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, 2021

or

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

For the transition period from ______ to ______

Commission file number: 001-37599

LivaNova 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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 was approximately $4.1 billion (based on the closing price of these shares on the NASDAQ Global Market on June 30, 2021, the last business day of the most recently completed second fiscal quarter). For purposes of this calculation, 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 24, 2022, 53,263,563 ordinary shares were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement of LivaNova PLC for the 2021 Annual General Meeting of Shareholders, which will be filed within 120 days of December 31, 2021, are incorporated by reference into Part III of this Annual Report on Form 10-K.

LIVANOVA PLC

TABLE OF CONTENTS

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 106 (AspireSR™), Model 1000 (SenTiva™), Model 1000-D (SenTiva™ Duo), Model 7103 (VITARIA™ and TitrationAssist™) and Model 8103 (Symmetry™).
- Trademarks for our Cardiopulmonary product systems: S5™, S3™, S5 Pro™, B-Capta™, Inspire™, Heartlink™, XTRA™, 3T Heater-Cooler™, Connect™, Revolution™ and Essenz™.
- 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 ™ symbol, 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 statements of historical or current fact, 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. Generally, 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, but are not limited to: the highly competitive nature of the global medical device industry; risks related to the reduction or interruption in our supply of components and raw materials; challenges relating to changes in and compliance with governmental laws and regulations affecting our U.S. and international businesses, including regulations of the U.S. Food and Drug Administration ("FDA") and foreign government regulators, such as more stringent requirements for regulatory clearance of products; the ability to remediate matters identified in any inspectional observations or warning letters issued by the FDA, while continuing to satisfy the demand for our products; the outcome of government investigations; the impact of healthcare reform measures; reductions in reimbursement levels by third-party payors and cost containment efforts of healthcare purchasing organizations; dependence on new product development, technological advances and innovation; control of costs and expenses; the ability to obtain and maintain adequate intellectual property protection; breaches or failures of our information technology systems or products, including by cyberattack, unauthorized access or theft; changes in applicable tax rates, laws and positions taken by taxing authorities; examinations by tax authorities; product liability, intellectual property, commercial and environmental litigation losses; compliance with evolving environmental laws and obligations; changes in general industry and market conditions, including domestic and international growth rates; changes in general domestic and international economic conditions, including interest rate and currency exchange rate fluctuations; COVID-19; and other unknown or unpredictable factors that could harm our financial performance.

See also the section titled "Risk Factors" (refer to Part I, Item 1A of this report) for further discussion of certain risks and uncertainties that could cause actual results and events to differ materially from the forward-looking statements. All forward-looking statements in this Annual Report on Form 10-K are expressly qualified in their entirety by the cautionary statements set forth above. Forward-looking statements speak only as of the date of this Annual Report on Form 10-K, and we expressly disclaim any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosures we make on related subjects in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. This cautionary note is applicable to all forward-looking statements contained in this report.

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 products and therapies for the benefit of patients, healthcare professionals and healthcare systems throughout the world. We design, develop, manufacture and sell innovative products and therapies that are consistent with our mission to provide hope to patients through innovative medical technologies, delivering life-changing improvements for both the Head and Heart.

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. ("Sorin"), 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 Overview

LivaNova is comprised of three reportable segments: Cardiopulmonary, Neuromodulation and Advanced Circulatory Support, corresponding to our primary business units. Other includes the results of our Heart Valves business, which was disposed of on June 1, 2021, and corporate shared service expenses for finance, legal, human resources, information technology and corporate business development.

For further information regarding our reportable 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.

Cardiopulmonary

Our Cardiopulmonary segment is engaged in the development, production and sale of cardiopulmonary products, including oxygenators, heart-lung machines, autotransfusion systems, perfusion tubing systems, cannulae and other related accessories.

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, autotransfusion systems, 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 product is comprised of 12 models and 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. The autotransfusion product group facilitates 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 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.

Neuromodulation

Our Neuromodulation segment designs, develops and markets devices that deliver neuromodulation therapy to treat drug-resistant epilepsy ("DRE") and difficult-to-treat depression ("DTD"). It encompasses the development and management of clinical testing of our aura6000 System for treating obstructive sleep apnea ("OSA"), a device that stimulates the hypoglossal nerve, which in turn, engages certain muscles in the tongue in order to open the airway while a patient is sleeping, as well as our VITARIA System for treating heart failure by stimulating the right vagus nerve.

Our principal Neuromodulation product, the LivaNova Vagus Nerve Stimulation Therapy ("VNS Therapy") System, is an implantable device authorized for the treatment of DRE and 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. Our VITARIA System for treating heart failure includes elements similar to the VNS Therapy System, i.e., the pulse generator, lead, programming computer and wand, though the pulse generator and lead are surgically implanted in a subcutaneous pocket in the upper right chest area.

Epilepsy

There are several broad types of treatment available to patients with epilepsy: multiple anti-seizure medications ("ASMs"); various forms of the ketogenic diet; vagus nerve stimulation ("VNS"); resective brain surgery and intracranial neurostimulation. ASMs typically serve as a first-line treatment and are prescribed for virtually all patients diagnosed with epilepsy. After two anti-seizure medications fail to deliver seizure control, the epilepsy is characterized as drug-resistant, at which point, adjunctive non-drug options are considered, including ketogenic diet, resective surgery, VNS therapy and other Neuromodulation therapies. Despite the regulatory approval and commercialization of more than 12 new seizure medications, the percentage of epilepsy patients diagnosed as drug-resistant has not improved over the past 30 years.

In 1997, our VNS Therapy System was the first medical device treatment approved by the FDA for drug-resistant epilepsy, and today is the only neuromodulation device approved for use in DRE patients as young as four years of age with partial onset (aka focal) seizures. Other worldwide regulatory bodies have also approved the VNS Therapy System for treating patients with DRE, many without age or seizure-type restrictions. Globally, VNS Therapy is the most widely reimbursed neuromodulation therapy available. In 2022, the U.S. Centers for Medicare and Medicaid Services ("CMS") expanded reimbursement for VNS Therapy use in the treatment of Lennox Gastaut Syndrome ("LGS") and Dravet Syndrome.

We distribute multiple VNS Therapy Systems for the treatment of epilepsy, including Model 103 (Demipulse), Model 104 (Demipulse Duo), Model 106 (AspireSR), Model 1000 (SenTiva) and Model 1000D (SenTiva Duo) pulse generators. The newest technology, SenTiva, which launched in 2017, now accounts for over 65% of our product mix. Our AspireSR and SenTiva generators provide the traditional benefits of VNS Therapy but add an additional stimulation capability: closed loop stimulation (AutoStim™) which responds to detection of changes in heart rate potentially indicative of a seizure. The SenTiva generator is the smallest and lightest VNS device capable of delivering responsive therapy for epilepsy and includes the additional flexibility of our Scheduled Programming and Day & Night Programming capabilities. In 2017, VNS Therapy devices were FDA approved for expanded magnetic resonance imaging ("MRI") access while similar CE Mark approval followed shortly thereafter. Currently, SenTiva, AspireHC and AspireSR models of VNS Therapy technology provide for this expanded MRI access.

Depression

US

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 non-coverage determination ("NCD") 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 March 2017, the American Journal of Psychiatry published the results of the longest and largest naturalistic study (the "D23 study") on treatments for patients experiencing chronic and severe DTD. The findings showed that the addition of the VNS Therapy System to traditional treatment is effective in significantly reducing symptoms of depression and well tolerated compared with traditional treatment alone. Following publication of the D23 study, we requested CMS to reconsider its previous NCD, and in May 2018, CMS published a tracking sheet to reconsider its NCD.

In February 2019, CMS produced a final decision providing 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 registry.

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 in the randomized part of the trial and up to an additional 5,800 patients in an open label registry.

In February 2020, we announced a research collaboration with Verily, a subsidiary of Alphabet Inc., to capture clinical biomarkers of depression within our RECOVER clinical study. Using technology and analytics by way of the Verily Study Watch and related Verily mobile phone application, LivaNova and Verily aim to gather quantitative data to further understand depressive episodes and a patient's response to treatment. These complementary approaches are expected to help investigators better understand the impact of depression and its treatment on study participants' lives in a more objective and multi-dimensional manner. In April 2021, LivaNova and Verily announced that the first patient had been enrolled in their collaborative UNCOVER study, a subset of the RECOVER study.

Outside the U.S.

In January 2018, we announced the launch and enrollment of the first patient in our 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.

In March 2020, our VNS Therapy System, Symmetry received CE mark approval for DTD.

Obstructive Sleep Apnea

In January 2018, we acquired full ownership of ImThera, a privately held, emerging-growth company developing an implantable neurostimulation device system for the treatment of obstructive sleep apnea. The device stimulates the hypoglossal nerve, which in turn, engages certain muscles in the tongue in order to open the airway while a patient is sleeping. We have a commercial presence in the European market.

In June 2021, LivaNova received approval from the FDA to proceed with its investigational device exemption clinical study, "Treating Obstructive Sleep Apnea using Targeted Hypoglossal Neurostimulation (OSPREY)." The OSPREY study seeks to confirm the safety and effectiveness of the aura6000 System, the LivaNova implantable hypoglossal neurostimulation device intended to treat adult patients with moderate to severe obstructive sleep apnea.

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 elements similar to the VNS Therapy System: pulse generator, lead, programming computer and wand. In 2012, we initiated a pilot study, ANTHEM-HF, outside the U.S., and the published results support the safety and efficacy of ART delivered to patients with advanced heart failure expressing symptoms despite guideline-directed medical therapy. The study was extended to continue follow-up of patients through 42 months, the results for which have been published in a peer-reviewed cardiology journal. During 2014, we initiated a second pilot study outside the U.S., ANTHEM-HFpEF, to study ART in patients experiencing symptomatic heart failure with preserved ejection fraction. The VITARIA System is not approved in the U.S. though it has been designated as a breakthrough technology by the FDA. The VITARIA System received CE Mark approval in 2015.

In September 2018, we announced the first successful implantation of the VITARIA System in a patient randomized in the ANTHEM-HFrEF Pivotal Study, an international, multi-center, randomized trial (adaptive sample size) to evaluate the VITARIA System (FDA's Breakthrough Technology designation) for the treatment of advanced heart failure. In December 2021, we enrolled the 400^{th} patient in the trial, and in January 2022, the 300^{th} patient completed the nine-month follow-up visit. Given these milestone achievements, the first interim analysis is being conducted by independent statisticians. Enrollment and screening continue despite ongoing COVID-19 headwinds, though we are monitoring relevant conditions at medical centers participating in the trial.

Advanced Circulatory Support

Our Advanced Circulatory Support segment is engaged in the development, production and sale of leading-edge temporary life support products. These products include cardiopulmonary and respiratory support solutions consisting of temporary life support controllers and product kits that can include a combination of pumps, oxygenators, and cannulae.

Advanced Circulatory Support products simplify 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.

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

Research and Development ("R&D")

The markets in which we participate are subject to rapid technological advances. Product improvement, software advancements 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.

We expect to continue to identify innovative technologies and continually assess the ability of our R&D programs to deliver economic value to the customer. Our current R&D expenses consist of product design and development efforts, including in relation to software and technology, clinical study programs and regulatory activities, which are essential to our strategic portfolio initiatives.

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, 2021, we held more than 750 issued patents worldwide, with approximately 230 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 cultivate and maintain close working relationships with professionals in the medical industry. These relationships provide us with a detailed understanding of therapeutic and diagnostic developments, trends and emerging opportunities, which enable us to respond 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. 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 with sales to approximately 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 Cardiopulmonary, Neuromodulation and Advanced Circulatory Support product groups are Terumo Medical Corporation, Maquet Medical Systems, Medtronic plc, Haemonetics Corporation, NeuroPace, Inc., Abiomed, Inc. and Abbott Laboratories, 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 8 manufacturing facilities located in Italy, Germany, the U.S., 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 example, our Mirandola, Italy plant is certified ISO 14001 and ISO 45001 and our Munich, Germany plant is certified ISO 14001. 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 extensive government regulation by numerous government agencies, both within and 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, and we continue to monitor such shifts. The Company believes it is in compliance with such laws and regulations, and while the impact of regulatory changes cannot be predicted with certainty, the Company does not expect compliance to have a material adverse effect upon the Company's earnings, competitive position or estimated capital expenditures. However, 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 our medical devices to their own approval and 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 510(k) process, also known as pre-market notification, requires us to demonstrate that our new medical device is substantially equivalent to a legally marketed medical device. The PMA process, which is more costly and rigorous than the 510(k) 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. In 2017, the EU published its Medical Device Regulation ("Reg MDR"), which imposed significantly more premarket and post-market requirements for medical devices upon conclusion of a three-year implementation period. We have initiated a plan of action to obtain the appropriate approvals for our products and intend to be fully compliant prior to the May 2024 deadline.

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 may include revocation or suspension of a company's business license and/or criminal sanctions. Japanese regulatory bodies also assess the quality management systems of the manufacturer and product conformity to the requirements of the PAL.

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, approval lead time, 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. The FDA and other regulatory agencies in and outside the U.S. 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. 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 are becoming increasingly strict; enforcement actions and financial penalties related to privacy issues in the EU are growing; and new privacy and data residency laws and restrictions are being passed in other countries including the U.S., China, and Brazil. The management of cross-border transfers of information among and outside of EU member countries is becoming more complex, which may complicate our business and clinical research activities, as well as product offerings that involve transmission or use of patient health information. We 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 are 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. One of the strictest and most comprehensive data privacy laws in the world, the GDPR, among other things, introduced proactive compliance measures, such as the requirement to carry out a Privacy Impact Assessment, Data Transfer Impact Assessment, and appoint a Data Protection Officer in organizations 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. In addition, the administrative fines that can be levied are significantly increased, the maximum being the higher of €20 million (approximately $22.7 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. 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 substances. To the best of our knowledge at this time, we do not expect that compliance with environmental protection laws related to our current operations, including but not limited to the Saluggia site as referenced in "Note 13. Commitments and Contingencies" in our consolidated financial statements and accompanying notes beginning on page F-1 of this Annual Report on Form 10-K, will have a material impact on our financial position or liquidity. In addition, as noted in Note 13 to such financial statements, we are engaged in litigation with respect to historical remediation claims at sites operated by subsidiaries of SNIA, unrelated to our current operations. For more information, see Note 13. Commitments and Contingencies to such financial statements.

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 work to optimize energy and resource usage, ultimately reducing greenhouse gas emissions and waste. In 2018, we implemented a new system called *trigeneration* in our plant in Mirandola, Italy which is designed to reduce CO2, energy consumption and costs, and generate energy savings. In

2019, we implemented a new vehicle policy, which in addition to generating cost savings and efficiencies throughout the Company, has contributed to our goal of decreasing our carbon output. Not only did we exclude certain vehicle models from our inventory due to their negative environmental impact, but we implemented a cap on our vehicles' CO_2 emissions at 130 g/km. In addition, 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 Mirandola, Italy plant is certified ISO 14001 and ISO 45001 and our Munich, Germany plant is certified ISO 14001.

Health Care Fraud and Abuse Laws

We are 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 utilizes the False Claims Act, and the accompanying threat of significant financial liability, to investigate and prosecute device and biotechnology companies 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 U.S. government's success with prosecuting claims under the False Claims Act, 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 report certain payments and other transfers of value we make to U.S. licensed physicians or U.S. teaching hospitals annually. Any failure to comply with such laws and regulations hold the potential for criminal and civil financial penalties.

The evolving 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.

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, among other things, 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 cardiopulmonary and neuromodulation products, to distributors and non-governmental organizations in Iran to support patient care in that country. We have limited visibility into the identity of these distributors' and non-governmental organizations' 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 $1.4 million and $0.7 million for the three months ended December 31, 2021, respectively, and $8.6 million and $3.8 million for the twelve months ended December 31, 2021, 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.

Human Capital Management

Our almost 3,000 employees worldwide are crucial in our mission to provide hope to our patients and their families through delivering life-changing medical innovation for the head and the heart. In order to meet the needs of our patients and customers, we retain, develop and reward exceptional talent. We have been successful in attracting talent in a highly competitive labor market due, in large part, to our proactive recruitment strategies, competitive compensation and benefits, collaborative and rewarding work environment, professional training and development programs for managers and employees, and health and wellness measures.

Our mission seeks to link our employees to our five core values: patients first, meaningful innovation, act with agility, commitment to quality and integrity, and collaborative culture. These values are how we evaluate ourselves and ultimately, achieve success as an organization. They are deeply embedded in our culture, from our field personnel and manufacturing floor to the executive leadership team and Board of Directors. We continually share best practice stories from our employee community throughout the organization, by way of emailed videos and virtual and in-person town halls and leadership meetings. Our values inspire our good citizenship and how we conduct our business responsibly and sustainably while interacting with our communities, employees and the environment.

Our Chief Human Resources Officer is responsible for developing and executing our human capital strategy, and with her team of Human Resources professionals, the Human Resources function is organized into two key areas: (1) Employee Experience, which addresses attraction and retention of talent, on-boarding, compensation and performance management, and ultimately, the employees' experience throughout their tenure in the organization; and (2) Talent, Leadership and Development, which includes internal career pathing, talent development, coaching and training, and diversity strategy and programming.

Compensation and Benefits

Our need for top talent demands desirable compensation and benefits packages. In addition to competitive salaries, our programs include, depending on jurisdiction, annual bonuses, stock awards, pensions, health benefits and health programs, paid time off and parental leave, flexible schedules, remote working, and employee stock purchase plans, among others. To ensure alignment with fair pay standards, we monitor and externally benchmark our compensation and benefits policies and practices annually with recognized professional partners. We also work closely with our trade unions and works councils to ensure that we apply compliant, equitable and fair work practices that are inclusive of the interests of our workers in our policies and decisions.

Importantly, we pride ourselves on forging a strong connection between performance and rewards within the Company. Annually, we define clear, SMART (Specific, Measurable, Achievable, Realizable and Timebound) goals and targets at the Company level, which translate into business unit and individual level goals for every employee in the organization. They are subsequently tracked by way of metrics and dashboards. Individual and Company success translate into rewarding packages, aimed to incentivize and encourage top talent. In addition, employees themselves can recognize their colleagues through a recently launched employee recognition program called Stars.

Culture

Maintaining a culture that embodies our values and mission is of the utmost importance. It demands self-reflection and a commitment to ensure that we take actions to address our employees' thoughts and opinions. Accordingly, we conduct an annual, anonymous employee survey called LivaNova4You to help measure the overall engagement and satisfaction level of our team. Thereafter, our senior leadership assess employee engagement to understand and identify potential opportunities for improvement.

In our 2021 survey, we achieved 89 percent participation across the Company. The majority of our engagement drivers improved when compared to our 2020 survey results, an encouraging result given the difficulties in working in a pandemic environment. We saw an increase in our employee satisfaction & motivation score and equivalent high marks on the employee loyalty score, with an increase in our overall engagement index.

The survey also revealed growth in collaboration, that is, employees showing high trust and respect for each other; an increased feeling of recognition on a job well done; empowerment and the feeling of being sufficiently challenged, despite a difficult pandemic environment; and flexibility in coming up with new and innovative ways to work. Our employees also acknowledged an improvement in the tools and opportunities for advancement, one of our highest improving scores as compared to 2020.

As with any employee engagement survey, we discovered areas with opportunities for improvement as well. Workload, clarification of processes, and perception surrounding benefits, for example, were all areas identified. Leaders within the Company are working with their teams to consider how to address these areas over the next year.

Development and Training

As part of our promotion and retention efforts, we organize annual performance reviews for all employees which involve an evaluation of goals and performance contributions. A portion of our employees, some of whom include operators involved in the direct production of our devices, receive performance feedback in a form and process based on jurisdiction and local rules and regulations. We also offer all employees performance management training and workshops to guide both managers and employees throughout the review process.

Our operators are onboarded and trained per requirements and processes specific to their jurisdiction and the product that is manufactured in their locations. Thereafter, they receive ongoing technical training to ensure they maintain excellent standards for production and manufacturing. Meanwhile, LivaNova offers programs to foster both leadership and professional skills development to its corporate employees. Newly hired corporate employees undergo a robust onboarding program through LivaNova University and, at any time, employees have access to a large offering of training on commercial, ethics and integrity, quality, product, leadership, business strategy, and other key topics and functions in the organization.

Our annual Talent Review process engages our corporate employees to establish development plans and document their skills and capabilities, while managers assess employee potential, create succession plans, and identify possible career path opportunities. In 2021, 1,600 employees documented at least one development plan. In addition, a targeted group of 22 top performers (up from six participants in 2020) were nominated to participate in our Leadership Conversation program, which puts these key employees in conversation with selected executive leaders to develop our Talent through close exposure and collaboration.

We take great pride in listening to our employees and making LivaNova a great place to work. LivaNova University is the direct result of our LivaNova4You survey where employees asked for flexible, scalable access to learning content for professional growth in the 2020 survey results. Through our Workday Learning platform, which hosts LivaNova University, approximately 2,000 employees have access to over 150 internally developed courses and programs and over 12,000 courses in multiple languages from LinkedIn Learning. Internal content is developed by a global cohort of eight learning partners trained to design, develop and deploy content to support skill development and strategic needs for the organization.

Throughout 2021, several global courses and programs for employees were developed, providing a spotlight on new employee and manager onboarding, anti-harassment and anti-discrimination campaigns, and the learning culture at LivaNova. Overall, during the initial nine months of LivaNova University, 12,456 enrollments were completed across 444 different courses by employees resulting in an average of 6.2 learning enrollments completed per employee. Learners rated the quality of these courses a 4.5 on a 5-point scale.

Finally, we offer internships and apprenticeships across functions around the globe which can, and do, lead to full-time employment. We believe in continuing education and development regardless of nationality and origin, which is why we partner with organizations to find new talent with hopes of welcoming future, full-time employees.

Mentoring & Women’s Networking

The LivaNova Women's Network (“LWN”), an organic, grassroots mentorship program, by women and for women, facilitates pairings between mentors and mentees. Originating in the U.S., it has since expanded to our Latin America and Asia Pacific regions. Topics range from career and financial advice to performance management and connection to the Company’s strategic triangle. This program continues to provide members with new perspectives, more personalized development and an opportunity to network with other women across the organization, thereby contributing to a better corporate culture based on strong, collaborative relationships and continuous opportunities to grow and develop.

Diversity

The success of LivaNova thrives on the diversity of perspective, thought, experience and background within our workforce. Accordingly, we closely monitor our diversity metrics. As of December 31, 2021, LivaNova had ten Directors on the Board of Directors, of whom 30% are female and 70% are male. Similarly, the Executive Team at the end of 2021 consisted of 10 individuals, 30% of which are female and 70% male. Of LivaNova's senior leadership team, which includes the executive team, vice presidents and directors, approximately 31% are women and 69% are men. Finally, as of December 31, 2021, LivaNova employed approximately 3,000 employees, 52% women and 48% men. Our strategy for accelerating diversity begins with creating new ways to find extraordinary talent, and examples of our efforts include accurately mapping the talent market, creating job postings that attract highly qualified diverse candidates, expanding the diversity within our interview panels and guiding interviewers to conduct a fair interview process.

To help promote diversity, we also have a variety of diversity affinity initiatives that span the globe. We host two Diversity, Inclusion and Belonging (DIBs) groups, one in North America and one in the Asia Pacific region, with a mission to empower an environment where conversations of diversity and inclusion develop a culture of belonging. These employee-led, executive-sponsored initiatives are committed to building a network of LivaNova employees who embrace an open mindset with an appreciation of diverse experiences and have been meeting regularly. On average, approximately 100 employees participate in these meetings. Topics range from inclusivity and harassment in the workplace to multigenerational integration and support for working parents. The discussions are open and thought-provoking, encouraging all to share their story, discuss views or simply be a supporter to the cause.

Finally, our senior leadership team monitors and reviews gender and ethnic diversity across our organization on a monthly, quarterly and annual basis. The Compensation Committee of the Board of Directors receives similar reports regularly and the entire Board of Directors is updated on an annual basis. In relation to Director onboarding, our Corporate Governance Guidelines require that Board candidates bring diversified attributes to the Board, which encompass gender, race, ethnicity, geography, professional experience, national origin, sexual orientation, life experience, skills and tenure, among others. In the summer of 2021, our Nominating and Corporate Governance Charter was updated to emphasize the benefits of diversity and it currently demands that every slate of Directors to be considered must include at least one woman and at least one underrepresented minority. Diversity, equity and inclusion metrics and conversations are actively pursued from the top down and are reflected in leadership's continual review of the numbers and commitment in working towards an appropriate balance with respect to ethnicity, age and gender in relation to leadership and development, promotions, and compensation and benefits.

Health and Safety

Saving the lives of our patients starts with the care and well-being of our employees. In response to the COVID-19 pandemic, physical and mental health has been at the forefront of our response. For our manufacturing, operations, and other personnel who have remained on site throughout the pandemic due to the essential nature of their work, we have implemented safety measures such as the use of personal protective equipment and social distancing measures. At the start of the pandemic, we instructed the majority of our employees at many of our facilities across the globe to work from home on a temporary basis and implemented company-wide travel restrictions. In 2021, we declared hybrid working patterns, allowing our employees across the globe – who can work from home – the flexibility to balance their personal and professional needs. Our office provides a safe place for purposeful collaboration, and through piloting and active listening to what employees want and need, we developed the Global Ways of Working guidelines, aimed at providing a consistent global framework to determine our future ways of working of all employees and teams to maintain the well-being of our people.

To support our employees in difficult times like the pandemic, we rolled out a global Employee Assistance program to support health, mental health, financial concerns and other challenges any of us can be faced with in our personal lives. To protect our employees, we rolled out a Healthy Habits program and global flu vaccination campaign and enabled a remote hybrid working approach and personal flexible working schedule. We also implemented an employee volunteering policy for those who want to support their communities during the pandemic or for other philanthropic purposes.

Ethical Standards

At LivaNova, we are committed to acting with integrity and maintaining high ethical standards. We understand and respect the obligation we have towards our patients, their families and their caregivers to operate at the topmost level of business ethics and compliance. It is not only what we do but how we do it, and this, too, is part of our mission.

Our commitment to integrity starts with our Code of Ethics and Business Conduct, which sets out the key expectations of behavior for our directors, officers, employees and contractors. In addition to that and as part of our ethics and compliance program, the company maintains a set of policies and procedures that provide a firm foundation for our program and provide ethical handrails for our employees in their day-to-day work life.

LivaNova values greatly its human capital and their physical, but also psychological safety. We have multiple reporting channels for employees as well as business partners to report concerns about potential violations of our Code of Business Conduct & Ethics, company policies, or applicable laws and regulations. Our third-party managed Ethics Line is available 24/7 across multiple time-zones and languages. Employees are encouraged to speak up in good faith over alleged misconduct. Every claim received is addressed per our internal investigation procedure, and this may result in corrective and/or disciplinary action. It is important to note that LivaNova does not tolerate any retaliation.

As part of our ongoing speak up program initiatives, we are committed to continue to promote awareness and education around LivaNova's Ethics Line and our stance against retaliation.

Seasonality

For Cardiopulmonary and Neuromodulation, 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*

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 operate in a highly competitive market characterized by increasingly complex products that are expensive and time consuming to develop and manufacture. 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, may make our products or proposed products less competitive. In addition, we face competition from providers of alternative medical therapies, such as pharmaceutical companies and providers of cannabis derived products, among others. 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 and training; price; capacity to recruit engineers, scientists and other qualified employees; and reimbursement approval. Difficulties in any of these areas may cause our operations and financial condition to suffer.

Reductions or interruptions in the supply of the materials and components used in manufacturing our products may adversely affect our financial condition and business operations, particularly in the wake of COVID-19.

We maintain manufacturing operations in five 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 limited cases, specific components and raw materials are purchased from primary or main suppliers (or in some cases, a single or sole supplier) for reasons related to quality assurance, cost-effectiveness ratio and availability. While we work closely with our suppliers to ensure supply continuity, minimize the instances in which we rely on a sole supplier and take other countermeasures to reduce our supply chain risk, 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 or at all in response to a supply reduction or interruption, with negative effects on our ability to manufacture our products effectively and timely.

The COVID-19 pandemic has exacerbated this risk by negatively impacting the global economy, by, among other things, causing global supply chain shortages. Increased demand and low capacity worldwide have caused longer lead times and put price pressure on key raw materials. We are managing our supply chain by giving long visibility to our suppliers, conducting regular supply critical risk reviews and closely monitoring our inventory, among other things, but any problem could quickly, negatively reverberate throughout the organization. While we have not experienced any material supply chain issues as a result of the pandemic to date, we continue to monitor the landscape closely.

Our products are subject to complex laws and 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 marketing clearance or approval process for new products and new indications for existing products, we conduct 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 markets' or FDA's perception of this clinical data, may adversely impact our ability to obtain product approvals. Currently, for example, we are conducting the RECOVER study and the ANTHEM and OSPREY trials - any delays or news regarding unfavorable or inconsistent data could have a material adverse effect on our business. Nevertheless, 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. 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.

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. Ultimately, we cannot guarantee that our clinical trials will be successful or that we will be able to obtain or maintain marketing clearance for new products or modifications to existing products, and any such issues, whether in relation to trials, approvals or clearances, could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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 subject to periodic inspections by the FDA, which can result in 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. In 2015, we received a warning letter from the FDA alleging certain violations of FDA regulations, which resulted in certain devices that were manufactured in Munich, Germany, to be denied admission to the U.S. until resolution of the issues set forth by the FDA in the warning letter. See "Note 13. Commitments and Contingencies" in our consolidated financial statements included in this Annual Report on Form 10-K for additional information. While we work diligently to manage our ongoing responsibilities, the FDA and other non-U.S. government agencies could assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis. The FDA could also recommend prosecution to the U.S. Department of Justice. An adverse regulatory action could restrict us from effectively marketing and selling our products, limit our ability to obtain future pre-market clearances or PMAs, and 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 (so called "off-label uses"). Our VNS Therapy System, for example, is indicated in the U.S., as an adjunctive therapy in reducing the frequency of seizures in patients 4 years of age and older with partial onset seizures that are refractory to antiepileptic medications, yet a number of physicians elect to prescribe our device for certain patients suffering from generalized seizures. While physicians may exercise their discretion in prescribing a device off-label, any failure on the part of the device manufacturer to comply with off-label regulations 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 (Medical Device Regulation) became effective in May 2021, resulting in significant additional premarket and post-market requirements which must be in place by May 2024. During this transition period, the European Commission is allowing companies to use their MDD (Medical Device Directive) certifications. LivaNova is working to obtain all appropriate approvals and intends to be fully compliant by the May 2024 deadline, as penalties for regulatory non-compliance can be severe, including fines and revocation or suspension of a company's business license, mandatory price reductions and criminal sanctions.

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, software 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, and we have initiated voluntary product recalls in the past. Any recall announcement could harm our reputation with customers and negatively affect our revenue. A recall could also impair our ability to produce our products in a cost-effective and timely manner. In the future, we may initiate voluntary withdrawal, removal or repair actions that we determine do not require notification as a recall. If a regulating authority were to disagree with our determinations, it could require us to report those actions as recalls.

In addition, depending on the corrective action taken to redress a device's deficiencies or defects, 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, and or all of which could have a material adverse effect on our business.

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

We manufacture and sell medical devices, both equipment and implantables, that pose product liability risks that are inherent in the design, manufacture and marketing of such devices. Component failures, manufacturing defects, software errors, 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, injury to, or death of, a patient. 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 and liquidity. In addition, future unanticipated large liability claims may raise substantial doubt about our ability to continue as a going concern.

As described in "Note 13. Commitments and Contingencies" in our consolidated financial statements included in this Annual Report on Form 10-K, we are involved in product liability litigation that may adversely affect our financial condition and may require us to devote significant resources to our defense of these claims. This product liability litigation relates to our cardiopulmonary 3T Heater-Cooler product, and as of March 1, 2022, we are aware of approximately 90 filed and unfiled claims worldwide, with the majority of the claims filed in various federal or state courts throughout the U.S. Although we are defending these matters vigorously, the outcome of such matters could have a material adverse effect on our business.

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 limits on the acceptance and use of our products. 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. Similarly, periodic changes to reimbursement methodologies could have an adverse impact on our business. Adoption of some or all of such healthcare policy and reimbursement proposals could have a material adverse effect on our financial position and results of operations.

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. Even an allegation of impropriety could adversely impact our reputation and/or business operations.

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 information technology systems and those of third parties to operate our business, and certain products of ours include integrated software and information technology. COVID-19 has exacerbated such dependencies due to the challenges in managing such a vast employee population working remotely. 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, patient health information and confidential business information. 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, to make ransom demands, or to remotely disrupt or access the systems of large health care providers by exploiting our products or systems. We maintain an information security risk insurance policy and continue to enhance our information security programs. While we have not fallen victim to any material cyber-attacks, such an incident or an incident at a third-party vendor could compromise our networks and our information could be accessed, publicly disclosed, lost or stolen. The negative publicity resulting from such disruptions could significantly impact our reputation and stock price, and the financial consequences could have a material effect on our business.

In addition, from time to time, we may acquire new businesses. 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. Similarly, we may divest and have divested portions of our business, resulting in the migration of data and overlapping data obligations. As a result of such divestitures, we may face risks due to migration or modification of controls, procedures and policies relating to data privacy and cybersecurity internally or enroute. 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.

The costs of complying with the requirements of federal, state and foreign laws pertaining to the privacy and security of personal information, including health related information and the potential liability associated with failure to do so could materially adversely affect our business and results of operations.

There is significant regulatory and enforcement focus on data protection in the U.S. (at both the state and federal level) and abroad, and an actual or alleged failure to comply with applicable U.S. or foreign data protection regulations or other data protection standards may expose us to litigation (including, in some instances, class action litigation), fines, sanctions or other penalties, which could harm our reputation and adversely impact our business, results of operations and financial condition. This regulatory environment is increasingly challenging and may present material obligations and risks to our business, including significantly expanded compliance burdens, costs and enforcement risks. If we are unable to maintain secure, reliable information technology systems and prevent data breaches, we may suffer legal and regulatory consequences in addition to business consequences. Our worldwide operations mean that we are subject to 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. Violations of GDPR can result in fines of as much as 4% of a company's annual revenue. Other governments have enacted or are enacting similar data protection laws, including data localization laws that require data to stay within their borders. Despite programs to comply with such laws and regulations and our purchase of a cyber insurance policy, 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.

We cannot guarantee that our internal R&D efforts and those R&D efforts that rely on investments and 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.

If we do not develop innovative new and enhanced products and services on a timely basis, our offerings will become obsolete over time and our business and financial results could be negatively impacted. Our success depends on several factors, including our ability to appropriately allocate our R&D funding to products and services with higher growth prospects, for example, further incorporation of software; hire and retain the necessary R&D talent; stimulate customer demand for and convince customers to adopt new technologies; innovate and develop new technologies and applications; and acquire or obtain third-party technologies that may have valuable applications in the markets that we serve.

We expect to make 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 acquisitions, 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. While we intend to defend against any threats to our intellectual property, any litigation to counter the infringement, misappropriation, or unauthorized use of our intellectual property may require the expenditure of significant financial and managerial resources, which may adversely affect our business, operating results and financial condition. Additionally, our patents, trade secrets, or other agreements may not prevent competitors from independently developing or selling similar products and services and may not adequately deter misappropriation or improper use of our technology. 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.

We operate in an industry characterized by extensive patent litigation and are subject to patent claims from time to time. While we intend to defend against any third-party intellectual property threats, intellectual property litigation is inherently complex and unpredictable. Such 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.

In addition, 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. We could also face competition in countries where we have not invested in an intellectual property portfolio, or where we have not invested in the same protection as in the U.S. 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 are subject to environmental laws and regulations and the risk of environmental liabilities, violations and litigation in multiple jurisdictions, including in Saluggia, where we are currently involved in the disposal of hazardous substances and in Italy in relation to SNIA's environmental liabilities.

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. In addition, 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 substances at their properties or at properties on which they have disposed of hazardous substances. For example, our Saluggia campus contains hazardous substances as a result of nuclear installations, built in 1960 under previous ownership, and the Italian Government has stated that we will eventually be responsible for dismantling the nuclear installation on Company property, which will involve cleaning and dismantling contaminated buildings and equipment as well as delivering the aforementioned waste to a national repository. We have recognized a liability of $39.3 million as of December 31, 2021. In addition, as described in "Note 13. Commitments and Contingencies" in our consolidated financial statements included in this Annual Report on Form 10-K along with the aforementioned matter, we are currently in litigation with the government in Italy stemming from a civil action where the Court of Appeal in Milan (Court of Appeal) declared LivaNova (formed through a merger with Sorin) jointly liable with SNIA (a former parent company of Sorin) for environmental liabilities incurred by SNIA's other subsidiaries. In November 2021, the Court of Appeal delivered the remainder of the decision, demanding that LivaNova pay damages of approximately €453.6 million (approximately $514.6 million as of December 31, 2021). LivaNova appealed both the liability and damages decisions, and they will be decided together at the Italian Supreme Court. In February 2022, the Court of Appeal granted a stay on the demand for payment from the Public Administrations pending resolution of the Company's appeal on liability and damages. The stay was granted with the condition that the Company provide a first demand bank surety of €270.0 million (approximately $306.2 million as of December 31, 2021) within 30 calendar days. For additional information, please refer to "Liquidity and Capital Resources" within "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report on Form 10-K. Our liquidity, business operations or results of operations could be adversely affected by a negative decision in the case of SNIA or increase in anticipated costs relating to transportation of hazardous waste in Saluggia.

It is also possible that, 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. Finally, 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 globally and under non-U.S. laws, regulations and customs. These risks include possible nationalization, invasions, wars, negative consequences associated with Brexit, expropriation, importation limitations, pricing restrictions, government shutdowns and violations of laws. On February 24, 2022, for example, Russia launched an invasion in Ukraine which has the potential to affect our ability to import certain materials used to manufacture our products and sell our products in these countries. 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; imposition of sanctions; 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 below 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.*" Any of the aforementioned risks could adversely affect our business, results of operations, financial conditions and cash flows.

From time to time, certain of our subsidiaries have limited business dealings in countries subject to comprehensive sanctions, including Iran, Sudan, and Syria. These business dealings represent an insignificant amount of our consolidated revenues and income, but expose us to a heightened risk of violating applicable sanctions regulations. Violations of these regulations are punishable by civil penalties including fines, denial of export privileges, injunctions, asset seizures, debarment from government contracts and revocations or restriction of licenses, as well as criminal fines and imprisonment. We have established policies and procedures designed to assist with our compliance with such laws and regulations, but there can be no assurance that our policies and procedures will prevent us from violating these regulations in every transaction in which we may engage, and such a violation could adversely affect our reputation, business, results of operations, financial conditions and cash flows.

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. For transactions denominated in currencies other than our functional currencies, fluctuations in the exchange rate 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.

COVID-19 has had, and we expect will continue to have, an adverse effect on our business, results of operations, financial condition and cash flows, the nature and extent of which are uncertain and unpredictable.

The continuing global spread of COVID-19 and its variants, including corresponding preventative and precautionary measures that we and other businesses, communities and governments are taking to mitigate the spread of the disease, has led to unprecedented restrictions on, disruptions in, and other related impacts on business. COVID-19 is affecting our employees, customers, facilities, communities and business operations, as well as the global economy and financial markets. As the COVID-19 crisis continues to evolve, the full extent to which the COVID-19 pandemic will impact our business, results of operations, financial condition and liquidity will depend on future developments that are highly uncertain and cannot be accurately predicted. In addition to travel restrictions, countries, states and governments may continue to close borders, impose prolonged quarantines or other restrictions and requirements on travel, and further limit our ability to conduct business in-person as we did prior to COVID-19.

While we are seeing improvement, we continue to experience ongoing COVID-19 related headwinds and are monitoring the potential for various strains of the virus to cause a resumption of high levels of infection and hospitalization, that in turn, may affect the demand for our products. In certain geographies, hospital systems continue to prioritize treatment of COVID-19 patients and otherwise comply with government guidelines, thereby resulting in the suspension or cancellation of elective medical procedures, which has caused a reduction in sales of these products. To the extent individuals and hospital systems continue to de-prioritize, delay or cancel these procedures, or if unemployment or loss of insurance coverage adversely impacts an individual’s ability to pay for our products and services, our business, cash flows, financial condition and results of operations will continue to be negatively affected. Further, the COVID-19 pandemic is straining hospital systems around the world, resulting in adverse financial impacts to those systems that could result in reduced future expenditures for our products. While our clinical trials have resumed, we continue to monitor relevant conditions as there can be no assurance that there will not be delays or closures of sites in the future should COVID-19 or variants thereof strengthen or reemerge.

While the industry has experienced supply chain, labor shortage, inflation and logistical issues in the wake of COVID-19, to date, the supply of raw materials and the production and distribution of finished products within LivaNova remain operational with no material constraints. Regardless, there can be no assurance that any negative impacts from supply chain, staffing shortages, inflation or logistics would not adversely affect our operating results. All of our manufacturing plants have been able to remain open during COVID-19. Regardless, there can be no assurance that any of our facilities will not need to shut down in the future as a direct result of the COVID-19 pandemic.

In addition, COVID-19 has impacted and may further impact the global economy and capital markets, including by negatively impacting demand for our products and foreign currency exchange rates, each of which may adversely impact our business. Further, the COVID-19 pandemic, and the volatile global economic conditions stemming from the pandemic, could precipitate or amplify the other risk factors that we identify here. We could experience loss of sales and profits due to delayed payments or insolvency of healthcare professionals, hospitals and other customers, suppliers and vendors facing liquidity issues. As a result, we may be compelled to take additional measures to preserve our cash flow.

Finally, COVID-19 could adversely impact our ability to retain key employees and the continued service and availability of skilled personnel necessary to run our productions and operations, including our executive officers and other members of our management team, as well as the ability of our third-party suppliers, manufacturers, distributors and vendors to retain their key employees. To the extent our management or other personnel are impacted in significant numbers by COVID-19 and are not available to perform their job duties, we could experience delays in, or the suspension of, our manufacturing operations, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions.

While the impact of COVID-19 has had, and we expect it to continue to have, an adverse effect on our business, results of operations, financial condition and cash flows, the nature and extent of such impact is uncertain and unpredictable. For more information on the impact of COVID-19 on the Company and LivaNova's mitigation measures, please refer to "Recent Developments Regarding COVID-19" within "Note 1. Nature of Operations," and "COVID-19" under "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations."

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, that 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. 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.

The impact of pending or existing climate change resulting from increased concentrations of carbon dioxide and other greenhouse gasses in the atmosphere could present major risks to our future operations.

The physical impacts of natural disasters and extreme weather conditions, such as hurricanes, tornadoes, earthquakes, wildfires or flooding could pose physical risks to our facilities, disrupt our supply chain operations, and negatively impact operational costs. In addition, as new legal and regulatory requirements designed to mitigate the effects of climate change on the environment are increasing, they may impose legal or regulatory requirements which may increase our compliance burdens and costs to meet these obligations. Individually or in the aggregate, such risks could materially negatively impact our future 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 may 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 incur costs in excess of what we anticipate.

We may incur impairments of intangible assets and goodwill, primarily acquired in acquisitions, that may adversely affect our financial results.

As of December 31, 2021, the carrying value of our net intangible assets and goodwill totaled $1.3 billion, which represents 59.0% of our total assets. During the year ended December 31, 2020, we entered into a Purchase Agreement for the divestiture of certain of LivaNova's subsidiaries as well as certain other assets and liabilities relating to the Company's Heart Valve business that resulted in an impairment of the Heart Valves disposal group of $180.2 million and a $21.3 million impairment to the goodwill. 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. Recent impairments have significantly affected our financial results and future impairments could significantly affect reported financial results.

The closing of the proposed sale of LivaNova Site Management ("LSM") in the context of the Heart Valves business divestment is subject to a number of conditions, satisfaction of which are beyond our control and there can be no assurance that such conditions will be satisfied or that the divestiture of LSM will be completed.

On December 2, 2020, we entered into a Purchase Agreement, amended and restated on April 9, 2021, with Mitral Holdco S.à r.l., a company incorporated under the laws of Luxembourg and wholly owned and controlled by funds advised by Gyrus Capital S.A., a Swiss private equity firm, which provides for the divestiture of LivaNova's Heart Valve business, as well as site management operations conducted by the Company's LSM subsidiary.

The divestiture of the Company's Heart Valve business has been substantially completed. The divestiture of LSM remains subject to a number of closing conditions that are beyond our control, and there can be no assurance that such conditions will be satisfied or that such divestiture will be completed.

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. As a result of the COVID-19 pandemic, our access to these professionals has been limited at times, and travel restrictions, shutdowns and similar measures have impacted our ability to maintain these relationships, thereby affecting our ability to develop, market and sell new and improved products. 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. 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.

We may experience volatility in the trading price of our shares due to fluctuations in our quarterly operating results, COVID-19 or other factors.

We experienced volatility in the trading price of our shares during 2019, 2020 and 2021, including following the pre-release of our earnings for the first quarter in 2019 as well as during COVID-19 in 2020. 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*."

Shareholder activists could cause a disruption to our business.

In mid-October 2020, an activist investor indicated its concerns with, among other things, our capital allocation, reporting transparency within our sub-segments, and corporate governance and leadership. In the future, our business, operating results or financial condition could be adversely affected because activist proposals can be a significant distraction for our Board of Directors, management and employees and may require us to expend significant time and resources. Shareholder activists may create uncertainty for our employees, investors and customers, additional risk and uncertainties with respect to our financial position, operations, strategies and management, and may adversely affect our ability to attract and retain key employees. Any perceived uncertainties as to our future direction also may affect the market price and volatility of our securities.

Risks Related to our Indebtedness

Paying amounts due in cash in respect of our outstanding Notes on interest payment dates, at maturity and upon exchange thereof will require a cash payment. We may not have sufficient cash flow from our business to pay when due, or raise the funds necessary to pay when due, amounts owed in respect of the Notes or any amounts owed under our revolving credit facility or bridge loan facility, which could adversely affect our business and results of operations.

On June 17, 2020, our wholly-owned subsidiary, LivaNova USA, Inc., issued $287.5 million aggregate principal amount of 3.00% Cash Exchangeable Senior Notes due in 2025 (the "Notes"). The ability to make scheduled payments of interest on, and principal of, to satisfy exchanges for cash in respect of, and/or to refinance, our outstanding Notes or other indebtedness (including any indebtedness under our revolving credit agreements) depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate enough cash flow to make payments on the Notes or other indebtedness when due, we may be required to adopt one or more alternatives, such as selling assets or obtaining additional debt financing or equity capital on terms that may be onerous or highly dilutive. Our ability to refinance the Notes or other indebtedness, which we may need to do in order to satisfy our obligations thereunder, will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on the Notes.

The holders of the Notes have the right to require us to repurchase their Notes upon the occurrence of a fundamental change (as defined in the indenture governing the Notes (the "Indenture")) at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. Upon repurchase of the Notes, we will be required to make cash payments as required by the Indenture. We may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of, or exchange of, the Notes for cash. Our failure to repurchase the Notes or exchange the Notes for cash at a time when the repurchase or exchange is required by the Indenture governing the Notes would constitute a default under such Indenture.

In addition, our indebtedness including under the Notes, combined with our other financial obligations and contractual commitments including those under our revolving credit facility or bridge loan facility, could have other important consequences. For example, it could:

- Make us more vulnerable to adverse changes in government regulation and in the worldwide economic, industry and competitive environment;
- Limit our flexibility in planning for, or reacting to, changes in our business and our industry;
- Place us at a disadvantage compared to our competitors who have less debt;
- Limit our ability to borrow additional amounts to fund acquisitions, for working capital and for other general corporate purposes; and
- Make an acquisition of the Company less attractive or more difficult.

Any of these factors could harm our business, results of operations and financial condition. In addition, if we incur additional indebtedness under the revolving credit facility or bridge loan facility, the risks related to our business and our ability to repay our indebtedness including under the Notes would increase. For additional information, please refer to "Note 10. Financing Arrangements" in the consolidated financial statements in this Annual report on Form 10-K.

The conditional exchange features of the Notes when triggered, may adversely affect our liquidity and operating results.

If the conditional exchange feature of the Notes is triggered, holders of Notes are entitled to exchange the Notes at any time during specified periods, at their option. Holders of the Notes for example, are entitled to exchange the Notes during any calendar quarter, if the last reported sale price of LivaNova's ordinary shares, with a nominal value of £1.00 per share for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the exchange price – the exchange price being $60.98 per share and the "conversion trigger" (subject to other conditions per the Indenture) being $79.27 per share – on each applicable trading day. The exchange condition was satisfied on December 20, 2021, which allows the holders of the Notes to request to exchange the Notes through March 31, 2022. If holders elect to exchange their Notes during future periods following the satisfaction of an exchange condition as laid out in the Indenture, we would be required to settle our exchange obligation through the payment of cash, which could adversely affect our liquidity. In addition, the Notes are currently redeemable and classified as current, resulting in a material reduction of our net working capital.

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

Certain restrictions and covenants in our debt instruments, including our revolving credit agreement and bridge loan facility, 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. (For more information on these debt instruments, please refer to "Note 10. Financing Arrangements.")

The accounting for the Notes will result in LivaNova having to recognize interest expense significantly greater than the stated interest rates of the Notes and may result in volatility to our reported financial results, which could adversely affect the price at which our ordinary shares trade.

We will settle exchanges of the Notes entirely in cash. Accordingly, the exchange feature that is part of the Notes is accounted for as a derivative pursuant to accounting standards relating to derivative instruments. This resulted in an initial valuation of the exchange feature, which was bifurcated from the debt component of the Notes, resulting in an original issue discount. The original issue discount is amortized and recognized as a component of interest expense over the term of the Notes, which results in an effective interest rate reported in our consolidated statements of operations in excess of the stated interest rate of the Notes. Although this accounting treatment does not affect the amount of cash interest paid to holders of the Notes or our cash flows, it reduces our earnings and could adversely affect the price at which our ordinary shares trade.

Additionally, for each financial statement period after issuance of the Notes, a derivative gain or loss is and will be reported in our consolidated statements of income (loss) to the extent the valuation of the exchange feature changes from the previous period. The capped call transactions described below and elsewhere in this annual report are also accounted for as derivative instruments. The valuation of the exchange feature of the Notes and capped call transactions utilizes significant observable and unobservable market inputs, including stock price, stock price volatility, risk-free interest rate, and time to expiration of the Notes. The change of inputs at period end from the previous period may result in a material change of the valuation and the gain or loss resulting from the exchange feature of the Notes and capped call transactions may not completely offset each other. As such, there may be a material net impact to our consolidated statements of operations, which could adversely affect the price at which our ordinary shares trade.

The arbitrage or hedging strategy by purchasers of the Notes and Option Counterparties in connection with our capped call transactions may affect the value of our ordinary shares.

We expect that many investors in, and potential purchasers of the Notes will employ, or seek to employ, an arbitrage strategy with respect to the Notes. Investors would typically implement such a strategy by selling short our ordinary shares underlying the Notes and dynamically adjusting their short position while continuing to hold the Notes. Investors may also implement this type of strategy by entering into swaps on our ordinary shares in lieu of or in addition to selling short our ordinary shares. This activity could decrease (or reduce the size of any increase in) the market price of our ordinary shares at that time.

In connection with the pricing of the Notes, we entered into privately negotiated capped call transactions with certain financial institutions (the “Option Counterparties”). The capped call transactions are expected generally to offset cash payments due upon exchange of the Notes in excess of the principal amount thereof in the event that the market value per ordinary share of the Company is at the time of exchange of the Notes greater than the strike price under the capped call transactions, with such offset subject to a cap based on the cap price. We understand the Option Counterparties, or their respective affiliates, in connection with establishing their initial hedges of the capped call transactions, purchased our ordinary shares and/or entered into various derivative transactions with respect to our ordinary shares concurrently with or shortly after the pricing of the Notes. The Option Counterparties or their respective affiliates may modify these initial hedge positions by entering into or unwinding various derivatives with respect to our ordinary shares and/or purchasing or selling our ordinary shares or other securities of ours in secondary market transactions prior to the maturity of the Notes (and are likely to do so during any observation period related to an exchange of the Notes or upon a repurchase or redemption of the Notes). This activity could cause or avoid an increase or decrease in the market price of our ordinary shares at that time.

We are subject to counterparty risk with respect to the capped call transactions.

The Option Counterparties are financial institutions, and we are subject to the risk that they might default under the capped call transactions. Our exposure to the credit risk of the Option Counterparties is not secured by any collateral.

If an Option Counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings, with a claim equal to our exposure at that time under the capped call transactions with that Option Counterparty. Our exposure will depend on many factors but, generally, an increase in our exposure will be correlated to an increase in the market price and in the volatility of our ordinary shares. In addition, upon a default by an Option Counterparty, we may suffer adverse tax consequences and may, on a net basis, have to pay more cash to settle exchanges of the Notes. We can provide no assurances as to the financial stability or viability of the Option Counterparties.

Risks Relating to Tax and Our Jurisdiction of Incorporation

We are incorporated in England and Wales, and governed by their laws which may afford less protection to shareholders than under U.S. laws.

Being that we are a public limited company incorporated under the laws of England and Wales, our shareholders may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction of the United States. It may be difficult to enforce any court judgments obtained in the U.S. against us in the U.K. based on the civil liability provisions of U.S. federal or state securities laws. In addition, there is also some uncertainty as to whether the courts of U.K. would recognize or enforce judgements of U.S. courts obtained against us or any of our directors or officers.

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 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 our case, we believe that the former stockholders of Cyberonics own less than the IRC's stated percentage of the Company. However, it cannot be assured that the IRS will agree with our position.

As an English public limited company, certain capital structure decisions 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. English law also generally provides shareholders with preemptive rights when new shares are issued for cash, which rights may be excluded by shareholders. In addition, English law generally prohibits a public company from repurchasing its own shares without the prior approval of shareholders. At the 2020 AGM, our shareholders approved the amendment of our articles of association to authorize the allotment of additional shares of up to 20% of our outstanding share capital without preemptive rights for a period of five years, though prior to the 2020 AGM, the Company declared, based on discussions with stakeholders and advisors, that it would not utilize such authorities for more than 18 months in excess of an amount equal to 10% of our then share capital. As a result, at future AGMs, we will be seeking shareholder approval to renew these authorities. If we do not receive shareholder approval of these matters, we may not be able to raise additional capital, in a timely manner or at all, if and as needed to fund our operations. In addition, we may not be able to continue to grant equity awards to employees, directors, officers and consultants under our incentive plans.

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 or 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, or 1.5% of the market value of the shares if there is no consideration. 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 segments have headquarters located in the U.S. for Neuromodulation and Advanced Circulatory Support and Italy for Cardiopulmonary. We have manufacturing and research facilities located in Brazil, Germany, Italy, Australia and the U.S. Our manufacturing and research facilities are approximately 1.0 million square feet. The manufacturing and research facilities located in the U.S., Italy and Brazil are substantially owned by us. Approximately 45% of our manufacturing and research facilities by square feet are located within the U.S. Approximately 58% of our manufacturing and research facilities by square feet are owned by us and the balance is leased.

We also maintain 22 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. We believe that all of our facilities are in good operating condition, suitable for their respective uses and adequate for current needs.

Item 3. *Legal Proceedings*

Information pertaining to certain material pending legal and regulatory proceedings and settlements is incorporated herein by reference to “Note 13. 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 24, 2022, according to data provided by our transfer agent, there were 21 stockholders of record. A substantially greater number of holders of our ordinary shares are "street name" or beneficial holders, whose shares of record are held by banks, brokers and other financial institutions.

Dividend Policy

We currently have no intention to declare and pay dividends.

Issuer Purchases of Securities

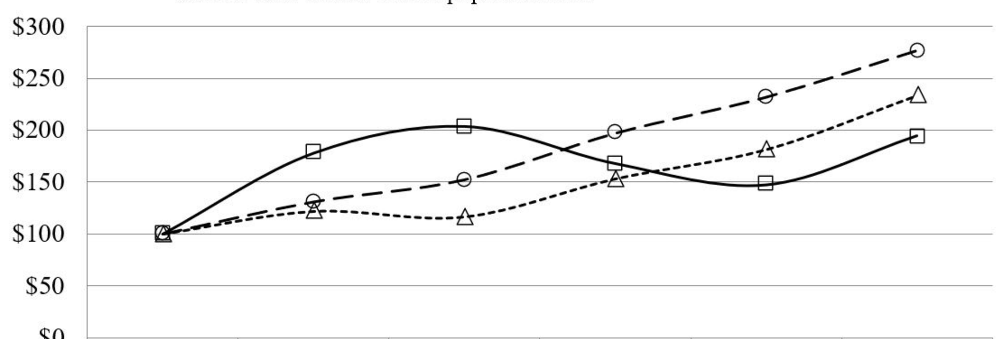
None.

Stock Performance Graph

The following graph compares our five-year cumulative total return with the five-year cumulative total return of the companies on the Standard & Poor's ("S&P's") 500 Index and the companies on the S&P Health Care Equipment Index. This graph assumes the investment of $100 on December 31, 2016 and the reinvestment of all dividends since that date.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*

Among LivaNova Plc, the S&P 500 Index and the S&P Health Care Equipment Index



	12/31/16	12/31/17	12/31/18	12/31/19	12/31/20	12/31/21
LivaNova Plc	$100.00	177.72	203.40	167.73	147.23	194.42
S&P 500	100.00	121.83	116.49	153.17	181.35	233.41
S&P Health Care Equipment Index	100.00	130.90	152.15	196.77	231.46	276.26

*$100 invested on 12/31/16 in stock or 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. [Reserved]

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

The following discussion and analysis should be read in conjunction with the consolidated financial statements and the corresponding notes included elsewhere in this Annual Report on Form 10-K. Certain percentages presented in this discussion and analysis are calculated from the underlying whole-dollar amounts and therefore may not be recalculated from the rounded numbers used for disclosure purposes. The following discussion, analysis and comparisons generally focus on the operating results for the years ended December 31, 2021 ("2021"), December 31, 2020 ("2020") and December 31, 2019 ("2019").

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, 2020, filed on March 1, 2021, for reference to discussion of the fiscal year ended December 31, 2019, the earliest of the three fiscal years presented.

COVID-19

Since early 2020, the COVID-19 pandemic ("COVID-19") has caused and may continue to cause unpredictable demand for our products. Throughout the pandemic, healthcare customers have diverted medical resources and priorities towards the treatment of COVID-19, and public health bodies have delayed elective procedures, which has negatively impacted the usage of our products. Further, some people have avoided seeking treatment for non-COVID-19 procedures and hospitals and clinics have experienced staffing shortages, which have negatively impacted the demand for our products. While we have seen improvement during 2021, we continue to experience ongoing COVID-19 related headwinds and are monitoring the potential for various strains of the virus to cause a resumption of high levels of infection and hospitalization, that in turn, may affect the demand for our products.

While our RECOVER study and ANTHEM-HFrEF pivotal trial experienced delays during 2020 due to COVID-19, work continued to progress throughout 2021. Impacts related to the Delta strain of COVID-19 created some delay in implants in the RECOVER study, and we continue to monitor relevant conditions at participating centers for both RECOVER and ANTHEM-HFrEF as there can be no assurance that there will not be closures of sites in the future should COVID-19 or variants thereof strengthen or reemerge.

Our business operations have been affected by a range of external factors related to the pandemic that are not within our control. For example, many jurisdictions have imposed, and in some cases reimposed, a wide range of restrictions to limit the spread of COVID-19. We continue to evaluate the evolving laws and regulations developing around the world and are working to meet customer-specific requirements to operate in a COVID-19 business environment. However, if the pandemic has a substantial impact on our employees, vendors, suppliers or productivity, our operations may suffer, and in turn our results of operations and overall financial performance may be harmed.

Importantly, we continue to take actions in managing the health and safety of our employees throughout the pandemic. As guidance from authorities such as the U.S. Centers for Disease Control and Prevention or the World Health Organization evolves, we update our practices accordingly. For our manufacturing, operations, and other personnel who have remained on site throughout the pandemic due to the essential nature of their work, we have implemented safety measures such as the use of personal protective equipment and social distancing measures. At the start of the pandemic, we instructed the majority of our employees at many of our facilities across the globe to work from home on a temporary basis and implemented company-wide travel restrictions. Though there has been no Company-wide mandate to return to the office, employees are encouraged to return for purposeful collaboration. We continue to maintain enhanced safety protocols and encourage our employees to seek vaccination. We have incurred additional expenses in connection with our response to the COVID-19 pandemic, including manufacturing inefficiencies and costs related to enabling our employees to support our customers while working remotely.

We have successfully implemented our business continuity plans, and our management team is responding to changes in our environment quickly and effectively. We have not closed any of our manufacturing plants. Additionally, while there are many supply chain, labor shortage, inflation and logistical issues emerging in the wake of COVID-19 related disruptions, to date, the supply of raw materials and the production and distribution of finished products remain operational with no material constraints relating to COVID-19. We continue to monitor the landscape for any potential disruptions.

We continue to implement cost reduction efforts. We have reduced expenses by evaluating whether projects and initiatives are critical to meet the needs of the Company, protecting strategic priorities for future growth, reducing discretionary spending and tightening management of personnel costs.

The extent to which the COVID-19 pandemic continues to impact the Company's results of operations and financial condition will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity and longevity of COVID-19 and its variants, the resurgence of COVID-19 in regions that have begun to recover from the initial impact of the pandemic, the impact of COVID-19 on economic activity and the actions to contain its impact on public health and the global economy.

For further discussion on COVID-19, refer to “Item 1A. Risk Factors” of this Annual Report on Form 10-K under the section entitled “*COVID-19 has had, and we expect will continue to have, an adverse effect on our business, results of operations, financial condition and cash flows, the nature and extent of which are uncertain and unpredictable*.”

Description of the Business

We are a public limited company organized under the laws of England and Wales and headquartered in London, England. We are a global medical device company focused on the development and delivery of important products and therapies for the benefit of patients, healthcare professionals and healthcare systems throughout the world. We design, develop, manufacture and sell innovative products and therapies that are consistent with our mission to provide hope to patients through innovative technologies, delivering life-changing improvements for both the Head and Heart.

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 Segments

LivaNova is comprised of three reportable segments: Cardiopulmonary, Neuromodulation and Advanced Circulatory Support, corresponding to our primary business units. Other includes the results of our Heart Valves business, which was disposed of on June 1, 2021, and corporate shared service expenses for finance, legal, human resources, information technology and corporate business development.

Effective in the fourth quarter of 2021, LivaNova changed its reportable segments corresponding to changes in how the Company’s chief operating decision maker regularly reviews information, allocates resources and assesses performance. The segment financial information presented herein reflects these changes for all periods presented. The Company’s changes to its reportable segments are summarized as follows:

- The Company’s Advanced Circulatory Support business is no longer assessed as part of the Company’s previously reported Cardiovascular reportable segment and is evaluated independently as its own reportable segment.
- The Company’s Cardiopulmonary business is no longer assessed as part of the Company’s previously reported Cardiovascular reportable segment and is evaluated independently as its own reportable segment.
- The Company’s Heart Valves business, which was disposed of on June 1, 2021, is now included within Other.

Cardiopulmonary

Our Cardiopulmonary segment is engaged in the development, production and sale of cardiopulmonary products, including oxygenators, heart-lung machines, autotransfusion systems, perfusion tubing systems, cannulae and other related accessories.

Cardiopulmonary Product Approval

In April 2021, the FDA provided 510(k) clearance for B-Capta, the new in-line, blood-gas monitoring system integrated into the Company’s S5 heart-lung machine. The system is designed to easily and accurately monitor arterial and venous blood gas parameters even during long and complex pediatric and adult cardiopulmonary bypass procedures. B-Capta, which received CE Mark in May 2020 and completed a successful limited commercial release in Europe, is now available globally.

Product Remediation

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 and issued inspectional observations on the 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. With this 510(k) clearance, all actions to remediate the FDA's inspectional observations in the Warning Letter are complete, and at this time, LivaNova is awaiting the FDA's close-out inspection.

For further information, refer to "Note 13. 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 ("NMT") 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. In April 2017, we obtained CE Mark in Europe for the design change of the 3T device, and in October 2018, the FDA concluded that we could commence the vacuum canister and internal sealing upgrade program in the U.S. 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. We are in the process of completing and closing out all recall activities with the FDA. While our vacuum canister and internal sealing upgrade program and deep cleaning service in the U.S. are substantially complete, these services will continue as a servicing option outside of the U.S.

On December 31, 2016, we recognized a liability for a product remediation plan related to our 3T Heater-Cooler device ("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 the fourth quarter of 2016, and furthermore, the cost associated with the plan was reasonably estimable. At December 31, 2021, the product remediation liability was $0.8 million. For further information, refer to "Note 6. Product Remediation Liability" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

Product Liability

The Company is currently involved in litigation involving our 3T device. The litigation includes 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. A class action, filed in February 2016 in the U.S. District Court for the Middle District of Pennsylvania, consisting of all Pennsylvania residents who underwent open heart surgery at WellSpan York Hospital and Penn State Milton S. Hershey Medical Center between 2011 and 2015 and who currently are asymptomatic for NTM infection, was dismissed on July 16, 2021.

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 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 and federal courts in the U.S. and in jurisdictions outside the U.S. continue to progress. As of March 1, 2022, including the cases encompassed in the settlement framework described above that have not yet been dismissed, we are aware of approximately 90 filed and unfiled claims worldwide, with the majority of the claims in various federal or state courts throughout the United States. This number includes seven 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.

At December 31, 2021, the provision for these matters was $39.5 million. While the amount accrued represents our best estimate for those filed and unfiled claims that are both probable and estimable, the actual liability for resolution of these matters may vary from our estimate.

Neuromodulation

Our Neuromodulation segment designs, develops and markets devices that deliver neuromodulation therapy to treat DRE, and DTD. It encompasses the development and management of clinical testing of our aura6000 System for treating OSA, a device that stimulates the hypoglossal nerve, which in turn, engages certain muscles in the tongue in order to open the airway while a patient is sleeping, as well as our VITARIA System for treating heart failure by stimulating the right vagus nerve.

Epilepsy

We continue to make significant investments in R&D focused on improving the VNS Therapy System with an enhanced pulse generator, lead and programming software, and we are developing new products that provide additional features and functionality. We also support studies for our product development efforts and to build clinical evidence for the VNS Therapy System.

Peer reviewed evidence published in 2021 and 2022 continues to confirm the safety, efficacy and cost effectiveness of VNS Therapy in both the adult and pediatric patient population. In January 2022, the Journal of Neurology published a meta-analysis and systematic review that demonstrated benefits of VNS Therapy in adults with DRE that demonstrates that seizure frequency improves without an increase in the rate of serious adverse events or discontinuations. These data further support consideration of VNS Therapy for people who are not responding to ASMs and those unsuitable or unwilling to undergo surgery.

Depression

US

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 non-coverage determination 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 March 2017, the American Journal of Psychiatry published the results of the longest and largest naturalistic study (the “D23 study”) on treatments for patients experiencing chronic and severe DTD. The findings showed that the addition of the VNS Therapy System to traditional treatment is effective in significantly reducing symptoms of depression and well tolerated compared with traditional treatment alone. Following publication of the D23 study, we requested CMS to reconsider its previous NCD, and in May 2018, CMS published a tracking sheet to reconsider its NCD.

In February 2019, CMS produced a final decision providing coverage for Medicare beneficiaries through 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 registry.

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 in the randomized part of the trial and up to an additional 5,800 patients in an open label registry.

In February 2020, we announced a research collaboration with Verily, a subsidiary of Alphabet Inc., to capture clinical biomarkers of depression within our RECOVER clinical study. Using technology and analytics by way of the Verily Study Watch and related Verily mobile phone application, LivaNova and Verily aim to gather quantitative data to further understand depressive episodes and a patient's response to treatment. These complementary approaches are expected to help investigators better understand the impact of depression and its treatment on study participants' lives in a more objective and multi-dimensional manner. In April 2021, LivaNova and Verily announced that the first patient had been enrolled in their collaborative UNCOVER study, a subset of the RECOVER study.

Outside the U.S.

In January 2018, we announced the launch and enrollment of the first patient in our 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.

In March 2020, our VNS Therapy System, Symmetry received CE mark approval for DTD.

Obstructive Sleep Apnea

In January 2018, we acquired full ownership of ImThera, a privately held, emerging-growth company developing an implantable neurostimulation device system for the treatment of obstructive sleep apnea. The device stimulates the hypoglossal nerve, which in turn, engages certain muscles in the tongue in order to open the airway while a patient is sleeping. We have a commercial presence in the European market.

In June 2021, LivaNova received approval from the FDA to proceed with its investigational device exemption clinical study, "Treating Obstructive Sleep Apnea using Targeted Hypoglossal Neurostimulation (OSPREY)." The OSPREY study seeks to confirm the safety and effectiveness of the aura6000 System, the LivaNova implantable hypoglossal neurostimulation device intended to treat adult patients with moderate to severe obstructive sleep apnea.

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 elements similar to the VNS Therapy System: pulse generator, lead, programming computer and wand. In 2012, we initiated a pilot study, ANTHEM-HF, outside the U.S., and the published results support the safety and efficacy of ART delivered to patients with advanced heart failure expressing symptoms despite guideline-directed medical therapy. The study was extended to continue follow-up of patients through 42 months, the results for which have been published in a peer-reviewed cardiology journal. During 2014, we initiated a second pilot study outside the U.S., ANTHEM-HFpEF, to study ART in patients experiencing symptomatic heart failure with preserved ejection fraction. The VITARIA System is not approved in the U.S. though it has been designated as a breakthrough technology by the FDA. The VITARIA System received CE Mark approval in 2015.

In September 2018, we announced the first successful implantation of the VITARIA System in a patient randomized in the ANTHEM-HFrEF Pivotal Study, an international, multi-center, randomized trial (adaptive sample size) to evaluate the VITARIA System (FDA's Breakthrough Technology designation) for the treatment of advanced heart failure. The trial was paused temporarily in March 2020 due to COVID-19 restrictions, but we were able to re-initiate enrollment and screening activities shortly thereafter in more than half of the sites. We continue to monitor relevant conditions at medical centers participating in the trial. In December 2021, we enrolled the 400th patient in the trial, and in January 2022, the 300th patient completed the nine-month follow-up visit. Given these milestone achievements, the first interim analysis is being conducted by independent statisticians.

Advanced Circulatory Support

Our Advanced Circulatory Support segment is engaged in the development, production and sale of leading-edge temporary life support products. These products include cardiopulmonary and respiratory support solutions consisting of temporary life support controllers and product kits that can include a combination of pumps, oxygenators, and cannulae.

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., followed by a full commercial launch in the second half of 2020.

Divestiture of Heart Valves Business

On December 2, 2020, LivaNova entered into a Share and Asset Purchase Agreement ("Purchase Agreement") with Mitral Holdco S.à r.l., a company incorporated under the laws of Luxembourg and wholly owned and controlled by funds advised by Gyrus Capital S.A., a Swiss private equity firm. The Purchase Agreement provided for the divestiture of certain of LivaNova's subsidiaries as well as certain other assets and liabilities relating to the Company's Heart Valve business and site management operations conducted by the Company's subsidiary LSM at the Company's Saluggia campus for €60.0 million (approximately $68.1 million as of December 31, 2021). On April 9, 2021, LivaNova and the Purchaser entered into an Amended and Restated Share and Asset Purchase Agreement (the "A&R Purchase Agreement") which amends and restates the original Purchase Agreement to, among other things, defer the closing of the sale and purchase of LSM by up to two years and include or amend certain additional terms relating to such deferral, including certain amendments relating to the potential hazardous substances liabilities of LSM and the related expense reimbursement provisions. The closing of the sale of the Heart Valve business occurred on June 1, 2021 and we received €34.8 million (approximately $42.5 million as of June 1, 2021), subject to customary trade working capital and net indebtedness adjustments, as set forth in the Purchase Agreement. We received $3.0 million in additional proceeds during the fourth quarter of 2021. An additional €9.3 million (approximately $10.6 million as of December 31, 2021) is payable to LivaNova in 2022.

Results of Operations

The following table summarizes our consolidated results for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	Year Ended December 31,		
	2021	2020 [(1)]	2019 [(1)]
Net sales	$ 1,035,365	$ 934,241	$ 1,084,170
Cost of sales	329,371	339,478	360,365
Gross profit	705,994	594,763	723,805
Operating expenses:			
Selling, general and administrative	471,904	446,561	528,466
Research and development	183,414	152,902	146,849
Impairment of disposal group	—	180,160	—
Impairment of goodwill	—	21,269	42,417
Impairment of long-lived assets	—	6,762	142,517
Other operating expenses	51,460	61,008	35,110
Operating loss from continuing operations	(784)	(273,899)	(171,554)
Interest income	435	131	803
Interest expense	(50,151)	(40,837)	(15,091)
Loss on debt extinguishment	(60,238)	(1,407)	—
Foreign exchange and other gains/(losses)	(13,734)	(32,010)	(2,536)
Loss from continuing operations before tax	(124,472)	(348,022)	(188,378)
Income tax expense (benefit)	11,198	(960)	(30,374)
Losses from equity method investments	(148)	(264)	—
Net loss from continuing operations	(135,818)	(347,326)	(158,004)
Net (loss) income from discontinued operations, net of tax	—	(1,493)	365
Net loss	$ (135,818)	$ (348,819)	$ (157,639)

(1) The consolidated results the years ended December 31, 2020 and 2019 have been revised. For further details refer to “Note 1. Nature of Operations” in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

Net Sales by Segment and Geographic Area:

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

	Year Ended December 31,			% Change	
	2021	2020	2019	2021 vs 2020	2020 vs 2019
Cardiopulmonary					
United States	$ 154,073	$ 132,543	$ 161,471	16.2 %	(17.9)%
Europe [1]	134,562	122,062	135,632	10.2 %	(10.0)%
Rest of World	194,344	192,127	207,613	1.2 %	(7.5)%
	482,979	446,732	504,716	8.1 %	(11.5)%
Neuromodulation					
United States	358,476	282,509	335,332	26.9 %	(15.8)%
Europe [1]	51,435	39,019	46,262	31.8 %	(15.7)%
Rest of World	46,261	32,916	42,953	40.5 %	(23.4)%
	456,172	354,444	424,547	28.7 %	(16.5)%
Advanced Circulatory Support					
United States	53,821	41,094	30,781	31.0 %	33.5 %
Europe [1]	1,120	1,027	741	9.1 %	38.6 %
Rest of World	518	200	401	159.0 %	(50.1)%
	55,459	42,321	31,923	31.0 %	32.6 %
Other [2]					
United States	4,929	12,488	18,900	(60.5)%	(33.9)%
Europe [1]	14,407	31,259	40,548	(53.9)%	(22.9)%
Rest of World	21,419	46,997	63,536	(54.4)%	(26.0)%
	40,755	90,744	122,984	(55.1)%	(26.2)%
Totals					
United States	571,299	468,634	546,484	21.9 %	(14.2)%
Europe [1]	201,525	193,367	223,183	4.2 %	(13.4)%
Rest of World	262,541	272,240	314,503	(3.6)%	(13.4)%
Total	$ 1,035,365	$ 934,241	$ 1,084,170	10.8 %	(13.8)%

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

(2) Other primarily includes the net sales of the Company's Heart Valves business, which was disposed of on June 1, 2021.

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

	Year Ended December 31,			% Change	
	2021	2020 [1]	2019 [1]	2021 vs 2020	2020 vs 2019
Cardiopulmonary	$ (6,429)	$ 35,735	$ 50,533	(118.0)%	(29.3)%
Neuromodulation	169,499	109,273	83,333	55.1 %	31.1 %
Advanced Circulatory Support	2,195	(575)	3,941	(481.7)%	(114.6)%
Other [2]	(129,082)	(365,116)	(233,275)	(64.6)%	56.5 %
Total reportable segment income (loss) from continuing operations [3]	$ 36,183	$ (220,683)	$ (95,468)	(116.4)%	131.2 %

(1) Segment loss from continuing operations for the years ended December 31, 2020 and 2019 have been revised. For further details refer to "Note 1. Nature of Operations" in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

(2) Other includes the results of the Company's Heart Valves business, which was disposed of on June 1, 2021, and corporate shared service expenses for finance, legal, human resources, information technology and corporate business development.

(3) For a reconciliation of segment income (loss) from continuing operations to our consolidated loss from continuing operations before tax, refer to "Note 19. 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.

Cardiopulmonary

Cardiopulmonary net sales for the year ended December 31, 2021 compared to the year ended December 31, 2020 increased 8.1% to $483.0 million primarily due to growth in oxygenator sales resulting from an increase in procedure volumes, across all regions, growth in heart-lung machine sales in the U.S. region, as well as the favorable impact of foreign currency fluctuations, partially offset by a reduction in capital equipment purchases in the Rest of World region.

Cardiopulmonary segment operating loss for the year ended December 31, 2021 was $6.4 million as compared to segment operating income for the year ended December 31, 2020 of $35.7 million. The decrease in segment operating income was primarily due to an increase in the litigation provision related to our 3T Heater-Cooler device and related legal costs of $37.8 million, as well as an increase in sales and marketing expenses due to lower 2020 commercial related variable and discretionary spending as a result of COVID-19 during the year ended December 31, 2020 and an increase in research and development expenses due to the upcoming launch of our next-generation heart-lung machine. These increases in expenses were partially offset by an increase in sales, as discussed above.

Cardiopulmonary net sales for the year ended December 31, 2020 compared to the year ended December 31, 2019 decreased 11.5% to $446.7 million primarily due to declines in heart lung machines (“HLM”) and oxygenator sales. HLM sales were negatively impacted due to COVID-19 impacts on hospital budgets for capital equipment, while oxygenator sales were negatively impacted by a decline of non-emergent cardiac surgery procedures globally resulting from COVID-19.

Cardiopulmonary segment operating income decreased 29.3% for the year ended December 31, 2020 as compared to the year ended December 31, 2019, primarily due to the decrease in net sales, as discussed above.

Neuromodulation

Neuromodulation net sales for the year ended December 31, 2021 compared to the year ended December 31, 2020 increased 28.7% to $456.2 million primarily due to improving market dynamics across all regions resulting from increased hospital access and patient willingness to return to clinics.

Neuromodulation segment operating income increased 55.1% for the year ended December 31, 2021 compared to the year ended December 31, 2020 primarily from an increase in sales, as discussed above. This increase was partially offset by the net impact of the change in fair value of the sales-based and milestone-based contingent consideration arrangement associated with the acquisition of ImThera of $21.5 million, as well as an increase in sales and marketing expenses due to lower 2020 commercial related variable and discretionary spending as a result of COVID-19 during the year ended December 31, 2020 and an increase in research and development expenses due to our DTD and heart failure clinical trials.

Neuromodulation net sales for the year ended December 31, 2020 compared to the year ended December 31, 2019 decreased 16.5% to $354.4 million. The decrease in net sales for the year ended December 31, 2020 was primarily due to declines in both new patient and end of service implants globally as patients and physicians delayed implant procedures due to COVID-19.

Neuromodulation segment operating income increased 31.1% for the year ended December 31, 2020 compared to the year ended December 31, 2019 primarily due to an increase in operating income resulting from the net impact of the change in fair value of contingent consideration arrangements of $27.6 million, a decrease in selling, general and administrative expense driven by cost containment actions, as well as a $50.3 million impairment of an IPR&D asset during the year ended December 31, 2019, partially offset by overall declines in net sales, as discussed above.

Advanced Circulatory Support

Advanced Circulatory Support net sales for the year ended December 31, 2021 compared to the year ended December 31, 2020 increased 31.0% to $55.5 million, resulting from continued adoption and utilization of LifeSPARC in the U.S. and an increase in procedure volumes.

Advanced Circulatory Support segment operating income increased 481.7% for the year ended December 31, 2021 compared to the year ended December 31, 2020 primarily from an increase in sales, as discussed above. This increase was partially offset by an increase in sales and marketing expenses due to lower commercial related variable and discretionary spending as a result of COVID-19 during the year ended December 31, 2020.

Advanced Circulatory Support net sales for the year ended December 31, 2020 compared to the year ended December 31, 2019 increased 32.6% to $42.3 million for the year ended December 31, 2020, resulting from the full U.S. commercial release of LifeSPARC during the second half of 2020.

Advanced Circulatory Support segment operating income decreased 114.6% for the year ended December 31, 2020 compared to the year ended December 31, 2019 primarily due to an increase in R&D expense resulting from the net impact of the change in fair value of a milestone-based contingent consideration arrangement of $8.5 million, partially offset by an increase in net sales, as discussed above.

Costs and Expenses

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

	Year Ended December 31,		
	2021	2020	2019
Cost of sales	31.8 %	36.3 %	33.2 %
Selling, general and administrative	45.6 %	47.8 %	48.7 %
Research and development	17.7 %	16.4 %	13.5 %
Impairment of disposal group	— %	19.3 %	— %
Impairment of goodwill	— %	2.3 %	3.9 %
Impairment of long-lived assets	— %	0.7 %	13.1 %
Other operating expenses	5.0 %	6.5 %	3.2 %

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 31.8% for the year ended December 31, 2021, a decrease of 4.5% as compared to 2020. The decrease was primarily due to favorable product mix, partially due to the sale of the Heart Valves business during the second quarter of 2021, unfavorable manufacturing variances during the year ended December 31, 2020, as well as a decline in product remediation expenses associated with our 3T Heater-Cooler device of $7.0 million. These decreases were partially offset by the net impact of the change in fair value of a sales-based contingent consideration arrangement of $4.5 million for the year ended December 31, 2021 compared to the year ended December 31, 2020.

Cost of sales as a percentage of net sales was 36.3% for the year ended December 31, 2020, an increase of 3.1% as compared to 2019. The increase was primarily due to product mix and unfavorable manufacturing variances of $20.0 million for the year ended December 31, 2020 due to the decline in demand resulting from COVID-19.

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

SG&A expenses are comprised of sales, marketing, general and administrative activities.

SG&A expenses as a percentage of net sales decreased for the year ended December 31, 2021 as compared to 2020 primarily due to an increase in sales, partially offset by an increase in sales and marketing expenses due to lower commercial related variable and discretionary spending as a result of COVID-19 during the year ended December 31, 2020.

SG&A expenses as a percentage of net sales decreased for the year ended December 31, 2020 as compared to 2019 primarily due to sales and marketing reductions from cost containment actions resulting from COVID-19, a decrease in 3T legal expenses and the settlement of tax litigation that resulted in the release of an uncertain tax position of $4.3 million.

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, OSA and heart failure.

R&D expenses as a percentage of net sales increased for the year ended December 31, 2021 as compared to 2020 primarily due to an increase in R&D expense resulting from the net impact of changes in fair value of milestone-based contingent consideration arrangements of $16.6 million as well as an increase in research and development expenses due to the upcoming launch of our next-generation heart-lung machine and due to our DTD and heart failure clinical trials.

R&D expenses as a percentage of net sales increased for the year ended December 31, 2020 as compared to 2019 primarily due to a decline in net sales as well as an increase in R&D expense resulting from the net impact of changes in fair value of milestone-based contingent consideration arrangements of $8.8 million.

Impairments of Disposal Group, Goodwill and Long-lived Assets

During the year ended December 31, 2020, we recognized an impairment of $180.2 million to record the Heart Valves disposal group at fair value less estimated cost to sell. Additionally, during the year ended December 31, 2020, we recorded a

$21.3 million impairment to the goodwill allocated to the Heart Valves disposal group based upon the relative fair values of the businesses. For further information refer to “Note 4. Divestiture of Heart Valve Business” in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

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.

The 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 associated with the Caisson business of $42.4 million and $89.0 million, respectively during the year ended December 31, 2019.

Other Operating Expenses

Other operating expenses consists primarily of the provision for litigation involving our 3T Heater-Cooler device, the provision for the decommissioning of hazardous substances at our site in Saluggia, Italy, merger and integration expense, restructuring expense, and the loss on the on sale of our Heart Valves business.

Other operating expenses as a percentage of net sales for the year ended December 31, 2021 compared to the year ended December 31, 2020 decreased primarily due to a $42.2 million provision recognized in 2020 for our obligation to clean and dismantle contaminated buildings and equipment at our Saluggia, Italy campus as well as to deliver hazardous substances to a national repository. For further information, refer to “Note 13. Commitments and Contingencies” in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K. This decrease was partially offset by an increase in the litigation provision related to our 3T Heater-Cooler device of $34.2 million.

Other operating expenses as a percentage of net sales for the year ended December 31, 2020 compared to the year ended December 31, 2019 increased primarily due to a $42.2 million provision for our obligation to clean and dismantle contaminated buildings and equipment at our Saluggia, Italy campus as well as to deliver hazardous substances to a national repository, as discussed above. This increase was partially offset by a decrease in merger and integration expenses primarily due to completion of certain integration activities associated with our merger and acquisitions.

Interest Expense

We incurred interest expense of $50.2 million for the year ended December 31, 2021, as compared to $40.8 million and $15.1 million for 2020 and 2019, respectively. The increase for the year ended December 31, 2021 as compared to 2020 was primarily due to $10.5 million in increased interest expense in 2021 from the exchangeable notes that were entered into in June 2020. The increase for the year ended December 31, 2020 as compared to 2019 was primarily due to increased average debt borrowings at increased effective borrowing rates. For further information on our debt refer to “Note 10. Financing Arrangements” in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

Loss on Debt Extinguishment

Loss on debt extinguishment for the year ended December 31, 2021 resulted from the early repayment and termination of the Company’s 2020 senior secured term loan and revolving credit facility with ACF FINCO I LP, respectively, totaling $60.2 million. For further details on the loss on debt extinguishment, refer to “Note 10. Financing Arrangements” in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

Foreign Exchange and Other Gains/(Losses)

Foreign exchange and other gains/(losses) consist primarily of gains and losses arising from transactions denominated in a currency different from an entity’s functional currency, foreign currency exchange rate derivative gains and losses and changes in the fair value of embedded and capped call derivatives.

Foreign exchange and other gains/(losses) was a loss of $13.7 million for the year ended December 31, 2021, as compared to losses of $32.0 million and $2.5 million for 2020 and 2019, respectively. For further details, refer to “Note 20. Supplemental Financial Information” in our consolidated financial statements and accompanying notes, beginning on page F-1 of this Annual Report on Form 10-K.

Income Taxes

LivaNova PLC is 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, changes in valuation allowances, 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 was (9.0%), 0.3% and 16.1% for the years ended December 31, 2021, 2020 and 2019, respectively. Our effective income tax rate fluctuates based on, among other factors, changes in pretax income in countries with varying statutory tax rates, changes in valuation allowances, changes in tax credits and incentives and changes in unrecognized tax benefits associated with uncertain tax positions.

Compared with the year ended December 31, 2020, the decrease in the effective tax rate for 2021 was primarily attributable to changes in valuation allowances, the tax impact of the sale of the Heart Valve business and the early repayment and termination of the Company's 2020 senior secured term loan. Comparatively, the effective tax rate for 2020 included the tax benefits related to the Coronavirus Aid, Relief and Economic Security ("CARES") Act, the release of the uncertain tax positions upon the settlement of tax litigation in Italy and other items, offset by an increase to the valuation allowance of the UK and other jurisdictions.

Compared with the year ended December 31, 2019, the decrease in the effective tax rate for 2020 was primarily attributable to a tax benefit related to the Coronavirus Aid, Relief and Economic Security ("CARES") Act, the tax benefit due to the release of the uncertain tax positions upon the settlement of tax litigation in Italy and other items, offset by an increase to the valuation allowance of the UK and other jurisdictions. Comparatively, the effective tax rate for 2019 included a release of uncertain tax positions and a U.S. federal tax benefit from a return to provision reconciliation, partly offset by the valuation allowance for a portion of the U.S. federal and state net operating losses and attributes.

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" and "Note 3. Revenue Recognition" 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 22. 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:

Goodwill and Long-Lived Assets

We allocate the purchase price consideration 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 allocate any excess purchase price over the fair value of the net tangible and identifiable intangible assets acquired to 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.

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 review, each reporting period if there are circumstances that warrant an evaluation of the carrying amounts of our property and equipment and our finite-lived 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. Long-lived assets held and used are assessed for possible impairment by comparing their carrying values with their associated undiscounted, future cash flows. In order to calculate the impairment charge, 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.

We estimate the useful lives of our finite-lived intangible assets, which requires significant management judgment. We evaluate our intangible assets each reporting period to determine whether events and circumstances indicate a different useful life.

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. Estimating the fair value of goodwill requires various assumptions, including revenue growth rates and discount rates. We performed a sensitivity analysis for our Cardiopulmonary, Neuromodulation and Advanced Circulatory Support reporting units, as of October 1, 2021, for each of these assumptions and determined that an increase of 0.5% in the discount rate used, or a decrease of 0.5% in the expected revenue growth rate would not result in an impairment of goodwill. Estimating the fair value of indefinite-lived intangible assets requires various assumptions, including revenue growth rates, timing and probability of commercialization, and discount rates. We performed a sensitivity analysis, as of October 1, 2021, for each of these assumptions and determined that an increase of 0.5% in the discount rate, or a decrease of 0.5% in the expected revenue growth rate would not result in an impairment of our indefinite-lived intangible asset. For additional information, please refer to “Note 4. Divestiture of Heart Valve Business” and “Note 7. Goodwill and Intangible Assets” in the consolidated financial statements in this Annual report on Form 10-K.

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 2015 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, 2021, if recognized, would reduce our income tax expense by approximately $1.7 million.

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.

For additional information, please refer to “Note 17. Income Taxes” in the consolidated financial statements in this Annual report on Form 10-K.

Legal and Other Contingencies

Provisions for legal contingencies are recognized when the Company determines it is probable that a loss has been incurred and the amount is reasonably estimable, the determination of which requires significant judgment. Estimates are used in assessing the likelihood of a loss being incurred and when determining a reasonable estimate of the loss for each claim. Final settlement amounts may be materially different from the provision recorded. For additional information, please refer to "Note 13. Commitments and Contingencies" in the consolidated financial statements in this Annual report on Form 10-K.

Contingent Consideration Liabilities

Contingent consideration liabilities are from 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 liabilities are measured at fair value each reporting period, the determination of which requires significant judgements and estimates. The fair value of contingent consideration is determined 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. For additional information, please refer to "Note 9. Fair Value Measurements" in the consolidated financial statements in this Annual report on Form 10-K.

Embedded Exchange Feature and Capped Call Derivatives

In June 2020, the Company issued cash exchangeable senior notes and entered into related capped call transactions. The cash exchangeable senior notes include an embedded exchange feature that is bifurcated from the cash exchangeable senior notes. The embedded exchange feature derivative is measured at fair value using a binomial lattice model and discounted cash flows that utilize observable and unobservable market data. The capped call derivative is measured at fair value using the Black-Scholes model utilizing observable and unobservable market data, including stock price, remaining contractual term, expected volatility, risk-free interest rate and expected dividend yield, as applicable. The Company uses historical volatility and implied volatility from options traded to determine expected stock price volatility which is an unobservable input that is significant to the valuation. For additional information, please refer to "Note 9. Fair Value Measurements" and "Note 10. Financing Arrangements" in the consolidated financial statements in this Annual report on Form 10-K.

New Accounting Pronouncements

For a discussion of new accounting standards and disclosure requirements, please refer to "Note 22. 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 sources of liquidity, which primarily consist of cash and cash equivalents, future cash generated from operations and available borrowings under our current debt facilities, will be sufficient to fund our uses of liquidity, primarily consisting of purchase obligations for expected operating, working capital and R&D needs, capital expenditures, and debt service requirements over the twelve-month period beginning from the issuance date of these consolidated financial statements. From time to time, we may decide to access debt and/or equity markets to optimize our capital structure, raise additional capital or increase liquidity as necessary, including to satisfy liabilities that may arise in connection with the SNIA litigation. On February 21, 2022, the Court of Appeal notified the Company that it granted the Company a suspension with respect to the payment of damages in the amount of €453.6 million (approximately U.S. $514.6 million at December 31, 2021) in the SNIA litigation until a decision has been reached on our appeal to the Italian Supreme Court. This suspension is subject to providing a first demand bank surety of €270.0 million (approximately U.S. $306.2 million) within 30 calendar days. On February 24, 2022, LivaNova PLC and its wholly-owned subsidiary, LivaNova USA, Inc. entered into an Incremental Facility Amendment No. 1 to the First Lien Credit Agreement with Goldman Sachs Bank USA, relating to a €200 million bridge loan facility (the "Bridge Loan Facility"). We intend to use the proceeds to secure the first demand bank surety of €270.0 million or, alternatively, for payment of court ordered damages or settlements (including interest, expenses and charges in connection therewith) in the event of a negative decision by the Italian Supreme Court. The Bridge Loan Facility has an availability period until June 30, 2022 and a maturity date 15 months after drawing. Borrowings under the Bridge Loan Facility bear interest at a rate equal to an adjusted EURIBOR (with a floor of 0.00%) plus 3.5% increasing by 0.25% 15 days after drawing and by an additional 0.5% 90 days after drawing and every 90 days thereafter, with a maximum margin of 5.25% over adjusted EURIBOR. Our liquidity could be adversely affected by the factors affecting future operating results, including those referred to in "Item 1A. Risk Factors" above and by the contingencies referred to in "Note 13. Commitments and Contingencies" in the consolidated financial statements in this Annual report on Form 10-K.

Our operating, working capital and R&D purchase obligations primarily consist of obligations arising from the normal course of business including inventory supply contract obligations, the future settlement of derivative instruments, and future payments of operating leases, as well as contingent consideration arrangements resulting from acquisitions, and obligations associated with legal and other accruals. The following table presents selected financial information related to our liquidity as of December 31, 2021 and 2020 (in thousands):

	December 31,	
	2021	2020
Sources of liquidity		
Cash and cash equivalents	$ 207,992	$ 252,832
Accounts receivable, net	185,354	184,356
Inventories	105,840	115,285
Short term derivative assets (1)	106,629	2,053
Availability under revolving credit facilities (2)	125,000	50,000
Short term uses of liquidity		
Short term derivative liabilities (1)	$ 183,109	$ 7,372
Short term debt (2)	229,673	13,343
Short term operating leases (3)	11,261	11,276
Short term contingent consideration (4)	11,552	13,968
Short term 3T litigation provision (5)	32,845	28,612
Long-term uses of liquidity		
Long-term debt (2)	$ 9,849	$ 642,298
Long-term operating leases (3)	35,919	42,221
Long-term contingent consideration (4)	86,830	89,850
Long-term Saluggia site liability (5)	38,788	42,476
Long-term 3T litigation provision (5)	6,625	7,878

(1) For additional information, please refer to “Note 11. Derivatives and Risk Management” in the consolidated financial statements in this Annual Report on Form 10-K.
(2) For additional information, please refer to “Note 10. Financing Arrangements” in the consolidated financial statements in this Annual Report on Form 10-K.
(3) For additional information, please refer to “Note 12. Leases” in the consolidated financial statements in this Annual Report on Form 10-K.
(4) For additional information, please refer to “Note 9. Fair Value Measurements” in the consolidated financial statements in this Annual Report on Form 10-K.
(5) For additional information, please refer to “Note 13. Commitments and Contingencies” in the consolidated financial statements in this Annual Report on Form 10-K.

Debt and Capital

Our capital structure consists of debt and equity. As of December 31, 2021, our total debt of $239.5 million was 18.5% of total equity of $1,294.6 million. As of December 31, 2020, our total debt of $655.6 million was 59.1% of total equity of $1,109.3 million.

During the year ended December 31, 2021, we repaid $452.3 million in long-term debt and paid $35.6 million for the make-whole premium associated with the early retirement of long-term debt. We received $322.6 million in net proceeds from the issuance of ordinary shares. Additionally, we reduced our short-term unsecured revolving credit agreements and other agreements with various banks by $2.0 million.

During the year ended December 31, 2020, we borrowed $886.9 million in long-term debt, incurred $23.7 million in debt issuance costs, and repaid $482.1 million in long-term debt. Additionally, we increased our short-term unsecured revolving credit agreements and other agreements with various banks by $1.3 million.

On June 17, 2020, our wholly-owned subsidiary, LivaNova USA, Inc., issued $287.5 million aggregate principal amount of 3.00% Cash Exchangeable Senior Notes due in 2025 (the “Notes”). Holders of the Notes are entitled to exchange the Notes at any time during specified periods, at their option. This includes the right to exchange the Notes during any calendar quarter, if the last reported sale price of LivaNova’s ordinary shares, with a nominal value of £1.00 per share, is greater than or equal to

130% of the exchange price, or $79.27 per share for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter. The exchange condition was satisfied on December 20, 2021, which allows the holders of the Notes to request to exchange the Notes through March 31, 2022. As a result, we have reclassified our obligations from the Notes and the associated embedded exchange feature derivative as a current liability on the consolidated balance sheet as of December 31, 2021. However, as of the date of filing of this Form 10-K, no holders have elected to exchange the Notes. The Notes are exchangeable solely into cash and are not exchangeable into ordinary shares of LivaNova or any other security under any circumstances. The initial exchange rate for the Notes is 16.3980 ordinary shares per $1,000 principal amount of Notes (equivalent to an initial exchange price of approximately $60.98 per share). The exchange rate is subject to adjustment in certain circumstances, as set forth in the indenture governing the Notes. If holders elect to exchange their Notes during the current period or any future periods in the event an exchange condition is met, we would be required to settle our exchange obligation through the payment of cash, which could adversely affect our liquidity. Currently, the Company believes it is unlikely the holders of the Notes will exchange significant amounts of the Notes.

The Company has also entered into privately negotiated capped call transactions with terms substantially similar to those applicable to the Notes. The capped call transactions are expected generally to offset any cash payments the Company is required to make upon exchange of the Notes in excess of the principal amount thereof in the event that the market value per ordinary share, as measured under the capped call transactions, is greater than the strike price of the capped call transactions, with such offset being subject to an initial cap price of $100.00 per share. The capped call transactions expire on December 15, 2025 and must be settled in cash. If the capped call transactions are converted or redeemed early, settlement occurs at their termination value, which is equal to their fair value at the time of the redemption. The capped call transactions are included at their estimated fair value as of December 31, 2021 within current derivative assets on the consolidated balance sheet.

On August 13, 2021, LivaNova PLC and its wholly-owned subsidiary, LivaNova USA, Inc. (the "Borrower") entered into a First Lien Credit Agreement with the lenders and issuing banks party thereto and Goldman Sachs Bank USA, as First Lien Administrative Agent and First Lien Collateral Agent, relating to a $125 million senior secured multi-currency revolving credit facility to be made available to the Borrower (the "2021 Revolving Credit Facility"). The 2021 Revolving Credit Facility is available for working capital and other general corporate purposes and, if drawn, can be repaid at any time without premium or penalty. There were no outstanding borrowings under the 2021 Revolving Credit Facility as of December 31, 2021.

On August 6, 2021, the Company closed an offering and issued 4,181,818 ordinary shares, par value £1.00 per share, at an offering price of $82.50 per share. Net proceeds from the offering were approximately $322.6 million, after deducting underwriting discounts, commissions and offering expenses. Proceeds from the offering were used to repay the Company's $450 million 2020 senior secured term loan.

Cash Flows

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

	Year Ended December 31,		
	2021	2020	2019
Operating activities	$ 102,544	$ (79,422)	$ (91,142)
Investing activities	36,904	(41,844)	(41,290)
Financing activities	(181,483)	310,756	146,581
Effect of exchange rate changes on cash and cash equivalents	(2,805)	2,205	(216)
Net (decrease) increase	$ (44,840)	$ 191,695	$ 13,933

Operating Activities

Cash provided by operating activities for the year ended December 31, 2021 increased $182.0 million as compared to the same prior-year period. The increase is primarily due to a decrease in 3T litigation settlement payments of $103.4 million, the receipt of a CARES Act tax refund of $24.5 million during the year ended December 31, 2021, and an increase in sales.

Cash used in operating activities for the year ended December 31, 2020 decreased $11.7 million as compared to 2019, primarily due to the effect of improved working capital management of $77.7 million, partially offset by a decrease in net income adjusted for non-cash items of $66.0 million, 3T litigation settlement payments made during 2019 and the change in operating assets and liabilities.

Investing Activities

Cash provided by investing activities during the year ended December 31, 2021 increased $78.7 million as compared to the same prior-year period. The increase is primarily due to proceeds from the sale of Heart Valves of $42.9 million, proceeds from the sale of LivaNova's investment in and loan to Respicardia totaling $23.1 million, as well as a decrease in purchases in property, plant and equipment of $9.5 million.

Cash used in investing activities during the year ended December 31, 2020 increased $0.6 million as compared to 2019. The increase is primarily due to an increase in purchases of property, plant and equipment of $10.3 million and an increase in purchases of investments and loans to investees totaling $3.4 million, partially offset by a decrease of $9.0 million in cash paid for acquisitions and a decrease in purchases of intangible assets of $3.3 million.

Financing Activities

Cash used in financing activities during the year ended December 31, 2021 increased $492.2 million as compared to the same prior year period. The increase is primarily due to a net repayment of borrowings during the year ended December 31, 2021 of $456.7 million compared to net proceeds from borrowings of $382.4 million in the prior year period, as well as a payment of $35.6 million for the make-whole premium on long-term debt obligations made during the year ended December 31, 2021. These increases were partially offset by the net proceeds from the issuance of ordinary shares of $322.6 million during the year ended December 31, 2021, as well as the purchase of a capped call associated with our Notes of $43.1 million and a closing adjustment payment for the sale of our former Cardiac Rhythm Management ("CRM") business of $14.9 million made during the year ended December 31, 2020.

Cash provided by financing activities during the year ended December 31, 2020 increased $164.2 million as compared to 2019, primarily due to an increase in net borrowings and associated costs of $214.5 million and a decrease in payments of contingents consideration of $6.9 million, partially offset by the purchase of a capped call associated with our Notes of $43.1 million and a closing adjustment payment for the sale of our former CRM business of $14.9 million.

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. 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, 2021.

(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, 2021 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, 2021.

The effectiveness of our internal control over financial reporting as of December 31, 2021 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 2021, 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.

Item 9B. *Other Information*

On February 24, 2022, LivaNova PLC and its wholly-owned subsidiary, LivaNova USA, Inc. entered into an Incremental Facility Amendment No. 1 to the First Lien Credit Agreement with Goldman Sachs Bank USA, with the lenders and issuing banks party thereto and Goldman Sachs Bank USA, as a First Lien Administrative Agent, relating to a €200 million bridge loan facility. The proceeds may be used to secure the first demand bank surety of €270.0 million required in connection with the SNIA litigation or, alternatively, for payment of court ordered damages or settlements (including interest, expenses and charges in connection therewith) in the event of a negative decision by the Italian Supreme Court. The Bridge Loan Facility has an availability period until June 30, 2022 and a maturity date 15 months after drawing. Borrowings under the Bridge Loan Facility bear interest at a rate equal to an adjusted EURIBOR (with a floor of 0.00%) plus 3.50% increasing by 0.25% 15 days after drawing and by an additional 0.5% 90 days after drawing and every 90 days thereafter, with a maximum margin of 5.25% over adjusted EURIBOR.

Item 9C. *Disclosure Regarding Foreign Jurisdictions that Prevent Inspections*

Not applicable.

PART III

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

The information required for this Item 10 is incorporated by reference from our definitive Proxy Statement for the annual meeting of stockholders to be held on June 13, 2022 (the "2022 Proxy Statement").

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 from our 2022 Proxy Statement.

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 from our 2022 Proxy Statement.

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

The information required for this Item 13 is incorporated by reference from our 2022 Proxy Statement.

Item 14. *Principal Accounting Fees and Services*

The information required for this Item 14 is incorporated by reference from our 2022 Proxy Statement.

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	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
2.2	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
2.3	Share and Asset Purchase Agreement, dated as of December 2, 2020, by and between LivaNova PLC and Mitral Holdco S.a.r.l., incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K, filed on December 3, 2020
3.1	Amended Articles of Association, incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020
4.1*	Description of Securities Registered Under Section 12 of the Exchange Act
4.2	Indenture, dated as of June 17, 2020, among LivaNova USA, Inc., as Issuer, LivaNova PLC, as Guarantor, and Citibank, N.A., as Trustee, incorporated by reference to Exhibit 4.1 of the Company's current Report on Form 8-K, filed on June 17, 2020
4.3	Form of 3.00% Cash Exchangeable Senior Notes due 2025 (included in Exhibit 4.1 of the Company's current Report on Form 8-K, filed on June 17, 2020)
10.1†	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
10.2†	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
10.3†	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
10.4†	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

10.5†	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
10.6	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
10.7†	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
10.8†	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
10.9†	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
10.10†	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
10.11†	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
10.12†	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
10.13	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
10.14	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
10.15†	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
10.16†	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
10.17†	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
10.18†	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
10.19†	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
10.20†	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
10.21†	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
10.22†	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
10.23†	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
10.24†	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
10.25†	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
10.26†	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
10.27†	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
10.28†	Separation Agreement, dated December 2019, between Edward S. Andrle and LivaNova USA, Inc., incorporated by reference to Exhibit 10.47 of the Company's Annual Report on Form 10-K for the year ended December 31, 2019
10.29	Credit Agreement, dated as of June 10, 2020 , among LivaNova USA, Inc., as Borrower, the Company, as Guarantor, the several lenders from time to time parties thereto, Ares Capital Corporation, as Administrative Agent, and Ares Capital Corporation, as Collateral Agent incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed on June 11, 2020
10.30	Form of Capped Call Confirmation incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed on June 17, 2020
10.31†	Amendment to Outstanding 2019 and 2020 Restricted Stock Unit Awards under the LivaNova PLC 2015 Incentive Award Plan, dated June 15, 2020, incorporated by reference to Exhibit 10.10 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020
10.32†	Amendment to Outstanding 2018 Restricted Stock Unit Awards under the LivaNova PLC 2015 Incentive Award Plan dated June 15, 2020, incorporated by reference to Exhibit 10.11 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020

10.33†	Amendment to Outstanding 2018, 2019 and 2020 Performance Stock Unit Awards under the LivaNova PLC 2015 Incentive Award Plan, dated June 15, 2020, incorporated by reference to Exhibit 10.12 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020
10.34†	Form of Long Term Incentive Plan Restricted Stock Unit Award Agreement, incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020
10.35†	Form of Long Term Incentive Plan Performance Stock Unit Award Agreement, incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020
10.36†	Form of Long Term Incentive Plan Stock Appreciation Right Award Agreement, incorporated by reference to Exhibit 10.3 of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020
10.37†	Form of Director Restricted Stock Unit Award Grant Notice, dated June 2020 and Director Restricted Stock Unit Award Agreement under the Company's 2015 Incentive Award Plan (Non-Employee Directors), incorporated by reference to Exhibit 10.42 of the Company's Annual Report on Form 10-K for the year ended December 31, 2020
10.38†	Form of Non-Executive Director Appointment Letter incorporated by reference to Exhibit 10.43 of the Company's Annual Report on Form 10-K for the year ended December 31, 2020
10.39†	Alex Shvartsburg offer of employment in the role of Vice President Strategy and Innovation, dated 21 September 2017 incorporated by reference to Exhibit 10.44 of the Company's Annual Report on Form 10-K for the year ended December 31, 2020
10.40†	Alex Shvartsburg letter, dated January 2019, regarding compensation increase incorporated by reference to Exhibit 10.45 of the Company's Annual Report on Form 10-K for the year ended December 31, 2020
10.41†	Alex Shvartsburg letter, dated October 2020, regarding additive compensation package for interim CFO position incorporated by reference to Exhibit 10.46 of the Company's Annual Report on Form 10-K for the year ended December 31, 2020
10.42†	Service Agreement, effective August 1, 2021, between the Company and Alex Shvartsburg, incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021
10.43†	Roy Khoury Separation and Settlement Agreement, dated February 2021 incorporated by reference to Exhibit 10.47 of the Company's Annual Report on Form 10-K for the year ended December 31, 2020
10.44	Conformed Copy Incorporating Amendment No. 1, dated December 30, 2020, to Credit Agreement, dated June 10, 2020, among LivaNova USA, Inc., as Borrower, the Company, as Guarantor, the several lenders from time to time parties thereto, Ares Capital Corporation, as Administrative Agent, and Ares Capital Corporation, as Collateral Agent incorporated by reference to Exhibit 10.48 of the Company's Annual Report on Form 10-K for the year ended December 31, 2020
10.45	Amendment No. 2 to Credit Agreement among LivaNova USA, Inc., as Borrower, LivaNova PLC, as Holdings, and Ares Capital Corporation, as Administrative Agent and Collateral Agent, and certain other Lenders party thereto, dated as of February 24, 2021 incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed on February 24, 2021
10.46†	Marco Dolci Confirmation Letter, effective January 1, 2020, as SVP Global Operations & Global Research and Development, incorporated by reference to Exhibit 10.2 of the Company Quarterly Report on Form 10-Q for the quarter ended June 30, 2020
10.47†	Executive Employment Contract between Sorin Group Italia S.r.l. and Marco Dolci, effective April 20, 2017, incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021
10.48	Amended and Restated Share and Asset Purchase Agreement, dated as of April 9, 2021, by and between LivaNova PLC and Mitral Holdco S.a.r.l., incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K, filed on April 15, 2021
10.49	Underwriting Agreement dated August 3, 2021, by and between LivaNova PLC and Goldman Sachs & Co. LLC, Barclays Capital Inc. and UBS Securities LLC as representatives of the underwriters listed on Schedule I thereto, incorporated by reference to Exhibit 1.1 of the Company's Current Report on Form 8-K, filed on August 3, 2021
10.50	First Lien Credit Agreement dated as of August 13, 2021 among LivaNova PLC, LivaNova USA, Inc., the lenders and issuing banks party thereto and Goldman Sachs Bank USA as First Lien Administrative Agent and First Lien Collateral Agent, incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K, filed on August 16, 2021
10.51*	Incremental Facility Amendment No. 1 to Credit Agreement, dated as of February 24, 2022, by and among LivaNova Plc, LivaNova USA, Inc., the lenders and issuing banks party thereto and Goldman Sachs Bank USA as First Lien Administrative Agent
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

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, 2021, December 31, 2020 and December 31, 2019, (ii) the Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2021, December 31, 2020 and December 31, 2019, (iii) the Consolidated Balance Sheets as of December 31, 2021 and December 31, 2020, (iv) the Consolidated Statements of Stockholders' Equity for the years ended December 31, 2021, December 31, 2020 and December 31, 2019, (v) the Consolidated Statements of Cash Flows for the years ended December 31, 2021, December 31, 2020 and December 31, 2019, 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/ ALEX SHVARTSBURG

Alex Shvartsburg
Chief Financial Officer
(Principal Accounting and Financial Officer)

Date: March 1, 2022

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/ WILLIAM A. KOZY William A. Kozy	Chairman of the Board of Directors	March 1, 2022
/s/ DAMIEN MCDONALD Damien McDonald	Director, Chief Executive Officer *(Principal Executive Officer)*	March 1, 2022
/s/ ALEX SHVARTSBURG Alex Shvartsburg	Chief Financial Officer *(Principal Accounting and Financial Officer)*	March 1, 2022
/s/ FRANCESCO BIANCHI Francesco Bianchi	Director	March 1, 2022
/s/ DANIEL J. MOORE Daniel J. Moore	Director	March 1, 2022
/s/ ALFRED J. NOVAK Alfred J. Novak	Director	March 1, 2022
/s/ SHARON O'KANE Sharon O'Kane, Ph.D.	Director	March 1, 2022
/s/ ARTHUR L. ROSENTHAL Arthur L. Rosenthal, Ph.D.	Director	March 1, 2022
/s/ ANDREA L. SAIA Andrea L. Saia	Director	March 1, 2022
/s/ TODD C. SCHERMERHORN Todd C. Schermerhorn	Director	March 1, 2022
/s/ STACY ENXING SENG Stacy Enxing Seng	Director	March 1, 2022

Item 16. Form 10-K Summary

None.

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, 2021 and 2020 and the related consolidated statements of income (loss), of comprehensive income (loss), of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2021, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 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, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

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 matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Goodwill Impairment Assessment – Cardiopulmonary (CP) and Advanced Circulatory Support (ACS) Reporting Units

As described in Notes 2 and 7 to the consolidated financial statements, the Company's consolidated goodwill balance was $899.5 million as of December 31, 2021, and the amount of goodwill associated with the CP and ACS reporting units was $398.2 million and $102.5 million, respectively. Management conducts impairment testing of goodwill on October 1st 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 using a discounted cash flow model and requires various assumptions, including revenue growth rates and discount rates.

The principal considerations for our determination that performing procedures relating to the goodwill impairment assessments of the CP and ACS reporting units is a critical audit matter are (i) the significant judgment by management when developing the fair value of the reporting units; (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating management's significant assumptions relating to revenue growth rates for CP and ACS, and discount rate for ACS; and (iii) the audit effort involved the use of professionals with specialized skill and knowledge.

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 assessments. These procedures also included, among others (i) testing management's process for developing the fair value of the CP and ACS reporting units; (ii) evaluating the appropriateness of the discounted cash flow model; (iii) testing the completeness and accuracy of underlying data used in the model; and (iv) evaluating the reasonableness of the significant assumptions used by management related to the revenue growth rates for CP and ACS, and the discount rate for ACS. Evaluating management's assumptions related to the revenue growth rates involved evaluating whether the assumptions used by management were reasonable considering (i) the current and past performance of the reporting units; (ii) the consistency with external market and industry data; and (iii) whether these 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 Company's discounted cash flow model and the discount rate assumption.

/s/ PricewaterhouseCoopers LLP
Houston, Texas
March 1, 2022

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

LIVANOVA PLC AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF INCOME (LOSS)

(In thousands, except per share amounts)

	Year Ended December 31,		
	2021	**2020 [1]**	**2019 [1]**
Net sales	$ 1,035,365	$ 934,241	$ 1,084,170
Cost of sales	329,371	339,478	360,365
Gross Profit	705,994	594,763	723,805
Operating expenses:			
Selling, general & administrative	471,904	446,561	528,466
Research & development	183,414	152,902	146,849
Impairment of disposal group	—	180,160	—
Impairment of goodwill	—	21,269	42,417
Impairment of long-lived assets	—	6,762	142,517
Other operating expenses	51,460	61,008	35,110
Operating loss from continuing operations	(784)	(273,899)	(171,554)
Interest income	435	131	803
Interest expense	(50,151)	(40,837)	(15,091)
Loss on debt extinguishment	(60,238)	(1,407)	—
Foreign exchange and other gains/(losses)	(13,734)	(32,010)	(2,536)
Loss from continuing operations before tax	(124,472)	(348,022)	(188,378)
Income tax expense (benefit)	11,198	(960)	(30,374)
Losses from equity method investments	(148)	(264)	—
Net loss from continuing operations	(135,818)	(347,326)	(158,004)
Net (loss) income from discontinued operations, net of tax	—	(1,493)	365
Net loss	$ (135,818)	$ (348,819)	$ (157,639)
Basic loss per share:			
Continuing operations	$ (2.68)	$ (7.15)	$ (3.27)
Discontinued operations	—	(0.03)	0.01
	$ (2.68)	$ (7.18)	$ (3.26)
Diluted loss per share:			
Continuing operations	$ (2.68)	$ (7.15)	$ (3.27)
Discontinued operations	—	(0.03)	0.01
	$ (2.68)	$ (7.18)	$ (3.26)
Shares used in computing basic loss per share	50,633	48,592	48,349
Shares used in computing diluted loss per share	50,633	48,592	48,349

(1) The consolidated statements of income (loss) for the years ended December 31, 2020 and 2019 have been revised. For further details refer to “Note 1. Nature of Operations.”

See accompanying notes to the consolidated financial statements

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

	Year Ended December 31,		
	2021	**2020 (1)**	**2019 (1)**
Net loss	$ (135,818)	$ (348,819)	$ (157,639)
Other comprehensive (loss) income:			
Net change in unrealized (loss) gain on derivatives	(3,997)	2,379	1,917
Tax effect	733	(573)	(460)
Net of tax	(3,264)	1,806	1,457
Foreign currency translation adjustment, net of tax	(31,722)	45,395	3,627
Total other comprehensive (loss) income	(34,986)	47,201	5,084
Total comprehensive loss	$ (170,804)	$ (301,618)	$ (152,555)

(1) The consolidated statements of comprehensive income (loss) for the years ended December 31, 2020 and 2019 have been revised. For further details refer to “Note 1. Nature of Operations.”

LIVANOVA PLC AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2021 and 2020
(In thousands, except share data)

ASSETS	**2021**	**2020 (1)**
Current Assets:		
Cash and cash equivalents	$ 207,992	$ 252,832
Accounts receivable, net of allowance of $13,512 at December 31, 2021 and $10,310 at December 31, 2020	185,354	184,356
Inventories	105,840	115,285
Prepaid and refundable taxes	37,621	60,240
Assets held for sale	—	70,539
Current derivative assets	106,629	2,053
Prepaid expenses and other current assets	35,745	22,739
Total Current Assets	679,181	708,044
Property, plant and equipment, net	150,066	163,805
Goodwill	899,525	922,318
Intangible assets, net	399,682	437,636
Operating lease assets (Note 12)	40,600	50,525
Investments	16,598	31,094
Deferred tax assets	2,197	2,990
Long-term derivative assets	—	72,302
Other assets	13,102	11,247
Total Assets	$ 2,200,951	$ 2,399,961
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Current debt obligations	$ 229,673	$ 13,343
Accounts payable	68,000	73,668
Accrued liabilities and other	88,937	88,036
Current derivative liabilities	183,109	7,372
Current litigation provision liability	32,845	28,612
Taxes payable	15,140	16,463
Accrued employee compensation and related benefits	79,266	51,879
Liabilities held for sale	—	29,679
Total Current Liabilities	696,970	309,052
Long-term debt obligations	9,849	642,298
Contingent consideration	86,830	89,850
Deferred tax liabilities	7,728	7,089
Long-term operating lease liabilities (Note 12)	35,919	42,221
Long-term employee compensation and related benefits	19,105	20,628
Long-term derivative liabilities	—	121,940
Other long-term liabilities	49,905	57,618
Total Liabilities	906,306	1,290,696
Commitments and contingencies (Note 13)		
Stockholders' Equity:		
Ordinary Shares, £1.00 par value: unlimited shares authorized; 53,761,510 shares issued and 53,263,297 shares outstanding at December 31, 2021; 49,447,473 shares issued and 48,655,863 shares outstanding at December 31, 2020	82,295	76,300
Additional paid-in capital	2,117,961	1,768,156
Accumulated other comprehensive (loss) income	(7,177)	27,809
Accumulated deficit	(897,784)	(761,966)
Treasury stock at cost, 498,213 ordinary shares at December 31, 2021, 791,610 ordinary shares at December 31, 2020	(650)	(1,034)
Total Stockholders' Equity	1,294,645	1,109,265
Total Liabilities and Stockholders' Equity	$ 2,200,951	$ 2,399,961

(1) The consolidated balance sheet as of December 31, 2020 has been revised. For further details refer to "Note 1. Nature of Operations."

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 [(1)]	Total Stockholders' Equity [(1)]
December 31, 2018	49,323	$ 76,144	$ 1,705,111	$ (1,462)	$ (24,476)	$ (254,869)	$ 1,500,448
Stock-based compensation plans	88	113	29,759	199	—	—	30,071
Net loss [(1)]	—	—	—	—	—	(157,639)	(157,639)
Other comprehensive income	—	—	—	—	5,084	—	5,084
December 31, 2019	49,411	76,257	1,734,870	(1,263)	(19,392)	(412,508)	1,377,964
Adoption of ASU No. 2016-13	—	—	—	—	—	(639)	(639)
Stock-based compensation plans	109	140	33,189	229	—	—	33,558
Cancellation of shares	(73)	(97)	97	—	—	—	—
Net loss [(1)]	—	—	—	—	—	(348,819)	(348,819)
Other comprehensive income	—	—	—	—	47,201	—	47,201
December 31, 2020	49,447	76,300	1,768,156	(1,034)	27,809	(761,966)	1,109,265
Issuance of shares	4,182	5,808	316,733	—	—	—	322,541
Stock-based compensation plans	133	187	33,072	384	—	—	33,643
Net loss	—	—	—	—	—	(135,818)	(135,818)
Other comprehensive loss	—	—	—	—	(34,986)	—	(34,986)
December 31, 2021	53,762	$ 82,295	$ 2,117,961	$ (650)	$ (7,177)	$ (897,784)	$ 1,294,645

(1) Accumulated deficit and total stockholders' equity as of December 31, 2020, 2019 and 2018, and net loss for the years ended December 31, 2020 and 2019 have been revised. For further details refer to "Note 1. Nature of Operations."

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

	Year Ended December 31,		
Operating Activities:	**2021**	**2020 [(1)]**	**2019 [(1)]**
Net loss	$ (135,818)	$ (348,819)	$ (157,639)
Non-cash items included in net loss:			
Loss on debt extinguishment	60,238	1,407	—
Stock-based compensation	40,564	35,089	32,553
Amortization	26,517	38,312	40,375
Depreciation	24,536	29,031	30,317
Remeasurement of derivative instruments	17,618	22,085	(26)
Amortization of operating lease assets	16,935	13,977	12,297
Amortization of debt issuance costs	16,657	9,710	2,204
Deferred tax expense (benefit)	2,852	37,068	(26,498)
Remeasurement of contingent consideration to fair value	564	(20,463)	(29,406)
Impairment of long-lived assets	—	6,762	142,517
Impairment of disposal group and loss on sale	1,942	180,160	—
Impairment of goodwill	—	21,269	42,417
Other	717	2,000	5,783
Changes in operating assets and liabilities:			
Accounts receivable, net	(15,745)	58,796	(5,321)
Inventories	4,484	5,438	(7,924)
Other current and non-current assets	24,127	(39,645)	(2,077)
Accounts payable and accrued current and non-current liabilities	12,993	(923)	(38,577)
Taxes payable	103	3,596	(8,442)
Litigation provision liability	3,260	(134,272)	(123,695)
Net cash provided by (used in) operating activities	**102,544**	**(79,422)**	**(91,142)**
Investing Activities:			
Proceeds from sale of Heart Valves, net of cash disposed	42,945	—	—
Purchases of property, plant and equipment	(25,478)	(35,024)	(24,691)
Proceeds from sale of Respicardia investment and loan	23,057	—	—
Purchase of investments	(3,653)	(3,184)	(2,500)
Acquisitions, net of cash acquired	(1,694)	(1,719)	(10,750)
Other	1,727	(1,917)	(3,349)
Net cash provided by (used in) investing activities	**36,904**	**(41,844)**	**(41,290)**
Financing Activities:			
Repayment of long-term debt obligations	(452,256)	(482,065)	(24,210)
Proceeds from issuance of ordinary shares, net	322,557	—	—
Payment of make-whole premium on long-term debt obligations	(35,594)	—	—
Shares repurchased from employees for minimum tax withholding	(12,942)	(5,601)	(7,064)
Payment of contingent consideration	(5,249)	(12,018)	(18,955)
Debt issuance costs	(2,450)	(23,736)	(3,795)
Proceeds from long-term debt obligations	—	886,899	197,160
Proceeds from short term borrowings (maturities greater than 90 days)	—	47,053	—
Repayments of short term borrowings (maturities greater than 90 days)	—	(44,838)	—
Purchase of capped call	—	(43,096)	—
Closing adjustment payment for sale of CRM business	—	(14,891)	—
Other	4,451	3,049	3,445
Net cash (used in) provided by financing activities	**(181,483)**	**310,756**	**146,581**
Effect of exchange rate changes on cash and cash equivalents	(2,805)	2,205	(216)
Net (decrease) increase in cash and cash equivalents	**(44,840)**	**191,695**	**13,933**
Cash and cash equivalents at beginning of period	252,832	61,137	47,204
Cash and cash equivalents at end of period	**$ 207,992**	**$ 252,832**	**$ 61,137**

(1) The consolidated statements of cash flows for the years ended December 31, 2020 and 2019 have been revised. For further details refer to "Note 1. Nature of Operations."

Supplementary Disclosures of Cash Flow Information:			
Cash paid for interest	$ 32,569	$ 28,573	$ 15,828
Cash paid for income taxes, net	(13,583)	7,493	2,011

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 products and therapies for the benefit of patients, healthcare professionals and healthcare systems throughout the world. We design, develop, manufacture and sell innovative products and therapies that are consistent with our mission to provide hope to patients through innovative medical technologies, delivering life-changing improvements for both the Head and Heart. We are a public limited company organized under the laws of England and Wales, and headquartered in London, England.

Business Segments

LivaNova is comprised of three reportable segments: Cardiopulmonary, Neuromodulation and Advanced Circulatory Support, corresponding to our primary business units. Other includes the results of our Heart Valves business, which was disposed of on June 1, 2021, and corporate shared service expenses for finance, legal, human resources, information technology and corporate business development.

Effective in the fourth quarter of 2021, LivaNova changed its reportable segments corresponding to changes in how the Company's chief operating decision maker regularly reviews information, allocates resources and assesses performance. The segment financial information presented herein reflects these changes for all periods presented. The Company's changes to its reportable segments are summarized as follows:

- The Company's Advanced Circulatory Support business is no longer assessed as part of the Company's previously reported Cardiovascular reportable segment and is evaluated independently as its own reportable segment.
- The Company's Cardiopulmonary business is no longer assessed as part of the Company's previously reported Cardiovascular reportable segment and is evaluated independently as its own reportable segment.
- The Company's Heart Valves business, which was disposed of on June 1, 2021, is now included within Other.

Recent Developments Regarding COVID-19

Since early 2020, the COVID-19 pandemic ("COVID-19") has caused and may continue to cause unpredictable demand for our products. Throughout the pandemic, healthcare customers have diverted medical resources and priorities towards the treatment of COVID-19, and public health bodies have delayed elective procedures, which has negatively impacted the usage of our products. Further, some people have avoided seeking treatment for non-COVID-19 procedures and hospitals and clinics have experienced staffing shortages, which has negatively impacted the demand for our products. While we have seen improvement during 2021, we continue to experience lingering COVID-19 related headwinds and are monitoring the potential for various strains of the virus to cause a resumption of high levels of infection and hospitalization, that in turn, may affect the demand for our products.

Revision of Previously Issued Financial Statements

During the fourth quarter of 2021, the Company identified and corrected an error related to foreign currency exchange rates utilized to calculate inventory and cost of sales for the years ended December 31, 2017 through 2020 and the nine months ended September 30, 2021. Using the guidance in ASC Topic 250, *Accounting Changes and Error Corrections*, ASC Topic 250-S99-1, *Assessing Materiality*, and ASC Topic 250-S99-2, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, we evaluated whether our previously issued consolidated financial statements were materially misstated due to these errors. Based upon our evaluation of both quantitative and qualitative factors, we believe that the effects of these errors were not material individually or in the aggregate to any previously reported quarterly or annual period. Accordingly, we have revised our previously issued financial statements as shown in Note 21 and below (in thousands):

Consolidated Statements of Income (Loss)

	Year Ended December 31, 2020			Year Ended December 31, 2019		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Cost of sales - exclusive of amortization	$ 308,062	$ 4,035	$ 312,097	$ 323,517	$ 2,684	$ 326,201
Operating loss from continuing operations	(269,864)	(4,035)	(273,899)	(168,870)	(2,684)	(171,554)
Loss from continuing operations before tax	(343,987)	(4,035)	(348,022)	(185,694)	(2,684)	(188,378)
Income tax benefit	(736)	(224)	(960)	(30,153)	(221)	(30,374)
Net loss from continuing operations	(343,515)	(3,811)	(347,326)	(155,541)	(2,463)	(158,004)
Net loss	(345,008)	(3,811)	(348,819)	(155,176)	(2,463)	(157,639)
Basic and diluted loss per share:						
Continuing operations	$ (7.07)	$ (0.08)	$ (7.15)	$ (3.22)	$ (0.05)	$ (3.27)
Discontinued operations	(0.03)	—	(0.03)	0.01	—	0.01
	$ (7.10)	$ (0.08)	$ (7.18)	$ (3.21)	$ (0.05)	$ (3.26)

Consolidated Statements of Comprehensive Income (Loss)

	Year Ended December 31, 2020			Year Ended December 31, 2019		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Net loss	$ (345,008)	$ (3,811)	$ (348,819)	$ (155,176)	$ (2,463)	$ (157,639)
Total comprehensive loss	(297,807)	(3,811)	(301,618)	(150,092)	(2,463)	(152,555)

Consolidated Balance Sheet

	December 31, 2020		
	As Previously Reported	Adjustments	As Revised
Inventories	$ 126,675	$ (11,390)	$ 115,285
Total Current Assets	719,434	(11,390)	708,044
Total Assets	2,411,351	(11,390)	2,399,961
Deferred tax liabilities	8,915	(1,826)	7,089
Total Liabilities	1,292,522	(1,826)	1,290,696
Accumulated deficit	(752,402)	(9,564)	(761,966)
Total Stockholders' Equity	1,118,829	(9,564)	1,109,265
Total Liabilities and Stockholders' Equity	2,411,351	(11,390)	2,399,961

Consolidated Statements of Stockholders' Equity

	As Previously Reported		Adjustments		As Revised	
	Accumulated Deficit	Total Stockholders' Equity	Accumulated Deficit	Total Stockholders' Equity	Accumulated Deficit	Total Stockholders' Equity
December 31, 2018	$ (251,579)	$ 1,503,738	$ (3,290)	$ (3,290)	$ (254,869)	$ 1,500,448
Net loss	(155,176)	(155,176)	(2,463)	(2,463)	(157,639)	(157,639)
December 31, 2019	(406,755)	1,383,717	(5,753)	(5,753)	(412,508)	1,377,964
Net loss	(345,008)	(345,008)	(3,811)	(3,811)	(348,819)	(348,819)
December 31, 2020	(752,402)	1,118,829	(9,564)	(9,564)	(761,966)	1,109,265

Consolidated Statements of Cash Flows

	Year Ended December 31, 2020			Year Ended December 31, 2019		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Net loss	$ (345,008)	$ (3,811)	$ (348,819)	$ (155,176)	$ (2,463)	$ (157,639)
Deferred tax expense (benefit)	37,292	(224)	37,068	(26,277)	(221)	(26,498)
Changes in operating assets and liabilities:						
Inventories	1,403	4,035	5,438	(10,608)	2,684	(7,924)
Net cash used in operating activities	(79,422)	—	(79,422)	(91,142)	—	(91,142)

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").

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, contingent consideration arrangements, legal and other contingencies, 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 on the consolidated statements of income (loss), the consolidated balance sheets and the consolidated statements of cash flows for comparative purposes. These reclassifications did not have a material effect on our financial condition, results of operations or cash flows. The prior period reclassifications on the consolidated statements of income (loss) are summarized and presented below (in thousands):

- Product remediation has been reclassified to cost of sales
- Merger and integration expenses have been reclassified to other operating expenses
- Restructuring expenses have been reclassified to other operating expenses
- Litigation provision, net has been reclassified to other operating expenses
- Amortization of intangibles has been reclassified to cost of sales or selling, general and administrative based on the nature of the underlying intangible asset

- Decommissioning provision has been reclassified to other operating expenses and
- Loss on debt extinguishment has been reclassified from foreign exchange and other gains/(losses) to loss on debt extinguishment.

	Year Ended December 31, 2020			Year Ended December 31, 2019		
	As Revised	Reclassifications	Current Presentation	As Revised	Reclassifications	Current Presentation
Net sales	$ 934,241	$ —	$ 934,241	$ 1,084,170	$ —	$ 1,084,170
Cost of sales	312,097	27,381	339,478	326,201	34,164	360,365
Product remediation	7,860	(7,860)	—	15,777	(15,777)	—
Gross profit	614,284	(19,521)	594,763	742,192	(18,387)	723,805
Operating expenses:						
Selling, general and administrative	427,770	18,791	446,561	506,478	21,988	528,466
Research and development	152,902	—	152,902	146,849	—	146,849
Merger and integration expenses	7,333	(7,333)	—	23,457	(23,457)	—
Restructuring expenses	7,571	(7,571)	—	12,254	(12,254)	—
Impairment of disposal group	180,160	—	180,160	—	—	—
Impairment of goodwill	21,269	—	21,269	42,417	—	42,417
Impairment of long-lived assets	6,762	—	6,762	142,517	—	142,517
Amortization of intangibles	38,312	(38,312)	—	40,375	(40,375)	—
Decommissioning provision	42,198	(42,198)	—	—	—	—
Litigation provision, net	3,906	(3,906)	—	(601)	601	—
Other operating expenses	—	61,008	61,008	—	35,110	35,110
Operating loss from continuing operations	(273,899)	—	(273,899)	(171,554)	—	(171,554)
Interest income	131	—	131	803	—	803
Interest expense	(40,837)	—	(40,837)	(15,091)	—	(15,091)
Loss on debt extinguishment	—	(1,407)	(1,407)	—	—	—
Foreign exchange and other gains/(losses)	(33,417)	1,407	(32,010)	(2,536)	—	(2,536)
Loss from continuing operations before tax	$ (348,022)	$ —	$ (348,022)	$ (188,378)	$ —	$ (188,378)

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 approximates 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")

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.

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 included on our consolidated statements of income (loss) within cost of sales or selling, general and administrative based on the nature of the underlying intangible asset. 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

Assets Held and Used

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.

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.

When an impairment of a disposal group is deemed necessary and the amount of the impairment exceeds the carrying value of the long-lived assets, we record the impairment to the disposal group rather than long-lived assets. We also allocate goodwill of the associated reporting unit to the disposal group based upon the relative fair value of the businesses within the reporting unit. The goodwill allocated to the disposal group is then tested for impairment.

Goodwill Impairment

We conduct impairment testing of our goodwill on October 1st each year. 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. 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.

If we determine that goodwill is more-likely-than-not impaired, we compare 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. Fair value is estimated using a discounted cash flow model and requires various assumptions, including revenue growth rates and discount rates. 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. 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.

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 to manage the impact of currency exchange 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.

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.

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

Our financial assets and liabilities classified as Level 3 include contingent consideration liability arrangements, derivative and embedded derivative instruments and convertible notes receivable.

Contingent consideration liabilities are from 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. For further information on our Level 3 contingent consideration liability arrangements, please refer to "Note 9. Fair Value Measurements." For further information on our Level 3 derivative and embedded derivative instruments, please refer to "Note 10. Financing Arrangements" and "Note 9. Fair Value Measurements." For further information on our Level 3 convertible notes receivable, please refer to "Note 8. Investments."

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 12. Leases.”

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.

Market Performance-Based RSU’s

We may grant market performance-based RSUs at no purchase cost to the grantee. The grantees of the units have no voting rights or rights to dividends. Sale or transfer of the units is restricted until they are vested. The number of shares that are ultimately transferred to the grantee is dependent upon the Company’s percentile rank of total shareholder return relative to a peer group. The fair market value of market performance-based RSUs is determined utilizing a Monte Carlo simulation on the grant date and compensation is expensed ratably over the service period. Calculation of compensation for market performance-based stock awards requires estimation of employee turnover, historical volatility and forfeiture rates.

Operating Performance-Based Awards RSU's

We may grant operating performance-based RSUs at no purchase cost to the grantee. The grantees of the units have no voting rights or rights to dividends. Sale or transfer of the units is restricted until they are vested. The number of shares that are ultimately transferred to the grantee is dependent upon the Company's achievement of certain thresholds for cumulative adjusted free cash flow and return on invested capital. The fair market value of operating performance-based RSUs is determined using the market closing price on the grant date. Compensation is expensed ratably over the service period and adjusted based upon the percent achievement of cumulative adjusted free cash flow. Calculation of compensation for operating performance-based stock awards requires estimation of employee turnover, adjusted free cash flow, return on invested capital 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 2015 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 gains/(losses) 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, environmental obligations, 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 19. Geographic and Segment Information.”

Cardiopulmonary Products and Services

Cardiopulmonary products include oxygenators, heart-lung machines, autotransfusion systems, perfusion tubing systems, cannulae and other related accessories.

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 Cardiopulmonary revenue and have been presented with the related equipment and accessories revenue.

Neuromodulation Products

Neuromodulation segment products are comprised of neuromodulation therapy systems for the treatment of DRE, DTD and OSA. 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 in turn, engages certain muscles in the tongue in order to open the airway while a patient is sleeping. We recognize revenue for Neuromodulation product sales when control passes to the customer.

Advanced Circulatory Support Products

Advanced Circulatory Support includes temporary life support product kits that can include a combination of pumps, oxygenators, and cannulae. Advanced Circulatory Support revenue is recognized when control passes to the customer, usually at the point of shipment.

Contract Balances

Due to the nature of our products and services, revenue producing activities may result in contract assets and contract liabilities. These activities relate primarily to Cardiopulmonary 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, 2021 and 2020. As of December 31, 2021 and December 31, 2020, contract liabilities of $9.8 million and $8.6 million, respectively, were included within accrued liabilities and other and other long-term liabilities on the consolidated balance sheets.

Note 4. Divestiture of Heart Valve Business

Heart Valves

On December 2, 2020, LivaNova entered into a Purchase Agreement with Mitral Holdco S.à r.l., a company incorporated under the laws of Luxembourg and wholly owned and controlled by funds advised by Gyrus Capital S.A., a Swiss private equity firm. The Purchase Agreement provides for the divestiture of certain of LivaNova’s subsidiaries as well as certain other assets and liabilities relating to the Company’s Heart Valve business and site management operations conducted by the Company’s subsidiary LSM at the Company’s Saluggia campus for €60.0 million (approximately $68.1 million as of December 31, 2021). On April 9, 2021, LivaNova and the Purchaser entered into an A&R Purchase Agreement which amends and restates the original Purchase Agreement to, among other things, defer the closing of the sale and purchase of LSM by up to two years and include or amend certain additional terms relating to such deferral, including certain amendments relating to the potential hazardous substances liabilities of LSM and the related expense reimbursement provisions.

As a result of entering into the Purchase Agreement, during the fourth quarter of 2020 the Company concluded that the assets and liabilities of the Heart Valve business being sold met the criteria to be classified as held for sale. As a result, we recognized an impairment of $180.2 million during the fourth quarter of 2020 to record the Heart Valves disposal group at fair value less estimated cost to sell. Additionally, we recorded a $21.3 million impairment to the goodwill allocated to the Heart Valves disposal group based upon the relative fair values of the businesses within Other.

The initial closing of the sale of the Heart Valve business occurred on June 1, 2021 and we received €34.8 million (approximately $42.5 million as of June 1, 2021), subject to customary trade working capital and net indebtedness adjustments, as set forth in the Purchase Agreement. We also received $3.0 million on December 17, 2021. An additional €9.3 million (approximately $10.6 million as of December 31, 2021) is payable to LivaNova in 2022. During the year ended December 31, 2021, we recognized a loss from the sale of the Heart Valve business of $1.9 million, which is included within other operating expenses on the consolidated statements of income (loss).

In conjunction with the sale, we entered into a transition services agreement to provide certain support services generally for up to twelve months from the closing date of the sale. These 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, 2021, we recognized income of $1.9 million for providing these services. Income recognized related to the transition services agreements is recorded as a reduction to the related expenses in the associated expense line items in the consolidated statements of income (loss).

The major classes of assets and liabilities of the Heart Valves business held for sale on the consolidated balance sheet as of December 31, 2020 were as follows (in thousands):

	December 31, 2020
Accounts receivable, net	$ 20,059
Inventories	45,081
Prepaid and refundable taxes	2,751
Prepaid expenses and other current assets	2,436
Property, plant and equipment, net	25,042
Intangible assets, net	153,632
Operating lease assets	1,698
Impairment charge of disposal group	(180,160)
Total assets held for sale	$ 70,539
Accounts payable	$ 9,518
Accrued liabilities and other	4,205
Taxes payable	363
Accrued employee compensation and related benefits	8,781
Deferred tax liabilities	671
Long-term employee compensation and related benefits	4,994
Long-term operating lease liabilities	841
Other long-term liabilities	306
Total liabilities held for sale	$ 29,679

Note 5. 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.

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 and $1.9 million during the year ended December 31, 2020, primarily associated with severance costs for approximately 35 impacted employees. The 2019 Plan was completed during 2020.

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 and $0.3 million during the year ended December 31, 2020, primarily associated with severance costs for approximately 50 impacted employees. The Caisson TMVR restructuring plan was completed during 2020.

During the fourth quarter of 2020, we initiated a reorganization plan (the “2020 Plan”) to reduce our cost structure. We incurred restructuring expenses of $5.3 million during the year ended December 31, 2020 primarily associated with severance costs for 54 employees, and $9.7 million during 2021, primarily associated with severance costs for 27 additional employees during 2021 under the 2020 Plan and lease abandonment costs.

The following table provides a reconciliation of the beginning and ending balance of the accruals and other reserves recorded in connection with our restructuring plans included within accrued liabilities on the consolidated balance sheet (in thousands):

	Employee Severance and Other Termination Costs	Other	Total
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	4,097	1,400	5,497
Charges	7,571	—	7,571
Cash payments	(5,919)	(854)	(6,773)
Balance at December 31, 2020	5,749	546	6,295
Charges	7,963	1,750	9,713
Cash payments	(12,876)	(2,296)	(15,172)
Balance at December 31, 2021 (1)	$ 836	$ —	$ 836

(1) Cumulatively, we have recognized a total of $128.8 million in restructuring expense, inclusive of discontinued operations.

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

	Year Ended December 31,		
	2021	2020	2019
Cardiopulmonary	$ 2,844	$ 1,040	$ 1,483
Neuromodulation	1,531	3,223	1,082
Other (1)	5,338	3,308	9,689
Total (2)	$ 9,713	$ 7,571	$ 12,254

(1) Other restructuring expense for the year ended December 31, 2019 included $3.5 million of Caisson restructuring expenses.
(2) Restructuring expense is included within other operating expenses on the consolidated statements of income (loss).

Note 6. Product Remediation Liability

On December 29, 2015, we received an FDA Warning Letter (the "Warning Letter") alleging certain violations of FDA regulations applicable to medical device manufacturing at our Munich, Germany and Arvada, Colorado facilities. On October 13, 2016, the 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.

On December 31, 2016, we recognized a liability for a product remediation plan related to our 3T device. The remediation plan consisted 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 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.

In April 2017, we obtained CE Mark in Europe for the design change of the 3T device, and in October 2018, the FDA concluded that we could commence the vacuum canister and internal sealing upgrade program in the U.S. 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 are in the process of completing and closing out all recall activities with the FDA. While our vacuum canister and internal sealing upgrade program and deep cleaning service in the U.S. are substantially complete, these services will continue as a servicing option outside of the U.S.

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

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
Adjustments	3,199
Remediation activity	(5,743)
Effect of changes in foreign currency exchange rates	349
Balance at December 31, 2020	1,056
Adjustments	712
Remediation activity	(880)
Effect of changes in foreign currency exchange rates	(81)
Balance at December 31, 2021	$ 807

We recognized product remediation expenses during the years ended December 31, 2021, 2020 and 2019 of $0.8 million, $7.9 million and $15.8 million, respectively. In addition to changes to the estimated product remediation liability, 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, 2021, the liability was $39.5 million. Our related legal costs are expensed as incurred. For further information, please refer to “Note 13. Commitments and Contingencies.”

Note 7. Goodwill and Intangible Assets

The following table represents our finite-lived and indefinite-lived intangible assets as of December 31, 2021 and 2020 (in thousands):

	2021	2020
Finite-lived intangible assets:		
Customer relationships	$ 192,800	$ 202,546
Developed technology	219,706	227,247
Trade names	25,154	26,261
Other intangible assets	616	1,035
Total gross finite-lived intangible assets	438,276	457,089
Accumulated amortization - Customer relationships	65,106	56,787
Accumulated amortization - Developed technology	68,488	56,933
Accumulated amortization - Trade names	16,500	16,837
Accumulated amortization - Other intangible assets	506	902
Total accumulated amortization	150,600	131,459
Net finite-lived intangible assets	$ 287,676	$ 325,630
Indefinite-lived intangible assets:		
IPR&D	$ 112,006	$ 112,006
Goodwill	899,525	922,318
Total indefinite-lived intangible assets	$ 1,011,531	$ 1,034,324

The amortization periods for our finite-lived intangible assets as of December 31, 2021, are as follows:

	Minimum Life in years	Maximum Life in years
Customer relationships	8	18
Developed technology	14	17
Trade names	15	15

The estimated future amortization expense based on our finite-lived intangible assets at December 31, 2021, is as follows (in thousands):

2022	$ 25,980
2023	25,980
2024	25,980
2025	25,980
2026	25,980
Thereafter	157,776
Total	$ 287,676

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 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.

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 following table represents the changes in the carrying amount of goodwill by reportable segment (in thousands):

	Cardiopulmonary	Neuromodulation	Advanced Circulatory Support	Other [1]	Total
December 31, 2019	$ 394,735	$ 398,754	$ 102,526	$ 19,779	$ 915,794
Impairment [2]	—	—	—	(21,269)	(21,269)
Foreign currency adjustments	26,303	—	—	1,490	27,793
December 31, 2020	421,038	398,754	102,526	—	922,318
Foreign currency adjustments	(22,793)	—	—	—	(22,793)
December 31, 2021	$ 398,245	$ 398,754	$ 102,526	$ —	$ 899,525

(1) Other includes goodwill associated the Company's Heart Valves business, which was disposed of on June 1, 2021.

(2) During the year ended December 31, 2020, the Company recognized a $21.3 million impairment of goodwill allocated to Heart Valves. Refer to "Note 4. Divestiture of Heart Valve Business" for additional information.

Due to our change in reportable segments, as discussed in "Note 1. Nature of Operations," we performed a quantitative assessment as of October 1, 2021 of the goodwill associated with the previously reported Cardiovascular reporting unit and concluded that the goodwill was not impaired. We then allocated $403.9 million and $102.5 million of the previously reported Cardiovascular goodwill to the new Cardiopulmonary and Advanced Circulatory Support reporting units, respectively, based on their relative fair values.

We performed a quantitative assessment for our Cardiopulmonary, Neuromodulation and Advanced Circulatory Support reporting units as of October 1, 2021. The quantitative impairment assessment was performed using management's current estimate of future cash flows. We concluded that the fair value of our Cardiopulmonary, Neuromodulation and Advanced Circulatory Support segments exceeded the carrying value of the respective reporting units by 60%, 658% and 45%, respectively, as evidenced by the estimated fair value of our Cardiopulmonary, Neuromodulation and Advanced Circulatory Support reporting units calculated for the purpose of reconciling the fair value of our reporting units to our market capitalization. Therefore, we concluded that our Cardiopulmonary, Neuromodulation and Advanced Circulatory Support reporting units' goodwill was not impaired on the October 1, 2021 test date.

On December 2, 2020, LivaNova entered into a Purchase Agreement for the divestiture of certain of LivaNova's subsidiaries as well as certain other assets and liabilities relating to the Company's Heart Valve business. We performed a quantitative assessment as of December 2, 2020 of the goodwill associated with the previously reported Cardiovascular reporting unit and concluded that the goodwill was not impaired. We then allocated $21.3 million of the previously reported Cardiovascular goodwill to the Heart Valves disposal group based on the relative fair values of the businesses within the previously reported Cardiovascular reporting unit and recognized a $21.3 million impairment to the allocated goodwill. For additional information refer to "Note 4. Divestiture of Heart Valve Business."

Cumulative goodwill impairments from continuing operations since the merger of Cyberonics, Inc. and Sorin S.p.A. in October 2015 total $63.7 million.

Note 8. 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, 2021 and 2020 (in thousands):

	2021	2020
ShiraTronics, Inc.	$ 3,331	$ 2,045
Noctrix Health, Inc.	3,159	1,359
ALung Technologies, Inc. (1)	3,000	3,000
Ceribell, Inc.	3,000	3,000
MD Start II (2)	1,135	1,227
Rainbow Medical Ltd.	1,111	1,201
Highlife S.A.S.	1,075	1,163
Respicardia Inc. (3)	—	17,706
	15,811	30,701
Equity method investment (4)	787	393
	$ 16,598	$ 31,094

(1) ALung Technologies, Inc. ("ALung") is a privately held medical device company focused on creating advanced medical devices for treating respiratory failure. We have a loan outstanding to ALung with a carrying amount of $2.5 million and $2.5 million as of December 31, 2021 and 2020, respectively, which is included in prepaid expenses and other current assets on the consolidated balance sheet.

(2) During the second quarter of 2021 the Company received a cash dividend from its investment in MD Start II of $3.1 million, which is included in foreign exchange and other gains/(losses) on the consolidated statements of income (loss) for the year ended December 31, 2021.

(3) In April 2021, Zoll Medical Corporation acquired Respicardia Inc. As a result of the acquisition we received proceeds of $23.1 million for our investment and loan receivable with carrying values of $17.7 million and $0.8 million as of December 31, 2020, respectively. The Company recorded a gain of $4.6 million during the first quarter of 2021 to adjust the investment and loans receivable to fair value, which is included in foreign exchange and other gains/(losses) on the consolidated statements of income (loss) for the year ended December 31, 2021.

(4) We are required to fund follow-on investments up to a total of approximately €5.0 million (approximately $5.7 million as of December 31, 2021) based on cash calls.

Note 9. 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, 2021, 2020 or 2019.

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, 2021	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")	$ 243	$ —	$ 243	$ —
Derivative assets - freestanding instruments (FX)	61	—	61	—
Derivative assets - capped call derivatives	106,629	—	—	106,629
Convertible notes receivable	2,767	—	—	2,767
	$ 109,700	$ —	$ 304	$ 109,396
Liabilities:				
Derivative liabilities - designated as cash flow hedges (FX)	$ 1,286	$ —	$ 1,286	$ —
Derivative liabilities - freestanding instruments (FX)	427	—	427	—
Derivative liabilities - embedded exchange feature	181,700	—	—	181,700
Contingent consideration arrangements	98,382	—	—	98,382
	$ 281,795	$ —	$ 1,713	$ 280,082

	Fair Value as of December 31, 2020	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")	$ 2,893	$ —	$ 2,893	$ —
Derivative assets - freestanding instruments (FX)	55	—	55	—
Derivative assets - capped call derivatives	72,302	—	—	72,302
Convertible notes receivable	2,775	—	—	2,775
	$ 78,025	$ —	$ 2,948	$ 75,077
Liabilities:				
Derivative liabilities - designated as cash flow hedges (FX)	$ 14	$ —	$ 14	$ —
Derivative liabilities - freestanding instruments (interest rate swaps)	74	—	74	—
Derivative liabilities - freestanding instruments (FX)	4,073	—	4,073	—
Derivative liabilities - embedded exchange feature	121,756	—	—	121,756
Derivative liabilities - other	4,290	—	—	4,290
Contingent consideration arrangements	103,818	—	—	103,818
	$ 234,025	$ —	$ 4,161	$ 229,864

The following table provides a reconciliation of the beginning and ending balances of our recurring fair value measurements, using significant unobservable inputs (Level 3) (in thousands):

	Capped Call Derivative Asset	Convertible Notes Receivable	Embedded Exchange Feature Derivative Liability	Other Derivative Liabilities	Contingent Consideration Liability Arrangements
December 31, 2019	$ —	$ —	$ —	$ —	$ 137,349
Additions	43,096	2,691	74,951	—	—
Payments (1)	—	—	—	—	(12,868)
Changes in fair value (2) (3) (4)	29,206	84	46,805	4,290	(20,463)
Effect of changes in FX	—	—	—	—	(200)
December 31, 2020	72,302	2,775	121,756	4,290	103,818
Additions	—	—	—	—	—
Payments (1)	—	—	—	—	(6,000)
Changes in fair value (2) (4)	34,327	(8)	59,944	(4,290)	564
Effect of changes in FX	—	—	—	—	—
December 31, 2021	106,629	2,767	181,700	—	98,382
Less current portion at December 31, 2021	106,629	2,495	181,700	—	11,552
Long-term portion at December 31, 2021	$ —	$ 272	$ —	$ —	$ 86,830

(1) During the year ended December 31, 2021, we paid $6.0 million under the contingent consideration arrangement for the acquisition of Miami Instruments, LLC ("Miami Instruments"). During the year ended December 31, 2020, we paid $11.8 million under the contingent consideration arrangement for the acquisition of TandemLife. Additionally, we made final payments under contingent consideration arrangements resulting from the acquisitions of two distributors.

(2) During the year ended December 31, 2021, the contingent consideration change in fair value resulted in a decrease of $8.5 million recorded to cost of sales and an increase of $9.1 million recorded to research and development. During the year ended December 31, 2020, the contingent consideration change in fair value resulted in a decrease of $13.0 million and $7.5 million recorded to cost of sales and research and development, respectively.

(3) The contingent consideration change in fair value during the year ended December 31, 2020 is primarily due to a one-year delay in the projected achievement of a certain regulatory milestone and timing of sales-based earnout payments for ImThera, and the impact of an increase in discount rates utilized in the valuation of contingent consideration. Refer to the tables below for further information regarding the fair value measurements of contingent consideration.

(4) Changes in the fair value of the embedded exchange feature derivative, capped call derivatives and other derivative liabilities are recognized in foreign exchange and other gains/(losses) in the consolidated statements of income (loss).

Embedded Exchange Feature and Capped Call Derivatives

In June 2020, the Company issued $287.5 million in cash exchangeable senior notes and entered into related capped call transactions. The cash exchangeable senior notes include an embedded exchange feature that is bifurcated from the cash exchangeable senior notes. Please refer to "Note 10. Financing Arrangements" for further details. The embedded exchange feature derivative is measured at fair value using a binomial lattice model and discounted cash flows that utilize observable and unobservable market data. The capped call derivative is measured at fair value using the Black-Scholes model utilizing observable and unobservable market data, including stock price, remaining contractual term, expected volatility, risk-free interest rate and expected dividend yield, as applicable.

The embedded exchange feature and capped call derivatives are classified as Level 3 as the Company uses historical volatility and implied volatility from options traded to determine expected stock price volatility which is an unobservable input that is significant to the valuation. In general, an increase in our stock price or stock price volatility would increase the fair value of the embedded exchange feature and capped call derivatives which would result in an increase in expense. As time to the expiration of the derivatives decreases with passage of time, the fair value of the derivatives would decrease. The future impact on net income depends on how significant inputs such as stock price, stock price volatility and time to the expiration of the derivatives change in relation to other inputs.

The stock price volatility as of December 31, 2021 was 33%. As of December 31, 2021, a 10% lower volatility, holding other inputs constant, would result in approximate fair value for the embedded exchange feature derivative of $166.1 million and a 10% higher volatility, holding other inputs constant, would result in approximate fair value of $200.0 million. As of December 31, 2021, a 10% lower volatility, holding other inputs constant would result in approximate fair value for the capped call derivatives of $119.6 million and a 10% higher volatility, holding other inputs constant, would result in approximate fair value of $95.8 million.

Contingent Consideration Arrangements

The following table provides the fair value of our Level 3 contingent consideration arrangements by acquisition (in thousands):

	December 31,	
	2021	2020
ImThera	$ 86,830	$ 89,436
TandemLife	11,552	8,809
Miami Instruments	—	5,573
	$ 98,382	$ 103,818

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. The sales-based earnout is valued using projected sales from our internal strategic plan. Both arrangements are Level 3 fair value measurements and include the following significant unobservable inputs as of December 31, 2021:

ImThera Acquisition	Valuation Technique	Unobservable Input	Ranges
Regulatory milestone-based payment	Discounted cash flow	Discount rate	3.6%
		Probability of payment	85%
		Projected payment year	2024
Sales-based earnout	Monte Carlo simulation	Risk-adjusted discount rate	12.4% - 12.8%
		Credit risk discount rate	3.9% - 4.6%
		Revenue volatility	32.5%
		Probability of payment	85%
		Projected years of earnout	2025 - 2028

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 as of December 31, 2021:

TandemLife Acquisition	Valuation Technique	Unobservable Input	Ranges
Regulatory milestone-based payment	Discounted cash flow	Discount rate	2.4%
		Probability of payments	90%
		Projected payment years	2022

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, 2021, was $236.8 million, which we believe approximates fair value.

Note 10. Financing Arrangements

The outstanding principal amount of our long-term debt as of December 31, 2021 and 2020, was as follows (in thousands, except interest rates):

	2021	2020	Maturity	Interest Rate
2020 Cash Exchangeable Senior Notes	$ 225,140	$ 212,073	December 2025	3.00%
Bank of America Merrill Lynch Banco Múltiplo S.A.	6,113	6,515	July 2023	7.24%
Mediocredito Italiano	3,379	5,406	December 2023	0.50 % - 2.74%
Bank of America, U.S.	1,500	2,019	January 2023	2.66%
2020 Senior Secured Term Loan	—	424,002		
Other	663	660		
Total long-term facilities	236,795	650,675		
Less current portion of long-term debt	226,946	8,377		
Total long-term debt	$ 9,849	$ 642,298		

Contractual annual principal maturities of our long-term debt facilities as of December 31, 2021, are as follows (in thousands):

2022	$ 1,806
2023	9,431
2024	87
2025	287,560
2026	—
Thereafter	327
Total payments	299,211
Less: Debt issuance costs	62,416
Total long-term facilities	$ 236,795

Revolving Credit

The outstanding principal amount of our short-term unsecured revolving credit agreements and other agreements with various banks was $2.7 million and $4.2 million at December 31, 2021 and December 31, 2020, respectively, with interest rates ranging from 2.85% to 7.24% and loan terms ranging from overnight to 364 days.

On August 13, 2021, LivaNova PLC and its wholly-owned subsidiary, LivaNova USA, Inc. (the "Borrower") entered into a First Lien Credit Agreement with the lenders and issuing banks party thereto and Goldman Sachs Bank USA, as First Lien Administrative Agent and First Lien Collateral Agent, and Goldman Sachs Bank USA, Barclays Bank PLC and UBS AG, Stamford Branch as lenders, relating to a $125 million senior secured multi-currency revolving credit facility to be made available to the Borrower (the "2021 Revolving Credit Facility"). The 2021 Revolving Credit Facility expires on August 13, 2026 and bears interest at a rate equal to, for U.S. dollar-denominated loans, an adjusted LIBOR (with LIBOR fallback language to address the announced future cessation of specified dollar LIBOR) with a floor of 0.00%, or a Base Rate, plus, in each case, a variable margin based on the Company's senior secured net leverage ratio. As of December 31, 2021, the applicable margin for Eurodollar loans was 3.00% per annum. Interest is paid monthly or quarterly, as selected by the Borrower, with any outstanding principal due at maturity. The 2021 Revolving Credit Facility also contemplates the payment of commitment fees on the unused portion of the commitments, at a variable percentage based on the Company's senior secured net leverage ratio. At December 31, 2021, the applicable commitment fee percentage was 0.25% per annum. The 2021 Revolving Credit Facility is available for working capital and other general corporate purposes and, if drawn, can be repaid at any time without premium or penalty. The 2021 Revolving Credit Facility contains customary representations, warranties and covenants, including the requirement to maintain a senior secured first lien net leverage ratio of less than 4.50 to 1.00 for as long as there are any revolving loans outstanding under the 2021 Revolving Credit Facility, as well as in order for the Company to borrow additional revolving loans.

There were no outstanding borrowings under the 2021 Revolving Credit Facility as of December 31, 2021.

On August 12, 2021, the Company terminated its previous $50.0 million revolving credit facility agreement with ACF FINCO I LP, which was undrawn, resulting in a loss on debt extinguishment of $1.6 million recognized during the year ended

December 31, 2021 primarily associated with the write-off of unamortized debt issuance costs, and is included within loss on debt extinguishment on the consolidated statements of income (loss).

Bridge Loan Facility

On February 24, 2022, LivaNova PLC and its wholly-owned subsidiary, LivaNova USA, Inc. entered into an Incremental Facility Amendment No. 1 to the First Lien Credit Agreement with Goldman Sachs Bank USA, relating to a €200 million bridge loan facility. The proceeds may be used to secure the first demand bank surety of €270.0 million required in connection with the SNIA litigation or, alternatively, for payment of court ordered damages or settlements (including interest, expenses and charges in connection therewith) in the event of a negative decision by the Italian Supreme Court. The Bridge Loan Facility has an availability period until June 30, 2022 and a maturity date 15 months after drawing. Borrowings under the Bridge Loan Facility bear interest at a rate equal to an adjusted EURIBOR (with a floor of 0.00%) plus 3.50% increasing by 0.25% 15 days after drawing and by an additional 0.5% 90 days after drawing and every 90 days thereafter, with a maximum margin of 5.25% over adjusted EURIBOR. For additional information regarding the SNIA litigation, please refer to “Note 13. Commitments and Contingencies.”

2020 Cash Exchangeable Senior Notes

On June 17, 2020, our wholly-owned subsidiary, LivaNova USA, Inc., issued $287.5 million aggregate principal amount of 3.00% Notes by private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The sale of the Notes resulted in approximately $278.0 million in net proceeds to the Company after deducting issuance costs. Interest is payable semiannually in arrears on June 15 and December 15 of each year, beginning on December 15, 2020. The effective interest rate of the Notes at December 31, 2021 was 9.95%. The Notes mature on December 15, 2025 unless earlier exchanged, repurchased, or redeemed.

Debt discounts and issuance costs related to the Notes were approximately $82.0 million and included $75.0 million of discount attributable to the embedded exchange feature, discussed below, and $7.0 million of allocated issuance costs to the Notes related to legal, bank and accounting fees. Amortization of debt discount and issuance costs was $13.1 million for the year ended December 31, 2021 and is included in interest expense on the consolidated statement of income (loss). The unamortized discount related to the Notes as of December 31, 2021 was $62.4 million.

Holders of the Notes are entitled to exchange the Notes at any time during specified periods, at their option. This includes the right to exchange the Notes during any calendar quarter, if the last reported sale price of LivaNova’s ordinary shares, with a nominal value of £1.00 per share, is greater than or equal to 130% of the exchange price, or $79.27 per share for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter. The exchange condition was satisfied on December 20, 2021, which allows the holders of the Notes to request to exchange the Notes through March 31, 2022. As a result, we have reclassified our obligations from the Notes and the associated embedded exchange feature derivative as a current liability on the consolidated balance sheet as of December 31, 2021. However, as of the date of filing of this Form 10-K, no holders have elected to exchange the Notes. The Notes are exchangeable solely into cash and are not exchangeable into ordinary shares of LivaNova or any other security under any circumstances. The initial exchange rate for the Notes is 16.3980 ordinary shares per $1,000 principal amount of Notes (equivalent to an initial exchange price of approximately $60.98 per share). The exchange rate is subject to adjustment in certain circumstances, as set forth in the indenture governing the Notes.

The Company may redeem the Notes at its option, on or after June 20, 2023 and prior to the 51st scheduled trading day immediately preceding the maturity date, in whole or in part, if the last reported sale price per ordinary share has been at least 130% of the exchange price then in effect for at least 20 trading days (whether or not consecutive), including the trading day immediately preceding the date on which the Company provides notice of redemption, during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption, at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. Additionally, the Company may redeem the Notes at its option, prior to their stated maturity, in whole but not in part, in connection with certain tax-related events.

Embedded Exchange Feature

The embedded exchange feature of the Notes requires bifurcation from the Notes and is accounted for as a derivative liability. The fair value of the Notes' embedded exchange feature derivative at the time of issuance was $75.0 million and was recorded as debt discount on the Notes. This discount is amortized as interest expense using the effective interest method over the term of the Notes. The Notes' embedded exchange feature derivative is carried on the consolidated balance sheets at its estimated fair value and is adjusted at the end of each reporting period, with unrealized gain or loss reflected in the consolidated statements of income (loss). The fair value of the embedded exchange feature derivative liability was $181.7 million as of December 31, 2021.

Capped Call Transactions

In connection with the pricing of the Notes, the Company entered into privately negotiated capped call transactions with certain of the initial purchasers of the Notes or their respective affiliates. The capped call transactions cover, subject to anti-dilution adjustments substantially similar to those applicable to the Notes, the number of LivaNova's ordinary shares underlying the Notes and are expected generally to offset any cash payments the Company is required to make upon exchange of the Notes in excess of the principal amount thereof in the event that the market value per ordinary share, as measured under the capped call transactions, is greater than the strike price of the capped call transactions, with such offset being subject to an initial cap price of $100.00 per share. The capped call transactions expire on December 15, 2025 and must be settled in cash. If the capped call transactions are converted or redeemed early, settlement occurs at their termination value, which is equal to their fair value at the time of the redemption. The capped call transactions are carried on the consolidated balance sheets as a derivative asset at their estimated fair value and are adjusted at the end of each reporting period, with unrealized gain or loss reflected within foreign exchange and other gains/(losses) in the consolidated statements of income (loss). The fair value of the capped call derivative assets was $106.6 million as of December 31, 2021. As of December 31, 2021, the capped call derivative assets are classified as current.

2020 Senior Secured Term Loan

The Company used the net proceeds from the 2020 senior secured term loan, together with a portion of the net proceeds of the Notes, after fees, discounts, commissions and other expenses, to repay outstanding indebtedness under the Company's 2017 European Investment Bank loan, 2014 European Investment Bank loan, Banca Nazionale del Lavoro S.p.A loan, and 2019 Debt Facility and related expenses. The Company repaid approximately $528.0 million in aggregate outstanding principal, accrued interest and associated fees, including breakage fees and legal fees. The Company recognized a loss on debt extinguishment of $1.4 million during the year ended December 31, 2020. The loss on debt extinguishment was recognized in foreign exchange and other gains/(losses) in the consolidated statements of income (loss). The remainder of the proceeds from the concurrent financing transactions were used to pay the cost of capped call transactions and for general corporate purposes.

On August 12, 2021, the Company repaid in full and terminated its previously outstanding $450 million 2020 senior secured term loan, resulting in a loss on debt extinguishment of $58.6 million recognized during the year ended December 31, 2021, which is comprised of a $35.6 million make-whole premium and $23.0 million associated with the write-off of unamortized debt issuance costs, and is included within loss on debt extinguishment on the consolidated statements of income (loss). For additional information, please refer to "Note 14. Stockholders' Equity."

Note 11. Derivatives and Risk Management

Due to the global nature of our operations, we are exposed to foreign currency exchange rate fluctuations. We enter into FX derivative contracts to reduce the impact of foreign currency exchange rate fluctuations on earnings and cash flow. We are also exposed to equity price risk in connection with our Notes, including exchange and settlement provisions based on the price of our ordinary shares at exchange or maturity of the Notes. In addition, the capped call transactions associated with the Notes also include settlement provisions that are based on the price of our ordinary shares, subject to a capped price per share.

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 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. 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, 2021 and December 31, 2020 was $136.7 million and $352.6 million, respectively. These derivative contracts are designed to offset the FX effects in earnings of various intercompany loans and trade receivables. We recorded net gains (losses) for these freestanding derivatives of $10.9 million, $(16.6) million and $3.1 million for the years ended December 31, 2021, 2020 and 2019, respectively. These (losses) and gains are included in foreign exchange and other gains/(losses) on our consolidated statements of income (loss).

Counterparty Credit Risk

We are exposed to credit risk in the event of non-performance by the counterparties to our derivatives.

The two counterparties to the capped call transactions are financial institutions. To limit our credit risk, we selected financial institutions with a minimum long-term investment grade credit rating. Our exposure to the credit risk of the counterparties is not secured by any collateral. If a counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings, with a claim equal to our exposure at that time under the capped call transactions with that counterparty.

To manage credit risk with respect to our other derivatives, the Company selects and periodically reviews counterparties based on credit ratings, limits its exposure with respect to each counterparty, and monitors the market positions. However, if one or more of these counterparties were in a liability position to the Company and were unable to meet their obligations, any transactions with the counterparty could be subject to early termination, which could result in substantial losses for the Company.

Cash Flow Hedges

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 and the Euro. We transfer to earnings from AOCI the gain or loss realized on the FX derivative contracts at the time of invoicing.

The gross notional amounts of open derivative contracts designated as cash flow hedges as of December 31, 2021 and 2020, were as follows (in thousands):

Description of Derivative Contract	**2021**	**2020**
FX derivative contracts to be exchanged for British Pounds	$ 11,160	$ 9,545
FX derivative contracts to be exchanged for Japanese Yen	6,648	18,637
FX derivative contracts to be exchanged for Euros	58,224	47,444
	$ 76,032	$ 75,626

After-tax net gain 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 Loss in AOCI as of December 31, 2021**	**After-tax Net Loss Expected to be Reclassified to Earnings in Next 12 Months**
FX derivative contracts	$ (945)	$ (945)

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

		Year Ended December 31, 2021	
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 gains/(losses)	$ (3,922)	$ (2,333)
FX derivative contracts	SG&A	—	2,408
		$ (3,922)	$ 75

		Year Ended December 31, 2020	
Description of Derivative Contract	**Location in Earnings of Reclassified Gain or Loss**	**Gains Recognized in OCI**	**(Losses) Gains Reclassified from AOCI to Earnings:**
FX derivative contracts	Foreign exchange and other gains/(losses)	$ 1,724	$ (1,522)
FX derivative contracts	SG&A	—	980
Interest rate swap contracts	Interest expense	—	(113)
		$ 1,724	$ (655)

		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 gains/(losses)	$ 2,757	$ 3,003
FX derivative contracts	SG&A	—	(2,071)
Interest rate swap contracts	Interest expense	—	(92)
		$ 2,757	$ 840

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, 2021	**Asset Derivatives**		**Liability Derivatives**	
Derivatives Designated as Hedging Instruments	**Balance Sheet Location**	**Fair Value (1)**	**Balance Sheet Location**	**Fair Value (1)**
FX derivative contracts	Accrued liabilities	$ 243	Accrued liabilities	$ 1,286
Total derivatives designated as hedging instruments		243		1,286
Derivatives Not Designated as Hedging Instruments				
FX derivative contracts	Accrued liabilities	61	Accrued liabilities	427
Capped call derivatives	Current derivative assets	106,629		
Embedded exchange feature			Current derivative liabilities	181,700
Total derivatives not designated as hedging instruments		106,690		182,127
Total derivatives		$ 106,933		$ 183,413

December 31, 2020	**Asset Derivatives**		**Liability Derivatives**	
Derivatives Designated as Hedging Instruments	**Balance Sheet Location**	**Fair Value (1)**	**Balance Sheet Location**	**Fair Value (1)**
FX derivative contracts	Prepaid expenses and other current assets	$ 1,998	Accrued liabilities	$ 14
FX derivative contracts	Accrued liabilities	895		
Total derivatives designated as hedging instruments		2,893		14
Derivatives Not Designated as Hedging Instruments				
Interest rate swap contracts			Accrued liabilities	74
FX derivative contracts	Prepaid expenses and other current assets	55	Accrued liabilities	4,073
Capped call derivatives	Long-term derivative assets	72,302		
Embedded exchange feature			Long-term derivative liability	121,756
Other derivatives			Accrued liabilities	4,106
Other derivatives			Long-term derivative liability	184
Total derivatives not designated as hedging instruments		72,357		130,193
Total derivatives		$ 75,250		$ 130,207

(1) For the classification of inputs used to evaluate the fair value of our derivatives, refer to “Note 9. Fair Value Measurements.”

Note 12. 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 11 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):

	December 31,	
Operating Lease Assets and Liabilities	**2021**	**2020**
Assets		
Operating lease right-of-use assets	$ 40,600	$ 50,525
Liabilities		
Accrued liabilities and other	$ 11,261	$ 11,276
Long-term operating lease liabilities	35,919	42,221
Total lease liabilities	$ 47,180	$ 53,497

	Year Ended December 31,		
Operating Lease Cost	**2021**	**2020**	**2019**
Operating lease cost	$ 18,070	$ 14,156	$ 14,002
Variable lease cost	1,200	1,097	873
Short-term lease cost	1,084	415	788
Total lease cost	$ 20,354	$ 15,668	$ 15,663

Contractual maturities of our lease liabilities as of December 31, 2021, are as follows (in thousands):

2022	$ 12,635
2023	10,146
2024	7,861
2025	5,011
2026	3,803
Thereafter	13,023
Total lease payments	52,479
Less: Amount representing interest	5,299
Present value of lease liabilities	$ 47,180

Lease Term and Discount Rate	**December 31, 2021**	**December 31, 2020**
Weighted Average Remaining Lease Term	5.8 years	6.3 years
Weighted Average Discount Rate	3.2 %	2.4 %

Other information (in thousands)	Year Ended December 31,		
	2021	**2020**	**2019**
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows for operating leases	$ 13,650	$ 14,601	$ 13,522
Operating lease assets obtained in exchange for lease liabilities	$ 9,037	$ 8,547	$ 8,712

Note 13. 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 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 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. With this 510(k) clearance, all actions to remediate the FDA's inspectional observations in the Warning Letter are complete, and at this time, LivaNova is awaiting the FDA's close-out inspection.

CDC and FDA Safety Communications and Company Field Safety Notice

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

Also on October 13, 2016, concurrent with the CDC's HAN and FDA's Safety Communication, we issued a Field Safety Notice Update for U.S. users of 3T devices to proactively and voluntarily contact facilities to aid in implementation of the CDC and FDA recommendations. In the fourth quarter of 2016, we initiated a program to provide existing 3T device users with a new loaner 3T device at no charge pending regulatory approval and implementation of additional risk mitigation strategies worldwide, including a vacuum canister and internal sealing upgrade program and a deep disinfection service. In April 2017, we obtained CE Mark in Europe for the design change of the 3T device, and in October 2018, the FDA concluded that we could commence the vacuum canister and internal sealing upgrade program in the U.S. 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. We are in the process of completing and closing out all recall activities with the FDA. While our vacuum canister and internal sealing upgrade program and deep cleaning service in the U.S. are substantially complete, these services will continue as a servicing option outside of the U.S.

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 the fourth quarter of 2016, and furthermore, the cost associated with the plan was reasonably estimable. At December 31, 2021, the product remediation liability was $0.8 million.

Saluggia Site Hazardous Substances

LSM, formerly a subsidiary of Sorin, one of the companies that merged into LivaNova PLC in 2015, manages site services for the campus in Saluggia, Italy. The Saluggia campus is the location of manufacturing facilities of third parties, including those who acquired our Cardiac Rhythm Management and Heart Valve businesses, a cafeteria for workers, and storage facilities for hazardous substances and equipment used between the 1960s and the late 1990s by a nuclear research center that evolved into a nuclear medicine business. Pursuant to authorization from the Italian government, LSM has, and continues to, perform ordinary maintenance, secure the facilities, monitor air and water quality and file applicable reports with the competent environmental authorities.

During 2020, LSM received correspondence from ISIN (a sub-body of the Italian Ministry of Economic Development) requesting that within five years, LSM demonstrate the financial capacity to meet its obligations under Italian law to clean and dismantle any contaminated buildings and equipment as well as to deliver hazardous substances to a national repository. This repository will be built by the Italian government at a location and time yet to be determined. ISIN subsequently published Technical Guide n. 30, which identifies the technical criteria, and general safety and protection requirements for the design, construction, operation and dismantling of temporary storage facilities for the hazardous substances. In January 2021, a list of 67 potential sites for the national repository was published. There is no legal obligation to begin any work or deliver the hazardous substances, as the performance of these obligations is contingent on the construction of the as-yet unbuilt national repository.

As a result of the above correspondence and publication from ISIN and the publication of potential sites for the national repository, some of the substantial uncertainties regarding the obligation became more certain. In connection with developing the plan required by ISIN, we retained a third party specialist to assist in the estimation of the potential costs. Based on the aforementioned factors, the Company concluded its obligation to clean, dismantle, and deliver any hazardous substances to a national repository, was probable and reasonably estimable as of December 31, 2020. Accordingly, in the fourth quarter of 2020, we recognized a $42.2 million provision for this matter, which is included within other operating expenses on the consolidated statements of income (loss). The liability as of December 31, 2020 was $43.0 million which represented the low end of the estimated range of loss of $43.0 million to $55.0 million. At December 31, 2021 the liability was $39.3 million. The decrease in the liability from December 31, 2020 was primarily due to the effects of foreign currency changes during the year ended December 31, 2021.

Litigation

Product Liability

The Company is currently involved in litigation involving our 3T device. The litigation includes 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. A class action, filed in February 2016 in the U.S. District Court for the Middle District of Pennsylvania, consisting of all Pennsylvania residents who underwent open heart surgery at WellSpan York Hospital and Penn State Milton S. Hershey Medical Center between 2011 and 2015 and who currently are asymptomatic for NTM infection, was dismissed on July 16, 2021.

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 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 and federal courts in the U.S. and in jurisdictions outside the U.S. continue to progress. As of March 1, 2022, including the cases encompassed in the settlement framework described above that have not yet been dismissed, we are aware of approximately 90 filed and unfiled claims worldwide, with the majority of the claims in various federal or state courts throughout the United States. This number includes seven 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.

During the years ended December 31, 2021, 2020 and 2019 we recognized additional litigation provisions of $38.1 million, $3.9 million and $33.2 million, respectively, due to new information received about the nature of certain claims. At December 31, 2021, the provision for these matters was $39.5 million. While the amount accrued represents our best estimate for those filed and unfiled claims that are both probable and estimable, the actual liability for resolution of these matters may vary from our estimate.

Changes in the carrying amount of the litigation provision liability are as follows (in thousands):

Total litigation provision liability at December 31, 2018	$	294,061
Payments		(156,928)
Adjustments [1]		33,233
FX and other		38
Total litigation provision liability at December 31, 2019		170,404
Payments		(138,178)
Adjustments [1]		3,906
FX and other		358
Total litigation provision liability at December 31, 2020		36,490
Payments		(34,808)
Adjustments [1]		38,068
FX and other		(280)
Total litigation provision liability at December 31, 2021		39,470
Less current portion of litigation provision liability at December 31, 2021		32,845
Long-term portion of litigation provision liability at December 31, 2021 [2]	$	6,625

(1) Adjustments to the litigation provision are included within other operating expenses on the consolidated statements of income (loss).

(2) Included within other long-term liabilities on the consolidated balance sheet.

Environmental Liability

Sorin was created as a result of a spin-off (the "Sorin spin-off") from SNIA in January 2004, and in October 2015, Sorin was merged into LivaNova. 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 were 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 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; the Public Administrations entered voluntarily into the proceeding, asking Sorin, as jointly liable with SNIA, to pay compensation for SNIA's environmental damages. 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 $331,000 as of December 31, 2021) 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, an estimated €572.1 million (approximately $649.1 million as of December 31, 2021). We appealed the partial decision on liability to the Italian Supreme Court in August 2019.

In November 2021, the Court of Appeal delivered the remainder of its decision, ordering LivaNova to pay damages of approximately €453.6 million (approximately $514.6 million as of December 31, 2021). We appealed the decision on damages in December 2021, and in early 2022, the Italian Supreme Court agreed to combine the appeals on liability and damages. On February 21, 2022, the Court of Appeal notified the Company that it granted the Company a suspension with respect to the payment of damages until a decision has been reached on the appeal to the Italian Supreme Court. This suspension is subject to providing a first demand bank surety of €270.0 million (approximately U.S. $306.2 million) within 30 calendar days.

On February 24, 2022, LivaNova PLC and its wholly-owned subsidiary, LivaNova USA, Inc. entered into an Incremental Facility Amendment No. 1 to the First Lien Credit Agreement with Goldman Sachs Bank USA, relating to a €200 million bridge loan facility. The proceeds may be used to secure the first demand bank surety of €270.0 million or, alternatively, for payment of court ordered damages or settlements (including interest, expenses and charges in connection therewith) in the event of a negative decision by the Italian Supreme Court.

In 2011, Caffaro, a former SNIA subsidiary, sold its Brescia chemical business to Caffaro Brescia, a third party belonging to the Todisco group, and as part of the acquisition, Caffaro Brescia agreed to secure hydraulic barriers at the site and maintain existing environmental security measures. In September 2020, Caffaro Brescia declared it was withdrawing from its agreement to maintain the environmental measures. In January 2021, we (in addition to Caffaro Brescia, and other non-LivaNova entities) received an administrative order ("Order") from the Italian Ministry of the Environment requiring us to ensure the maintenance of the environmental measures and to guarantee that such works remain fully operational, the annual management and maintenance for which is estimated at approximately €1 million per year. LivaNova's receipt of the Order appears to be based on the aforementioned Court of Appeals decision regarding our alleged joint liability with SNIA for SNIA's environmental liabilities. Our response, dated February 16, 2021, disputes the grounds upon which the Order is based. We also appealed the Order in the Administrative Court in Brescia.

We have not recognized a liability in connection with these related matters because any potential loss is not currently probable.

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, and on May 18, 2020, the Patent Office issued a Final Written Decision determining that all challenged claims are unpatentable. On November 16, 2021, the district court dismissed NCT's compliant with prejudice, which concluded the litigation.

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 a liability related to this matter because any potential loss is not currently probable or reasonably estimable.

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 14. Stockholders' Equity

On August 6, 2021, the Company closed an offering and issued 4,181,818 ordinary shares, par value £1.00 per share, at an offering price of $82.50 per share. Net proceeds from the offering were approximately $322.6 million, after deducting underwriting discounts, commissions and offering expenses. Proceeds from the offering were used to repay the Company's $450 million 2020 senior secured term loan.

Accumulated other comprehensive income (loss)

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, 2021, 2020 and 2019 (in thousands):

	Change in Unrealized Gain (Loss) on Cash Flow Hedges	Foreign Currency Translation Adjustments (1)	Total
As of December 31, 2018	**$ (944)**	**$ (23,532)**	**$ (24,476)**
Other comprehensive income before reclassifications, before tax	2,757	3,627	6,384
Tax expense	(661)	—	(661)
Other comprehensive income 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 income, net of tax	1,457	3,627	5,084
As of December 31, 2019	**513**	**(19,905)**	**(19,392)**
Other comprehensive income before reclassifications, before tax	1,724	45,395	47,119
Tax expense	(415)	—	(415)
Other comprehensive income before reclassifications, net of tax	1,309	45,395	46,704
Reclassification of loss from accumulated other comprehensive income (loss), before tax	655	—	655
Reclassification of tax benefit	(158)	—	(158)
Reclassification of loss from accumulated other comprehensive income (loss), after tax	497	—	497
Net current-period other comprehensive income, net of tax	1,806	45,395	47,201
As of December 31, 2020	**2,319**	**25,490**	**27,809**
Other comprehensive loss before reclassifications, before tax	(3,922)	(31,722)	(35,644)
Tax benefit	719	—	719
Other comprehensive loss before reclassifications, net of tax	(3,203)	(31,722)	(34,925)
Reclassification of gain from accumulated other comprehensive income (loss), before tax	(75)	—	(75)
Reclassification of tax expense	14	—	14
Reclassification of gain from accumulated other comprehensive income (loss), after tax	(61)	—	(61)
Net current-period other comprehensive loss, net of tax	(3,264)	(31,722)	(34,986)
As of December 31, 2021	**$ (945)**	**$ (6,232)**	**$ (7,177)**

(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 15. 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, 2021, there were approximately 3,098,419 shares available for future grants under the 2015 Plan. During the year ended December 31, 2021, we issued stock-based compensatory awards with terms approved by the Compensation Committee of our Board of Directors. The awards with service conditions generally vest ratably from two to four years and are subject to forfeiture unless service conditions are met. Market performance-based awards were issued that cliff vest after three years subject to the rank of our total shareholder return for the three-year period ending December 31, 2023 relative to the total shareholder returns for a peer group of companies. Operating performance-based awards were issued that cliff vest after three years subject to the achievement of a target based on the adjusted free cash flow for fiscal year 2021. Additionally, operating performance-based awards were issued that cliff vest after three years subject to the achievement of a target based on the return on invested capital for fiscal year 2021.

On January 1, 2019, we initiated the LivaNova Global Employee Share Purchase Plan ("ESPP"). Compensation expense related to the ESPP for the years ended December 31, 2021, 2020 and 2019 was $1.5 million, $1.2 million and $1.3 million, respectively.

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,		
	2021	2020	2019
Cost of goods sold	$ 2,451	$ 1,898	$ 1,343
Selling, general and administrative	29,449	29,661	25,588
Research and development	8,664	3,530	5,622
Total stock-based compensation expense	40,564	35,089	32,553
Income tax benefit	588	992	6,590
Total expense, net of income tax benefit	$ 39,976	$ 34,097	$ 25,963

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,		
	2021	2020	2019
Service-based restricted stock units	$ 19,614	$ 18,320	$ 14,113
Service-based stock appreciation rights	12,489	12,715	10,349
Market performance-based restricted stock units	3,522	3,200	2,900
Operating performance-based restricted stock units	3,434	(370)	3,918
Employee stock purchase plan	1,505	1,224	1,273
Total stock-based compensation expense from continuing operations	$ 40,564	$ 35,089	$ 32,553

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, 2021, are as follows (in thousands):

	Unrecognized Compensation Cost	Weighted Average Remaining Vesting Period (in years)
Service-based stock appreciation rights	$ 25,025	2.59
Service-based restricted stock unit awards	35,770	2.46
Performance-based restricted stock unit awards	11,208	2.03
Total stock-based compensation cost unrecognized	$ 72,003	2.36

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,		
	2021	2020	2019
Dividend yield (1)	—	—	—
Risk-free interest rate (2)	1.0%	0.4%	1.4 % - 2.2 %
Expected option term - in years (3)	5.6	5.4	5.0 - 5.1
Expected volatility at grant date (4)	42.1%	39.5%	32.2 % - 35.7 %

(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, 2020	2,884,020	$ 63.20		
Granted	594,617	$ 73.25		
Exercised	(424,122)	$ 52.95		
Forfeited	(291,534)	$ 62.36		
Expired	(128,608)	$ 88.67		
Outstanding — at December 31, 2021	2,634,373	$ 65.94	7.2	$ 61,693
Fully vested and exercisable — end of year	1,154,459	$ 68.18	5.6	$ 25,149
Fully vested and expected to vest — end of year (2)	2,579,659	$ 66.01	7.1	$ 60,305

(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, 2021, 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,		
	2021	2020	2019
Weighted average grant date fair value of SARs granted during the year (per share)	$ 29.22	$ 15.73	$ 31.22
Aggregate intrinsic value of SARs and stock options exercised during the year (in thousands)	$ 12,223	$ 773	$ 2,064

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, 2020	848,459	$ 58.00
Granted	363,372	$ 74.17
Vested	(279,064)	$ 61.82
Forfeited	(141,610)	$ 55.85
Non-vested shares at December 31, 2021	791,157	$ 64.53

	Year Ended December 31,		
	2021	2020	2019
Weighted average grant date fair value of service-based RSUs issued during the year (per share)	$ 74.17	$ 44.28	$ 92.54
Aggregate fair value of RSUs that vested during the year (in thousands)	$ 21,501	$ 13,674	$ 12,710

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, 2020	380,799	$ 56.55
Granted	123,956	$ 89.29
Vested	(107,455)	$ 67.09
Forfeited	(51,356)	$ 28.42
Non-vested shares at December 31, 2021	345,944	$ 68.36

	Year Ended December 31,		
	2021	2020	2019
Weighted average grant date fair value of performance and market-based restricted share units granted during the year (per share)	$ 89.29	$ 41.70	$ 98.50
Aggregate fair value of performance and market-based restricted share units that vested during the year (in thousands)	$ 8,268	$ 4,106	$ 6,697

Note 16. 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,		
	2021	2020	2019
Accumulated benefit obligations at year end	$ 12,578	$ 13,085	$ 11,232
Change in projected benefit obligation:			
Projected benefit obligation at beginning of year	$ 13,085	$ 11,232	$ 10,591
Interest cost	224	290	382
Plan settlement	(972)	(384)	(366)
Actuarial loss	527	2,225	871
Benefits paid	(286)	(278)	(246)
Projected benefit obligation at end of year	$ 12,578	$ 13,085	$ 11,232
Change in plan assets:			
Fair value of plan assets at beginning of year	$ 8,688	$ 7,574	$ 6,767
Actual return on plan assets	189	646	628
Employer contributions	401	1,130	546
Plan settlement	(972)	(384)	(366)
Benefits paid	(286)	(278)	(1)
Fair value of plan assets at end of year	$ 8,020	$ 8,688	$ 7,574
Funded status at end of year:			
Fair value of plan assets	$ 8,020	$ 8,688	$ 7,574
Projected benefit obligations	12,578	13,085	11,232
Underfunded status of the plans	4,558	4,397	3,658
Recognized liability	$ 4,558	$ 4,397	$ 3,658
Amounts recognized on the consolidated balance sheets consist of:			
Non-current liabilities	$ 4,558	$ 4,397	$ 3,658
Recognized liability	$ 4,558	$ 4,397	$ 3,658

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,		
	2021	2020	2019
Accumulated benefit obligations at year end	$ 10,522	$ 12,091	$ 17,744
Change in projected benefit obligation:			
Projected benefit obligation at beginning of year	$ 13,039	$ 18,087	$ 18,975
Service cost	354	691	478
Interest cost	56	121	232
Actuarial loss (gain)	(1,372)	(208)	1,071
Benefits paid	(294)	(1,245)	(2,380)
Reclassified to liabilities held for sale (1)	—	(6,012)	—
Foreign currency exchange rate changes and other	(966)	1,605	(289)
Projected benefit obligation at end of year	$ 10,817	$ 13,039	$ 18,087
Change in plan assets:			
Fair value of plan assets at beginning of year	$ 2,816	$ 3,423	$ 3,341
Actual return on plan assets	61	52	(34)
Employer contributions	302	454	383
Benefits paid	(78)	(290)	(332)
Reclassified to liabilities held for sale (1)	—	(1,018)	—
Foreign currency exchange rate changes and other	41	195	65
Fair value of plan assets at end of year	$ 3,142	$ 2,816	$ 3,423
Funded status at end of year:			
Fair value of plan assets	$ 3,142	$ 2,816	$ 3,423
Projected benefit obligations	10,817	13,039	18,087
Underfunded status of the plans (2)	7,675	10,223	14,664
Recognized liability	$ 7,675	$ 10,223	$ 14,664
Amounts recognized on the consolidated balance sheets consist of:			
Non-current liabilities	$ 7,675	$ 10,223	$ 14,664
Recognized liability	$ 7,675	$ 10,223	$ 14,664

(1) Refer to “Note 4. Divestiture of Heart Valve Business.”
(2) 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,		
	2021	2020	2019
Interest cost	$ 224	$ 290	$ 382
Expected return on plan assets	(358)	(318)	(298)
Settlement and curtailment loss	471	180	—
Amortization of net actuarial loss	264	182	148
Net periodic benefit cost	$ 601	$ 334	$ 232

	Non-U.S. Pension Benefits		
	Year Ended December 31,		
	2021	2020	2019
Service cost	$ 354	$ 691	$ 478
Interest cost	56	121	232
Expected return on plan assets	(61)	(52)	34
Amortization of net actuarial loss (gain)	(1,372)	(208)	1,071
Net periodic benefit cost	$ (1,023)	$ 552	$ 1,815

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, 2021, 2020 and 2019, are presented in the following table:

	U.S. Pension Benefits		
	2021	2020	2019
Weighted-average assumptions used to determine benefit obligation:			
Discount rate	2.41%	1.91%	2.88%
Weighted-average assumptions used to determine net periodic benefit cost:			
Discount rate	1.91%	2.88%	3.97%
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, 2021, 2020 and 2019, are presented in the following table:

	Non-U.S. Pension Benefits		
	2021	2020	2019
Weighted-average assumptions used to determine benefit obligation:			
Discount rate	0.15% - 1.00%	0.23% - 0.35%	0.20% - 0.71%
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	0.15% - 1.00%	0.23% - 0.35%	0.20% - 0.71%
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, 2021:

Equity securities	29%
Debt securities	70%
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, 2021	Fair Value Measurement Using Inputs Considered as:		
		Level 1	Level 2	Level 3
Equity mutual funds	$ 2,341	$ —	$ 2,341	$ —
Fixed income mutual funds	5,587	—	5,587	—
Money market funds and cash	82	82	—	—
	$ 8,010	$ 82	$ 7,928	$ —

	Fair Value as of December 31, 2020	Fair Value Measurement Using Inputs Considered as:		
		Level 1	Level 2	Level 3
Equity mutual funds	$ 2,405	$ —	$ 2,405	$ —
Fixed income mutual funds	5,788	—	5,788	—
Money market funds	94	94	—	—
	$ 8,287	$ 94	$ 8,193	$ —

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 $0.7 million, $1.6 million and $0.9 million to the pension plans (U.S. and non-U.S.) during the years ended December 31, 2021, 2020 and 2019, respectively. We anticipate that we will make contributions to the U.S. pension plan of approximately $0.4 million during the year ended December 31, 2022.

Benefit payments, including amounts to be paid from our assets, and reflecting expected future service as of December 31, 2021, are expected to be paid as follows (in thousands):

	U.S. Plans	Non-U.S. Plans
2022	4,487	476
2023	744	738
2024	764	526
2025	928	572
2026	941	5,632
2027 - 2031	2,633	3,087

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 $10.2 million, $11.8 million and $12.4 million for the years ended December 31, 2021, 2020 and 2019, respectively.

Note 17. 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,		
	2021	2020 (1)	2019 (1)
Income (loss) from continuing operations before income taxes:			
UK and Non-U.S.	$ 22,094	$ (262,501)	$ 26,104
U.S.	(146,566)	(85,521)	(214,482)
	$ (124,472)	$ (348,022)	$ (188,378)
Total income tax expense (benefit) from continuing operations consisted of the following:			
Current:			
UK and Non-U.S.	$ 4,296	$ 2,899	$ 1,112
U.S.	4,050	(41,010)	(4,988)
	8,346	(38,111)	(3,876)
Deferred:			
UK and Non-U.S.	2,852	37,151	(7,628)
U.S.	—	—	(18,870)
	2,852	37,151	(26,498)
Total income tax expense (benefit) from continuing operations	$ 11,198	$ (960)	$ (30,374)

(1) Income (loss) from continuing operations before income taxes and deferred income tax expense for UK and Non-U.S. for the years ended December 31, 2020 and 2019 have been revised. For further details refer to "Note 1. Nature of Operations."

Effective Income Tax Rate Reconciliation

LivaNova PLC is resident in the UK for tax purposes. 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,		
	2021	2020 (1)	2019 (1)
Statutory tax rate at UK Rate	19.0 %	19.0 %	19.0 %
Deferred tax valuation allowance	(47.7)	(34.9)	(17.3)
Foreign tax rate differential	7.1	6.6	6.4
U.S. state and local tax expense, net of federal benefit	(0.3)	1.5	6.1
Effect of changes in tax rate	18.9	2.2	(3.1)
Write-off/impairment of investments	(1.8)	1.8	(2.7)
Reserve for uncertain tax positions	—	0.8	2.5
Research and development tax credits	0.3	0.9	2.2
UK CFC tax	—	—	2.1
U.S. tax on non-U.S. operations	—	—	(1.6)
Base erosion anti-abuse tax	(3.1)	(0.7)	1.5
Exempt income	—	—	1.2
Foreign tax withholding and credits	(0.2)	(0.2)	—
CARES Act rate differential	—	2.8	—
Disallowable professional fees	(1.5)	—	—
Other, net	0.3	0.5	(0.2)
Effective tax rate	(9.0)%	0.3 %	16.1 %

(1) Reconciliation amounts for the years ended December 31, 2020 and 2019 have been revised. For further details refer to "Note 1. Nature of Operations."

CARES Act

On March 27, 2020, the U.S. enacted the CARES Act, which contains numerous income tax provisions and other stimulus measures. Of the tax measures that impact our income tax provision, the ability to carry back, U.S. tax net operating losses ("NOL") generated in 2018, 2019, or 2020 to tax years with a higher statutory tax rate has the most significant impact. Based on our analysis as of December 31, 2021, we recorded an overall tax benefit of approximately $43.2 million with a permanent benefit of $9.6 million. This tax benefit reflects the carryback of all of the 2019 and a portion of the 2020 U.S. tax losses, inclusive of release of valuation allowance previously recorded on these losses.

UK Tax Increase

Due to the change in law effective April 1, 2023, which received royal assent in July 2021, and provided for the UK tax rate to increase to 25%, there was a revaluation to increase deferred taxes in 2021. Similarly, the UK valuation allowance was also increased by the revaluation.

Deferred Income Tax Assets and Liabilities

The significant components of our deferred tax assets and liabilities as of December 31, 2021 and 2020, are as follows (in thousands):

	2021	2020 [1]
Deferred tax assets:		
Net operating loss carryforwards	$ 152,491	$ 133,504
Tax credit carryforwards	40,931	37,629
Interest expense carryforward	65,141	43,155
Accruals and reserves	36,796	25,589
Deferred compensation	13,262	11,868
Inventories	8,844	8,454
Other	19,119	17,522
Gross deferred tax assets	336,584	277,721
Valuation allowance	(244,978)	(186,425)
Net deferred tax assets	91,606	91,296
Deferred tax liabilities:		
Property, equipment & intangible assets	(70,573)	(54,326)
Gain on sale of intellectual property	(26,564)	(41,069)
Investments	—	—
Other	—	—
Gross deferred tax liabilities:	(97,137)	(95,395)
Net deferred tax liabilities	$ (5,531)	$ (4,099)
Reported on the consolidated balance sheet as (after valuation allowance and jurisdictional netting):		
Net deferred tax assets	$ 2,197	$ 2,990
Net deferred tax liabilities	(7,728)	(7,089)
Net deferred tax liabilities	$ (5,531)	$ (4,099)

(1) Deferred tax assets for inventories, the valuation allowance and net deferred tax liabilities as of December 31, 2020 have been revised. For further details refer to "Note 1. Nature of Operations."

Net operating loss ("NOL") and tax credit carryforwards as of December 31, 2021, 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	$ 395,393	$ 94,681	$ 94,621	$ 60	2026 - 2026
U.S. Federal NOL	169,127	35,517	4,456	31,061	2023 - 2038
U.S. State NOL	275,780	15,434	2,673	12,761	2022 - 2041
S. America & other regions NOL	18,054	6,066	6,035	31	2029 - 2037
Far East NOL	3,150	795	152	643	2025 - 2031
U.S. foreign tax credits	—	15,850	—	15,850	2025 - 2029
U.S. tax credits	—	16,623	—	16,623	2022 - 2041
U.S. State research & development tax credits	—	6,499	1,068	5,431	2030 - 2041
Other non-U.S. tax credits	—	1,959	824	1,135	2022 - 2034
	$ 861,504	$ 193,424	$ 109,829	$ 83,595	

We review the realizability of our deferred tax assets by jurisdiction regularly. As of December 31, 2021 and 2020, we had valuation allowances of $245.0 million and $188.1 million, respectively. These valuation allowances were primarily related to continuing operations and are a result of significant negative evidence in the form of cumulative losses in certain jurisdictions, including the extended impact of COVID-19 globally.

No provision has been made for income taxes on undistributed earnings of foreign subsidiaries as of December 31, 2021 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, 2021, it was not practicable to determine the exact 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,		
	2021	**2020**	**2019**
Balance at beginning of year	$ 3,433	$ 15,995	$ 22,883
Increases:			
Tax positions related to current year	—	—	176
Decreases:			
Tax positions related to prior years for settlement with tax authorities	(1,434)	(13,989)	(2,104)
Tax positions related to prior years for lapses of statute of limitations	—	—	(4,632)
Impact of foreign currency exchange rates	(258)	1,427	(328)
Balance at end of year	$ 1,741	$ 3,433	$ 15,995

The $1.4 million decrease in the 2021 tax positions related to prior years for settlements with tax authorities reflects a settlement of the Germany tax audit for the years 2014-2018. The $14.0 million decrease in the 2020 tax positions related to prior years for settlements with tax authorities reflects a decrease of $13.3 million due to the settlement of the outstanding Cobe tax litigation in Italy.

Unrecognized tax benefits of $11.4 million at December 31, 2019, 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 $0.2 million, $0.4 million and $5.7 million as of December 31, 2021, 2020 and 2019, respectively, and were included in other long-term liabilities on our consolidated balance sheets.

We operate in multiple jurisdictions with complex legal and tax regulatory environments and our tax returns are periodically audited or subjected to review by tax authorities. We monitor tax law changes and the potential impact to our results of operations. 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, 2021 were recognized, $1.7 million would impact our effective tax rate. We believe it is reasonably possible that, within the next twelve months, due to the settlement of uncertain tax positions with various tax authorities and the expiration of statutes of limitations, unrecognized tax benefits should decrease by up to approximately $0.6 million.

We record accrued interest and penalties related to unrecognized tax benefits in interest expense and foreign exchange and other gains/(losses), 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	2015
Italy	2015
Germany	2019
England and Wales	2020
Canada	2017

Note 18. Earnings 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,		
	2021	2020	2019
Basic and diluted weighted average shares outstanding [(1)]	50,633	48,592	48,349

(1) Excluded from the computation of diluted earnings per share for the years ended December 31, 2021, 2020 and 2019 were stock options, SARs and RSUs totaling 3.9 million, 4.1 million and 2.9 million because to include them would have been anti-dilutive under the treasury stock method.

Note 19. 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 three reportable segments: Cardiopulmonary, Neuromodulation and Advanced Circulatory Support.

Effective in the fourth quarter of 2021, LivaNova changed its reportable segments corresponding to changes in how the Company's chief operating decision maker regularly reviews information, allocates resources and assesses performance. The segment financial information presented herein reflects these changes for all periods presented. The Company's changes to its reportable segments are summarized as follows:

- The Company's Advanced Circulatory Support business is no longer assessed as part of the Company's previously reported Cardiovascular reportable segment and is evaluated independently as its own reportable segment.
- The Company's Cardiopulmonary business is no longer assessed as part of the Company's previously reported Cardiovascular reportable segment and is evaluated independently as its own reportable segment.
- The Company's Heart Valves business, which was disposed of on June 1, 2021, is now included within Other.

Our Cardiopulmonary segment is engaged in the development, production and sale of cardiopulmonary products, including oxygenators, heart-lung machines, autotransfusion systems, perfusion tubing systems, cannulae and other related accessories.

Our Neuromodulation segment generates its revenue from the design, development and marketing of devices that deliver neuromodulation therapy to treat DRE, DTD and OSA. Neuromodulation products include the VNS Therapy System, which consists of an implantable pulse generator, a lead that connects the generator to the vagus nerve, and other accessories.

Our Advanced Circulatory Support segment is engaged in the development, production and sale of leading-edge temporary life support products. These products include cardiopulmonary and respiratory support solutions consisting of temporary life support controllers and product kits that can include a combination of pumps, oxygenators, and cannulae.

"Other" includes the results of our Heart Valves business, which was disposed of on June 1, 2021, and corporate shared service expenses for finance, legal, human resources, information technology and corporate business development.

Net sales of our reportable segments include revenues from the sale of products that each reportable segment develops and manufactures or distributes. We define segment income as operating income before merger and integration, restructuring and amortization of intangibles.

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

	Year Ended December 31,		
	2021	2020	2019
Cardiopulmonary			
United States	$ 154,073	$ 132,543	$ 161,471
Europe	134,562	122,062	135,632
Rest of World	194,344	192,127	207,613
	482,979	446,732	504,716
Neuromodulation			
United States	358,476	282,509	335,332
Europe	51,435	39,019	46,262
Rest of World	46,261	32,916	42,953
	456,172	354,444	424,547
Advanced Circulatory Support			
United States	53,821	41,094	30,781
Europe	1,120	1,027	741
Rest of World	518	200	401
	55,459	42,321	31,923
Other (1)			
United States	4,929	12,488	18,900
Europe	14,407	31,259	40,548
Rest of World	21,419	46,997	63,536
	40,755	90,744	122,984
Totals			
United States	571,299	468,634	546,484
Europe (2)	201,525	193,367	223,183
Rest of World	262,541	272,240	314,503
Total (3) (4)	$ 1,035,365	$ 934,241	$ 1,084,170

(1) Other primarily includes the net sales of the Company's Heart Valves business, which was disposed of on June 1, 2021.

(2) 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.

(3) Net sales to external customers includes $35.8 million, $29.7 million and $37.7 million in the United Kingdom, our country of domicile, for the years ended December 31, 2021, 2020 and 2019, respectively.

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

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

	Year Ended December 31,		
	2021	2020 [1]	2019 [1]
Cardiopulmonary [2]	$ (6,429)	$ 35,735	$ 50,533
Neuromodulation [3]	169,499	109,273	83,333
Advanced Circulatory Support	2,195	(575)	3,941
Other [4] [5]	(129,082)	(365,116)	(233,275)
Total reportable segment income (loss) from continuing operations	36,183	(220,683)	(95,468)
Other expenses [6]	36,967	53,216	76,086
Operating loss from continuing operations	(784)	(273,899)	(171,554)
Interest income	435	131	803
Interest expense	(50,151)	(40,837)	(15,091)
Loss on debt extinguishment	(60,238)	(1,407)	—
Foreign exchange and other gains/(losses)	(13,734)	(32,010)	(2,536)
Loss from continuing operations before tax	$ (124,472)	$ (348,022)	$ (188,378)

(1) Segment loss from continuing operations for the years ended December 31, 2020 and 2019 have been revised. For further details refer to "Note 1. Nature of Operations."

(2) Results for the years ended December 31, 2021, 2020 and 2019 include a Litigation provision, net of $38.1 million, $3.9 million and $(0.6) million, respectively. Refer to "Note 13. Commitments and Contingencies" for additional information.

(3) Results for the year ended December 31, 2019 include the ImThera impairment of the IPR&D asset of $50.3 million. Refer to "Note 7. Goodwill and Intangible Assets" for additional information.

(4) Results for the year ended December 31, 2020 include $180.2 million and $21.3 million in impairments of the Heart Valves disposal group and allocated goodwill, respectively. Refer to "Note 4. Divestiture of Heart Valve Business" for additional information. Additionally, the results for the year ended December 31, 2020 include a $42.2 million decommissioning provision at our Saluggia site. Refer to "Note 13. Commitments and Contingencies" for additional information. 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 7. Goodwill and Intangible Assets" for additional information.

(5) Other includes the results of the Company's Heart Valves business, which was disposed of on June 1, 2021, and corporate shared service expenses for finance, legal, human resources, information technology and corporate business development.

(6) Other expenses consists of merger and integration expense, restructuring expense and amortization of intangible assets.

Assets by reportable segment as of December 31, 2021 and 2020, was as follows (in thousands):

Total Assets	2021	2020 [1]
Cardiopulmonary	$ 921,481	$ 1,040,318
Neuromodulation	646,394	673,579
Advanced Circulatory Support	231,846	239,404
Other [2]	401,230	446,660
	$ 2,200,951	$ 2,399,961

(1) Total assets as of December 31, 2020 have been revised. For further details refer to "Note 1. Nature of Operations."

(2) Other includes corporate assets as of December 31, 2021 and 2020, and the assets of the Company's Heart Valves business, which was disposed of on June 1, 2021 as of December 31, 2020.

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

Capital Expenditures	Year Ended December 31, 2021	2020	2019
Cardiopulmonary	$ 14,824	$ 20,975	$ 16,302
Neuromodulation	179	7,318	3,415
Advanced Circulatory Support	1,326	733	540
Other [(1)]	5,984	6,890	7,720
	$ 22,313	$ 35,916	$ 27,977

(1) Other includes corporate capital expenditures as well as capital expenditures for the Company's Heart Valves business, which was disposed of on June 1, 2021.

Geographic Information

Property, plant and equipment, net by geographic region as of December 31, 2021 and 2020, was as follows (in thousands):

Property, Plant and Equipment, Net	2021	2020
United States	$ 60,852	$ 64,553
Europe	85,313	93,821
Rest of World	3,901	5,431
	$ 150,066	$ 163,805

Note 20. Supplemental Financial Information

Inventories as of December 31, 2021 and 2020, consisted of the following (in thousands):

Inventories	2021	2020 [(1)]
Raw materials	$ 43,958	$ 43,257
Work-in-process	14,161	8,055
Finished goods	47,721	63,973
	$ 105,840	$ 115,285

(1) Finished goods and total inventories as of December 31, 2020 have been revised. For further details refer to "Note 1. Nature of Operations."

Inventories included adjustments totaling $8.9 million and $6.6 million at December 31, 2021 and 2020, respectively, to record balances at lower of cost or net realizable value.

Property, plant and equipment, net as of December 31, 2021 and 2020, consisted of the following (in thousands):

Property, Plant and Equipment, Net	2021	2020	Lives in Years
Land	$ 15,099	$ 15,750	
Building and building improvements	79,475	77,061	3 to 39
Equipment, software, furniture and fixtures	195,919	200,696	3 to 18
Other	9,246	9,390	3 to 15
Capital investment in process	12,112	19,531	
Total gross property, plant and equipment	311,851	322,428	
Accumulated depreciation	(161,785)	(158,623)	
Property, plant and equipment, net	$ 150,066	$ 163,805	

Accrued liabilities and other as of December 31, 2021 and 2020, consisted of the following (in thousands):

Accrued Liabilities and Other	**2021**	**2020**
Contingent consideration [(1)]	$ 11,552	$ 13,968
Amount payable to Gyrus Capital S.A.	11,418	—
Operating lease liabilities [(2)]	11,261	11,276
Legal and other administrative costs	8,948	15,820
Contract liabilities	8,419	6,929
Research and development costs	5,329	4,257
Provisions for agents, returns and other	2,535	3,063
Restructuring related liabilities [(3)]	836	6,258
Other accrued expenses	28,639	26,465
	$ 88,937	$ 88,036

(1) Refer to "Note 9. Fair Value Measurements."
(2) Refer to "Note 12. Leases."
(3) Refer to "Note 5. Restructuring."

The table below presents the items included within foreign exchange and other gains/(losses) on the consolidated statements of income (loss) (in thousands):

	Year Ended December 31, 2021		
Foreign exchange and other gains/(losses)	**2021**	**2020**	**2019**
Exchangeable Notes fair value adjustment [(1)]	$ (59,944)	$ (46,805)	$ —
Capped call fair value adjustment [(1)]	34,327	29,206	—
Investment revaluation [(2)]	4,642	—	—
Other derivative liabilities fair value adjustment [(1)]	4,290	(4,290)	—
Dividend income [(2)]	3,415	—	—
Foreign exchange rate fluctuations	(1,243)	(4,851)	(570)
Exchangeable Notes issuance costs	—	(2,482)	—
Other	779	(2,788)	(1,966)
	$ (13,734)	$ (32,010)	$ (2,536)

(1) Refer to "Note 9. Fair Value Measurements."
(2) Refer to "Note 8. Investments."

Note 21. Quarterly Financial Information (Unaudited)

The tables below present the quarterly results for the years ended December 31, 2021 and 2020 (in thousands except for share data):

Year Ended December 31, 2021	**First Quarter [(1)]**	**Second Quarter [(1)]**	**Third Quarter [(1)]**	**Fourth Quarter**
Net sales	$ 247,603	$ 264,483	$ 253,215	$ 270,064
Gross profit	163,408	172,279	168,664	201,643
Operating (loss) income from continuing operations	(5,698)	(36,262)	16,422	24,754
Net loss from continuing operations	(30,761)	(56,487)	(43,443)	(5,127)
Net loss	(30,761)	(56,487)	(43,443)	(5,127)
Diluted (loss) earnings per share:				
Continuing operations	$ (0.63)	$ (1.15)	$ (0.84)	$ (0.10)
Discontinued operations	—	—	—	—
	$ (0.63)	$ (1.15)	$ (0.84)	$ (0.10)

Year Ended December 31, 2020	First Quarter (1)	Second Quarter (1)	Third Quarter (1)	Fourth Quarter (1)
Net sales	$ 242,397	$ 182,206	$ 240,083	$ 269,555
Gross profit	165,307	114,970	147,591	166,895
Operating loss from continuing operations	(581)	(16,743)	(7,552)	(249,023)
Net income (loss) from continuing operations	37,455	(89,415)	(14,814)	(280,552)
Net loss from discontinued operations, net of tax	(995)	—	—	(498)
Net income (loss)	36,460	(89,415)	(14,814)	(281,050)
Diluted earnings (loss) per share:				
Continuing operations	$ 0.77	$ (1.84)	$ (0.30)	$ (5.77)
Discontinued operations	(0.02)	—	—	(0.01)
	$ 0.75	$ (1.84)	$ (0.30)	$ (5.78)

(1) This period's quarterly financial information has been revised. For further details refer to "Note 1. Nature of Operations."

Note 22. New Accounting Pronouncements

Adoption of New Accounting Pronouncements

The following table provides a description of our adoption of new ASUs issued by the FASB and the impact of the adoption on our consolidated financial statements:

Issue Date & Standard	Description	Date of Adoption	Effect on Financial Statements or Other Significant Matters
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.	January 1, 2021	There was no material impact to our consolidated financial statements as a result of adopting this ASU.
December 2019 ASU No. 2019-12, Income Taxes (Topic 740): *Simplifying the Accounting for Income Taxes*	This update simplifies various aspects related to the accounting for income taxes. The standard removes certain exceptions to the general principles in Topic 740 and also clarifies and modifies existing guidance to improve consistent application of Topic 740.	January 1, 2021	There was no material impact to our consolidated financial statements as a result of adopting this ASU.
August 2020 ASU No. 2020-06, Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*	This update simplifies the accounting for convertible debt instruments by removing certain accounting separation models as well as the accounting for debt instruments with embedded conversion features that are not required to be accounted for as derivative instruments. The update also improves the consistency of earnings per share calculations for convertible instruments.	January 1, 2021	There was no material impact to our consolidated financial statements as a result of adopting this ASU.