows:

	Minimum Life in years	Maximum Life in years
Customer relationships	15	18
Developed technology	2	19
Trade names	15	15
Other intangible assets	5	10

The estimated future amortization expense based on our finite-lived intangible assets at December 31, 2019, is as follows (in thousands):

2020	$	39,901
2021		39,102
2022		39,102
2023		39,102
2024		39,102
Thereafter		295,437
Total	$	491,746

Intangible Asset Impairments

In November 2019, we announced that we would be ending our Caisson TMVR program. The announcement triggered an evaluation of finite and indefinite lived assets for impairment. As a result, we fully impaired the IPR&D asset and goodwill of $89.0 million and $42.4 million, respectively.

During the second quarter of 2019, we determined that there would be a delay in the estimated commercialization date of our obstructive sleep apnea product currently under development, which was acquired in the ImThera acquisition. This delay constituted a triggering event that required an 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 carrying value of the IPR&D asset as of December 31, 2019 is $112.0 million. The estimated fair value of IPR&D was determined using the income approach. Estimating the fair value of the IPR&D asset requires various assumptions, including revenue growth rates, timing and probability of commercialization and the discount rate. Future delays in commercialization or changes in management estimates could result in further impairment. Refer to “Note 4. Business Combinations.”

Intangible Asset Reclassification

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

Goodwill

The changes in the carrying amount of goodwill by reportable segment are as follows (in thousands):

	Cardiovascular	Neuromodulation	Other	Total
December 31, 2017	$ 425,882	$ 315,943	$ 42,417	$ 784,242
Goodwill as a result of acquisitions [1]	121,446	82,596	—	204,042
Foreign currency adjustments	(31,469)	—	—	(31,469)
December 31, 2018	515,859	398,539	42,417	956,815
Goodwill as a result of acquisitions [1]	1,550	—	—	1,550
Measurement period adjustments [2]	(3,326)	—	—	(3,326)
Impairment	—	—	(42,417)	(42,417)
Foreign currency adjustments	2,957	215	—	3,172
December 31, 2019	$ 517,040	$ 398,754	$ —	$ 915,794

(1) Goodwill recognized during the year ended December 31, 2019 was the result of the Miami Instruments acquisition. Goodwill recognized during the year ended December 31, 2018 was the result of the ImThera and TandemLife acquisitions. Refer to "Note 4. Business Combinations."

(2) Refer to "Note 4. Business Combinations."

We performed a quantitative assessment for our Cardiovascular and Neuromodulation reporting units as of October 1, 2019. The quantitative impairment assessment was performed using management's current estimate of future cash flows. We concluded that the fair value of our Cardiovascular and Neuromodulation segments exceeded the carrying value of the respective reporting units by 24% and 584%, respectively, as evidenced by the estimated fair value of our Cardiovascular and Neuromodulation reporting units calculated for the purpose of reconciling the fair value of our reporting units to our market capitalization. Therefore, we concluded that our Cardiovascular and Neuromodulation reporting units' goodwill was not impaired.

Note 9. 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 below equity investments are included in investments on the consolidated balance sheets as of December 31, 2019 and 2018 (in thousands):

	2019	2018
Respicardia Inc. [1]	$ 17,706	$ 17,706
Ceribell, Inc. [2]	3,000	3,000
ShiraTronics, Inc. [3]	2,045	—
Rainbow Medical Ltd. [4]	1,099	1,119
MD Start II [5]	1,121	1,144
Highlife S.A.S. [6]	1,064	1,084
Other	770	770
	26,805	24,823
Equity method investments [7]	451	—
	$ 27,256	$ 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 and $0.6 million as of December 31, 2019 and December 31, 2018, respectively, which is included in prepaid expenses and other current assets on the consolidated balance sheet. Refer to the paragraph below for further details regarding this investment.

(2) On September 7, 2018, we acquired 1,007,319 shares of Series B Preferred Stock of Ceribell, Inc. ("Ceribell"). Ceribell is focused on utilizing electroencephalography to improve the diagnosis and treatment of patients at risk for seizures.

(3) ShiraTronics, Inc. ("ShiraTronics") is a privately held early-stage medical device company located in the U.S. and Ireland and is focused on developing neuromodulation technologies for the treatment of debilitating migraine headaches. We are required to invest up to a total of $5 million dependent upon ShiraTronics achieving certain milestones.

(4) Rainbow Medical Ltd. (“Rainbow Medical”) is a private Israeli venture capital company that seeds and grows companies developing medical devices in a diverse range of medical fields. Refer to the paragraph below for further details.
(5) MD Start II is a private venture capital collaboration for the development of medical device technology in Europe.
(6) Highlife S.A.S. (“Highlife”) is a privately held clinical-stage medical device company located in France and is focused on the development of a unique TMRV replacement system to treat patients with MR. Refer to the paragraph below for further details. Due to an additional investment by a third party during the year ended December 31, 2018, our equity interest in Highlife decreased to 7.8% from 24.6%. We determined that we no longer had significant influence over Highlife and, as a result, we no longer accounted for Highlife under the equity method.
(7) During 2019 we invested $0.5 million in equity securities that we account for under the equity method of accounting. We are required to fund up to a total of approximately €5.0 million (approximately $5.6 million as of December 31, 2019) based on cash calls.

Respicardia Impairment

We recognized an impairment of our investment in Respicardia during the year ended December 31, 2017 based on the terms of an additional round of financing with a new strategic investor that indicated the carrying value of our aggregate investment might not be recoverable and that the decrease in value of our aggregate investment was other than temporary. The estimated fair value using the income approach was below the carrying value by $5.5 million. The impairment was included in impairment of investments on our consolidated statement of income (loss).

Rainbow Medical Impairment

We recognized an impairment of our investment in Rainbow Medical during the year ended December 31, 2017. An additional round of financing, which included a new investor, indicated that the carrying value of our investment might not be recoverable and that the decrease in value of our investment was other than temporary. We, therefore, estimated the fair value of our investment using the income approach. The estimated fair value of our investment was below our carrying value by $3.0 million. This impairment was included in impairment of investments on our consolidated statement of income (loss).

Highlife Impairment

We recognized an impairment of our investment in, and notes receivable from, Highlife, during the year ended December 31, 2017. Certain factors, including a revision in our investment strategy and a new strategic investor, indicated that the carrying value of our aggregate investment might not be recoverable and that the decrease in value of our aggregate investment was other than temporary. We, therefore, estimated the fair value of our investment and notes receivable using the market approach. The estimated fair value of our aggregate investment was below our carrying value by $13.0 million. This aggregate impairment was included in losses from equity method investments on our consolidated statement of income (loss).

Istituto Europeo di Oncologia S.R.L Sale

During the year ended December 31, 2017, we sold our investment in Istituto Europeo di Oncologia S.R.L, for a gain of $3.2 million. This gain is included in foreign exchange and other (losses) gains on our consolidated statement of income (loss).

Note 10. 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 years ended December 31, 2019, 2018 or 2017.

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 as of December 31, 2019	Fair Value Measurements Using Inputs Considered as:		
		Level 1	Level 2	Level 3
Assets:				
Derivative assets - designated as cash flow hedges (foreign currency exchange rate "FX")	$ 535	$ —	$ 535	$ —
Derivative assets - freestanding instruments (FX)	26	—	26	—
Total assets	$ 561	$ —	$ 561	$ —
Liabilities:				
Derivative liabilities - designated as cash flow hedges (FX)	$ 169	$ —	$ 169	$ —
Derivative liabilities - designated as cash flow hedges (interest rate swaps)	374	—	374	—
Derivative liabilities - freestanding instruments (FX)	3,137	—	3,137	—
Contingent consideration [(1)]	137,349	—	—	137,349
Total liabilities	$ 141,029	$ —	$ 3,680	$ 137,349

	Fair Value as of December 31, 2018	Fair Value Measurements Using Inputs Considered as:		
		Level 1	Level 2	Level 3
Assets:				
Derivative assets - freestanding instruments (foreign currency exchange rate "FX")	$ 236	$ —	$ 236	$ —
Total assets	$ 236	$ —	$ 236	$ —
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	179,911	—	—	179,911
Total liabilities	$ 185,303	$ —	$ 5,392	$ 179,911

(1) The contingent consideration liability at December 31, 2019 represents contingent payments related to four completed acquisitions, including: Inversiones Drilltex SAS ("Drilltex"), 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):

Balance at December 31, 2017	$	33,973
Purchase price - ImThera contingent consideration [(1)]		112,744
Purchase price - TandemLife contingent consideration [(1)]		40,190
Payments [(2)]		(2,661)
Changes in fair value [(3)]		(4,311)
Effect of changes in foreign currency exchange rates		(24)
Balance at December 31, 2018		179,911
Additions [(1)]		7,184
Payments [(2)]		(20,204)
Changes in fair value [(3) (4) (5)]		(29,406)
Effect of changes in foreign currency exchange rates		(136)
Balance at December 31, 2019		137,349
Less current portion of contingent consideration liability at December 31, 2019		22,953
Long-term portion of contingent consideration liability at December 31, 2019	$	114,396

(1) See “Note 4. Business Combinations” for additional discussion.

(2) Payments during the year ended December 31, 2018 are for sales-based earnouts for Cellplex and for Drilltex. 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.

(3) During the year ended December 31, 2019, the change in fair value resulted in a decrease of $13.2 million and $16.2 million recorded to cost of sales - exclusive of amortization and research and development, respectively. During the year ended December 31, 2018, the change in fair value resulted in a decrease of $3.6 million and $0.7 million recorded to cost of sales - exclusive of amortization and research and development, respectively.

(4) In November 2019, we announced that we would be ending our Caisson TMVR program effective December 31, 2019. As such, we released the contingent consideration provision associated with the acquisition of Caisson. At December 31, 2018, the fair value of the Caisson contingent consideration provision was $27.9 million.

(5) The change in fair value during the year 2019 reflects a delay in the 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 8. Goodwill and Intangible Assets” for additional discussion.

Assets and Liabilities Measured at Fair Value on a Nonrecurring Basis

Our investments in equity securities of non-consolidated affiliates without readily determinable fair values 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. Our investments in non-financial assets such as, goodwill, intangible assets, and PP&E, are measured at fair value if there is an indication of impairment and recorded at fair value only when an impairment is recognized. We classify the measurement input for these assets as Level 3 inputs within the fair value hierarchy.

Other

The carrying values of our cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair values due to the short-term nature of these items.

The carrying value of our long-term debt including the current portion, as of December 31, 2019, was $333.5 million, which we believe approximates fair value.

Note 11. Financing Arrangements

The outstanding principal amount of our long-term debt as of December 31, 2019 and 2018, was as follows (in thousands, except interest rates):

	2019	2018	Maturity	Interest Rate
2019 Debt Facility [1]	$ 184,275	$ —	March 2022	1.40% - 3.56%
2017 European Investment Bank [2]	103,570	103,570	June 2026	3.31% - 3.37%
2014 European Investment Bank [3]	28,053	47,606	June 2021	1.01%
Mediocredito Italiano	6,222	7,623	December 2023	0.50% - 2.93%
Bank of America Merrill Lynch Banco Múltiplo S.A.	8,422	—	July 2021	8.08%
Bank of America, U.S.	2,004	—	January 2021	3.76%
Banca del Mezzogiorno	—	2,718	—	—
Other	965	1,324	—	—
Total long-term facilities	333,511	162,841		
Less current portion of long-term debt	73,181	23,303		
Total long-term debt	$ 260,330	$ 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 multi-currency 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 quarter 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 product development projects. The interest rate for the EIB loan is reset by the lender each quarter based on the Euribor. Interest payments are paid quarterly and principal payments are paid semi-annually.

Contractual annual principal maturities of our long-term debt facilities as of December 31, 2019, are as follows (in thousands):

2020	$ 73,497
2021	111,370
2022	91,930
2023	17,614
2024	15,996
Thereafter	24,261
Total payments	334,668
Less: Debt issuance costs	1,157
Total long-term facilities	$ 333,511

In connection with the CRM sale, on May 1, 2018, the borrowing capacity of the 2017 EIB loan decreased from €100.0 million (approximately $114.3 million as of December 31, 2018) to €90.0 million (approximately $103 million as of December 31, 2018).

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 December 31, 2019, LivaNova was in compliance with all covenants.

Revolving Credit

The outstanding principal amount of our short-term unsecured revolving credit agreements and other agreements with various banks was $4.2 million and $5.5 million at December 31, 2019 and December 31, 2018, respectively, with interest rates ranging from 2.72% to 8.29% and loan terms ranging from 10 days to 220 days.

On April 10, 2018, we entered into an amendment and restatement agreement with Barclays Bank PLC amending the revolving facility agreement originally dated October 21, 2016 (the "Amendment"). The Amendment increased our borrowing capacity under the facility from $40.0 million to $70.0 million and extended the term of the facility one year. The facility terminated on October 20, 2019.

On July 25, 2019, we entered into a €40.0 million (approximately $44.9 million as of December 31, 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 2 years and borrowings bear interest at Euribor plus 0.8%. There were no borrowings under the 2019 Revolving Credit Facility during 2019.

Bridge Facility Agreement

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

Note 12. 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 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 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 consolidated statements of income (loss). We evaluate hedge effectiveness at inception. Cash flows from derivative contracts are reported as operating activities on our consolidated statements of cash flows.

Freestanding FX Derivative Contracts

The gross notional amount of FX derivative contracts, not designated as hedging instruments, outstanding at December 31, 2019 and December 31, 2018 was $338.0 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 (losses) for these freestanding derivatives of $3.1 million, $(11.2) million and $(11.7) million for the years ended December 31, 2019, 2018 and 2017, respectively. These gains and (losses) are included in foreign exchange and other gains (losses) on our consolidated statements of income (loss).

Cash Flow Hedges

Foreign Currency Risk

We utilize FX derivative contracts, designed as cash flow hedges, to hedge the variability of cash flows associated with our 12 months U.S. dollar forecasts of revenues and costs denominated in British Pound, Japanese Yen, Canadian Dollars and the Euro. We transfer to earnings from AOCI, the gain or loss realized on the FX derivative contracts at the time of invoicing.

Interest Rate Risk

The 2014 EIB loan agreement matures in June 2021. The variable interest rate for the 2014 EIB loan is reset by the lender each quarter based on the Euribor. To minimize the impact of changes in interest rates we entered into interest rate swap agreement programs to swap the 2014 EIB loan's floating-rate interest payments for fixed-rate interest payments. The interest rate swap contracts qualify for, and are designated as, cash flow hedges.

The notional amounts of open derivative contracts designated as cash flow hedges as of December 31, 2019 and 2018, were as follows (in thousands):

Description of Derivative Contract	2019	2018
FX derivative contracts to be exchanged for British Pounds	$ 10,128	$ 9,629
FX derivative contracts to be exchanged for Japanese Yen	25,342	23,985
FX derivative contracts to be exchanged for Canadian Dollars	—	7,637
FX derivative contracts to be exchanged for Euros	48,838	29,768
Interest rate swap contracts	22,442	38,115
	$ 106,750	$ 109,134

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

Description of Derivative Contract	After-tax net gain (loss) in AOCI as of December 31, 2019	Amount Expected to be Reclassified to Earnings in Next 12 Months
FX derivative contracts	$ 600	$ 600
Interest rate swap contracts	(86)	(57)
	$ 514	$ 543

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 were as follows (in thousands):

		Year Ended December 31, 2019	
Description of Derivative Contract	Location in Earnings of Reclassified Gain or Loss	Gains Recognized in OCI	Gains (Losses) Reclassified from AOCI to Earnings:
FX derivative contracts	Foreign exchange and other (losses) gains	$ 2,757	$ 3,003
FX derivative contracts	SG&A	—	(2,071)
Interest rate swap contracts	Interest expense	—	(92)
		$ 2,757	$ 840

		Year Ended December 31, 2018	
Description of Derivative Contract	Location in Earnings of Reclassified Gain or Loss	Gains Recognized in OCI	Gains (Losses) Reclassified from AOCI to Earnings:
FX derivative contracts	Foreign exchange and other (losses) gains	$ 44	$ 2,697
FX derivative contracts	SG&A	—	(2,554)
Interest rate swap contracts	Interest expense	—	(66)
		$ 44	$ 77

		Year Ended December 31, 2017	
Description of Derivative Contract	**Location in Earnings of Reclassified Gain or Loss**	**Losses Recognized in OCI**	**(Losses) Gains Reclassified from AOCI to Earnings:**
FX derivative contracts	Foreign exchange and other (losses) gains	$ (9,861)	$ (6,471)
FX derivative contracts	SG&A	—	2,084
Interest rate swap contracts	Interest expense	—	939
		$ (9,861)	$ (3,448)

We offset fair value amounts associated with our derivative instruments on our 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 on the consolidated balance sheets (in thousands):

December 31, 2019	**Asset Derivatives**		**Liability Derivatives**	
Derivatives Designated as Hedging Instruments	**Balance Sheet Location**	**Fair Value [1]**	**Balance Sheet Location**	**Fair Value [1]**
Interest rate swap contracts			Accrued liabilities	$ 313
Interest rate swap contracts			Other long-term liabilities	61
FX derivative contracts	Prepaid expenses and other current assets	$ 148	Accrued liabilities	169
FX derivative contracts	Accrued liabilities	387		
Total derivatives designated as hedging instruments		535		543
Derivatives Not Designated as Hedging Instruments				
FX derivative contracts	Accrued liabilities	26	Accrued liabilities	3,104
FX derivative contracts			Prepaid expenses and other current assets	33
Total derivatives not designated as hedging instruments		26		3,137
Total derivatives		$ 561		$ 3,680

December 31, 2018	**Asset Derivatives**		**Liability Derivatives**	
Derivatives Designated as Hedging Instruments	**Balance Sheet Location**	**Fair Value [1]**	**Balance Sheet Location**	**Fair Value [1]**
Interest rate swap contracts			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
Derivatives Not Designated as Hedging Instruments				
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		$ 236		$ 5,392

(1) For the classification of inputs used to evaluate the fair value of our derivatives, refer to "Note 10. Fair Value Measurements."

Note 13. 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):

Operating Lease Assets and Liabilities	**December 31, 2019**
Assets	
Operating lease right-of-use assets	$ 54,372
Liabilities	
Accrued liabilities and other	$ 11,110
Long-term operating lease liabilities	46,027
Total lease liabilities	$ 57,137

Operating Lease Cost	**Year Ended December 31, 2019**
Operating lease cost	$ 14,002
Variable lease cost	873
Short-term lease cost	788
Total lease cost	$ 15,663

Contractual maturities of our lease liabilities as of December 31, 2019, are as follows (in thousands):

2020	$ 12,399
2021	10,402
2022	9,224
2023	7,524
2024	5,975
Thereafter	16,907
Total lease payments	62,431
Less: Amount representing interest	5,294
Present value of lease liabilities	$ 57,137

Lease Term and Discount Rate	**December 31, 2019**
Weighted Average Remaining Lease Term	7.0 years
Weighted Average Discount Rate	2.4%

Other information (in thousands)	**Year Ended December 31, 2019**
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows for operating leases	$ 13,522
Operating lease assets obtained in exchange for lease liabilities	$ 8,712

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 2. Basis of Presentation, Use of Accounting Estimates and Significant Accounting Policies." 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 14. 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 were 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 had informed us that the import alert was limited to the 3T devices, but that the agency reserved the right to expand the scope of the import alert if future circumstances warranted 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 were 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 were reasonably related would not be approved until the violations had been corrected; however, this restriction applied only to the Munich and Arvada facilities, which do not manufacture or design devices subject to Class III premarket approval.

On February 25, 2020, LivaNova received clearance for K191402, a 510(k) for the 3T devices that addressed issues contained in the 2015 Warning Letter along with design changes that further mitigate the potential risk of aerosolization. Concurrent with this clearance, (1) 3T devices manufactured in accordance with K191402 will not be subjected to the import alert and (2) LivaNova initiated a correction to distribute the updated Operating Instructions cleared under K191402.

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 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. and was rolled out in Europe shortly thereafter. It 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 scaling upgrade program in the U.S., and on February 25, 2020, LivaNova received clearance for K191402, a 510(k) for the 3T devices that addressed issues contained in the 2015 Warning Letter along with design changes that further mitigate the potential risk of aerosolization. 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 December 31, 2019, the product remediation liability was $3.3 million. Refer to "Note 7. 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 second payment of $90 million was paid in January 2020. Cases covered by the settlement are being 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 March 2, 2020, including the cases encompassed in the settlement framework described above that have not yet been dismissed, we are aware of approximately 95 filed and unfiled claims worldwide, with the majority of the claims in various federal or state courts throughout the United States. This number includes cases that have settled but have not yet been dismissed. 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 for these matters. In the fourth quarter of 2019, we recorded an additional liability of $33.2 million due to additional information obtained, including but not limited to: the nature

and quantity of filed and unfiled claims; certain settlement discussions with plaintiffs' counsel; and the current stage of litigation in our remaining filed and unfiled claims. At December 31, 2019, the provision was $170.4 million. While the amount accrued represents our best estimate, the actual liability for resolution of these matters may vary from our estimate.

The changes in the litigation provision liability for the year ended December 31, 2019, are as follows (in thousands):

Total litigation provision liability at December 31, 2018	$	294,061
Payments		(156,928)
Adjustments		33,233
FX and other		38
Total litigation provision liability at December 31, 2019		170,404
Less current portion of litigation provision liability at December 31, 2019		146,026
Long-term portion of litigation provision liability at December 31, 2019	$	24,378

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 recorded in litigation provision, net on the consolidated statements of income (loss) during the third quarter of the current fiscal year.

Environmental Liability

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 €292,000 (approximately $328,000 as of December 31, 2019) 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 because 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 costs 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 Administration 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 $449,000 as of December 31, 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 the decision authorizing the merger but annulled the penalty for frivolous litigation and reduced the overall contribution of legal fees to €84,000 (approximately $94,000 as of December 31, 2019). On February 28, 2020, the Supreme Court confirmed the decision, authorizing the merger and increasing the overall

contribution of legal fees to LivaNova to €98,000 (approximately $110,000 as of December 31, 2019). There is no further avenue of appeal in this matter, and the matter is now concluded.

Patent Litigation

On May 11, 2018, Neuro and Cardiac Technologies LLC ("NCT"), a non-practicing entity, filed a complaint in the United States District Court for the Southern District of Texas asserting that the VNS Therapy System, when used with the SenTiva Model 1000 generator, infringes the claims of U.S. Patent No. 7,076,307 owned by NCT. The complaint requests damages that include a royalty, costs, interest, and attorneys' fees. On September 13, 2018, we petitioned the Patent Trial and Appeal Board of the U. S. Patent and Trademark Office (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.

Contract Litigation

On November 25, 2019, LivaNova received notice of a lawsuit initiated by former members of Caisson Interventional, LLC ("Caisson"), a subsidiary of the Company acquired in 2017. The lawsuit, Todd J. Mortier, as Member Representative of the former Members of Caisson Interventional, LLC v. LivaNova USA, Inc., is currently pending in the United States District Court for the District of Minnesota. The complaint alleges (i) breach of contract, (ii) breach of the covenant of good faith and fair dealing and (iii) unjust enrichment in connection with the Company's operation of Caisson's Transcatheter Mitral Valve Replacement ("TMVR") program and the Company's November 20, 2019 announcement that it was ending the TMVR program at the end of 2019. The lawsuit seeks damages arising out of the 2017 acquisition agreement, including various regulatory milestone payments. We intend to vigorously defend this claim. The Company has not recognized an expense related to 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 $115.1 million as of December 31, 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 2nd 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 $70.2 million as of December 31, 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 €15.5 million reserve for uncertain tax position (approximately $17.4 million, as of December 31, 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 15. Stockholders' Equity

Share repurchase plans

On August 1, 2016, the Board of Directors of LivaNova approved the authorization of a share repurchase plan (the "Share Repurchase Program") pursuant to an authority granted by shareholders at the 2016 annual general meeting held on June 15, 2016. The authority granted by the shareholders has a five-year expiration. The Share Repurchase Program was structured to enable us to buy back up to $150.0 million of our shares on NASDAQ between September 1, 2016 through December 31, 2016. On November 15, 2016, the Board of Directors approved an amendment (the "Amended Share Repurchase Program") to the Share Repurchase Program authorizing the Company to repurchase up to $150.0 million of our shares between September 1, 2016 and December 31, 2018.

For the year ended December 31, 2018, we repurchased and canceled 500,333 shares under this plan at a cost of $50.0 million and an average price per share of $99.91. We did not purchase any shares during the years ended December 31, 2017 and December 31, 2019.

Treasury Stock

For the year ended December 31, 2018, we issued 1.4 million shares to our Employee Benefit Trust (“EBT”). Shares held by the EBT are issued to employees and directors at exercise of stock-based compensation grants. The balance of shares in the EBT are reported as treasury shares. We did not issue any additional shares to our EBT during the year ended December 31, 2019.

Accumulated other comprehensive (loss) income

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 years ended December 31, 2019, 2018 and 2017 (in thousands):

	Change in Unrealized Gain (Loss) on Cash Flow Hedges	Foreign Currency Translation Adjustments [1]	Total
As of December 31, 2016	**$ 3,619**	**$ (72,106)**	**$ (68,487)**
Other comprehensive (loss) income before reclassifications, before tax	(9,861)	118,338	108,477
Tax benefit	2,653	—	2,653
Other comprehensive (loss) income before reclassifications, net of tax	(7,208)	118,338	111,130
Reclassification of loss from accumulated other comprehensive income (loss), before tax	3,448	—	3,448
Reclassification of tax benefit	(778)	—	(778)
Reclassification of gain from accumulated other comprehensive income (loss), after tax	2,670	—	2,670
Net current-period other comprehensive (loss) income, net of tax	(4,538)	118,338	113,800
As of December 31, 2017	**(919)**	**46,232**	**45,313**
Other comprehensive income (loss) before reclassifications, before tax	44	(69,764)	(69,720)
Tax expense	(11)	—	(11)
Other comprehensive income (loss) before reclassifications, net of tax	33	(69,764)	(69,731)
Reclassification of gain from accumulated other comprehensive income (loss), before tax	(77)	—	(77)
Reclassification of tax expense	19	—	19
Reclassification of gain from accumulated other comprehensive income (loss), after tax	(58)	—	(58)
Net current-period other comprehensive loss, net of tax	(25)	(69,764)	(69,789)
As of December 31, 2018	**(944)**	**(23,532)**	**(24,476)**
Other comprehensive income (loss) before reclassifications, before tax	2,757	3,627	6,384
Tax expense	(661)	—	(661)
Other comprehensive income (loss) before reclassifications, net of tax	2,096	3,627	5,723
Reclassification of gain from accumulated other comprehensive income (loss), before tax	(840)	—	(840)
Reclassification of tax expense	201	—	201
Reclassification of gain from accumulated other comprehensive income (loss), after tax	(639)	—	(639)
Net current-period other comprehensive loss, net of tax	1,457	3,627	5,084
As of December 31, 2019	**$ 513**	**$ (19,905)**	**$ (19,392)**

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

Note 16. Stock-Based Incentive Plans

Stock-Based Incentive Plans

Stock-based awards may be granted under the 2015 Incentive Award Plan (the "2015 Plan") in the form of stock options, SARs, RSUs and other stock-based and cash-based awards. As of December 31, 2019, there were approximately 4,904,000 shares available for future grants under the 2015 Plan. During the year ended December 31, 2019, we awarded SARs and RSUs with service conditions that generally vest ratably over 4 years, subject to forfeiture unless service conditions are met. In

addition, during the year ended December 31, 2019, we awarded market performance-based awards that 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, and we issued operating performance-based awards that 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.

On January 1, 2019, we initiated the LivaNova Global Employee Share Purchase Plan ("ESPP"). Compensation expense related to the ESPP for the year ended December 31, 2019 was $1.3 million.

The stock-based compensation tables below include expense and share activity related to discontinued operations.

Stock-Based Compensation

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

	Year Ended December 31,		
	2019	2018	2017
Cost of goods sold	$ 1,343	$ 1,060	$ 450
Selling, general and administrative	25,588	19,393	16,118
Research and development	5,622	4,510	1,119
Stock-based compensation from continuing operations	32,553	24,963	17,687
Stock-based compensation from discontinued operations	—	1,960	1,375
Total stock-based compensation expense	32,553	26,923	19,062
Income tax benefit	6,590	6,443	4,236
Total expense, net of income tax benefit	$ 25,963	$ 20,480	$ 14,826

Amounts of stock-based compensation expense recognized on our consolidated statements of income (loss), by type of arrangement, are as follows (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Service-based stock appreciation rights	$ 10,349	$ 8,282	$ 6,916
Service-based restricted stock units	14,113	10,622	8,223
Market performance-based restricted stock units	2,900	2,357	732
Operating performance-based restricted stock units	3,918	3,702	1,816
Employee stock purchase plan	1,273	—	—
Total stock-based compensation expense from continuing operations	$ 32,553	$ 24,963	$ 17,687

Unrecognized Stock-Based Compensation

Amounts of stock-based compensation cost not yet recognized related to non-vested awards, including awards assumed or issued, as of December 31, 2019, are as follows (in thousands):

	Unrecognized Compensation Cost	Weighted Average Remaining Vesting Period (in years)
Service-based stock appreciation rights	$ 25,508	2.67
Service-based restricted stock unit awards	33,456	2.73
Performance-based restricted stock unit awards	10,587	1.65
Total stock-based compensation cost unrecognized	$ 69,551	2.35

Stock Appreciation Rights and Stock Options

We use the Black-Scholes option pricing methodology to calculate the grant date fair market value of SARs. The following table lists the assumptions we utilized as inputs to the Black-Scholes model:

	Year Ended December 31,		
	2019	2018	2017
Dividend yield [1]	—	—	—
Risk-free interest rate [2]	1.4% - 2.2%	2.5% - 2.9%	1.7% - 2.2%
Expected option term - in years [3]	5.0 - 5.1	5.0 - 5.1	4.6 - 5.2
Expected volatility at grant date [4]	32.2% - 35.7%	29.2% - 29.9%	29.6% - 30.4%

(1) We have not paid dividends and no future dividends have been approved.
(2) We use yield rates on U.S. Treasury securities for a period that approximates the expected term of the awards granted to estimate the risk-free interest rate.
(3) We estimated the expected term of the awards granted using historic data of actual time elapsed between the date of grant and the exercise or forfeiture of options or SARs for employees.
(4) We determine the expected volatility of the awards based on historical volatility.

The following tables detail the activity for service-based SARs and stock option awards:

SARs and Stock Options	Number of Optioned Shares	Wtd. Avg. Exercise Price per Share	Wtd. Avg. Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands) [1]
Outstanding — at December 31, 2018	1,941,587	$ 67.33		
Granted	591,845	96.60		
Exercised	(121,534)	61.50		
Forfeited	(171,282)	83.44		
Expired	(25,560)	72.60		
Outstanding — at December 31, 2019	2,215,056	74.41	7.0	$ 22,195
Fully vested and exercisable — end of year	951,797	61.45	5.2	$ 15,495
Fully vested and expected to vest — end of year [2]	2,173,525	$ 74.08	7.0	$ 22,117

(1) The aggregate intrinsic value of SARs and options is based on the difference between the fair market value of the underlying stock at December 31, 2019, using the market closing stock price, and exercise price for in-the-money awards.
(2) Includes the impact of expected future forfeitures.

	Year Ended December 31,		
	2019	2018	2017
Weighted average grant date fair value of SARs granted during the year (per share)	$ 31.22	$ 28.13	$ 17.19
Aggregate intrinsic value of SARs and stock options exercised during the year (in thousands)	$ 2,064	$ 27,281	$ 5,462

Restricted Stock Units Awards

The following tables detail the activity for service-based RSU awards:

RSUs	Number of Shares	Wtd. Avg. Grant Date Fair Value
Non-vested shares at December 31, 2018	450,297	$ 78.70
Granted	294,460	$ 92.54
Vested	(147,969)	$ 74.53
Forfeited	(72,955)	$ 92.62
Non-vested shares at December 31, 2019	523,833	$ 84.98

	Year Ended December 31,		
	2019	2018	2017
Weighted average grant date fair value of service-based RSUs issued during the year (per share)	$ 92.54	$ 95.63	$ 61.37
Aggregate fair value of RSUs that vested during the year (in thousands)	$ 12,710	$ 11,505	$ 9,966

The following tables detail the activity for performance-based and market-based RSU awards:

Performance-based and market-based RSUs	Number of Shares	Wtd. Avg. Grant Date Fair Value
Non-vested shares at December 31, 2018	295,364	$ 56.48
Granted	88,453	$ 98.50
Vested	(69,646)	$ 41.52
Forfeited	(28,502)	$ 75.97
Non-vested shares at December 31, 2019	285,669	$ 71.02

	Year Ended December 31,		
	2019	2018	2017
Weighted average grant date fair value of performance and market-based restricted share units granted during the year (per share)	$ 98.50	$ 95.62	$ 42.11
Aggregate fair value of performance and market-based restricted share units that vested during the year (in thousands)	$ 6,697	$ 9,409	$ 110

Note 17. Employee Retirement Plans

Defined Benefit Plans

We sponsor several defined benefit pension plans, which include plans in the U.S., Italy, Germany, Japan and France. We maintain a frozen cash balance retirement plan in the U.S. that is a contributory, defined benefit plan designed to provide the benefit in terms of a stated account balance dependent on the employer's promised interest-crediting rate. In Italy and France, we maintain a severance pay defined benefit plan that obligates the employer to pay a severance payment in case of resignation, dismissal or retirement. In other jurisdictions, we sponsor non-contributory, defined benefit plans designated to provide a guaranteed minimum retirement benefits to eligible employees.

The change in benefit obligations and funded status of our U.S. pension benefits is as follows (in thousands):

	U.S. Pension Benefits		
	Year Ended December 31,		
	2019	2018	2017
Accumulated benefit obligations at year end	$ 11,232	$ 10,591	$ 11,191
Change in projected benefit obligation:			
Projected benefit obligation at beginning of year	$ 10,591	$ 11,001	$ 10,425
Interest cost	382	336	361
Plan settlement	(366)	(340)	—
Actuarial loss	871	8	770
Benefits paid	(246)	(414)	(555)
Projected benefit obligation at end of year	$ 11,232	$ 10,591	$ 11,001
Change in plan assets:			
Fair value of plan assets at beginning of year	$ 6,767	$ 6,879	$ 5,925
Actual return on plan assets	628	(405)	444
Employer contributions	546	1,047	870
Plan settlement	(366)	(340)	—
Benefits paid	(1)	(414)	(360)
Fair value of plan assets at end of year	$ 7,574	$ 6,767	$ 6,879
Funded status at end of year:			
Fair value of plan assets	$ 7,574	$ 6,767	$ 6,879
Projected Benefit obligations	11,232	10,591	11,001
Underfunded status of the plans	3,658	3,824	4,122
Recognized liability	$ 3,658	$ 3,824	$ 4,122
Amounts recognized on the consolidated balance sheets consist of:			
Non-current liabilities	$ 3,658	$ 3,824	$ 4,122
Recognized liability	$ 3,658	$ 3,824	$ 4,122

The change in benefit obligations and funded status of our non-U.S. pension benefits is as follows (in thousands):

	Non-U.S. Pension Benefits		
	Year Ended December 31,		
	2019	2018	2017
Accumulated benefit obligations at year end	$ 17,744	$ 18,676	$ 23,785
Change in projected benefit obligation:			
Projected benefit obligation at beginning of year	$ 18,975	$ 21,548	$ 20,402
Service cost	478	478	503
Interest cost	232	289	291
Actuarial loss (gain)	1,071	(818)	(27)
Benefits paid	(2,380)	(1,631)	(2,222)
Foreign currency exchange rate changes and other	(289)	(891)	2,601
Projected benefit obligation at end of year	$ 18,087	$ 18,975	$ 21,548
Change in plan assets:			
Fair value of plan assets at beginning of year	$ 3,341	$ 3,075	$ 2,898
Actual return on plan assets	(34)	51	54
Employer contributions	383	361	369
Benefits paid	(332)	(156)	(393)
Foreign currency exchange rate changes	65	10	147
Fair value of plan assets at end of year	$ 3,423	$ 3,341	$ 3,075
Funded status at end of year:			
Fair value of plan assets	$ 3,423	$ 3,341	$ 3,075
Projected Benefit obligations	18,087	18,975	21,548
Underfunded status of the plans [1]	14,664	15,634	18,473
Recognized liability	$ 14,664	$ 15,634	$ 18,473
Amounts recognized on the consolidated balance sheets consist of:			
Non-current liabilities	$ 14,664	$ 15,634	$ 18,473
Recognized liability	$ 14,664	$ 15,634	$ 18,473

(1) In certain non-U.S. countries, fully funding pension plans is not a common practice. Consequently, certain pension plans have been partially funded.

The tables below present net periodic benefit cost of the defined benefit pension plans by component (in thousands):

	U.S. Pension Benefits		
	Year Ended December 31,		
	2019	2018	2017
Interest cost	$ 382	$ 336	$ 361
Expected return on plan assets	(298)	(318)	(282)
Settlement and curtailment loss	—	135	—
Amortization of net actuarial loss	148	571	527
Net periodic benefit cost	$ 232	$ 724	$ 606

	Non-U.S. Pension Benefits		
	Year Ended December 31,		
	2019	2018	2017
Service cost	$ 478	$ 478	$ 503
Interest cost	232	289	291
Expected return on plan assets	34	(51)	(54)
Amortization of net actuarial loss (gain)	1,071	(818)	(27)
Net periodic benefit cost	$ 1,815	$ (102)	$ 713

To determine the discount rate for our U.S. benefit plan, we used the FTSE Above Median Pension Discount Curve. For the discount rate used for the other non-U.S. benefit plans we consider local market expectations of long-term returns, primarily utilizing the Iboxx Corporate Index Bond rating AA, duration higher than 10 years. The resulting discount rates are consistent with the duration of plan liabilities.

The expected long-term rate of return on plan assets assumption for our U.S. benefit plan was derived from a study conducted by our investment managers. The study includes a review of anticipated future long-term performance of individual asset classes and consideration of the appropriate asset allocation strategy given the anticipated requirements of the plan to determine the average rate of earnings expected on the funds invested to provide for the pension plan benefits.

Major actuarial assumptions used in determining the benefit obligations and net periodic benefit cost for our significant U.S. benefit plans as of December 31, 2019, 2018 and 2017, are presented in the following table:

	U.S. Pension Benefits		
	2019	2018	2017
Weighted-average assumptions used to determine benefit obligation:			
Discount rate	2.88%	3.97%	3.28%
Weighted-average assumptions used to determine net periodic benefit cost:			
Discount rate	3.97%	3.28%	3.63%
Expected return on plan assets	5.00%	5.00%	5.00%

Major actuarial assumptions used in determining the benefit obligations and net periodic benefit cost for our significant non-U.S. benefit plans as of December 31, 2019, 2018 and 2017, are presented in the following table:

	Non-U.S. Pension Benefits		
	2019	2018	2017
Weighted-average assumptions used to determine benefit obligation:			
Discount rate	0.20% - 0.71%	0.20% - 1.55%	0.27% - 2.73%
Rate of compensation increase	2.50% - 3.00%	2.50% - 3.00%	2.50% - 3.00%
Weighted-average assumptions used to determine net periodic benefit cost:			
Discount rate	0.20% - 0.71%	0.27% - 1.55%	0.27% - 2.73%
Rate of compensation increase	2.50% - 3.00%	2.50% - 3.00%	2.50% - 3.00%

Retirement Benefit Plan Investment Strategy

In the U.S., we have an account that holds the defined benefit frozen balance pension plan assets. The Qualified Plan Committee (the "Plan Committee") sets investment guidelines for U.S. pension plans. The plan assets in the U.S. are invested in accordance with sound investment practices that emphasize long-term fundamentals. The investment objectives for the plan assets in the U.S. are to achieve a positive rate of return that would be expected to close the current funding deficit and so enable us to terminate the frozen pension plan at a reasonable cost. The Plan Committee also oversees the investment allocation process, selects the investment managers, and monitors asset performance. The investment portfolio contains a diversified

portfolio of fixed income and equity index funds. Securities are also diversified in terms of domestic and international securities, short- and long-term securities, growth and value styles, large cap and small cap stocks.

Outside the U.S., pension plan assets are typically managed by decentralized fiduciary committees. There is a significant variation in policy asset allocation from country to country. Local regulations, local funding rules, and local financial and tax considerations are part of the funding and investment allocation process in each country.

The table below presents our U.S. pension plan target allocations by asset category as of December 31, 2019:

Equity securities	30%
Debt securities	69%
Other	1%

Retirement Benefit Fair Values

The following is a description of the valuation methodologies used for retirement benefit plan assets measured at fair value:

Equity Mutual Funds: Valued based on the year-end net asset values of the investment vehicles. The net asset values of the investment vehicles are based on the fair values of the underlying investments of the partnerships valued at the closing price reported in the active markets in which the individual security is traded. Equity mutual funds have a daily reported net asset value.

Fixed Income Mutual Funds: Valued based on the year-end net asset values of the investment vehicles. The net asset values of the investment vehicles are based on the fair values of the underlying investments of the partnerships valued based on inputs other than quoted prices that are observable.

Money Markets: Valued based on quoted prices in active markets for identical assets.

The following tables provide information by level for the retirement benefit plan assets that are measured at fair value, as defined by U.S. GAAP (in thousands):

	Fair Value as of December 31, 2019	Fair Value Measurement Using Inputs Considered as:		
		Level 1	Level 2	Level 3
Equity mutual funds	$ 2,262	$ —	$ 2,262	$ —
Fixed income mutual funds	5,225	—	5,225	—
Money market funds	74	74	—	—
	$ 7,561	$ 74	$ 7,487	$ —

	Fair Value as of December 31, 2018	Fair Value Measurement Using Inputs Considered as:		
		Level 1	Level 2	Level 3
Equity mutual funds	$ 1,961	$ —	$ 1,961	$ —
Fixed income mutual funds	4,734	—	4,734	—
Money market funds	72	72	—	—
	$ 6,767	$ 72	$ 6,695	$ —

Refer to “Note 2. Basis of Presentation, Use of Accounting Estimates and Significant Accounting Policies” for discussion of the fair value measurement terms of Levels 1, 2, and 3.

Defined Benefit Retirement Funding

We make the minimum required contribution to fund the U.S. pension plan as determined by MAP - 21 and the Highway and Transportation Funding Act of 2014 (“HAFTA”). We contributed $0.9 million, $1.4 million and $1.2 million to the pension plans (U.S. and non-U.S.) during the years ended December 31, 2019, 2018 and 2017, respectively. We anticipate that we will make contributions to the U.S. pension plan of approximately $1.4 million during the year ended December 31, 2020.

Benefit payments, including amounts to be paid from our assets, and reflecting expected future service as of December 31, 2019, are expected to be paid as follows (in thousands):

	U.S. Plans	Non-U.S. Plans
2020	3,026	894
2021	812	723
2022	994	966
2023	612	1,066
2024	707	889
2025 - 2029	3,262	5,327

Severance Indemnity

In Italy, upon termination of employment for any reason, employers are required to pay a termination indemnity (*Trattamento di fine Rapporto* or "TFR") to all employees as required by Italian Civil Code. The TFR serves as a backup in the event of redundancy or as an additional pension benefit after retirement. The TFR is considered a defined contribution plan with respect to amounts vesting as of January 1, 2007 for employees who have opted for supplementary pensions, or who have chosen to maintain the TFR at the company, for companies with more than 50 employees. We have incurred expenses related to the Italian TFR of approximately $1.0 million, $(0.2) million and $0.4 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Defined Contribution Plans

We sponsor defined contribution plans in the U.S. including the Cyberonics, Inc. Employee Retirement Savings Plan, which qualifies under Section 401(k) of the IRC covering U.S. employees and the Cyberonics, Inc. Non-Qualified Deferred Compensation Plan (the "Deferred Compensation"), covering certain U.S. middle and senior management. In addition, we sponsor the Belgium Defined Contribution Pension Plan for Cyberonics' Belgium employees. We incurred expenses for our defined contribution plans of $12.4 million, $12.0 million and $13.9 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Note 18. Income Taxes

Earnings Before Income Taxes and Components of Income Tax Provision

The U.S. and non-U.S. components of income (loss) from continuing operations before income taxes and our income tax expense (benefit) from continuing operations (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Income (loss) from continuing operations before income taxes:			
UK and Non-U.S.	$ 28,788	$ 59,528	$ 71,980
U.S.	(214,482)	(306,975)	49,158
	$ (185,694)	$ (247,447)	$ 121,138
Total income tax expense (benefit) from continuing operations consisted of the following:			
Current:			
UK and Non-U.S.	$ 1,112	$ 9,645	$ 12,771
U.S.	(4,988)	1,291	26,743
	(3,876)	10,936	39,514
Deferred:			
UK and Non-U.S.	(7,407)	533	(4,140)
U.S.	(18,870)	(81,098)	14,580
	(26,277)	(80,565)	10,440
Total income tax (benefit) expense from continuing operations	$ (30,153)	$ (69,629)	$ 49,954

Effective Income Tax Rate Reconciliation

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 from one reporting period to another.

The following table is a reconciliation of the statutory income tax rate to our effective income tax rate expressed as a percentage of income from continuing operations before income taxes:

	Year Ended December 31,		
	2019	**2018**	**2017**
Statutory tax rate at UK Rate	19.0%	19.0%	19.0%
Deferred tax valuation allowance	(17.6)	(0.8)	10.6
Foreign tax rate differential	6.7	3.0	10.7
U.S. state and local tax expense, net of federal benefit	6.1	4.3	1.2
Effect of changes in tax rate	(3.1)	0.6	(19.9)
Write-off/impairment of investments	(2.8)	(1.3)	(14.8)
Reserve for uncertain tax positions	2.5	(0.7)	1.2
Research and development tax credits	2.2	1.1	(1.6)
UK CFC tax	2.1	(1.0)	0.2
U.S. tax on non-U.S. operations	(1.6)	(0.5)	1.5
Base erosion anti-abuse tax	1.5	(1.2)	—
Exempt income	1.2	6.1	(13.5)
Transaction costs	—	(0.8)	2.0
Sale of intellectual property	—	—	44.3
Domestic manufacturing deduction	—	—	(1.8)
Other, net	—	0.3	2.1
Effective tax rate	16.2%	28.1%	41.2%

U.S. Tax Reform

On December 22, 2017, the U.S. enacted the Tax Act, which significantly changed U.S. corporate income tax laws by, among other things, reducing the U.S. corporate income tax rate to 21%, which commenced in 2018. In addition, the Tax Act created a mandatory deemed repatriation tax (“transition tax”) on previously deferred foreign earnings of non-U.S. subsidiaries controlled by a U.S. corporation, or, in our case, a non-U.S. subsidiary controlled by one of our U.S. subsidiaries. We recorded no transition tax for the year ended December 31, 2017 as we had no previously deferred foreign earnings of U.S. controlled foreign subsidiaries as of the measurement dates. During the fourth quarter of 2018, we finalized our accounting under Staff Accounting Bulletin No. 118 for the remeasurement of the deferred tax assets and liabilities and impairment of foreign tax credits related to the Tax Act. Our accounting for the remeasurement is complete with a final non-cash net charge of $21.0 million.

Deferred Income Tax Assets and Liabilities

The significant components of our deferred tax assets and liabilities as of December 31, 2019 and 2018, are as follows (in thousands):

	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 125,883	$ 87,406
Tax credit carryforwards	28,272	26,152
Accruals and reserves	69,562	96,483
Deferred compensation	9,692	5,757
Inventory	9,436	3,956
Other	12,135	6,043
Gross deferred tax assets	254,980	225,797
Valuation allowance	(76,317)	(40,255)
Net deferred tax assets	178,663	185,542
Deferred tax liabilities:		
Property, equipment & intangible assets	(89,115)	(122,035)
Gain on sale of intellectual property	(53,091)	(59,249)
Investments	—	(3,561)
Other	—	(740)
Gross deferred tax liabilities:	(142,206)	(185,585)
Net deferred tax assets (liabilities)	$ 36,457	$ (43)
Reported on the consolidated balance sheet as (after valuation allowance and jurisdictional netting):		
Net deferred tax assets	$ 68,676	$ 68,146
Deferred tax liabilities	(32,219)	(68,189)
Net deferred tax assets (liabilities)	$ 36,457	$ (43)

Tax Attributes

Net operating loss ("NOL") and tax credit carryforwards as of December 31, 2019, which can be used to reduce our income tax payable in future years (in thousands):

Region	Gross Amount	Tax Benefit	Amount with No Expiration	Amount with Expiration	Carryforward Period
Europe NOL	$ 254,869	$ 52,408	$ 49,032	$ 3,376	2022 - 2026
U.S. Federal NOL	252,283	52,979	17,872	35,107	2021 - 2036
U.S. State NOL	307,525	14,611	5,431	9,180	2020 - 2038
South America NOL	17,263	5,859	5,521	338	2028 - 2030
Far East NOL	86	26	—	26	2029
U.S. foreign tax credits	—	14,832	—	14,832	2025 - 2029
U.S. research & development tax credits	—	6,552	—	6,552	2020 - 2039
U.S. State research & development tax credits	—	5,126	—	5,126	2022 - 2039
Other non-U.S. tax credits	—	1,259	—	1,259	2020 - 2032
Other U.S. tax credits	—	503	503	—	
	$ 832,026	$ 154,155	$ 78,359	$ 75,796	

As of December 31, 2019 and 2018, we had a valuation allowance of $76.3 million and $40.3 million, respectively. These valuation allowances were primarily related to continuing operations.

As of December 31, 2017, we had a valuation allowance of $93.3 million, which includes $48.7 million related to discontinued operations and $44.6 million related to continuing operations.

As a result of the business combination during the transitional period to December 31, 2015, the historic NOL's of Sorin U.S. are limited by IRC section 382. The annual limitation is approximately $18.3 million, which is sufficient to absorb the U.S. net operating losses prior to their expiration. As a result of the April 2018 acquisition of TandemLife, there is an IRC section 382 annual limitation of approximately $17.2 million, which is sufficient to absorb the U.S. net operating losses prior to their expiration.

In 2016, we consolidated certain of our intangible assets into an entity organized under the laws of England and Wales. Because the intangible assets were sold and purchased inter-company, the tax expense on the inter-company gain was deferred and amortized to current income tax expense on our consolidated statements of income (loss). With our adoption of Accounting Standards Update 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory* on January 1, 2018, we no longer record the income tax on the deferred inter-company gain in prepaid expense and other assets on the consolidated balance sheets; rather, the income tax expense on the gain of the asset sale is recognized in the corresponding jurisdictions for the seller and buyer, refer to "Note 23. New Accounting Pronouncements" for further information.

A significant portion of the net deferred tax liability worldwide included above relates to the tax effect of the step-up in value of the assets acquired in the combination with Sorin.

No provision has been made for income taxes on undistributed earnings of foreign subsidiaries as of December 31, 2019 because it is our intention to indefinitely reinvest undistributed earnings of our foreign subsidiaries. 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 and withholding taxes. As of December 31, 2019, it was not practicable to determine the amount of the deferred tax liability related to those investments.

Uncertain Income Tax Positions

The following is a roll-forward of our total gross unrecognized tax benefit (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Balance at beginning of year	$ 22,883	$ 26,137	$ 22,374
Increases:			
Tax positions related to current year	176	671	324
Tax positions related to prior year	—	3,309	1,153
Decreases:			
Tax positions related to prior years for settlement with tax authorities	(2,104)	(3,999)	—
Tax positions related to prior years for lapses of statute of limitations	(4,632)	(2,343)	—
Impact of foreign currency exchange rates	(328)	(892)	2,286
Balance at end of year	$ 15,995	$ 22,883	$ 26,137

Unrecognized tax benefits of $11.4 million, $11.6 million and $12.2 million at December 31, 2019, 2018 and 2017, respectively, included in the table above are presented in the balance sheet as a reduction to the related deferred tax assets for net operating loss carryforwards.

Accrued interest and penalties totaled $5.7 million, $6.3 million and $8.0 million as of December 31, 2019, 2018 and 2017, respectively, and were included in other long-term liabilities on our consolidated balance sheets.

Tax authorities may disagree with certain positions we have taken and assess additional taxes. We regularly assess the likely outcomes of our tax positions in order to determine the appropriateness of our reserves for uncertain tax positions. However, there can be no assurance that we will accurately predict the outcome of these audits and the actual outcome of an audit could have a material impact on our consolidated results of income, financial position or cash flows. If all of our unrecognized tax benefits as of December 31, 2019 were recognized, $12.9 million would impact our effective tax rate. We believe it is reasonably possible that the amount of gross unrecognized tax benefits could be reduced by up to $12.0 million in the next 12 months as a result of the resolution of tax matters in various global jurisdictions and the lapses of statutes of limitations. Refer to "Note 14. Commitments and Contingencies" for additional information regarding the status of current tax litigation.

We record accrued interest and penalties related to unrecognized tax benefits in interest expense and foreign exchange and other (losses) gains, respectively, on our consolidated statements of income (loss).

The major jurisdictions where we are subject to income tax examinations are as follows:

Jurisdiction	Earliest Year Open
U.S. - federal and state	2001
Italy	2015
Germany	2014
England and Wales	2017
Canada	2015

Brexit

On January 31, 2020, the UK departed from the EU (in a move commonly referred to as "Brexit"), and the UK will now enter a transition period that is scheduled to end on December 31, 2020, unless requested to be extended before July 1, 2020. During the transition period, the UK will cease to be an EU member, but the trading relationship will remain the same under the EU's rules. Although the long-term effects of Brexit will depend on any agreements the UK makes to retain access to the EU markets during the transition period, Brexit has created additional uncertainties that may ultimately result in new regulatory costs and challenges for medical device companies and increased restrictions on imports and exports throughout Europe. This could adversely affect our ability to conduct and expand our operations in Europe and may have an adverse effect on our business, financial condition and results of operations.

The notification does not change the application of existing tax laws and does not establish a clear framework for what the ultimate outcome of the negotiations and legislative process will be. Various tax reliefs and exemptions that apply to transactions between EU Member States under existing tax laws may cease to apply to transactions between the UK and EU Member States when the transition period concludes. It is unclear at this stage if or when any new tax treaties between the UK and the EU or individual EU Member States will replace those reliefs and exemptions. It is also unclear at this stage what financial, trade and legal implications will ensue from Brexit and how Brexit may affect us, our customers, suppliers, vendors, or our industry.

We and several of our wholly owned subsidiaries that are domiciled either in the UK, various EU Member States, or in the 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 are not renegotiated or replaced with new treaties containing terms, conditions and attributes similar to those of the existing treaties, Brexit may have a material adverse impact on our future financial results and results of operations. We continue to monitor and assess the potential impact of this event and explore possible tax-planning strategies that may mitigate or eliminate any such potential adverse impact.

We will not account for the impact of Brexit in our income tax provisions until there are material changes in tax laws or treaties between the UK and other countries.

European Union State Aid Challenge

On October 26, 2017, the European Commission ("EC") announced that an investigation would be opened with respect to the UK's controlled foreign company ("CFC") rules for the period January 1, 2013 through December 31, 2018. Under the CFC rules, financing profits of entities controlled by UK parent companies are taxed when the funding originates in the UK, or Significant People Functions relating to the financing are located in the UK. The provisions under investigation provide group finance exemptions related to the profits of entities involved in financing of the non-UK group activities. 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. On July 5, 2019, HMRC began the first step in the recovery process to identify beneficiaries and sent letters asking for information. Based upon our assessment of the technical arguments as to whether the exemption is State aid, together with no UK activities involved in our financing, no uncertain tax position reserve has been recognized related to this matter. Furthermore, in

December 2019, we amended our 2017 tax return filing to avail ourselves of different rules to determine UK taxation, which are not subject to the EU decision. We filed our 2018 tax return similarly, and therefore, we do not believe that the EU state aid decision will result in a material liability.

Note 19. Net Income Per Share

The following table sets forth the basic and diluted weighted-average shares outstanding used in the computation of basic and diluted net income per share (in thousands of shares):

	Year Ended December 31,		
	2019	2018	2017
Basic weighted average shares outstanding	48,349	48,497	48,157
Add effects of stock-based compensation instruments [1]	—	—	344
Diluted weighted average shares outstanding	48,349	48,497	48,501

(1) Excluded from the computation of diluted earnings per share for the years ended December 31, 2019, 2018 and 2017 were stock options, SARs and RSUs totaling 2.9 million, 2.7 million and 1.2 million because to include them would have been anti-dilutive under the treasury stock method.

Note 20. Geographic and Segment Information

Segment Information

We identify operating segments based on the way we manage, evaluate and internally report our business activities for purposes of allocating resources, 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 related products 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, related repair products and minimally invasive surgical instruments. 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, DTD and obstructive sleep apnea. 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.

“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 and 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):

	Year Ended December 31,		
	2019	2018	2017
Cardiopulmonary			
United States	$ 161,471	$ 161,134	$ 152,828
Europe	135,632	141,720	133,585
Rest of World	207,613	233,554	210,911
	504,716	536,408	497,324
Heart Valves			
United States	18,900	24,709	24,977
Europe	40,548	44,258	42,120
Rest of World	60,559	56,989	71,096
	120,007	125,956	138,193
Advanced Circulatory Support			
United States	30,781	18,588	—
Europe	741	580	—
Rest of World	401	293	—
	31,923	19,461	—
Cardiovascular			
United States	211,152	204,431	177,805
Europe	176,921	186,558	175,705
Rest of World	268,573	290,836	282,007
	656,646	681,825	635,517
Neuromodulation			
United States	335,332	348,980	316,916
Europe	46,262	42,443	34,765
Rest of World	42,953	31,567	23,295
	424,547	422,990	374,976
Other	2,977	2,146	1,784
Totals			
United States	546,484	553,411	494,721
Europe [1]	223,183	229,001	210,470
Rest of World	314,503	324,549	307,086
Total [2] [3]	$ 1,084,170	$ 1,106,961	$ 1,012,277

(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) Net sales to external customers includes $37.7 million, $34.8 million and $30.8 million in the United Kingdom, our country of domicile, for the years ended December 31, 2019, 2018 and 2017, respectively.

(3) 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 (loss) income from continuing operations to consolidated (loss) income from continuing operations before tax (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Cardiovascular [1]	$ 28,460	$ (258,493)	$ 81,412
Neuromodulation [2]	83,483	184,674	183,228
Other [3]	(204,727)	(96,724)	(102,425)
Total reportable segment (loss) income from continuing operations	(92,784)	(170,543)	162,215
Merger and integration expenses	23,457	24,420	15,528
Restructuring expenses	12,254	15,915	17,056
Amortization of intangibles	40,375	37,194	33,144
Operating (loss) income from continuing operations	(168,870)	(248,072)	96,487
Interest income	803	847	1,318
Interest expense	(15,091)	(9,825)	(7,797)
Gain on acquisitions	—	11,484	39,428
Impairment of investments	—	—	(8,565)
Foreign exchange and other (losses) gains	(2,536)	(1,881)	267
(Loss) income from continuing operations before tax	$ (185,694)	$ (247,447)	$ 121,138

(1) Results for the years ended December 31, 2019 and 2018 include Litigation provision, net of $(0.6) million and $294.0 million, respectively. Refer to "Note 14. Commitments and Contingencies" for additional information.

(2) Results for the year ended December 31, 2019 include the ImThera impairment of the IPR&D asset of $50.3 million. Refer to "Note 8. Goodwill and Intangible Assets" for additional information.

(3) Results for the year ended December 31, 2019 include the Caisson impairments of goodwill and the IPR&D asset of $42.4 million and $89.0 million, respectively. Refer to "Note 8. Goodwill and Intangible Assets" for additional information.

Assets by reportable segment as of December 31, 2019 and 2018, was as follows (in thousands):

Assets	2019	2018
Cardiovascular	$ 1,546,520	$ 1,532,825
Neuromodulation	749,069	731,840
Other	116,208	285,036
Total	$ 2,411,797	$ 2,549,701

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

	Year Ended December 31,		
Capital Expenditures	2019	2018	2017
Cardiovascular	$ 20,779	$ 27,621	$ 18,985
Neuromodulation	3,415	1,728	2,504
Other	3,783	7,630	7,010
Discontinued operations	—	1,018	5,608
Total	$ 27,977	$ 37,997	$ 34,107

Geographic Information

Property, plant, and equipment, net by geographic region as of December 31, 2019 and 2018, was as follows (in thousands):

PP&E	2019	2018
United States	$ 61,410	$ 68,862
Europe	110,270	112,376
Rest of World	9,674	10,162
Total	$ 181,354	$ 191,400

Note 21. Supplemental Financial Information

Inventories, net as of December 31, 2019 and 2018, consisted of the following (in thousands):

	2019	2018
Raw materials	$ 45,225	$ 40,387
Work-in-process	14,581	15,999
Finished goods	104,348	97,149
	$ 164,154	$ 153,535

Inventories are reported net of the provision for obsolescence. The provision, which reflects normal obsolescence and includes components that are phased out or expired, totaled $12.7 million and $11.6 million at December 31, 2019 and December 31, 2018, respectively.

PP&E as of December 31, 2019 and 2018, consisted of the following (in thousands):

	2019	2018	Lives in Years
Land	$ 15,165	$ 15,866	
Building and building improvements	86,814	82,035	3 to 39
Equipment, software, furniture and fixtures	205,711	195,008	2 to 16
Other	9,431	8,298	1 to 10
Capital investment in process	18,220	20,228	
Total	335,341	321,435	
Accumulated depreciation	(153,987)	(130,035)	
Net	$ 181,354	$ 191,400	

Accrued liabilities as of December 31, 2019 and 2018, consisted of the following (in thousands):

	2019	2018
Contingent consideration [1]	$ 22,953	$ 18,530
CRM purchase price adjustments payable to MicroPort Scientific Corporation	14,891	14,891
Operating lease liabilities [2]	11,110	—
Legal and other administrative costs	11,066	9,189
Contract liabilities	6,728	3,304
Research and development costs	5,160	1,841
Restructuring related liabilities [3]	4,315	9,393
Provisions for agents, returns and other	3,922	4,934
Product remediation [4]	3,251	13,945
Derivative contract liabilities [5]	3,173	5,063
Other amounts payable to MicroPort Scientific Corporation	1,340	9,319
Other accrued expenses	32,191	33,876
	$ 120,100	$ 124,285

(1) Refer to "Note 10. Fair Value Measurements."
(2) Refer to "Note 13. Leases."
(3) Refer to "Note 6. Restructuring."
(4) Refer to "Note 7. Product Remediation Liability."
(5) Refer to "Note 12. Derivatives and Risk Management."

Note 22. Quarterly Financial Information (unaudited)

The tables below present the quarterly results for the years ended December 31, 2019 and 2018 (in thousands except for share data):

Year Ended December 31, 2019	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net sales	$ 250,801	$ 277,169	$ 268,610	$ 287,590
Gross profit [1]	163,600	197,114	179,406	204,638
Operating income (loss) from continuing operations [2]	(20,779)	(29,876)	25,761	(143,976)
Net (loss) income from continuing operations [2]	(14,849)	(29,393)	32,118	(143,417)
Net income from discontinued operations, net of tax	—	178	—	187
Net (loss) income [2]	$ (14,849)	$ (29,215)	$ 32,118	$ (143,230)
Diluted (loss) earnings per share:				
Continuing operations	$ (0.31)	$ (0.61)	$ 0.66	$ (2.96)
Discontinued operations	—	0.01	—	—
	$ (0.31)	$ (0.60)	$ 0.66	$ (2.96)

Year Ended December 31, 2018	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Net sales	$ 250,398	$ 287,498	$ 272,082	$ 296,983
Gross profit [1]	162,085	193,963	174,348	204,073
Operating income (loss) from continuing operations [3]	12,530	21,607	(5,757)	(276,452)
Net income (loss) from continuing operations [3]	17,822	19,528	(6,273)	(209,539)
Net loss from discontinued operations, net of tax	(4,549)	(4,462)	(904)	(1,022)
Net income (loss) [3]	$ 13,273	$ 15,066	$ (7,177)	$ (210,561)
Diluted earnings (loss) per share:				
Continuing operations	$ 0.36	$ 0.40	$ (0.13)	$ (4.32)
Discontinued operations	(0.09)	(0.09)	(0.02)	(0.02)
	$ 0.27	$ 0.31	$ (0.15)	$ (4.34)

(1) Gross profit excludes amortization of developed technology intangible assets of approximately $3.7 million, $5.5 million and $3.6 million for the first and second quarters in 2019, the third and fourth quarters in 2019 and for each quarter in 2018, respectively.

(2) The second quarter of 2019 includes a $50.3 million impairment of the ImThera IPR&D asset arising from the ImThera acquisition. The fourth quarter of 2019 includes a $42.4 million impairment of Caisson's goodwill arising from the Caisson acquisition and a $89.0 million impairment of Caisson's IPR&D asset arising from the Caisson acquisition. For further information, please refer to "Note 8. Goodwill and Intangible Assets."

(3) The fourth quarter of 2018 includes a $294.1 million litigation provision associated with our 3T devices. For further information, please refer to "Note 14. Commitments and Contingencies."

Note 23. 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
May 2014 ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606)	This ASU requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers and replaces most existing revenue recognition guidance.	January 1, 2018	We elected the cumulative effect transition method; however, we recognized no cumulative effect to the opening balance of retained earnings because the impact on the timing of when revenue is recognized within our Cardiovascular segment, specifically related to heart-lung machines and preventative maintenance contracts on cardiopulmonary equipment was insignificant. The timing of revenue recognition for products and related revenue streams within our Neuromodulation segment and discontinued operations did not change. Upon adoption of the new standard, we implemented new internal controls related to our accounting policies and procedures, including review controls to ensure contractual terms and conditions that may require consideration under the standard are properly identified and analyzed.

January 2016 ASU No. 2016-01, Financial Instruments - Overall (Subtopic 825-10): *Recognition and Measurement of Financial Assets and Financial Liabilities*	This update requires equity investments that do not result in consolidation and are not accounted for under the equity method to be measured at fair value with changes recognized in net income. However, an entity may elect to measure equity investments that do not have readily determinable fair values at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for an identical or a similar investment of the same issuer.	January 1, 2018	There was no material impact to our consolidated financial statements as a result of adopting this ASU.
February 2016 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 13. Leases."
August 2016 ASU No. 2016-15, Statement of Cash Flows (Topic 230): *Classification of Certain Cash Receipts and Cash Payments*	This update provides guidance on the presentation and classification of certain cash receipts and cash payments in the statement of cash flows.	January 1, 2018	There was no material impact to our consolidated financial statement of cash flows as a result of adopting this ASU.
October 2016 ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory.	This update simplifies the accounting for the income tax consequences of transfers of assets from one unit of a corporation to another unit or subsidiary by eliminating an accounting exception that prevents the recognition of current and deferred income tax consequences for such "intra-entity transfers" until the assets have been sold to an outside party.	January 1, 2018	We recognized the following cumulative-effect adjustments, including to retained earnings, upon adoption at January 1, 2018: Prepaid expenses and other current assets decreased by $12.6 million, deferred tax assets increased by $58.3 million, other assets decreased by $68.1 million and the accumulated deficit increased by $22.5 million.
January 2017 ASU No. 2017-01, Business Combinations (Topic 805): *Clarifying the Definition of a Business*	This update clarifies when a set of assets and activities is a business.	January 1, 2018	The ImThera, TandemLife and Miami Instruments acquisitions were considered acquisitions of a business. Refer to "Note 4. Business Combinations" for a discussion of our acquisitions.
March 2017 ASU No. 2017-07, Compensation—Retirement Benefits (Topic 715): *Improving the Presentation of Net Periodic Pension Cost and Net Periodic Post Retirement Benefit Cost*.	This update requires that an employer report the service cost component in the same line item or items as other compensation costs arising from services rendered by the pertinent employees during the period.	January 1, 2018	Our adoption resulted in an immaterial impact to our consolidated financial statements. The consolidated statements of income (loss) for the years ended December 31, 2017 and December 31, 2016 have been recast for the adoption of this update.

June 2018 ASU No. 2018-07, Compensation—Stock Compensation (Topic 718): *Improvements to Nonemployee Share-Based Payment Accounting*	This update simplifies the accounting for non-employee share-based payment transactions.	January 1, 2019	There was no material impact to our 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
June 2016 ASU No. 2016-13, *Financial Instruments—Credit Losses* (Topic 326)	The amendments in this update require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The 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.
January 2017 ASU No. 2017-04, Intangibles-Goodwill and Other (Topic 350): *Simplifying the Test for Goodwill Impairment*	This update removes step 2 of the goodwill impairment test that compares the implied fair value of goodwill with its carrying amount. Instead, an impairment test is performed by comparing the fair value of a reporting unit with its carrying amount. An impairment charge will be recorded by the amount a reporting unit's carrying amount exceeds its fair value. 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.
August 2018 ASU No. 2018-13, Fair Value Measurement (Topic 820): *Changes to the Disclosure Requirements for Fair Value Measurement*	This update removes, modifies and adds certain disclosure requirements related to fair value measurements. 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.
August 2018 ASU No. 2018-14, Compensation—Retirement Benefits—Defined Benefit Plans—General (Subtopic 715-20): *Changes to the Disclosure Requirements for Defined Benefit Plans*	This update adds and removes certain disclosure requirements related to defined benefit plans. 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.
August 2018 ASU No. 2018-15, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*	This update clarifies and aligns the accounting for implementation costs for hosting arrangements with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. This 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.

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