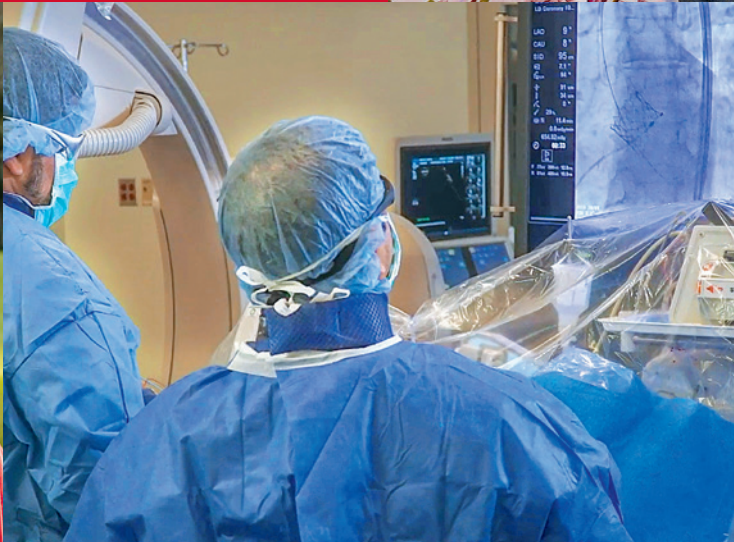




Edwards Lifesciences

2020 Annual Report



Edwards

Edwards Lifesciences is the global leader of patient-focused medical innovations for structural heart disease and critical care monitoring. Driven by a passion for patients, the company is dedicated to improving and enhancing lives through partnerships with clinicians and stakeholders across the global healthcare landscape.



To Our Shareholders

In mid-December 2020, for the first time ever, Edwards Lifesciences hosted its annual investor conference as a virtual event. Rather than standing in a room with several hundred people discussing Edwards' strategy for long-term growth, I was joined by only a handful of colleagues. Separated by plexiglass partitions, socially distanced and fresh off COVID testing for all, this experience underscored what made 2020 so unprecedented.

There is no doubt that the ongoing pandemic resulted in one of the most challenging years in recent history – for our global community, clinicians, partners, our employees and especially our patients.

“As we look to 2021 and beyond, I am more excited than ever before about the work happening at Edwards and, more importantly, what we envision for the future of patient care.”



Tremendous progress has been made on vaccines and other therapeutic advancements from medical technology innovators and I find myself hopeful and optimistic about 2021 and beyond.

Remarkable Patient-Focused Team

As a member of the critical healthcare infrastructure, Edwards and our employees never stopped during the pandemic. In fact, our employees have been more patient focused than ever before in their relentless pursuit to deliver life-saving technologies. A recent survey of our global employees found that 94 percent of them consider what's important to patients when making decisions. We saw this in action as extraordinary efforts across our company ensured that the patients we serve received the help they needed throughout 2020. Our employees kept the last sentence of our Credo as their North Star: "Helping patients is our life's work, and life is now."

Navigating through the challenges brought by the pandemic, our Board of Directors also advanced their commitment and focus on their service to Edwards. We added Ramona Sequeira and Paul LaViolette to our Board, and Martha Marsh assumed the role of lead independent director. Bringing such highly respected, diverse and talented leaders to our Board provides us with valuable insights, along with unique and varying perspectives on our strategy.

We understand the strength of community and diversity, and I'm proud of the inclusive culture that we've built at Edwards where all employees can grow, thrive and belong.

Though we believe we exhibit strength in this area, we continue to listen and evolve, focusing on sustainable systemic improvement. We've expanded our performance metrics to further that commitment as well as made significant contributions to support organizations addressing needs and racial disparities in healthcare.

Our strategy for giving back has always focused on helping underserved patients, and supporting the communities where we live and work across the globe is central to our company culture and values. In 2020, the Edwards Lifesciences Foundation celebrated an extraordinary milestone for Every Heartbeat Matters, our signature philanthropic initiative, of impacting more than 1.7 million underserved people – exceeding our goal. We are well on our way to reaching our new bold goal to improve the lives of 2.5 million more underserved structural heart and critical care patients by 2025. I'm pleased to share that with an increase in our in-kind and financial support through the Foundation and the tripling of our employees' donations with our matching gift program, 2020 was our biggest year of giving ever – doubling our charitable support to nearly \$20 million. This is a remarkable and humbling commitment by everyone at Edwards, and we are so grateful to our outstanding partners for their dedicated efforts.

There have been countless stories told this year at Edwards about the way our employees have positively impacted the lives of others. One story that stuck with me is that of a surgical patient from Singapore who shared with us how his Edwards valve has a “multiplier effect of positivity,” bringing a better life not just to him, but also to others around the world. This is a bright reminder of the importance of our work, and the critical need of our current and future therapies.

Innovative Strategic Focus

Despite the pandemic, our commitment to our patient-focused innovation strategy remained unwavering. We continued to safely, but aggressively,

pursue breakthrough therapies for the millions of patients with structural heart diseases and critical illnesses. And, while many other medtech companies have diversified, we continued to be focused, as we know there are still many structural heart disease and critically ill patients who need life-saving treatment.

With this focus, we are able to bring our decades of expertise, clinical knowledge, resources and understanding of the patient journey to developing and advancing potential solutions. We are focused on bold innovations and continuing with our rich pipeline of future therapies. These innovations that “change the practice of medicine” are supported by rigorous clinical trials and best-in-class outcomes. While some evidence collection was slowed due to the pandemic, we and the clinical community are enthusiastic about continuing our trials and generating robust evidence.

Our citizenship and sustainability efforts are aligned to our aspirations and integrated into our overall strategic planning process. This past year, we were honored to have been recognized once again for our efforts in these areas by the Dow Jones Sustainability Indices, America's Most JUST Companies and the World's Most Ethical Companies by the Ethisphere Institute, among others.

Transforming Patient Care

Putting patients first has never been more important, and I am proud of the steadfast work we maintained throughout the year.

We've continued to invest in developing solutions that extend lives, improve quality of life and bring value to the healthcare system. Our consistent and significant R&D investments allowed us to fuel this progress.

To support our innovation and growth, we continued investing in our people, technology pipeline, robust evidence and our infrastructure. During a year when many companies furloughed or reduced employees because of COVID, we prioritized protecting jobs and were able to grow our team to nearly 15,000 employees worldwide.

Helping patients and developing innovations for structural heart disease and critical care monitoring remains our strategic focus.



As I write this letter, construction is continuing on our headquarters and research expansion in Irvine. We have also continued to grow our international footprint, with our facility in Costa Rica coming online midyear, and significant progress on new facilities in Limerick, Ireland, and Caesarea, Israel. These important additions to our global supply chain and R&D capabilities will further diversify our network and our ability to serve patients around the world.

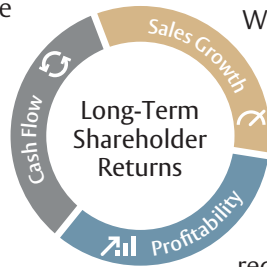
We celebrated some exciting milestones this year that directly impact patients. More than 100,000 TAVR patients were treated with SAPIEN valves worldwide in 2020. We were also very encouraged to receive approval for the SAPIEN 3 valve in China, distinguishing Edwards as the first global company to introduce TAVR to China. In Surgical Structural Heart, we launched our KONECT aortic valved conduit and our INSPIRIS valve became the leading aortic surgical valve worldwide. We've seen early positive clinical evidence across the TMTT platform, physician feedback is encouraging, and patient outcomes have been distinguished. In Critical Care, we met the increased demand for core pressure monitoring products due to the pandemic and we are proud that we were able to help over one million COVID patients globally with our monitoring technology. We began shifting focus to Smart Recovery, which helps patients in the hospital recover more quickly and go home sooner.

Strong Global Performance

Though COVID significantly impacted our financial performance, I'm pleased that we were able to match our impressive 2019 sales. This consistency demonstrates patients' need for the work that we do.

2020 adjusted sales grew one percent to \$4.4 billion and adjusted earnings per share were in line with the prior year.

We also executed a 3-for-1 stock split, increasing the number of common shares, and repurchased \$615 million of stock.



Looking to the Future

In 2021, we anticipate returning to strong double-digit revenue growth as patients still require life-saving treatments for structural heart disease, even during a pandemic. And while we recognize the uncertainty of when the pandemic will subside, we remain confident in our continued investment in our patient-focused innovation strategy, which will position us to emerge even more prepared to embrace the future.

As we look to 2021 and beyond, I am more excited than ever before about the work happening at Edwards and, more importantly, what we envision for the future of patient care. I continue to believe we are poised for long-term success, built on a track record of credibility and trust. Our innovation and cultural imperative to put patients first is driving strong long-term organic sales growth and exceptional shareholder returns. As I stand with our employees worldwide and the global community, we are filled with gratitude and hope for the future. Thank you for your continued support of our quest to deliver innovations to even more patients around the world.

Michael A. Mussallem
Chairman & Chief Executive Officer

This Annual 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. 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, the statements made by the Company's executives, the Company's future financial and strategic goals for 2021 and beyond as well as its expectations for the results of research and development and clinical evidence, the timing and impact of new product introductions, expected patient benefits of new products, and opportunities for growth and stockholder value, 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. Statements of past performance, efforts, or results about which inferences or assumptions may be made can also be forward-looking statements and are not indicative of future performance or results; these statements can be identified by the use of words such as "preliminary," "initial," "diligence," "industry-leading," "compliant," "indications," or "early feedback" or 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 in the Form 10-K attached hereto for a discussion of these risks, as such risks and uncertainties may be amended, supplemented or superseded from time to time by our subsequent reports on Forms 10-Q and 8-K that we file with the Securities and Exchange Commission. 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. "Adjusted" or "underlying" amounts are non-GAAP. Refer to "Non-GAAP Financial Information" starting on page 11 as well as our IR website under "Historical financial information" for the most directly comparable GAAP financial measure.

Even in the midst of a global pandemic, some things never stopped.

Despite unprecedented challenges throughout 2020, we continued our mission to transform patient lives with breakthrough technologies and remained steadfast in our commitment to behaving as a trusted partner through distinguished quality and integrity.

Transcatheter Aortic Valve Replacement



► Bob

“Because of TAVR, I can keep going and do the things that I really want to do, such as sharing with others in my community.”

In his neighborhood, Bob is known as a good-hearted person always looking to help others. Last year, amid the global pandemic, he was unexpectedly diagnosed with severe aortic stenosis. Even though he was quickly identified as a TAVR candidate, Bob’s procedure was postponed due to COVID protocols. While waiting for treatment, he and his wife kept their spirits high by recognizing a local need and created a community garden to help their neighbors. Ultimately, Bob received treatment with an Edwards SAPIEN 3 valve and was then able to be back home with his family.

Transcatheter Mitral & Tricuspid Therapies

Larry ►

“I had shortness of breath just while walking. The more I talk about my participation in the PASCAL clinical trial, the more choked up I get – this research was extremely meaningful to me.”

A couple of years ago, Larry experienced a significant decline in his health. He started coughing, feeling dizzy and losing balance and was soon diagnosed with mitral regurgitation. Due to his complicated anatomy, Larry’s doctor recommended enrolling in the ongoing PASCAL clinical trial. He was identified as a candidate and shortly after, was treated with the PASCAL valve repair system as part of the clinical research. Today, Larry is grateful to have been a part of groundbreaking medical research and is encouraged by spending more time with his son.



Patient care *never stopped.*

Case support *never stopped.*

Our team *never stopped.*

Innovation *never stopped.*

Surgical Structural Heart



▶ Daniel

“INSPIRIS RESILIA valve is the valve that is going to let me get back to my high-performance lifestyle.”

Even though he was younger than the conventional heart patient, one day Daniel started feeling out of breath and was becoming pale. Soon after, he was diagnosed with a severely damaged aortic valve in need of replacement. Being an energetic individual, Daniel spent months researching the best technology that would allow him to return to his active lifestyle, and he decided upon the Edwards INSPIRIS RESILIA valve. Daniel is a supercar designer by trade, however he spent much of last year helping develop ventilators needed by hospitals impacted by the pandemic. After the procedure to replace his damaged valve, Daniel is back to doing all the things he is used to doing, including mountain biking and go-karting, and he even hopes to do some car racing soon.

Critical Care

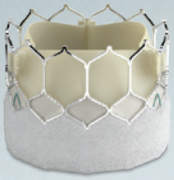
Phil ▶

***“A week later, I was on a driving range.
A month after that, I was walking eighteen holes.”***

Several years ago, Phil, a retired U.S. Navy Air Controller, was diagnosed with early-stage lung cancer. His cancer was considered operable but required intense surgery. During Phil's procedure, his anesthesiologist relied on Edwards' FloTrac and ForeSight sensors to continuously monitor blood flow and oxygen levels in his heart and brain. The use of advanced hemodynamic monitoring helps clinicians stay ahead of critical moments during surgery. Phil's surgical procedure was a success, and he is now back at the golf course cancer-free.



Transcatheter Aortic Valve Replacement



Edwards SAPIEN 3 Ultra transcatheter heart valve

Edwards leads the world in the development of new therapies designed for the nonsurgical replacement of heart valves. The proven SAPIEN 3 System is commercially available in over 75 countries and is now an approved treatment option for patients at low risk to surgery in Europe, the U.S. and other countries around the world based on the superiority of outcomes demonstrated in the PARTNER 3 trial.

The Edwards SAPIEN 3 Ultra transcatheter heart valve system is built upon the proven SAPIEN platform featuring a ~40 percent taller*, textured outer skirt to further reduce paravalvular leak.



Edwards SAPIEN 3 Ultra transcatheter heart valve and delivery system

Its short frame height is designed to facilitate coronary access, factoring in the future needs of patients in the treatment of severe symptomatic aortic stenosis.

*Compared to the Edwards SAPIEN 3 valve.

Long-Term Growth Drivers

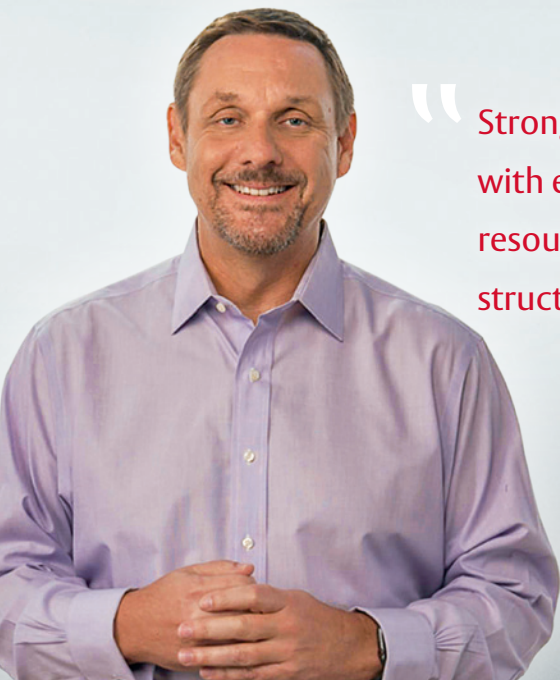
- Therapy expansion
- Increasing awareness
- Technological advances

100,000+
Patients treated globally in 2020



Alterra Adaptive Present and SAPIEN 3 transcatheter heart valve

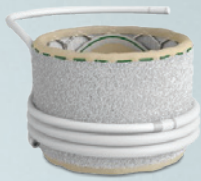
The Edwards Pulmonic platform combines the SAPIEN 3 valve and the Alterra adaptive present to expand transcatheter therapy for congenital heart disease patients.



“ Strong evidence indicates that TAVR is a proven therapy with excellent outcomes. It offers efficient use of hospital resources and can benefit many more patients whose structural heart disease is deadly and undertreated today. ”

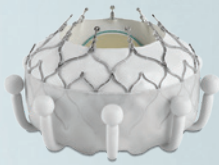
Larry Wood
Corporate Vice President,
Transcatheter Aortic
Valve Replacement

Transcatheter Mitral & Tricuspid Therapies



Edwards SAPIEN M3*
mitral valve replacement

Edwards' focused investment in structural heart initiatives has resulted in the development of multiple breakthrough therapies for patients suffering from mitral and tricuspid diseases.



Edwards EVOQUE*
tricuspid valve replacement

Our SAPIEN M3 valve and Edwards EVOQUE valve are transcatheter valve replacement systems. The SAPIEN M3 valve is designed to treat patients with mitral valve disease, while the EVOQUE valve is designed to expand treatment options for both mitral and tricuspid patients.



Edwards PASCAL**
valve repair system



Edwards PASCAL Ace**
valve repair system

The PASCAL transcatheter valve repair system is designed to treat mitral and tricuspid valve regurgitation with differentiated innovation enabling treatment of a broader patient population. High touch procedural and imaging support enables optimal outcomes for these patients.



Edwards Cardioband**
reconstruction system

The Cardioband reconstruction system is designed to provide individualized annular reduction with real-time confirmation of results, leaving options open for future intervention if required.

Long-Term Growth Drivers

Differentiated portfolio

Clinical evidence

Real world outcomes

~2,000

Patients treated globally in 2020

“ TMTT is committed to a consistent cadence of differentiated innovations, coupled with world-class clinical evidence to drive leadership and provide optimal therapies for mitral and tricuspid patients. ”

Bernard Zovighian
Corporate Vice President,
Transcatheter Mitral &
Tricuspid Therapies

*Investigational devices. Limited to investigational use only.

**CE Mark in EU. Investigational device and not available for sale in the U.S.



Surgical Structural Heart



**INSPIRIS
RESILIA** aortic valve

As a leading manufacturer of tissue heart valves and repair therapies, Edwards offers leading innovations to treat a patient's diseased heart valves. We are committed to being the partner of choice for cardiac surgeons and helping transform patients' lives by advancing surgical structural heart innovations.



HARPOON*
beating heart mitral
valve repair system

The INSPIRIS RESILIA aortic valve is right for today, and ready for tomorrow. This valve features RESILIA tissue, a bovine pericardial tissue with advanced anti-calcification properties and proprietary VFit technology, which is designed for potential future valve-in-valve procedures.

The HARPOON system transforms surgery for many patients with degenerative mitral regurgitation. This novel therapy standardizes mitral repair with an echo-guided, beating-heart procedure.



**KONNECT
RESILIA**
aortic valved conduit

KONNECT RESILIA aortic valved conduit is the second offering in Edwards Lifesciences' class of resilient RESILIA tissue valves. This ready-to-implant aortic valved conduit helps patients maintain their active lifestyles and reduces the complexity of bio-Bentall procedures.

Long-Term Growth Drivers

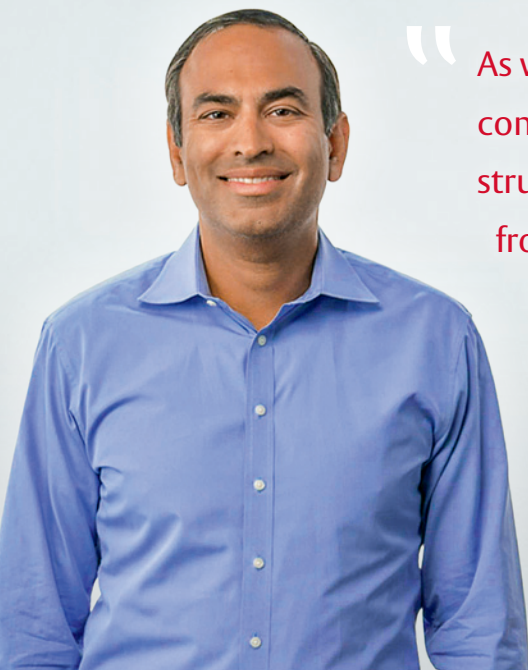
Surgeon partnerships

Premium innovations

Emerging regions

~500,000

Patients treated
globally in 2020



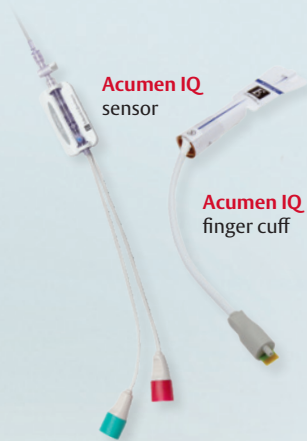
“As we look to the future, we believe our innovations will continue to drive balanced growth within our surgical structural heart portfolio by lowering our relative contribution from SAVR, increasing growth contribution from mitral, and finally, providing solutions for unmet needs in surgical structural heart for surgeons and their patients.”

Daveen Chopra
Corporate Vice President,
Surgical Structural Heart

Critical Care



HemoSphere advanced monitoring platform with HPI software



Acumen IQ sensor

Acumen IQ finger cuff



ForeSight Elite tissue oximetry sensor

Edwards is the leader in hemodynamic monitoring solutions including monitoring platforms, predictive software and sensors ranging from invasive to noninvasive, all of which play an important role in enhancing patient recovery.

Acumen Hypotension Prediction Index (HPI) software is a first-of-its-kind predictive software developed with machine learning. It detects the likelihood of a patient trending towards a hypotensive event before the event occurs. This software is available on the HemoSphere monitoring platform, which is the latest monitor from Edwards and is compatible with our portfolio of Smart Recovery sensors and catheters.

Our latest Smart Recovery solutions, such as Acumen IQ sensor and Acumen IQ finger cuff, work with our predictive software to provide clinicians decision support and help them stay a step ahead of their patient's rapidly evolving status. With the addition of our noninvasive ForeSight Elite tissue oximetry sensor to HemoSphere monitor, Edwards became the first to offer clinicians the ability to monitor the brain and the heart from one screen.

Long-Term Growth Drivers

Smart technologies

HemoSphere growth

Portfolio expansion

~15,500,000

Patients helped globally in 2020

(includes 1M+ COVID patients)

“ We are grateful that our products have been able to monitor and help over one million patients during the pandemic and we are so proud to have been a part of the stories where patients were able to leave the isolation of the ICU and get home to their families. ”

Katie M. Szyman
Corporate Vice President,
Critical Care



2020 Financial Highlights

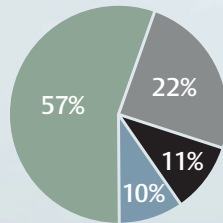
	Adjusted Net Sales	Adjusted Earnings Per Share	Research and Development	Adjusted Free Cash Flow
2020 \$4,386	\$1.86	\$761	\$734	
2019 \$4,348	\$1.86	\$753	\$1,067	
2018 \$3,813	\$1.57	\$622	\$786	
2017 \$3,434	\$1.27	\$553	\$695	
2016 \$2,962	\$0.97	\$442	\$527	

(In millions, except EPS)

"Adjusted net sales", "adjusted earnings per share" and "adjusted free cash flow" are all non-GAAP numbers. Refer to pages 11 and 12 for reconciliations to the most directly comparable GAAP financial measure.

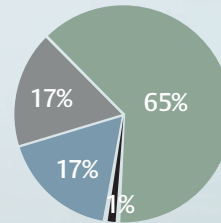
2020 Sales by Geographic Region

- United States
- Europe
- Japan
- Rest of World



2020 Sales by Product Line

- TAVR
- Surgical
- Critical Care
- TMTT



Edwards Sales (\$ in billions)



“ Strong sales growth, healthy profitability and robust cash flow are financial objectives that help us guide our internal decisions and yield long-term shareholder returns. ”

Scott Ullem
Corporate Vice President,
Chief Financial Officer

Non-GAAP Financial Information

To supplement the consolidated financial results prepared in accordance with Generally Accepted Accounting Principles (“GAAP”), the Company uses non-GAAP historical financial measures. Management makes adjustments to the GAAP measures for items (both charges and gains) that (a) do not reflect the core operational activities of the Company, (b) are commonly adjusted within the Company’s industry to enhance comparability of the Company’s financial results with those of its peer group, or (c) are inconsistent in amount or frequency between periods (albeit such items are monitored and controlled with equal diligence relative to core operations). The Company uses the term “adjusted sales” or “underlying growth rate” when referring to non-GAAP sales information, which excludes foreign exchange fluctuations, the conversion to a consignment inventory system for surgical structural heart (“Surgical”), sales return reserves associated with transcatheter aortic valve replacement (“TAVR”) product upgrades, the positive impact of TAVR stocking sales in Germany and the negative impact of de-stocking, and includes the prior year sales results of a business acquired as if the acquisition had occurred at the beginning of the earliest period presented. The Company uses the terms “adjusted” to also exclude intellectual property litigation income and expenses, amortization of intangible assets, fair value adjustments to contingent consideration liabilities arising from acquisitions, gains from significant investments, the positive impact of TAVR stocking sales in Germany and the negative impact of de-stocking, realignment expenses, the conversion to a consignment inventory for Surgical, sales return reserves and related costs associated with TAVR product upgrades, charitable contributions to the Edwards Lifesciences Foundation, significant pension curtailment gains, significant charges associated with TAVR inventory write offs, impairment of long-lived assets, the purchase of intellectual property, and the impact from implementation of tax law changes and settlements.

Management uses non-GAAP financial measures internally for strategic decision making, forecasting future results, and evaluating current performance. These non-GAAP financial measures are used in addition to, and in conjunction with, results presented in

accordance with GAAP and reflect an additional way of viewing aspects of the Company’s operations by investors that, when viewed with its GAAP results, provide a more complete understanding of factors and trends affecting the Company’s business and facilitate comparability to historical periods.

Non-GAAP financial measures are not prepared in accordance with GAAP; therefore, the information is not necessarily comparable to other companies and should be considered as a supplement to, and not as a substitute for, or superior to, the corresponding measures calculated in accordance with GAAP. A reconciliation of non-GAAP historical financial measures to the most comparable GAAP measure is provided in the tables below.

Fluctuations in exchange rates impact the comparative results and sales growth rates of the Company’s underlying business. Management believes that excluding the impact of foreign exchange rate fluctuations from its sales growth provides investors a more useful comparison to historical financial results.

Guidance for sales and sales growth rates is provided on an “underlying basis,” and projections for diluted earnings per share, net income and growth, gross profit margin, taxes, and free cash flow are also provided on a non-GAAP basis as adjusted for the items identified above due to the inherent difficulty in forecasting such items without unreasonable effort. The Company is not able to provide a reconciliation of the non-GAAP guidance to comparable GAAP measures due to the unknown effect, timing, and potential significance of special charges or gains, and management’s inability to forecast charges associated with future transactions and initiatives.

Management considers free cash flow to be a liquidity measure which provides useful information to management and investors about the amount of cash generated by business operations, after deducting payments for capital expenditures, which can then be used for strategic opportunities or other business purposes including, among others, investing in the Company’s business, making strategic acquisitions, strengthening the balance sheet, and repurchasing stock.

Adjusted Net Sales

Twelve months ended December 31 (in millions)

	2020	2019	2018	2017	2016
GAAP Net Sales	\$4,386.3	\$4,348.0	\$3,722.8	\$3,435.3	\$2,963.7
Impact of Surgical consignment	–	–	82.5	–	–
Impact of Germany stocking	–	–	8.0	(1.4)	–
Impact of sales return reserve	–	–	–	–	(1.7)
Adjusted Net Sales	\$4,386.3	\$4,348.0	\$3,813.3	\$3,433.9	\$2,962.0

Note: Numbers may not calculate due to rounding.

Reconciliation of GAAP to Adjusted Net Income

Twelve months ended December 31 (in millions, except per share data)	2020	2019	2018	2017	2016
GAAP Net Income	\$823.4	\$1,046.9	\$722.2	\$583.6	\$569.5
Non-GAAP adjustments:					
Litigation settlement	305.1	–	137.5	(70.3)	–
Intellectual property litigation expenses, net	28.5	25.2	26.4	24.5	20.8
Change in fair value of contingent consideration liabilities, net	12.3	(7.1)	(8.0)	(9.8)	1.1
Amortization of intangible assets	4.6	4.0	2.4	5.3	5.1
TAVR inventory write off	–	55.2	–	–	–
Surgical consignment conversion	–	–	54.7	–	–
TAVR Germany stocking sales	–	–	4.7	(0.4)	–
Impairment of long-lived assets	–	40.6	109.3	19.5	–
Pension curtailment gain	–	–	(6.3)	–	–
Charitable fund contribution	–	–	–	15.6	–
Investment gain	–	–	–	(6.5)	–
Realignment expenses	–	–	–	9.1	–
Purchased in-process research and development	–	18.1	–	–	34.5
TAVR sales returns reserve and related costs	–	–	–	–	0.1
Impact from U.S. tax legislation	–	–	(2.5)	262.0	–
Tax audit settlements	–	–	(36.1)	(12.9)	–
Adjusted Net Income	\$1,173.9	\$1,182.9	\$1,004.3	\$819.7	\$631.1

Reconciliation of GAAP to Adjusted Diluted Earnings Per Share

GAAP Diluted Earnings Per Share	\$1.30	\$1.64	\$1.13	\$0.90	\$0.87
Non-GAAP adjustments:					
Litigation settlement	0.48	–	0.21	(0.11)	–
Intellectual property litigation expenses, net	0.05	0.04	0.04	0.04	0.03
Change in fair value of contingent consideration liabilities	0.02	(0.01)	(0.01)	(0.01)	–
Amortization of intellectual property	0.01	0.01	–	0.01	0.01
TAVR inventory write off	–	0.09	–	–	–
Surgical consignment conversion	–	–	0.09	–	–
TAVR Germany stocking sales	–	–	0.01	–	–
Impairment of long-lived assets	–	0.06	0.17	0.03	–
Pension curtailment gain	–	–	(0.01)	–	–
Charitable fund contribution	–	–	–	0.02	–
Investment gain	–	–	–	(0.01)	–
Realignment expenses	–	–	–	0.02	–
Purchased in-process research and development	–	0.03	–	–	0.06
Impact from U.S. tax legislation	–	–	–	0.40	–
Tax audit settlements	–	–	(0.06)	(0.02)	–
Adjusted Diluted Earnings Per Share	\$1.86	\$1.86	\$1.57	\$1.27	\$0.97

Adjusted Free Cash Flow

Twelve months ended December 31 (in millions)	2020	2019	2018	2017	2016
Net cash provided by operating activities	\$1,054.3	\$1,182.9	\$926.7	\$1,000.8	\$703.2
Capital expenditures	(407.0)	(254.4)	(238.7)	(168.1)	(176.1)
Litigation settlements	86.4	138.3	–	(112.5)	–
Tax audit settlement	–	–	56.7	–	–
Repatriation tax payments	–	–	41.0	–	–
Deposit of cash in escrow	–	–	–	(25.0)	–
Adjusted Free Cash Flow	\$733.7	\$1,066.8	\$785.7	\$695.2	\$527.1

Adjusted Net Sales Growth

Twelve months ended December 31	2020	2019	2018	2017	2016
GAAP Net Sales Growth Rate	0.9%	16.8%	8.4%	15.9%	18.8%
Impact of Surgical consignment	0.0%	(2.5%)	2.4%	0.0%	0.0%
Impact of Germany stocking	0.0%	(0.3%)	0.3%	0.0%	0.0%
Impact of sales return reserve	0.0%	0.0%	0.0%	0.0%	(0.1%)
Impact of CASMED acquisition	0.0%	(0.5%)	0.0%	0.0%	0.0%
Impact of foreign exchange	(0.3%)	1.8%	(1.1%)	(0.2%)	(0.2%)
Adjusted Net Sales Growth Rate	0.6%	15.3%	10.0%	15.7%	18.5%

Note: Numbers may not calculate due to rounding.

Our Credo

At Edwards Lifesciences, we are dedicated to providing innovative solutions for people fighting cardiovascular disease.

Through our actions, we will become trusted partners with customers, colleagues and patients creating a community unified in its mission to improve the quality of life around the world. Our results will benefit customers, patients, employees and shareholders.

We will celebrate our successes, thrive on discovery and continually expand our boundaries. We will act boldly, decisively and with determination on behalf of people fighting cardiovascular disease.

Helping patients is our life's work, and

life is now

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

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2020

OR

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

For the Transition Period From _____ to _____
Commission File Number 1-15525

EDWARDS LIFESCIENCES CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

36-4316614
(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:

Title of each class	Trading Symbols(s)	Name of each exchange on which registered:
Common Stock, par value \$1.00 per share	EW	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 No

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 No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

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

The aggregate market value of the registrant's common stock held by non-affiliates as of June 30, 2020 (the last trading day of the registrant's most recently completed second quarter): \$42,640,586,293 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, 2021, was 624,518,873.

Documents Incorporated by Reference

Portions of the registrant's proxy statement for the 2021 Annual Meeting of Stockholders (to be filed within 120 days of December 31, 2020) are incorporated by reference into Part III, as indicated herein.

EDWARDS LIFESCIENCES CORPORATION
Form 10-K Annual Report—2020
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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. Some 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, the expected impact of COVID-19 on our business, any predictions, opinions, expectations, plans, strategies, objectives and any statements of assumptions underlying any of the foregoing relating to the company’s current and future business and operations, including, but not limited to, financial matters, development activities, clinical trials and regulatory matters, manufacturing and supply operations, and product sales and demand. 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. Statements of past performance, efforts, or results about which inferences or assumptions may be made can also be forward-looking statements and are not indicative of future performance or results; these statements can be identified by the use of words such as “preliminary,” “initial,” “diligence,” “industry-leading,” “compliant,” “indications,” or “early feedback” or other forms of these words or similar words or expressions or the negative thereof. 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. These risks and uncertainties include, but are not limited to: uncertainties regarding the severity and duration of the COVID-19 pandemic and its impact on our business and the economy generally, clinical trial or commercial results or new product approvals and therapy adoption; inability or failure to comply with regulations; unpredictability of product launches; competitive dynamics; changes to reimbursement for the company’s products; the company’s success in developing new products and avoiding manufacturing and quality issues; the impact of currency exchange rates; the timing or results of research and development and clinical trials; unanticipated actions by the U.S. Food and Drug Administration and other regulatory agencies; unexpected litigation impacts or expenses; and other risks detailed under “Risk Factors” in Part I, Item 1A below, as such risks and uncertainties may be amended, supplemented or superseded from time to time by our subsequent reports on Forms 10-Q and 8-K we file with the Securities and Exchange Commission. 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 been a leader in these areas for over six decades. 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 and noninvasive brain and tissue oxygenation 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 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. Our products and technologies are categorized into four main areas: Transcatheter Aortic Valve Replacement, Transcatheter Mitral and Tricuspid Therapies, Surgical Structural Heart, and Critical Care. For more information on net sales from these four 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.*"

Transcatheter Aortic Valve Replacement

We are the global leader in transcatheter heart valve replacement technologies designed for the minimally invasive 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 their respective

delivery systems, are used to treat heart valve disease using catheter-based approaches for patients who have severe symptomatic aortic stenosis and certain patients with congenital heart disease. 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 65%, 63%, and 61% of our net sales in 2020, 2019, and 2018, 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 many of these technologies are in early development and clinical phases, the *PASCAL* transcatheter valve repair system and the *Cardioband* systems for mitral and tricuspid valve repair are commercially available in Europe. The *PASCAL* system provides a differentiated, minimally-invasive therapy to address the needs of patients with mitral or tricuspid regurgitation through leaflet approximation, while the *Cardioband* system enables clinicians to restore a patient's mitral or tricuspid valve to a more functional state by reducing the annulus and lowering regurgitation. In addition to transcatheter repair, we believe transcatheter replacement is key to unlocking the full mitral and tricuspid opportunity, given the complex and diverse patient population. Our two-platform strategy positions us for leadership in the mid-to-long term. *SAPIEN M3* is based on the proven *SAPIEN* valve, paired with a novel docking system. We are also continuing to advance our *EVOQUE* platform for both mitral and tricuspid replacement. Both *SAPIEN M3* and *EVOQUE* transfemoral delivery systems are sub 30-French, which has benefits for femoral puncture and septal crossing, contributing to ease of use, and patient safety.

Surgical Structural Heart

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 innovation, the *INSPIRIS RESILIA* aortic valve, is built on our *PERIMOUNT* platform and offers *RESILIA* tissue and *VFit* technology. *INSPIRIS* is now the leading aortic surgical valve in the world. In addition to our replacement valves, we are the worldwide leader in surgical heart valve repair therapies. In 2020, we launched the *HARPOON Beating Heart Mitral Valve Repair System*, which can help transform care for many patients with degenerative mitral regurgitation. We are also a global leader in cardiac cannula devices and offer a variety of procedure-enabling innovations that advance minimally invasive surgery. We believe the demand for surgical structural heart therapies is growing worldwide and that our innovation strategy will continue to extend our leadership and patient impact.

Sales of our surgical tissue heart valve products represented 16%, 17%, and 18% of our net sales in 2020, 2019, and 2018, respectively.

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 plays an important role in enhancing surgical recovery. Edwards' complete hemodynamic portfolio helps clinicians make proactive clinical decisions that can improve patient outcomes, and includes the minimally invasive *FloTrac* system, the noninvasive *ClearSight* system, and *ForeSight*, the noninvasive tissue oximetry system. We also support clinical

needs with our well-established *Swan-Ganz* line of pulmonary artery catheters, arterial pressure monitoring products, and *Edwards Oximetry Central Venous Catheters*. In conjunction with our sensors, our *HemoSphere* monitoring platforms display valuable physiological information in an easy to understand and actionable manner. Amplifying our sensor and monitoring platform portfolio is the addition of our first predictive algorithm, *Acumen Hypotension Prediction Index*, which alerts clinicians in advance of a patient developing low blood pressure.

Sales of our core hemodynamic products represented 9%, 9%, and 10% of our net sales in 2020, 2019, and 2018, respectively.

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 are competitive primarily because we deliver superior clinical outcomes that are supported by extensive data, and innovative features that enhance patient benefit, product performance, and reliability; these superior clinical outcomes are in part due to the level of customer and clinical support we provide.

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 Abbott Laboratories (“Abbott”). In Transcatheter Mitral and Tricuspid Therapies, our primary competitor is Abbott, and there are a considerable number of large and small companies with development efforts in these fields. In Surgical Structural Heart, our primary competitors include Medtronic PLC, Abbott, and CryoLife. 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, Cheetah Medical, Inc., a subsidiary of Baxter International, and LiDCO Group PLC, now part of Masimo.

Sales and Marketing

Our portfolio includes some of the most recognizable cardiovascular device product brands in treating structural heart disease today. We have a number of product lines that require sales and marketing strategies tailored to deliver high-quality, cost-effective products and technologies to customers worldwide. 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 2020.

To ensure optimal outcomes for patients, we conduct educational symposia and best practices training for our physician, hospital executive, service line leadership, nursing, and clinical-based customers. 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. 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.

United States. In the United States, we sell substantially all of our products through our direct sales forces. In 2020, 57% of our net sales were derived from sales to customers in the United States.

International. In 2020, 43% of our net sales were derived internationally through our direct sales forces and independent distributors. Of the total international sales, 52% were in Europe, 25% 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, 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, Transcatheter Mitral and Tricuspid technologies, and Structural Surgical Heart products primarily in the United States (California and Utah), Singapore, Costa Rica, and Ireland. We manufacture our Critical Care products primarily in our facilities located in Puerto Rico and the Dominican Republic.

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 with our suppliers to mitigate risk and seek continuity of supply while maintaining 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 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”), 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 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

In 2020, we made significant investments in research and development as we worked to develop therapies that we believe have the potential to change the practice of medicine. Research and development spending increased 1% year over year to 17% of 2020 sales. This increase was primarily the result of significant investments in our transcatheter structural heart programs, including an increase in clinical research for our mitral and tricuspid therapies business. 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.

In Transcatheter Mitral and Tricuspid Therapies, we are making significant investments in innovation and clinical evidence to develop technologies designed to treat mitral and tricuspid valve diseases. 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 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. Lastly, we are developing a connectivity platform that will offer clinicians additional clinical support, remote monitoring capability, analytics, and insights for their patients' hemodynamic status.

Our research and development activities are conducted primarily in facilities located in the United States and Israel. Our experienced research and development staff are 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.

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, licensing opportunities, and non-disclosure agreements to develop and maintain our competitive position.

We own or have rights to a substantial number of patents and have patent applications pending both in the U.S. and in foreign countries. We continue to innovate and file new patent applications to protect the full range of our products and technologies.

Additionally, we are a party to numerous license agreements with various 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 undertake reasonable measures to protect our patent rights, including monitoring 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.

Moreover, we own certain U.S. 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 U.S. FDA, European Union Member States competent authorities, 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. Compliance with these regulations has not had a material effect on our capital expenditures, earnings, or competitive position to date, but new regulations or amendments to existing regulations to make them more stringent could have such an effect in the future. We cannot estimate the expenses we may incur to comply with potential new laws or changes to existing laws, or the other potential effects these laws may have on our business.

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 regulatory standards. Additionally, even if a product is cleared or approved, the FDA may impose restrictions or 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, suspensions or withdrawals 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 medical devices into the United States, which could also subject us to sanctions for noncompliance.

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 anyone, including physicians as an inducement to purchase or recommend 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 United States companies for arrangements with foreign government officials or other parties, or for not keeping accurate financial records or maintaining adequate internal controls to prevent and detect arrangements with foreign government officials or other parties.

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 work to adhere to many codes of ethics and conduct regarding our business 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 (the “EU”) implemented a new regulatory scheme for medical devices under the Medical Device Regulation (“MDR”). The MDR becomes fully effective in 2021 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, new definitions and registration of economic operators throughout the distribution chain, and additional post-market surveillance and vigilance. Compliance with the MDR requires re-certification of many of our products to the enhanced standards, and has resulted in and will continue to result in substantial additional expense. In addition, in the EU, we import some of our devices through our offices in Switzerland. Switzerland is not a member state of the EU, but is linked to the EU through bilateral treaties; therefore, the free movement of goods, including medical devices, between the EU and Switzerland after implementation of the MDR requires a revised Mutual Recognition Agreement (“MRA”), which continues to be under negotiation for the MDR. If an MRA covering the MDR is not put in place, then non-EU manufacturers may be required to make significant changes, including replacement of Swiss economic operators with operators based in EU Member States, and changes will need to be made to our device labeling and/or packaging to satisfy MDR requirements. If these measures are unable to be taken, it may no longer be possible to place such devices on the EU market.

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 Japanese “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.

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 United States Department of Health and Human Services (“HHS”) 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. The CMS National Coverage Determination for Transcatheter Aortic Valve Replacement was issued in June 2019. The modernized requirements and more streamlined patient evaluation process are meaningful enhancements that may help ensure equitable access for more patients suffering from severe aortic stenosis.

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 have a material impact on product pricing.

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.

Human Capital Management Strategy

Human Capital Management (“HCM”) Governance

Attracting, developing, and retaining talent is fundamental to our success. The primary goals of our talent management strategy are to attract and maintain a motivated, professional workforce and to ensure alignment on our patient-focused innovation strategy.

Our Board of Directors has oversight over human capital management with time dedicated at each regularly scheduled meeting to discuss talent management, including, among other things, talent strategy, diversity, succession planning, employee development, employee health, safety, and welfare, results of employee surveys, and compensation. The Board of Directors also approves Key Operating Drivers, which are strategic milestones that include financial objectives and are tracked using a point system across our entire organization, that focus the Company and management toward short, medium, and long-term goals that align with our talent management strategy. In addition, the Chief Executive Officer (“CEO”) has talent management related performance goals tied to his compensation; these Performance Management Objectives are tracked and, then, reported to and evaluated by our Board of Directors.

Our HCM governance includes a global talent development review (“TDR”) process as well as an HCM dashboard. The purpose of our TDR process is to align our business strategy with talent strategies, assess talent against future organizational needs, evaluate critical talent populations, and enhance the strength of our succession planning. Our HCM dashboard is generated quarterly and provides insights on key metrics related to areas such as attraction and growth rates, retention trends, diversity, and employee sentiment.

Culture

Investing in our workforce means our employees can stay focused on our patient-focused innovation strategy and the development of life-saving therapies for the patients we serve. We are committed to maintaining a culture where we celebrate diversity, ensure that employees’ voices are heard, and promote good health and safety. We strive to offer competitive employee benefits packages and are committed to fair and equitable pay practices. We track compensation patterns in all geographies where we operate, and we regularly look for ways to ensure fair and equitable pay.

We are committed to fostering an environment where all employees can grow and thrive. A diverse workforce results in a broader range of perspectives, helping drive our commitment to innovation.

We believe in empowering our employees and providing avenues that enable their voices to be heard. We conduct a multilingual global employee survey, called *myVoice*, to pulse our employees and gain their feedback in a confidential manner. We gain insights on various topics including patient focus, diversity, inclusion and belonging, quality, innovation, and engagement. Speak-Up is a resource available to all employees to bring forth compliance related concerns. In addition, during each quarterly townhall meeting, our CEO has an “Ask Mike” section in which he answers questions that have been submitted to him by employees. Answers to questions that are not covered in the townhall meeting are posted online internally.

We understand that good health leads to better performance. Edwards offers a competitive employee benefits package that includes, among other things, health and welfare insurance, health savings accounts, family support services, and a variety of site-specific programs. We regularly evaluate our benefits package to make modifications that are aligned with the competitive landscape, legislative changes, and the unique needs of our population. We also provide robust wellness programs that address prevention, nutrition, mental health, physical activity, education, financial fitness, and community service.

Talent Development

In addition to our robust TDR process and tuition reimbursement programs, we provide a variety of leadership, technical, and professional development programs around the globe.

Headcount and Labor Representation

As of December 31, 2020, we had approximately 14,900 employees worldwide, the majority of whom were located in the United States, Singapore, and the Dominican Republic. 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 employees.

Additional details regarding diversity, talent development, compensation, and employee health and safety can be found in our Sustainability Report posted on our website at www.edwards.com under “About Us — Corporate Responsibility.”

References to our website in this Annual Report on Form 10-K are provided for convenience only and the content on our website does not constitute a part of this Report.

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

We are subject to risks associated with public health threats and epidemics, including the novel coronavirus (“COVID-19”).

We are subject to risks associated with public health threats and epidemics, including the global health concerns relating to the COVID-19 pandemic. The global pandemic has adversely impacted and is likely to further adversely impact nearly all aspects of our business and markets, including our workforce and operations and the operations of our customers, suppliers, and business partners. In particular, we may experience material financial or operational impacts, including:

- Significant volatility or reductions in demand for our products;
- Impacts and delays to clinical trials, our pipeline milestones, or regulatory clearances and approvals; or
- The inability to meet our customers’ needs or other obligations due to disruptions to our operations or the operations of our third-party partners, suppliers, contractors, logistics partners, or customers including disruptions to production, development, manufacturing, administrative, and supply operations and arrangements.

The extent to which the COVID-19 global pandemic and measures taken in response thereto impact our business, results of operations, and financial condition will depend on future developments, which are highly uncertain and are difficult to predict. These developments include, but are not limited to, the duration and spread of the outbreak (including new variants of COVID-19), its severity, the actions to contain the virus or address its impact, the timing, distribution, and efficacy of vaccines and other treatments, U.S. and foreign government actions to respond to the reduction in global economic activity, and how quickly and to what extent normal economic and operating conditions can resume.

Failure to successfully innovate and develop new and differentiated products in a timely manner and effectively market these products could have a material effect on our prospects.

Our continued growth and success depend on our ability to innovate and develop new and differentiated products in a timely manner and effectively market these products. Without the timely innovation and development of products, our products could be rendered obsolete or less competitive by changing customer preferences or because of the introduction of a competitor's newer technologies. Innovating products requires the devotion of significant financial and other resources to research and development activities; however, there is no certainty that the products we are currently developing will complete the development process, or that we will obtain the regulatory or other approvals required to market such products in a timely manner or at all. Even if we timely innovate and develop products, our ability to market them could be constrained by a number of different factors, including barriers in patients' treatment pathway (including disease awareness, detection, and diagnosis), the need for regulatory clearance, restrictions imposed on approved indications, and uncertainty over third-party reimbursement. Failure in any of these areas could have a material effect on our prospects.

Unsuccessful clinical trials or procedures relating to products 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 indication; failure to do so 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 analyses. 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.

We operate in highly competitive markets, and if we do not compete effectively, our business will be harmed.

We face substantial competition and compete with companies of all sizes on the basis of cost-effectiveness, technological innovations, product performance, brand name recognition, breadth of product offerings, real or perceived product advantages, pricing and availability and rate of reimbursement. 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" in Part I, Item 1 included herein.

If we identify underperforming operations or products or if there are unforeseen operating difficulties and expenditures in connection with business acquisitions or strategic alliances, we may be required, from time to time, to recognize charges, which could be substantial and which could adversely affect our results of operations.

We actively manage a portfolio of research and development products, and we regularly explore potential acquisitions of complementary businesses, technologies, services, or products, as well as potential strategic alliances. From time to time, we identify operations and products that are underperforming, do not fit with our longer-term business strategy or there may be unforeseen operating difficulties and significant expenditures

during the integration of an acquired business, technology, service, or product into our existing operations. We may seek to dispose of these underperforming operations or products, and 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. In addition, we may be required to take charges or write-downs in connection with acquisitions and divestitures. 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 assets. To the extent that the value of these assets decline, 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 in-process research and development assets. Any of these events could result in charges, which could be substantial and which could adversely affect our results of operations.

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

We 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 appropriately engage these professionals or to continue to receive their advice and input, the development, marketing, and successful use of our products could suffer, which could have a material adverse effect on our business, financial condition, and results of operations.

If we or one of our suppliers or logistics partners encounters manufacturing, logistics, or quality problems, our business could be materially adversely affected.

The manufacture and sterilization of many of our products is highly complex due in part to rigorous regulatory requirements. Quality is extremely important due to the serious and costly consequences of a product failure. Problems can arise 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. Disruptions can occur at any time, including during production line transfers and expansions. Disruptions can also occur if our manufacturing and warehousing facilities are damaged by earthquakes, hurricanes, volcanoes, fires, and other natural disasters or catastrophic circumstances. As we expand into new markets and scale new products for commercial production, we may face unanticipated delays or surges in demand which could strain our production capacity and lead to other types of disruption. If any of these manufacturing, logistics, or quality problems arise or if we or one of our suppliers or logistics partner otherwise fail to meet internal quality standards or those of the FDA or other applicable regulatory body, 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 and production could be delayed, and our business could otherwise be materially adversely affected.

We rely on third parties in the design, manufacture, and sterilization of our products. Any failure by or loss of a vendor could result in delays and increased costs, which may adversely affect our business.

We rely on third parties for a broad range of raw and organic materials and other items in the design, manufacture, and sterilization of our products, and we purchase certain supplies and services from single sources for reasons of quality assurance, cost-effectiveness, availability, constraints resulting from regulatory requirements, and other reasons. We may experience supply interruptions due to a variety of factors, including:

- General economic conditions that could adversely affect the financial viability of our vendors;
- Vendors' election to no longer service medical technology companies due to the burdens of applicable quality requirements and regulations;
- The limitation or ban of certain materials used in the manufacture of our products; and
- Delays or shortages due to trade or regulatory embargoes.

A change or addition to our vendors could require significant effort due to the rigorous regulations and requirements of the FDA and other regulatory authorities; it could be difficult to establish additional or replacement sources on a timely basis, which could have a material adverse effect on our business.

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, but are not limited to, computer viruses, computer denial-of-service attacks, phishing attacks, ransomware 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 and the California Consumer Privacy Act, 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 operations or result in decreased sales, result in liability claims or regulatory penalties, or lead to 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.

Our business and results of operations may be adversely affected if we are unable to recruit and retain qualified management and other personnel.

Our continued success depends, in large part, on our ability to hire and retain qualified people or otherwise have access to such qualified people globally and if we are unable to do so, our business and operations may be impaired or disrupted. See "Human Capital Management Strategy" under "Business" in Part I, Item 1 included herein. Competition for highly qualified people is intense, and there is no assurance that we will be successful in attracting or retaining replacements to fill vacant positions, successors to fill retirements or employees moving to new positions, or other highly qualified personnel.

Market and Other External Risks

Because we operate globally, our business is subject to a variety of risks associated with international sales and operations.

Our extensive global operations and business activity as well as the fact that many of our manufacturing facilities and suppliers are outside of the United States are accompanied by certain financial, economic, political, and other risks, including those listed below.

Domestic and Global Economic Conditions. We cannot predict to what extent general domestic and global economic conditions may negatively impact our business. These include, but are not limited to, credit and capital

markets, interest rates, tax law, including tax rate and policy changes, factors affecting global economic stability, the political environment relating to health care, and the potential implications of the U.K. “Brexit” or the withdrawal from the European Union of other member countries. These and other conditions could also adversely affect our customers, payers, vendors and other stakeholders and may impact their ability or decision to purchase our products or make payments on a timely basis.

Health Care Legislation and Other Regulations. We are subject to various federal and foreign laws that govern our domestic and international business practices. For example, in the U.S., 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. In addition, a Mutual Recognition Agreement still under negotiation for the Medical Device Regulation can result in a lack of free movement of medical devices between the European Union and Switzerland, can impact our access in the European Union and can, ultimately, have a material effect on our business, financial condition, and results of operations. For more information about these laws as they relate to our business, see the section entitled “*Health Care Legislation*” and “*Government Regulation and Other Matters*” in Part I, Item 1, “*Business*.”

In addition, 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. Penalties resulting from any violation of these laws could adversely affect us and our business.

Taxes. We are subject to income taxes in the United States as well as other jurisdictions.

- ***Provision for Income Taxes.*** Our provision for income taxes and our underlying effective tax rate could fluctuate due to changes in the mix of earnings and losses in countries with differing statutory tax rates. Our income tax provision could also be impacted by changes in excess tax benefits of stock-based compensation, federal and state tax credits, non-deductible expenses, changes in the valuation of deferred tax assets and liabilities and our ability to utilize them, the applicability and creditability of withholding taxes, and effects from acquisitions.
- ***Tax Reform.*** Our provision for income taxes could be materially impacted by changes in accounting principles or evolving tax laws, including, but not limited to, global corporate tax reform and base-erosion and tax transparency efforts. For example, many countries are aligning their international tax rules with the Organisation for Economic Co-operation and Development’s Base Erosion and Profit Shifting recommendations and action plans that aim to standardize and modernize international corporate tax policy, including changes to cross-border taxes, transfer pricing documentation rules, nexus-based tax practices, and taxation of digital activities.
- ***Tax Audits.*** We are subject to ongoing tax audits in the various jurisdictions in which we operate. Tax authorities may disagree with certain positions we have taken and assess additional taxes. Although we regularly assess the likely outcomes of the audits and record reserves for potential tax payments, the calculation of tax liabilities involves the application of complex tax laws, and our estimates could be different than the amounts for which we are ultimately liable.
- ***Tax Incentives.*** We benefit from various global tax incentives extended to encourage investment or employment. Several foreign jurisdictions have granted us tax incentives which require renewal at various times in the future. If our incentives are not renewed or we cannot or do not wish to satisfy all or part of the tax incentive conditions, we may lose the tax incentives and could be required to refund tax incentives previously realized. As a result, our provision for income taxes could be higher than it would have been had we maintained the benefits of the tax incentives.

Other economic, political, and social risks. Our future results could be harmed by a variety of other factors associated with doing business internationally such as those enumerated in these risk factors as well as the following:

- trade protection measures, quotas, embargoes, import or export requirements, and duties, tariffs, or surcharges;
- cultural or other local factors affecting financial terms with customers;
- differing labor regulations; and
- currency exchange rate fluctuations; that is, 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 adverse effect on our revenues, cost of sales, or 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, nearly 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 our success. 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. Reimbursement levels may be decreased in the future. Additionally, future legislation, regulation, or reimbursement policies of third-party payors may 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.

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 and quality of life benefits 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.

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 drive consolidation and increase pricing pressure.

Legal, Compliance, and Regulatory Risks

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 ability to protect our proprietary intellectual property through a combination of patents and trade secrets. We cannot guarantee that the protective steps we take 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.
- As our patents expire, we may be unsuccessful in extending their protection through patent term extensions.
- Confidentiality agreements with certain employees, consultants, and other third parties intended to protect, in part, trade secrets and other proprietary information could be breached, and we may not have adequate remedies.
- Others could independently develop substantially equivalent proprietary information or gain access to our trade secrets or proprietary information, design around our technology, or develop competing technologies.
- 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, theft, 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.
- We may not detect infringement.
- Intellectual property protection may also be unavailable or limited in some foreign countries.

We spend significant resources to protect and enforce our intellectual property rights, sometimes resulting in expensive and time-consuming litigation that is complex and may ultimately be unsuccessful. Our inability to protect our intellectual property could have a material adverse effect on our business 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 which is typically costly and time-consuming. We may be forced to defend against claims and legal actions alleging infringement of the intellectual property rights of others, and, if our defense is unsuccessful, Edwards could have significant liabilities to third parties or face injunctions that bar the sale of our products, or could require us to seek licenses from third parties. Such licenses may not be available on commercially reasonable terms, may prevent us from manufacturing, selling, or using certain products, or may be non-exclusive, which could provide our competitors access to the same technologies.

In addition, third parties could also obtain patents that may require us to either redesign products, negotiate licenses from such third parties, which may be costly, unavailable or require us to exit a particular product offering.

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 create, study, manufacture and market globally are subject to rigorous regulation and scrutiny by the FDA and various other federal, state, and foreign governmental authorities. Government regulation applies to nearly all aspects of our products' lifecycles, including testing, clinical study, manufacturing, transporting, sourcing, safety, labeling, storing, packaging, recordkeeping, reporting, advertising, promoting, distributing, marketing, and importing or exporting of medical devices and products. In general, unless an exemption applies, a medical device or product must receive regulatory approval or clearance before it can be marketed or sold. Modifications to existing products or the marketing of new uses for existing products also may require regulatory approvals, approval supplements, or clearances. If we are unable to obtain these required approvals, we may be required to cease manufacturing and sale, or recall or restrict the use of such modified device, pay fines, or take other action until such time as appropriate clearance or approval is obtained.

Regulatory agencies may refuse to grant approval or clearance, or review and disagree with our interpretation of approvals or clearances, or with our decision that regulatory approval is not required or has been maintained. Regulatory submissions may require the provision of additional data and may be time consuming and costly, and their outcome is uncertain. Regulatory agencies may also change policies, adopt additional regulations, or revise existing regulations, each of which could prevent or delay approval or clearance of devices, or could impact our ability to market a previously cleared, approved, or unregulated device. Our failure to comply with these regulatory requirements of the FDA or other applicable regulatory requirements in the United States or elsewhere might subject us to administratively or judicially imposed sanctions. These sanctions include, among others, warning letters, fines, civil penalties, criminal penalties, injunctions, debarment, product seizure or detention, product recalls and total or partial suspension of production, sale and/or promotion. Any of the foregoing actions could result in decreased sales including 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.

Also, we are 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. If we are found not to be in compliance, we may be required to alter our practices or have sanctions imposed against us and our officers and employees, including substantial fines, imprisonment, and exclusion from participation in governmental health care programs.

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 information could result in an unsafe condition, injury to, or 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. We establish reserves and may incur charges in excess of those reserves. Although we maintain product liability and other insurance with coverages we believe are adequate, product liability or other claims may exceed insurance coverage limits, fines, and penalties. In addition, regulatory sanctions may not be covered by insurance, or insurance may not continue to be available or available on commercially reasonable terms. These litigation matters and regulatory actions, recalls or other actions, regardless of outcome, could have a material adverse effect on our business, reputation, and ability to attract and retain customers.

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 conducted in compliance with applicable laws, and therefore, is mainly 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.

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

Certain of our products, including pericardial tissue valves, are manufactured using bovine tissue. Concerns relating to the potential transmission of animal borne illnesses, including 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.

Item 1B. Unresolved Staff Comments

None.

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),(2)	Manufacturing, Administration
Haina, Dominican Republic	(1),(2)	Manufacturing
Añasco, Puerto Rico	(2)	Manufacturing

Central America

Cartago, Costa Rica	(1),(2)	Manufacturing
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Europe

Nyon, Switzerland	(1)	Administration, Marketing
Prague, Czech Republic	(2)	Administration
Shannon, Limerick, Ireland	(1),(2)	Manufacturing (under construction)

Asia

Singapore	(1),(2)	Manufacturing, Distribution, Administration
Tokyo, Japan	(2)	Administration, Marketing, Distribution
Shanghai, China	(2)	Administration, Marketing
Caesarea, Israel	(2)	Research and Development
Or Yehuda, Israel	(2)	Research and Development

(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; Singapore has one land lease that expires in 2036 and one that expires in 2041; Caesarea, Israel has one lease that expires in 2021 and one that expires in 2030; and the Or Yehuda, Israel lease expires in 2023. We believe our properties have been well maintained, are in good operating condition, and are adequate for current needs. We do not anticipate difficulty in renewing existing leases as they expire or in finding alternative facilities.

Item 3. Legal Proceedings

For a description of our material pending legal proceedings, please see Note 18 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.

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, 2021, there were 8,876 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.

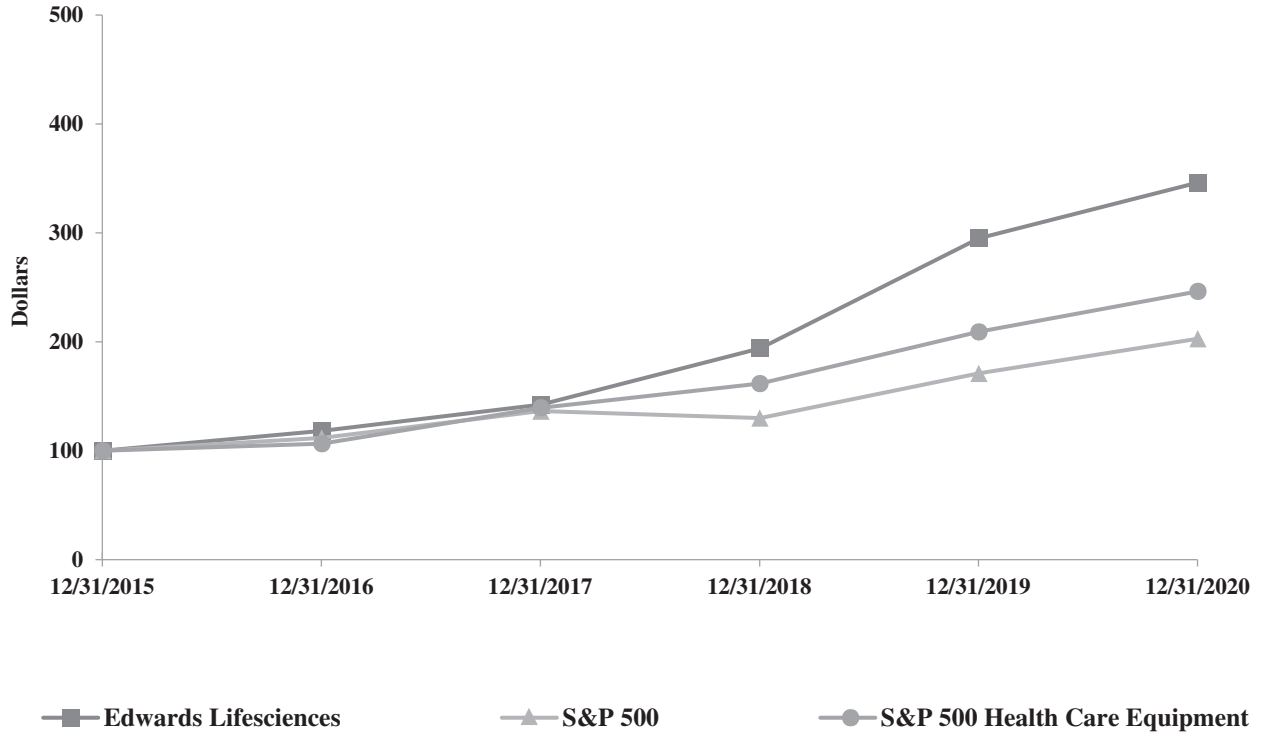
Issuer Purchases of Equity Securities

On May 8, 2019, 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 and in privately negotiated transactions, up to \$1.0 billion of our common stock. The repurchase program does not have an expiration date. We did not purchase any of our common stock during the fourth quarter of 2020 and, as of December 31, 2020, we had remaining authority to purchase \$625.0 million of common stock.

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, 2015 and reinvestment of dividends. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.

COMPARISON OF 5-YEAR CUMULATIVE TOTAL RETURN



	Total Cumulative Return				
	2016	2017	2018	2019	2020
Edwards Lifesciences	\$118.64	\$142.71	\$193.94	\$295.38	\$346.53
S&P 500	111.96	136.40	130.42	171.49	203.04
S&P 500 Health Care Equipment	106.48	139.38	162.02	209.52	246.47

Item 6. Selected Financial Data

		As of or for the Years Ended December 31,				
		2020	2019	2018	2017	2016
		(in millions, except per share data)				
OPERATING RESULTS ..	Net sales	\$4,386.3	\$4,348.0	\$3,722.8	\$3,435.3	\$2,963.7
	Gross profit	3,305.7	3,233.6	2,783.4	2,560.0	2,166.3
	Operating income (a) ..	897.6	1,146.8	748.2	1,089.4	751.2
	Net income (a)	823.4	1,046.9	722.2	583.6	569.5
COMMON STOCK INFORMATION	Net income per common share (a) (c):					
	Basic	\$ 1.32	\$ 1.68	\$ 1.15	\$ 0.92	\$ 0.89
	Diluted	1.30	1.64	1.13	0.90	0.87
	Cash dividends declared per common share	—	—	—	—	—
BALANCE SHEET DATA	Total assets	\$7,237.1	\$6,488.1	\$5,323.7	\$5,666.4	\$4,518.5
	Long-term debt (b)	595.0	594.4	593.8	438.4	822.3

- (a) The above results for 2020 include a \$367.9 million pre-tax charge (\$305.1 million, net of tax) related to a litigation settlement. The above results for 2019 include special charges of \$64.6 million (\$58.7 million, net of tax), primarily the impairment of certain assets and the acquisition of early-stage intellectual property. The above results for 2018 include special charges of \$109.1 million (\$103.0 million, net of tax), primarily the impairment of intangible assets and a \$180.0 million (\$137.5 million, net of tax) charge related to a litigation settlement. The above results for 2017 include a \$112.5 million (\$70.3 million, net of tax) gain for a litigation payment received in 2017 and 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 17 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 as of December 31, 2020, 2019 and 2018. 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.
- (c) The per share amounts for the prior periods presented have been retroactively adjusted to reflect the three-for-one stock split effected in the second quarter of 2020.

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

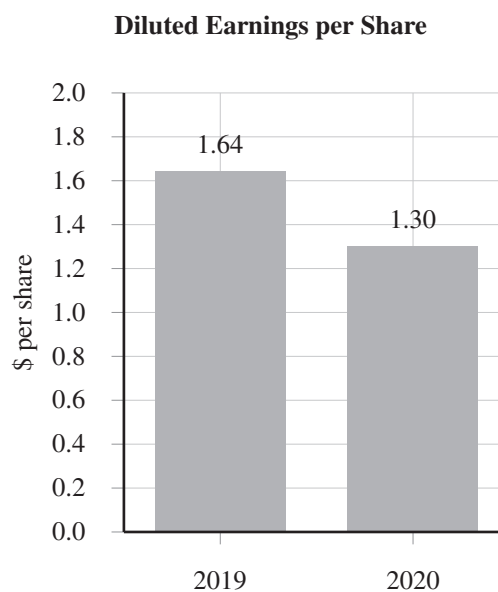
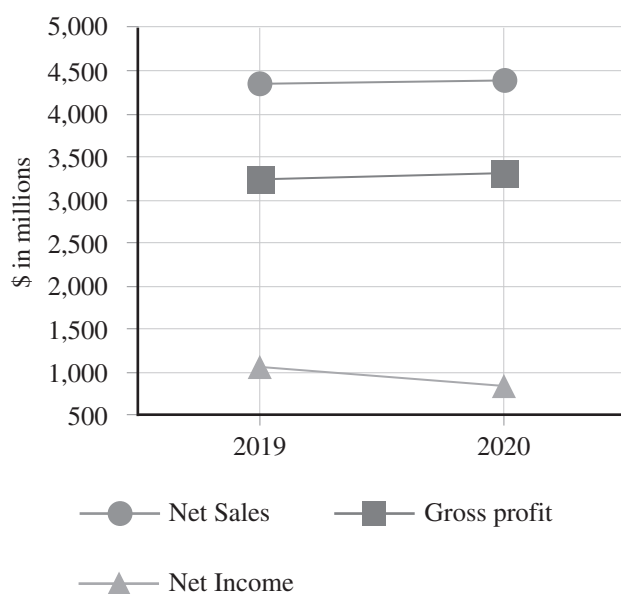
The following discussion and analysis presents the factors that had a material effect on our results of operations during the two years ended December 31, 2020. Also discussed is our financial position as of December 31, 2020. You should read this discussion in conjunction with the historical consolidated financial statements and related notes included elsewhere in this Form 10-K. For a discussion related to the results of operations for 2019 compared to 2018 and a discussion related to our consolidated cash flows for 2019 compared to 2018, refer to Part II, Item 7, “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*” in our 2019 Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 14, 2020.

Overview

We are the global leader in patient-focused medical innovations for structural heart disease, as well as critical care and surgical 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 Aortic Valve Replacement ("TAVR"), Transcatheter Mitral and Tricuspid Therapies ("TMTT"), Surgical Structural Heart ("Surgical"), and Critical Care.

On May 7, 2020, our Board of Directors declared a three-for-one stock split of our outstanding shares of common stock effected in the form of a stock dividend, distributed on May 29, 2020 to stockholders of record on May 18, 2020. We distributed two newly issued shares of common stock to holders of record of each share of common stock to effect the stock split. All applicable share and per-share amounts in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" have been retroactively adjusted to give effect to this stock split.

Financial Highlights and COVID-19



In March 2020, the World Health Organization categorized the Coronavirus disease 2019 ("COVID-19") as a pandemic. COVID-19 continues to spread throughout the United States and other countries across the world, and the duration and severity of its effects are currently unknown. The global pandemic has adversely impacted and is likely to further adversely impact nearly all aspects of our business and markets, including our workforce and the operations of our customers, suppliers, and business partners. Our priority has been to support our clinician partners, protect the well-being of our employees, and maintain continuous access to our life-saving technologies while offering front-line in-hospital support. Our manufacturing operations have continued to respond to impacts related to COVID-19, and we have been able to supply our technologies around the world. Across the organization, we are proactively managing inventory, assessing alternative logistics options, and closely monitoring the supply of components.

TAVR and Surgical procedure volumes varied greatly since the middle of March 2020 by geography, and even by hospital, as patients and their physicians analyzed the trade-off between aortic stenosis and their concern

for COVID-19. In the last few weeks of the first quarter of 2020, procedure volumes related to our TAVR and Surgical products dropped significantly. Beginning in the second quarter of 2020, procedure volumes improved. In the second quarter of 2020, we also started to progressively resume patient enrollment in all clinical trials that were voluntarily paused or slowed at the end of the first quarter of 2020. While we saw improvements to pre-COVID levels when we resumed enrollment, procedure volumes and enrollment in our clinical trials have since been negatively impacted due to a resurgence of COVID-19 in late 2020. Even though health systems adapted to the challenge, the resurgence of COVID-19 late in 2020 continued to impact these patients who need care. In Critical Care, there was greater demand in Europe and the United States for our pressure monitoring products, but demand for other Critical Care products began to decrease at the end of the first quarter of 2020 due to COVID-19, and that trend continued through the fourth quarter of 2020.

Despite the challenges associated with COVID-19, our net sales for 2020 were \$4.4 billion, representing an increase of \$38.3 million over 2019, driven by sales growth of our TAVR products.

Our gross profit increase in 2020 was driven by a charge of \$73.1 million recorded in 2019, primarily comprised of the write off of inventory related to strategic decisions regarding our TAVR portfolio, including the decision to discontinue our *CENTERA* program.

The decrease in our diluted earnings per share in 2020 was driven by an after-tax charge of \$305.1 million to settle certain patent litigation related to transcatheter mitral and tricuspid repair products.

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. While some evidence collection was slowed due to the COVID-19 pandemic, we and the clinical community are committed to continuing our trials and generating robust evidence. In 2020, we invested 17.3% of our net sales in research and development. The following is a summary of important developments during 2020:

- in response to the urgent COVID-19 response around the globe, we temporarily paused new enrollments in our active pivotal clinical trials of transcatheter mitral and tricuspid therapies, which began resuming in the second quarter of 2020;
- we received CE Mark for the *Edwards PASCAL* transcatheter valve repair system for the treatment of European patients with tricuspid regurgitation;
- we received Chinese regulatory approval for the *Edwards SAPIEN 3* transcatheter heart valve for the treatment of severe, symptomatic aortic stenosis patients at high risk for or unable to undergo open-heart surgery;
- we reached an agreement with Abbott to settle all outstanding patent disputes between the companies in cases related to transcatheter mitral and tricuspid repair products;
- we received FDA approval for the *KONECT RESILIA* aortic valved conduit, the first ready-to-implant solution for bio-Bentall procedures, a complex surgery that involves replacement of a patient's aortic valve, aortic root, and the ascending aorta.
- we treated our first patient in the RESTORE clinical trial, which will evaluate the safety and effectiveness of the investigational *HARPOON Beating Heart Mitral Valve Repair System* in the United States and Canada.

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	
	2020	2019	\$	%
United States	\$2,516.8	\$2,532.7	\$(15.9)	(0.6)%
Europe	973.6	941.2	32.4	3.4%
Japan	460.1	444.7	15.4	3.5%
Rest of World	435.8	429.4	6.4	1.5%
International	1,869.5	1,815.3	54.2	3.0%
Total net sales	<u>\$4,386.3</u>	<u>\$4,348.0</u>	<u>\$ 38.3</u>	<u>0.9%</u>

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.*”

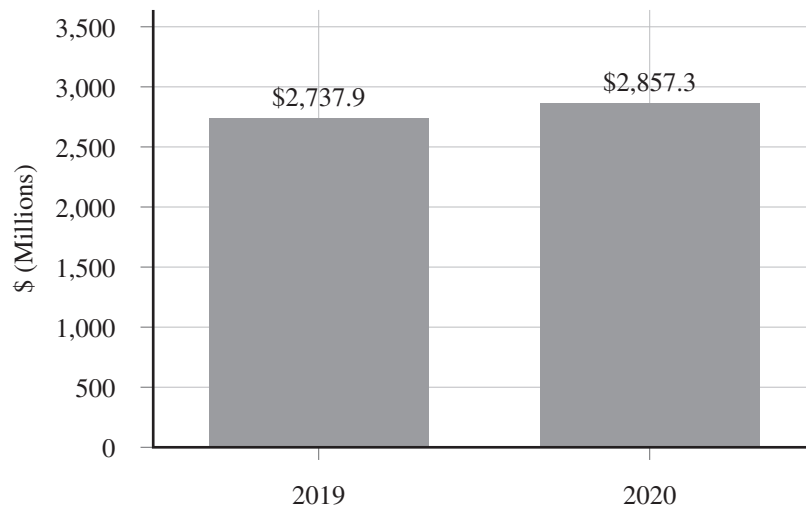
Net Sales by Product Group

(dollars in millions)

	Years Ended December 31,		Change	
	2020	2019	\$	%
Transcatheter Aortic Valve Replacement	\$2,857.3	\$2,737.9	\$119.4	4.4%
Transcatheter Mitral and Tricuspid Therapies	41.8	28.2	13.6	48.5%
Surgical Heart Valve Therapy	761.8	841.7	(79.9)	(9.5)%
Critical Care	725.4	740.2	(14.8)	(2.0)%
Total net sales	<u>\$4,386.3</u>	<u>\$4,348.0</u>	<u>\$ 38.3</u>	<u>0.9%</u>

Transcatheter Aortic Valve Replacement

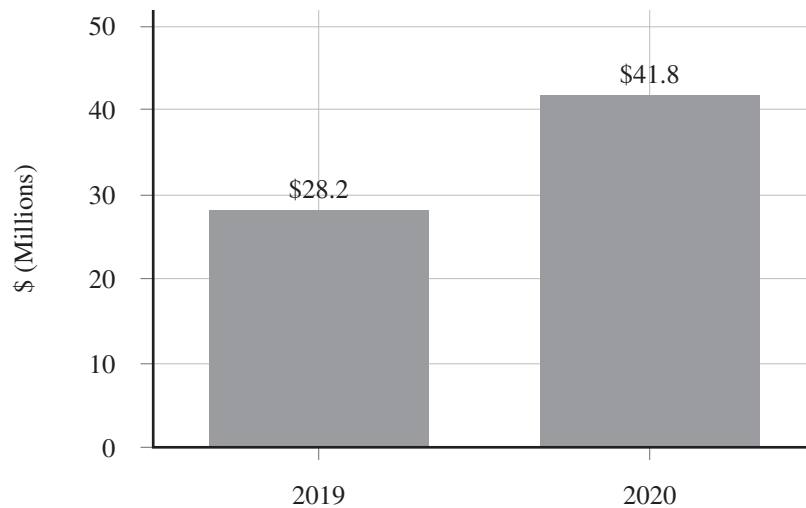
For the years ended December 31, 2020 and 2019:



The increase in net sales of TAVR products was due primarily to higher sales of the *Edwards SAPIEN 3 Ultra System* following its regulatory approval in the United States (December 2018) and in Europe (November 2018). The adoption of the *Edwards SAPIEN 3 Ultra System* continued to be very positive in 2020. However, our sales in 2020 were negatively impacted by the COVID-19 pandemic, and these challenges have continued in early 2021. Our procedure volumes dropped significantly beginning in March 2020 due to COVID-19, and began to steadily improve beginning in May 2020. In the first quarter of 2020, to ensure the safety of our employees and clinician partners from the threat of COVID-19, we decided to pause proctoring at centers that were not already trained on the *Edwards SAPIEN 3 Ultra System*. In the second quarter of 2020, we resumed proctoring.

Transcatheter Mitral and Tricuspid Therapies

For the years ended December 31, 2020 and 2019:

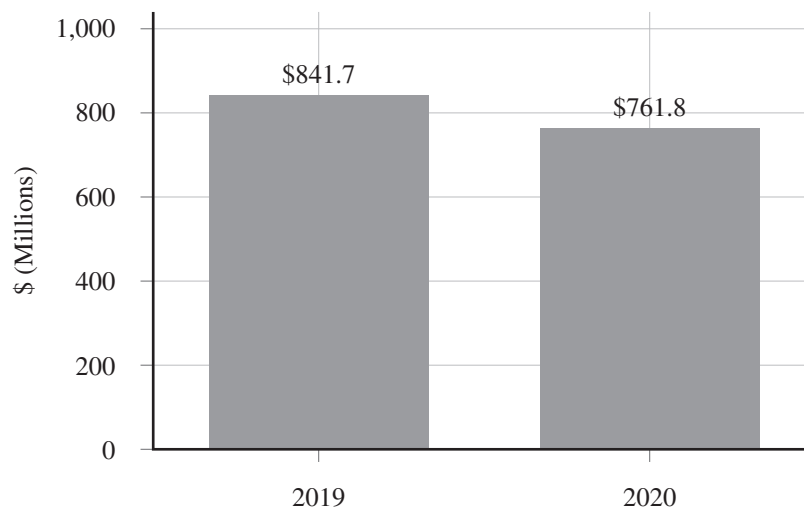


The increase in net sales of TMTT products was due primarily to sales in Europe of the *Edwards PASCAL* transcatheter valve repair system, which received CE Mark in February 2019. Our sales in 2020 were negatively impacted by the COVID-19 pandemic. Our procedure volumes for *PASCAL* dropped significantly in March 2020 due to COVID-19, and began to improve beginning in May 2020.

At the end of March 2020, we temporarily paused new enrollments in our active pivotal clinical trials of transcatheter mitral and tricuspid therapies in response to the COVID-19 response around the globe. In the second quarter of 2020, we began resuming enrollments. However, due to a resurgence of COVID-19 in late 2020, we are experiencing a negative impact to clinical trial enrollment. In May 2020, we received CE Mark for the *PASCAL Ace* implant system for mitral and tricuspid repair.

Surgical Structural Heart

For the years ended December 31, 2020 and 2019:

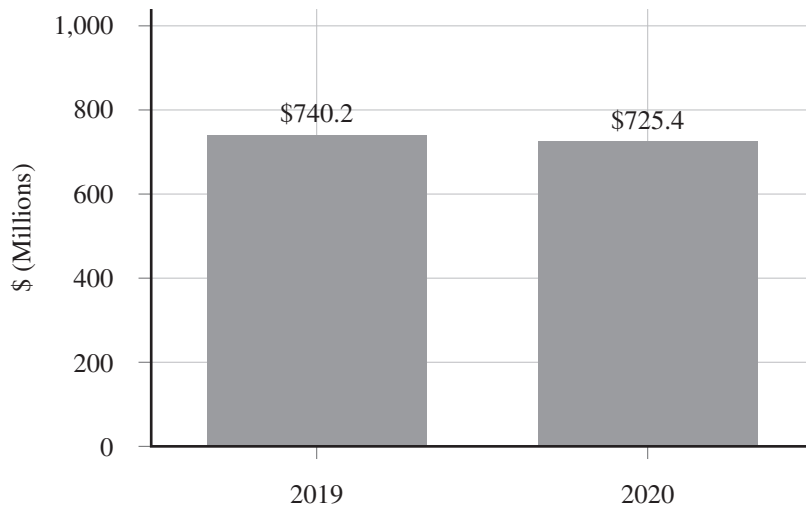


The decrease in net sales of Surgical products was due primarily to decreased sales of aortic tissue valves, primarily in the United States and Europe, due to the impact of COVID-19. The ongoing adoption of TAVR also contributed to the decrease in United States surgical aortic valve sales. These decreases were partially offset by increased sales of the *INSPIRIS RESILIA* aortic valve and the *KONECT* aortic valved conduit, primarily in the United States. Increased and improved management of intensive care unit capacity, as well as prioritization of heart surgery in many hospitals, contributed to rebounding procedure volumes late in the second quarter of 2020. In the fourth quarter of 2020, hospitals experienced an influx of COVID-19 patients, limiting surgical valve procedures.

In Europe, our *HARPOON Beating Heart Mitral Valve Repair System* became available commercially at the end of 2019, and the first commercial case was successfully completed in Europe in the second quarter of 2020. In addition, we received FDA approval in April 2020 to begin our U.S. pivotal investigational device exemption study. *HARPOON* offers the potential for earlier treatment of degenerative mitral valve disease, with faster recovery and more consistent outcomes for surgical patients.

Critical Care

For the years ended December 31, 2020 and 2019:

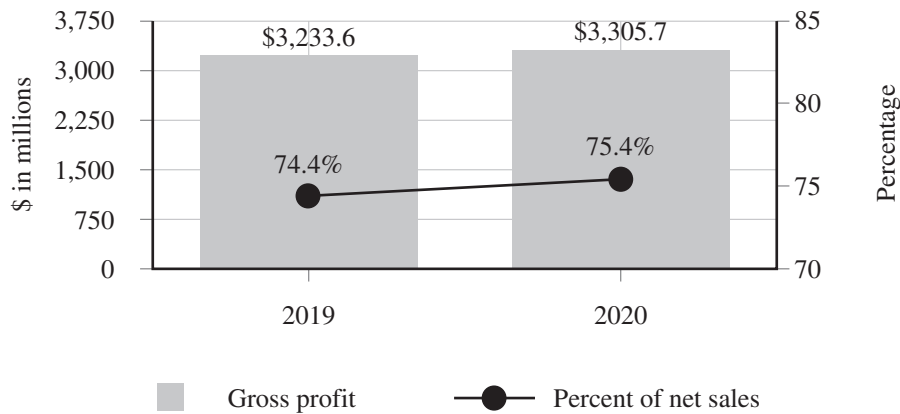


The decrease in net sales of Critical Care products was driven by a decline in sales of our enhanced surgical recovery products, primarily in the United States, as many surgical procedures were delayed due to COVID-19 beginning in March 2020. We also experienced a decline in orders of our *HemoSphere* advanced monitoring platform in the United States as hospitals limited their capital spending due to COVID-19.

These decreases in net sales were partially offset by increased demand for our pressure monitoring products, primarily in Europe and the United States, as COVID-19 hospitalizations increased. In addition, our sales in 2020 and 2019 included \$22.6 million and \$16.8 million, respectively, related to CAS Medical Systems, Inc. (“CASMED”), which we acquired on April 18, 2019. CASMED is a medical technology company dedicated to non-invasive monitoring of tissue oxygenation in the brain.

Gross Profit

For the years ended December 31, 2020 and 2019:

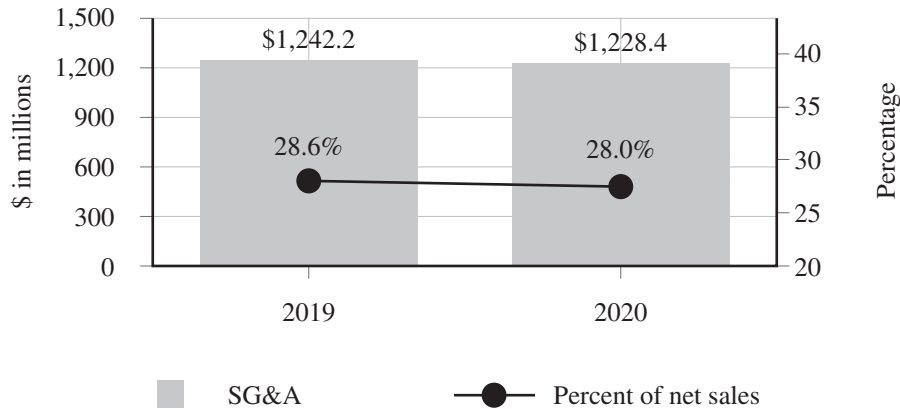


Our gross profit was higher as a percentage of net sales in 2020 compared to 2019. In 2019, our gross profit was reduced by \$73.1 million due to the decision to discontinue our CENTERA program, resulting in a 1.7

percentage point increase in 2020 compared to 2019. This increase was partially offset by a) a 1.0 percentage point decrease in 2020 due to the impact of foreign currency exchange rate fluctuations, net of hedging, and b) incremental costs associated with COVID-19.

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

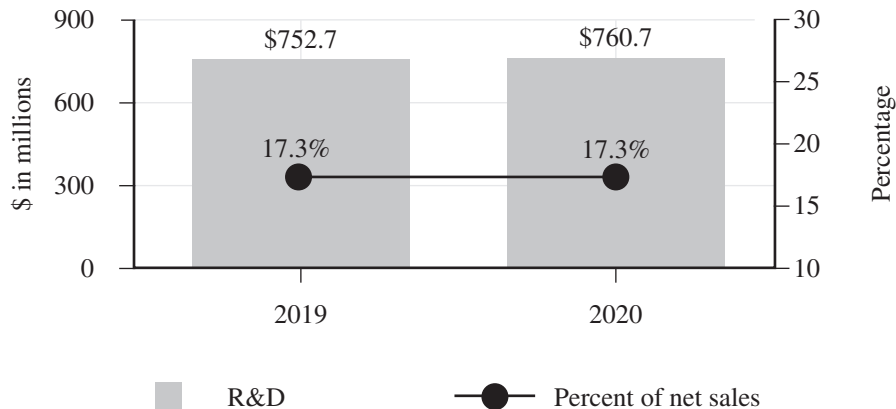
For the years ended December 31, 2020 and 2019:



The decrease in SG&A expenses in 2020 compared to 2019 was due primarily to a) decreased sales, marketing and travel- related expense associated with COVID-19 and b) lower performance-based compensation, partially offset by increased sales and marketing expenses related to transcatheter structural heart field personnel, primarily in the United States.

Research and Development (“R&D”) Expenses

For the years ended December 31, 2020 and 2019:



The increase in R&D expenses in 2020 compared to 2019 was due primarily to a) investments in our transcatheter mitral and tricuspid therapies and our aortic valve replacement programs and b) costs associated with discontinuing our *SUTRAFIX* program. These increases were partially offset by a) decreased spending on transcatheter aortic valve clinical trials and b) decreased performance-based compensation.

Intellectual Property Litigation Expenses, net

We incurred intellectual property litigation expenses, including settlements and external legal costs, of \$405.4 million and \$33.4 million during 2020 and 2019, respectively. On July 12, 2020, we reached an agreement with Abbott Laboratories and its direct and indirect subsidiaries (“Abbott”) to, among other things, settle all outstanding patent disputes between the companies (the “Settlement Agreement”) in cases related to transcatheter mitral and tricuspid repair products. See Note 18 to the “*Consolidated Financial Statements*” for additional information. The Settlement Agreement resulted in us recording an estimated \$367.9 million pre-tax charge and related liability in June 2020 related to past damages. In addition, we will incur royalty expenses through May 2024 totaling an estimated \$100 million. We made a one-time \$100.0 million payment to Abbott in July 2020, and will make quarterly payments in future years.

Change in Fair Value of Contingent Consideration Liabilities, net

The change in fair value of contingent consideration liabilities resulted in expense of \$13.6 million in 2020 and income of \$6.1 million in 2019. The expense in 2020 was primarily driven by the accretion of interest due to the passage of time and adjustments to discount rates, partially offset by changes in the projected probability and timing of milestone achievements, and the projected timing of cash inflows. The income in 2019 was due primarily to longer product development timelines, which reduced the probability of milestone achievements, partially offset by the accretion of interest due to the passage of time and discount rate adjustments.

Special Charges (Gain), net

For information on special charges and gains, see Note 4 to the “*Consolidated Financial Statements*.”

Interest Expense

Interest expense was \$15.8 million and \$20.7 million in 2020 and 2019, respectively. The decrease in interest expense resulted primarily from higher capitalized interest due to facilities construction.

Interest Income

Interest income was \$23.4 million and \$32.2 million in 2020 and 2019, respectively. The decrease in interest income resulted primarily from lower average interest rates, partially offset by a higher average investment balance.

Other Income, net

(in millions)

	Years Ended December 31,	
	2020	2019
Foreign exchange gains, net	\$(12.3)	\$(5.9)
Gain on investments	(0.6)	(0.5)
Non-service cost components of net periodic pension benefit cost	0.4	0.2
Other	1.0	(2.0)
Total other income, net	<u>\$(11.5)</u>	<u>\$(8.2)</u>

The net foreign exchange gains relate 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 gain on investments represents our net share of gains and losses in investments accounted for under the equity method, and realized gains and losses on investments in equity securities.

The non-service cost components of net periodic pension benefit 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.

Provision for Income Taxes

	Years Ended December 31,		Change	
	2020	2019	\$	%
Provision for income taxes	93.3	119.6	(26.3)	(22.0)%
Effective tax rate	10.2%	10.3%		

Our effective income tax rate in 2020 and 2019 was 10.2% and 10.3%, respectively. Our effective tax rate for 2020 decreased slightly in comparison to 2019 primarily due to the tax benefit from the Settlement Agreement with Abbott (see Notes 3 and 18 to the “*Consolidated Financial Statements*”), partially offset by the increase in the U.S. tax on global intangible low-taxed income and the decrease in the tax benefit from employee share-based compensation.

In 2020, the difference between our 10.2% effective tax rate and the Federal statutory rate of 21% was primarily due to a) foreign earnings taxed at lower rates, b) Federal and California research and development credits, and c) the tax benefit from employee share-based compensation.

As of December 31, 2020, we have \$145.1 million of California research expenditure tax credits that we expect to use in future periods. The credits may be carried forward indefinitely. Based upon anticipated future taxable income, we expect that it is more likely than not that all California research expenditure tax credits will be utilized, although the utilization of the full benefit is expected to occur over a number of years and into the distant future.

As of December 31, 2020, gross uncertain tax positions were \$281.8 million. We estimate that these liabilities would be reduced by \$95.1 million from offsetting tax benefits associated with the correlative effects of potential transfer pricing adjustments, state income taxes, and timing adjustments. The net amount of \$186.7 million, if not required, would favorably affect our effective tax rate.

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, 2020, all material state, local, and foreign income tax matters have been concluded for years through 2015. While not material, we continue to address matters in Wisconsin and India for years from 2010.

During 2018, we executed an Advance Pricing Agreement (“APA”) between the United States and Switzerland governments for tax years 2009 through 2020 covering various, but not all, transfer pricing matters.

The unagreed transfer pricing matters, namely Surgical Structural Heart and Transcatheter Aortic Valve Replacement intercompany royalty transactions, then reverted to Internal Revenue Service (“IRS”) Examination for further consideration as part of the respective years’ regular tax audit. In addition, we signed agreements during 2018 with the IRS to settle open tax years 2009 through 2014, including all transfer pricing matters for those years 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 and later added the 2017 tax year to this audit cycle during the first quarter of 2019. The IRS audit field work for the 2015 through 2017 tax years was substantially completed during the fourth quarter of 2020, except for transfer pricing matters.

As a result, certain intercompany transactions covering tax years 2015 through 2020 that were not resolved under the APA program remain subject to IRS examination, and those transactions and related tax positions remain uncertain as of December 31, 2020. The IRS has signaled that it may be preparing proposed audit adjustments related to these intercompany transactions for the 2015 through 2017 tax years which, if issued, could be provided to us during 2021. We have considered this information in our evaluation of our reserves for uncertain tax positions.

These unresolved transfer pricing matters, net of any correlative repatriation tax adjustment, may be significant to our consolidated financial statements. Based on the information currently available and numerous possible outcomes, we cannot reasonably estimate what, if any, changes to our existing uncertain tax positions may occur in the next 12 months and, therefore, have continued to record the gross uncertain tax positions as a long-term liability.

We intend to file to renew the APA between the United States and Switzerland for the years 2021 and forward. 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 and between Switzerland and Japan covering tax years 2015 through 2019. We have filed to renew these APAs related to Japan for the years 2020 and forward. The execution of some or all of these APAs depends on a number of variables outside of our control.

We have received tax incentives in certain non-U.S. tax jurisdictions, the primary benefit for which will expire in 2029. The tax reductions as compared to the local statutory rates were \$189.2 million (\$0.30 per diluted share) and \$157.6 million (\$0.25 per diluted share) for the years ended December 31, 2020 and 2019, respectively.

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 Tax Cuts and Jobs Act of 2017 (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 one-time transition tax liability, as adjusted, is payable in five remaining annual installments, as outlined in the contractual obligations table below. As of December 31, 2020, we had a remaining tax obligation of \$238.7 million related to the deemed repatriation. See Note 17 to the “*Consolidated Financial Statements*” for additional information about the one-time transition tax.

As of December 31, 2020, cash and cash equivalents and short-term investments held in the United States and outside the United States were \$618.8 million and \$783.8 million, respectively. During 2020, we repatriated cash of \$600.0 million. We assert that \$1.1 billion of our foreign earnings continue to be permanently reinvested and our intent is to repatriate \$599.8 million of our foreign earnings as of December 31, 2020.

On July 12, 2020, we reached the Settlement Agreement with Abbott to settle all outstanding patent disputes between the companies in cases related to transcatheter mitral and tricuspid repair products. The Settlement Agreement resulted in us recording an estimated \$367.9 million pretax charge in June 2020 related to past damages. In addition, we will incur royalty expenses through May 2024 totaling an estimated \$100 million. We made a one-time \$100.0 million payment to Abbott in July 2020, and will make quarterly payments in future years. For further information, see Notes 3 and 18 to the “*Consolidated Financial Statements*.”

On April 18, 2019, we acquired CASMED for an aggregate cash purchase price of \$2.45 per share of common stock, or \$100.8 million. For more information, see Note 8 to the “*Consolidated Financial Statements*.”

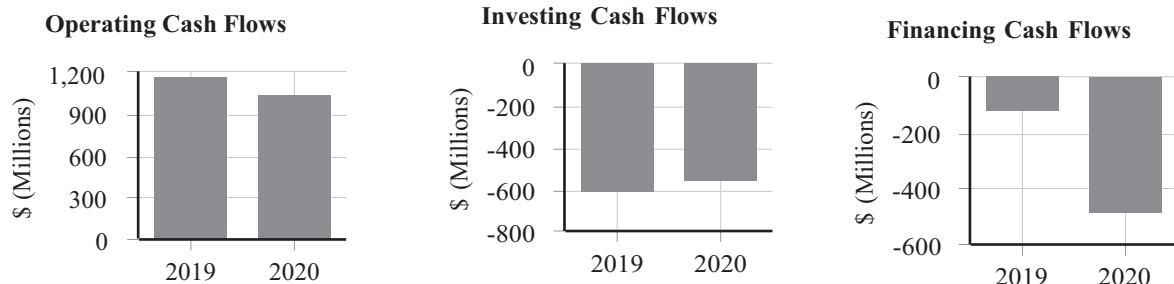
Certain of our business acquisitions involve contingent consideration arrangements. Payment of additional consideration in the future may be required, contingent upon the acquired company reaching certain performance milestones, such as attaining specified revenue levels or obtaining regulatory approvals. For further information, see Note 8 to the “*Consolidated Financial Statements*.”

We have a Five-Year Credit Agreement (“the Credit Agreement”) which matures on April 28, 2023. 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, 2020, 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, 2020.

In June 2018, we issued \$600.0 million of 4.3% fixed-rate unsecured senior notes (the “2018 Notes”) due June 15, 2028. We may redeem the 2018 Notes, in whole or in part, at any time and from time to time at specified redemption prices. As of December 31, 2020, we have not elected to redeem any of the 2018 Notes. As of December 31, 2020, the total carrying value of our 2018 Notes was \$595.0 million. For further information on our debt, see Note 10 to the “*Consolidated Financial Statements*.”

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 2020, under the Board authorized repurchase programs, we repurchased a total of 3.0 million shares at an aggregate cost of \$614.7 million, and as of December 31, 2020, we had remaining authority to purchase \$625.0 million of our common stock. For further information, see Note 14 to the “*Consolidated Financial Statements*.” In February 2021, we entered into an accelerated share repurchase agreement to repurchase \$250.0 million of our common stock. For further information, see Note 22 to the “*Consolidated Financial Statements*.”

Consolidated Cash Flows—For the twelve months ended December 31, 2020 and 2019



Net cash flows provided by **operating activities** of \$1.1 billion for 2020 decreased \$128.6 million from 2019 due primarily to lower operating profits in 2020 and a payment of \$100.0 million for a litigation settlement, partially offset by a payment of \$180.0 million in 2019 for a litigation settlement.

Net cash used in **investing activities** of \$531.1 million in 2020 consisted primarily of capital expenditures of \$407.0 million and net purchases of investments of \$87.6 million.

Net cash used in investing activities of \$595.8 million in 2019 consisted primarily of a) capital expenditures of \$254.4 million, b) net purchases of investments of \$174.9 million, c) a \$100.2 million net cash payment associated with the acquisition of CASMED, d) a \$35.0 million payment for an option to acquire a company, and e) a \$24.0 million payment to acquire certain early-stage transcatheter intellectual property and associated clinical and regulatory experience.

We currently anticipate making capital expenditures of approximately \$350 million in 2021 as we continue to invest in our operations.

Net cash used in **financing activities** of \$486.9 million in 2020 consisted primarily of purchases of treasury stock of \$625.4 million, partially offset by proceeds from stock plans of \$140.5 million.

Net cash used in financing activities of \$115.6 million in 2019 consisted primarily of purchases of treasury stock of \$263.3 million, partially offset by proceeds from stock plans of \$160.5 million.

Contractual Obligations

A summary of all of our contractual obligations and commercial commitments as of December 31, 2020 is as follows (in millions):

Contractual Obligations	Payments Due by Period				
	Total	Year 1	Years 2-3	Years 4-5	After 5 Years
Debt	\$ 600.0	\$ —	\$ —	\$ —	\$600.0
Operating leases	108.1	30.0	35.1	14.9	28.1
Interest on debt	148.9	20.5	40.5	39.4	48.5
Transition tax on unremitted foreign earnings and profits (a)	238.7	25.1	72.2	141.4	—
Litigation settlement obligation (minimum payments)	250.0	50.0	100.0	100.0	—
Pension obligations (b)	2.5	2.5	—	—	—
Purchase and other commitments (c)	26.7	13.7	9.7	1.5	1.8
Total contractual cash obligations (d), (e)	<u>\$1,374.9</u>	<u>\$141.8</u>	<u>\$257.5</u>	<u>\$297.2</u>	<u>\$678.4</u>

-
- (a) As of December 31, 2020, we had recorded \$238.7 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, with the first annual installment paid in 2018, the second annual installment paid in 2019 and the third annual installment paid in 2020. The remaining installment amounts will be equal to 8% of the total liability, payable in fiscal years 2021 through 2022, 15% in fiscal year 2023, 20% in fiscal year 2024, and 25% in fiscal year 2025. See Note 17 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, 2020 was \$52.9 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 13 to the “*Consolidated Financial Statements*” for further information.
- (c) Purchase and other commitments consists primarily of open purchase orders for the acquisition of goods and services in the normal course of business. We have excluded open purchase orders with a remaining term of less than one year. For certain purchase and other commitments, such as commitments to fund equity method or other investments, the timing of the payment is not certain. In these cases, the maturity dates in the table reflect our best estimates.
- (d) As of December 31, 2020, the gross liability for uncertain tax positions, including interest, was \$301.2 million and relates primarily to transfer pricing matters. During 2018, we executed an APA between the United States and Switzerland governments for tax years 2009 through 2020 covering various but not all transfer pricing matters. As a result, certain intercompany transactions covering tax years 2015 through 2020 that were not resolved under the APA program remain subject to IRS examination, and those transactions and related tax positions remain uncertain as of the balance sheet date. These unresolved 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.
- (e) 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 \$810.0 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, and certain sales-based royalties in excess of minimum payment thresholds related to litigation settlements.

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.

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.

In-process research and development assets 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 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:

- discount rates used to present value the projected cash flows;
- the probability of success of clinical events and regulatory approvals, and/or meeting commercial milestones;
- projected payment dates; and
- volatility of future revenue.

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 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 17 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 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.

Legal Contingencies

We are or may be a party to, or may otherwise be responsible for, pending or threatened lawsuits including those related to products and services currently or formerly manufactured or performed, as applicable, by us, workplace and employment matters, matters involving real estate, our operations or health care regulations, or governmental investigations. We accrue for loss contingencies to the extent that we conclude that it is probable that a loss will be incurred and the amount of the loss can be reasonably estimated. These matters raise difficult and complex factual and legal issues and are subject to many uncertainties, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. As such, significant judgment is required in determining our legal accruals. We describe our legal proceedings in Note 18 to the “*Consolidated Financial Statements*.”

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 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, 2020, we had \$985.9 million of investments in debt securities which had an average remaining term to maturity of approximately 1.56 years. Taking into consideration the average maturity of our debt securities, a hypothetical 0.5% to 1.0% absolute increase in interest rates at December 31, 2020 would have resulted in a \$7.8 million to \$15.6 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 investments, see Note 7 to the “*Consolidated Financial Statements.*”

We are also exposed to interest rate risk on our debt obligations. As of December 31, 2020, 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, 2020, there were no borrowings outstanding under the Credit Agreement. Based on our December 31, 2020 variable debt levels, a hypothetical 1.0% absolute increase in floating market interest rates would not have impacted our interest expense since we had no variable debt outstanding during the year. As of December 31, 2020, a hypothetical 1.0% absolute increase in market interest rates would decrease the fair value of the fixed-rate debt by approximately \$43.2 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 10 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 subsidiary’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, 2020 was \$1.8 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 \$141.5 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 12 to the “*Consolidated Financial Statements.*”

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, 2020, 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 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 2020, 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, 2020, we had \$985.9 million of investments in debt securities of various companies, of which \$766.5 million were long-term. In addition, we had \$35.1 million of investments in equity instruments of public and private companies. Should these companies experience a decline in financial performance, financial condition or credit capacity, or fail to meet certain development milestones, including as a result of the impact from COVID-19 on their business or operations or otherwise, a decline in the investments' value may occur, resulting in unrealized or realized losses.

Item 8. Financial Statements and Supplementary Data

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DECEMBER 31, 2020**

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All other schedules are omitted as they are not applicable or the required information is furnished in the Consolidated Financial Statements or notes thereto.

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, 2020 and 2019, and the related consolidated statements of operations, of comprehensive income, of stockholders’ equity and of cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 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, 2020, based on criteria established in *Internal Control—Integrated Framework* (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

Basis for Opinions

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

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

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

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

Critical Audit Matters

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

Uncertain Tax Positions Related to Intercompany Transfer Pricing

As described in Notes 2 and 17 to the consolidated financial statements, the Company had a gross uncertain tax position liability balance of \$281.8 million as of December 31, 2020, primarily related to transfer pricing. The Company is subject to income taxes in the United States and numerous foreign jurisdictions. As disclosed by management, the Company's income tax returns in these jurisdictions are periodically audited by domestic and foreign tax authorities. These audits include questions regarding the Company's tax filing positions, including the timing and amount of deductions and the allocation of income amongst various tax jurisdictions. Significant judgment is required by management in evaluating uncertain tax positions, including estimating the ultimate resolution to intercompany pricing controversies between countries when there are numerous possible outcomes.

The principal considerations for our determination that performing procedures relating to uncertain tax positions related to intercompany transfer pricing is a critical audit matter are the significant judgment by management when determining uncertain tax positions related to intercompany transfer pricing, including a high degree of estimation uncertainty in evaluating whether certain tax filing positions taken by management will be upheld by the related local tax authority. This in turn led to a high degree of auditor judgment, effort, and subjectivity in performing procedures to evaluate the accurate measurement of uncertain tax positions related to intercompany transfer pricing. Also, the evaluation of audit evidence available to support the tax liabilities for uncertain tax positions related to intercompany transfer pricing is complex and required significant auditor judgment as the nature of the evidence is highly subjective and the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness

of controls relating to recognition of the liability for uncertain tax positions related to intercompany transfer pricing and controls over measurement of the liability. These procedures also included, among others, (i) testing the information used in the calculation of the liability for uncertain tax positions, including U.S. federal filing positions and the related final tax returns; (ii) testing the calculation of the liability for uncertain tax positions related to intercompany transfer pricing, by jurisdiction, including management's assessment of the technical merits of tax positions and estimates of the amount of tax benefit expected to be sustained; (iii) testing of management's assessment of possible outcomes of uncertain tax positions related to intercompany transfer pricing; and (iv) evaluating the status and results of income tax audits with the relevant tax authorities. Professionals with specialized skill and knowledge were used to assist in the evaluation of the completeness and measurement of the Company's uncertain tax positions related to intercompany transfer pricing, including evaluating the reasonableness of management's assessment of whether tax positions are more-likely-than-not to be sustained and the amount of potential benefit to be realized, and the application of relevant tax laws.

Fair Value of Contingent Consideration Liabilities

As described in Note 11 to the consolidated financial statements, certain of the Company's acquisitions involve contingent consideration arrangements. As of December 31, 2020, the Company had a contingent consideration liability of \$186.1 million. As disclosed by management, payment of additional consideration is contingent upon the acquired company reaching certain performance milestones, such as attaining specified revenue levels or obtaining regulatory approvals. These contingent consideration liabilities are measured by management at estimated fair value using either a probability weighted discounted cash flow analysis or a Monte Carlo simulation model, both of which consider significant unobservable inputs. These inputs include (1) the discount rate used to present value the projected cash flows, (2) the probability of milestone achievement, (3) the projected payment dates, and (4) the volatility of future revenue.

The principal considerations for our determination that performing procedures relating to the fair value of contingent consideration liabilities is a critical audit matter are the significant judgment by management when estimating the fair value of these contingent consideration liabilities, including a high degree of estimation uncertainty in evaluating the discount rate, the probability of milestone achievement, the projected payment dates, and the volatility of future revenue. This in turn led to a high degree of auditor judgment, effort, and subjectivity in performing procedures to evaluate the fair value of contingent consideration liabilities. Also, the evaluation of audit evidence available to support the fair value of the contingent consideration liabilities is complex and resulted in significant auditor judgment as the nature of the evidence is highly subjective and the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to management's process for estimating the fair value of contingent consideration liabilities, including controls over the determination of the significant unobservable inputs selected by management. These procedures also included, among others, (i) testing management's process for estimating the fair value of contingent consideration liabilities and (ii) testing management's probability weighted discounted cash flow analysis or a Monte Carlo simulation used to estimate the fair value of the contingent consideration liabilities. Testing management's process included evaluating the appropriateness of the valuation methods used and the reasonableness of the significant assumptions related to the discount rate, the probability of milestone achievement, the projected payment dates, and the volatility of future revenue. Evaluating the reasonableness of the probability of milestone achievement and projected payment date of each milestone involved consideration of information obtained from the Company's product engineers, clinical trial data, and third-party industry data. The discount rate was evaluated by considering the cost of capital of comparable businesses and other industry factors. Professionals with specialized skill and knowledge were used to assist in the evaluation of certain significant assumptions, including the discount rate and volatility of future revenue.

/s/ PricewaterhouseCoopers LLP
Irvine, California
February 12, 2021

We have served as the Company's auditor since 1999

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED BALANCE SHEETS

(in millions, except par value)

	December 31,	
	2020	2019
ASSETS		
Current assets		
Cash and cash equivalents	\$ 1,183.2	\$ 1,179.1
Short-term investments (Note 7)	219.4	337.8
Accounts receivable, net of allowances of \$9.6 and \$8.7, respectively	514.6	543.6
Other receivables	88.2	55.5
Inventories (Note 5)	802.3	640.9
Prepaid expenses	75.1	59.1
Other current assets	208.2	168.0
Total current assets	3,091.0	2,984.0
Long-term investments (Note 7)	801.6	585.5
Property, plant, and equipment, net (Note 5)	1,395.2	1,060.3
Operating lease right-of-use assets (Note 6)	94.2	80.1
Goodwill (Note 9)	1,173.2	1,167.7
Other intangible assets, net (Note 9)	331.4	336.5
Deferred income taxes	230.9	172.2
Other assets	119.6	101.8
Total assets	\$ 7,237.1	\$ 6,488.1
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 196.5	\$ 180.4
Accrued and other liabilities (Note 5)	670.2	696.5
Operating lease liabilities (Note 6)	27.2	25.5
Total current liabilities	893.9	902.4
Long-term debt (Note 10)	595.0	594.4
Contingent consideration liabilities (Notes 8 and 11)	186.1	172.5
Taxes payable (Note 17)	215.3	236.6
Operating lease liabilities (Note 6)	72.7	58.9
Uncertain tax positions (Note 17)	214.4	171.7
Litigation settlement accrual (Notes 3 and 18)	233.0	—
Other long-term liabilities	252.4	203.3
Commitments and contingencies (Notes 6, 10 and 18)		
Stockholders' equity (Note 14)		
Preferred stock, \$0.01 par value, authorized 50.0 shares, no shares outstanding	—	—
Common stock, \$1.00 par value, 1,050.0 shares authorized, 636.4 and 218.1 shares issued, and 624.3 and 209.1 shares outstanding, respectively	636.4	218.1
Additional paid-in capital	1,438.1	1,623.3
Retained earnings	4,565.0	3,741.6
Accumulated other comprehensive loss	(161.1)	(156.0)
Treasury stock, at cost, 12.1 and 9.0 shares, respectively	(1,904.1)	(1,278.7)
Total stockholders' equity	4,574.3	4,148.3
Total liabilities and stockholders' equity	\$ 7,237.1	\$ 6,488.1

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

EDWARDS LIFESCIENCES CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

(in millions, except per share information)

	Years Ended December 31,		
	2020	2019	2018
Net sales	\$4,386.3	\$4,348.0	\$3,722.8
Cost of sales	1,080.6	1,114.4	939.4
Gross profit	3,305.7	3,233.6	2,783.4
Selling, general, and administrative expenses	1,228.4	1,242.2	1,088.5
Research and development expenses	760.7	752.7	622.2
Intellectual property litigation expenses, net (Note 3)	405.4	33.4	214.0
Change in fair value of contingent consideration liabilities	13.6	(6.1)	(5.7)
Special charges (Note 4)	—	64.6	116.2
Operating income	897.6	1,146.8	748.2
Interest expense	15.8	20.7	29.9
Interest income	(23.4)	(32.2)	(32.0)
Special gain (Note 4)	—	—	(7.1)
Other income, net (Note 16)	(11.5)	(8.2)	(4.0)
Income before provision for income taxes	916.7	1,166.5	761.4
Provision for income taxes (Note 17)	93.3	119.6	39.2
Net income	<u>\$ 823.4</u>	<u>\$1,046.9</u>	<u>\$ 722.2</u>
Share information (Note 2):			
Earnings per share:			
Basic	\$ 1.32	\$ 1.68	\$ 1.15
Diluted	\$ 1.30	\$ 1.64	\$ 1.13
Weighted-average number of common shares outstanding:			
Basic	622.6	624.8	627.6
Diluted	631.9	636.7	640.9

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

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(in millions)

	Years Ended December 31,		
	2020	2019	2018
Net income	\$823.4	\$1,046.9	\$722.2
Other comprehensive (loss) income, net of tax (Note 15):			
Foreign currency translation adjustments	32.4	(11.2)	(38.6)
Unrealized (loss) gain on hedges	(40.2)	(11.1)	40.4
Unrealized pension costs	(4.2)	(1.9)	0.6
Unrealized gain (loss) on available-for-sale investments	6.6	6.3	(3.3)
Reclassification of net realized investment loss to earnings	0.3	0.4	2.9
Other comprehensive (loss) income, net of tax	(5.1)	(17.5)	2.0
Comprehensive income	\$818.3	\$1,029.4	\$724.2

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

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in millions)

	Years Ended December 31,		
	2020	2019	2018
Cash flows from operating activities			
Net income	\$ 823.4	\$1,046.9	\$ 722.2
Adjustments to reconcile net income to cash provided by operating activities:			
Depreciation and amortization	107.2	89.3	77.4
Non-cash operating lease cost	28.2	25.3	—
Stock-based compensation (Notes 2 and 14)	92.6	81.3	71.0
Inventory write off	—	73.1	—
Impairment charges (Note 4)	—	40.6	118.8
Change in fair value of contingent consideration liabilities, net (Note 11)	13.6	(6.1)	(5.7)
Deferred income taxes	(49.4)	12.1	(27.3)
Purchased in-process research and development	—	24.0	—
Other	(3.5)	(2.8)	13.0
Changes in operating assets and liabilities:			
Accounts and other receivables, net	41.9	(88.0)	(28.7)
Inventories	(120.6)	(105.4)	(65.7)
Prepaid expenses and other current assets	(28.5)	(6.8)	15.6
Accounts payable and accrued liabilities	(84.5)	116.5	12.5
Litigation settlement accrual	270.5	(180.0)	180.0
Income taxes	(52.9)	43.2	(157.8)
Other	16.3	19.7	1.4
Net cash provided by operating activities	<u>1,054.3</u>	<u>1,182.9</u>	<u>926.7</u>
Cash flows from investing activities			
Capital expenditures	(407.0)	(254.4)	(238.7)
Purchases of held-to-maturity investments (Note 7)	(162.0)	(130.2)	(210.0)
Proceeds from sales and maturities of held-to-maturity investments (Note 7)	212.2	50.0	578.1
Purchases of available-for-sale investments (Note 7)	(689.7)	(437.9)	(249.3)
Proceeds from sales and maturities of available-for-sale investments (Note 7)	564.8	359.9	223.2
Acquisition (Notes 8 and 9)	—	(100.2)	—
Payment for acquisition option	(10.0)	(35.0)	—
Issuances of notes receivable	(27.0)	(12.9)	(0.6)
Investments in intangible assets and in-process research and development	(0.3)	(24.0)	(3.0)
Other	(12.1)	(11.1)	(23.0)
Net cash (used in) provided by investing activities	<u>(531.1)</u>	<u>(595.8)</u>	<u>76.7</u>
Cash flows from financing activities			
Proceeds from issuance of debt	16.2	18.9	688.0
Payments on debt and finance lease obligations	(17.0)	(28.9)	(1,125.3)
Purchases of treasury stock	(625.4)	(263.3)	(795.5)
Proceeds from stock plans	140.5	160.5	147.0
Payment of contingent consideration	—	—	(15.1)
Other	(1.2)	(2.8)	(0.3)
Net cash used in financing activities	<u>(486.9)</u>	<u>(115.6)</u>	<u>(1,101.2)</u>
Effect of currency exchange rate changes on cash, cash equivalents, and restricted cash	(20.5)	(3.0)	(6.5)
Net increase (decrease) in cash, cash equivalents, and restricted cash	15.8	468.5	(104.3)
Cash, cash equivalents, and restricted cash at beginning of year	<u>1,184.4</u>	<u>715.9</u>	<u>820.2</u>
Cash, cash equivalents, and restricted cash at end of year	<u>\$1,200.2</u>	<u>\$1,184.4</u>	<u>\$ 715.9</u>

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

EDWARDS LIFESCIENCES CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in millions)

	Common Stock		Treasury Stock		Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Par Value	Shares	Amount				
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
Other comprehensive income, net of tax							2.0	2.0
Common stock issued under equity plans	3.2	3.2			143.8			147.0
Stock-based compensation expense					71.0			71.0
Shares issued in payment for contingent consideration liabilities			(0.3)	32.2	2.7			34.9
Purchases of treasury stock			5.5	(795.5)				(795.5)
BALANCE AT DECEMBER 31, 2018	215.2	215.2	7.5	(1,015.4)	1,384.4	2,694.7	(138.5)	3,140.4
Net income						1,046.9		1,046.9
Other comprehensive loss, net of tax							(17.5)	(17.5)
Common stock issued under equity plans	2.9	2.9			157.6			160.5
Stock-based compensation expense					81.3			81.3
Purchases of treasury stock			1.5	(263.3)	—			(263.3)
BALANCE AT DECEMBER 31, 2019	218.1	218.1	9.0	(1,278.7)	1,623.3	3,741.6	(156.0)	4,148.3
Net income						823.4		823.4
Other comprehensive loss, net of tax							(5.1)	(5.1)
Common stock issued under equity plans	4.5	4.5			136.0			140.5
Stock-based compensation expense					92.6			92.6
Purchases of treasury stock			3.1	(625.4)				(625.4)
Stock issued to effect stock split	413.8	413.8			(413.8)			—
BALANCE AT DECEMBER 31, 2020	636.4	\$636.4	12.1	\$(1,904.1)	\$1,438.1	\$4,565.0	\$(161.1)	\$4,574.3

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

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS

Edwards Lifesciences Corporation (“Edwards Lifesciences” or the “Company”) conducts operations worldwide and is managed in the following geographical regions: United States, Europe, Japan, and Rest of World. Edwards Lifesciences is focused on technologies that treat structural heart disease and critically ill patients. The products and technologies provided by Edwards Lifesciences are categorized into the following main areas: Transcatheter Aortic Valve Replacement, Transcatheter Mitral and Tricuspid Therapies, Surgical Structural Heart, and Critical Care.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Edwards Lifesciences and its majority-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. The Company reviews its investments in other entities to determine whether the Company is the primary beneficiary of a variable interest entity (“VIE”). The Company would be the primary beneficiary of the VIE, and would be required to consolidate the VIE, if it has the power to direct the significant activities of the entity and the obligation to absorb losses or receive benefits from the entity that may be significant to the VIE. Based on the Company’s analysis, it determined it is not the primary beneficiary of any VIEs; however, future events may require VIEs to be consolidated if the Company becomes the primary beneficiary.

Certain reclassifications of previously reported amounts have been made to conform to classifications used in the current year.

Stock Split

On May 7, 2020, the Company’s Board of Directors declared a three-for-one stock split of its outstanding shares of common stock effected in the form of a stock dividend, distributed on May 29, 2020 to stockholders of record on May 18, 2020. The Company distributed two newly issued shares of common stock to holders of record of each share of common stock to effect the stock split. All applicable share and per-share amounts in the consolidated financial statements and the notes to consolidated financial statements have been retroactively adjusted to reflect this stock split. The consolidated balance sheet as of December 31, 2019 and the consolidated statements of stockholders’ equity for the twelve months ended December 31, 2019 have not been retroactively adjusted to reflect the stock split.

Use of Estimates

The consolidated financial statements of Edwards Lifesciences have been prepared in accordance with generally accepted accounting principles in the United States of America (“GAAP”) which have been applied consistently in all material respects. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements. Actual results could differ from those estimates. In particular, the novel Coronavirus (“COVID-19”) pandemic has adversely impacted and is likely to further adversely impact nearly all aspects of our business and markets, including our workforce and the operations of our customers, suppliers, and business partners. The full extent to which the pandemic will directly or indirectly impact the Company’s business, results of operations and financial condition, including sales, expenses, manufacturing, clinical trials, research and development costs, reserves and allowances, fair value measurements, asset impairment charges, contingent consideration obligations, and the effectiveness of the Company’s hedging instruments, will depend on future developments that are highly

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

uncertain and difficult to predict. These developments include, but are not limited to, the duration and spread of the outbreak (including new variants of COVID-19), its severity, the actions to contain the virus or address its impact, the timing, distribution, and efficacy of vaccines and other treatments, U.S. and foreign government actions to respond to the reduction in global economic activity, and how quickly and to what extent normal economic and operating conditions can resume.

Foreign Currency Translation

When the local currency of the Company's foreign entities is the functional currency, all assets and liabilities are translated into United States dollars at the rate of exchange in effect at the balance sheet date. Income and expense items are translated at the weighted-average exchange rate prevailing during the period. The effects of foreign currency translation adjustments for these entities are deferred and reported in stockholders' equity as a component of "*Accumulated Other Comprehensive Loss*." The effects of foreign currency transactions denominated in a currency other than an entity's functional currency are included in "*Other Income, net*."

Revenue Recognition

Revenue is recognized when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those products or services.

The Company generates nearly all of its revenue from direct product sales and sales of products under consignment arrangements. Revenue from direct product sales is recognized at a point in time when the performance obligation is satisfied upon delivery of the product. Revenue from sales of consigned inventory is recognized at a point in time when the performance obligation is satisfied once the product has been implanted or used by the customer. The Company periodically reviews consignment inventories to confirm the accuracy of customer reporting. The Company also generates a small portion of its revenue from service contracts, and recognizes revenue from service contracts ratably over the term of the contracts. Sales taxes and other similar taxes that the Company collects concurrent with revenue-producing activities are excluded from revenue. The Company does not typically have any significant unusual payment terms beyond 90 days in its contracts with customers. In addition, the Company receives royalty payments for the licensing of certain intellectual property and recognizes the royalty when the subsequent sale of product using the intellectual property occurs.

The amount of consideration the Company ultimately receives varies depending upon the return terms, sales rebates, discounts, and other incentives that the Company may offer, which are accounted for as variable consideration when estimating the amount of revenue to recognize. The Company includes 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.

The Company's sales adjustment related to distributor rebates given to the Company's United States distributors represents the difference between the Company's sales price to the distributor and the negotiated price to be paid by the end-customer. This distributor rebate is recorded as a reduction to sales and a reduction to the distributor's accounts receivable at the time of sale to a distributor. The Company periodically monitors current pricing trends and distributor inventory levels to ensure the credit for future distributor rebates is fairly stated.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The Company offers volume rebates to certain group purchasing organizations (“GPOs”) and customers based upon targeted sales levels. Volume rebates offered to GPOs are recorded as a reduction to sales and an obligation to the GPOs, as the Company expects to pay in cash. Volume rebates offered to customers are recorded as a reduction to sales and either accounts receivable if the Company expects a net payment from the customer, or as an obligation to the customer if the Company expects to pay in cash. The provision for volume rebates is estimated based upon customers’ contracted rebate programs, projected sales levels, and historical experience of rebates paid. The Company periodically monitors its customer rebate programs to ensure that the allowance and liability for accrued rebates is fairly stated.

Product returns are typically not significant because returns are generally not allowed unless the product is damaged at time of receipt. In limited circumstances, the Company may allow customers to return previously purchased products, such as for next-generation product offerings. For these transactions, the Company defers 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.

The Company sells separately priced service contracts, which range from 12 to 36 months, to owners of its hemodynamic monitors. The Company invoices the customer the total amount of consideration at the inception of the contract and recognizes revenue ratably over the term of the contract. As of December 31, 2020 and December 31, 2019, \$6.3 million and \$8.4 million, respectively, of deferred revenue associated with outstanding service contracts was recorded in “*Accrued and Other Liabilities*” and “*Other Long-term Liabilities*.” During 2020, the Company recognized as revenue \$6.3 million that was included in the balance of deferred revenue as of December 31, 2019, and during 2019, the Company recognized as revenue \$5.5 million that was included in the balance of deferred revenue as of December 31, 2018.

A limited number of the Company’s contracts with customers contain multiple performance obligations. For these contracts, the transaction price is allocated to each performance obligation based on its relative standalone selling price charged to other customers.

The Company applies the optional exemption of not disclosing the amount of the transaction price allocated to unsatisfied performance obligations for contracts with an original expected duration of one year or less.

Shipping and Handling Costs

Shipping costs, which are costs incurred to physically move product from the Company’s premises or third party distribution centers, including storage, to the customer’s premises, are included in “*Selling, General, and Administrative Expenses*.” Handling costs, which are costs incurred to store at the Company’s premises, move, and prepare products for shipment, are included in “*Cost of Sales*.” For the years ended December 31, 2020, 2019, and 2018, shipping costs of \$74.0 million, \$71.5 million, and \$70.6 million, respectively, were included in “*Selling, General, and Administrative Expenses*.”

Cash Equivalents

The Company considers highly liquid investments with original maturities of three months or less to be cash equivalents. These investments are valued at cost, which approximates fair value.

Investments

The Company invests its excess cash in debt securities, including time deposits, commercial paper, U.S. government and agency securities, asset-backed securities, corporate debt securities, and municipal debt

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

securities. Investments with maturities of one year or less are classified as short-term, and investments with maturities greater than one year are classified as long-term. Investments that the Company has the ability and intent to hold until maturity are classified as held-to-maturity and carried at amortized cost. Investments in debt securities that are classified as available-for-sale are carried at fair value with unrealized gains and losses included in “*Accumulated Other Comprehensive Loss.*” The Company determines the appropriate classification of its investments in debt securities at the time of purchase and reevaluates such designation at each balance sheet date.

The Company also has long-term equity investments in companies that are in various stages of development. These investments are reported at fair value or under the equity method of accounting, as appropriate. Equity investments that do not have readily determinable fair values are recorded at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. The Company accounts for investments in limited partnerships and limited liability corporations, whereby the Company owns a minimum of 5% of the investee’s outstanding voting stock, under the equity method of accounting. These investments are recorded at the amount of the Company’s investment and adjusted each period for the Company’s share of the investee’s income or loss, and dividends paid.

Realized gains and losses on investments that are sold are determined using the specific identification method, or the first-in, first-out method, depending on the investment type, and recorded to “*Other Income, net.*” Income relating to investments in debt securities is recorded to “*Interest Income.*”

Equity investments without readily determinable fair value are considered impaired when there is an indication that the fair value of the Company’s interest is less than the carrying amount. Equity method investments are considered impaired when there is an indication of an other-than-temporary decline in value below the carrying amount. Impairments of equity investments are recorded in “*Other Income, net.*”

Debt securities in an unrealized loss position are written down to fair value through “*Other Income, net*” if the Company intends to sell the security or it is more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis. For debt securities in an unrealized loss position that do not meet the aforementioned criteria, the Company assesses whether the decline in fair value has resulted from credit losses or other factors. In making this assessment, the Company considers the extent to which fair value is less than amortized cost, changes to the rating of the security by a rating agency, and any adverse conditions specifically related to the security, among other factors. When a credit loss exists, the Company compares the present value of cash flows expected to be collected from the debt security to the amortized cost basis of the security to determine the allowance amount that should be recorded, if any. For available-to-sale debt securities, any additional impairment not recorded through an allowance for credit losses is recognized in “*Accumulated Other Comprehensive Loss.*”

Accounts Receivable

The majority of the Company’s accounts receivable arise from direct product sales and sales of products under consignment arrangements, and have payment terms that generally require payment within 30 to 90 days. The Company does not adjust its receivables for the effects of a significant financing component at contract exception if collection of the receivable is expected within one year or less from the time of sale. In countries where the Company has experienced a pattern of payments extending beyond the stated terms and collection of the receivable is expected beyond one year from the time of sale, the Company assesses whether the customer

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

has a significant financing component and discounts the receivable and reduces the related revenues over the period of time that the Company estimates those amounts will be paid using the country's market-based borrowing rate for such period.

The Company provides reserves against accounts receivable for estimated losses that may result from a customer's inability to pay based on customer-specific analysis and general matters such as current assessments of past due balances, economic conditions and forecasts, and historical credit loss activity. Amounts determined to be uncollectible are charged or written-off against the reserve.

Inventories

Inventories are stated at the lower of cost (first-in, first-out method) or net realizable value. Market value for raw materials is based on replacement costs, and for other inventory classifications is based on net realizable value.

A write-down for excess or slow moving inventory is recorded for inventory which is obsolete, damaged, nearing its expiration date (generally triggered at six months prior to expiration), or slow moving (generally defined as quantities in excess of a two-year supply).

The Company allocates to inventory general and administrative costs that are related to the production process. These costs include insurance, manufacturing accounting personnel, human resources personnel, and information technology. During the years ended December 31, 2020, 2019, and 2018, the Company allocated \$63.1 million, \$56.6 million, and \$45.0 million, respectively, of general and administrative costs to inventory. General and administrative costs included in inventory at December 31, 2020 and 2019 were \$30.7 million and \$22.8 million, respectively.

At December 31, 2020 and 2019, \$130.0 million and \$117.8 million, respectively, of the Company's finished goods inventories were held on consignment.

Property, Plant, and Equipment

Property, plant, and equipment are recorded at cost. Depreciation is principally calculated for financial reporting purposes on the straight-line method over the estimated useful lives of the related assets, which range from 10 to 40 years for buildings and improvements, from 3 to 15 years for machinery and equipment, and from 3 to 5 years for software. Leasehold improvements are amortized over the life of the related facility leases or the asset, whichever is shorter. Straight-line and accelerated methods of depreciation are used for income tax purposes. Construction in progress is not depreciated until the asset is ready for its intended use.

Depreciation expense for property, plant, and equipment was \$101.8 million, \$84.7 million, and \$74.9 million for the years ended December 31, 2020, 2019, and 2018, respectively.

Leases

On January 1, 2019, the Company adopted an amendment to the guidance on leases using a modified retrospective transition approach. The Company determines whether a contract is, or contains, a lease at inception. Right-of-use assets represent the Company's right to use an underlying asset during the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Right-of-use

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

assets and lease liabilities are recognized at lease commencement based upon the estimated present value of unpaid lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at lease commencement in determining the present value of unpaid lease payments. The Company's incremental borrowing rate is determined based on the estimated rate of interest for collateralized borrowing over a similar term as the associated lease. Right-of-use assets also include any lease payments made at or before lease commencement and any initial direct costs incurred, and exclude any lease incentives received.

The Company determines the lease term as the noncancellable period of the lease, and may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Leases with a term of 12 months or less are not recognized on the balance sheet. Certain of the Company's leases include variable lease payments that are based on costs incurred or actual usage, or adjusted periodically based on an index or a rate. The Company's leases do not contain any residual value guarantees.

The Company accounts for the lease and non-lease components as a single lease component for all of its leases except vehicle leases, for which the lease and non-lease components are accounted for separately.

Operating leases are included in "*Operating Lease Right-of-Use Assets*" and "*Operating Lease Liabilities*" on the Company's consolidated balance sheets. See Note 6 for further information.

Impairment of Goodwill and Long-lived Assets

Goodwill is reviewed for impairment annually in the fourth quarter of each fiscal year, or whenever an event occurs or circumstances change that would indicate that the carrying amount may be impaired. Goodwill is tested for impairment at the reporting unit level by first performing a qualitative assessment to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying value. If the reporting unit does not pass the qualitative assessment, then the Company performs a quantitative impairment test. The Company determined, after performing a qualitative review of each reporting unit, that it is more likely than not that the fair value of each of its reporting units substantially exceeds the respective carrying amounts. Accordingly, in 2020, 2019, and 2018, the Company did not record any impairment loss.

Indefinite-lived intangible assets relate to in-process research and development acquired in business combinations. The estimated fair values of in-process research and development projects acquired in a business combination which have not reached technological feasibility are capitalized and accounted for as indefinite-lived intangible assets subject to impairment testing until completion or abandonment of the projects. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If the project is abandoned, all remaining capitalized amounts are written off immediately. Indefinite-lived intangible assets are reviewed for impairment annually in the fourth quarter of each fiscal year, or whenever an event occurs or circumstances change that would indicate the carrying amount may be impaired. An impairment loss is recognized when the asset's carrying value exceeds its fair value. In-process research and development projects acquired in an asset acquisition are expensed unless the project has an alternative future use.

Management reviews the carrying amounts of other finite-lived intangible assets and long-lived tangible assets whenever events or circumstances indicate that the carrying amounts of an asset may not be recoverable. Impairment indicators include, among other conditions, cash flow deficits, historic or anticipated declines in revenue or operating profit, and adverse legal or regulatory developments. If it is determined that such indicators are present and the review indicates that the assets will not be fully recoverable, based on undiscounted estimated cash flows over the remaining amortization periods, their carrying values are reduced to estimated fair market

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

value. Estimated fair market value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. For the purposes of identifying and measuring impairment, long-lived assets are grouped with other assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities.

In 2020, the Company did not record any impairment loss related to its in-process research and development assets. In 2019, the Company recorded a \$40.6 million charge related to the impairment of certain in-process research and development assets. In 2018, the Company recorded a \$116.2 million charge related to the impairment of certain developed technology and in-process research and development assets. See Note 4 for further information.

Income Taxes

The Company is subject to income taxes in the United States and numerous foreign jurisdictions. Significant judgment is required in evaluating the Company's uncertain tax positions and determining its provision for income taxes. The Company recognizes the financial statement benefit of a tax position only after determining that a position would more likely than not be sustained based upon its technical merit if challenged by the relevant taxing authority and taken by management to the court of last resort. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the consolidated financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon settlement with the relevant tax authority. The Company recognizes interest and penalties related to income tax matters in income tax expense. The Company has made an accounting policy election to recognize the U.S. tax effects of global intangible low-taxed income as a component of income tax expense in the period the tax arises.

Deferred tax assets and liabilities are recognized for the expected future tax consequences of events that have been recognized in the Company's financial statements or tax returns. The Company evaluates quarterly the realizability of its deferred tax assets by assessing its valuation allowance and adjusting the amount, if necessary. The factors used to assess the likelihood of realization are both historical experience and the Company's forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. 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 the Company's effective tax rate on future earnings.

Research and Development Costs

Research and development costs are charged to expense when incurred.

Earnings per Share

Basic earnings per share is computed by dividing net income by the weighted-average common shares outstanding during a period. Diluted earnings per share is computed based on the weighted-average common shares outstanding plus the effect of dilutive potential common shares outstanding during the period calculated using the treasury stock method. Dilutive potential common shares include employee equity share options, nonvested shares, and similar equity instruments granted by the Company. Potential common share equivalents have been excluded where their inclusion would be anti-dilutive.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The table below presents the computation of basic and diluted earnings per share (in millions, except for per share information):

	<u>Years Ended December 31,</u>		
	<u>2020</u>	<u>2019</u>	<u>2018</u>
Basic:			
Net income	\$823.4	\$1,046.9	\$722.2
Weighted-average shares outstanding	622.6	624.8	627.6
Basic earnings per share	<u>\$ 1.32</u>	<u>\$ 1.68</u>	<u>\$ 1.15</u>
Diluted:			
Net income	\$823.4	\$1,046.9	\$722.2
Weighted-average shares outstanding	622.6	624.8	627.6
Dilutive effect of stock plans	9.3	11.9	13.3
Dilutive weighted-average shares outstanding	<u>631.9</u>	<u>636.7</u>	<u>640.9</u>
Diluted earnings per share	<u>\$ 1.30</u>	<u>\$ 1.64</u>	<u>\$ 1.13</u>

Stock options, restricted stock units, and market-based restricted stock units to purchase approximately 2.0 million, 1.5 million, and 3.2 million shares were outstanding for the years ended December 31, 2020, 2019, and 2018, respectively, but were not included in the computation of diluted earnings per share because the effect would have been anti-dilutive.

Stock-based Compensation

The Company measures and recognizes compensation expense for all stock-based awards based on estimated fair values. Stock-based awards consist of stock options, restricted stock units (service-based, market-based, and performance-based), and employee stock purchase subscriptions. Stock-based compensation expense is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period (vesting period) on a straight-line basis. For performance-based restricted stock units, the Company recognizes stock-based compensation expense if and when the Company concludes that it is probable that the performance condition will be achieved, net of estimated forfeitures. The Company reassesses the probability of vesting at each quarter end and adjusts the stock-based compensation expense based on its probability assessment. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Upon exercise of stock options or vesting of restricted stock units, the Company issues common stock.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Total stock-based compensation expense was as follows (in millions):

	Years Ended December 31,		
	2020	2019	2018
Cost of sales	\$ 17.2	\$ 14.7	\$ 11.4
Selling, general, and administrative expenses	56.6	51.2	46.3
Research and development expenses	18.8	15.4	13.3
Total stock-based compensation expense	92.6	81.3	71.0
Income tax benefit	(15.4)	(14.8)	(13.4)
Total stock-based compensation expense, net of tax	\$ 77.2	\$ 66.5	\$ 57.6

Upon a participant's retirement, all unvested stock options and performance-based restricted stock units are immediately forfeited. In addition, upon retirement, a participant will immediately vest in 25% of service-based restricted stock units for each full year of employment with the Company measured from the grant date. All remaining unvested service-based restricted stock units are immediately forfeited. For market-based restricted stock units, upon retirement and in certain other specified cases, a participant will receive a pro-rated portion of the shares that would ultimately be issued based on attainment of the performance goals as determined on the vesting date. The pro-rated portion is based on the participant's whole months of service with the Company during the performance period prior to the date of termination.

Derivatives

The Company uses derivative financial instruments to manage interest rate and foreign currency risks. It is the Company's policy not to enter into derivative financial instruments for speculative purposes.

Derivative financial instruments involve credit risk in the event the counterparty should default. It is the Company's policy to execute such instruments with global financial institutions that the Company believes to be creditworthy. The Company diversifies its derivative financial instruments among counterparties to minimize exposure to any one of these entities. The Company also uses International Swap Dealers Association master-netting agreements. The master-netting agreements provide for the net settlement of all contracts through a single payment in a single currency in the event of default, as defined by the agreements.

The Company uses foreign currency forward exchange contracts, cross currency swap contracts, and foreign currency denominated debt to manage its exposure to changes in currency exchange rates from (1) future cash flows associated with intercompany transactions and certain local currency expenses expected to occur within the next 13 months (designated as cash flow hedges), (2) its net investment in certain foreign subsidiaries (designated as net investment hedges) and (3) foreign currency denominated assets or liabilities (designated as fair value hedges). The Company also uses foreign currency forward exchange contracts that are not designated as hedging instruments to offset the transaction gains and losses associated with certain assets and liabilities denominated in currencies other than their functional currencies resulting principally from intercompany and local currency transactions.

All derivative financial instruments are recognized at fair value in the consolidated balance sheets. For each derivative instrument that is designated as a fair value hedge, the gain or loss on the derivative included in the assessment of hedge effectiveness is recognized immediately to earnings, and offsets the loss or gain on the underlying hedged item. The Company reports in "Accumulated Other Comprehensive Loss" the gain or loss on

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

derivative financial instruments that are designated, and that qualify, as cash flow hedges. The Company reclassifies these gains and losses into earnings in the same line item and in the same period in which the underlying hedged transactions affect earnings. Changes in the fair value of net investment hedges are reported in “*Accumulated Other Comprehensive Loss*” as a part of the cumulative translation adjustment and would be reclassified into earnings if the underlying net investment is sold or substantially liquidated. The portion of the change in fair value related to components excluded from the hedge effectiveness assessment are amortized into earnings over the life of the derivative. The gains and losses on derivative financial instruments for which the Company does not elect hedge accounting treatment are recognized in the consolidated statements of operations in each period based upon the change in the fair value of the derivative financial instrument. Cash flows from net investment hedges are reported as investing activities in the consolidated statements of cash flows, and cash flows from all other derivative financial instruments are reported as operating activities.

Recently Adopted Accounting Standards

In August 2018, the Financial Accounting Standards Board (“FASB”) issued an amendment to the accounting guidance on cloud computing service arrangements. The guidance aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The guidance also requires an entity to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. The guidance was effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. The adoption of this guidance on January 1, 2020 did not have a material impact on the Company’s consolidated financial statements.

In August 2018, the FASB issued an amendment to the accounting guidance on fair value measurements. The guidance modifies the disclosure requirements on fair value measurements, including the removal of disclosures of the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, the policy for timing of transfers between levels, and the valuation processes for Level 3 fair value measurements. The guidance also adds certain disclosure requirements related to Level 3 fair value measurements. The guidance was effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The adoption of this guidance on January 1, 2020 did not have a material impact on the Company’s consolidated financial statements.

In June 2016, the FASB issued an amendment to the guidance on the measurement of credit losses on financial instruments. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the “incurred loss” model with an “expected loss” model. Accordingly, these financial assets will be presented at the net amount expected to be collected. The amendment also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The guidance was effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The adoption of this guidance on January 1, 2020 did not have a material impact on the Company’s consolidated financial statements.

3. INTELLECTUAL PROPERTY LITIGATION EXPENSES, NET

The Company incurred intellectual property litigation expenses, including settlements and external legal costs, of \$405.4 million, \$33.4 million and \$214.0 million during 2020, 2019 and 2018, respectively.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. INTELLECTUAL PROPERTY LITIGATION EXPENSES, NET (Continued)

On July 12, 2020, the Company reached an agreement with Abbott Laboratories and its direct and indirect subsidiaries (“Abbott”) to, among other things, settle all outstanding patent disputes between the companies (the “Settlement Agreement”) in cases related to transcatheter mitral and tricuspid repair products. See Note 18 for additional information. The Settlement Agreement resulted in the Company recording an estimated \$367.9 million pre-tax charge and related liability in June 2020 related to past damages. In addition, the Company will incur royalty expenses through May 2024 totaling an estimated \$100 million. The Company made a one-time \$100.0 million payment to Abbott in July 2020, and will make quarterly payments in future years.

In January 2019, the Company reached an agreement with Boston Scientific Corporation (“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 covered alleged past damages and no further royalties will be owed by either party.

4. SPECIAL CHARGES (GAIN)

Impairment of Long-lived Assets

In December 2019, the Company recorded a charge of \$40.6 million related to the impairment of certain in-process research and development assets, and in December 2018, the Company recorded a charge of \$116.2 million related to the impairment of certain developed technology and in-process research and development assets. These assets were acquired as part of the acquisition of Valtech Cardio Ltd. (“Valtech”). The Company measured the amount of the impairments by calculating the amount by which the carrying values exceeded the estimated fair values, which were based on projected discounted future net cash flows. Based on market and clinical trial developments at the time of the impairments, the Company re-evaluated the clinical development plans for the technologies acquired from Valtech, which resulted in a reduction to the projected near-term discounted future net cash flows related to the acquired mitral technology for the 2018 charge, and related to the acquired mitral and tricuspid technology for the 2019 charge. The impairments were recorded to the Company’s Rest of World segment.

Acquisition of Intellectual Property

In March 2019, the Company recorded a \$24.0 million charge related to the acquisition of early-stage transcatheter intellectual property and associated clinical and regulatory experience.

Pension Gain

In March 2018, the Company recorded a \$7.1 million gain related to the curtailment of its defined benefit plan in Switzerland resulting from the closure of its manufacturing plant.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. OTHER CONSOLIDATED FINANCIAL STATEMENT DETAILS

Composition of Certain Financial Statement Captions

Components of selected captions in the consolidated balance sheets are as follows:

	<u>As of December 31,</u>	
	<u>2020</u>	<u>2019</u>
	(in millions)	
Inventories		
Raw materials	\$ 136.7	\$ 118.0
Work in process	140.0	121.7
Finished products	525.6	401.2
	<u>\$ 802.3</u>	<u>\$ 640.9</u>
Property, plant, and equipment, net		
Land	\$ 97.6	\$ 98.0
Buildings and leasehold improvements	881.5	619.8
Machinery and equipment	564.9	466.3
Equipment with customers	42.2	35.6
Software	94.2	87.9
Construction in progress	313.3	265.0
	1,993.7	1,572.6
Accumulated depreciation	(598.5)	(512.3)
	<u>\$1,395.2</u>	<u>\$1,060.3</u>
Accrued and other liabilities		
Employee compensation and withholdings	\$ 236.7	\$ 295.8
Accrued rebates	67.2	67.1
Property, payroll, and other taxes	49.7	51.4
Research and development accruals	52.3	51.4
Litigation settlement (Notes 3 and 18)	37.5	—
Litigation and insurance reserves (Note 18)	23.3	20.0
Taxes payable	18.6	52.9
Fair value of derivatives	39.3	6.4
Accrued marketing expenses	14.3	17.5
Accrued professional services	7.6	10.1
Accrued realignment reserves	14.5	16.7
Accrued relocation related costs	21.0	17.4
Other accrued liabilities	88.2	89.8
	<u>\$ 670.2</u>	<u>\$ 696.5</u>

In 2019, the Company recorded a \$73.1 million charge to “*Cost of Sales*,” primarily comprised of the write off of inventory related to strategic decisions regarding its transcatheter aortic valve portfolio, including the decision to discontinue its *CENTERA* program.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. OTHER CONSOLIDATED FINANCIAL STATEMENT DETAILS (Continued)

Supplemental Cash Flow Information

(in millions)

	<u>Years Ended December 31,</u>		
	<u>2020</u>	<u>2019</u>	<u>2018</u>
Cash paid during the year for:			
Interest	\$ 19.9	\$19.9	\$ 30.1
Income taxes	\$197.9	\$61.5	\$223.7
Amounts included in the measurement of lease liabilities:			
Operating cash flows from operating leases	\$ 29.7	\$28.6	\$ —
Non-cash investing and financing transactions:			
Fair value of shares issued in payment for contingent consideration liabilities ...	\$ —	\$—	\$ 34.3
Right-of-use assets obtained in exchange for new lease liabilities	\$ 39.7	\$49.6	\$ —
Capital expenditures accruals	\$ 80.4	\$50.8	\$ 18.7

Cash, Cash Equivalents, and Restricted Cash

(in millions)

	<u>Years Ended December 31,</u>		
	<u>2020</u>	<u>2019</u>	<u>2018</u>
Cash and cash equivalents	\$1,183.2	\$1,179.1	\$714.1
Restricted cash included in other current assets	16.6	1.6	1.5
Restricted cash included in other assets	0.4	3.7	0.3
Total cash, cash equivalents, and restricted cash	<u>\$1,200.2</u>	<u>\$1,184.4</u>	<u>\$715.9</u>

Amounts included in restricted cash primarily represent funds placed in escrow related to litigation and real estate purchases, and funds restricted for construction.

6. LEASES

The Company leases certain office space, manufacturing facilities, land, apartments, warehouses, vehicles, and equipment with remaining lease terms ranging from less than 1 year to 20 years, some of which include options to extend or terminate the leases.

Operating lease costs for the years ended December 31, 2020, 2019, and 2018 were \$30.5 million, \$27.9 million, and \$27.0 million, respectively. Short-term and variable lease costs were not material for the years ended December 31, 2020 and 2019.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. LEASES (Continued)

Supplemental balance sheet information related to operating leases was as follows (in millions, except lease term and discount rate):

	<u>As of December 31,</u>	
	<u>2020</u>	<u>2019</u>
Operating lease right-of-use assets	\$94.2	\$80.1
Operating lease liabilities, current portion	\$27.2	\$25.5
Operating lease liabilities, long-term portion	72.7	58.9
Total operating lease liabilities	<u>\$99.9</u>	<u>\$84.4</u>

Maturities of operating lease liabilities at December 31, 2020 were as follows (in millions):

2021	\$ 30.0
2022	20.7
2023	14.4
2024	8.8
2025	6.1
Thereafter	<u>28.1</u>
Total lease payments	108.1
Less: imputed interest	<u>(8.2)</u>
Total lease liabilities	<u>\$ 99.9</u>

The following table provides information on the lease terms and discount rates:

	<u>Years Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>
Weighted-average remaining lease term (in years)	6.6	5.3
Weighted-average discount rate	2.7 %	2.8 %

As of December 31, 2020, the Company had no additional operating lease commitments for office space that have not yet commenced.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. INVESTMENTS

Debt Securities

Investments in debt securities at the end of each period were as follows (in millions):

	December 31, 2020				December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
<u>Held-to-maturity</u>								
Bank time deposits	\$ 50.0	\$ —	\$ —	\$ 50.0	\$100.2	\$ —	\$ —	\$100.2
<u>Available-for-sale</u>								
Bank time deposits	\$ 24.1	\$ —	\$ —	\$ 24.1	\$ 13.1	\$ —	\$ —	\$ 13.1
Commercial paper	—	—	—	—	34.3	—	—	34.3
U.S. government and agency securities	147.0	2.2	—	149.2	113.2	0.6	—	113.8
Foreign government bonds	—	—	—	—	1.7	—	—	1.7
Asset-backed securities	149.6	1.9	—	151.5	141.2	0.6	(0.1)	141.7
Corporate debt securities . . .	600.8	7.5	—	608.3	487.0	2.3	(0.1)	489.2
Municipal securities	2.8	—	—	2.8	—	—	—	—
	\$924.3	\$11.6	\$—	\$935.9	\$790.5	\$ 3.5	\$(0.2)	\$793.8

The cost and fair value of investments in debt securities, by contractual maturity, as of December 31, 2020 were as follows:

	Held-to-Maturity		Available-for-Sale	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
	(in millions)			
Due in 1 year or less	\$50.0	\$50.0	\$168.4	\$169.4
Due after 1 year through 5 years	—	—	578.2	586.5
Instruments not due at a single maturity date	—	—	177.7	180.0
	\$50.0	\$50.0	\$924.3	\$935.9

Actual maturities may differ from the contractual maturities due to call or prepayment rights.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. INVESTMENTS (Continued)

There were no investments that were in an unrealized loss position as of December 31, 2020. The following table presents gross unrealized losses and fair values for those investments that were in an unrealized loss position as of December 31, 2019, aggregated by investment category and the length of time that individual securities have been in a continuous loss position (in millions):

	December 31, 2019					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
Asset-backed securities	\$ 73.4	\$(0.1)	\$—	\$—	\$ 73.4	\$(0.1)
Corporate debt securities	81.4	(0.1)	—	—	81.4	(0.1)
	<u>\$154.8</u>	<u>\$(0.2)</u>	<u>\$—</u>	<u>\$—</u>	<u>\$154.8</u>	<u>\$(0.2)</u>

Investments in Unconsolidated Affiliates

The Company has a number of equity investments in privately and publicly held companies. Investments in these unconsolidated affiliates are recorded in “*Long-term Investments*” on the consolidated balance sheets, and are as follows:

	December 31,	
	2020	2019
	(in millions)	
Equity method investments		
Carrying value of equity method investments	\$ 5.7	\$ 6.2
Equity securities		
Carrying value of non-marketable equity securities	29.4	23.1
Total investments in unconsolidated affiliates	<u>\$35.1</u>	<u>\$29.3</u>

Non-marketable equity securities consist of investments in privately held companies without readily determinable fair values, and are reported at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or similar investment of the same issuer. The Company recorded an upward adjustment of \$1.8 million based on observable price changes and a downward adjustment of \$0.7 million due to an impairment during 2020, and an upward adjustment of \$0.3 million based on observable price changes during 2019. As of December 31, 2020 and 2019, the Company had recorded accumulated upward adjustments of \$3.8 million and \$2.0 million, respectively, based on observable price changes, and accumulated downward adjustments of \$2.6 million and \$1.9 million, respectively, due to impairment and observable price changes.

During 2020, 2019, and 2018, the gross realized gains or losses from sales of available-for-sale investments were not material.

8. ACQUISITIONS

CAS Medical Systems, Inc.

On February 11, 2019, the Company entered into an agreement and plan of merger to acquire all the outstanding shares of CAS Medical Systems, Inc. (“CASMED”) for an aggregate cash purchase price of \$2.45

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. ACQUISITIONS (Continued)

per share of common stock, or an equity value of approximately \$100 million. The transaction closed on April 18, 2019, and the cash purchase price was \$100.8 million. Acquisition-related costs of \$2.0 million were recorded in “*Selling, General, and Administrative Expenses*” during the year ended December 31, 2019.

CASMED is a medical technology company dedicated to noninvasive monitoring of tissue oxygenation in the brain. The Company integrated the acquired technology platform into its hemodynamic monitoring platform. The acquisition was accounted for as a business combination. Tangible and intangible assets acquired were recorded based on their estimated fair values at the acquisition date. The excess of the purchase price over the fair value of net assets acquired was recorded to goodwill. The following table summarizes the fair values of the assets acquired and liabilities assumed (in millions):

Current assets	\$ 6.1
Property and equipment, net	1.3
Goodwill	64.4
Developed technology	35.9
Customer relationships	8.8
Deferred tax assets	2.2
Liabilities assumed	<u>(17.9)</u>
Total purchase price	100.8
Less: cash acquired	<u>(0.6)</u>
Total purchase price, net of cash acquired	<u><u>\$100.2</u></u>

Goodwill includes expected synergies and other benefits the Company believes will result from the acquisition. Goodwill was assigned to the Company’s United States segment and is not deductible for tax purposes. Developed technology assets are being amortized over a weighted-average useful life of 14 years. Customer relationships assets are being amortized over a weighted-average useful life of 10 years.

The results of operations for CASMED have been included in the accompanying consolidated financial statements from the date of acquisition. Pro forma results have not been presented as the results of CASMED are not material in relation to the consolidated financial statements of Edwards Lifesciences.

Harpoon Medical, Inc.

On December 1, 2017, the Company acquired all the outstanding shares of Harpoon Medical, Inc. for an aggregate cash purchase price of \$119.5 million, which includes \$16.0 million paid previously for a cost method investment and an exclusive option to acquire Harpoon Medical, Inc., and is net of \$8.0 million received from the sale of the Company’s previous ownership interest. In addition, the Company agreed to pay up to an additional \$150.0 million in pre-specified milestone-driven payments over the next 10 years. The Company recognized in “*Contingent Consideration Liabilities*” a \$59.7 million liability for the estimated fair value of the contingent milestone payments. The fair value of the contingent milestone payments are remeasured each quarter, with changes in the fair value recognized within operating expenses on the consolidated statements of operations. For further information on the fair value of the contingent milestone payments, see Note 11.

In-process research and development assets acquired as part of this transaction were capitalized at fair value, which was determined using the income approach. This approach determines fair value based on cash flow projections which are discounted to present value using a risk-adjusted rate of return. Completion of successful

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. ACQUISITIONS (Continued)

design developments, bench testing, pre-clinical studies and human clinical studies are required prior to selling any product. The risks and uncertainties associated with completing development within a reasonable period of time include those related to the design, development, and manufacturability of the product, the success of pre-clinical and clinical studies, and the timing of regulatory approvals. The valuation assumed \$41.4 million of additional research and development expenditures would be incurred prior to the date of product introduction. In the valuation, net cash inflows were modeled to commence in Europe in 2018, and in the United States and Japan in 2022. The Company does not currently anticipate significant changes to forecasted research and development expenditures, and net cash inflows commenced in Europe in 2020 and are now expected to commence in the United States and Japan in 2023. Upon completion of development, the underlying in-process research and development asset will be amortized over its estimated useful life.

Valtech Cardio Ltd.

On November 26, 2016, the Company entered into an agreement and plan of merger to acquire Valtech Cardio Ltd. (“Valtech”) for approximately \$340.0 million, subject to certain adjustments, with the potential for up to an additional \$350.0 million in pre-specified milestone-driven payments over the next 10.0 years. The transaction closed on January 23, 2017, and the consideration paid included the issuance of approximately 2.8 million shares of the Company’s common stock (fair value of \$266.5 million) and cash of \$86.2 million. The Company recognized in “*Contingent Consideration Liabilities*” a \$162.9 million liability for the estimated fair value of the contingent milestone payments. For further information on the fair value of the contingent milestone payments, see Note 11.

Prior to the close of the transaction, Valtech spun off its early-stage transseptal mitral valve replacement technology program. Concurrent with the closing, the Company entered into an agreement for an exclusive option to acquire that program and its associated intellectual property for approximately \$200.0 million, subject to certain adjustments, plus an additional \$50.0 million if a certain European regulatory approval is obtained within 10 years of the acquisition closing date. The option expired in January 2020.

In-process research and development assets acquired as part of this transaction were capitalized at fair value, which was determined using the income approach. This approach determines fair value based on cash flow projections which are discounted to present value using a risk-adjusted rate of return. The valuation assumed \$87.3 million of additional research and development expenditures would be incurred prior to the date of product introduction and that net cash inflows would commence in 2019. In December 2018, the Company recorded a \$116.2 million impairment charge related to Valtech’s intangible assets, and in December 2019, the Company recorded a \$40.6 million impairment charge to write off the remaining in-process research and development assets. For further information, see Note 4.

CardiAQ Valve Technologies, Inc.

On July 3, 2015, the Company entered into an agreement and plan of merger to acquire CardiAQ Valve Technologies, Inc. (“CardiAQ”) for an aggregate cash purchase price of \$350.0 million, subject to certain adjustments. The transaction closed on August 26, 2015, and the cash purchase price after the adjustments was \$348.0 million. In addition, the Company agreed to pay an additional \$50.0 million if a certain European regulatory approval is obtained within 48 months of the acquisition closing date. The Company recognized in “*Contingent Consideration Liabilities*” a \$30.3 million liability for the estimated fair value of this contingent milestone payment. The Company estimated this milestone would not be achieved and reversed the liability in 2018. For further information on the fair value of the contingent milestone payment, see Note 11.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. ACQUISITIONS (Continued)

In-process research and development assets acquired as part of this acquisition were capitalized at fair value, which was determined using the income approach. This approach determines fair value based on cash flow projections which are discounted to present value using a risk-adjusted rate of return. Completion of successful design developments, bench testing, pre-clinical studies and human clinical studies are required prior to selling any product. The risks and uncertainties associated with completing development within a reasonable period of time include those related to the design, development, and manufacturability of the product, the success of pre-clinical and clinical studies, and the timing of regulatory approvals. The valuation assumed \$97.7 million of additional research and development expenditures would be incurred prior to the date of product introduction and that net cash inflows would commence in late 2018. As a result of certain design enhancements to increase the product's commercial life and applicability to a broader group of patients, the Company has incurred incremental research and development expenditures; however, the Company expects an increase in the net cash inflows, commencing in 2023. Upon completion of development, the underlying research and development intangible asset will be amortized over its estimated useful life.

9. GOODWILL AND OTHER INTANGIBLE ASSETS

Goodwill and in-process research and development assets resulting from purchase business combinations are not subject to amortization. Other acquired intangible assets with finite lives are amortized over their expected useful lives on a straight-line basis, or if reliably determinable, based on the pattern in which the economic benefit of the asset is expected to be used. The Company expenses costs incurred to renew or extend the term of acquired intangible assets.

In April 2019, the Company acquired CASMED. This transaction resulted in an increase to goodwill of \$64.4 million and developed technology of \$35.9 million. For further information, see Note 8.

The changes in the carrying amount of goodwill, by segment, during the years ended December 31, 2020 and 2019 were as follows:

	<u>United States</u>	<u>Europe</u>	<u>Rest of World</u>	<u>Total</u>
	(in millions)			
Goodwill at December 31, 2018	\$709.3	\$64.2	\$338.7	\$1,112.2
Goodwill acquired during the year	64.4	—	—	64.4
Currency translation adjustment	—	(1.4)	(7.5)	(8.9)
Goodwill at December 31, 2019	<u>773.7</u>	<u>62.8</u>	<u>331.2</u>	<u>1,167.7</u>
Currency translation adjustment	—	5.5	—	5.5
Goodwill at December 31, 2020	<u>\$773.7</u>	<u>\$68.3</u>	<u>\$331.2</u>	<u>\$1,173.2</u>

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

9. GOODWILL AND OTHER INTANGIBLE ASSETS (Continued)

Other intangible assets consist of the following (in millions):

	Weighted-Average Useful Life (in years)	December 31,					
		2020			2019		
		Cost	Accumulated Amortization	Net Carrying Value	Cost	Accumulated Amortization	Net Carrying Value
Finite-lived intangible assets							
Patents	7.4	\$186.1	\$(183.6)	\$ 2.5	\$185.7	\$(182.1)	\$ 3.6
Developed technology	13.1	155.2	(51.0)	104.2	153.5	(46.6)	106.9
Other	10.0	12.6	(6.0)	6.6	12.3	(4.4)	7.9
	<u>12.6</u>	<u>353.9</u>	<u>(240.6)</u>	<u>113.3</u>	<u>351.5</u>	<u>(233.1)</u>	<u>118.4</u>
Indefinite-lived intangible assets							
In-process research and development		<u>218.1</u>	<u>—</u>	<u>218.1</u>	<u>218.1</u>	<u>—</u>	<u>218.1</u>
		<u>\$572.0</u>	<u>\$(240.6)</u>	<u>\$331.4</u>	<u>\$569.6</u>	<u>\$(233.1)</u>	<u>\$336.5</u>

Amortization expense related to other intangible assets for the years ended December 31, 2020, 2019, and 2018 was \$5.4 million, \$4.6 million, and \$2.5 million, respectively. Estimated amortization expense for each of the years ending December 31 is as follows (in millions):

2021	\$ 5.2
2022	7.6
2023	10.1
2024	12.2
2025	14.8

10. DEBT AND CREDIT FACILITIES

In June 2018, the Company issued \$600.0 million of fixed-rate unsecured senior notes (the “Notes”) due June 15, 2028. Interest is payable semi-annually in arrears, with payments due in June and December of each year. The Company may redeem the Notes, in whole or in part, at any time and from time to time at specified redemption prices. In addition, upon the occurrence of certain change of control triggering events, the Company may be required to repurchase all or a portion of the Notes at a price equal to 101% of their principal amount, plus accrued and unpaid interest. The Notes also include covenants that limit the Company’s ability to incur secured indebtedness, enter into sale and leaseback transactions, and consolidate, merge, or transfer all or substantially all of its assets.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. DEBT AND CREDIT FACILITIES (Continued)

The following is a summary of the Notes as of December 31, 2020 and 2019:

	December 31,			
	2020		2019	
	Amount (in millions)	Effective Interest Rate	Amount (in millions)	Effective Interest Rate
Fixed-rate 4.300% 2018 Notes	\$600.0	4.329%	\$600.0	4.329%
Unamortized discount	(1.1)		(1.2)	
Unamortized debt issuance costs	(3.9)		(4.4)	
Total carrying amount	<u>\$595.0</u>		<u>\$594.4</u>	

As of December 31, 2020 and 2019, the fair value of the Notes was \$711.2 million and \$667.6 million, respectively, based on observable market prices in less active markets and categorized as Level 2 (Note 11). The debt issuance costs, as well as the discount, are being amortized to interest expense over the term of the notes.

The Company has a Five-Year Credit Agreement (“the Credit Agreement”) which matures on April 28, 2023. The Credit Agreement provides up to an aggregate of \$750.0 million in borrowings in multiple currencies. The Company may increase the amount available under the Credit Agreement, subject to agreement of the lenders, by up to an additional \$250.0 million in the aggregate. Borrowings generally bear interest at the London interbank offered rate (“LIBOR”), or a comparable or successor rate, plus a spread ranging from 0.9% to 1.3%, depending on the leverage ratio, as defined in the Credit Agreement. The Company also pays a facility fee ranging from 0.1% to 0.2%, depending on the leverage ratio, on the entire credit commitment available, whether drawn or not. The facility fee is expensed as incurred. During 2020, the spread over LIBOR was 0.9% and the facility fee was 0.1%. Issuance costs of \$2.4 million are being amortized to interest expense over the term of the Credit Agreement. As of December 31, 2020 and 2019, there were no borrowings outstanding under the Credit Agreement. Amounts outstanding under the Credit Agreement, if any from time to time, are classified as long-term obligations in accordance with the terms of 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, 2020.

The weighted-average interest rate under all debt obligations was 3.5% and 3.4% at December 31, 2020 and 2019, respectively.

11. FAIR VALUE MEASUREMENTS

The consolidated financial statements include financial instruments for which the fair market value of such instruments may differ from amounts reflected on a historical cost basis. Financial instruments of the Company consist of cash deposits, accounts and other receivables, investments, accounts payable, certain accrued liabilities, and borrowings under a revolving credit agreement. The carrying value of these financial instruments generally approximates fair value due to their short-term nature. Financial instruments also include notes payable. See Note 10 for further information on the fair value of the notes payable.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. The Company prioritizes the inputs used to determine fair values in one of the following three categories:

Level 1—Quoted market prices in active markets for identical assets or liabilities.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. FAIR VALUE MEASUREMENTS (Continued)

Level 2—Inputs, other than quoted prices in active markets, that are observable, either directly or indirectly.

Level 3—Unobservable inputs that are not corroborated by market data.

In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the level in the fair value hierarchy within which the fair value measurement in its entirety falls has been determined based on the lowest level input that is significant to the fair value measurement in its entirety.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. FAIR VALUE MEASUREMENTS (Continued)

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following table summarizes the Company's financial instruments which are measured at fair value on a recurring basis as of December 31, 2020 and 2019 (in millions):

<u>December 31, 2020</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Assets				
Cash equivalents	\$ 16.2	\$ —	\$ —	\$ 16.2
Available-for-sale investments:				
Bank time deposits	—	24.1	—	24.1
Corporate debt securities	—	608.3	—	608.3
Asset-backed securities	—	151.5	—	151.5
U.S. government and agency securities	56.9	92.2	—	149.1
Municipal securities	—	2.8	—	2.8
Investments held for deferred compensation plans . . .	111.2	—	—	111.2
Derivatives	—	8.1	—	8.1
	<u>\$184.3</u>	<u>\$887.0</u>	<u>\$ —</u>	<u>\$1,071.3</u>
Liabilities				
Derivatives	\$ —	\$ 39.3	\$ —	\$ 39.3
Deferred compensation plans	111.6	—	—	111.6
Contingent consideration liabilities	—	—	186.1	186.1
	<u>\$111.6</u>	<u>\$ 39.3</u>	<u>\$186.1</u>	<u>\$ 337.0</u>
<u>December 31, 2019</u>				
Assets				
Cash equivalents	\$ 0.7	\$ 31.7	\$ —	\$ 32.4
Available-for-sale investments:				
Bank time deposits	—	13.1	—	13.1
Corporate debt securities	—	489.2	—	489.2
Asset-backed securities	—	141.7	—	141.7
U.S. government and agency securities	76.1	37.7	—	113.8
Foreign government bonds	—	1.7	—	1.7
Commercial paper	—	34.3	—	34.3
Investments held for deferred compensation plans . . .	88.9	—	—	88.9
Derivatives	—	30.7	—	30.7
	<u>\$165.7</u>	<u>\$780.1</u>	<u>\$ —</u>	<u>\$ 945.8</u>
Liabilities				
Derivatives	\$ —	\$ 6.4	\$ —	\$ 6.4
Deferred compensation plans	88.7	—	—	88.7
Contingent consideration liabilities	—	—	172.5	172.5
	<u>\$ 88.7</u>	<u>\$ 6.4</u>	<u>\$172.5</u>	<u>\$ 267.6</u>

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. FAIR VALUE MEASUREMENTS (Continued)

The following table summarizes the changes in fair value of the contingent consideration obligation for the years ended December 31, 2020 and 2019 (in millions):

	December 31,	
	2020	2019
Fair value, beginning of year	\$172.5	\$178.6
Changes in fair value	13.6	(6.1)
Fair value, end of year	\$186.1	\$172.5

The changes in 2020 in fair value of the contingent consideration obligation were primarily driven by the accretion of interest due to the passage of time and adjustments to discount rates, partially offset by a \$12.7 million reduction to the liability due to changes in the projected probability and timing of milestone achievements, and the projected timing of cash inflows. During 2019, the contingent consideration liability was reduced by \$24.1 million due to delays in product development, which reduced the probability of milestone achievement. This reduction was partially offset by changes in the fair value of the liabilities associated primarily with adjustments to discount rates and accretion of interest due to the passage of time.

Cash Equivalents and Available-for-sale Investments

The Company estimates the fair values of its money market funds based on quoted prices in active markets for identical assets. The Company estimates the fair values of its time deposits, commercial paper, U.S. and foreign government and agency securities, municipal securities, asset-backed securities, and corporate debt securities by taking into consideration valuations obtained from third-party pricing services. The pricing services use industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades and broker-dealer quotes on the same or similar securities, benchmark yields, credit spreads, prepayment and default projections based on historical data, and other observable inputs. The Company independently reviews and validates the pricing received from the third-party pricing service by comparing the prices to prices reported by a secondary pricing source. The Company's validation procedures have not resulted in an adjustment to the pricing received from the pricing service.

Deferred Compensation Plans

The Company holds investments in trading securities related to its deferred compensation plans. The investments are in a variety of stock, bond, and money market mutual funds. The fair values of these investments and the corresponding liabilities are based on quoted market prices.

Derivative Instruments

The Company uses derivative financial instruments in the form of foreign currency forward exchange contracts and cross currency swap contracts to manage foreign currency exposures. All derivatives contracts are recognized on the balance sheet at their fair value. The fair value of foreign currency derivative financial instruments and the cross currency swap contracts was estimated based on quoted market foreign exchange rates, cross currency swap basis rates, and market discount rates. Judgment was employed in interpreting market data to develop estimates of fair value; accordingly, the estimates presented herein are not necessarily indicative of the amounts that the Company could realize in a current market exchange. The use of different market assumptions or valuation methodologies could have a material effect on the estimated fair value amounts.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. FAIR VALUE MEASUREMENTS (Continued)

Contingent Consideration Liabilities

Certain of the Company's acquisitions involve contingent consideration arrangements. Payment of additional consideration is contingent upon the acquired company reaching certain performance milestones, such as attaining specified revenue levels or obtaining regulatory approvals. These contingent consideration liabilities are measured at estimated fair value using either a probability weighted discounted cash flow analysis or a Monte Carlo simulation model, both of which consider significant unobservable inputs. These inputs include (1) the discount rate used to present value the projected cash flows (ranging from 0.08% to 8.53%; weighted average of 3.1%), (2) the probability of milestone achievement (ranging from 0.4% to 99.7%; weighted average of 70.7%), (3) the projected payment dates (ranging from 2023 to 2027; weighted average of 2026), and (4) the volatility of future revenue (ranging from 37.0% to 40.0%; weighted average of 38.8%). The weighted average of each of the above inputs was determined based on the relative fair value of each obligation. The use of different assumptions could have a material effect on the estimated fair value amounts.

12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES

The Company uses derivative financial instruments to manage its currency exchange rate risk and its interest rate risk as summarized below. Notional amounts are stated in United States dollar equivalents at spot exchange rates at the respective dates. The Company does not enter into these arrangements for trading or speculation purposes.

	Notional Amount	
	December 31, 2020	December 31, 2019
	(in millions)	
Foreign currency forward exchange contracts	\$1,525.5	\$1,336.5
Cross currency swap contracts	300.0	300.0

The following table presents the location and fair value amounts of derivative instruments reported in the consolidated balance sheets (in millions):

	Balance Sheet Location	Fair Value	
		December 31, 2020	December 31, 2019
Derivatives designated as hedging instruments			
Assets			
Foreign currency contracts	Other current assets	\$ 7.3	\$14.2
Foreign currency contracts	Other assets	\$—	\$3.2
Cross currency swap contracts	Other assets	\$0.8	\$13.3
Liabilities			
Foreign currency contracts	Accrued and other liabilities	\$39.3	\$ 6.4

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)

The following table presents the effect of master-netting agreements and rights of offset on the consolidated balance sheets (in millions):

	Gross Amounts	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts Presented in the Consolidated Balance Sheet	Gross Amounts Not Offset in the Consolidated Balance Sheet		
				Financial Instruments	Cash Collateral Received	Net Amount
December 31, 2020						
Derivative Assets						
Foreign currency contracts	\$ 7.3	\$—	\$ 7.3	\$(6.1)	\$—	\$ 1.2
Cross currency swap contracts	\$ 0.8	\$—	\$ 0.8	\$—	\$—	\$ 0.8
Derivative Liabilities						
Foreign currency contracts	\$39.3	\$—	\$39.3	\$(6.1)	\$—	\$33.2
December 31, 2019						
Derivative Assets						
Foreign currency contracts	\$17.4	\$—	\$17.4	\$(5.7)	\$—	\$11.7
Cross currency swap contracts	\$13.3	\$—	\$13.3	\$—	\$—	\$13.3
Derivative Liabilities						
Foreign currency contracts	\$ 6.4	\$—	\$ 6.4	\$(5.7)	\$—	\$ 0.7

The following tables present the effect of derivative and non-derivative hedging instruments on the consolidated statements of operations and consolidated statements of comprehensive income:

	Amount of Gain or (Loss) Recognized in OCI on Derivative (Effective Portion)		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Amount of Gain or (Loss) Reclassified from Accumulated OCI into Income	
	2020	2019		2020	2019
	(in millions)			(in millions)	
Cash flow hedges					
Foreign currency contracts . . .	\$(33.7)	\$23.5	Cost of sales	\$18.4	\$40.9
			Selling, general, and administrative expenses	\$ 2.2	\$ 1.9
	Amount of Gain or (Loss) Recognized in OCI on Derivative (Effective Portion)		Location of Gain or (Loss) Reclassified from Accumulated OCI into Income	Amount of Gain or (Loss) Recognized in Income on Derivative (Amount Excluded from Effectiveness Testing)	
	2020	2019		2020	2019
	(in millions)			(in millions)	
Net investment hedges					
Cross currency swap contracts	\$(12.6)	\$12.5	Interest expense	\$6.4	\$6.6

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)

The cross currency swaps have an expiration date of June 15, 2028. At maturity of the cross currency swap contracts, the Company will deliver the notional amount of €257.2 million and will receive \$300.0 million from the counterparties. The Company will receive semi-annual interest payments from the counterparties based on a fixed interest rate until maturity of the agreements.

	Location of Gain or (Loss) Recognized in Income on Derivative	Amount of Gain or (Loss) Recognized in Income on Derivative		
		2020	2019	2018
		(in millions)		
Fair value hedges				
Foreign currency contracts	Other income, net	\$(1.4)	\$1.4	\$0.5

	Location of Gain or (Loss) Recognized in Income on Derivative	Amount of Gain or (Loss) Recognized in Income on Derivative		
		2020	2019	2018
		(in millions)		
Derivatives not designated as hedging instruments				
Foreign currency contracts	Other income, net	\$(15.1)	\$0.3	\$9.7

The following table presents the effect of fair value and cash flow hedge accounting on the consolidated statements of operations:

	Location and Amount of Gain or (Loss) Recognized in Income on Fair Value and Cash Flow Hedging Relationships Twelve Months Ended December 31, 2020		
	Cost of sales	Selling, general, and administrative expenses	Other Income, net
Total amounts of income and expense line items shown in the consolidated statements of operations in which the effects of fair value or cash flow hedges are recorded	\$(1,080.6)	\$(1,228.4)	\$11.5
The effects of fair value and cash flow hedging:			
Gain (loss) on fair value hedging relationships:			
Foreign currency contracts:			
Hedged items	—	—	4.8
Derivatives designated as hedging instruments	—	—	(4.8)
Amount excluded from effectiveness testing recognized in earnings based on an amortization approach	—	—	3.4
Gain (loss) on cash flow hedging relationships:			
Foreign currency contracts:			
Amount of gain (loss) reclassified from accumulated OCI into income	18.4	2.2	—

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. DERIVATIVE INSTRUMENTS AND HEDGING ACTIVITIES (Continued)

	Location and Amount of Gain or (Loss) Recognized in Income on Fair Value and Cash Flow Hedging Relationships Twelve Months Ended December 31, 2019		
	Cost of sales	Selling, general, and administrative expenses	Other Income, net
Total amounts of income and expense line items shown in the consolidated statements of operations in which the effects of fair value or cash flow hedges are recorded	\$(1,114.4)	\$(1,242.2)	\$ 8.2
The effects of fair value and cash flow hedging:			
Gain (loss) on fair value hedging relationships:			
Foreign currency contracts:			
Hedged items	—	—	2.9
Derivatives designated as hedging instruments	—	—	(2.9)
Amount excluded from effectiveness testing recognized in earnings based on an amortization approach	—	—	4.3
Gain (loss) on cash flow hedging relationships:			
Foreign currency contracts:			
Amount of gain (loss) reclassified from accumulated OCI into income	40.9	1.9	—

The Company expects that during 2021 it will reclassify to earnings a \$7.0 million loss currently recorded in “Accumulated Other Comprehensive Loss.” For the years ended December 31, 2020, 2019, and 2018, the Company did not record any gains or losses due to hedge ineffectiveness.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS

Defined Benefit Plans

Edwards Lifesciences maintains defined benefit pension plans in Japan and certain European countries. In 2018, the Company curtailed its defined benefit plan in Horw, Switzerland (see Note 4).

	Years Ended December 31,	
	2020	2019
	(in millions)	
Change in projected benefit obligation:		
Beginning of year	\$ 105.2	\$ 97.4
Service cost	6.3	5.2
Interest cost	0.5	0.9
Participant contributions	1.5	1.3
Actuarial loss	2.9	8.2
Benefits paid	(0.6)	(4.2)
Plan amendment	—	(4.6)
Currency exchange rate changes and other	10.4	1.0
End of year	<u>\$ 126.2</u>	<u>\$ 105.2</u>
Change in fair value of plan assets:		
Beginning of year	\$ 63.2	\$ 60.4
Actual return on plan assets	0.4	2.0
Employer contributions	2.8	2.6
Participant contributions	1.5	1.3
Benefits paid	(0.6)	(4.2)
Currency exchange rate changes and other	6.0	1.1
End of year	<u>\$ 73.3</u>	<u>\$ 63.2</u>
Funded Status		
Projected benefit obligation	\$(126.2)	\$(105.2)
Plan assets at fair value	73.3	63.2
Underfunded status	<u>\$ (52.9)</u>	<u>\$ (42.0)</u>
Net amounts recognized on the consolidated balance sheet:		
Other long-term liabilities	<u>\$ 52.9</u>	<u>\$ 42.0</u>
Accumulated other comprehensive loss, net of tax:		
Net actuarial loss	\$ (30.8)	\$ (26.3)
Net prior service cost	6.6	6.7
Deferred income tax benefit	4.6	4.2
Total	<u>\$ (19.6)</u>	<u>\$ (15.4)</u>

The accumulated benefit obligation (“ABO”) for all defined benefit pension plans was \$120.9 million and \$101.1 million as of December 31, 2020 and 2019, respectively. The projected benefit obligation and ABO were in excess of plan assets for all pension plans as of December 31, 2020 and 2019.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS (Continued)

The components of net periodic pension benefit cost (credit) are as follows (in millions):

	Years Ended December 31,		
	2020	2019	2018
Service cost, net	\$ 6.3	\$ 5.2	\$ 6.0
Interest cost	0.5	0.9	0.8
Expected return on plan assets	(1.0)	(1.4)	(1.3)
Settlements and curtailment gain	—	—	(7.4)
Amortization of actuarial loss	1.6	0.9	0.8
Amortization of prior service credit	(0.7)	(0.2)	(0.1)
Net periodic pension benefit cost (credit)	<u>\$ 6.7</u>	<u>\$ 5.4</u>	<u>\$(1.2)</u>

Expected long-term returns for each of the plans' strategic asset classes were developed through consultation with investment advisors. Several factors were considered, including a survey of investment managers' expectations, current market data, minimum guaranteed returns in certain insurance contracts, and historical market returns over long periods. Using policy target allocation percentages and the asset class expected returns, a weighted-average expected return was calculated.

To select the discount rates for the defined benefit pension plans, the Company uses a modeling process that involves matching the expected duration of its benefit plans to a yield curve constructed from a portfolio of AA-rated fixed-income debt instruments, or their equivalent. For each country, the Company uses the implied yield of this hypothetical portfolio at the appropriate duration as a discount rate benchmark.

The weighted-average assumptions used to determine the benefit obligations are as follows:

	December 31,	
	2020	2019
Discount rate	0.3%	0.5%
Rate of compensation increase	2.6%	2.7%
Cash balance interest crediting rate	2.5%	2.6%
Social securities increase	1.6%	1.6%
Pension increase	1.8%	1.8%

The weighted-average assumptions used to determine the net periodic pension benefit cost are as follows:

	Years ended December 31,		
	2020	2019	2018
Discount rate	0.5%	0.9%	0.9%
Expected return on plan assets	1.5%	2.3%	2.3%
Rate of compensation increase	2.7%	2.8%	2.6%
Cash balance interest crediting rate	1.5%	1.5%	1.5%
Social securities increase	1.6%	1.8%	1.5%
Pension increase	1.8%	1.8%	1.8%

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS (Continued)

Plan Assets

The Company’s investment strategy for plan assets is to seek a competitive rate of return relative to an appropriate level of risk and to earn performance rates of return in accordance with the benchmarks adopted for each asset class. Risk management practices include diversification across asset classes and investment styles, and periodic rebalancing toward asset allocation targets.

The Administrative and Investment Committee decides on the defined benefit plan provider in each location and that provider decides the target allocation for the Company’s defined benefit plan at that location. The target asset allocation selected reflects a risk/return profile the Company feels is appropriate relative to the plans’ liability structure and return goals. In certain plans, asset allocations may be governed by local requirements. Target weighted-average asset allocations at December 31, 2020, by asset category, are as follows:

Equity securities	25.3%
Debt securities	47.5%
Real estate	7.7%
Other	<u>19.5%</u>
Total	<u><u>100.0%</u></u>

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS (Continued)

The fair values of the Company's defined benefit plan assets at December 31, 2020 and 2019, by asset category, are as follows (in millions):

<u>December 31, 2020</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Asset Category				
Cash	\$ 3.0	\$—	\$—	\$ 3.0
Equity securities:				
United States equities	3.3	—	—	3.3
International equities	16.1	—	—	16.1
Debt securities:				
United States government bonds	7.4	—	—	7.4
International government bonds	26.0	—	—	26.0
Real estate	—	5.6	—	5.6
Mortgages	—	3.1	—	3.1
Insurance contracts	—	—	1.0	1.0
Total plan assets measured at fair value	<u>\$55.8</u>	<u>\$ 8.7</u>	<u>\$ 1.0</u>	\$65.5
Alternative investments measured at net asset value (a)				<u>7.8</u>
Total plan assets				<u>\$73.3</u>
<u>December 31, 2019</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Asset Category				
Cash	\$ 3.8	\$—	\$—	\$ 3.8
Equity securities:				
United States equities	3.0	—	—	3.0
International equities	11.2	—	—	11.2
Debt securities:				
United States government bonds	8.2	—	—	8.2
International government bonds	22.3	—	—	22.3
Real estate	—	4.4	—	4.4
Mortgages	—	2.3	—	2.3
Insurance contracts	—	—	0.9	0.9
Total plan assets	<u>\$48.5</u>	<u>\$ 6.7</u>	<u>\$ 0.9</u>	\$56.1
Alternative investments measured at net asset value (a)				<u>7.1</u>
Total plan assets				<u>\$63.2</u>

(a) Certain investments that were measured at net asset value per share have not been classified in the fair value hierarchy. The fair value amounts presented in this table are intended to permit reconciliation of the fair value hierarchy to the total plan assets.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS (Continued)

The following table summarizes the changes in fair value of the Company's defined benefit plan assets that have been classified as Level 3 for the years ended December 31, 2020 and 2019 (in millions):

	Insurance Contracts
Balance at December 31, 2018	\$ 1.0
Purchases, sales and settlements	(0.1)
Balance at December 31, 2019	0.9
Currency exchange rate impact	0.1
Balance at December 31, 2020	\$ 1.0

Equity and debt securities are valued at fair value based on quoted market prices reported on the active markets on which the individual securities are traded. Real estate investments are valued by discounting to present value the cash flows expected to be generated by the specific properties. Investments in mortgages are valued at cost, which is deemed to approximate its fair value. The insurance contracts are valued at the cash surrender value of the contracts, which is deemed to approximate its fair value. Alternative investments include hedge funds, private equity funds and other miscellaneous investments, and are valued using the net asset value provided by the fund administrator as a practical expedient. The net asset value is based on the fair value of the underlying assets owned by the fund divided by the number of shares outstanding.

The following benefit payments, which reflect expected future service, as appropriate, at December 31, 2020, are expected to be paid (in millions):

2021	\$ 4.6
2022	4.9
2023	6.7
2024	5.6
2025	5.3
2024-2026	36.7

As of December 31, 2020, expected employer contributions for 2021 are \$2.5 million.

Defined Contribution Plans

The Company's employees in the United States and Puerto Rico are eligible to participate in a qualified defined contribution plan. In the United States, participants may contribute up to 25% of their eligible compensation (subject to tax code limitation) to the plan. Edwards Lifesciences matches the first 4% of the participant's annual eligible compensation contributed to the plan on a dollar-for-dollar basis. Edwards Lifesciences matches the next 2% of the participant's annual eligible compensation to the plan on a 50% basis. In Puerto Rico, participants may contribute up to 25% of their annual compensation (subject to tax code limitation) to the plan. Edwards Lifesciences matches the first 4% of participant's annual eligible compensation contributed to the plan on a 50% basis. The Company also provides a 2% profit sharing contribution calculated on eligible earnings for each employee. Matching contributions relating to Edwards Lifesciences employees were \$36.6 million, \$31.4 million, and \$26.6 million in 2020, 2019, and 2018, respectively.

The Company also has nonqualified deferred compensation plans for a select group of employees. The plans provide eligible participants the opportunity to defer eligible compensation to future dates specified by the

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. EMPLOYEE BENEFIT PLANS (Continued)

participant with a return based on investment alternatives selected by the participant. The amount accrued under these nonqualified plans was \$111.6 million and \$88.7 million at December 31, 2020 and 2019, respectively.

14. COMMON STOCK

Treasury Stock

In May 2019, the Board of Directors approved a stock repurchase program authorizing the Company to purchase up to \$1.0 billion of the Company's common stock. The repurchase program does not have an expiration date. Stock repurchased under the program may be used to offset obligations under the Company's employee stock-based benefit programs and stock-based business acquisitions, and will reduce the total shares outstanding.

During 2020, 2019, and 2018, the Company repurchased 3.1 million, 1.5 million, and 5.5 million shares, respectively, at an aggregate cost of \$625.4 million, \$263.3 million, and \$795.5 million, respectively, including shares purchased under the accelerated share repurchase ("ASR") agreements described below and shares acquired to satisfy tax withholding obligations in connection with the vesting of restricted stock units issued to employees. The timing and size of any future stock repurchases are subject to a variety of factors, including expected dilution from stock plans, cash capacity, and the market price of the Company's common stock.

Accelerated Share Repurchase

During 2019 and 2018, the Company entered into ASR agreements providing for the repurchase of the Company's common stock based on the volume-weighted average price ("VWAP") of the Company's common stock during the term of the agreements, less a discount. The following table summarizes the terms of the ASR agreements (dollars and shares in millions, except per share data):

<u>Agreement Date</u>	<u>Amount Paid</u>	<u>Initial Delivery</u>			<u>Final Settlement</u>		
		<u>Shares Received</u>	<u>Price per Share (a)</u>	<u>Value of Shares as % of Contract Value</u>	<u>Settlement Date</u>	<u>Total Shares Received</u>	<u>Average Price per Share (a)</u>
April 2018	\$400.0	2.5	\$127.36	80%	July 2018	2.8	\$142.37
October 2018	\$250.0	1.4	\$139.22	80%	November 2018	1.7	\$150.54
May 2019	\$150.0	0.7	\$178.66	80%	May 2019	0.8	\$178.42
May 2019	\$100.0	0.5	\$170.02	80%	June 2019	0.6	\$178.46

(a) The three-for-one stock split distributed on May 29, 2020 excluded treasury shares. The shares and per share prices in the table are reflected at the pre-split amounts and prices at the time of the transaction.

The ASR agreements were accounted for as two separate transactions: (1) the value of the initial delivery of shares was recorded as shares of common stock acquired in a treasury stock transaction on the acquisition date and (2) the remaining amount of the purchase price paid was recorded as a forward contract indexed to the Company's own common stock and was recorded in "Additional Paid-in Capital" on the consolidated balance sheets. The initial delivery of shares resulted in an immediate reduction of the outstanding shares used to calculate the weighted-average common shares outstanding for basic and diluted earnings per share. The Company determined that the forward contract indexed to the Company's common stock met all the applicable criteria for equity classification and, therefore, was not accounted for as a derivative instrument.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. COMMON STOCK (Continued)

Employee and Director Stock Plans

The Edwards Lifesciences Corporation Long-term Stock Incentive Compensation Program (the “Program”) provides for the grant of incentive and non-qualified stock options, restricted stock, and restricted stock units for eligible employees of the Company. Under the Program, these grants are awarded at a price equal to the fair market value at the date of grant based upon the closing price on that date. Options to purchase shares of the Company’s common stock granted under the Program generally vest over predetermined periods of between three to four years and expire seven years after the date of grant. Service-based restricted stock units of the Company’s common stock granted under the Program generally vest over predetermined periods ranging from three to four years after the date of grant. Market-based restricted stock units of the Company’s common stock granted under the Program vest over three years based on a combination of certain service and market conditions. The actual number of shares issued will be determined based on the Company’s total stockholder return relative to a selected industry peer group. Performance-based restricted stock units vest based on a combination of certain service conditions and upon achievement of specified milestones. Under the Program, the number of shares of common stock available for issuance under the Program was 327.6 million shares. No more than 33.6 million shares reserved for issuance may be granted in the form of restricted stock or restricted stock units.

The Company also maintains the Nonemployee Directors Stock Incentive Compensation Program (the “Nonemployee Directors Program”). Under the Nonemployee Directors Program, annually each nonemployee director may receive up to 120,000 stock options or 48,000 restricted stock units of the Company’s common stock, or a combination thereof, provided that in no event may the total value of the combined annual award exceed \$0.2 million. These grants generally vest over one year from the date of grant. Under the Nonemployee Directors Program, an aggregate of 8.4 million shares of the Company’s common stock has been authorized for issuance.

The Company has an employee stock purchase plan for United States employees and a plan for international employees (collectively “ESPP”). Under the ESPP, eligible employees may purchase shares of the Company’s common stock at 85% of the lower of the fair market value of Edwards Lifesciences common stock on the effective date of subscription or the date of purchase. Under the ESPP, employees can authorize the Company to withhold up to 12% (15% effective January 1, 2021) of their compensation for common stock purchases, subject to certain limitations. The ESPP is available to all active employees of the Company paid from the United States payroll and to eligible employees of the Company outside the United States, to the extent permitted by local law. The ESPP for United States employees is qualified under Section 423 of the Internal Revenue Code. The number of shares of common stock authorized for issuance under the ESPP was 45.9 million shares.

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 that uses the assumptions noted in the following tables. The risk-free interest rate is estimated using the U.S. Treasury yield curve and is based on the expected term of the award. Expected volatility is estimated based on a blend of the weighted-average of the historical volatility of Edwards Lifesciences’ stock and the implied volatility from traded options on Edwards Lifesciences’ stock. The expected term of awards granted is estimated from the vesting period of the award, as well as historical exercise behavior, and represents the period of time that awards granted are expected to be outstanding. The Company uses historical data to estimate forfeitures and has estimated an annual forfeiture rate of 6.4%.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. COMMON STOCK (Continued)

The Black-Scholes option pricing model was used with the following weighted-average assumptions for options granted during the following periods:

Option Awards

	<u>2020</u>	<u>2019</u>	<u>2018</u>
Average risk-free interest rate	0.3%	2.3%	2.9%
Expected dividend yield	None	None	None
Expected volatility	33%	30%	29%
Expected life (years)	5.0	5.1	5.0
Fair value, per share	\$21.70	\$18.17	\$14.17

The Black-Scholes option pricing model was used with the following weighted-average assumptions for ESPP subscriptions granted during the following periods:

ESPP

	<u>2020</u>	<u>2019</u>	<u>2018</u>
Average risk-free interest rate	1.3%	2.4%	1.7%
Expected dividend yield	None	None	None
Expected volatility	33%	27%	31%
Expected life (years)	0.6	0.6	0.6
Fair value, per share	\$16.61	\$16.43	\$12.18

The fair value of market-based restricted stock units was determined using a Monte Carlo simulation model, which uses multiple input variables to determine the probability of satisfying the market condition requirements. The weighted-average assumptions used to determine the fair value of the market-based restricted stock units during the years ended December 31, 2020, 2019, and 2018 included a risk-free interest rate of 0.2%, 2.2%, and 2.7%, respectively, and an expected volatility rate of 32.7%, 29.4%, and 29.7%, respectively.

Stock option activity during the year ended December 31, 2020 under the Program and the Nonemployee Directors Program was as follows (in millions, except years and per-share amounts):

	<u>Shares</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted-Average Remaining Contractual Term</u>	<u>Aggregate Intrinsic Value</u>
Outstanding as of December 31, 2019	17.1	\$32.19		
Options granted	1.8	73.02		
Options exercised	(4.3)	18.16		
Options forfeited	(0.3)	49.74		
Outstanding as of December 31, 2020	<u>14.3</u>	41.27	3.4 years	\$712.5
Exercisable as of December 31, 2020	<u>9.5</u>	32.32	2.5 years	558.1
Vested and expected to vest as of December 31, 2020	<u>13.6</u>	40.37	3.3 years	690.4

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. COMMON STOCK (Continued)

The following table summarizes nonvested restricted stock unit activity during the year ended December 31, 2020 under the Program and the Nonemployee Directors Program (in millions, except per-share amounts):

	Shares	Weighted-Average Grant-Date Fair Value
Nonvested as of December 31, 2019	2.7	\$46.89
Granted (a)	0.9	71.31
Vested	(0.9)	40.03
Forfeited	(0.1)	49.90
Nonvested as of December 31, 2020	2.6	57.59

- (a) The shares granted includes 0.1 million shares of market-based restricted stock units granted during 2020, which represents the target number of shares to be issued, and 0.1 million shares related to a previous year's grant of market-based restricted stock units since the payout percentage achieved at the end of the performance period was in excess of target. As described above, the actual number of shares ultimately issued is determined based on the Company's total stockholder return relative to a selected industry peer group.

The intrinsic value of stock options exercised and restricted stock units vested during the years ended December 31, 2020, 2019, and 2018 were \$323.5 million, \$382.1 million, and \$281.1 million, respectively. The intrinsic value of stock options is calculated as the amount by which the market price of the Company's common stock exceeds the exercise price of the option. During the years ended December 31, 2020, 2019, and 2018, the Company received cash from exercises of stock options of \$79.2 million, \$110.4 million, and \$103.7 million, respectively, and tax benefits from exercises of stock options and vesting of restricted stock units of \$72.1 million, \$85.1 million, and \$62.5 million, respectively. The total grant-date fair value of stock options vested during the years ended December 31, 2020, 2019, and 2018 were \$34.0 million, \$31.2 million, and \$29.0 million, respectively.

As of December 31, 2020, the total remaining unrecognized compensation expense related to nonvested stock options, restricted stock units, and employee stock purchase subscriptions amounted to \$140.9 million, which will be amortized over the weighted-average remaining requisite service period of 30 months.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. ACCUMULATED OTHER COMPREHENSIVE LOSS

Presented below is a summary of activity for each component of “*Accumulated Other Comprehensive Loss*” for the years ended December 31, 2020, 2019, and 2018.

	<u>Foreign Currency Translation Adjustments</u>	<u>Unrealized (Loss) Gain on Hedges</u>	<u>Unrealized (Loss) Gain on Available-for- sale Investments</u> (in millions)	<u>Unrealized Pension Costs (a)</u>	<u>Total Accumulated Other Comprehensive Loss</u>
December 31, 2017	\$(100.1)	\$(13.9)	\$(4.6)	\$(14.1)	\$(132.7)
Impact from adoption of ASU 2016-16 and ASU 2018-02	<u>(4.9)</u>	<u>(2.9)</u>	<u>—</u>	<u>—</u>	<u>(7.8)</u>
January 1, 2018	(105.0)	(16.8)	(4.6)	(14.1)	(140.5)
Other comprehensive (loss) income before reclassifications	(36.7)	35.1	(3.1)	7.6	2.9
Amounts reclassified from accumulated other comprehensive loss	—	19.1	2.9	(6.7)	15.3
Deferred income tax expense	<u>(1.9)</u>	<u>(13.8)</u>	<u>(0.2)</u>	<u>(0.3)</u>	<u>(16.2)</u>
December 31, 2018	(143.6)	23.6	(5.0)	(13.5)	(138.5)
Other comprehensive (loss) income before reclassifications	(1.5)	27.9	7.9	(3.2)	31.1
Amounts reclassified from accumulated other comprehensive loss	(6.6)	(44.2)	0.4	0.7	(49.7)
Deferred income tax (expense) benefit	<u>(3.1)</u>	<u>5.2</u>	<u>(1.6)</u>	<u>0.6</u>	<u>1.1</u>
December 31, 2019	(154.8)	12.5	1.7	(15.4)	(156.0)
Other comprehensive income (loss) before reclassifications	35.7	(34.8)	8.0	(5.5)	3.4
Amounts reclassified from accumulated other comprehensive loss	(6.4)	(19.2)	0.3	0.9	(24.4)
Deferred income tax benefit (expense)	<u>3.1</u>	<u>13.8</u>	<u>(1.4)</u>	<u>0.4</u>	<u>15.9</u>
December 31, 2020	<u><u>\$(122.4)</u></u>	<u><u>\$(27.7)</u></u>	<u><u>\$ 8.6</u></u>	<u><u>\$(19.6)</u></u>	<u><u>\$(161.1)</u></u>

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. ACCUMULATED OTHER COMPREHENSIVE LOSS (Continued)

(a) For the years ended December 31, 2020, 2019, and 2018, the change in unrealized pension costs consisted of the following (in millions):

	<u>Pre-Tax Amount</u>	<u>Tax (Expense) Benefit</u>	<u>Net of Tax Amount</u>
<u>2020</u>			
Prior service credit arising during period	\$ 0.6	\$(0.2)	\$ 0.4
Amortization of prior service credit	<u>(0.7)</u>	<u>0.1</u>	<u>(0.6)</u>
Net prior service cost arising during period	(0.1)	(0.1)	(0.2)
Net actuarial loss arising during period	<u>(4.5)</u>	<u>0.5</u>	<u>(4.0)</u>
Unrealized pension costs, net	<u><u>\$(4.6)</u></u>	<u><u>\$ 0.4</u></u>	<u><u>\$(4.2)</u></u>
<u>2019</u>			
Prior service credit arising during period	\$ 4.6	\$(0.6)	\$ 4.0
Amortization of prior service credit	<u>(0.2)</u>	<u>0.1</u>	<u>(0.1)</u>
Net prior service credit arising during period	4.4	(0.5)	3.9
Net actuarial loss arising during period	<u>(6.9)</u>	<u>1.1</u>	<u>(5.8)</u>
Unrealized pension costs, net	<u><u>\$(2.5)</u></u>	<u><u>\$ 0.6</u></u>	<u><u>\$(1.9)</u></u>
<u>2018</u>			
Prior service credit arising during period	\$ 3.3	\$(0.9)	\$ 2.4
Amortization of prior service credit	<u>(0.1)</u>	<u>—</u>	<u>(0.1)</u>
Net prior service credit arising during period	3.2	(0.9)	2.3
Net actuarial loss arising during period	<u>(2.3)</u>	<u>0.6</u>	<u>(1.7)</u>
Unrealized pension credits, net	<u><u>\$ 0.9</u></u>	<u><u>\$(0.3)</u></u>	<u><u>\$ 0.6</u></u>

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. ACCUMULATED OTHER COMPREHENSIVE LOSS (Continued)

The following table provides information about amounts reclassified from “Accumulated Other Comprehensive Loss” (in millions):

Details about Accumulated Other Comprehensive Loss Components	Years Ended December 31,		Affected Line on Consolidated Statements of Operations
	2020	2019	
Foreign currency translation adjustments	\$ 6.4	\$ 6.6	Other income, net
	(1.6)	(1.6)	Provision for income taxes
	<u>\$ 4.8</u>	<u>\$ 5.0</u>	Net of tax
(Loss) gain on hedges	\$18.4	\$ 40.9	Cost of sales
	2.2	1.9	Selling, general, and administrative expenses
	(1.4)	1.4	Other income, net
	<u>19.2</u>	<u>44.2</u>	Total before tax
	(5.0)	(11.0)	Provision for income taxes
	<u>\$14.2</u>	<u>\$ 33.2</u>	Net of tax
(Loss) gain on available-for-sale investments	\$ (0.3)	\$ (0.4)	Other income, net
	(0.6)	(0.3)	Provision for income taxes
	<u>\$ (0.9)</u>	<u>\$ (0.7)</u>	Net of tax
Amortization of pension adjustments	\$ (0.9)	\$ (0.7)	Other income, net
	0.2	0.1	Provision for income taxes
	<u>\$ (0.7)</u>	<u>\$ (0.6)</u>	Net of tax

16. OTHER INCOME, NET

	Years Ended December 31,		
	2020	2019	2018
	(in millions)		
Foreign exchange gains, net	\$(12.3)	\$(5.9)	\$(6.7)
Gain on investments	(0.6)	(0.5)	1.7
Non-service cost components of net periodic pension benefit cost (credit)	0.4	0.2	(0.1)
Other	1.0	(2.0)	1.1
Total other income, net	<u>\$(11.5)</u>	<u>\$(8.2)</u>	<u>\$(4.0)</u>

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. INCOME TAXES

The Company's income before provision for income taxes was generated from United States and international operations as follows (in millions):

	<u>Years Ended December 31,</u>		
	<u>2020</u>	<u>2019</u>	<u>2018</u>
United States	\$151.3	\$ 383.4	\$266.1
International, including Puerto Rico	765.4	783.1	495.3
	<u>\$916.7</u>	<u>\$1,166.5</u>	<u>\$761.4</u>

The provision for income taxes consists of the following (in millions):

	<u>Years Ended December 31,</u>		
	<u>2020</u>	<u>2019</u>	<u>2018</u>
Current			
United States:			
Federal	\$ 23.4	\$ 31.3	\$ 10.9
State and local	48.2	48.7	13.6
International, including Puerto Rico	73.9	29.1	35.9
Current income tax expense	<u>\$145.5</u>	<u>\$109.1</u>	<u>\$ 60.4</u>
Deferred			
United States:			
Federal	\$ 11.0	\$ 28.3	\$(16.1)
State and local	(32.9)	(18.3)	(22.4)
International, including Puerto Rico	(30.3)	0.5	17.3
Deferred income tax (benefit) expense	<u>(52.2)</u>	<u>10.5</u>	<u>(21.2)</u>
Total income tax provision	<u>\$ 93.3</u>	<u>\$119.6</u>	<u>\$ 39.2</u>

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. INCOME TAXES (Continued)

The components of deferred tax assets and liabilities are as follows (in millions):

	December 31,	
	2020	2019
Deferred tax assets		
Compensation and benefits	\$ 88.6	\$ 90.1
Benefits from uncertain tax positions	27.0	22.5
Net tax credit carryforwards	125.5	108.4
Net operating loss carryforwards	64.1	57.6
Accrued liabilities	105.0	41.3
Inventories	16.3	12.9
Cash flow and net investment hedges	3.3	—
State income taxes	0.5	0.5
Investments	1.8	1.5
Lease liability obligations	7.7	18.4
Other	3.6	3.4
Total deferred tax assets	443.4	356.6
Deferred tax liabilities		
Property, plant, and equipment	(53.4)	(22.6)
Cash flow and net investment hedges	—	(6.8)
Deferred tax on foreign earnings	(29.2)	(35.3)
Right-of-use assets	(7.0)	(17.5)
Other intangible assets	(76.3)	(71.0)
Other	(3.1)	(2.2)
Total deferred tax liabilities	(169.0)	(155.4)
Valuation allowance	(71.6)	(65.8)
Net deferred tax assets	\$ 202.8	\$ 135.4

During 2020, net deferred tax assets increased \$67.4 million, including items that were recorded to stockholders' equity and which did not impact the Company's income tax provision.

The valuation allowance of \$71.6 million as of December 31, 2020 reduces certain deferred tax assets to amounts that are more likely than not to be realized. This allowance primarily relates to the net operating loss carryforwards of certain non- United States subsidiaries and certain non-United States credit carryforwards.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. INCOME TAXES (Continued)

Net operating loss and capital loss carryforwards and the related carryforward periods at December 31, 2020 are summarized as follows (in millions):

	<u>Carryforward Amount</u>	<u>Tax Benefit Amount</u>	<u>Valuation Allowance</u>	<u>Net Tax Benefit</u>	<u>Carryforward Period Ends</u>
United States federal net operating losses	\$ 26.6	\$ 5.6	\$ —	\$ 5.6	2030-2037
United States federal net operating losses	11.3	2.4	—	2.4	Indefinite
United States state net operating losses	33.5	2.1	(2.1)	—	2026-2039
United States state net operating losses	1.0	0.1	(0.1)	—	Indefinite
Non-United States net operating losses	18.2	4.7	(3.6)	1.1	2020-2027
Non-United States net operating losses	295.1	49.2	(39.9)	9.3	Indefinite
United States capital losses	34.1	0.2	(0.2)	—	2024
Total	<u>\$419.8</u>	<u>\$64.3</u>	<u>\$(45.9)</u>	<u>\$18.4</u>	

Certain tax attributes are subject to an annual limitation as a result of the acquisitions of Harpoon Medical, Inc. and CASMED (see Note 8), which constitute a change of ownership as defined under Internal Revenue Code Section 382.

The gross tax credit carryforwards and the related carryforward periods at December 31, 2020 are summarized as follows (in millions):

	<u>Carryforward Amount</u>	<u>Valuation Allowance</u>	<u>Net Tax Benefit</u>	<u>Carryforward Period Ends</u>
California research expenditure tax credits	\$ 145.1	\$ —	\$145.1	Indefinite
Federal research expenditure tax credits	1.5	—	1.5	2026-2039
Puerto Rico purchases credit	23.4	(23.4)	—	Indefinite
Total	<u>\$ 170.0</u>	<u>\$ (23.4)</u>	<u>\$146.6</u>	

The Company has \$145.1 million of California research expenditure tax credits it expects to use in future periods. The credits may be carried forward indefinitely. Based upon anticipated future taxable income, the Company expects that it is more likely than not that all California research expenditure tax credits will be utilized, although the utilization of the full benefit is expected to occur over a number of years and into the distant future. Accordingly, no valuation allowance has been provided. The Company has \$23.4 million of Puerto Rico purchases credit. Throughout its history and into the future, the Puerto Rico operations generate, or are expected to generate, credits each year in excess of its ability to utilize credits in those years. As a result, even though the credits have an indefinite life, the Company continues to record a valuation allowance on the credit carryforwards.

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 a) reduced the U.S. federal corporate tax rate from 35 percent to 21 percent for tax years beginning after December 31, 2017, b) 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 c) 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 in situations when a

EDWARDS LIFESCIENCES CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. INCOME TAXES (Continued)

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, the Company had estimated provisional amounts for a) \$3.3 million of tax benefits in connection with the remeasurement of certain tax assets and liabilities, b) \$297.4 million of net tax expense in connection with the one-time mandatory deemed repatriation tax on cumulative earnings of certain foreign subsidiaries, and c) \$32.3 million of tax benefits associated with a tax reform related restructuring. In accordance with SAB 118, during 2018 the Company 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 2018. In addition, during 2018, the Company 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, the Company completed its accounting for the 2017 Act during the fourth quarter of 2018. In addition, the Company elected to pay the repatriation tax in installments over eight years.

The Company asserts that \$1.1 billion of its foreign earnings continue to be indefinitely reinvested and it intends to repatriate \$599.8 million of its foreign earnings as of December 31, 2020. The estimated net tax liability on the indefinitely reinvested earnings if repatriated is \$21.1 million.

The Company has received tax incentives in certain non-U.S. tax jurisdictions, the primary benefit for which will expire in 2029. The tax reductions as compared to the local statutory rates were \$189.2 million (\$0.30 per diluted share), \$157.6 million (\$0.25 per diluted share), and \$144.9 million (\$0.23 per diluted share) for the years ended December 31, 2020, 2019, and 2018, respectively.

A reconciliation of the United States federal statutory income tax rate to the Company’s effective income tax rate is as follows (in millions):

	Years Ended December 31,		
	2020	2019	2018
Income tax expense at U.S. federal statutory rate	\$192.5	\$245.0	\$159.9
Foreign income taxed at different rates	(80.5)	(75.0)	(16.2)
State and local taxes, net of federal tax benefit	5.0	11.9	6.8
Tax credits, federal and state	(43.1)	(42.9)	(36.7)
Build (release) of reserve for prior years’ uncertain tax positions	4.2	5.0	(35.5)
U.S. tax on foreign earnings, net of credits	1.5	(2.9)	(12.2)
Tax on global intangible low-taxed income	49.2	32.0	—
Foreign-derived intangible income deduction	(2.6)	(7.2)	(6.6)
U.S. federal deductible employee share-based compensation	(48.3)	(57.6)	(41.8)
Nondeductible employee share-based compensation	4.2	3.2	2.8
Impact related to 2017 U.S. Tax Reform	—	2.8	15.8
Other	11.2	5.3	2.9
Income tax provision	<u>\$ 93.3</u>	<u>\$ 119.6</u>	<u>\$ 39.2</u>

The Company’s effective tax rate for 2020 decreased slightly in comparison to 2019 primarily due to the tax benefit from the Settlement Agreement with Abbott (see Notes 3 and 18), partially offset by the increase in the

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. INCOME TAXES (Continued)

U.S. tax on global intangible low-taxed income and the decrease in the tax benefit from employee share-based compensation. The Company's effective tax rate for 2019 increased in comparison to 2018 primarily because of the increase in the U.S. tax on global intangible low-taxed income and the tax benefit in 2018 from audit settlements.

Uncertain Tax Positions

As of December 31, 2020 and 2019, the gross uncertain tax positions were \$281.8 million and \$203.1 million, respectively. The Company estimates that these liabilities would be reduced by \$95.1 million and \$50.1 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 \$186.7 million and \$153.0 million, respectively, if not required, would favorably affect the Company's 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):

	December 31,		
	2020	2019	2018
Uncertain gross tax positions, January 1	\$203.1	\$150.7	\$225.6
Current year tax positions	86.4	55.4	37.8
Increase in prior year tax positions	6.0	0.8	13.9
Decrease in prior year tax positions	(10.0)	(3.8)	(78.8)
Settlements	(3.7)	—	(46.5)
Lapse of statutes of limitations	—	—	(1.3)
Uncertain gross tax positions, December 31	<u>\$281.8</u>	<u>\$203.1</u>	<u>\$150.7</u>

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.

The Company recognizes interest and penalties, if any, related to uncertain tax positions in the provision for income taxes. As of December 31, 2020, the Company had accrued \$14.3 million (net of \$5.1 million tax benefit) of interest related to uncertain tax positions, and as of December 31, 2019, the Company had accrued \$9.3 million (net of \$3.5 million tax benefit) of interest related to uncertain tax positions. During 2020, 2019, and 2018, the Company recognized interest expense (benefit), net of tax benefit, of \$5.0 million, \$4.7 million, and \$(2.8) million, respectively, in "Provision for Income Taxes" on the consolidated statements of operations.

The Company strives to resolve open matters with each tax authority at the examination level and could reach agreement with a tax authority at any time. While the Company has accrued for matters it believes 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, the Company may later decide to challenge any assessments, if made, and may exercise its 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. 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 from these uncertain tax positions.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. INCOME TAXES (Continued)

At December 31, 2020, all material state, local, and foreign income tax matters have been concluded for years through 2015. While not material, the Company continues to address matters in Wisconsin and India for years from 2010.

During 2018, the Company executed an Advance Pricing Agreement (“APA”) between the United States and Switzerland governments for tax years 2009 through 2020 covering various, but not all, transfer pricing matters. The unagreed transfer pricing matters, namely Surgical Structural Heart and Transcatheter Aortic Valve Replacement intercompany royalty transactions, then reverted to IRS Examination for further consideration as part of the respective years’ regular tax audit. In addition, the Company signed agreements during 2018 with the IRS to settle open tax years 2009 through 2014, including all transfer pricing matters for those years 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 and later added the 2017 tax year to this audit cycle during the first quarter of 2019. The IRS audit field work for the 2015-2017 tax years was substantially completed during the fourth quarter of 2020, except for transfer pricing matters.

As a result, certain intercompany transactions covering tax years 2015 through 2020 that were not resolved under the APA program remain subject to IRS examination, and those transactions and related tax positions remain uncertain as of December 31, 2020. The IRS has signaled that it may be preparing proposed audit adjustments related to these intercompany transactions for the 2015-2017 tax years which, if issued, could be provided to the Company during 2021. The Company has considered this information in its evaluation of its uncertain tax positions.

These unresolved transfer pricing matters, net of any correlative repatriation tax adjustment, may be significant to the Company’s consolidated financial statements. Based on the information currently available and numerous possible outcomes, the Company cannot reasonably estimate what, if any, changes to its existing uncertain tax positions may occur in the next 12 months and, therefore, has continued to record the gross uncertain tax positions as a long-term liability.

The Company intends to file to renew the APA between the United States and Switzerland for the years 2021 and forward. In addition, the Company 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 and between Switzerland and Japan covering tax years 2015 through 2019. The Company has filed to renew these APAs related to Japan for the years 2020 and forward. The execution of some or all of these APAs depends on a number of variables outside of the Company’s control.

18. LEGAL PROCEEDINGS

In January 2019, Abbott filed lawsuits against Edwards Lifesciences and its direct and indirect subsidiaries (“Edwards”) in the Federal District Court in the District of Delaware, in the United Kingdom, Germany, Switzerland and Italy, and, in February 2020, in Ireland, alleging patent infringement involving Edwards’ *PASCAL* heart valve repair system (collectively, the “*PASCAL* litigation”). In February 2019, Edwards filed a lawsuit against Abbott in the Federal District Court in the Central District of California alleging patent infringement involving Abbott’s *MITRACLIP* device (with the *PASCAL* litigation, the “Abbott Matters”). On July 12, 2020, Edwards entered into the Settlement Agreement with Abbott to, among other things, settle all patent litigation between the parties related to alleged patent infringement involving Edwards’ *PASCAL* heart valve repair system and Abbott’s *MITRACLIP* device. Pursuant to the Settlement Agreement, all of the Abbott

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

18. LEGAL PROCEEDINGS (Continued)

Matters and related appeals in courts worldwide were dismissed. The Settlement Agreement resulted in the Company recording an estimated \$367.9 million pre-tax net charge in June 2020 related to past damages. See Note 3 for additional information.

In addition, the Company is or may be a party to, or may otherwise be responsible for, pending or threatened lawsuits including those related to products and services currently or formerly manufactured or performed, as applicable, by the Company, workplace and employment matters, matters involving real estate, Company operations or health care regulations, or governmental investigations (the “Other Lawsuits”). The Other Lawsuits raise difficult and complex factual and legal issues and are subject to many uncertainties, including, but not limited to, the facts and circumstances of each particular case or claim, the jurisdiction in which each suit is brought, and differences in applicable law. Management does not believe that any loss relating to the Other Lawsuits would have a material adverse effect on the Company’s overall financial condition, results of operations or cash flows. However, the resolution of one or more of the Other Lawsuits in any reporting period, could have a material adverse impact on the Company’s financial results for that period. The Company is not able to estimate the amount or range of any loss for legal contingencies related to the Other Lawsuits for which there is no reserve or additional loss for matters already reserved.

The Company is subject to various environmental laws and regulations both within and outside of the United States. The Company’s operations, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. While it is difficult to quantify the potential impact of continuing compliance with environmental protection laws, management believes that such compliance will not have a material impact on the Company’s financial results. The Company’s threshold of disclosing material environmental legal proceedings involving a governmental authority where potential monetary exposure is involved is \$1 million.

19. SEGMENT INFORMATION

The Company conducts operations worldwide and is managed in the following geographical regions: United States, Europe, Japan, and Rest of World. All regions sell products that are used to treat advanced cardiovascular disease.

The Company’s geographic segments are reported based on the financial information provided to the Chief Operating Decision Maker (the Chief Executive Officer). The Company evaluates the performance of its geographic segments based on net sales and operating income. The accounting policies of the segments are substantially the same as those described in Note 2. Segment net sales and segment operating income are based on internally derived standard foreign exchange rates, which may differ from year to year, and do not include inter-segment profits. Because of the interdependence of the reportable segments, the operating profit as presented may not be representative of the geographical distribution that would occur if the segments were not interdependent. Net sales by geographic area are based on the location of the customer.

Certain items are maintained at the corporate level and are not allocated to the segments. The non-allocated items include net interest expense, global marketing expenses, corporate research and development expenses, manufacturing variances, corporate headquarters costs, special gains and charges, stock-based compensation, foreign currency hedging activities, certain litigation costs, changes in the fair value of contingent consideration liabilities, and most of the Company’s amortization expense. Although most of the Company’s depreciation expense is included in segment operating income, due to the Company’s methodology for cost build-up, it is impractical to determine the amount of depreciation expense included in each segment, and, therefore, a portion

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

19. SEGMENT INFORMATION (Continued)

is maintained at the corporate level. The Company neither discretely allocates assets to its operating segments, nor evaluates the operating segments using discrete asset information.

The table below presents information about Edwards Lifesciences' reportable segments (in millions):

	Years Ended December 31,		
	2020	2019	2018
Segment Net Sales			
United States	\$2,516.8	\$2,532.7	\$2,055.2
Europe	945.2	926.1	826.4
Japan	448.6	441.4	398.4
Rest of World	451.5	433.3	396.0
Total segment net sales	<u>\$4,362.1</u>	<u>\$4,333.5</u>	<u>\$3,676.0</u>
Segment Operating Income			
United States	\$1,727.3	\$1,742.3	\$1,368.1
Europe	479.3	472.0	394.8
Japan	286.4	272.3	237.0
Rest of World	150.1	127.9	115.6
Total segment operating income	<u>\$2,643.1</u>	<u>\$2,614.5</u>	<u>\$2,115.5</u>

The table below presents reconciliations of segment net sales to consolidated net sales and segment operating income to consolidated income before provision for income taxes ("pre-tax income") (in millions):

	Years Ended December 31,		
	2020	2019	2018
Net Sales Reconciliation			
Segment net sales	\$ 4,362.1	\$ 4,333.5	\$ 3,676.0
Foreign currency	24.2	14.5	46.8
Consolidated net sales	<u>\$ 4,386.3</u>	<u>\$ 4,348.0</u>	<u>\$ 3,722.8</u>
Pre-tax Income Reconciliation			
Segment operating income	\$ 2,643.1	\$ 2,614.5	\$ 2,115.5
Unallocated amounts:			
Corporate items	(1,358.0)	(1,439.7)	(1,058.1)
Special charges	—	(64.6)	(116.2)
Intellectual property litigation expenses, net	(405.4)	(33.4)	(214.0)
Change in fair value of contingent consideration liabilities, net	(13.6)	6.1	5.7
Foreign currency	31.5	63.9	15.3
Consolidated operating income	<u>897.6</u>	<u>1,146.8</u>	<u>748.2</u>
Non-operating income	19.1	19.7	13.2
Consolidated pre-tax income	<u>\$ 916.7</u>	<u>\$ 1,166.5</u>	<u>\$ 761.4</u>

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

19. SEGMENT INFORMATION (Continued)

Enterprise-Wide Information

Enterprise-wide information is based on actual foreign exchange rates used in the Company's consolidated financial statements.

	As of or for the Years Ended December 31,		
	2020	2019	2018
	(in millions)		
Net Sales by Geographic Area			
United States	\$2,516.8	\$2,532.7	\$2,055.3
Europe	973.6	941.2	885.1
Japan	460.1	444.7	396.8
Rest of World	435.8	429.4	385.6
	<u>\$4,386.3</u>	<u>\$4,348.0</u>	<u>\$3,722.8</u>
Net Sales by Major Product Area			
Transcatheter Aortic Valve Replacement	\$2,857.3	\$2,737.9	\$2,283.8
Transcatheter Mitral and Tricuspid Therapies	41.8	28.2	2.9
Surgical Structural Heart	761.8	841.7	761.6
Critical Care	725.4	740.2	674.5
	<u>\$4,386.3</u>	<u>\$4,348.0</u>	<u>\$3,722.8</u>
Long-lived Tangible Assets by Geographic Area			
United States	\$1,084.3	\$ 849.1	\$ 642.1
Europe	192.7	101.5	36.6
Japan	20.4	21.7	6.7
Rest of World	311.0	269.4	214.4
	<u>\$1,608.4</u>	<u>\$1,241.7</u>	<u>\$ 899.8</u>

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

20. QUARTERLY FINANCIAL RESULTS AND MARKET FOR THE COMPANY'S STOCK (UNAUDITED)

Years Ended December 31,	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>	<u>Total Year</u>
	(in millions, except per share data)				
2020					
Net sales	\$1,128.7	\$ 925.0	\$1,140.9	\$1,191.7	\$4,386.3
Gross profit	863.6	686.8	859.9	895.4	3,305.7
Net income (loss) (a)	310.6	(121.9)	325.2	309.5	823.4
Earnings (loss) per common share (a):					
Basic	0.50	(0.20)	0.52	0.50	1.32
Diluted	0.49	(0.20)	0.52	0.49	1.30
Market price:					
High	\$ 81.90	\$ 78.43	\$ 87.79	\$ 92.08	\$ 92.08
Low	51.51	56.44	66.87	70.92	51.51
2019					
Net sales	\$ 993.0	\$1,086.9	\$1,094.0	\$1,174.1	\$4,348.0
Gross profit	761.2	782.9	801.6	887.9	3,233.6
Net income (b)	249.7	242.3	274.7	280.2	1,046.9
Earnings per common share (b):					
Basic	0.40	0.39	0.44	0.45	1.68
Diluted	0.39	0.38	0.43	0.44	1.64
Market price:					
High	\$ 65.95	\$ 65.00	\$ 76.06	\$ 82.55	\$ 82.55
Low	46.95	55.23	61.00	71.08	46.95

- (a) The second quarter of 2020 includes a \$367.9 million charge related to a litigation settlement.
- (b) The first quarter of 2019 includes a \$24.0 million charge related to the acquisition of early-stage transcatheter intellectual property and associated clinical and regulatory experience. The second and third quarters of 2019 include a \$46.2 million and \$26.9 million charge, respectively, related to the write off of inventory. The fourth quarter of 2019 includes a \$40.6 million charge related to the impairment of certain in-process research and development assets.

EDWARDS LIFESCIENCES CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

21. VALUATION AND QUALIFYING ACCOUNTS

	Balance at Beginning of Period	Additions		Deductions	Balance at End of Period
		Charged to Costs and Expenses	Charged to Other Accounts		
(in millions)					
Year ended December 31, 2020					
Allowance for doubtful accounts (a)	\$14.7	\$ 3.1	\$—	\$(1.4)	\$16.4
Tax valuation allowance (b)	64.0	6.3	0.6	(1.1)	69.8
Year ended December 31, 2019					
Allowance for doubtful accounts (a)	\$13.6	\$ 4.7	\$ 0.2	\$(3.8)	\$14.7
Tax valuation allowance (b)	44.9	18.9	0.2	—	64.0
Year ended December 31, 2018					
Allowance for doubtful accounts (a)	\$13.7	\$ 2.2	\$ 1.0	\$(3.3)	\$13.6
Tax valuation allowance (b)	41.6	7.1	(1.8)	(2.0)	44.9

- (a) The deductions related to allowances for doubtful accounts represent accounts receivable which are written off.
- (b) The tax valuation allowances are provided for other-than-temporary impairments and unrealized losses related to certain investments that may not be recognized due to the uncertainty of the ready marketability of certain impaired investments, and net operating loss and credit carryforwards that may not be recognized due to insufficient taxable income.

22. SUBSEQUENT EVENT

In February 2021, Edwards entered into an ASR agreement to repurchase \$250.0 million of the Company’s common stock based on the volume-weighted average price (“VWAP”) of the Company’s common stock during the term of the agreements, less a discount. Upon entering into the agreement, Edwards received an initial delivery of 2.4 million shares, representing approximately 80% of the shares to be repurchased. At the termination of the ASR, Edwards may receive additional shares or may be required to pay additional cash or shares (at the Company’s election). The final settlement is based on the VWAP over the term of the agreement, less a discount. The ASR agreement has a scheduled termination date of March 18, 2021.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. The Company's management, including the Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of December 31, 2020.

Based on their evaluation, the Chief Executive Officer and Chief Financial Officer have concluded as of December 31, 2020 that the Company's disclosure controls and procedures are designed at a reasonable assurance level and are effective in providing reasonable assurance that the information required to be disclosed by the Company in the reports it files or submits under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting. The Company's management, including the Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its internal control over financial reporting based on the framework in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that evaluation, the Company's management concluded that its internal control over financial reporting was effective as of December 31, 2020. The effectiveness of the Company's internal control over financial reporting as of December 31, 2020 has been audited by PricewaterhouseCoopers LLP, the independent registered public accounting firm that audited the financial statements included in this Annual Report on Form 10-K, as stated in their report which appears herein.

Changes in Internal Control Over Financial Reporting. There have been no changes in the Company's internal control over financial reporting that occurred during the Company's fourth fiscal quarter of 2020 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. We have not experienced any material impact to our internal control over financial reporting despite the fact that many of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the potential impact of COVID-19 on our internal controls to minimize the impact on their design and operating effectiveness.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Certain information required by this Item will be set forth under the headings “Board of Directors Matters—Proposal 1 - Election of Directors—Board of Director Nominees,” “Board of Directors Matters—Corporate Governance Policies and Practices,” and “Executive Compensation and Other Information—Executive Officers” in the definitive proxy statement to be filed in connection with the Company’s 2021 Annual Meeting of Stockholders (the “Proxy Statement”) (which Proxy Statement will be filed with the SEC within 120 days of December 31, 2020). The information required by this Item to be contained in the Proxy Statement is incorporated herein by reference. The Company has adopted a code of ethics that applies to all directors and employees, including the Company’s principal executive officer, principal financial officer, and principal accounting officer, or persons performing similar functions. The code of ethics (business practice standards) is posted on the Company’s website, which is found at www.edwards.com under “Investors—Corporate governance—Corporate responsibility—Global Integrity Program.” To the extent required by applicable rules of the SEC and the New York Stock Exchange, the Company intends to disclose on its website any amendments to, or waivers from, any provision of its code of ethics that apply to the Company’s directors and executive officers, including the principal executive officer, principal financial officer or controller or persons performing similar functions.

Item 11. Executive Compensation

The information contained under the heading “Executive Compensation and Other Information” in the Proxy Statement is incorporated herein by reference.

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

The information contained under the headings “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plan Information” in the Proxy Statement is incorporated herein by reference.

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

The information contained under the heading “Other Matters and Business—Related Persons Transactions” and under the heading “Corporate Governance Policies and Practices—Director Independence” in the Proxy Statement is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information contained under the headings “Audit Matters—Fees Paid to Principal Accountants” and “Audit Matters—Pre-Approval of Services” in the Proxy Statement is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this report:

1. Consolidated Financial Statements. See “Index to Consolidated Financial Statements” in Part II, Item 8 herein.

2. Financial Statement Schedules. Other schedules are not applicable and have not been included herein.

3. Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation of Edwards Lifesciences Corporation, dated May 16, 2013 (incorporated by reference to Exhibit 3.1 in Edwards Lifesciences’ report on Form 8-K filed on May 17, 2013)
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Edwards Lifesciences Corporation, dated May 7, 2020 (incorporated by reference to Exhibit 3.1 in Edwards Lifesciences’ report on Form 8-K filed on May 8, 2020)
3.3	Bylaws of Edwards Lifesciences Corporation, as amended and restated as of February 25, 2016 (incorporated by reference to Exhibit 3.1 in Edwards Lifesciences’ report on Form 8-K filed on March 2, 2016)
4.1	Specimen form of certificate representing Edwards Lifesciences Corporation common stock (incorporated by reference to Exhibit 4.1 in Edwards Lifesciences’ Registration Statement on Form 10 (File No. 001-15525) filed on March 15, 2000)
+4.2	Description of Edwards Lifesciences Corporation’s Capital Stock
4.3	Indenture, dated as of September 6, 2013, between Edwards Lifesciences Corporation and Wells Fargo Bank, National Association, as trustee (incorporated by reference to Exhibit 4.5 in Edwards Lifesciences’ Registration Statement on Form S-3 (File No. 333-191022) filed on September 6, 2013) (the “Indenture”)
4.4	First Supplemental Indenture, dated as of October 3, 2013, to the Indenture (incorporated by reference to Exhibit 4.1 in Edwards Lifesciences’ report on Form 8-K filed on October 3, 2013)
4.5	Second Supplemental Indenture, dated as of June 15, 2018, to the Indenture (incorporated by reference to Exhibit 4.2 in Edwards Lifesciences’ report on Form 8-K filed on June 15, 2018) (“Second Supplemental Indenture”)
4.6	Form of Global Note for the 4.300% Senior Notes due 2028 (incorporated by reference to Exhibit A in the Second Supplemental Indenture filed as Exhibit 4.2 in Edwards Lifesciences’ report on Form 8-K filed on June 15, 2018)
10.1	Five-Year Credit Agreement, dated as of April 30, 2018, among Edwards Lifesciences Corporation and certain of its subsidiaries, as Borrowers, the lenders signatory thereto, Bank of America, N.A., as Administrative Agent, JPMorgan Chase Bank, N.A., as Syndication Agent, and Morgan Stanley MUFG Loan Partners, LLC, Deutsche Bank Securities Inc., HSBC Bank USA, National Association, and Wells Fargo Bank, National Association, as Co-Documentation Agents (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences’ report on Form 8-K filed on April 30, 2018)
#10.2	Settlement Agreement, dated May 19, 2014, between Edwards Lifesciences Corporation and Medtronic, Inc. (incorporated by reference to Exhibit 10.2 in Edwards Lifesciences’ report on Form 10-Q for the quarterly period ended June 30, 2014)

Exhibit No.	Description
*10.3	Edwards Lifesciences Corporation Form of Employment Agreement (incorporated by reference to Exhibit 10.8 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2003)
*10.4	Edwards Lifesciences Corporation Amended and Restated Employment Agreement for Michael A. Mussallem, dated March 30, 2009 (incorporated by reference to Exhibit 10.2 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2009)
*10.5	Edwards Lifesciences Corporation Amended and Restated Chief Executive Officer Change-in-Control Severance Agreement, dated October 9, 2012 (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended September 30, 2012)
*10.6	Edwards Lifesciences Corporation Form of Change-in-Control Severance Agreement (incorporated by reference to Exhibit 10.2 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended September 30, 2012)
*10.7	Edwards Lifesciences Corporation 2018 Edwards Incentive Plan (incorporated by reference to Exhibit 10.7 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2018)
*10.8	Edwards Lifesciences Corporation Long-Term Stock Incentive Compensation Program, as amended and restated as of May 7, 2020 (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended June 30, 2020)
*10.9	Edwards Lifesciences Corporation Form of Participant Stock Option Statement and related Long-Term Stock Program Global Nonqualified Stock Option Award Agreement for awards granted prior to May 2015 (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2011)
*10.10	Edwards Lifesciences Corporation Form of Participant Restricted Stock Unit Statement and related Long-Term Stock Program Global Restricted Stock Unit Award Agreement for awards granted prior to May 2015 (incorporated by reference to Exhibit 10.2 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2011)
*10.11	Edwards Lifesciences Corporation Form of Long-Term Stock Incentive Compensation Program Global Nonqualified Stock Option Award Agreement for awards granted beginning May 2015 (incorporated by reference to Exhibit 10.3 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended June 30, 2015)
*10.12	Edwards Lifesciences Corporation Form of Long-Term Stock Incentive Compensation Program Global Restricted Stock Unit Award Agreement for awards granted beginning May 2015 (incorporated by reference to Exhibit 10.4 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended June 30, 2015)
*10.13	Edwards Lifesciences Corporation Form of Performance-Based Restricted Stock Unit Award Statement and related Long-Term Stock Program Global Performance-Based Restricted Stock Unit Award Agreement for awards granted beginning May 2015 (incorporated by reference to Exhibit 10.5 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended June 30, 2015)
*10.14	Edwards Lifesciences Corporation Nonemployee Directors Stock Incentive Program, as amended and restated as of February 25, 2016 (incorporated by reference to Exhibit 10.1 in Edwards Lifesciences' report on Form 10-Q for the quarterly period ended March 31, 2016)
*10.15	Edwards Lifesciences Corporation 2020 Nonemployee Directors Stock Incentive Program (incorporated by reference to Appendix B in Edwards Lifesciences' Definitive Proxy Statement filed on March 25, 2020)

Exhibit No.	Description
+*10.16	Edwards Lifesciences Corporation Form of Participant Stock Option Statement and related Nonemployee Directors Stock Incentive Program Nonqualified Stock Option Award Agreement
+*10.17	Edwards Lifesciences Corporation Form of Nonemployee Directors Stock Incentive Program Restricted Stock Units Agreement
+*10.18	Edwards Lifesciences Corporation Form of Nonemployee Directors Stock Incentive Program Restricted Stock Agreement
*10.19	Edwards Lifesciences Corporation Executive Deferred Compensation Plan, as amended and restated effective as of November 9, 2011 (incorporated by reference to Exhibit 10.7 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2011)
*10.20	Edwards Lifesciences Corporation Officer Perquisite Program Guidelines, as of February 20, 2013 (incorporated by reference to Exhibit 10.25 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2012)
*10.21	Edwards Lifesciences Corporation Form of Indemnification Agreement (incorporated by reference to Exhibit 10.20 in Edwards Lifesciences' report on Form 10-K for the fiscal year ended December 31, 2011)
21.1	Subsidiaries of Edwards Lifesciences Corporation
23	Consent of Independent Registered Public Accounting Firm
31.1	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
+32	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

Pursuant to a request for confidential treatment, confidential portions of this exhibit have been redacted and have been filed separately with the Securities and Exchange Commission

* Represents management contract or compensatory plan

+ Furnished herewith

Item 16. Form 10-K Summary

None.

SIGNATURES

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

EDWARDS LIFESCIENCES CORPORATION

February 12, 2021

By: /s/ MICHAEL A. MUSSALLEM
Michael A. Mussallem
*Chairman of the Board and
Chief Executive Officer*

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u> /s/ MICHAEL A. MUSSALLEM </u> Michael A. Mussallem	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	February 12, 2021
<u> /s/ SCOTT B. ULLEM </u> Scott B. Ullem	Corporate Vice President, Chief Financial Officer (Principal Financial Officer)	February 12, 2021
<u> /s/ ROBERT W.A. SELLERS </u> Robert W.A. Sellers	Vice President, Corporate Controller (Principal Accounting Officer)	February 12, 2021
<u> /s/ KIERAN T. GALLAHUE </u> Kieran T. Gallahue	Director	February 12, 2021
<u> /s/ LESLIE S. HEISZ </u> Leslie S. Heisz	Director	February 12, 2021
<u> /s/ PAUL A. LAVIOLETTE </u> Paul A. LaViolette	Director	February 12, 2021
<u> /s/ WILLIAM J. LINK, PH.D. </u> William J. Link, Ph.D.	Director	February 12, 2021
<u> /s/ STEVEN R. LORANGER </u> Steven R. Loranger	Director	February 12, 2021
<u> /s/ MARTHA H. MARSH </u> Martha H. Marsh	Director	February 12, 2021
<u> /s/ RAMONA SEQUEIRA </u> Ramona Sequeira	Director	February 12, 2021
<u> /s/ NICHOLAS J. VALERIANI </u> Nicholas J. Valeriani	Director	February 12, 2021

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-33054, 333-33056, 333-40434, 333-52334, 333-52346, 333-60670, 333-98219, 333-105961, 333-127260, 333-150810, 333-154242, 333-168462, 333-183106, 333-192229, 333-195853, 333-204180, 333-211333, and 333-217909) and Form S-3 (No. 333-232866) of Edwards Lifesciences Corporation of our report dated February 12, 2021 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Irvine, California
February 12, 2021

**EDWARDS LIFESCIENCES CORPORATION
CERTIFICATIONS PURSUANT TO
SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002
CERTIFICATION**

I, Scott B. Ullem, certify that:

1. I have reviewed this annual report on Form 10-K of Edwards Lifesciences Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: _____ /s/ SCOTT B. ULLEM
Scott B. Ullem
*Corporate Vice President,
Chief Financial Officer*

February 12, 2021

**EDWARDS LIFESCIENCES CORPORATION
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Edwards Lifesciences Corporation (the “Company”) on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), we, Michael A. Mussallem, Chairman of the Board and Chief Executive Officer of the Company, and Scott B. Ullem, Corporate Vice President, Chief Financial Officer, certify, pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ MICHAEL A. MUSSALLEM

Michael A. Mussallem
Chairman of the Board and Chief Executive Officer

February 12, 2021

/s/ SCOTT B. ULLEM

Scott B. Ullem
*Corporate Vice President,
Chief Financial Officer*

February 12, 2021

Intended for Investor audience only. Patients and caregivers should talk to their physician about any of the procedures or devices discussed herein. For patient-focused information, please see www.newheartvalve.com or www.edwards.com.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician. See instructions for use for the important safety information, including indications, contraindications, warnings, precautions, and adverse events.

Edwards devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Important Safety Information: INSPIRIS RESILIA Aortic Valve

Indications: For use in replacement of native or prosthetic aortic heart valves.

Contraindications: There are no known contraindications with the use of the INSPIRIS RESILIA aortic valve.

Complications and Side Effects: Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, any of which could lead to reoperation, explantation, permanent disability, and death.

Warnings: DO NOT ADJUST THE VALVE DIAMETER BY EXPANDING THE BAND PRIOR TO/OR DURING IMPLANTATION OF THE SURGICAL VALVE. The expandable band is not designed to allow for compression or expansion during implantation of the surgical valve. This will cause damage to the valve and may result in aortic incompetence. DO NOT PERFORM STAND-ALONE BALLOON AORTIC VALVULOPLASTY PROCEDURES ON THIS VALVE FOR THE SIZES 19 – 25mm as this may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Valve-in-Valve sizing in the INSPIRIS valve has only been tested with specific Edwards transcatheter heart valves. Use of other transcatheter valves may result in embolization of transcatheter devices anchored within or result in annular rupture.

Important Safety Information: KONECT RESILIA Aortic Valved Conduit

Indications: For use in replacement of native or prosthetic aortic heart valves and the associated repair or replacement of a damaged or diseased ascending aorta.

Contraindications: There are no known contraindications with the use of the KONECT RESILIA aortic valved conduit.

Complications and Side Effects: Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, any of which could lead to reoperation, explantation, permanent disability, and death. Adverse events potentially associated with the use of polyester vascular grafts include hemorrhage, thrombosis, graft infection, embolism, aneurysm, pseudoaneurysm, seroma, occlusion (anastomotic intimal hyperplasia), immunological reaction to collagen (shown to be a weak immunogen; infrequent, mild, localized and self-limiting), intimal peel formation, and conduit dilatation.

Important Safety Information: Edwards SAPIEN 3 and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve system

Indications: The Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve system is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.

The Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve system is indicated for patients with symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic valve or surgical bioprosthetic mitral valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality $\geq 8\%$ at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

Contraindications (Who should not use): The Edwards SAPIEN 3 Transcatheter Heart Valve System and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System should not be used in patients who:

- Cannot tolerate medications that thin the blood or prevent blood clots from forming.
- Have an active infection in the heart or elsewhere.

Warnings:

- There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, compared to other standard treatments for aortic stenosis in the high or greater risk population.
- If an incorrect valve size for your anatomy is used, it may lead to heart injury, valve leakage, movement, or dislodgement.
- Patients should talk to their doctor if they have significant heart disease, a mitral valve device or are sensitive to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials.
- The Edwards SAPIEN 3 Ultra and SAPIEN 3 valves may not last as long in younger patients, or patients with a disease that results in more calcium in their blood.
- During the procedure, your doctors should monitor the dye used in the body; if used in excess it could lead to kidney damage. X-ray guidance used during the procedure may cause injury to the skin, which may be painful, damaging, and long-lasting.
- Patient's creatinine level should be measured prior to the procedure.
- Patients who have already had a valve replaced should be carefully assessed by their physician prior to receiving a new valve to ensure proper placement of the new valve.
- Injury can occur if the delivery system is not used properly.
- Transcatheter heart valve patients should talk to their physicians about the potential need for medications that thin the blood or prevent blood clots from forming.

Precautions:

The long-term durability of the Edwards SAPIEN 3 Ultra and SAPIEN 3 transcatheter heart valves are not known at this time. Regular medical follow-up is recommended to evaluate how well a patient's heart valve is performing. Limited clinical data are available for transcatheter aortic valve replacement in patients who are born with an aortic heart valve that has only two leaflets and who are determined to be at low risk for open heart surgery. Long-term durability of the valve has not been established.

The safety and effectiveness of the transcatheter heart valves are also not known for patients who have:

- An aortic heart valve that is not calcified, contains only one leaflet, has leaflets with large pieces of calcium that may block the vessels that supply blood to the heart or in which the main problem is that the valve leaks.
- Previous prosthetic ring in any position.
- Previous atrial septal occlude.
- A heart that does not pump well, has thickening of the heart muscle, with or without blockage, unusual ultrasound images of the heart that could represent irregularities such as a blood clot, a diseased mitral valve that is calcified or leaking, or Gorlin syndrome, a condition that affects many areas of the body and increases the risk of developing various cancers and tumors.
- Low white, red or platelet blood cell counts, or history of bleeding because the blood does not clot properly.
- Diseased, abnormal or irregularly shaped vessels leading to the heart. Vessels which are heavily diseased or too small for associated delivery devices, or a large amount of calcification at the point of entry.
- Allergies to blood-thinning medications or dye injected during the procedure.
- For a valve-in-valve procedure, there is a risk of leakage if the previously implanted tissue valve is not securely in place or if it is damaged. There is also the possibility that a partially detached valve leaflet from the previously implanted valve could block a blood vessel.
- Additional pre-procedure imaging will be completed to evaluate proper sizing.

Potential risks associated with the procedure include:

- Death, stroke, paralysis (loss of muscle function), permanent disability, or severe bleeding.
- Risks to the heart, including heart attack or heart failure, a heart that does not pump well, irregular heartbeat that may result in a need for a permanent pacemaker, chest pain, heart murmur, false aneurysm, recurring aortic stenosis (narrowing), too much fluid around the heart, injury to the structure of the heart.
- Risks to your lungs or breathing, including difficulty breathing, fainting, buildup of fluid in or around the lungs, weakness or inability to exercise.

- Risks involving bleeding or your blood supply, including formation of a blood clot, high or low blood pressure, limited blood supply, a decrease in red blood cells, or abnormal lab values, bleeding in the abdominal cavity, collection of blood under the skin.
- Additional risks, including life-threatening infection, dislodgement of calcified material, air embolism (air bubbles in the blood vessels), poor kidney function or failure, nerve injury, fever, allergic reaction to anesthesia or dye, reoperation, pain, infection or bleeding at incision sites, or swelling.

Additional potential risks specifically associated with the use of the heart valves include:

- Valve movement after deployment, blockage or disruption of blood flow through the heart, need for additional heart surgery and possible removal of the Edwards SAPIEN 3 Ultra and SAPIEN 3 valves, a blood clot that requires treatment, damage to the valve (e.g., wear, breakage, recurring aortic stenosis), nonstructural valve dysfunction (e.g., leakage, inappropriate sizing or positioning, blockage, excess tissue in growth, blood cell damage, etc.) or mechanical failure of the delivery system and/or accessories.

CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician.

Edwards EVOQUE Tricuspid Valve Replacement System / Edwards Cardioband System / PASCAL System / HARPOON Beating Heart Mitral Valve Repair System

CAUTION: Investigational devices. Limited by Federal (United States) law to investigational use. These devices are not available for marketing or commercial sale in the United States. The PASCAL system and Harpoon Beating Heart Mitral Valve Repair System bear the CE marking of conformity.

The Edwards SAPIEN 3 transcatheter heart valve and Edwards Alterra

CAUTION: Investigational devices. The Edwards SAPIEN 3 transcatheter heart valve and Edwards Alterra adaptive prenent are investigational devices when used in patients with a dysfunctional right ventricular outflow tract/pulmonary valve (RVOT/PV) who are indicated for treatment of pulmonary regurgitation (PR). Limited by Federal (USA) law to investigational use only.

Edwards SAPIEN M3 System

CAUTION: Investigational devices. The Edwards SAPIEN M3 System consists of investigational devices, limited by Federal (United States) law to investigational use. These devices are not available for marketing or commercial sale in the United States.

Corporate Information

Corporate Headquarters

Edwards Lifesciences Corporation
One Edwards Way, Irvine, California 92614
1-800-4-A-HEART or (949) 250-2500

Annual Meeting

The virtual Annual Meeting of Stockholders will be held on May 4, 2021 at 10:00 a.m. (Pacific).

Stock Symbol



Edwards Lifesciences' stock is traded on The New York Stock Exchange (NYSE) under the symbol EW.

Information on the Internet

Edwards Lifesciences' "Investor Relations" section of our web site – ir.edwards.com – provides access to a wide range of information including our press releases, SEC filings and other company information.

Investor Information

Members of the investing public should contact Investor Relations at (949) 250-2806 or investor_relations@edwards.com.

Corporate Public Relations

Members of the news media should call (949) 250-5070.

Transfer Agent

Correspondence about shares, stock certificates and account information may be directed to:

Computershare Investor Services
P.O. Box 30170
College Station, TX 77842-3170
(800) 446-2617
(781) 575-3120/outside U.S.
computershare.com/investor

Independent Registered Public Accounting Firm

PricewaterhouseCoopers LLP
Orange County, CA

Edwards Lifesciences is an affirmative action, equal opportunity employer.

Board of Directors

Michael A. Mussallem
Chairman & Chief Executive Officer,
Edwards Lifesciences Corporation

Kieran T. Gallahue
Former Chairman &
Chief Executive Officer,
CareFusion Corporation

Leslie S. Heisz
Former Managing Director,
Lazard Frères & Co.

Paul A. LaViolette
Managing Partner &
Chief Operating Officer,
SV Health Investors LLC

William J. Link, Ph.D.
Managing Director & Co-Founder,
Versant Ventures

Steven R. Loranger
Former Chairman, President
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