Edwards Lifesciences Corp
Form 10-K
February 15, 2019
Table of Contents

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

FORM 10-K
(Mark One)
ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended December 31, 2018
OR
o 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 1-15525

EDWARDS LIFESCIENCES CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	36-4316614
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

One Edwards Way, Irvine, California 92614
(Address of principal executive offices) (ZIP Code)
(949) 250-2500
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:	Name of each exchange on which registered:
Common Stock, par value $1.00 per share	New York Stock Exchange

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 by Rule 405 of the Securities Act. Yes ý No o
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes o No ý
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 ý No o
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 ý No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o
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 ý	Accelerated filer o	Non-accelerated filer o	Smaller reporting company o	Emerging growth company o

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. o

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

The aggregate market value of the registrant's common stock held by non-affiliates as of June 29, 2018 (the last trading day of the registrant's most recently completed second quarter): $27,160,261,560 based on the closing price of the registrant's common stock on the New York Stock Exchange. This calculation does not reflect a determination that persons are affiliates for any other purpose.

The number of shares outstanding of the registrant's common stock, $1.00 par value, as of January 31, 2019, was 207,766,329.

Documents Incorporated by Reference

Portions of the registrant's proxy statement for the 2019 Annual Meeting of Stockholders (to be filed within 120 days of December 31, 2018) are incorporated by reference into Part III, as indicated herein.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION
Form 10-K Annual Report—2018
Table of Contents

PART I		
Item 1.	Business	1
Item 1A.	Risk Factors	9
Item 1B.	Unresolved Staff Comments	18
Item 2.	Properties	19
Item 3.	Legal Proceedings	19
Item 4.	Mine Safety Disclosures	19
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	20
Item 6.	Selected Financial Data	22
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	22
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	38
Item 8.	Financial Statements and Supplementary Data	40
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	92
Item 9A.	Controls and Procedures	92
Item 9B.	Other Information	93
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	94
Item 11.	Executive Compensation	94
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	94
Item 13.	Certain Relationships and Related Transactions, and Director Independence	94
Item 14.	Principal Accounting Fees and Services	94
PART IV		
Item 15.	Exhibits and Financial Statement Schedules	95
Item 16.	Form 10-K Summary	98
	Signatures	99

Table of Contents

PART I

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. We intend the forward-looking statements contained in this report to be covered by the safe harbor provisions of such Acts. All statements other than statements of historical fact in this report or referred to or incorporated by reference into this report are "forward-looking statements" for purposes of these sections. These statements include, among other things, any predictions of earnings, revenues, expenses or other financial items, plans or expectations with respect to development activities, clinical trials or regulatory approvals, any statements of plans, strategies and objectives of management for future operations, any statements concerning our future operations, financial conditions and prospects, and any statements of assumptions underlying any of the foregoing. These statements can sometimes be identified by the use of the forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "goal," "continue," "seek," "pro forma," "forecast," "intend," "guidance," "optimistic," "aspire," "confident," other forms of these words or similar words or expressions or the negative thereof. Investors are cautioned not to unduly rely on such forward-looking statements. These forward-looking statements are subject to substantial risks and uncertainties that could cause our results or future business, financial condition, results of operations or performance to differ materially from our historical results or experiences or those expressed or implied in any forward-looking statements contained in this report. See "Risk Factors" in Part I, Item 1A below for a discussion of these risks, as well as our subsequent reports on Forms 10-Q and
8-K. These forward-looking statements speak only as of the date on which they are made and we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement. If we do update or correct one or more of these statements, investors and others should not conclude that we will make additional updates or corrections.

Unless otherwise indicated or otherwise required by the context, the terms "we," "our," "it," "its," "Company," "Edwards," and "Edwards Lifesciences" refer to Edwards Lifesciences Corporation and its subsidiaries.

Item 1. Business

Overview

Edwards Lifesciences Corporation is the global leader in patient-focused medical innovations for structural heart disease and critical care monitoring. Driven by a passion to help patients, we partner with the world’s leading clinicians and researchers and invest in research and development to transform care for those impacted by structural heart disease or who require hemodynamic monitoring during surgery or in intensive care. Edwards Lifesciences has a proud six-decade history as a leader in these areas. Since our founder, Lowell Edwards, first dreamed of using engineering to address diseases of the human heart, we have steadily built a company on the premise of imagining, building, and realizing a better future for patients.

A pioneer in the development of heart valve therapies, we are the world's leading manufacturer of heart valve systems and repair products used to replace or repair a patient's diseased or defective heart valve. Our innovative work in heart valves encompasses both surgical and transcatheter therapies for heart valve replacement and repair. In addition, our robust pipeline of future technologies is focused on the less invasive repair or replacement of the mitral and tricuspid valves of the heart, which are more complex and more challenging to treat than the aortic valve that is currently the focus of many of our commercially approved valve technologies. We are also a global leader in hemodynamic monitoring systems used to measure a patient's cardiovascular function in the hospital setting.

Cardiovascular disease is the number-one cause of death in the world, and is the top disease in terms of health care spending in nearly every country. Cardiovascular disease is progressive in that it tends to worsen over time and often affects the structure of an individual's heart.

Patients undergoing treatment for cardiovascular disease can be treated with a number of our medical technologies, which are designed to address individual patient needs with respect to disease process, comorbidities, and health status. For example, an individual with a heart valve disorder may have a faulty valve that is affecting the function of his or her heart or blood flow throughout his or her body. A clinician may elect to remove the valve and replace it with one of our bioprosthetic surgical tissue heart valves or surgically re-shape and repair the faulty valve with an Edwards Lifesciences annuloplasty ring. Alternatively, a clinician may implant an Edwards Lifesciences transcatheter valve or repair system via a catheter-based approach that does not require traditional open-heart surgery and can be done while the heart continues to beat. Patients in the hospital setting, including high-risk patients in the operating room or intensive care unit, are candidates for having their cardiac function or fluid

Table of Contents

levels monitored by our Critical Care products through multiple monitoring options, including noninvasive and minimally invasive technologies. These technologies enable proactive clinical decisions while also providing the opportunity for improving diagnoses and developing individualized therapeutic management plans for patients.

Corporate Background

Edwards Lifesciences Corporation was incorporated in Delaware on September 10, 1999.

Our principal executive offices are located at One Edwards Way, Irvine, California 92614. The telephone number at that address is (949) 250-2500. We make available, free of charge on our website located at www.edwards.com, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after filing such reports with the Securities and Exchange Commission ("SEC"). The contents of our website are not incorporated by reference into this report.

Edwards Lifesciences' Product and Technology Offerings

The following discussion summarizes the main areas of products and technologies we offer to treat advanced cardiovascular disease. Through the end of 2018, our products and technologies were categorized into three main areas: Transcatheter Heart Valve Therapy (including Transcatheter Aortic Valve Replacement and Transcatheter Mitral and Tricuspid Therapies), Surgical Heart Valve Therapy, and Critical Care. For more information on net sales from these three main areas, see "Net Sales by Product Group" in Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations." Beginning in 2019, we will report our sales in four main areas: Transcatheter Aortic Valve Replacement, Surgical Structural Heart, Critical Care, and Transcatheter Mitral and Tricuspid Therapies ("TMTT"). Going forward, TMTT will be reported as a separate product category to allow greater visibility into our performance in transcatheter mitral and tricuspid therapies.

Transcatheter Aortic Valve Replacement (formerly Transcatheter Heart Valve Therapy)

We are a global leader in transcatheter heart valve replacement technologies designed for the nonsurgical replacement of heart valves. The Edwards SAPIEN family of valves, including Edwards SAPIEN XT, the Edwards SAPIEN 3, and the Edwards SAPIEN 3 Ultra transcatheter aortic heart valves, and the CENTERA transcatheter aortic heart valve, and their respective delivery systems, are used to treat heart valve disease using catheter-based approaches for certain patients for whom traditional open-heart surgery is not optimal. Delivered while the heart is beating, these valves can enable patients to experience a better quality of life sooner than patients receiving traditional surgical therapies. We began offering our transcatheter heart valves to patients commercially in Europe in 2007, in the United States in 2011, and in Japan in 2013. Supported by extensive customer training and service, and a growing body of compelling clinical evidence, our SAPIEN family of transcatheter aortic heart valves are the most widely prescribed transcatheter heart valves in the world.

Sales of our transcatheter aortic valve replacement products represented 61%, 59%, and 55% of our net sales in 2018, 2017, and 2016, respectively.

Surgical Structural Heart (formerly Surgical Heart Valve Therapy)

The core of our surgical tissue heart valve product line is the Carpentier-Edwards PERIMOUNT pericardial valve platform, including the line of PERIMOUNT Magna Ease pericardial valves for aortic and mitral surgical valve replacement. With more long-term clinical publications on durability and performance than any other surgical valve, PERIMOUNT valves are the most widely implanted surgical tissue heart valves in the world. Our latest innovations

include the INSPIRIS RESILIA aortic valve, which offers RESILIA tissue and VFit technology, and the EDWARDS INTUITY Elite Valve System, which is designed to enable faster procedures, shorter cardiopulmonary bypass times, and smaller incisions. In addition to our replacement valves, we are the worldwide leader in surgical heart valve repair therapies, which include annuloplasty rings. We are also a global leader in cardiac cannula devices and offer a variety of procedure-enabling innovations that advance minimally invasive surgery.

Sales of our surgical tissue heart valve products represented 18%, 21%, and 23% of our net sales in 2018, 2017, and 2016, respectively.

Table of Contents

Critical Care

We are a world leader in hemodynamic monitoring systems used to measure a patient's heart function and fluid status in surgical and intensive care settings. Hemodynamic monitoring enables a clinician to balance the supply and demand of oxygen in critically ill patients, and plays an important role in enhancing surgical recovery by enabling appropriate tissue and organ perfusion, which can improve patient outcomes and survival. Edwards' complete hemodynamic portfolio helps clinicians make proactive clinical decisions for their patients, and includes the minimally invasive FloTrac system and the noninvasive ClearSight system. Our hemodynamic monitoring portfolio also comprises the Swan-Ganz line of pulmonary artery catheters and the Edwards Oximetry Central Venous Catheters. Our EV1000 and HemoSphere clinical monitoring platforms display a patient's physiological status and integrate many of our sensors and catheters into the platforms. In addition to our sensors and platforms, we have added Acumen Hypotension Prediction Index, an advanced algorithm that indicates the likelihood of a patient developing hypotension. We are also the global leader in disposable pressure monitoring devices and innovative closed blood sampling systems to help protect both patients and clinicians from the risk of infection.

Sales of our core hemodynamic products represented 10%, 10%, and 12% of our net sales in 2018, 2017, and 2016, respectively.

Transcatheter Mitral and Tricuspid Therapies

We are making significant investments in the development of transcatheter heart valve repair and replacement technologies designed to treat mitral and tricuspid valve diseases. While most of these technologies are in early clinical phases, the Cardioband systems for mitral and tricuspid valve reconstruction are commercially available in Europe. Cardioband enables clinicians to restore a patient's mitral or tricuspid valve to a more functional state by reducing the annulus and lowering regurgitation.

Competition

The medical technology industry is highly competitive. We compete with many companies, including divisions of companies much larger than us and smaller companies that compete in specific product lines or certain geographies. Furthermore, new product development and technological change characterize the areas in which we compete. Our present or future products could be rendered obsolete or uneconomical as a result of technological advances by one or more of our present or future competitors or by other therapies, including drug therapies. We must continue to develop and commercialize new products and technologies to remain competitive in the cardiovascular medical technology industry. We believe that we compete primarily on the basis of clinical superiority supported by extensive data, and innovative features that enhance patient benefit, product performance, and reliability. Customer and clinical support, and data that demonstrate both improvement in a patient's quality of life and a product's cost-effectiveness, are additional aspects of competition.

The cardiovascular segment of the medical technology industry is dynamic and subject to significant change due to cost-of-care considerations, regulatory reform, industry and customer consolidation, and evolving patient needs. The ability to provide products and technologies that demonstrate value and improve clinical outcomes is becoming increasingly important for medical technology manufacturers.

We believe that we are a leading global competitor in each of our product lines. In Transcatheter Aortic Valve Replacement, our primary competitors include Medtronic PLC and Boston Scientific Corporation. In Surgical Structural Heart, our primary competitors include Medtronic PLC, Abbott Laboratories, and LivaNova PLC. In Critical Care, we compete primarily with a variety of companies in specific product lines including ICU Medical, Inc.,

PULSION Medical Systems SE, a subsidiary of Getinge AB, and LiDCO Group PLC. In Transcatheter Mitral and Tricuspid Therapies, our primary competitor is Abbott Laboratories, although there are a considerable number of large and small companies with development efforts in these fields.

Sales and Marketing

We have a number of product lines that require sales and marketing strategies tailored to deliver high-quality, cost-effective products and technologies to all of our customers worldwide. Our portfolio includes some of the most recognizable cardiovascular device product brands in treating structural heart disease today. To help provide awareness of our products and technologies, we conduct educational symposia and best practices training for our physician, hospital executive, service line leadership, nursing, and clinical-based customers.

Table of Contents

Because of the diverse global needs of the population that we serve, our distribution system consists of several direct sales forces as well as independent distributors.

We are not dependent on any single customer and no single customer accounted for 10% or more of our net sales in 2018.

Where we choose to market our products is also influenced by the existence of, or potential for, adequate reimbursement to hospitals and other providers by national healthcare systems. We rely extensively on our sales and field clinical specialist personnel who work closely with our customers in hospitals. Field clinical specialists routinely attend procedures where Edwards' products are being used in order to provide guidance on the use of our devices, thereby enabling physicians and staff to reach expert proficiency and deliver positive patient outcomes. Our customers include physicians, nurses, and other clinical personnel, but can also include decision makers such as service line leaders, material managers, biomedical staff, hospital administrators and executives, purchasing managers, and ministries of health. Also, for certain of our product lines and where appropriate, our corporate sales team actively pursues approval of Edwards Lifesciences as a qualified supplier for hospital group purchasing organizations ("GPOs") that negotiate contracts with suppliers of medical products. Additionally, we have contracts with a number of United States and European national and regional buying groups, including healthcare systems and Integrated Delivery Networks.

United States. In the United States, we sell substantially all of our products through our direct sales forces. In 2018, 55% of our net sales were derived from sales to customers in the United States.

International. In 2018, 45% of our net sales were derived internationally through our direct sales forces and independent distributors. Of the total international sales, 53% were in Europe, 24% were in Japan, and 23% were in Rest of World. We sell our products in approximately 100 countries, and our major international markets include Canada, China, France, Germany, Italy, Japan, Spain, and the United Kingdom. A majority of the sales and marketing approach outside the United States is direct sales, although it varies depending on each country's size and state of development.

Raw Materials and Manufacturing

We operate manufacturing facilities in various geographies around the world. We manufacture our Transcatheter Aortic Valve Replacement and Structural Surgical Heart products primarily in the United States (California and Utah) and Singapore. Heart valve manufacturing facilities are also currently under construction in Costa Rica and Ireland. We manufacture our Critical Care products primarily in our facilities located in Puerto Rico and the Dominican Republic. We manufacture our Cardioband Transcatheter Mitral and Tricuspid Reconstruction Systems in Israel, with plans to transfer production to other Edwards' manufacturing locations.

We use a diverse and broad range of raw and organic materials in the design, development, and manufacture of our products. We manufacture our non-implantable products from fabricated raw materials including resins, chemicals, electronics, and metals. Most of our replacement heart valves are manufactured from natural tissues harvested from animal tissue, as well as fabricated materials. We purchase certain materials and components used in manufacturing our products from external suppliers. In addition, we purchase certain supplies from single sources for reasons of sole source availability or constraints resulting from regulatory requirements.

We work closely with our suppliers to mitigate risk and seek continuity of supply while maintaining uncompromised quality and reliability. Alternative supplier options are generally considered, identified, and approved for materials deemed critical to our products, although we do not typically pursue immediate regulatory qualification of alternative

sources due to the strength of our existing supplier relationships and the time and expense associated with the regulatory validation process.

We comply with all current global guidelines regarding risks for products incorporating animal tissue intended to be implanted in humans. We follow rigorous sourcing and manufacturing procedures intended to safeguard humans from potential risks associated with diseases such as bovine spongiform encephalopathy ("BSE"). We obtain bovine tissue used in our pericardial tissue valve products only from sources within the United States and Australia, where strong control measures and surveillance programs exist. In addition, bovine tissue used in our pericardial tissue valve products is from tissue types considered by global health and regulatory organizations to have shown no risk of infectibility. Our manufacturing and sterilization processes are designed to render tissue biologically safe from all known infectious agents and viruses.

Quality Assurance

We are committed to providing to our patients quality products and have implemented modern quality systems and concepts throughout the organization. The quality system starts with the initial design concept, risk management, and product

Table of Contents

specification, and continues through the design of the product, packaging and labeling, and the manufacturing, sales, support, and servicing of the product. The quality system is intended to design quality into the products and utilizes continuous improvement concepts, including Lean/Six Sigma principles, throughout the product lifecycle.

Our operations are frequently inspected by the many regulators that oversee medical device manufacturing, including the United States Food and Drug Administration ("FDA"), our European Notified Bodies, and other regulatory entities. The medical technology industry is highly regulated and our facilities and operations are designed to comply with all applicable quality systems standards, including the International Organization for Standardization ("ISO") 13485. These standards require, among other items, quality system controls that are applied to product design, component material, suppliers, and manufacturing operations. These regulatory approvals and ISO certifications can be obtained only after a successful audit of a company's quality system has been conducted by regulatory or independent outside auditors. Periodic reexamination by an independent outside auditor is required to maintain these certifications.

Environmental, Health, and Safety

We are committed to providing a safe and healthy workplace, promoting environmental excellence in our communities, and complying with all relevant regulations and medical technology industry standards. Through our corporate and site level Environmental, Health, and Safety functions, we establish and monitor programs to reduce pollution, prevent injuries, and maintain compliance with applicable regulations. In order to measure performance, we monitor and report on a number of metrics, including regulated and non-regulated waste disposal, energy usage, water consumption, air toxic emissions, and injuries from our production activities. Each of our manufacturing sites is evaluated regularly with respect to a broad range of Environmental, Health, and Safety criteria.

Research and Development

We are engaged in ongoing research and development to deliver clinically advanced new products, to enhance the effectiveness, ease of use, safety, and reliability of our current leading products, and to expand the applications of our products as appropriate. We focus on opportunities within specific areas of structural heart disease and critical care monitoring.

A considerable portion of our research and development investment includes clinical trials and the collection of evidence that provide data for use in regulatory submissions, and required post-market approval studies involving applications of our products. Our investment in clinical studies also includes outcomes and cost-effectiveness data for payers, clinicians, and healthcare systems.

In Transcatheter Aortic Valve Replacement, we are developing new products to further improve and streamline transcatheter aortic heart valve replacement procedures, and developing pulmonic platforms to expand therapies for congenital heart disease patients.

Our Surgical Structural Heart development programs include innovative platforms for patients who are best treated surgically, specifically active patients and patients with more complex combined procedures.

In our Critical Care product line, we are pursuing the development of a variety of decision support solutions for our clinicians. This includes next-generation noninvasive and minimally invasive hemodynamic monitoring systems, and a next-generation monitor platform. We are also developing a decision support software suite with advanced algorithms for proactive hemodynamic management, including a semi-closed loop system for standardized management of patient fluid levels.

In Transcatheter Mitral and Tricuspid Therapies, we are making significant investments in the development of technologies designed to treat mitral and tricuspid valve diseases and other structural heart conditions. In addition to our internally developed programs, we have made investments in several companies that are independently developing minimally-invasive technologies to treat structural heart diseases.

Our research and development activities are conducted primarily in facilities located in the United States and Israel. Our experienced research and development staff is focused on product design and development, quality, clinical research, and regulatory compliance. To pursue primary research efforts, we have developed alliances with several leading research institutions and universities, and also work with leading clinicians around the world in conducting scientific studies on our existing and developing products.

Table of Contents

Proprietary Technology

Patents, trademarks, and other proprietary rights are important to the success of our business. We also rely upon trade secrets, know-how, continuing innovations, and licensing opportunities to develop and maintain our competitive position.

We own more than 3,900 issued United States patents, pending United States patent applications, issued foreign patents, and pending foreign patent applications. We also have licensed various United States and foreign patents and patent applications that relate to aspects of the technology incorporated in certain of our products, including our heart valves and annuloplasty rings. We also own or have rights in United States and foreign patents and patent applications in the field of transcatheter heart valve repair and replacement. In addition, we own or have rights in United States and foreign patents and patent applications that cover catheters, systems and methods for hemodynamic monitoring, and vascular access products, among others.

We are a party to several license agreements with unrelated third parties pursuant to which we have obtained, for varying terms, the exclusive or non-exclusive rights to certain patents held by such third parties in consideration for cross-licensing rights and/or royalty payments. We have also licensed certain patent rights to others.

We monitor the products of our competitors for possible infringement of our owned and licensed patents. Litigation has been necessary to enforce certain patent rights held by us, and we plan to continue to defend and prosecute our rights with respect to such patents.

We own certain United States registered trademarks used in our business. Many of our trademarks have also been registered for use in certain foreign countries where registration is available and where we have determined it is commercially advantageous to do so.

Government Regulation and Other Matters

Our products and facilities are subject to regulation by numerous government agencies, including the FDA, European Community Notified Bodies, and the Japanese Pharmaceuticals and Medical Devices Agency, to confirm compliance with the various laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our products. We are also governed by federal, state, local, and international laws of general applicability, such as those regulating employee health and safety, and the protection of the environment. Overall, the amount and scope of domestic and foreign laws and regulations applicable to our business has increased over time.

United States Regulation. In the United States, the FDA has responsibility for regulating medical devices. The FDA regulates design, development, testing, clinical studies, manufacturing, labeling, promotion, and record keeping for medical devices, and reporting of adverse events, recalls, or other field actions by manufacturers and users to identify potential problems with marketed medical devices. Many of the devices that we develop and market are in a category for which the FDA has implemented stringent clinical investigation and pre-market clearance or approval requirements. The process of obtaining FDA clearance or approval to market a product is resource intensive, lengthy, and costly. FDA review may involve substantial delays that adversely affect the marketing and sale of our products. A number of our products are pending regulatory clearance or approval to begin commercial sales in various markets. Ultimately, the FDA may not authorize the commercial release of a medical device if it determines the device is not safe and effective or does not meet other standards for clearance. Additionally, even if a product is cleared or approved, the FDA may require testing and surveillance programs to monitor the effects of these products once commercialized.

The FDA has the authority to halt the distribution of certain medical devices, detain or seize adulterated or misbranded medical devices, order the repair, replacement, or refund of the costs of such devices, or preclude the importation of devices that are or appear violative. The FDA also conducts inspections to determine compliance with the quality system regulations concerning the manufacturing and design of devices and current medical device reporting regulations, recall regulations, clinical testing regulations, and other requirements. The FDA may withdraw product clearances or approvals due to failure to comply with regulatory standards, or the occurrence of unforeseen problems following initial approval, and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. Additionally, the failure to comply with FDA or comparable regulatory standards or the discovery of previously unknown product problems could result in fines, delays, or suspensions of regulatory clearances or approvals, seizures, injunctions, recalls, refunds, civil money penalties, or criminal prosecution. Our compliance with applicable regulatory requirements is subject to continual review. Moreover, the FDA and several other United States agencies administer controls over the export of medical devices from the United States and the import of devices into the United States, which could also subject us to sanctions for noncompliance.

Table of Contents

We are also subject to additional laws and regulations that govern our business operations, products, and technologies, including:

- federal, state, and foreign anti-kickback laws and regulations, which generally prohibit payments to physicians or other purchasers of medical products as an inducement to purchase a product;
- the Stark law, which prohibits physicians from referring Medicare or Medicaid patients to a provider that bills these programs for the provision of certain designated health services if the physician (or a member of the physician's immediate family) has a financial relationship with that provider;
- federal and state laws and regulations that protect the confidentiality of certain patient health information, including patient records, and restrict the use and disclosure of such information, in particular, the Health Insurance Portability and Accountability Act of 1996;
- the Physician Payments Sunshine Act, which requires public disclosure of the financial relationships of United States physicians and teaching hospitals with applicable manufacturers, including medical device, pharmaceutical, and biologics companies;
- the False Claims Act, which prohibits the submission of false or otherwise improper claims for payment to a federally funded health care program, and health care fraud statutes that prohibit false statements and improper claims to any third-party payor; and
- the United States Foreign Corrupt Practices Act, which can be used to prosecute companies in the United States for arrangements with foreign government officials or other parties outside the United States.

Failure to comply with these laws and regulations could result in criminal liability, significant fines or penalties, negative publicity, and substantial costs and expenses associated with investigation and enforcement activities. To assist in our compliance efforts, we adhere to many codes of ethics and conduct regarding our sales and marketing activities in the United States and other countries in which we operate. In addition, we have in place a dedicated team to improve our internal business compliance programs and policies.

International Regulation. Internationally, the regulation of medical devices is complex. In Europe, our products are subject to extensive regulatory requirements. The regulatory regime in the European Union for medical devices became mandatory in June 1998. It requires that medical devices may only be placed on the market if they do not compromise safety and health when properly installed, maintained, and used in accordance with their intended purpose. National laws conforming to the European Union's legislation regulate our products under the medical devices regulatory system. Although the more variable national requirements under which medical devices were formerly regulated have been substantially replaced by the European Union Medical Devices Directive, individual nations can still impose unique requirements that may require supplemental submissions. The European Union medical device laws require manufacturers to declare that their products conform to the essential regulatory requirements after which the products may be placed on the market bearing the CE Mark. Manufacturers' quality systems for products in all but the lowest risk classification are also subject to certification and audit by an independent notified body. In Europe, particular emphasis is being placed on more sophisticated and faster procedures for the reporting of adverse events to the competent authorities.

In May 2017, the European Union implemented a new regulatory scheme for medical devices under the Medical Device Regulation ("MDR"). The MDR becomes fully effective in 2020 and will bring significant new requirements

for many medical devices, including enhanced requirements for clinical evidence and documentation, increased focus on device identification and traceability, and additional postmarket surveillance and vigilance. Compliance with the MDR will require re-certification of many of our products to the enhanced standards, and will result in substantial additional expense.

In Japan, pre-market approval and clinical studies are required as is governmental pricing approval for medical devices. Clinical studies are subject to a stringent "Good Clinical Practices" standard. Approval time frames from the Japanese Ministry of Health, Labour and Welfare vary from simple notifications to review periods of one or more years, depending on the complexity and risk level of the device. In addition, importation of medical devices into Japan is subject to the "Good Import Practices" regulations. As with any highly regulated market, significant changes in the regulatory environment could adversely affect future sales.

Table of Contents

In many of the other foreign countries in which we market our products, we may be subject to regulations affecting, among other things:

- product standards and specifications;
- packaging requirements;
- labeling requirements;
- product collection and disposal requirements;
- quality system requirements;
- import restrictions;
- tariffs;
- duties; and
- tax requirements.

Many of the regulations applicable to our devices and products in these countries are similar to those of the FDA. In some regions, the level of government regulation of medical devices is increasing, which can lengthen time to market and increase registration and approval costs. In many countries, the national health or social security organizations require our products to be qualified before they can be marketed and considered eligible for reimbursement.

Health Care Initiatives. Government and private sector initiatives to limit the growth of health care costs, including price regulation and competitive pricing, coverage and payment policies, comparative effectiveness reviews, technology assessments, increasing evidentiary demands, and managed-care arrangements, are continuing in many countries where we do business, including the United States, Europe, and Japan. As a result of these changes, the marketplace has placed increased emphasis on the delivery of more cost-effective medical therapies. For example, government programs, private health care insurance, and managed-care plans have attempted to control costs by restricting coverage and limiting the level of reimbursement for procedures or treatments, and some third-party payors require their pre-approval before new or innovative devices or therapies are utilized by patients. These various initiatives have created increased price sensitivity over medical products generally and may impact demand for our products and technologies.

The delivery of our products is subject to regulation by the Department of Health and Human Services ("HHS") in the United States and comparable state and foreign agencies responsible for reimbursement and regulation of health care items and services. Foreign governments also impose regulations in connection with their health care reimbursement programs and the delivery of health care items and services. Reimbursement schedules regulate the amount the United States government will reimburse hospitals and doctors for the inpatient care of persons covered by Medicare. HHS' Centers for Medicare & Medicaid Services ("CMS") may also review whether and/or under what circumstances a procedure or technology is reimbursable for Medicare beneficiaries. Changes in current coverage and reimbursement levels could have an adverse effect on market demand and our pricing flexibility. Currently, CMS is reviewing the National Coverage Determination for Transcatheter Aortic Valve Replacement that has been in place since 2012. An updated final policy is expected to be issued in 2019.

Health care cost containment efforts have also prompted domestic hospitals and other customers of medical device manufacturers to consolidate into larger purchasing groups to enhance purchasing power. The medical technology industry has also experienced some consolidation, partly in order to offer a broader range of products to large purchasers. As a result, transactions with customers are larger, more complex, and tend to involve more long-term contracts than in the past. These larger customers, due to their enhanced purchasing power, may attempt to increase the pressure on product pricing.

Health Care Legislation. In 2010, significant reforms to the health care system were adopted as law in the United States as part of the Affordable Care Act ("ACA"). The law included provisions that, among other things, created programs to encourage a shift to value-based care, required all individuals to have health insurance (with limited exceptions), and imposed increased taxes. The law requires the medical technology industry to pay a 2.3% excise tax on United States sales of most medical devices. The excise tax, which increased our operating expenses, was suspended for calendar years 2016 through 2019.

Table of Contents

These laws or any future legislation, including deficit reduction legislation, could impact medical procedure volumes, reimbursement for our products, and demand for our products or the prices at which we sell our products.

Seasonality

Our quarterly net sales are influenced by many factors, including new product introductions, acquisitions, regulatory approvals, patient and physician holiday schedules, and other factors. Net sales in the third quarter are typically lower than other quarters of the year due to the seasonality of the United States and European markets, where summer vacation schedules normally result in fewer medical procedures.

Employees

As of December 31, 2018, we had approximately 12,800 employees worldwide, the majority of whom were located in the United States, Singapore, the Dominican Republic, and Puerto Rico. We emphasize competitive compensation, benefits, equity participation, and a positive and attractive work environment in our efforts to attract and retain qualified personnel, and employ a rigorous talent management system. None of our North American employees are represented by a labor union. In various countries outside of North America, we interact with trade unions and work councils that represent a limited number of employees.

Item 1A. Risk Factors

Our business and assets are subject to varying degrees of risk and uncertainty. An investor should carefully consider the risks described below, as well as other information contained in this Annual Report on Form 10-K and in our other filings with the SEC. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business. If any of these events or circumstances occurs, our business, financial condition, results of operations, or prospects could be materially harmed. In that case, the value of our securities could decline and an investor could lose part or all of his or her investment. In addition, forward-looking statements within the meaning of the federal securities laws that are contained in this Annual Report on Form 10-K or in our other filings or statements may be subject to the risks described below as well as other risks and uncertainties. Please read the cautionary notice regarding forward-looking statements in Part I above.

Business and Operating Risks

If we do not introduce new and differentiated products in a timely manner, our products may become more susceptible to competition or technologically obsolete and our operating results may suffer.

The cardiovascular products industry is characterized by technological changes, frequent new product introductions, and evolving industry standards. Without the timely introduction of new and differentiated products, our products could become more susceptible to competition or technologically obsolete and our revenue and operating results would suffer. Even if we are able to develop new or differentiated products, our ability to market them could be limited by the need for regulatory clearance, restrictions imposed on approved indications, entrenched patterns of clinical practice, uncertainty over third-party reimbursement, or other factors. We devote significant financial and other resources to our research and development activities; however, the research and development process is prolonged and entails considerable uncertainty. Accordingly, products we are currently developing may not complete the development process or obtain the regulatory or other approvals required to market such products in a timely manner or at all.

Technical innovations often require substantial time and investment before we can determine their commercial viability. We may not have the financial resources necessary to fund all of these projects. In addition, even if we are able to successfully develop new or differentiated products, they may not produce revenue in excess of the costs of development, and they may be rendered obsolete or less competitive by changing customer preferences or the introduction by our competitors of products with newer technologies or features or other factors.

We may experience supply interruptions that could harm our ability to manufacture products.

We use a broad range of raw and organic materials and other items from third party vendors in the design and manufacture of our products. Our Surgical Structural Heart, Transcatheter Aortic Valve Replacement, and Transcatheter Mitral and Tricuspid Therapies products are manufactured from treated natural animal tissue and man-made materials. Our non-implantable products are manufactured from man-made raw materials including resins, chemicals, electronics, and metals. We purchase certain of the materials and components used in the manufacture of our products from external suppliers, and we

Table of Contents

purchase certain supplies from single sources for reasons of quality assurance, cost-effectiveness, availability, or constraints resulting from regulatory requirements. We also contract with third parties for important services related to infrastructure and information technology. General economic conditions could adversely affect the financial viability of our suppliers, resulting in their inability to provide materials and components used in the manufacture of our products. While we work closely with suppliers to monitor their financial viability, assure continuity of supply, and maintain high quality and reliability, these efforts may not be successful. In addition, due to the rigorous regulations and requirements of the FDA and foreign regulatory authorities regarding the manufacture of our products (including the need for approval of any change in supply arrangements), we may have difficulty establishing additional or replacement sources on a timely basis or at all if the need arises. Certain suppliers may also elect to no longer service medical technology companies due to the high amount of requirements and regulation. Although alternative supplier options are considered and identified, we typically do not pursue regulatory qualification of alternative sources due to the strength of our existing supplier relationships and the time and expense associated with the regulatory validation process. A change in suppliers could require significant effort or investment in circumstances where the items supplied are integral to product performance or incorporate unique technology, and the loss of any existing supply contract could have a material adverse effect on us.

Regulatory agencies in the United States or other international geographies from time to time have limited or banned the use of certain materials used in the manufacture of our products. In these circumstances, transition periods typically provide time to arrange for alternative materials. In addition, the SEC enacted disclosure rules regarding products that may contain certain minerals that originate from conflict areas in and around the Democratic Republic of Congo. If we find that certain minerals that are necessary to the functionality or production of our products directly or indirectly finance or benefit armed groups, we may need to source components from alternative suppliers. If we are unable to identify alternative materials or suppliers and secure approval for their use in a timely manner, our business could be harmed.

Some of our suppliers are located outside the United States. As a result, trade or regulatory embargoes imposed by foreign countries or the United States could result in delays or shortages that could harm our business.

The manufacture of many of our products is highly complex and subject to strict quality controls. If we or one of our suppliers or logistics partners encounters manufacturing, logistics, or quality problems, including as a result of natural disasters, our business could suffer.

The manufacture of many of our products is highly complex and subject to strict quality controls, due in part to rigorous regulatory requirements. In addition, quality is extremely important due to the serious and costly consequences of a product failure. Problems can arise during the manufacturing process for a number of reasons, including disruption of facility utilities, equipment malfunction, failure to follow protocols and procedures, raw material problems, software problems, or human error. Although closely managed, disruptions can occur during implementation of new equipment and systems to replace aging equipment, as well as during production line transfers and expansions. As we expand into new markets, we may face unanticipated surges in demand which could strain our production capacity. Also, as we expand our manufacturing footprint, significant delays in construction and process validation could impact our production capacity. Further, scaling a new product for commercial production can sometimes be delayed. If these problems arise or if we otherwise fail to meet our internal quality standards or those of the FDA or other applicable regulatory body, which include detailed record-keeping requirements, our reputation could be damaged, we could become subject to a safety alert or a recall, we could incur product liability and other costs, product approvals could be delayed, and our business could otherwise be adversely affected.

In addition, our manufacturing and warehousing facilities, as well as those of our suppliers and logistics partners, could be materially damaged by earthquakes, hurricanes, volcanoes, fires, and other natural disasters or catastrophic

circumstances. While we believe that our exposure to significant losses from a catastrophic disaster could be partially mitigated by our ability to manufacture, store, and distribute some of our products at other facilities, the losses could have a material adverse effect on our business for an indeterminate period of time before this transition is complete and operates without significant disruption.

We may be required, from time to time, to recognize charges in connection with the write-down of our assets or dispositions of business operations or for other reasons.

We manage a portfolio of research and development products. From time to time, we identify operations and products that are underperforming or not a fit with our longer term business strategy. We may seek to dispose of these underperforming operations or products. We may also seek to dispose of other operations or products for strategic or other business reasons. If we cannot dispose of an operation or product on acceptable terms, we may voluntarily cease operations related to that product. Any of these events could result in charges, which could be substantial and which could adversely affect our results of operations.

Table of Contents

We may not successfully identify and complete acquisitions or strategic alliances on favorable terms or achieve anticipated synergies relating to any acquisitions or alliances, and such acquisitions could result in unforeseen operating difficulties and expenditures, require significant management resources, and require significant charges or write-downs.

We regularly explore potential acquisitions of complementary businesses, technologies, services, or products, as well as potential strategic alliances. We may be unable to find suitable acquisition candidates or appropriate partners with which to form alliances. Even if we identify appropriate acquisition or alliance candidates, we may be unable to complete the acquisitions or alliances on favorable terms, if at all. In addition, the process of integrating an acquired business, technology, service, or product into our existing operations could result in unforeseen difficulties and expenditures. Integration of an acquired company often requires significant expenditures as well as significant management resources that otherwise would be available for ongoing development of our other businesses. Moreover, we may not realize the anticipated financial or other benefits of an acquisition or alliance.

We may be required to take charges or write-downs in connection with acquisitions. In particular, acquisitions of businesses engaged in the development of new products may give rise to developed technology and/or in-process research and development ("IPR&D") assets. To the extent that the value of these assets declines, we may be required to write down the value of the assets. Also, in connection with certain asset acquisitions, we may be required to take an immediate charge related to acquired IPR&D. Either of these situations could result in substantial charges, which could adversely affect our results of operations.

Acquisitions could also involve the issuance of equity securities, the incurrence of debt, contingent liabilities, or amortization of expenses related to other intangible assets, any of which could adversely impact our financial condition or results of operations. In addition, equity or debt financing required for such acquisitions may not be available.

We face intense competition, and if we do not compete effectively, our business will be harmed.

The cardiovascular medical technology industry is highly competitive. We compete with many companies, some of which are larger, with better brand or name recognition, and broader product offerings. Our customers consider many factors when selecting a product, including product reliability, breadth of product line, clinical outcomes, product availability, price, availability and rate of reimbursement, and services provided by the manufacturer. In addition, our ability to compete will depend in large part on our ability to develop and acquire new or differentiated products and technologies, anticipate technology advances, and keep pace with other developers of cardiovascular therapies and technologies. Our sales, technical, and other key personnel play an integral role in the development, marketing, and selling of new and existing products. If we are unable to recruit, hire, develop, and retain a talented, competitive workforce, our ability to compete may be adversely affected. Our competitive position can also be adversely affected by product problems, physician advisories, and safety alerts, reflecting the importance of quality in the medical technology industry. Our position can shift as a result of any of these factors. In addition, given the trend toward value-based healthcare, if we are not able to continue to demonstrate the full value of our differentiated products to healthcare providers and payors, our competitive position could be adversely affected. See "Competition" under "Business" included herein.

Unsuccessful clinical trials or procedures relating to products under development could have a material adverse effect on our prospects.

The regulatory approval process for new products and new indications for existing products requires extensive clinical trials and procedures, including early clinical feasibility and regulatory studies. Unfavorable or inconsistent clinical

data from current or future clinical trials or procedures conducted by us, our competitors, or third parties, or perceptions regarding this clinical data, could adversely affect our ability to obtain necessary approvals and the market's view of our future prospects. Such clinical trials and procedures are inherently uncertain and there can be no assurance that these trials or procedures will be enrolled or completed in a timely or cost-effective manner or result in a commercially viable product or expanded indication. Failure to successfully complete these trials or procedures in a timely and cost-effective manner could have a material adverse effect on our prospects. Clinical trials or procedures may experience significant setbacks even after earlier trials have shown promising results. Further, preliminary results from clinical trials or procedures may be contradicted by subsequent clinical analysis. In addition, results from our clinical trials or procedures may not be supported by actual long-term studies or clinical experience. If preliminary clinical results are later contradicted, or if initial results cannot be supported by actual long-term studies or clinical experience, our business could be adversely affected. Clinical trials or procedures may be delayed, suspended, or terminated by us, the FDA, or other regulatory authorities at any time if it is believed that the trial participants face unacceptable health risks or any other reasons.

Table of Contents

The success of many of our products depends upon strong relationships with certain key physicians.

The development, marketing, and sale of many of our products requires us to maintain working relationships with physicians upon whom we rely to provide considerable knowledge and experience. These physicians may assist us as researchers, marketing consultants, product trainers and consultants, inventors, and as public speakers. If new laws, regulations, or other developments limit our ability to maintain strong relationships with these professionals or to continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions or data corruption could materially disrupt our operations and adversely affect our business and operating results.

The operation of our business depends on our information technology systems. We rely on our information technology systems to, among other things, effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, clinical data, customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, power losses, computer system or data network failures, security breaches, data corruption, and cyber-based attacks. Cyber-based attacks can include computer viruses, computer denial-of-service attacks, worms, and other malicious software programs or other attacks, covert introduction of malware to computers and networks, impersonation of authorized users, and efforts to discover and exploit any design flaws, bugs, security vulnerabilities, or security weaknesses, as well as intentional or unintentional acts by employees or other insiders with access privileges, intentional acts of vandalism by third parties and sabotage. In addition, federal, state, and international laws and regulations, such as the General Data Protection Regulation adopted by the European Union, can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail. In addition, a variety of our software systems are cloud based data management applications, hosted by third party service providers whose security and information technology systems are subject to similar risks.

The failure of either our or our service providers' information technology could disrupt our entire operation or result in decreased sales, increased overhead costs, product shortages, loss or misuse of proprietary or confidential information, intellectual property, or sensitive or personal information, all of which could have a material adverse effect on our reputation, business, financial condition, and operating results.

Market and Other External Risks

General economic and political conditions could have a material adverse effect on our business.

External factors can affect our profitability and financial condition. Such external factors include general domestic and global economic conditions, such as interest rates, tax law including tax rate changes, and factors affecting global economic stability, and the political environment regarding health care in general. We cannot predict to what extent the global economic conditions may negatively impact our business. For example, negative conditions in the credit and capital markets could impair our ability to access the financial markets for working capital or other funds, and could negatively impact our ability to borrow. An increase in interest rates could result in an increase in our borrowing costs and could otherwise restrict our ability to access the capital markets. Such conditions could result in decreased liquidity and impairments in the carrying value of our investments, and could adversely affect our results of operations and financial condition. These and other conditions could also adversely affect our customers, and may impact their ability or decision to purchase our products or make payments on a timely basis.

Various laws, including the Affordable Care Act, the Medicare Access and CHIP Reauthorization Act of 2015, and the 21st Century Cures Act, or any future legislation, including deficit reduction legislation, could impact medical procedure volumes, reimbursement for our products, and demand for our products or the prices at which we sell our products. For more information about these laws as they relate to our business, see the section entitled “Health Care Legislation” in Part I, Item 1, “Business.”

In addition, Public Law 115-97, commonly referred to as the Tax Cuts and Jobs Act ("the 2017 Tax Act"), has resulted in significant changes to the U.S. corporate income tax system. These changes include a federal statutory rate reduction from 35% to 21%, various new international provisions, the elimination or reduction of certain domestic deductions and credits, and limitations on the deductibility of interest expense and executive compensation. The 2017 Tax Act also transitions international taxation from a worldwide system to a modified territorial system and includes base erosion prevention measures on non-U.S.

Table of Contents

earnings, which has the effect of subjecting certain earnings of our foreign subsidiaries to U.S. taxation as global intangible low-taxed income. These changes became effective beginning in 2018.

The 2017 Tax Act also includes the Transition Toll Tax, which is a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings. The Transition Toll Tax will be paid over an eight-year period that began in 2018, and will not accrue interest. In addition, subsequent U.S. Treasury regulations, administrative interpretations or court decisions interpreting the 2017 Tax Act could have a material adverse effect on our business, results of operations or financial condition.

Our business is subject to economic, political, and other risks associated with international sales and operations.

Because we sell our products in a number of countries, our business is subject to the risks of doing business internationally, including risks associated with anti-corruption and anti-bribery laws. Our net sales originating outside the United States, as a percentage of total net sales, were 45% in 2018. We anticipate that sales from international operations will continue to represent a substantial portion of our total sales. In addition, many of our manufacturing facilities and suppliers are located outside of the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- changes in local medical reimbursement policies and programs;
- changes in foreign regulatory requirements;
- changes in a specific country's or region's political or economic conditions, including changing circumstances in emerging regions, that may reduce the number of procedures that use our products;
- trade protection measures, quotas, embargoes, import or export licensing requirements, and duties, tariffs, or surcharges;
- potentially negative impact of tax laws, including transfer pricing liabilities and tax costs associated with the repatriation of cash;
- difficulty in staffing and managing global operations;
- currency exchange rate fluctuations;
- cultural or other local factors affecting financial terms with customers;
- local economic and financial conditions, including sovereign defaults and decline in sovereign credit ratings, affecting the collectability of receivables, including receivables from sovereign entities;
- an outbreak of any life-threatening communicable disease;
- economic and political instability and local economic and political conditions;
- differing labor regulations; and
- differing protection of intellectual property.

Substantially all of our sales outside of the United States are denominated in local currencies, principally in Europe (and primarily denominated in the Euro) and in Japan. The United States dollar value of our international sales varies with currency exchange rate fluctuations. Decreases in the value of the United States dollar to the Euro or the Japanese yen, as well as other currencies, have the effect of increasing our reported revenues even when the volume of international sales has remained constant. Increases in the value of the United States dollar relative to the Euro or the Japanese yen, as well as other currencies, have the opposite effect. Significant increases or decreases in the value of the United States dollar could have a material effect on our revenues, cost of sales, and results of operations. We have a hedging program for certain currencies that attempts to manage currency exchange rate risks to an acceptable level based on management's judgment of the appropriate trade-off between risk, opportunity, and cost; however, this hedging program does not completely eliminate the effects of currency exchange rate fluctuations.

Table of Contents

The United States Foreign Corrupt Practices Act, the United Kingdom Bribery Act, and similar laws in other jurisdictions contain prohibitions against bribery and other illegal payments, and make it an offense to fail to have procedures in place that prevent such payments. Recent years have seen an increasing number of investigations and other enforcement activities under these laws. Although we have compliance programs in place with respect to these laws, which may be used as a defense to prove we had adequate procedures, no assurance can be given that a violation will not be found, and if found, the resulting penalties could adversely affect us and our business.

The stock market can be volatile and fluctuations in our quarterly sales and operating results as well as other factors could cause our financial guidance to vary from actual results and our stock price to decline.

From time to time, the stock market experiences extreme price and volume fluctuations. This volatility can have a significant effect on the market prices of securities for reasons unrelated to underlying performance. These broad market fluctuations may materially adversely affect our stock price, regardless of our operating results. In addition, the market price of our common stock could fluctuate substantially in response to any of the other risk factors set out above and below, as well as a number of other factors, including the performance of comparable companies or the medical technology industry, or changes in financial estimates and recommendations of securities analysts.

Our sales and operating results may vary significantly from quarter to quarter. A high proportion of our costs are fixed, due in part to significant selling, research and development, and manufacturing costs. Thus, small declines in revenue could disproportionately affect our operating results in a quarter, and the price of our common stock could fall. Other factors that could affect our quarterly sales and operating results include:

- announcements of innovations, new products, strategic developments, or business combinations by us or our competitors;
- demand for and clinical acceptance of products;
- the timing and execution of customer contracts, particularly large contracts that would materially affect our operating results in a given quarter;
- the timing of sales of products and of the introduction of new products;
- the timing of marketing, training, and other expenses related to the introduction of new products;
- the timing of regulatory approvals;
- changes in foreign currency exchange rates;
- delays or problems in introducing new products, such as slower than anticipated adoption of transcatheter heart valves;
- changes in our pricing policies or the pricing policies of our competitors;
- the timing of approvals of governmental reimbursement rates or changes in reimbursement rates for our products;
- increased expenses, whether related to sales and marketing, raw materials or supplies, product development, or administration;

- changes in the level of economic activity in the United States or other regions in which we do business;

- changes to accounting standards;

- costs related to acquisitions of technologies or businesses; and

- our ability to expand our operations and the amount and timing of expansion-related expenditures.

The quarterly and full-year financial guidance we provide to investors and analysts with insight to our view of our future performance is based on assumptions about our sales and operating results. Due to the nature of our business and the numerous factors that can impact our sales and operating performance, including those described above, our financial guidance may vary

Table of Contents

from actual results. If we fail to meet any financial guidance that we provide, or if we find it necessary to revise such guidance during the year, the price of our common stock could decline.

Continued consolidation in the health care industry could have an adverse effect on our sales and results of operations.

The health care industry has been consolidating, and organizations such as GPOs, independent delivery networks, and large single accounts, such as the United States Veterans Administration, continue to consolidate purchasing decisions for many of our health care provider customers. As a result, transactions with customers are larger and more complex, and tend to involve more long-term contracts. The purchasing power of these larger customers has increased, and may continue to increase, causing downward pressure on product pricing. If we are not one of the providers selected by one of these organizations, we may be precluded from making sales to its members or participants. Even if we are one of the selected providers, we may be at a disadvantage relative to other selected providers that are able to offer volume discounts based on purchases of a broader range of medical equipment and supplies. Further, we may be required to commit to pricing that has a material adverse effect on our revenues, profit margins, business, financial condition, and results of operations. We expect that market demand, governmental regulation, third-party reimbursement policies, and societal pressures will continue to change the worldwide health care industry, resulting in further business consolidations and alliances, which may exert further downward pressure on the prices of our products and could adversely impact our business, financial condition, and results of operations.

If government and other third-party payors decline to reimburse our customers for our products or impose other cost containment measures to reduce reimbursement levels, our ability to profitably sell our products will be harmed.

We sell our products and technologies to hospitals and other health care providers, all of which receive reimbursement for the health care services provided to patients from third-party payors, such as government programs (both domestic and international), private insurance plans, and managed care programs. The ability of customers to obtain appropriate reimbursement for their products from private and governmental third-party payors is critical to the success of medical technology companies. The availability of reimbursement affects which products customers purchase and the prices they are willing to pay. Reimbursement varies from country to country and can significantly impact acceptance of new products.

Government and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. There can be no assurance that levels of reimbursement, if any, will not be decreased in the future, or that future legislation, regulation, or reimbursement policies of third-party payors will not otherwise adversely affect the demand for and price levels of our products. The introduction of cost containment incentives, combined with closer scrutiny of health care expenditures by both private health insurers and employers, has resulted in increased discounts and contractual adjustments to hospital charges for services performed. Hospitals or physicians may respond to such cost-containment pressures by substituting lower cost products or other therapies.

Initiatives to limit the growth of health care costs, including price regulation, are underway in several countries around the world. In many countries, customers are reimbursed for our products under a government operated insurance system. Under such a system, the government periodically reviews reimbursement levels and may limit patient access. If a government were to decide to reduce reimbursement levels, our product pricing could be adversely affected.

Third-party payors may deny reimbursement if they determine that a device used in a procedure was not used in accordance with cost-effective treatment methods as determined by such third-party payors, or was used for an unapproved indication. Third-party payors may also deny reimbursement for experimental procedures and devices.

We believe that many of our existing products are cost-effective, even though the one-time cost may be significant, because they are intended to improve quality of life and reduce overall health care costs over a long period of time. We cannot be certain that these third-party payors will recognize these cost savings instead of merely focusing on the lower initial costs associated with competing therapies. If our products are not considered cost-effective by third-party payors, our customers may not be reimbursed for them, resulting in lower sales of our products.

Legal, Compliance, and Regulatory Risks

We may incur losses from product liability or other claims that could adversely affect our operating results.

Our business exposes us to potential product liability risks that are inherent in the design, manufacture, and marketing of medical technologies. Our products are often used in surgical and intensive care settings with seriously ill patients. In addition, many of the devices we manufacture and sell are designed to be implanted in the human body for long periods of time. Component failures, manufacturing and assembly flaws, design defects, software defects, medical procedure errors, or inadequate disclosure of product-related risks or product-related information could result in an unsafe condition or injury to, or

Table of Contents

death of, patients. Such problems could result in product liability, medical malpractice or other lawsuits and claims, safety alerts, or product recalls in the future, which, regardless of their ultimate outcome, could have a material adverse effect on our business, reputation, and ability to attract and retain customers. Product liability claims may be brought from time to time either by individuals or by groups seeking to represent a class. We may incur charges related to such matters in excess of any established reserves and such charges, including the establishment of any such reserves, could have a material adverse impact on our net income and net cash flows.

Our inability to protect our intellectual property or failure to maintain the confidentiality and integrity of data or other sensitive company information, by cyber-attack or other event, could have a material adverse effect on our business.

Our success and competitive position are dependent in part upon our proprietary intellectual property. We rely on a combination of patents and trade secrets to protect our proprietary intellectual property, and we expect to continue to do so. Although we seek to protect our proprietary rights through a variety of means, we cannot guarantee that the protective steps we have taken are adequate to protect these rights. Patents issued to or licensed by us in the past or in the future may be challenged and held invalid. In addition, as our patents expire, we may be unsuccessful in extending their protection through patent term extensions. The expiration of, or the failure to maintain or extend our patents, could have a material adverse effect on us.

We also rely on confidentiality agreements with certain employees, consultants, and other third parties to protect, in part, trade secrets and other proprietary information. These agreements could be breached, and we may not have adequate remedies for such a breach. In addition, others could independently develop substantially equivalent proprietary information or gain access to our trade secrets or proprietary information.

Our intellectual property, other proprietary technology, and other sensitive company information is dependent on sophisticated information technology systems and is potentially vulnerable to cyber-attacks, loss, damage, destruction from system malfunction, computer viruses, loss of data privacy, or misappropriation or misuse of it by those with permitted access, and other events. While we have invested to protect our intellectual property and other information, and continue to work diligently to upgrade and enhance our systems to keep pace with continuing changes in information processing technology, there can be no assurance that our precautionary measures will prevent breakdowns, breaches, cyber-attacks, or other events. Such events could have a material adverse effect on our reputation, financial condition, or results of operations.

We spend significant resources to enforce our intellectual property rights, sometimes resulting in litigation. Intellectual property litigation is complex and can be expensive and time-consuming. However, our efforts in this regard may not be successful. We may not be able to detect infringement. In addition, competitors may design around our technology or develop competing technologies. Patent litigation can result in substantial cost and diversion of effort. Intellectual property protection may also be unavailable or limited in some foreign countries, enabling our competitors to capture increased market position. The invalidation of key intellectual property rights or an unsuccessful outcome in lawsuits filed to protect our intellectual property could have a material adverse effect on our financial condition, results of operations, or prospects.

Third parties may claim we are infringing their intellectual property, and we could suffer significant litigation or licensing expenses or be prevented from selling products.

During recent years, we and our competitors have been involved in substantial litigation regarding patent and other intellectual property rights in the medical technology industry. From time to time, we have been and may in the future be forced to defend against claims and legal actions alleging infringement of the intellectual property rights of others, and such intellectual property litigation is typically costly and time-consuming. Adverse determinations in any such

litigation could result in significant liabilities to third parties or injunctions that bar the sale of our products, or could require us to seek licenses from third parties and, if such licenses are not available on commercially reasonable terms, prevent us from manufacturing, selling, or using certain products, any one of which could have a material adverse effect on us. In addition, some licenses may be non-exclusive, which could provide our competitors access to the same technologies.

Third parties could also obtain patents that may require us to either redesign products or, if possible, negotiate licenses from such third parties. Such licenses may materially increase our expenses. If we are unable to redesign products or obtain a license, we might have to exit a particular product offering.

Table of Contents

We and our customers are subject to rigorous governmental regulations and we may incur significant expenses to comply with these regulations and develop products that are compatible with these regulations. In addition, failure to comply with these regulations could subject us to substantial sanctions which could adversely affect our business, results of operations, and financial condition.

The medical technologies we manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state, and foreign governmental authorities, including regulations that cover the composition, labeling, testing, clinical study, design, sourcing, manufacturing, packaging, marketing, advertising, promotion, and distribution of our products.

We are required to register with the FDA as a device manufacturer. As a result, we are subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulation ("QSR") requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, design, quality control, and documentation procedures. The FDA may also inspect our compliance with requirements related to adverse event reporting, recalls or corrections (field actions), the conduct of clinical studies, and other requirements. In the European Union, we are required to maintain certain CE Mark and ISO certifications in order to sell our products, and are subject to periodic inspections by notified bodies to obtain and maintain these certifications. If we or our suppliers fail to adhere to QSR, CE Mark, ISO, or similar requirements, this could delay or interrupt product production or sales and/or lead to fines, difficulties in obtaining regulatory clearances, recalls, or other consequences, which in turn could have a material adverse effect on our financial condition and results of operations or prospects.

Medical devices must receive FDA clearance or approval before they can be commercially marketed in the United States. In addition, the FDA may require testing and surveillance programs to monitor the effects of approved products that have been commercialized, and can prevent or limit further marketing of a product based upon the results of post-marketing programs. In addition, the federal Medical Device Reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, would be likely to cause or contribute to a death or serious injury. Federal regulations also require us to report certain recalls or corrective actions to the FDA. Furthermore, most major markets for medical devices outside the United States require clearance, approval, or compliance with certain standards before a product can be commercially marketed. The process of obtaining regulatory clearances or approvals to market a medical device, particularly from the FDA and certain foreign governmental authorities, can be costly and time-consuming, and clearances or approvals may not be granted for products or product improvements on a timely basis, if at all. Delays in receipt of, or failure to obtain, clearances or approvals for products or product improvements could result in delayed realization of product revenues or in substantial additional costs, which could have a material adverse effect on our business or results of operations or prospects. At any time after approval of a product for commercial sale, the FDA may conduct periodic inspections to determine compliance with QSR requirements, and/or current Medical Device Reporting regulations, or other regulatory requirements. Noncompliance with applicable requirements may subject us or responsible individuals to sanctions including civil money penalties, product seizure, injunction, or criminal prosecution. In addition, the FDA may withhold or delay pre-market approval of our products until the noncompliance is resolved. Product approvals by the FDA can also be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval.

Regulatory agencies in the United States or other international geographies from time to time limit or ban the use of certain materials used in the manufacture of our products, require collection and disposal of products at the end of their lifecycle, and require disclosure of the origin of certain raw materials in our products. Noncompliance with applicable requirements could have a material adverse effect on our business.

The United States Physician Payment Sunshine Act, and similar laws in other jurisdictions, also impose reporting and disclosure requirements on device, pharmaceutical, and biologics companies for certain financial relationships with United States health care providers and teaching hospitals. Failure to submit required information or submitting incorrect information may result in significant civil monetary penalties.

We are also subject to various United States and international laws pertaining to health care pricing, anti-corruption, and fraud and abuse, including prohibitions on kickbacks and the submission of false claims laws and restrictions on relationships with physicians and other referral sources. These laws are broad in scope and are subject to evolving interpretation, which could require us to incur substantial costs to monitor compliance or to alter our practices if we are found not to be in compliance. Violations of these laws may be punishable by criminal or civil sanctions against us and our officers and employees, including substantial fines, imprisonment, and exclusion from participation in governmental health care programs.

Despite our implementation of robust compliance processes, we may be subject, from time to time, to inspections, investigations, and other enforcement actions by governmental authorities. If we are found not to be in compliance with

Table of Contents

applicable laws or regulations, the applicable governmental authority can impose fines, delay, suspend, or revoke regulatory clearances or approvals, institute proceedings to detain or seize our products, issue a recall, impose marketing or operating restrictions, enjoin future violations and assess civil penalties against us or our officers or employees, and institute criminal prosecution. Moreover, governmental authorities can ban or request the recall, repair, replacement, or refund of the cost of any device or product we manufacture or distribute. Any of the foregoing actions could result in decreased sales as a result of negative publicity and product liability claims, and could have a material adverse effect on our financial condition, results of operations, and prospects. In addition to the sanctions for noncompliance described above, commencement of an enforcement proceeding, inspection, or investigation could divert substantial management attention from the operation of our business and have an adverse effect on our business, results of operations, and financial condition.

Our industry is experiencing greater scrutiny and regulation by governmental authorities, which may lead to greater governmental regulation in the future.

In recent years, the medical technology industry has been subject to increased regulatory scrutiny, including by the FDA, numerous other federal, state, and foreign governmental authorities, as well as members of Congress. This has included increased regulation, enforcement, inspections, and governmental investigations of the medical technology industry and disclosure of financial relationships with health care professionals. We anticipate that the government will continue to scrutinize our industry closely, and that additional regulation by governmental authorities, both foreign and domestic, may increase compliance costs, exposure to litigation, and other adverse effects to our operations.

We are subject to risks arising from concerns and/or regulatory actions relating to “mad cow disease.”

Certain of our products, including pericardial tissue valves, are manufactured using bovine tissue. Concerns relating to the potential transmission of BSE, commonly known as "mad cow disease," from cows to humans may result in reduced acceptance of products containing bovine materials. Certain medical device regulatory agencies have considered whether to continue to permit the sale of medical devices that incorporate bovine material. We obtain bovine tissue only from closely controlled sources within the United States and Australia. The bovine tissue used in our pericardial tissue valves is from tissue types considered by global health and regulatory organizations to have shown no risk of infectibility for the suspected BSE infectious agent. We have not experienced any significant adverse impact on our sales as a result of concerns regarding BSE, but no assurance can be given that such an impact may not occur in the future.

Use of our products in unapproved circumstances could expose us to liabilities.

The marketing approval from the FDA and other regulators of certain of our products are, or are expected to be, limited to specific indications. We are prohibited from marketing or promoting any unapproved use of our products. Physicians, however, can use these products in ways or circumstances other than those strictly within the scope of the regulatory approval. Although the product training we provide to physicians and other health care professionals is limited to approved uses or for clinical trials, no assurance can be given that claims might not be asserted against us if our products are used in ways or for procedures that are not approved.

Our operations are subject to environmental, health, and safety regulations that could result in substantial costs.

Our operations are subject to environmental, health, and safety laws, and regulations concerning, among other things, the generation, handling, transportation, and disposal of hazardous substances or wastes, the cleanup of hazardous substance releases, and emissions or discharges into the air or water. We have incurred and may incur in the future

expenditures in connection with environmental, health and safety laws, and regulations. New laws and regulations, violations of these laws or regulations, stricter enforcement of existing requirements, or the discovery of previously unknown contamination could require us to incur costs or could become the basis for new or increased liabilities that could be material.

Item 1B. Unresolved Staff Comments

None.

Table of Contents

Item 2. Properties

The locations and uses of our major properties are as follows:

North America		
Irvine, California	(1)	Corporate Headquarters, Research and Development, Regulatory and Clinical Affairs, Manufacturing, Marketing, Administration
Draper, Utah	(1)	Manufacturing, Administration
Haina, Dominican Republic	(2)	Manufacturing
Añasco, Puerto Rico	(2)	Manufacturing
Central America		
Cartago, Costa Rica	(2)	Manufacturing (under construction)
Europe		
Nyon, Switzerland	(1)	Administration, Marketing
Prague, Czech Republic	(2)	Administration
Shannon, Ireland	(2)	Manufacturing (under construction)
Asia		
Tokyo, Japan	(2)	Administration, Marketing, Distribution
Shanghai, China	(2)	Administration, Marketing
Singapore	(1),(2)	Manufacturing, Distribution, Administration

(1) Owned property.

(2) Leased property.

The Dominican Republic lease expires in 2022; the Puerto Rico property has two leases that expire in 2023; the Costa Rica lease expires in 2021; the Prague, Czech Republic lease expires in 2026; the Shannon, Ireland lease expires in 2024; the Tokyo, Japan lease expires in 2021; the Shanghai, China lease expires in 2021; and Singapore has one land lease that expires in 2036 and one that expires in 2041. We believe our properties have been well maintained, are in good operating condition, and are adequate for current needs.

Item 3. Legal Proceedings

For a description of our material pending legal proceedings, please see Note 17 to the "Consolidated Financial Statements" of this Annual Report on Form 10-K, which is incorporated by reference.

Item 4. Mine Safety Disclosures

Not applicable.

Table of Contents

PART II

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

Market Information

Our common stock is traded on the New York Stock Exchange (the "NYSE") under the symbol "EW."

Number of Stockholders

On January 31, 2019, there were 10,014 stockholders of record of our common stock.

Dividends

We have never paid any cash dividends on our capital stock and have no current plans to pay any cash dividends. Our current policy is to retain any future earnings for use in our business.

Unregistered Sales of Equity Securities

On November 26, 2016, we entered into an agreement and plan of merger to acquire Valtech Cardio Ltd. Pursuant to that agreement, on May 25, 2018, we issued 252,497 shares of its common stock to certain former shareholders of Valtech Cardio Ltd. in connection with the achievement of a milestone.

Issuer Purchases of Equity Securities

Period	Total Number of Shares (or Units) Purchased (a)	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (in millions) (b), (c)
October 1, 2018 through October 31, 2018	1,475,683	$ 150.26	1,475,683	$ 544.8
November 1, 2018 through November 30, 2018	597	147.80	—	544.8
	338,086	148.05	338,086	494.6

December 1, 2018 through December 31, 2018			
Total	1,814,366	149.84	1,813,769

(a) The difference between the total number of shares (or units) purchased and the total number of shares (or units) purchased as part of publicly announced plans or programs is due to shares withheld by us to satisfy tax withholding obligations in connection with the vesting of restricted stock units issued to employees.

(b) On November 15, 2017, the Board of Directors approved a stock repurchase program authorizing us to purchase on the open market, including pursuant to a Rule 10b5-1 plan, or in privately negotiated transactions, up to $1.0 billion of our common stock. The repurchase program does not have an expiration date.

(c) In October 2018, we paid $250.0 million under our accelerated share repurchase ("ASR") agreement and received an initial delivery of 1.4 million shares of our common stock, representing approximately 80 percent of the total contract value. In November 2018, the ASR agreement concluded and we received an additional 0.3 million shares. Shares purchased pursuant to the ASR agreement are presented in the table above in the periods in which they were received.

Table of Contents

Performance Graph

The following graph compares the performance of our common stock with that of the S&P 500 Index and the S&P 500 Health Care Equipment Index. The cumulative total return listed below assumes an initial investment of $100 at the market close on December 31, 2013 and reinvestment of dividends. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.

	Total Cumulative Return				
	2014	2015	2016	2017	2018
Edwards Lifesciences	$193.70	$240.21	$284.98	$342.79	$465.85
S&P 500	113.69	115.26	129.05	157.22	150.33
S&P 500 Health Care Equipment	126.28	133.82	142.50	186.53	216.82

Table of Contents

Item 6. Selected Financial Data

		As of or for the Years Ended December 31,				
		2018	2017	2016	2015	2014
		(in millions, except per share data)				
OPERATING RESULTS	Net sales	$3,722.8	$3,435.3	$2,963.7	$2,493.7	$2,322.9
	Gross profit	2,783.4	2,560.0	2,166.3	1,876.5	1,697.3
	Operating income (a)	748.2	1,089.4	751.2	636.1	1,212.5
	Net income (a)	722.2	583.6	569.5	494.9	811.1
COMMON STOCK INFORMATION	Net income per common share (a):					
	Basic	$3.45	$2.77	$2.67	$2.30	$3.81
	Diluted	3.38	2.70	2.61	2.25	3.74
	Cash dividends declared per common share	—	—	—	—	—
BALANCE SHEET DATA	Total assets	$5,323.7	$5,666.4	$4,518.5	$4,056.3	$3,519.0
	Long-term debt (b)	593.8	438.4	822.3	596.9	594.1

(a) The above results include special charges of $109.1 million during 2018 and $59.9 million during 2017. Also, the above results include a $180.0 million ($137.5 million, net of tax) charge related to a litigation settlement, a $112.5 million ($70.3 million, net of tax) gain for a litigation payment received in 2017, and a $750.0 million ($487.9 million, net of tax) gain for a payment received in 2014 under a litigation settlement. In addition, in 2017, the above results reflect a $262.0 million tax expense related to the implementation of U.S. tax law changes. See Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Note 3, Note 4 and Note 16 to the "Consolidated Financial Statements" for additional information.

(b) In October 2013, we issued $600.0 million of 2.875% fixed-rate unsecured senior notes due October 15, 2018 (the "2013 Notes"). At December 31, 2017, the 2013 Notes were classified as short-term obligations as these obligations were due within one year. These 2013 Notes were paid in October 2018. In June 2018, we issued $600.0 million of 4.3% fixed-rate unsecured senior notes due June 15, 2028, which were classified as long-term obligations. Amounts outstanding under our Five-Year Credit Agreement ("Credit Agreement") have been classified as long-term obligations in accordance with the terms of the Credit Agreement.

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

The following discussion and analysis presents the factors that had a material effect on our results of operations during the three years ended December 31, 2018. Also discussed is our financial position as of December 31, 2018. You should read this discussion in conjunction with the historical consolidated financial statements and related notes included elsewhere in this Form 10-K.

Overview

We are the global leader in patient-focused medical innovations for structural heart disease and critical care monitoring. Driven by a passion to help patients, we partner with the world's leading clinicians and researchers and invest in research and development to transform care for those impacted by structural heart disease or who require hemodynamic monitoring during surgery or in intensive care. We conduct operations worldwide and are managed in the following geographical regions: United States, Europe, Japan, and Rest of World. Our products are categorized

into the following main areas: Transcatheter Heart Valve Therapy ("THVT"), Surgical Heart Valve Therapy ("SHVT"), and Critical Care. Beginning in 2019, we will report our sales in four main areas: Transcatheter Aortic Valve Replacement, Surgical Structural Heart, Critical Care, and Transcatheter Mitral and Tricuspid Therapies ("TMTT"). Going forward, TMTT will be reported as a separate product category to allow greater visibility into our performance in transcatheter mitral and tricuspid therapies.

Table of Contents

Financial Highlights

Our sales growth was led by our THVT products, primarily due to increased sales of the Edwards SAPIEN 3 transcatheter heart valve across all regions, primarily the United States, and our Critical Care products, primarily the introduction of our HemoSphere advanced monitoring platform in the United States. Our 2018 SHVT net sales in the United States decreased compared to 2017, primarily related to a $82.5 million sales return reserve related to our conversion to a consignment inventory model for surgical valves. Our gross profit margin in 2018 and 2017 was positively impacted by an improved product mix, led by THVT products.

The increase in our net income in 2018 was primarily driven by the aforementioned operating performance, combined with tax benefits from a reduction in the U.S. federal corporate rate from 35% to 21% and the settlement of tax audits. This increase was partially offset by charges for a litigation settlement and impairment of intangible assets. The increase in our net income in 2017 was primarily driven by our increased sales and a gain from litigation related to the theft of trade secrets, partially offset by increased tax expenses associated with the Tax Cuts and Jobs Act.

Healthcare Environment, Opportunities, and Challenges

The medical technology industry is highly competitive and continues to evolve. Our success is measured both by the development of innovative products and the value we bring to our stakeholders. We are committed to developing new technologies and providing innovative patient care, and we are committed to defending our intellectual property in support of those developments. In 2018, we invested 16.7% of our net sales in research and development. The following is a summary of important developments during 2018:

- we received CE Mark for the SAPIEN 3 Ultra system for transcatheter aortic valve replacement in severe, symptomatic aortic stenosis patients and we received FDA approval for the SAPIEN 3 Ultra system for those patients who are determined to be at intermediate or greater risk of open-heart surgery;
- we received CE Mark for our self-expanding CENTERA valve for severe, symptomatic aortic stenosis patients at high risk of open-heart surgery, and we initiated a pivotal trial in the United States to study CENTERA for severe, symptomatic aortic stenosis patients at intermediate risk of open-heart surgery;
- we received regulatory approval of our Acumen Hypotension Prediction Index in the United States. This technology leverages predictive analytics to alert clinicians of hypotension, or low blood pressure, before it occurs in their surgical patients;
- we received CE Mark for the Edwards Cardioband tricuspid valve reconstruction system for the treatment of tricuspid regurgitation;

Table of Contents

- we received FDA approval for the Acumen suite of intelligent decision-support solutions for use on the HemoSphere advanced monitoring platform; and
- we reached an agreement with Boston Scientific Corporation ("Boston Scientific") in January 2019 to settle all outstanding patent disputes for a one-time payment to Boston Scientific of $180.0 million.

We are dedicated to generating robust clinical, economic, and quality of life evidence increasingly expected by patients, clinicians, and payors in the current healthcare environment, with the goal of encouraging the adoption of innovative new medical therapies that demonstrate superior outcomes.

Results of Operations

Net Sales by Major Regions
(dollars in millions)

	Years Ended December 31,			Change		Percent Change	
	2018	2017	2016	2018	2017	2018	2017
United States	$2,055.3	$1,907.6	$1,615.7	$147.7	$291.9	7.7 %	18.1%
Europe	885.1	831.0	749.0	54.1	82.0	6.5 %	10.9%
Japan	396.8	350.3	309.3	46.5	41.0	13.3%	13.3%
Rest of World	385.6	346.4	289.7	39.2	56.7	11.4%	19.5%
International	1,667.5	1,527.7	1,348.0	139.8	179.7	9.2 %	13.3%
Total net sales	$3,722.8	$3,435.3	$2,963.7	$287.5	$471.6	8.4 %	15.9%

International net sales include the impact of foreign currency exchange rate fluctuations. The impact of foreign currency exchange rate fluctuations on net sales is not necessarily indicative of the impact on net income due to the corresponding effect of foreign currency exchange rate fluctuations on international manufacturing and operating costs, and our hedging activities. For more information, see "Quantitative and Qualitative Disclosures About Market Risk."

Net Sales by Product Group
(dollars in millions)

	Year Ended December 31,			Change		Percent Change	
	2018	2017	2016	2018	2017	2018	2017
Transcatheter Heart Valve Therapy	$2,286.7	$2,027.2	$1,628.5	$259.5	$398.7	12.8 %	24.5%
Surgical Heart Valve Therapy	761.6	807.1	774.9	(45.5)	32.2	(5.6)%	4.2 %
Critical Care	674.5	601.0	560.3	73.5	40.7	12.2 %	7.3 %
Total net sales	$3,722.8	$3,435.3	$2,963.7	$287.5	$471.6	8.4 %	15.9%

Table of Contents

Transcatheter Heart Valve Therapy
2018 Compared with 2017

The increase in net sales of THVT products was due primarily to:

- higher sales of the Edwards SAPIEN 3 valve across all regions, particularly the United States and Japan, driven by strong therapy adoption; and
- foreign currency exchange rate fluctuations, which increased net sales by $20.0 million, due primarily to the strengthening of the Euro against the United States dollar.

2017 Compared with 2016

The increase in net sales of THVT products in the United States was due primarily to:

- the Edwards SAPIEN 3 valve, driven by strong therapy adoption.

The increase in international net sales of THVT products was due primarily to:

- the Edwards SAPIEN 3 valve, due primarily to increased sales in Japan, driven by its launch in March 2016, and Europe, driven by strong therapy adoption;

partially offset by:

- lower sales of the Edwards SAPIEN XT valve as customers converted to Edwards SAPIEN 3.

In February 2018, we received CE Mark for our self-expanding CENTERA valve for severe, symptomatic aortic stenosis patients at high risk of open-heart surgery. Also, in April 2018, we received approval to initiate a United States pivotal trial to study CENTERA for severe, symptomatic aortic stenosis patients at intermediate risk of open-heart surgery, and commenced the trial in October 2018. In April 2018, we received United States Food and Drug Administration approval for a limited continued access protocol of our PARTNER 3 Trial for low-risk patients with severe aortic stenosis in the United States, which we began enrolling late in the third quarter of 2018. Also in April 2018, we received CE Mark for the Edwards Cardioband tricuspid valve reconstruction system for the treatment of tricuspid regurgitation. In November 2018, we received CE Mark for the Edwards SAPIEN 3 Ultra System, which features the SAPIEN 3 Ultra valve with a heightened outer skirt, and a delivery system that incorporates an on-balloon design that is compatible with the low-profile Axela sheath. In December 2018, we received

Table of Contents

FDA approval for the Edwards SAPIEN 3 Ultra System for severe, symptomatic aortic stenosis patients who are determined to be at intermediate or greater risk of open-heart surgery.

Surgical Heart Valve Therapy

2018 Compared with 2017

The decrease in net sales of SHVT products was due primarily to:

- sales return reserves in the United States related to our conversion to a consignment inventory model for surgical valves;

partially offset by:

- increased sales of surgical aortic tissue valves in the United States and Rest of World; and
- foreign currency exchange rate fluctuations, which increased net sales by $9.2 million, due primarily to the strengthening of the Euro against the United States dollar.

2017 Compared with 2016

The increase in net sales of SHVT products was due primarily to:

- surgical aortic tissue valves in Europe and the United States, primarily due to increased sales of the EDWARDS INTUITY Elite Valve System, and growth in our core products, partially offset by the continuing shift from our surgical aortic tissue valves to transcatheter aortic valves; and
- mitral tissue valves, due to increased sales in Rest of World, primarily China.

In September 2018, we began launching our INSPIRIS RESILIA aortic valve in Japan. The INSPIRIS RELILIA valve is the first in a new class of resilient heart valves designed to be an option for active patients.

Table of Contents

Critical Care
2018 Compared with 2017

The increase in net sales of Critical Care products was driven by our HemoSphere advanced monitoring platform, core hemodynamic products, and our enhanced recovery products, primarily in the United States. In addition, foreign currency exchange rate fluctuations increased net sales by $5.1 million, due primarily to the strengthening of the Euro against the United States dollar.

2017 Compared with 2016

The increase in net sales of Critical Care products was due primarily to enhanced surgical recovery products and core hemodynamic products, primarily in the United States and Rest of World.

During the first quarter of 2018, we received regulatory approval of our Acumen Hypotension Prediction Index in the United States. This technology leverages predictive analytics to alert clinicians of hypotension, or low blood pressure, before it occurs in their surgical patients. In the fourth quarter of 2018, we received FDA approval of our Acumen Hypotension Prediction Index for use on the HemoSphere platform.

Table of Contents

Gross Profit

The increase in gross profit as a percentage of net sales in 2018 compared to 2017 was driven by:

- a 0.7 percentage point increase in the United States and a 0.2 percentage point increase in international markets due to an improved product mix, driven by THVT products;

partially offset by:

- the impact of multiple investments in our operations, including an increase in costs to improve our manufacturing processes; and
- a 0.2 percentage point decrease due to the impact of foreign currency exchange rate fluctuations, including the settlement of foreign currency hedging contracts.

The increase in gross profit as a percentage of net sales in 2017 compared to 2016 was driven by:

- a 1.3 percentage point increase in the United States and a 0.3 percentage point increase in international markets due to an improved product mix, driven by THVT products;

partially offset by:

- expenses associated with flooding from Hurricane Maria in Puerto Rico and the planned closure of our manufacturing plant in Switzerland.

Table of Contents

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

The increase in SG&A expenses in 2018 compared to 2017 was due primarily to (1) higher sales and marketing expenses in the United States, Europe and Rest of World, mainly to support the THVT program, (2) higher personnel-related costs, and (3) the impact of foreign currency, which increased expenses by $10.6 million primarily due to the strengthening of the Euro against the United States dollar. The increase in SG&A expenses as a percentage of net sales in 2018 was due primarily to the previously mentioned expense increases.

The increase in SG&A expenses in 2017 compared to 2016 was due primarily to higher sales and marketing expenses in the United States and Europe, mainly to support the THVT program, and higher personnel-related costs. The decrease in SG&A expenses as a percentage of net sales in 2017 was due primarily to leverage from our higher THVT sales in the United States and Japan.

Research and Development ("R&D") Expenses
The increase in R&D expenses in 2018 compared to 2017 was due primarily to investments in our transcatheter structural heart programs, including spending on clinical trials.

The increase in R&D expenses in 2017 compared to 2016 was due primarily to investments in our transcatheter structural heart programs, including development expenses associated with the Cardioband Reconstruction System.

Table of Contents

Intellectual Property Litigation Expenses (Income), net

We incurred intellectual property litigation expenses, including settlements and external legal costs, of $214.0 million, $39.2 million and $32.6 million during 2018, 2017 and 2016, respectively. In January 2019, we reached an agreement with Boston Scientific to settle all outstanding patent disputes for a one-time payment to Boston Scientific of $180.0 million, which was included as an expense in 2018. The settlement covers alleged past damages and no further royalties will be owed by either party. In November 2017, we recorded a $112.5 million litigation gain related to the theft of trade secrets.

Change in Fair Value of Contingent Consideration Liabilities, net

The change in fair value of contingent consideration liabilities resulted in income of $5.7 million, income of $9.9 million, and expense of $1.1 million for the years ended December 31, 2018, 2017, and 2016, respectively. The income in 2018 and 2017 was due primarily to longer product development timelines, which reduced the probability of milestone achievements. These gains were net of expenses associated with changes in the fair value of the liabilities associated with the December 2017 acquisition of Harpoon Medical Inc., the achievement by Valtech Cardio Ltd. of a regulatory milestone, adjustments to discount rates, and accretion of interest due to the passage of time. For further information, see Note 10 to the "Consolidated Financial Statements."

Special Charges, net

For information on special charges, see Note 4 to the "Consolidated Financial Statements."

Interest Expense

Interest expense was $29.9 million, $23.2 million, and $19.2 million in 2018, 2017, and 2016, respectively. The increase in interest expense for 2018 as compared to 2017 resulted primarily from higher average interest rates. The increase in interest expense for 2017 as compared to 2016 resulted primarily from a higher average debt balance, partially offset by lower average interest rates.

Interest Income

Interest income was $32.0 million, $20.3 million, and $10.8 million in 2018, 2017, and 2016, respectively. The increase in interest income for 2018 and 2017 resulted primarily from higher average interest rates.

Other (Income) Expense, net
(in millions)

	Years Ended December 31,		
	2018	2017	2016
Foreign exchange (gains) losses, net	$(6.7)	$5.4	$0.5
Loss (gain) on investments	1.7	2.7	(0.2)
Non-service cost components of net periodic pension benefit (credit) cost	(0.1)	(6.1)	—
Charitable foundation contribution	—	—	5.0
Other	1.1	(0.6)	(0.4)
Total other (income) expense, net	$(4.0)	$1.4	$4.9

The net foreign exchange (gains) losses relate primarily to the foreign currency fluctuations in our global trade and intercompany receivable and payable balances, offset by the gains and losses on derivative instruments intended as an economic hedge of those exposures.

The loss (gain) on investments primarily represents our net share of gains and losses in investments accounted for under the equity method, and realized gains and losses on our available-for-sale money market and cost method investments.

The non-service cost components of net periodic pension benefit (credit) cost includes the costs of our defined benefit plans that are not attributed to services rendered by eligible employees during the year, such as interest costs, expected return on plan assets, and amortization of actuarial gains or losses. Certain costs associated with realignments, including settlements

Table of Contents

and curtailments, have been included as a component of "Special (Gains) Charges, net." For further information, see Notes 4 and 12 to the "Consolidated Financial Statements."

In March 2016, we contributed $5.0 million to the Edwards Lifesciences Foundation, a related-party not-for-profit organization intended to provide philanthropic support to health- and community-focused charitable organizations. The
contribution was irrevocable and was recorded as an expense at the time of payment.

Provision for Income Taxes

Our effective income tax rates for 2018, 2017, and 2016 were impacted as follows (in millions):

	Years Ended December 31,		
	2018	2017	2016
Income tax expense at U.S. federal statutory rate	$159.9	$362.2	$258.3
Foreign income taxed at different rates	(16.2)	(106.9)	(88.6)
State and local taxes, net of federal tax benefit	6.8	11.5	9.7
Tax credits, federal and state	(36.7)	(25.8)	(21.3)
(Release) build of reserve for prior years' uncertain tax positions	(35.5)	(7.7)	4.6
U.S. tax on foreign earnings, net of credits	(12.2)	(30.3)	5.1
Foreign-derived intangible income deduction	(6.6)	—	—
Deductible employee share-based compensation	(41.8)	(48.2)	—
Nondeductible employee share-based compensation	2.8	3.9	3.6
Impacts related to 2017 U.S. Tax Reform	15.8	294.1	—
Other	2.9	(1.5)	(3.0)
Income tax provision	$39.2	$451.3	$168.4

On December 22, 2017, Public Law 115-97, commonly referred to as the Tax Cuts and Jobs Act (the "2017 Act"), was signed into law. The 2017 Act (1) reduced the U.S. federal corporate tax rate from 35 percent to 21 percent for tax years beginning after December 31, 2017, (2) required companies to pay a one-time mandatory deemed repatriation tax on the cumulative earnings of certain foreign subsidiaries that were previously tax deferred, and (3) created new taxes on certain foreign earnings in future years.

On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of generally accepted accounting principles in the United States of America ("GAAP") in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the 2017 Act. In accordance with SAB 118, as of December 31, 2017, we estimated provisional amounts for (1) $3.3 million of tax benefits in connection with the remeasurement of certain tax assets and liabilities, (2) $297.4 million of net tax expense recorded in connection with the one-time mandatory deemed repatriation tax on cumulative earnings of certain foreign subsidiaries, and (3) $32.3 million of tax benefits associated with a tax reform related restructuring. In accordance with SAB 118, during 2018 we adjusted the provisional amounts as described below.

As a result of Internal Revenue Service ("IRS") guidance issued subsequent to the 2017 Act, the $32.3 million of tax benefits associated with the tax reform related restructuring mentioned above were reversed. In addition, during 2018, we recorded a $12.8 million reduction in the repatriation tax and an additional benefit of $3.7 million in connection with the remeasurement of deferred tax assets. In accordance with SAB 118, we completed our accounting for the

2017 Act during the fourth quarter of 2018.

Our effective tax rate for 2018 is lower than our effective tax rate for 2017 primarily because of the benefit from the reduction in the U.S. federal corporate rate from 35% to 21% and tax benefits related to the settlement of tax audits. In addition, the effective rate for 2017 included the one-time impact of the mandatory taxation of previously unrepatriated earnings, partially offset by the revaluation of tax-related balance sheet items due to the U.S. tax rate changes required by the 2017 Act.

Table of Contents

Uncertain Tax Positions

As of December 31, 2018 and 2017, gross uncertain tax positions were $150.7 million and $225.6 million, respectively. We estimate that these liabilities would be reduced by $42.7 million and $94.0 million, respectively, from offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes, and timing adjustments. The net amounts of $108.0 million and $131.6 million, respectively, if not required, would favorably affect our effective tax rate.

A reconciliation of the beginning and ending amount of uncertain tax positions, excluding interest, penalties, and foreign exchange, is as follows (in millions):

	Years Ended December 31,		
	2018	2017	2016
Uncertain gross tax positions, January 1	$225.6	$245.5	$216.1
Current year tax positions	37.8	77.7	29.0
Increase in prior year tax positions	13.9	63.7	2.7
Decrease in prior year tax positions	(78.8)	(65.0)	(0.9)
Settlements	(46.5)	(95.3)	(0.3)
Lapse of statutes of limitations	(1.3)	(1.0)	(1.1)
Uncertain gross tax positions, December 31	$150.7	$225.6	$245.5

The table above summarizes the gross amounts of uncertain tax positions without regard to reduction in tax liabilities or additions to deferred tax assets and liabilities if such uncertain tax positions were settled.

We recognize interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. As of December 31, 2018, we had accrued $4.6 million (net of $1.9 million tax benefit) of interest related to uncertain tax positions, and as of December 31, 2017, we had accrued $7.4 million (net of $2.9 million tax benefit) of interest related to uncertain tax positions. During 2018, 2017, and 2016, we recognized interest (benefit) expense, net of tax benefit, of $(2.8) million, $(7.3) million, and $4.0 million, respectively, in “Provision for Income Taxes” on the consolidated statements of operations.

We strive to resolve open matters with each tax authority at the examination level and could reach agreement with a tax authority at any time. While we have accrued for matters we believe are more likely than not to require settlement, the final outcome with a tax authority may result in a tax liability that is more or less than that reflected in the consolidated financial statements. Furthermore, we may later decide to challenge any assessments, if made, and may exercise our right to appeal. The uncertain tax positions are reviewed quarterly and adjusted as events occur that affect potential liabilities for additional taxes, such as lapsing of applicable statutes of limitations, proposed assessments by tax authorities, negotiations between tax authorities, identification of new issues, and issuance of new legislation, regulations, or case law. We believe that adequate amounts of tax and related penalty and interest have been provided in income tax expense for any adjustments that may result from our uncertain tax positions.

At December 31, 2018, all material state, local, and foreign income tax matters have been concluded for years through 2008. During 2018, we signed agreements with the IRS to settle tax years 2009 through 2014 including transfer pricing matters and the tax treatment of a portion of a litigation settlement payment received in 2014. The IRS began its examination of the 2015 and 2016 tax years during the fourth quarter of 2018.

During 2018, we executed an Advance Pricing Agreement ("APA") between the United States and Switzerland governments for tax years 2009 through 2020 covering various transfer pricing matters and we have updated our transfer pricing policies accordingly. Certain intercompany transactions covering tax years 2015 through 2018 were not resolved and those related tax positions remain uncertain. These transfer pricing matters may be significant to our consolidated financial statements. In addition, we executed other APAs as follows: during 2017, an APA between the United States and Japan covering tax years 2015 through 2019, and during 2018, APAs between Japan and Singapore as well as Switzerland and Japan covering tax years 2015 through 2019.

Based upon the information currently available and numerous possible outcomes, we cannot reasonably estimate what, if any, changes in our existing uncertain tax positions may occur in the next 12 months and thus have recorded the gross uncertain tax positions as a long-term liability.

Table of Contents

We have received tax incentives in certain non-U.S. tax jurisdictions, the primary benefit of which will expire in 2024. The tax reductions as compared to the local statutory rates were $144.9 million ($0.70 per diluted share), $81.0 million ($0.39 per diluted share), and $78.7 million ($0.32 per diluted share) for the years ended December 31, 2018, 2017, and 2016, respectively.

Our Dominican Republic branch receives tax incentives, including an exemption from paying Dominican Republic income taxes, under a Free Trade Zone law. Effective November 9, 2012, the Dominican Republic enacted a law which, among other tax provisions, would apply a 10% withholding tax on dividends or branch remittances from a Free Trade Zone company to its shareholder(s). The Dominican Republic withholding tax provision was, however, contingent upon certain future events. On October 5, 2016, the Dominican Republic Ministry of Finance published a notification confirming that the 10% withholding tax on branch remittances would be due and payable by Dominican Republic Free Trade Zone companies for dividends and remittances paid on or after October 5, 2016. The impact of this withholding tax has been reflected in our income tax provision.

Liquidity and Capital Resources

Our sources of cash liquidity include cash and cash equivalents, short-term investments, amounts available under credit facilities, and cash from operations. We believe that these sources are sufficient to fund the current requirements of working capital, capital expenditures, and other financial commitments for the next twelve months from the financial statement issuance date. However, we periodically consider various financing alternatives and may, from time to time, seek to take advantage of favorable interest rate environments or other market conditions.

The 2017 Act, which was signed into law on December 22, 2017, included extensive changes to the international tax regime. The 2017 Act required a deemed repatriation of post-1986 undistributed foreign earnings and profits. The deemed repatriation resulted in a $270.5 million tax obligation as of December 31, 2018. The one-time transition tax liability, as adjusted, is payable in seven remaining annual installments, as outlined in the contractual obligations table below. See Note 16 to the "Consolidated Financial Statements" for additional information about the one-time transition tax.

As of December 31, 2018, cash and cash equivalents and short-term investments held in the United States and outside the United States were $659.3 million and $297.2 million, respectively. During 2018, we repatriated cash and short-term investments of $1.4 billion. We assert that $1.1 billion of our foreign earnings continue to be permanently reinvested and our intent is to repatriate $0.6 billion of our foreign earnings as of December 31, 2018.

Certain of our business acquisitions involve contingent consideration arrangements. Payment of additional consideration in the future may be required, contingent upon the acquired company reaching certain performance milestones, such as attaining specified revenue levels, or obtaining regulatory approvals. For further information, see Note 7 to the "Consolidated Financial Statements."

In April 2018, we entered into a new Five-Year Credit Agreement ("the Credit Agreement") which matures on April 28, 2023, and the previous Five-Year Credit Agreement was terminated. The Credit Agreement provides up to an aggregate of$750.0 million in borrowings in multiple currencies. Subject to certain terms and conditions, we may increase the amount available under the Credit Agreement by up to an additional $250.0 million in the aggregate. As of December 31, 2018, there were no borrowings outstanding under the Credit Agreement. The Credit Agreement is unsecured and contains various financial and other covenants, including a maximum leverage ratio, as defined in the Credit Agreement. The Company was in compliance with all covenants at December 31, 2018.

In October 2013, we issued $600.0 million of 2.875% fixed-rate unsecured senior notes (the "2013 Notes") due October 15, 2018. The 2013 Notes were repaid in October 2018. In June 2018, we issued $600.0 million of 4.3% fixed-rate unsecured senior notes (the "2018 Notes") due June 15, 2028. A portion of the proceeds from the 2018 Notes were used to repay amounts outstanding under our previous Five-Year Credit Agreement, and the remainder was used to partially repay the maturing 2013 Notes and for general corporate purposes. As of December 31, 2018, the total carrying value of our 2018 Notes was $593.8 million. For further information on our debt, see Note 9 to the "Consolidated Financial Statements."

We reached an agreement with Boston Scientific to settle all outstanding patent disputes for a one-time payment to Boston Scientific of $180.0 million, which was paid in January 2019.

From time to time, we repurchase shares of our common stock under share repurchase programs authorized by the Board of Directors. We consider several factors in determining when to execute share repurchases, including, among other things, expected dilution from stock plans, cash capacity, and the market price of our common stock. During 2018, under the Board

Table of Contents

authorized repurchase programs, we repurchased a total of 5.4 million shares at an aggregate cost of $784.3 million, and as of December 31, 2018, we had remaining authority to purchase $0.5 billion of our common stock. For further information, see Note 13 to the "Consolidated Financial Statements."

Consolidated Cash Flows - For the twelve months ended December 31, 2018, 2017, and 2016

Net cash flows provided by operating activities of $926.8 million for 2018 decreased $73.9 million from 2017 due primarily to higher tax payments and a higher bonus payout in 2018 associated with 2017 performance, partially offset by improved operating performance in 2018 and higher working capital needs in 2017.

Net cash flows provided by operating activities of $1.0 billion for 2017 increased $296.3 million from 2016 due primarily to improved operating performance and receipt of a litigation payment, partially offset by higher working capital needs associated with growth in the business and the timing of tax payments.

Net cash provided by investing activities of $76.7 million in 2018 consisted primarily of net proceeds from investments of $323.2 million, partially offset by capital expenditures of $238.7 million.

Net cash used in investing activities of $647.2 million in 2017 consisted primarily of net purchases of investments of $235.7 million, capital expenditures of $168.1 million, a $100.0 million net cash payment associated with the acquisition of Harpoon Medical, Inc., and an $81.9 million net cash payment associated with the acquisition of Valtech Cardio Ltd.

Net cash used in investing activities of $211.7 million in 2016 consisted primarily of capital expenditures of $176.1 million and $41.3 million for the acquisition of intangible assets.

Net cash used in financing activities of $1.1 billion in 2018 consisted primarily of purchases of treasury stock of $795.5 million and net debt repayments of $437.3 million, partially offset by proceeds from stock plans of $147.0 million.

Net cash used in financing activities of $473.2 million in 2017 consisted primarily of purchases of treasury stock of $763.3 million, partially offset by (1) net proceeds from the issuance of debt of $176.3 million and (2) proceeds from stock plans of $113.8 million.

Net cash used in financing activities of $268.5 million in 2016 consisted primarily of purchases of treasury stock of $662.3 million, partially offset by (1) net proceeds from the issuance of debt of $222.1 million, (2) proceeds from stock plans of $103.3 million, and (3) the excess tax benefit from stock plans of $64.3 million.

Table of Contents

A summary of all of our contractual obligations and commercial commitments as of December 31, 2018 is as follows (in millions):

	Payments Due by Period				
Contractual Obligations	Total	Less Than 1 Year	1-3 Years	4-5 Years	After 5 Years
Debt	$600.0	$—	$—	$—	$600.0
Operating leases	91.2	25.6	35.0	16.3	14.3
Interest on debt	185.5	20.0	40.1	39.6	85.8
Transition tax on unremitted foreign earnings and profits (a)	270.5	8.9	49.8	71.6	140.2
Litigation settlement obligation	180.0	180.0	—	—	—
Pension obligations (b)	1.9	1.9	—	—	—
Purchase and other commitments	34.6	12.6	19.5	0.6	1.9
Total contractual cash obligations (c), (d)	$1,363.7	$249.0	$144.4	$128.1	$842.2

(a) As of December 31, 2018, we had recorded $270.5 million of income tax liabilities related to the one-time transition tax that resulted from the enactment of the 2017 Act. The transition tax is due in eight annual installments, and the first annual installment was paid in 2018. The second annual installment is 8% of the total liability, net of a $16.1 million overpayment of 2017 federal income taxes. The remaining installment amounts will be equal to 8% of the total liability, payable in fiscal years 2020 through 2022, 15% in fiscal year 2023, 20% in fiscal year 2024, and 25% in fiscal year 2025. See Note 16 to the "Consolidated Financial Statements" for additional information about the one-time transition tax.

(b) The amount included in "Less Than 1 Year" reflects anticipated contributions to our various pension plans. Anticipated contributions beyond one year are not determinable. The total accrued benefit liability for our pension plans recognized as of December 31, 2018 was $37.0 million. This amount is impacted by, among other items, pension expense funding levels, changes in plan demographics and assumptions, and investment returns on plan assets. Therefore, we are unable to make a reasonably reliable estimate of the amount and period in which the liability might be paid, and did not include this amount in the contractual obligations table. See Note 12 to the "Consolidated Financial Statements" for further information.

(c) As of December 31, 2018, the gross liability for uncertain tax positions, including interest, was $157.2 million and relates primarily to transfer pricing matters. During 2018, we executed an Advance Pricing Agreement ("APA") between the United States and Switzerland governments for tax years 2009 through 2020 covering various transfer pricing matters and we have updated our transfer pricing policies accordingly. Certain intercompany transactions covering tax years 2015 through 2018 were not resolved and those related tax positions remain uncertain. These transfer pricing matters may be significant to our consolidated financial statements, and the final outcome of the negotiations is uncertain. Management believes that adequate amounts of tax and related penalty and interest have been provided in income tax expense for any adjustments that may result for our uncertain tax positions. We are unable to make a reasonably reliable estimate of the amount and period in which the liability might be paid, and did not include this amount in the contractual obligations table.

(d) We acquire assets still in development, enter into research and development arrangements, acquire businesses, and sponsor certain clinical trials that often require milestone, royalty, or other future payments to third-parties, contingent upon the occurrence of certain future events. In situations where we have no ability to influence the achievement of the milestone or otherwise avoid the payment, we have included those payments in the table above. However, we have excluded from the table contingent milestone payments and other contingent liabilities for which we cannot reasonably predict future payments or for which we can avoid making payment by unilaterally

deciding to stop development of a product or cease progress of a clinical trial. We estimate that these contingent payments could be up to $585.0 million if all milestones or other contingent obligations are met. This amount includes certain milestone-based contingent obligations that may be paid through a combination of cash and issuance of common stock.

Critical Accounting Policies and Estimates

Our results of operations and financial position are determined based upon the application of our accounting policies, as discussed in the notes to the "Consolidated Financial Statements." Certain of our accounting policies represent a selection among acceptable alternatives under GAAP. In evaluating our transactions, management assesses all relevant GAAP and chooses the accounting policy that most accurately reflects the nature of the transactions.

Table of Contents

The application of accounting policies requires the use of judgment and estimates. These matters that are subject to judgments and estimation are inherently uncertain, and different amounts could be reported using different assumptions and estimates. Management uses its best estimates and judgments in determining the appropriate amount to reflect in the consolidated financial statements, using historical experience and all available information. We also use outside experts where appropriate. We apply estimation methodologies consistently from year to year.

We believe the following are the critical accounting policies which could have the most significant effect on our reported results and require subjective or complex judgments by management.

Revenue Recognition

When we recognize revenue from the sale of our products, 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 include estimated amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. The estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely upon an assessment of historical payment experience, historical relationship to revenues, estimated customer inventory levels, and current contract sales terms with direct and indirect customers. Product returns are typically not significant because returns are generally not allowed unless the product is damaged at time of receipt. If the historical data and inventory estimates used to calculate the variable consideration do not approximate future activity, our financial position, results of operations, and cash flows could be impacted.

In addition, in limited circumstances, we may allow customers to return previously purchased products, such as for next-generation product offerings. For these transactions, we defer recognition of revenue on the sale of the earlier generation product based upon an estimate of the amount of product to be returned when the next-generation products are shipped to the customer. Uncertain timing of next-generation product approvals, variability in product launch strategies, product recalls, and variation in product utilization all affect the estimates related to sales returns and could cause actual returns to differ from these estimates.

Our sales adjustment related to distributor rebates given to our United States distributors represents the difference between our sales price to the distributor and the negotiated price to be paid by the end-customer. We validate the distributor rebate accrual quarterly through either a review of the inventory reports obtained from our distributors or an estimate of the distributor's inventory. This distributor inventory information is used to verify the estimated liability for future distributor rebate claims based on historical rebates and contract rates. We periodically monitor current pricing trends and distributor inventory levels to ensure the credit for future distributor rebates is fairly stated.

Excess and Obsolete Inventory

The valuation of our inventory requires us to estimate excess, obsolete, and expired inventory. We base our provisions for excess, obsolete, and expired inventory on our estimates of forecasted net sales. A significant change in the timing or level of demand for our products as compared to forecasted amounts may result in recording additional allowances for excess, obsolete, and expired inventory in the future. In addition, our industry is characterized by rapid product development and frequent new product introductions. Uncertain timing of next-generation product approvals, variability in product launch strategies, product recalls, increasing levels of consigned inventory, and variation in product utilization all affect our estimates related to excess, obsolete, and expired inventory.

Intangible Assets and Long-lived Assets

We acquire intangible assets in connection with business combinations and asset purchases. The acquired intangible assets are recorded at fair value, which is determined based on a discounted cash flow analysis. The determination of fair value requires significant estimates, including, but not limited to, the amount and timing of projected future cash flows, the discount rate used to discount those cash flows, the assessment of the asset's life cycle, including the timing and expected costs to complete in-process projects, and the consideration of legal, technical, regulatory, economic, and competitive risks.

IPR&D acquired in business combinations is reviewed for impairment annually, or whenever an event occurs or circumstances change that would indicate the carrying amount may be impaired. Additionally, management reviews the carrying amounts of other intangible and long-lived assets whenever events or circumstances indicate that the carrying amounts

Table of Contents

of an asset may not be recoverable. The impairment reviews require significant estimates about fair value, including estimation of future cash flows, selection of an appropriate discount rate, and estimates of long-term growth rates.

Contingent Consideration

We record contingent consideration resulting from a business combination at its fair value on the acquisition date. We determine the fair value of the contingent consideration based primarily on the following factors:

- timing and probability of success of clinical events or regulatory approvals;
- timing and probability of success of meeting commercial milestones; and
- discount rates.

On a quarterly basis, we revalue these obligations and record changes in their fair value as an adjustment to earnings. Changes to contingent consideration obligations can result from adjustments to discount rates, accretion of the discount rates due to the passage of time, changes in our estimates of the likelihood or timing of achieving development or commercial milestones, changes in the probability of certain clinical events, or changes in the assumed probability associated with regulatory approval.

The assumptions related to determining the value of contingent consideration include a significant amount of judgment, and any changes in the underlying estimates could have a material impact on the amount of contingent consideration expense recorded in any given period.

Income Taxes

The determination of our provision for income taxes requires significant judgment, the use of estimates, and the interpretation and application of complex tax laws. Realization of certain deferred tax assets, primarily tax credits, net operating loss and other carryforwards, is dependent upon generating sufficient taxable income in the appropriate jurisdiction prior to the expiration of the carryforward periods. Failure to achieve forecasted taxable income in the applicable taxing jurisdictions could affect the ultimate realization of deferred tax assets and could result in an increase in our effective tax rate on future earnings.

We have made an accounting policy election to recognize the U.S. tax effects of global intangible low-taxed income ("GILTI") as a component of income tax expense in the period the tax arises.

We are subject to income taxes in the United States and numerous foreign jurisdictions. Our income tax returns are periodically audited by domestic and foreign tax authorities. These audits include questions regarding our tax filing positions, including the timing and amount of deductions and the allocation of income amongst various tax jurisdictions. We evaluate our tax positions and establish liabilities in accordance with the applicable accounting guidance on uncertainty in income taxes. Significant judgment is required in evaluating our uncertain tax positions, including estimating the ultimate resolution to intercompany pricing controversies between countries when there are numerous possible outcomes. We review these tax uncertainties quarterly and adjust the liability as events occur that affect potential liabilities for additional taxes, such as the progress of tax audits, lapsing of applicable statutes of limitations, negotiations between tax authorities, identification of new issues, and issuance of new legislation, regulations, or case law.

For additional details on our income taxes, see Note 2 and Note 16 to the "Consolidated Financial Statements."

Stock-based Compensation

We measure and recognize compensation expense for all stock-based awards based on estimated fair values. Stock-based awards consist of stock options, service-based restricted stock units, market-based restricted stock units, performance-based restricted stock units, and employee stock purchase subscriptions. The fair value of each option award and employee stock purchase subscription is estimated on the date of grant using the Black-Scholes option valuation model. The fair value of market-based restricted stock units is determined using a Monte Carlo simulation model, which uses multiple input variables to determine the probability of satisfying the market condition requirements. The Black-Scholes and Monte Carlo models require various highly judgmental assumptions, including stock price volatility, risk-free interest rate, and expected option term. For performance-based restricted stock units, expense is recognized if and when we conclude that it is probable that the performance condition will be achieved, which requires judgment. Stock-based compensation expense is recorded net of

Table of Contents

estimated forfeitures. Judgment is required in estimating the stock awards that will ultimately be forfeited. If actual results differ significantly from these estimates, stock-based compensation expense and our results of operations would be impacted.

New Accounting Standards

Information regarding new accounting standards is included in Note 2 to the "Consolidated Financial Statements."

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Our business and financial results are affected by fluctuations in world financial markets, including changes in currency exchange rates and interest rates. We manage these risks through a combination of normal operating and financing activities and derivative financial instruments. We do not use derivative financial instruments for trading or speculative purposes.

Interest Rate Risk

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. Our investment strategy is focused on preserving capital and supporting our liquidity requirements, while earning a reasonable market return. We invest in a variety of fixed-rate debt securities, primarily time deposits, commercial paper, U.S. and foreign government and agency securities, asset-backed securities, corporate debt securities, and municipal debt securities. The market value of our investments may decline if current market interest rates rise. As of December 31, 2018, we had $726.2 million of investments in fixed-rate debt securities which had an average remaining term to maturity of approximately 1.0 years. Taking into consideration the average maturity of our fixed-rate debt securities, a hypothetical 0.5% to 1.0% absolute increase in interest rates at December 31, 2018 would have resulted in a $3.5 million to $7.0 million decrease in the fair value of these investments. Such a decrease would only result in a realized loss if we choose or are forced to sell the investments before the scheduled maturity, which we currently do not anticipate.

For more information related to outstanding debt obligations, see Note 6 to the "Consolidated Financial Statements."

We are also exposed to interest rate risk on our debt obligations. As of December 31, 2018, we had $600.0 million of Notes outstanding that carry a fixed rate, and also had available a $750.0 million Credit Agreement that carries a variable interest rate based on the London interbank offered rate ("LIBOR"). As of December 31, 2018, there were no borrowings outstanding under the Credit Agreement. Based on our December 31, 2018 variable debt levels, a hypothetical 1.0% absolute increase in our floating market interest rates would increase our interest expense by approximately $6.0 million, most of which would be offset by increased returns on our short-term investments. The impact on net interest would be immaterial to our financial condition and results of operations. As of December 31, 2018, a hypothetical 1.0% absolute increase in market interest rates would decrease the fair value of the fixed-rate debt by approximately $44.7 million. This hypothetical change in interest rates would not impact the interest expense on the fixed-rate debt.

For more information related to outstanding debt obligations, see Note 9 to the "Consolidated Financial Statements."

Currency Risk

We are exposed to foreign currency risks that arise from normal business operations. These risks include the translation of local currency balances and results of our non-United States subsidiaries into United States dollars,

currency gains and losses related to intercompany and third-party transactions denominated in currencies other than a location's functional currency, and currency gains and losses associated with intercompany loans. Our principal currency exposures relate to the Euro and the Japanese yen. Our objective is to minimize the volatility of our exposure to these risks through a combination of normal operating and financing activities and the use of derivative financial instruments in the form of foreign currency forward exchange contracts and cross currency swap contracts. The total notional amount of our derivative financial instruments entered into for foreign currency management purposes at December 31, 2018 was $1.4 billion. A hypothetical 10% increase/decrease in the value of the United States dollar against all hedged currencies would increase/decrease the fair value of these derivative contracts by $61.2 million. Any gains or losses on the fair value of derivative contracts would generally be offset by gains and losses on the underlying transactions, so the net impact would not be significant to our financial condition or results of operations.

For more information related to outstanding foreign exchange contracts, see Note 2 and Note 11 to the "Consolidated Financial Statements."

Table of Contents

Credit Risk

Derivative financial instruments involve credit risk in the event the financial institution counterparty should default. It is our policy to execute such instruments with major financial institutions that we believe to be creditworthy. At December 31, 2018, all derivative financial instruments were with bank counterparties assigned investment grade ratings by national rating agencies. We further diversify our derivative financial instruments among counterparties to minimize exposure to any one of these entities. We have not experienced a counterparty default and do not anticipate any non-performance by our current derivative counterparties.

Concentrations of Risk

We invest excess cash in a variety of fixed-rate debt securities, and diversify the investments between financial institutions. Our investment policy limits the amount of credit exposure to any one issuer.

In the normal course of business, we provide credit to customers in the health care industry, perform credit evaluations of these customers, and maintain allowances for potential credit losses, which have historically been adequate compared to actual losses. In 2018, we had no customers that represented 10% or more of our total net sales or accounts receivable, net.

Investment Risk

We are exposed to investment risks related to changes in the underlying financial condition and credit capacity of certain of our investments. As of December 31, 2018, we had $726.2 million of investments in fixed-rate debt securities of various companies, of which $483.8 million were long-term. In addition, we had $22.5 million of investments in equity instruments of public and private companies. Should these companies experience a decline in financial condition or credit capacity, or fail to meet certain development milestones, a decline in the investments' values may occur, resulting in unrealized or realized losses.

Table of Contents

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2018

Report of Independent Registered Public Accounting Firm 41

Financial Statements:

Consolidated Balance Sheets as of December 31, 2018 and 2017 43

For the Years Ended December 31, 2018, 2017, and 2016:

Consolidated Statements of Operations 44

Consolidated Statements of Comprehensive Income 45

Consolidated Statements of Cash Flows 46

Consolidated Statements of Stockholders' Equity 47

Notes to Consolidated Financial Statements 48

Other schedules are not applicable and have not been submitted.

Table of Contents

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Edwards Lifesciences Corporation:

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Edwards Lifesciences Corporation and its subsidiaries (the “Company”) as of December 31, 2018 and December 31, 2017, and the related consolidated statements of operations, comprehensive income, cash flows, and stockholders’ equity for each of the three years in the period ended December 31, 2018, 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, 2018, 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, 2018 and December 31, 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 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, 2018, 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.

Table of Contents

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.

/s/ PricewaterhouseCoopers LLP
Irvine, California
February 15, 2019

We have served as the Company’s auditor since 1999.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED BALANCE SHEETS

(in millions, except par value)

	December 31,	
	2018	2017
ASSETS		
Current assets		
Cash and cash equivalents	$714.1	$818.3
Short-term investments (Note 6)	242.4	519.2
Accounts receivable, net (Note 5)	456.9	438.7
Other receivables	80.4	40.6
Inventories (Note 5)	607.0	554.9
Prepaid expenses	54.3	60.6
Other current assets	131.8	116.9
Total current assets	2,286.9	2,549.2
Long-term investments (Note 6)	506.3	567.0
Property, plant, and equipment, net (Note 5)	867.5	679.7
Goodwill (Note 8)	1,112.2	1,126.5
Other intangible assets, net (Note 8)	343.2	468.0
Deferred income taxes	174.0	167.1
Other assets	33.6	108.9
Total assets	$5,323.7	$5,666.4
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$134.0	$116.6
Accrued and other liabilities (Note 5)	742.6	653.7
Short-term debt (Note 9)	—	598.0
Contingent consideration liabilities (Notes 7 and 10)	—	51.7
Total current liabilities	876.6	1,420.0
Long-term debt (Note 9)	593.8	438.4
Contingent consideration liabilities (Notes 7 and 10)	178.6	192.6
Taxes payable (Note 16)	259.4	347.5
Uncertain tax positions (Note 16)	124.9	164.6
Other long-term liabilities	150.0	147.1
Commitments and contingencies (Notes 9 and 17)		
Stockholders' equity (Note 13)		
Preferred stock, $.01 par value, authorized 50.0 shares, no shares outstanding	—	—
Common stock, $1.00 par value, 350.0 shares authorized, 215.2 and 212.0 shares issued, and 207.7 and 209.7 shares outstanding, respectively	215.2	212.0
Additional paid-in capital	1,384.4	1,166.9
Retained earnings	2,694.7	1,962.1
Accumulated other comprehensive loss	(138.5)	(132.7)
Treasury stock, at cost, 7.5 and 2.3 shares, respectively	(1,015.4)	(252.1)
Total stockholders' equity	3,140.4	2,956.2
Total liabilities and stockholders' equity	$5,323.7	$5,666.4

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(in millions, except per share information)

	Years Ended December 31,		
	2018	2017	2016
Net sales	$3,722.8	$3,435.3	$2,963.7
Cost of sales	939.4	875.3	797.4
Gross profit	2,783.4	2,560.0	2,166.3
Selling, general, and administrative expenses	1,088.5	990.8	904.7
Research and development expenses	622.2	552.6	442.2
Intellectual property litigation expenses (income), net (Note 3)	214.0	(73.3)	32.6
Change in fair value of contingent consideration liabilities	(5.7)	(9.9)	1.1
Special charges, net (Note 4)	116.2	9.7	34.5
Other operating expenses	—	0.7	—
Operating income	748.2	1,089.4	751.2
Interest expense	29.9	23.2	19.2
Interest income	(32.0)	(20.3)	(10.8)
Special (gains) charges, net (Note 4)	(7.1)	50.2	—
Other (income) expense, net (Note 15)	(4.0)	1.4	4.9
Income before provision for income taxes	761.4	1,034.9	737.9
Provision for income taxes (Note 16)	39.2	451.3	168.4
Net income	$722.2	$583.6	$569.5
Share information (Note 2):			
Earnings per share:			
Basic	$3.45	$2.77	$2.67
Diluted	$3.38	$2.70	$2.61
Weighted-average number of common shares outstanding:			
Basic	209.2	210.9	213.0
Diluted	213.6	215.9	217.8

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(in millions)

	Years Ended December 31,		
	2018	2017	2016
Net income	$722.2	$583.6	$569.5
Other comprehensive (loss) income, net of tax (Note 14):			
Foreign currency translation adjustments	(38.6)	97.5	(16.1)
Unrealized gain (loss) on cash flow hedges	40.4	(30.6)	4.9
Defined benefit pension plans	0.6	3.5	(6.2)
Unrealized (loss) gain on available-for-sale investments	(3.3)	(7.8)	0.5
Reclassification of net realized investment loss to earnings	2.9	3.1	1.1
Other comprehensive (loss) income, net of tax	2.0	65.7	(15.8)
Comprehensive income	$724.2	$649.3	$553.7

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in millions)

	Years Ended December 31,		
	2018	2017	2016
Cash flows from operating activities			
Net income	$722.2	$583.6	$569.5
Adjustments to reconcile net income to cash provided by operating activities:			
Depreciation and amortization	77.4	81.9	71.2
Stock-based compensation (Notes 2 and 13)	71.0	61.6	56.9
Excess tax benefit from stock plans	—	—	(64.3)
Impairment charges (Note 4)	118.8	31.0	—
Change in fair value of contingent consideration liabilities, net (Note 10)	(5.7)	(9.9)	1.1
Deferred income taxes	(27.3)	17.8	(37.4)
Purchased in-process research and development	—	6.7	34.5
Other	13.0	(6.2)	7.9
Changes in operating assets and liabilities:			
Accounts and other receivables, net	(28.7)	(27.8)	(60.4)
Inventories	(65.7)	(124.0)	(65.6)
Accounts payable and accrued liabilities	192.5	93.8	77.7
Income taxes	(157.8)	293.7	105.1
Prepaid expenses and other current assets	15.7	(9.9)	(12.6)
Other	1.4	8.4	20.8
Net cash provided by operating activities	926.8	1,000.7	704.4
Cash flows from investing activities			
Capital expenditures	(238.7)	(168.1)	(176.1)
Deposit of cash in escrow	—	(25.0)	—
Purchases of held-to-maturity investments (Note 6)	(210.0)	(804.9)	(594.7)
Proceeds from held-to-maturity investments (Note 6)	578.1	654.7	852.5
Purchases of available-for-sale investments (Note 6)	(249.3)	(529.8)	(470.4)
Proceeds from available-for-sale investments (Note 6)	223.2	448.7	232.6
Investments in unconsolidated affiliates (Note 6)	(6.6)	—	(7.6)
Proceeds from unconsolidated affiliates (Note 6)	0.4	8.3	1.9
Investments in trading securities, net	(12.6)	(12.7)	(9.8)
Payment of contingent consideration	(10.0)	—	—
Acquisitions (Notes 7 and 8)	—	(192.9)	—
Issuances of notes receivable	—	(18.9)	—
Investments in intangible assets and in-process research and development	(3.0)	(7.4)	(41.3)
Other	5.2	0.8	1.2
Net cash provided by (used in) investing activities	76.7	(647.2)	(211.7)
Cash flows from financing activities			
Proceeds from issuance of debt	688.0	994.7	253.5
Payments on debt and capital lease obligations	(1,125.3)	(818.4)	(31.4)
Purchases of treasury stock	(795.5)	(763.3)	(662.3)

Proceeds from stock plans	147.0	113.8	103.3
Payment of contingent consideration	(15.1)	—	—
Excess tax benefit from stock plans	—	—	64.3
Other	(0.3)	—	4.1
Net cash used in financing activities	(1,101.2)	(473.2)	(268.5)
Effect of currency exchange rate changes on cash and cash equivalents	(6.5)	7.9	(12.5)
Net (decrease) increase in cash and cash equivalents	(104.2)	(111.8)	211.7
Cash and cash equivalents at beginning of year	818.3	930.1	718.4
Cash and cash equivalents at end of year	$714.1	$818.3	$930.1

The accompanying notes are an integral part of these consolidated financial statements.

Table of Contents

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in millions)

	Common Stock		Treasury Stock					
	Shares	Par Value	Shares	Amount	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
BALANCE AT DECEMBER 31, 2015	239.1	$239.1	23.7	$(1,837.0)	$946.8	$3,336.8	$(182.6)	$2,503.1
Net income						569.5		569.5
Other comprehensive loss, net of tax							(15.8)	(15.8)
Common stock issued under equity plans, including tax benefits	3.5	3.5			164.1			167.6
Stock-based compensation expense					56.9			56.9
Purchases of treasury stock			7.3	(662.3)				(662.3)
BALANCE AT DECEMBER 31, 2016	242.6	242.6	31.0	(2,499.3)	1,167.8	3,906.3	(198.4)	2,619.0
Impact to retained earnings from adoption of ASU 2016-09						9.3		9.3
BALANCE AT JANUARY 1, 2017	242.6	242.6	31.0	(2,499.3)	1,167.8	3,915.6	(198.4)	2,628.3
Net income						583.6		583.6
Other comprehensive income, net of tax							65.7	65.7
Common stock issued under equity plans	3.0	3.0			110.8			113.8
Stock-based compensation expense					61.6			61.6
Shares issued to acquire business			(2.8)	264.3	2.2			266.5
Purchases of treasury stock			7.7	(763.3)				(763.3)
Retirement of treasury stock	(33.6)	(33.6)	(33.6)	2,746.2	(175.5)	(2,537.1)		—
BALANCE AT DECEMBER 31, 2017	212.0	212.0	2.3	(252.1)	1,166.9	1,962.1	(132.7)	2,956.2
Impact to retained earnings from adoption of ASU 2016-16 and ASU 2018-02						10.4	(7.8)	2.6
BALANCE AT JANUARY 1, 2018	212.0	212.0	2.3	(252.1)	1,166.9	1,972.5	(140.5)	2,958.8
Net income						722.2		722.2
							2.0	2.0

Other comprehensive loss, net of tax				
Common stock issued under equity plans	3.2	3.2	143.8	147.0
Stock-based compensation expense				